IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

HUMANA INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:23-cv-909-O
	)	
XAVIER BECERRA, et al.,	)	
	)	
Defendants.	)	
	)	

DECLARATION OF JAMES BICKFORD

I, James Bickford, declare as follows:

1. I am counsel for Defendants in the above-captioned case, and make this declaration in support of Defendants' cross-motion for summary judgment.

2. This declaration constitutes Page 1 of Defendants' appendix, which is submitted in compliance with Local Civil Rules 7.1(i) and 56.6.

3. Pages 2 through 649 of this appendix are true and correct copies of selected documents from the certified administrative record in this case.

4. Pages 650 through 682 of this appendix are a true and correct copy of a declaration submitted by Jennifer Dupee and its attachments.

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Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 5th day of December 2024.

/s/ James Bickford
James Bickford

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS–4185–P]

RIN 0938–AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Bipartisan Budget Act of 2018; improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA plans, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. This proposed rule would also revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals to implement certain provisions of the Bipartisan Budget Act of 2018.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS–4185–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4185–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4185–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Theresa Wachter, (410) 786–1157, or Cali Diehl, (410) 786–4053, MA/Part C Issues.

Elizabeth Goldstein, (410) 786–6665, Parts C and D Quality Ratings Issues.

Mark Smith, (410) 786–8015, Prescription Drug Plan Access to Parts A and B Data Issues.

Vanessa Duran, (410) 786–8697, D–SNP Issues.

Frank Whelan, (410) 786–1302, Preclusion List Issues.

Jonathan Smith (410) 786–4671, or Joanne Davis, (410) 786–5127, MA RADV Issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary

A. Purpose

The primary purposes of this proposed rule are to: make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Bipartisan Budget Act of 2018. The proposed changes are necessary to—

- Implement the Bipartisan Budget Act of 2018 provisions;
- Improve program quality and accessibility;
- Clarify program integrity policies; and
- Implement other changes.

This proposed rule would meet the Administration's priorities to reduce burden across the Medicare program by reducing unnecessary regulatory complexity, and improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs. Because the Bipartisan Budget Act of 2018 requires the Secretary to establish procedures, to the extent feasible, for integration and unification of the appeals and grievance processes for dually eligible beneficiaries who are enrolled in Medicaid and in MA special needs plans for dually eligible individuals, this proposed rule also includes proposals to revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals. We note CMS plans to release a proposed Medicare rule in the near future to further the President's agenda of reducing drug costs.

B. Summary of the Major Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 50323 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) created a new section 1852(m) of the Social Security Act (the Act), which allows MA plans to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. The statute limits these authorized additional telehealth benefits to services for which benefits are available under Medicare Part B, but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (section 1852(m)(2)(A)(i) of the Act). Under this proposal, MA plans would be permitted to offer—as part of the basic benefit package—additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit. In addition, we propose to continue authority for

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++ New § 498.5(n)(1)(ii)(B) would state: ''The individual or entity may not submit separate reconsideration requests under paragraph (n)(1)(ii)(A) of this section for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.''

2. Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

a. Background

Subpart G of the MA regulations at part 422 describes how payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates.

Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses and encounters, as specified by the International Classification of Disease, currently the Tenth Revision Clinical Modification guidelines (ICD–10–CM), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes determine the risk scores, which in turn determine the risk-adjusted payments. As a result, MA organizations and providers must focus attention on complete, truthful, and accurate diagnosis reporting according to the official ICD–10–CM coding guidelines.

As the ICD–10–CM guidelines emphasize, ''accurate coding cannot be achieved'' without ''consistent, complete documentation in the medical record.'' Diagnoses submitted for payment by MA organizations must be supported by medical record documentation. This requirement has been in place since the beginning of the MA program. It has been explained in every edition of the Medicare Managed Care Manual, with which MA organizations agree to comply as a condition of their participation. (See the 2013 Medicare Managed Care Manual, § 40; 2004 Medicare Managed Care Manual, § 111.1, Ex. 30 & § 111.4; 2001 Medicare Managed Care Manual, § 110.4.) It has also been emphasized in numerous trainings provided to MA organizations and their subcontractors.

The diagnosis data submitted by MA organizations must conform to all relevant national standards. (See 42 CFR 422.310(d)(1).) As discussed earlier, the Clinical Modification of the International Classification of Disease, published by the federal government, is the chief national standard for diagnosis coding. It is the coding system on which MA risk adjustment is run. Medical record documentation is a core principle of the ICD–10–CM diagnosis coding system and was equally central to the Ninth Revision (ICD–9–CM), which preceded it. A federal court of appeals has recognized the requirement of medical record documentation for diagnosis codes submitted for payment by MA organizations. *United States ex rel. Swoben* v. *United Health Ins. Co.,* 848 F.3d 1161, 1168, 1176 (9th Cir. 2016). When MA organizations certify that their diagnosis codes are ''accurate'' and ''truthful'' to the ''best knowledge, information, and belief'' of the certifying individual, the existence of adequate medical record documentation is one important standard by which accuracy and truthfulness are measured (42 CFR 422.504(l)(1)). As we have previously explained, our ''risk adjustment methodology provides that a specific amount be paid if an enrollee has a particular condition'' (75 FR 19745). The medical record documentation requirement is ''designed to ensure that the enrollee in fact has th[e] condition'' for which an MA organization is requesting payment under the risk adjustment model (75 FR 19745).

The current risk adjustment model employed in adjusting MA plan payments is known as the CMS Hierarchical Condition Category (CMS–HCC) model. It functions by categorizing ICD–10–CM codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. The CMS–HCC model is recalibrated approximately every 2 years to reflect newer treatment and coding patterns in Medicare FFS. This recalibration is made through the annual advance notice of methodological changes authorized by 42 U.S.C. 1395w–23(b)(2). Since 2007, when a demographic data-only payment method was completely phased-out for MA plans, 100 percent of payment has been risk-adjusted. The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence.

b. Risk Adjustment Data Validation Initiatives

MA enrollee HCCs are assigned based on data submitted to us by MA organizations via the Risk Adjustment Payment System (RAPS) and Encounter Data System (EDS). The HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee. The HCC data that MA organizations submit to CMS via the RAPS and EDS systems is self-reported by the MA organization and does not go through a validation review before being incorporated into a given beneficiary's risk-profile. Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, the Department audits plan-submitted diagnosis data a few years later to ensure they are supported by medical record documentation.

Verifiable medical record documentation is key to accurate payment and successful data validation. We annually select MA organizations for risk adjustment data validation (RADV) audits.[23] RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record documentation. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year. The audits validate the HCC data submitted by MA organizations by reviewing hospital inpatient, hospital outpatient, and physician/practitioner provider medical records. The focus of this medical record review activity is on diagnoses related to the enrollee's HCC profile. Risk adjustment discrepancies are identified when the enrollee's HCCs used for payment (based upon MA organization-submitted data) differ from the HCCs assigned based on the medical record, pursuant to the RADV audit

[23] Any changes to the CMS–HCC payment model are published in the annual payment notice.

process. Risk adjustment discrepancies can be aggregated to determine an overall level of payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate. Although we have the authority to extrapolate from a statistically valid sample to calculate a contract-level audit recovery, we have not yet done so.

From 1999 until 2003, our payment validation activity for the MA program had both an educational and audit focus and was intended to improve the accuracy of the risk adjustment data that was being submitted to CMS for payment. Payment adjustments were limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. At the time, only 10 percent of the MA payment amount was risk adjusted. As a result, payment recovery amounts for the small number of plans audited was very small. Since payment year 2004 was the first year for which MA payments were based on the current HCC risk adjustment model, we considered payment years 2004 through 2006 as pilot years for the purpose of RADV and no payment recovery activity occurred.

Payment recovery resumed for payment year 2007, when we audited 37 MA contracts and recouped $13.7 million. Payment adjustments were again limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. (Although we suggested that we would make contract-level payment adjustments for the payment year 2007 audits, we did not ultimately do so.) In the course of that audit process, as in previous years, we reviewed medical record documentation provided by each audited MA organization to substantiate conditions reported by the organization for beneficiaries in each audit sample. After CMS' findings were reported to each MA organization, any organization that disagreed with CMS' determinations could challenge them through a three-stage administrative process established by regulation in 2010. (See 42 CFR 422.311). This dispute and appeals process is currently ongoing.

No payment validation audits were conducted for payment years 2008, 2009, or 2010. In those years, we were considering the development of a methodology for calculating payment adjustments based on statistical RADV MA contract-level payment error audit findings. The development of contract-level RADV audits would enable us to make contract-level payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample, as we had done previously.

On December 20, 2010, we proposed a methodology on the CMS website for selecting a statistically-valid sample of enrollees from each audited MA contract and extrapolating from the results of that sample audit to calculate a contract-level payment adjustment. We invited public comment on this proposed methodology, and received more than 500 comments, which we carefully reviewed. On February 24, 2012, we published what we described as the final methodology for RADV contract-level payment error calculation.[24] That methodology described sampling techniques and the statistical calculation to be used to extrapolate from the sample selected. In brief, up to 201 enrollees from each audited MA contract would be selected according to certain criteria, including their continuous enrollment in the contract for the entire data collection year and January of the payment year; their lack of end-stage renal disease (ESRD) status and hospice status for that entire period; their enrollment in Medicare Part B coverage for the entire data collection year; and their submission of at least one diagnosis during the data collection year leading to at least one CMS–HCC assignment in the payment year. The RADV-eligible enrollees would be ranked by risk score and then divided into three equal strata. An equal number of enrollees would then be randomly selected from each stratum (67 enrollees per stratum in the case of an audit of 201 enrollees). After medical records were reviewed, payment errors would be calculated for each selected enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year. A payment error rate for each stratum would be calculated, and then an overall payment error rate for the audited contract, computed at a ninety-nine percent confidence interval. We stated that this methodology would be applied to the next round of RADV audits, which would be conducted on payment year 2011. Audits for payment years 2011, 2012, and 2013 have been conducted according to this methodology, at a total cost of approximately $150 million to the agency, but have not yet been finalized. These audits are in addition to RADV and related MA audits conducted by the Office of Inspector General, which are conducted pursuant to OIG's independent authorities at sections 2(1) and 4(a)(1) of the Inspector General Act.

We also stated in 2012 that, after using this methodology to calculate a preliminary payment recovery amount, we would apply a FFS Adjuster as an offset before finalizing the audit recovery. The FFS Adjuster was intended to account for any effect of erroneous diagnosis codes in the data from Medicare Parts A and B (often referred to as ''Fee-For-Service'' Medicare) that are used to calibrate the MA risk adjustment model. We stated that the FFS Adjuster would calculate a permissible level of payment error (for example, a percentage of the total payments made on an MA contract in a given year) and limit RADV audit recovery to payment errors above that level. The FFS Adjuster was never intended to set a permissible rate for the submission of erroneous diagnosis codes. We stated that the FFS Adjuster would be calculated based on a RADV-like review of records submitted to support the Medicare Part A and B diagnosis codes. That review is now complete, and will be discussed later.

c. Discussion of Proposals

(1) Extrapolation

The Secretary intends to recover overpayments based on extrapolated audit findings through the use of statistically valid random sampling techniques. Although we described our February 2012 publication as the final methodology to be used to calculate contract-level RADV audit recoveries for payment year 2011, it has never been implemented. As we stated earlier, audits for payment years 2011, 2012, and 2013 have been conducted according to this methodology, but contract-level recoveries have not yet been sought. We are now providing additional notice and again welcoming public input on the agency's methodology for calculating a contract-level payment error in RADV audits, including the sample sizes used in these contract-level audits. CMS is not required to set forth the methodology for calculating an extrapolated payment error through regulatory provisions (it does not do so in Parts A and B, where Medicare Administrative Contractors (MACs) may use any statistically valid sampling and extrapolation methodology they determine to be appropriate), however, in the interest of transparency, we are updating

[24] Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits, *available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.*

stakeholders on our plans to use various sampling and extrapolation methodologies in RADV audits, as CMS deems appropriate.[25] All audits will be based on statistically valid sampling and extrapolation methodologies.

In addition to the contract-level methodology described earlier, we have identified other potential methodologies for sampling and extrapolation, which would calculate improper payments made on the audited MA contract for a particular sub-cohort or sub-cohorts in a given payment year, and the agency may also use such a methodology to calculate improper payments made to the audited MA contract. For example, a sub-cohort could be the enrollees for whom a particular HCC or one of a related set of HCCs (such as the three diabetes HCCs) was reported. After choosing an MA contract and a sub-cohort or sub-cohorts to audit, we would select a statistically significant sample of enrollees for the sub-cohort or sub-cohorts. After reviewing the medical records of those enrollees, we would use statistical extrapolation to calculate and recoup the improper payments made to the audited MA contract for covering enrollees for the sub-cohort or sub-cohorts in that payment year. We would use the same statistical calculation for this sub-cohort-level extrapolation as we do for the contract-level extrapolation (although we welcome comment as to whether to stratify the sample population for the sub-cohort audits, as we currently anticipate doing for the contract-level audits).

We believe that, because any sub-cohort is necessarily a subset of the enrollees covered through a particular MA contract, we could often use a much smaller sample size to calculate a statistically significant extrapolated recovery for a sub-cohort than would be required to calculate a contract-level recovery (up to 201 enrollees, according to our anticipated contract-level methodology). This smaller sample size would allow us to spread our audit resources across a wider range of MA contracts, while still generating statistically significant recoveries. This sub-cohort-based audit methodology would allow us to focus on cohorts of enrollees that appear to raise programmatic concerns.

We invite comment on both the contract-level audit methodology published in February 2012, and our proposal for an extrapolated audit methodology based on sub-cohorts of enrollees. We also seek comment on whether there are particular situations in which one methodology may be preferable to the other, and whether the agency should revise the contract-level audits that have been conducted but not finalized for payment years 2011, 2012, and 2013. Neither proposed methodology is meant to displace our longstanding authority to audit the medical records of particular enrollees who we believe may be associated with improper payments or to use any statistically valid audit methodology.[26]

If we finalize one or more sampling and extrapolation methodologies through this rulemaking, we would make any future changes to that methodology (or those methodologies) through the Health Plan Management System.

We are also considering whether to explicitly expand the MA organizations' RADV appeal rights, particularly in light of the upcoming auditing and recoveries in the MA program. One option would be to permit appeal of the RADV payment error calculation methodology used in a RADV audit similar to practices in the Part A and Part B space of Medicare FFS. We invite comments on this matter.

(2) Application to Payment Year 2011 and Subsequent Years

We intend to apply the finalized RADV payment error methodology or methodologies to payment year 2011, and all subsequent years. (However, we do not expect to use a sub-cohort-based methodology, if finalized, for any payment year before 2014). Section 1871(e)(1)(A) of the Act authorizes retroactive application of rules where ''(i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change would be contrary to the public interest.'' We are considering whether application of the finalized methodology or methodologies to payment year 2011, and all subsequent years, would require the exercise of this statutory authority to engage in retroactive rulemaking. We invite comment on the subject.

In any case, we believe that failure to apply the finalized RADV payment error methodology or methodologies to those payment years would be contrary to the public interest. The public has a substantial interest in the recoupment of millions of dollars of public money improperly paid to private insurers. The public also has a significant interest in providing incentives for those insurers to claim only proper payments in the future, which would be promoted by the recoupment of funds improperly paid in the past. Given the amount of improper payments identified under the MA program (estimated to be $14.35 billion in FY 2017,[27] the $650 million in recovered improper payments represents, if this policy was finalized, 3 years improper payment for 30 plans), the interest in determining an accurate recovery amount for each audited MA plan, and the importance of protecting the overall integrity of the program, we believe that it is in the public interest for CMS to apply the RADV payment error methodology or methodologies adopted through this rulemaking to payment year 2011 and all subsequent years. In applying this methodology (or these methodologies) to those payment years, CMS would be acting in compliance with the IPERIA statute[28] as

[25] The Office of the Inspector General, which is required by law to conduct audits and follow generally accepted government auditing standards, does not seek comment on its methodology for risk adjustment audit work that may lead to overpayment recoveries from MA organizations.

[26] We may begin to conduct RADV audits for payment years 2014 and 2015 before this proposal is finalized, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup any improper payments identified. Although we would design these audits so that the individuals selected would form a statistically significant sample that would support an extrapolated recovery, we would not seek to recover on an extrapolated basis until the rule is final. At the very least, these audits would support enrollee-level recoveries.

[27] CMS has historically reported high levels of payment error in the Part C program. The Part C error rate has ranged between 11 percent and 9 percent between fiscal years (FY) 2011 and 2014, respectively. In FY 2017, the reported Part C error rate was 8.31 percent or $14.35 billion.

[28] Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA, Pub. L. 112–248). The RADV program is a corrective audit activity developed by CMS to address provisions included in the IPIA of 2002, as amended by the IPERA of 2010, and further amended by IPERIA. These statutes require that government agencies annually estimate and report improper payments. RADV audits were initiated because Part C payment error was out of compliance with IPIA. The IPERIA requires the Office of Management and Budget (OMB) to annually identify agencies for greater levels of oversight and review, and with that agency ''establish annual targets and semi-annual or quarterly actions for reducing improper payments associated with each high-priority program.'' In November 2009, Executive Order (E.O.) 13520 was signed in an effort to reduce improper payments by increasing transparency in government and holding agencies accountable for reducing improper payments. In March 2010, OMB issued guidance for agencies regarding the implementation of E.O. 13520 entitled Part III to OMB Circular A–123, Appendix C (Appendix C). Appendix C outlines the responsibilities of agencies, determines the programs subject to E.O. 13520, defines supplemental measures and targets for high priority programs, and establishes reporting requirements under E.O. 13520 and procedures to identify entities with outstanding payments. One of those remedies is payment recapture audits, a requirement that any program that expends at least $1 million must implement payment recapture audits. A recovery audit, or payment recapture audit, is a review process designed to identify erroneous payments. Additionally, it is a corrective

Continued

well as its own fiduciary responsibility to recover funds due and owing to the Medicare Trust Funds. We note also that our February 2012 publication put MA organizations on notice that CMS expected to calculate a contract-level payment error for payment year 2011 and beyond by extrapolating from its review of a statistically valid sample of enrollees, and that (as explained earlier) MA organizations have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records. Application of the finalized RADV payment error methodology or methodologies to payment year 2011 and all subsequent years therefore would not upset any settled interest.

If the finalized contract-level audit methodology differs from the one we published in February 2012, we will also consider whether to apply the new contract-level payment error methodology to payment years 2011, 2012, and 2013, or to only apply it to payment year 2014 and subsequent years, and to finalize the audits for those earlier payment years according to the methodology published in February 2012. We invite comment on this subject, as well. In any event, and however audits for prior years are ultimately handled, we believe that it is vitally important for the health of the MA program to have extrapolated recoveries available for future audit years.

(3) Implementation

This proposal would announce CMS' intention to recover improper payments based on extrapolation of payment error from RADV audit samples to MA organization specified populations. CMS would calculate and recover improper payments based on extrapolation methodologies. MA organizations would be required to remit extrapolated recovery amounts from audit findings as calculated by CMS through its payment system, Medicare Advantage and Prescription Drug system (MARx). MARx is the CMS system that makes monthly payments and payment adjustments to the MA organizations and Part D sponsors. Overpayment recoveries of all types are considered payment adjustments which are done as offsets to the plans' monthly payments. RADV recovery amounts are included in this category. In the month the plan has been notified that the recovery amount will be offset, the MARx system makes an offset to the plans monthly payment equal to the amount of the recovery amount. In the event the recovery amount exceeds the payment in 1 month, the recovery will be spread across adjustments for multiple months until the full amount is recovered. CMS may likewise require MA organizations to remit such recovery amounts based upon audit findings by OIG.

(4) Recoupment of Improper Payments in Part C

Improper payments identified by CMS outside of the RADV audit process or self-identified by the MA organization that are not returned in accordance with §§ 422.330, and are identified and/or estimated through extrapolation or other estimation methodologies as a result of CMS audits will be recovered following CMS audit processes including payment offset. We propose that MA organizations be required to remit funds that CMS calculates as improper payments through the extrapolated RADV audit findings in accordance with §§ 422.310(e). RADV audit results can be appealed by MA organizations using the regulatory administrative appeals process outlined in § 422.311.

(5) FFS Adjuster

After our 2012 RADV publication, we conducted an extensive study regarding the presence and impact of diagnosis error in FFS claims data. Our study suggests that errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS–HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations.[29]

The study began by auditing 8,630 outpatient claims paid through Medicare Part B in a given year. We reviewed the medical records associated with each claim (a small subset of the medical records associated with each beneficiary) to determine whether the diagnosis associated with the claim was supported by medical record documentation. A discrepancy rate for each CMS–HCC was then calculated. For example, the data set contained 484 claims submitted with a diagnosis of chronic obstructive pulmonary disease, which is CMS–HCC 108. Of those diagnoses, 388 were supported by medical record documentation, and 96 were not, for a discrepancy rate of 19.8 percent. To account for the fact that the data set contained extremely small samples of many CMS–HCCs—for example, one diagnosis of extensive third degree burns and two diagnoses of severe head injury—we calculated a high, low, and baseline discrepancy rate. Each CMS–HCC was assigned one of these three mean discrepancy rates depending on its relationship to the bassline discrepancy rate: CMS–HCCs with a discrepancy rate significantly higher than the baseline were assigned to the high category, and those with a discrepancy rate significantly lower than the baseline were assigned to the low category. All other CMS–HCCs were assigned the baseline discrepancy rate. These rates were 46.2 percent, 33.8 percent, and 20.9 percent.

In a given year, multiple claims are submitted for Medicare Part B services received by a given beneficiary and associated with a given diagnosis. For example, an average beneficiary with metastatic cancer or acute leukemia, which is CMS–HCC 7, has seven claims associated with that diagnosis. Because we were interested in determining whether a given beneficiary had a documented diagnosis in a given year, and not whether any particular claim was associated with medical record documentation, we used the claim-level discrepancy rates described above to calculate beneficiary-level discrepancy rates.[30]

After calculating this beneficiary-level discrepancy rate for each HCC, we ran fifty simulations in which we removed diagnoses from a data set of more than 1.4 million Medicare Part A and B beneficiaries at the beneficiary-level discrepancy rate.[31] After removing diagnoses at the indicated rates, we used each simulated ''corrected'' data set to recalibrate the CMS–HCC risk adjustment model, applied the recalibrated risk coefficients to a data set of MA beneficiaries, and compared their original risk scores to the risk

control activity designed to identify and recapture erroneous payments, and, as such, is a management function and responsibility.

[29] We are aware of the district court's recent ruling in *United HealthCare Insurance Co.* v. *Azar,* No. 16-cv-157 (D.D.C. September 7, 2018), and the government is reviewing that decision and considering its response. In any event, that ruling was made on the basis of the administrative record before the court, which did not include the results of our study.

[30] For example, metastatic cancer or acute leukemia was assigned the baseline discrepancy rate of 33.8%. We therefore reasoned that each of the seven claims associated with the average beneficiary for whom such a diagnosis was reported had a 66.2% chance of being supported by medical record documentation, and only one instance of medical record support was necessary to make the diagnosis valid for that year. If each beneficiary with such a reported diagnosis has 7 claims associated with that diagnosis, and each claim has a 66.2% chance of being supported by medical record documentation, then 99.95% of all beneficiaries will have at least one instance of medical record support, and only 0.05% of beneficiaries will lack any medical record documentation of their reported diagnosis.

[31] For metastatic cancer and acute leukemia, 1 in 2,000 diagnoses was removed (corresponding to an error rate of 0.05%).

scores calculated with the recalibrated model. We found that the difference between the risk scores was very small, and that the recalibrated risk scores tended to be slightly lower than the original risk scores. Therefore, we concluded that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program.

An executive summary of the findings and a technical appendix describing the data and methodology can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html.* Because it appears that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program, we propose not to include an FFS Adjuster in any final RADV payment error methodology.

Moreover, even if we had found that diagnosis error in FFS claims data led to systematic payment error in the MA program, we no longer believe that a RADV-specific payment adjustment would be appropriate. RADV audits are used to recover payments based on diagnoses that are not supported by medical record documentation, which thus should not have been reported to CMS. If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met, and the MA organization is not entitled to any payment for that diagnosis. RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation. Consequently, an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate. For this reason, we believe that it would not be appropriate to correct any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts. Doing so would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans.

Because our study suggests that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program and because we believe it would be inequitable to correct any systematic errors in the payments made to audited plans only, we would not include an FFS Adjuster in any RADV extrapolated audit methodology. We welcome public comments on this study.

d. Proposed Changes

In this section, we discuss the proposed changes to the regulation in Parts 422 and 423 governing the MA Program. We are proposing to apply extrapolation to plan year audits for payment year 2011 forward.

The following is a summary of the proposed changes included in this proposed revision:

We propose to revise § 422.300 to include ''collection of improper payments.''

We propose to amend § 422.310(e) Validation of risk adjustment data, to apply extrapolation to plan year audits for payment year 2011 forward.

We propose to amend § 422.310(e) Validation of risk adjustment data, by adding a requirement to set forth the provision for MA organizations to remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS.

We propose to amend § 422.311, the RADV audit dispute and appeal process section, by adding language to clarify that recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error extrapolation and recovery methodologies and that CMS will apply extrapolation to plan year audits for payment year 2011 forward.

D. Implementing Other Changes

1. Clarification Regarding Accreditation for Quality Improvement Programs

Section 1852(e) of the Act requires each MA organization to have an ongoing quality improvement program to improve the quality of care provided to its enrollees and establishes the requirements for the quality improvement programs. Section 1852(e)(4) of the Act requires the Secretary to deem that an MA Organization has met all of the requirements for any one out of the six program areas listed in section 1852(e)(4)(B) of the Act if the MA Organization is accredited in that area by an accrediting organization that has been approved by CMS and that uses the same (or stricter) standards than CMS uses to evaluate compliance with the applicable requirements. Section 1852(e)(4)(B)(i) of the Act references the quality improvement programs in section 1852(e) of the Act. Thus, an MA Organization could be deemed to meet CMS' requirements related to quality improvement programs by a CMS-approved accrediting organization.

Section 722(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) revised the quality improvement program requirements in the Act. Section 1852(e) of the Act was revised by adding a new clause ''(2) Chronic Care Improvement Programs'' and renumbering the existing clauses accordingly (that is, existing clause ''(2) Data'' became ''(3) Data''). Section 722(a) of the MMA also revised section 1852(e)(4)(B)(i) of the Act. Prior to the MMA, section 1852(e)(4)(B)(i) of the Act indicated that the requirements in clauses (e)(1) (general requirements for quality improvement programs) and (e)(2) (the collection, analysis, and reporting of data related to quality improvement programs) could be deemed. Consistent with the changes made to section 1852(e) of the Act described earlier, section 722(a) of the MMA amended section 1852(e)(4)(B)(i) of the Act to provide, ''(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).'' However, the printed and online versions of section 1852(e)(4)(B)(i) of the Act continue to cross-reference clauses (e)(1) and (e)(2) erroneously. Therefore, we are clarifying in this proposed rule that the requirements in section 1852(e)(3) of the Act and the subsections of § 422.152 related to section 1852(e)(3) of the Act may be deemed.

2. Delete the Reference to Quality Improvement Projects in § 422.156(b)(1)

Section 1852(e) of the Act requires each MAO to have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to its enrollees. Our regulations at § 422.152 outline the QI Program requirements MA Organizations. Section 422.152(a)(3) requires each MA Organization to conduct quality improvement projects (QIPs) for its enrollees, and § 422.152(d) establishes the requirements for the QIPs. Effective January 1, 2019, CMS eliminated the requirements for QIPs in §§ 422.152(a)(3) and 422.152(d) in the April 2018 final rule (83 FR 16440). However, the reference to QIPs was not deleted in § 422.156(b)(1), which says QIPs are exempt from the process for deeming compliance based on accreditation. Therefore, we are proposing a technical correction in this rule that would delete the phrase ''the quality improvement projects (QIPs) and'' from § 422.156(b)(1).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of

§ 422.254 Submission of bids.

* * * * *

(b) * * *

(1) * * *

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing basic benefits as defined in § 422.100(c)(1).

* * * * *

(3) * * *

(i) MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments relating to such benefits from their bid submission.

(ii) [Reserved]

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1) must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare fee-for-service program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

* * * * *

(c) * * *

(3) * * *

(i) The provision of basic benefits as defined in § 422.100(c)(1);

* * * * *

(e) * * *

(2) The amount of the MA monthly MSA premium for basic benefits (as defined in § 422.252);

* * * * *

■ 16. Section 422.264 is amended by revising paragraph (a) to read as follows:

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks*—(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted MA statutory non-drug monthly bid amount (defined at § 422.254(b)(1)(i)), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a local MA plan, adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a regional MA plan, adjusted using the factors described in paragraph (e) of this section.

* * * * *

■ 17. Section 422.300 is revised to read as follows:

§ 422.300 Basis and scope.

This subpart is based on 42 U.S.C. 1106, 1128j(d), 1852, 1853, 1854, and 1858. It sets forth the rules for making payments to MA organizations offering local and regional MA policies, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, collection of improper payments and other payment rules. See § 422.458 for rules on risk sharing payments to MA regional organizations.

■ 18. Section 422.310 is amended by revising paragraph (e) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings to Payment Year 2011 forward.

* * * * *

■ 19. Section 422.311 is amended by revising paragraph (a) to read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy. Recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error extrapolation and recovery methodologies. CMS will apply extrapolation to plan year audits for payment year 2011 forward.

* * * * *

■ 20. Section 422.504 is amended by adding paragraph (g)(1)(iv) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) * * *

(iv) The enrollee shall not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

* * * * *

■ 21. Section 422.560 is amended by adding paragraphs (a)(4) and (b)(5) to read as follows:

§ 422.560 Basis and scope.

(a) * * *

(4) Section 1859(f)(8) of the Act provides for, to the extent feasible, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for Medicare and Medicaid covered items and services provided by specialized MA plans for special needs individuals described in subsection 1859(b)(6)(B)(ii) of the Act for individuals who are eligible under titles XVIII and XIX. Procedures established under section 1859(f)(8) of the Act apply in place of otherwise applicable grievances and appeals procedures with respect to Medicare and Medicaid covered items and services provided by applicable integrated plans.

(b) * * *

(5) Requirements for applicable integrated plans with respect to procedures for integrated grievances, integrated organization determinations, and integrated reconsiderations.

* * * * *

■ 22. Section 422.561 is amended by adding definitions of ''Applicable integrated plans'', ''Integrated appeal'', ''Integrated grievance'', ''Integrated organization determination'', and ''Integrated reconsideration'' in alphabetical order to read as follows:

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means:

(1) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment, and

(2) The Medicaid managed care organization, as defined in section

Gov't Appx.000008

As of: February 03, 2023
Received: August 27, 2019
Status: Posted
Posted: August 28, 2019
Tracking No. 1k3-9bul-3158
Comments Due: August 28, 2019
Submission Type: Web

PUBLIC SUBMISSION

Docket: CMS-2018-0133
Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, and Medicaid Managed Care Programs for Contract Year 2020 CMS-4185-P

Comment On: CMS-2018-0133-0001
Medicare and Medicaid Programs: Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly, Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Policy and Technical Changes CMS-4185-P

Document: CMS-2018-0133-0250
Comment on CMS-2018-0133-0001

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General Comment

See attached.

Attachments

AHIP_RADV_comments_FINAL_8_27

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Matthew Eyles
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August 27, 2019

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
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RE: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 ("Proposed Rule")

Dear Administrator Verma:

America's Health Insurance Plans (AHIP) appreciates the opportunity to comment on the Risk Adjustment Data Validation (RADV) proposal put forward by the Center for Program Integrity (CPI) and included in the Proposed Rule. AHIP is the national association whose members provide coverage for health care and related services for millions of Americans. Through these offerings, including Medicare Advantage (MA) plans, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers. The MA program is critical to achieving national policy goals for improved health care, and we share your strong commitment to delivering better health outcomes, value, and satisfaction to Medicare beneficiaries.

Proposed Rule Is Fatally Flawed and Should Be Withdrawn

The MA program and its payment structure are designed to encourage MA plans to maximize the efficient provision of high-quality health care treatments and services to Medicare beneficiaries. They are also designed to ensure that MA plans have the resources needed to provide high-quality benefits and coordinated care to seniors and people with disabilities.

As part of this structure, Congress directed CMS to adjust payments to each plan to account for the health status of its population.[1] CMS carries out this mandate through a risk adjustment model that is based on data from traditional Medicare. Congress also required CMS to ensure the risk adjustment model achieves actuarial equivalence between MA and traditional Medicare.[2] This actuarial equivalence requirement is fundamental to the proper functioning of the MA risk adjustment model, and therefore is a core component of a stable MA program.

[1] 42 USC 1395w-23(a)(3).
[2] 42 USC 1395w-23(a)(1)(C)(i) – "…the Secretary shall adjust the payment…for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), ***so as to ensure actuarial equivalence***." (emphasis added)

As we note in our comments below, we believe the Proposed Rule violates this critical actuarial equivalence requirement. First and foremost, it fails to include a fee-for-service (FFS) adjuster to ensure actuarial equivalence between payments to MA plans and payments under the traditional Medicare program.[3] The rule also suffers from other serious substantive and procedural defects. Given our very strong legal and policy objections, we urge CMS to withdraw the RADV proposal.

Proposed Rule Undermines MA and Confidence in Government as Fair Business Partner
We appreciate CMS' decision to provide data and additional methodological explanations regarding its technical study relating to the proposal in response to requests from stakeholders and the agency's decision to extend the comment deadline on the RADV proposal, accordingly. However, these data and explanations do not solve or mitigate our serious concerns with the RADV proposal.

Health insurance providers are accountable to the consumers they serve as well as the taxpayers who fund the MA program. Since 2010, MA plan sponsors have requested that CMS engage in a dialogue to develop a fair and appropriate oversight process. Rather than engage with its private-sector partners, CPI released a proposal that is neither fair nor appropriate. It would reverse the well-established and long-held principle that a FFS adjuster is necessary to meet statutory and actuarial requirements.[4] The Proposed Rule would also permit actions that exceed the agency's legal authority, including collecting contract-wide payment amounts and retroactively changing rules going back almost a decade (to 2011).

If CMS were to finalize the RADV provisions in the Proposed Rule, it would undermine stakeholder confidence in the agency's willingness to comply with the law and to act as a fair partner with the private sector. Private-sector partners must be able to rely on the government's word and know that the government will adhere to its commitments, whether stemming from statute or otherwise. A lack of trust injects significant uncertainty and risk into the system, undermines how the free market and public programs work together, and fundamentally weakens the integrity of the MA program. As a result, seniors and hardworking taxpayers might see higher costs, reduced benefits, and fewer MA plan options.

There is a better way. We ask that CMS withdraw these provisions and work with us on real solutions that are fair, accurate, and legally permissible.

Growing Value and Attractiveness of MA over Traditional Medicare
MA plans deliver better care and better value through innovative, patient-centered programs that improve quality and reduce costs. In the past decade, enrollment in MA has nearly doubled. More

[3] The FFS adjuster accounts for the fact that the documentation standard used in RADV – that claims must be submitted absolutely free of diagnosis coding errors – is different from the documentation standard used to calculate the risk adjustment model, which includes unsubstantiated FFS claims data with diagnosis coding errors.
[4] Centers for Medicare & Medicaid Services, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits, February 24, 2012. "…to determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount…The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)." Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.

than 22 million Americans – over one-third of all Medicare beneficiaries – have chosen to enroll in MA plans. These plans provide financial security by limiting out-of-pocket costs, offering integrated drug coverage, and providing a rich array of benefits not available in traditional Medicare, including dental, vision, hearing, and other supplemental benefits. Enrollees in MA plans are highly satisfied with the MA program.[5] MA plans provide these benefits at the same cost as traditional Medicare.[6] And in areas of the country where MA is popular, additional enrollment leads to slower traditional Medicare spending growth as providers employ MA practice patterns and care guidelines for their remaining traditional Medicare patients.[7]

Summary of Key RADV Concerns
We have attached comments with significantly more detail about our legal and policy concerns with the RADV changes in the Proposed Rule. They include the following:

- **A FFS Adjuster is required to ensure actuarial equivalence.** We have attached an analysis from the actuarial firm Milliman, based on CMS' data and methodologies as presented in the CMS technical study included with the Proposed Rule and subsequent data releases, that shows a FFS adjuster, or other similar adjustment, is necessary to ensure actuarial equivalence between payments to MA plans and payments under the FFS program. This adjustment is required due to the different documentation standards for the determination of diagnoses under MA and traditional Medicare. Milliman makes adjustments to address errors in CMS' methodology to find that a FFS adjuster would be both positive and material, and concludes that the CMS technical analysis "cannot appropriately be used to conclude a FFS adjuster is not required." Another study highlighted in our comments, and two recent federal district court decisions, also conclude that a FFS adjuster is required. In addition, the CMS technical study and addendum fail to address the key issue of actuarial equivalence in the context of RADV audits, contain multiple flaws and questionable assumptions, and in short, appear to have been designed to minimize error rates, enabling CMS to arrive at the conclusion that a FFS adjuster is not warranted. Further, CMS' claim that a FFS adjuster would create inequity among plans is neither credible, reasonable, nor consistent with a recent court decision which confirms that the statute requires CMS adjust payments to ensure actuarial equivalence. We believe strongly that CMS is required to implement a FFS adjuster in payment recovery activities, and that such an adjustment is not only necessary to achieve actuarial equivalence but is equitable for both audited and unaudited plans in that context.

- **CPI has no legal authority for extrapolation and, even if it did, is proposing to use a flawed methodology.** In RADV audits, CMS reviews medical records from a sample of beneficiaries. The Proposed Rule would provide for "extrapolation" – i.e., CMS would use the sample to calculate a contract-wide error rate and recover payments accordingly. The Social Security Act (SSA) provides authority to extrapolate, but only for Medicare

[5] Morning Consult National Poll. November 28-29, 2018. In this poll, 90 percent of MA members reported satisfaction with their health care coverage and preventive services, and 84 percent reported satisfaction with their prescription drug coverage.
[6] Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy. March 2019. For 2019, MA plan payments are equivalent to traditional Medicare costs.
[7] Johnson, Garret, Figuero, Jose F., Zhou, Xiner, et al. Recent growth in Medicare Advantage enrollment associated with decreased fee-for-service spending in certain US counties. *Health Affairs* 35(9): 1707-1715. September 2016.

contractors auditing providers under Parts A and B, and only in limited circumstances.[8] The Proposed Rule provides no legal justification for extrapolation. CPI simply asserts it has such authority.[9] Further, based on the findings of a study by Wakely (attached) that identified several significant areas of concern, we believe the extrapolation methodology CMS published in 2012 raises serious policy concerns because it will produce arbitrary results.[10]

- **Retroactivity is prohibited by federal law and is unnecessary and unjustified.** CMS proposes to grant itself authority to extrapolate audits for plan years 2011 and forward. The SSA clearly prohibits retroactive rules absent a statutory requirement, significant public safety concern, or other critical need[11] – none of which are present here. In addition, retroactivity poses major operational barriers for plans and providers. For example, CPI has recently begun conducting RADV audits for 2014 which review services rendered in 2013. This long passage of time could make it extremely difficult for plans to obtain medical records with respect to providers who, for example, are deceased, closed their practices, changed to new recordkeeping systems, etc.

- **Implementation of the RADV audit methodology would violate rulemaking requirements.** The methodology used by CPI for 2011, 2012, and 2013 audits was never subject to prior notice and comment rulemaking. And while CPI is now soliciting comments, the Proposed Rule indicates that CPI can implement changes solely through Health Plan Management System (HPMS) notices. CPI also has begun moving forward with audits for 2014, using a new methodology, without allowing a comment opportunity or broadly providing any details to the public on the methodology it is using. These actions are inconsistent with the SSA requirements for notice-and-comment rulemaking as indicated by the U.S. Supreme Court in its recent ruling in *Azar v. Allina Health Services.*[12]

RADV Recommendations

Based upon the legal and policy reasons above, we urge CMS to take the following steps:

- **Withdraw the RADV proposal.** The RADV provisions in the Proposed Rule should not be finalized. The provisions should be withdrawn in their entirety so together we can develop a collaborative and constructive solution.

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[8] 42 U.S.C. 1395ddd.

[9] See, e.g., 83 Fed. Reg. 54982, 54984 (Nov 1, 2018), where CMS asserts that extrapolation is "based on longstanding case law and best practices from HHS and other federal agencies" but provides no citations to or analysis of this authority.

[10] Murray, T., Morgan, E., Sauter, M. Medicare RADV: Review of CMS sampling and extrapolation methodology. Wakely Consulting Group. July 2018. Available at: https://www.ahip.org/wp-content/uploads/2018/07/Wakely-Medicare-RADV-Report-2018.07.pdf.

[11] 42 USC 1395hh(e)(1)(A) – "A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that- (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest."

[12] 139 S.Ct. 1804 (2019).

- **Affirm that regulatory changes cannot be applied retroactively.** CMS should follow the clear directive in the SSA to avoid retroactive application of new requirements. Any changes that impose new obligations on MA plans should be developed after appropriate and substantive interaction with the industry and apply only to payment years arising after the RADV proposal is finalized (i.e., prospectively). In other words, CMS can only apply changes in RADV methodology to payment years after publication of a final rule, and plans must have the ability to factor the RADV rules into their bids. Thus, even if CMS were to finalize any changes to the RADV methodology in 2019, the earliest it could apply would be 2021.

- **Acknowledge that a FFS adjuster is required under statute and improve CMS' audit methodology.** For many years, CMS expressly stated that a FFS adjuster is needed to meet statutory requirements for actuarial equivalence. CMS has reversed that long-held position with this rule. We strongly urge CMS to keep its word and develop a FFS adjuster, taking into account the multiple recent independent analyses finding such an adjustment is necessary, material, and legally required. In addition, the agency should improve the RADV audit methodology, including the design of a better process for determining whether a patient in fact has a given health condition through use of pertinent data sources.

- **Engage in meaningful, collaborative dialogue with plan partners to implement changes.** We urge CMS to create a fair and open process to develop appropriate payment oversight standards, similar to processes used in the traditional Medicare program and in certain aspects of the Food and Drug Administration's oversight of the pharmaceutical industry. This is especially important given the complexities of the MA payment system where various components (from benchmark-setting to risk adjustment to oversight) determine payments. Adopting such an approach is critical to the continued strength of the MA program and the ability of plans to meet the needs of the people they serve. The industry stands ready to work closely and collaboratively with CMS on the issues described here and other matters related to oversight of the MA program.

Conclusion
The RADV proposal violates numerous statutory requirements and is fundamentally unfair and ill-conceived. We urge CMS in the strongest possible terms to withdraw it and establish a collaborative process with stakeholders to create a workable alternative. We look forward to providing any additional information you may need and to continuing to work together to improve the health of the millions of Medicare beneficiaries our members serve.

Sincerely,



Matthew Eyles
President and CEO

Enclosure

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 ("Proposed Rule")

I. Summary: The Centers for Medicare & Medicaid Services' (CMS) proposed changes to the Risk Adjustment Data Validation (RADV) program fail to satisfy the Social Security Act, are based on flawed data, and are procedurally defective

The Proposed Rule includes several critical changes relating to RADV audits:

- CMS would extrapolate RADV audit findings to Medicare Advantage (MA) contract level payments.
- The extrapolation would be applied retroactively, going back to audits from 2011 and after.
- RADV audits for payment years 2011, 2012, and 2013 would be extrapolated based on a methodology described in a notice dated February 24, 2012 posted on the CMS website[1] (the 2012 RADV Notice).
- Audits for payment years 2014 and beyond would also be extrapolated. CMS has subsequently noted that it will extrapolate some, but not all, of the 2014 audits. In the Proposed Rule, CMS indicates it could use a different methodology for extrapolation including a potential approach that would use sub-cohorts of enrollees and has subsequently indicated that a sub-cohort methodology will be used for the 2014 audits.
- In the 2012 RADV Notice, CMS stated that it would apply a fee-for-service (FFS) adjuster as an offset to any RADV recovery amount. CMS also stated that it would conduct a study to determine the amount of the FFS adjuster. Specifically, in the 2012 RADV Notice, CMS stated: "The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)." However, under the Proposed Rule, CMS reverses course by stating that a FFS adjuster is not appropriate as an offset for RADV recoveries.
- CMS states that based on a technical analysis of "audit miscalibration error" in the risk adjustment model (the CMS technical study[2]), a FFS adjuster is unnecessary because the impact of audit miscalibration is negative and extremely close to zero. Separately, CMS asserts that a FFS adjuster is not appropriate, regardless of what the study found, because

[1] Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits, accessed at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.

[2] Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits - Technical Appendix, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Technical-Appendix.pdf.

it would only correct payments to audited plans, which would be inequitable to unaudited plans.

- Following the publication of the Proposed Rule, CMS published additional data regarding the technical study and also released an addendum that contained additional information on the study's assumptions and methodology.[3]

Below we highlight our strong policy and legal objections to each component of the RADV proposal, beginning with the FFS adjuster. We have attached an analysis from the actuarial firm Milliman[4], based on CMS' data and methodologies as presented in the CMS technical study and the addendum to the study, that shows a FFS adjuster, or other similar adjustment, is necessary to ensure actuarial equivalence between payments to MA plans and payments under the FFS program, as required by the Social Security Act (SSA). Milliman finds that the CMS technical analysis "cannot appropriately be used to conclude a FFS adjuster is not required." Milliman adjusts for errors in CMS' methodology to find that an FFS adjuster is both positive and material. As such, Milliman's study refutes CMS' conclusion that a FFS adjuster is not necessary. Another study highlighted below, and two recent federal district court decisions, also conclude that a FFS adjuster is required.

In addition, CMS' separate argument that it would be inequitable to have a FFS adjuster is a distraction from the question at hand – which is whether or not a FFS adjuster is required to ensure actuarial equivalence. The issue of actuarial equivalence arises whenever CMS seeks to apply a documentation standard for payment (medical records) that differs from the standard used in developing the risk adjustment model (claims). Plans not subject to a RADV audit may still be subjected to different document standards if they face overpayment claims by the government, and two district courts have recently held that the actuarial equivalence requirement must be satisfied in the overpayment context. Thus, equity in fact requires the application of a FFS adjuster to RADV audits. Further, unaudited plans that do not face payment recovery issues are not adversely affected by different documentation standards, and therefore the use of a FFS adjuster would not adversely affect them. In any event, as a membership organization representing the MA industry, we can say, without hesitation, that our members support a FFS adjuster regardless of whether one of their contracts is selected for audit.

The proposal also includes several other substantive and procedural defects. For example, CMS does not have statutory authority to use its proposed extrapolation methodology. Even if it did, CMS' published 2012 extrapolation methodology is so flawed that implementation would be arbitrary and capricious. (We have also attached an analysis from the actuarial firm Wakely that identifies the significant concerns with the 2012 RADV methodology.)

Further, CMS' proposed retroactive application of the regulation going back almost a decade – to audit results for the 2011 payment year, based on diagnosis data from 2010 – is impermissible under the law. In addition, CMS proposes to apply its 2012 published extrapolation methodology

[3] Addendum to the Fee-for-Service Adjuster study, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/RADV-Provision-CMS-4185-N4-Data-Release-June-2019.zip.

[4] Available at: http://us.milliman.com/insight/2019/Medicare-Advantage-RADV-FFS-adjuster/.

to 2011-2013 audits using an extrapolation methodology never developed through rulemaking. CMS is also moving forward with a new methodology for audits of the 2014 plan year without providing adequate detail or any opportunity for comment, despite statutory rulemaking requirements. These actions are inconsistent with the SSA requirement for notice-and-comment rulemaking as indicated by the U.S. Supreme Court in its recent ruling in *Azar v. Allina Health Services*.[5]

Given the substantive and procedural defects in CMS' proposals, we urge CMS to take the following steps:

- Withdraw these proposals in their entirety.
- Affirm that the agency cannot change regulations retroactively.
- Acknowledge that a FFS adjuster is required under statute to ensure actuarial equivalence since documentation standards applied to payment differ from the standards used in developing the risk adjustment model.
- Improve the agency's audit methodology.
- Note that CMS does not have statutory authority to conduct extrapolations under RADV.
- Engage in meaningful, collaborative dialogue with the industry to address these issues going forward.

II. FFS adjuster is required by law

The Medicare statute clearly requires actuarial equivalence in payments between traditional Medicare and the MA program.[6] Actuarial equivalence can either be achieved through a FFS adjuster in assessing payment errors in the MA program, or, alternatively, through CMS estimating the risk adjustment model using audited FFS data. This interpretation was supported by CMS itself and has been upheld by two recent court decisions. The Milliman study shows that a FFS adjuster, or other similar adjustment, is necessary to ensure actuarial equivalence between payments to MA plans and payments under the FFS program. In addition, CMS' claim that equity concerns would prevent application of a FFS adjuster is meritless. Each of these issues are discussed in detail below.

A. FFS adjuster is required by statutory language ensuring actuarial equivalence

i. Background on statute and risk adjustment

Section 1853(a)(1)(C)(i) of the Social Security Act (SSA) states in relevant part that the Secretary of HHS:

> shall adjust the payment amount [to an MA plan] for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . , so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for

[5] 139 S.Ct. 1804 (2019).
[6] See Section 1853(a)(1)(C)(i) of the SSA.

such adjustment factors if such changes will improve the determination of actuarial equivalence.

CMS makes the required statutory adjustments for health status through a risk adjustment model that applies a risk score to the MA payment for each enrollee. A risk score represents the relative costs of an individual compared to that for an average beneficiary. CMS uses the CMS-Hierarchical Condition Category (HCC) model to calculate these risk scores, which are determined based on demographic (e.g., age, gender, Medicaid status) and disease characteristics. Diseases are assigned to HCCs. In this sense, each HCC represents a disease group (e.g., diabetes, congestive heart failure). In general, each plan is paid its bid, multiplied by the risk score for that enrollee. The bid represents the average costs for an enrollee in that plan to receive Medicare Parts A and B items and services, standardized to a 1.0 risk score. The risk model pays more for sicker enrollees, and less for healthier enrollees.

The CMS-HCC risk model is estimated – or calibrated – on claims data from traditional Medicare (also known as Medicare FFS). Diagnoses from a previous year are used to estimate costs in a current year (e.g., 2013 diagnoses to predict 2014 costs). CMS uses a weighted least squares regression to determine the dollar amount associated with each HCC (e.g., chronic obstructive pulmonary disease, diabetes, etc.) and for demographic characteristics (e.g., age, gender, etc.). These estimated dollar amounts for each HCC or demographic characteristic are also known as model coefficients.

Through a process that CMS describes as “normalization”, CMS runs the model on FFS claims data to determine the total predicted spending for the population. CMS divides the total predicted spending by the number of enrollees to determine the average predicted spending for the population. CMS then converts the dollar amounts for the model coefficients to relative factors by dividing each coefficient by the average predicted costs for the population. The sum of these relative factors is the beneficiary risk score. This process leads to an average risk score of 1.0, because all dollar coefficients are divided by the average predicted spending for the population.

As noted earlier, plans submit bids to CMS that estimate the expected costs for their population to provide Medicare Part A and B items and services. For example, if the plan’s standardized bid is $1,000 per member per month, and the risk score for an enrollee is 1.1, the plan will be paid $1,100 for that enrollee.

CMS conducted audits for plan years 2011, 2012, and 2013 to determine whether diagnoses submitted by plans and used by CMS to determine risk scores were supported by medical records.[7] CMS used a documentation standard for these audits that differed from the documentation standard used to develop the risk adjustment model. The standard CMS used to determine payment errors under a RADV audit of an MA plan was the medical record, while the documentation standard used to develop the relative values in the HCC model was unaudited FFS claims data. This different documentation standard is why a FFS adjuster is necessary.

[7] CMS also conducted pilot and contract-level audits for plan year 2007.

ii. Actuarial experts and court decisions affirm the need for a FFS adjuster to ensure actuarial equivalence

The Actuarial Standards Board's Actuarial Standards of Practice (ASOP) provide guidelines for an actuarial review of risk adjustment models. These standards expressly provide that "[t]he type of input data that is used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model."[8] ASOP No. 45 requires consistency between how the model is developed and how it is applied in payment. However, the documentation standards used in the RADV audit to determine a plan's payment error are different from the documentation standards used to develop the risk adjustment model.

In addition, the United States District Court for the District of Columbia recently examined the underlying principle of actuarial equivalence and its applicability to section 1853(a)(1)(C)(i)'s actuarial equivalence requirement in a clearly written and well-reasoned opinion. *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173 (D.D.C. 2018) (Collyer, J.), *appeal docketed*, No. 18-5326 (D.C. Cir. Nov. 14, 2018).[9]

The *UnitedHealthcare* court found that section 1853(a)(1)(C)(i) imposes a non-discretionary duty on CMS whereby the agency must ensure that "two modes of payment" – payment to providers and suppliers under Medicare Parts A and B, on the one hand, and payment to MA plans under Medicare Part C, on the other – result in "present values [that] are equal under a given set of actuarial assumptions." 330 F. Supp. 3d at 185 (citations omitted). And by "given," the *UnitedHealthcare* court meant "'the same,' as in two figures are actuarially equivalent when they share the same set of actuarial assumptions." Id. at 185-86. And that "[d]ifferent assumptions behind the elements of a calculation would, *necessarily*, result in actuarially non-equivalent results." Id. at 186 (emphasis added). In other words, the assumptions used in Medicare FFS payments *must* hold true for payments to MA plans.

Applying the plain meaning of what constitutes "actuarial equivalence", the *UnitedHealthcare* court vacated the CMS final rule on overpayments promulgated in 2014. A critical part of the holding was that CMS violated the actuarial equivalence requirement by calculating risk adjustment payments to MA plans using unsubstantiated FFS diagnosis codes to determine the expected additional costs of providing coverage to a beneficiary with a particular medical condition, while holding MA plans to a standard of perfection whereby diagnosis codes on claims submitted by MA plans had to be absolutely free of diagnosis error. The court found that "CMS cannot subject the diagnosis codes underlying [MA] payments to a different level of scrutiny than it applies to its own payments under traditional Medicare without impermissibly skewing the

[8] Actuarial Standard of Practice No. 45 § 3.2.

[9] However, despite the significance of this decision, the Proposed Rule makes only passing mention of it in a footnote that states: "We are aware of the district court's recent ruling in *United HealthCare Insurance Co.* v. *Azar*, No. 16-cv-157 (D.D.C. September 7, 2018), and the government is reviewing that decision and considering its response. In any event, that ruling was made on the basis of the administrative record before the court, which did not include the results of our study." 83 Fed. Reg. at 55,040 n.29. A few days after the Proposed Rule was published, the government filed a motion for reconsideration in the district court citing the study and claiming that it constitutes "new evidence." *See* Defs.' R. 60(b) Mot. for Partial Recons., *UnitedHealthcare Ins. Co. v. Azar*, No. 1:16-cv-00157 (D.D.C. Nov. 5, 2018), ECF No. 76.

calculus: by doing so, it ensures that there will *not* be actuarial equivalence between traditional Medicare payments and [MA] payments for comparable patients." Id. at 186. The court took particular note of the fact CMS had acknowledged this very principle in 2012 when it promised that in determining the final payment recovery amount in RADV audits, CMS would "apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount." Id. at 188.

That is, if the documentation standard used in determining payments to MA plans is not the same as the standard used to calibrate risk model coefficients based on FFS claims data, there must be an adjustment. Alternatively, CMS could achieve actuarial equivalence by estimating the risk adjustment model using audited FFS data. However, by eliminating the FFS adjuster and continuing to estimate the risk model based on unaudited FFS claims data, CMS would hold MA organizations to a perfection standard for medical record documentation that is clearly not applied in the FFS program – as shown in the error rates by HCC that CMS identified in its own study. To do so would contravene the SSA's "actuarial equivalence requirement."

In another recent decision, the United States District Court for the Central District of California also examined the statutory provision in section 1853(a)(1)(C)(i) on actuarial equivalence. *See United States ex rel. Benjamin Poehling v. UnitedHealth Group, Inc.*, No. 16-08697, 2019 WL 2353125 (C.D. Cal. Mar. 28, 2019). The government argued that the statutory language "merely arms the Secretary with broad ***discretionary*** power to adjust payment levels based on the health status of Medicare beneficiaries." Id. at 5 (emphasis in original). In denying the government's motion for partial summary judgment, the court stated that it was "unpersuaded by the Government's argument in light of the plain language of the statute, which provides that the Secretary ***shall*** adjust the payment amount for factors the Secretary deems appropriate ***so as to ensure*** actuarial equivalence. Such language is far from discretionary." Id. at 6 (emphasis in original). The court also cited the decision in *UnitedHealthcare Ins. Co. v. Azar* on the need for a FFS adjuster as "persuasive authority". Id.

iii. Independent actuarial analyses clearly demonstrate the need for a FFS adjuster

Since CMS published the Proposed Rule, two independent analyses – one by Avalere (the Avalere study[10]) and one by Milliman (the Milliman study) – clearly demonstrate the need for a FFS adjuster. Importantly, neither analysis estimates the appropriate amount of the FFS adjuster. Rather, each study demonstrates that CMS' methodology, after adjusting for methodological flaws, would lead to a FFS adjuster that is ***not zero***. Thus, CMS' conclusion – that the audit miscalibration error is negative and extremely close to zero and therefore a FFS adjuster is not necessary – cannot be supported by its own technical study.[11]

[10] Avalere Health. Eliminating the FFS Adjuster from the RADV methodology may affect plan payment. March 2019. Available at: https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf.

[11] The methodological flaws demonstrate that, at a minimum, CMS has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [proposed a course of action that] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

a. Avalere study

Avalere analyzed CMS' conclusion in the Proposed Rule that re-estimating risk scores from the HCC model, based on coding errors in FFS claims, does not have an impact on risk scores. According to CMS, the risk scores from the re-estimated model were almost equal to those produced by the original model. This led CMS to determine that erroneous coding in FFS has minimal impact on MA risk scores, and therefore no FFS adjuster is needed.

Avalere noted that "certain key assumptions embedded in CMS' analysis do not appropriately capture the full variation in the data and minimized the impact of documentation error." For example, Avalere explained that CMS' simplifying assumption that each person in the sample has an average number of claims supporting a particular disease group, or HCC, is flawed because the distribution of Medicare claims is skewed. That is, the average number of claims is higher than the median, or midpoint. Avalere found, just by applying CMS' methodology to the ***actual*** distribution of error rates, that MA risk scores from the re-estimated model accounting for coding errors in FFS claims would be almost 8 percent lower than the original model. Avalere also says that "assuming that each claim supporting an HCC has an equal probability of error suggests that coding and documentation errors occur randomly. However, it is probable that there are correlations in errors."

b. Milliman study

AHIP sponsored an analysis by Milliman to evaluate CMS' conclusion that a FFS adjuster is not necessary. Milliman reproduced CMS' methodology and used CMS' published assumptions, the data, and the related files CMS provided.[12]

The Milliman study identifies multiple significant issues in the CMS assumptions and methodologies. The Milliman study focused on and adjusted for significant shortcomings in CMS' assumptions relating to how: 1) CMS normalized the risk adjustment model, and 2) CMS derived and applied beneficiary-level diagnosis error rates. Milliman found that CMS did not state that it calculated a FFS adjuster in the technical analysis accompanying the Proposed Rule and that "the CMS analysis measured a model calibration difference rather than addressing the question of whether a FFS adjuster is required in RADV audits."

The study explains it did not attempt to identify all potential issues and makes no judgment about the appropriateness of other methodologies that could be used to determine an appropriate FFS

[12] These data, released by CMS in March and June 2019, include: diagnosis data used to calibrate the CMS-HCC model through 2011; the model calibration file used to calculate 2009 MA payments; medical record review findings from the 2008 Comprehensive Error Rate Testing review; a mapping of ICD-9 diagnosis codes to version 12 of the CMS-HCC model; MA data for a sample of RADV eligible and non-RADV eligible beneficiaries from the CMS Enrollment Data Base, Model Output File, and Monthly Membership Report for 2011; dollar coefficients and risk factors for the original data, as well as 50 simulated 'corrected' iterations of the data, both before and after an adjustment to account for deletion bias is made to each iteration; text file versions of the SAS programs used to conduct the analysis summarized in the study and addendum; and a variable crosswalk and sort file used in the program to conduct the analysis. Upon review of the published SAS code, Milliman verified that the CMS implementation of the process described in the technical appendix was not materially different from its reproduction of the CMS analysis.

adjuster. Milliman further notes that, depending on other potential issues and alternative assumptions and methodologies used, other valid analyses may lead to reasonable FFS adjusters that are outside the ranges considered in the paper. Milliman states in the study that "we have not been able to conceive of a reasonable methodology that would lead to the conclusion a FFS adjuster is unnecessary."

Milliman summarizes its findings in the Executive Summary of the study as follows:

> The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule[13] on November 1, 2018, which contained provisions regarding risk adjustment data validation (RADV) audits. In particular, this proposed rule removed what is known as the fee-for-service (FFS) adjuster, which is a mechanism for adjusting RADV audit recoveries to ensure actuarial equivalence between FFS and MA payments. Actuarial equivalence is required by law[14]. Based on the analysis described in this white paper, we determined:
>
> - A FFS adjuster, or other similar adjustment, is necessary to ensure actuarial equivalence between payments to Medicare Advantage Organizations (MAOs) and payments under Medicare FFS.
> - CMS analyzed the difference between two calibrations of the CMS Hierarchical Condition Category (HCC) model to investigate what it referred to as "audit miscalibration." [15] CMS normalized the revised model inconsistently within the context of a FFS adjuster or a RADV audit; therefore its technical analysis cannot appropriately be used to conclude a FFS adjuster is not required.
> - CMS underestimates the level of diagnosis coding errors present in FFS claims data. Notably:
>   - CMS assumes diagnosis coding errors are independent from each other, which materially understates HCC error rates in FFS.
>   - CMS uses an average number of claims per HCC in its estimation of error rates rather than a distribution of the number of claims, which materially understates HCC error rates in FFS.

[13] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (2018).
[14] Title 42 U.S. Code § 1395w–23(a)(1)(C)(i).
[15] CMS coins the term "audit miscalibration" in its FFS adjuster executive summary. Retrieved December 20, 2018, from https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Excecutive-Summary.pdf. The proposed rule describes a similar concept. 83 Fed. Reg. 55041 (2018).

- CMS excludes claims that do not have medical records or necessary documentation available, which also understates the HCC error rates in FFS relative to RADV audit procedures.

> This white paper discusses and supports our findings that a FFS adjuster is required in RADV audits. The CMS technical analysis excluded simulated unsupported diagnoses in the calibration of the CMS-HCC model, but included them in the normalization of the model. CMS should have excluded unsupported FFS diagnoses in all steps of creating the CMS HCC model to properly address the question of whether a FFS adjuster is required in RADV audits. This paper shows had CMS excluded unsupported diagnoses from all steps, their analysis would have confirmed that a FFS adjuster is required.

Milliman further explains the purpose of their study as follows:

> The purpose of this study is to evaluate the CMS conclusion that a FFS adjuster is not appropriate; it is not to determine the appropriate amount of a FFS adjuster. The study shows that using CMS' methodology and data but adjusting for certain issues with that methodology, as described in this paper, leads to a conclusion that a FFS adjuster is required and is likely significantly greater than zero. As described in various sections of this paper, including those titled (a) 'CMS underestimated error rates for HCCs – Overview', (b) 'CMS underestimated error rates for HCCs – Is the sample size sufficient?', (c) 'Technical analysis - Model and data selection', and (d) 'Conclusion', further study of error rates is necessary to determine the true magnitude of a FFS adjuster.

While the Milliman study does not determine the appropriate amount of a FFS adjuster, it includes an estimate of what the FFS adjuster would be if it were to be calculated using the CMS error rates and methodology with an adjustment for the normalization process and the actual number of diagnoses per beneficiary (rather than the average).[16] Milliman explains that:

> Under this approach, we calculated a FFS adjuster using claim level error rates, actual distributions of the number of diagnoses (assuming full *independence*[17]), and an HCC error rate of 33% (assuming full *dependence*[18]), in addition to several scenarios in between. This approach resulted in estimated values of a FFS adjuster[19]

[16] Milliman's study is based on CMS' data and methodology. We discuss additional flaws with the CMS data and methodology that Milliman did not correct for in Sections II.B.ii-iv below.

[17] Independence, in this context, means diagnosis coding errors on individual claims are not related to diagnosis coding errors on other claims.

[18] Dependence, in this context, means diagnosis coding errors on claims are made in the same way for all claims for a particular HCC for each beneficiary.

[19] We define the FFS adjuster as the percentage reduction to a risk score based upon claim diagnoses to move to a medical record diagnosis basis for a FFS population. We calculated this percentage including beneficiaries with no HCCs and beneficiaries with one or more HCCs. When applying a FFS adjuster, care must be taken to apply it to the correct population, as the difference between the two definitions is significant. If this adjuster is applied to only beneficiaries who are RADV-eligible under the current CMS rules, the adjuster would need to be grossed up to apply only to that population.

between 8% and 21%. For perspective, 8% of federal payments to MAOs exceeds $16 billion and 21% exceeds $42 billion per year,[20] the majority of which are risk-adjusted.

A FFS adjuster, based on CMS's data modified to reflect reasonable error rates using an adjusted methodology (e.g., adjusts for the normalization process, the distribution of claims, and claim independence) likely lies somewhere between the two endpoints, 8% and 21%. We also note that CMS clarified in the June 2019 Addendum that they "…excluded claims where providers refused to submit medical records, or did not provide sufficient documentation." Although we do not have the information to evaluate the impact of these exclusions on the error rates, this exclusion is inconsistent with the RADV audit process. Properly including these unsupported diagnoses in the calculation of error rates would increase the magnitude of a FFS adjuster from the figures described in this paper.

As noted above, we make no judgment about the appropriateness of other methodologies that could be used to determine an appropriate FFS adjuster. Depending on other potential issues and alternative assumptions and methodologies used, other valid analyses may lead to reasonable FFS adjusters that are outside the range considered in this paper.

The magnitude of a FFS adjuster is highly sensitive to the specific HCC error rates used in the analysis, and the HCC error rates in the CMS analysis are highly sensitive to both the use of an average number of claims (versus a distribution of the number of claims) within an HCC and how independent the coding of one claim is to the next.

Further analysis must be completed to calculate an accurate FFS adjuster. In any case, the range is wide and even the bottom end is material and significant.

iv. Simplified illustrations of why actuarial equivalence requires a FFS adjuster

To see how actuarial equivalence works in practice, and why CMS violates actuarial equivalence if it does not apply a FFS adjuster, consider the following example. It is described in Table 1 and discussed in the Milliman study. This simplified example is based on an example that CMS developed when considering the need for a FFS adjuster.[21]

Assume CMS develops a risk model based on four individuals in FFS Medicare. In the example, the only cost of treatment is associated with diabetes. Each of the four is coded as having diabetes. The cost of treating a person with diabetes (which is supported in the medical record) is $4,000. The cost of a person who actually does not have diabetes (the medical record has no support for diabetes) is $0. Because CMS estimates the HCC model on diagnoses codes from

[20] Based on $204.7 billion in 2017 Part C federal spending. See HHS FY 2017 Budget in Brief - CMS – Medicare, available at https://www.hhs.gov/about/budget/fy2017/budget-in-brief/cms/medicare/index.html.
[21] See Decl. of Daniel Meron, Ex. B at 8, *UnitedHealthcare Ins. Co. v. Azar*, No. 1:16-cv-00157 (D.D.C. Oct. 2, 2017), ECF No. 44-3.

claims, regardless of whether they are supported by the medical record, CMS divides the $12,000 of total cost by the count of beneficiaries with a diabetes diagnosis on a claim. In this example, because four beneficiaries have diabetes on the claims, the estimated payment to treat diabetes is $12,000 divided by 4, or $3,000. Importantly, beneficiary D in Table 1 below does not have diabetes coded on the medical record, but since it is included on the claim, that person is used to determine the payment for an individual with diabetes.

Table 1. Example Showing Calculation of MA Payment Amount for Diabetes

	Diabetes on Claim?	Diabetes in Medical Record?	FFS Cost
Beneficiary A	Yes	Yes	$4,000
Beneficiary B	Yes	Yes	$4,000
Beneficiary C	Yes	Yes	$4,000
Beneficiary D	Yes	No	$0
		Total	$12,000
		Diabetes Value for MA Payment	$3,000

Now consider the example illustrated in Table 2 below, which is also described in the Milliman study and based on an example from CMS. In this example, a plan has five enrollees who had diabetes coded on claims, but three of them have diabetes supported in the medical record, and two do not. The total cost for the five beneficiaries in FFS is $12,000. However, if CMS were to recover funds for unsupported codes in a RADV audit without a FFS adjuster, CMS would take back $6,000 (for Beneficiaries D and E). This means the plan would be paid only $9,000, which is $3,000 less than under FFS.[22] The example clearly demonstrates there is not actuarial equivalence between FFS and MA when a RADV audit is performed without a FFS adjuster.

Table 2. Example Showing Actuarial Equivalence Not Achieved

	Diabetes on Claim?	Diabetes in Medical Record?	CMS Payment to Plan	Plan Cost	RADV	CMS Payment to Plan
Beneficiary A	Yes	Yes	$3,000	$4,000		$3,000
Beneficiary B	Yes	Yes	$3,000	$4,000		$3,000
Beneficiary C	Yes	Yes	$3,000	$4,000		$3,000
Beneficiary D	Yes	No	$3,000	$0	($3,000)	$0
Beneficiary E	Yes	No	$3,000	$0	($3,000)	$0
		Total	$15,000	$12,000	($6,000)	$9,000

[22] As Milliman notes, in this example, no normalization step is required because total FFS dollar costs are shown; therefore the $12,000 is already effectively normalized to a risk score of 1.0.

v. Applied example demonstrating the need for a FFS adjuster that includes risk adjustment model calibration

The Milliman study builds on the above example to show the need for a FFS adjuster within the MA payment framework. Below and in Table 3 are the key elements of the analysis.

For this example, Milliman created a simplified risk model using a least squares regression[23] that includes demographic and disease components, which is what CMS does when it estimates the CMS-HCC model. In this example, there are four individuals – two are 70 years old, one is 75, and one is 80 – and all have diabetes coded on their claims. Milliman estimated the model using the same set of assumptions that CMS uses, where only the claim is used as documentation.

Table 3. Model Estimated Based on Claim Information

	On Claim?	FFS Cost (Actual)	Predicted FFS Cost	Relative Coefficient
Beneficiary 1				
70 year old			$6,500	0.650
Diabetes	Yes		$3,000	0.300
Subtotal		$9,000	$9,500	0.950
Beneficiary 2				
70 year old			$6,500	0.650
Diabetes	Yes		$3,000	0.300
Subtotal		$10,000	$9,500	0.950
Beneficiary 3				
75 year old			$7,000	0.700
Diabetes	Yes		$3,000	0.300
Subtotal		$10,000	$10,000	1.000
Beneficiary 4				
80 year old			$8,000	0.800
Diabetes	Yes		$3,000	0.300
Subtotal		$11,000	$11,000	1.100
Total		$40,000	$40,000	1.000

Milliman then applies these figures to a case in which a plan has four individuals with a claim of diabetes, but only three have the diagnosis supported in the medical record. This example assumes a plan bid of $10,000 per year. See Table 4. As discussed further in the attached Milliman report, without a FFS adjuster, actuarial equivalence will not be achieved because plan payments will be $37,000 when the actuarially equivalent amount is $40,000.

[23] As noted in the Milliman study, due to the simplistic nature of this example, the least squares regression does not produce a unique solution. Milliman used SAS for the regression calculations and seeded the starting values to ensure the particular solution would most resemble the original CMS example we are expanding upon.

Table 4. RADV With and Without a FFS Adjuster

				MA Payment Without FFS Adjuster		MA Payment With FFS Adjuster	
	On Claim?	On Medical Record?	Coefficient	Before RADV	After RADV	Before RADV	After RADV
Beneficiary 1							
70 year old			0.650	$6,500	$6,500	$6,500	$6,500
Diabetes	Yes	Yes	0.300	$3,000	$3,000	$3,000	$3,000
Subtotal			0.950	$9,500	$9,500	$9,500	$9,500
Beneficiary 2							
70 year old			0.650	$6,500	$6,500	$6,500	$6,500
Diabetes	Yes	Yes	0.300	$3,000	$3,000	$3,000	$3,000
Subtotal			0.950	$9,500	$9,500	$9,500	$9,500
Beneficiary 3							
75 year old			0.700	$7,000	$7,000	$7,000	$7,000
Diabetes	Yes	Yes	0.300	$3,000	$3,000	$3,000	$3,000
Subtotal			1.000	$10,000	$10,000	$10,000	$10,000
Beneficiary 4							
80 year old			0.800	$8,000	$8,000	$8,000	$8,000
Diabetes	Yes	No	0.300	$3,000	$0	$3,000	$0
Subtotal			1.100	$11,000	$8,000	$11,000	$8,000
Total			1.000	$40,000	$37,000	$40,000	$37,000
Raw RADV Recovery					$3,000		$3,000
FFS Adjuster					$0		$3,000
Final RADV Recovery					$3,000		$0
Final Payment to MAO				$40,000	$37,000	$40,000	$40,000
Actuarially Equivalent?				Yes	No	Yes	Yes

The Milliman study includes several additional scenarios that review the impact of calibrating the risk model with one set of documentation standards yet recovering funds in RADV audits using a different set of documentation standards. All these examples demonstrate that when the CMS-HCC model is calibrated and normalized based on unaudited claims data, a FFS adjuster is necessary under a RADV audit to maintain actuarial equivalence as required by statute.

vi. Nothing in SSA sections 1853(a)(1)(C)(ii) or (iii) change the requirement for a FFS adjuster.

In the request for additional comment published in the Federal Register on June 28, 2019, CMS sought input "on whether section 42 U.S.C. 1395w–23 [section 1853 of the SSA]—and in particular clause (a)(1)(C), which requires risk adjustment in subclause (a)(1)(C)(i), mandates a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C)(iii)—mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology."

As stated above, section 1853(a)(1)(C)(i) clearly requires actuarial equivalence in payments between traditional Medicare and the MA program.[24] Actuarial equivalence can either be achieved through a FFS adjuster in assessing payment errors in the MA program, or, alternatively, through CMS estimating the risk adjustment model using audited FFS data. This interpretation was supported by CMS itself and has been upheld by two recent court decisions. The provisions in subsections (ii) and (iii) relate to adjustments for coding intensity and for risk adjustment for new enrollees in chronic condition special needs plans. They have nothing to do with the requirement for a FFS adjuster under subsection (i). For example:

- Under the plain language of the statute, subsection (i) does not refer to subsections (ii) or (iii). The requirements are completely independent. Congress added subsections (ii) and (iii) a number of years after subsection (i), but despite multiple chances to change the actuarial equivalence language in subsection (i), did not do so. Thus, there is nothing in the statute to suggest subsections (ii) and (iii) support removal of the FFS adjuster from RADV methodology.
- The coding intensity adjustment in subsection (ii) addresses coding pattern differences between MA and FFS. CMS has expressly stated that RADV audits address coding *accuracy* issues, not coding pattern differences.[25] Accordingly, even if the statute gave CMS discretion to not apply a FFS adjuster based on provisions in subsection (ii) (which it does not), CMS could not avoid applying a FFS adjuster without explaining its shift in legal interpretation that the two provisions are unrelated; providing a detailed analysis demonstrating how the coding intensity adjustment allegedly undercut the need for a FFS adjuster; and providing a comment opportunity through formal notice-and-comment rulemaking.
- Subsection (iii) requires CMS to apply a higher risk score for new enrollees in special needs plans for those with chronic conditions. This provision is clearly irrelevant to the general actuarial equivalence requirement in subsection (i) or the need for a FFS adjuster.

[24] See Section 1853(a)(1)(C)(i) of the Social Security Act.
[25] Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, at 38-39 (April 2, 2018).

B. CMS' study fails to support its position on the FFS adjuster

Notwithstanding the *UnitedHealthcare* decision and its reliance on the 2012 RADV Notice, CMS now proposes to eliminate the FFS adjuster and offers two flawed and unsupportable reasons for doing so:

- Systematic Effect: Ignoring the agency's previous conclusion that the FFS adjuster "accounts for the fact that the documentation standard used in RADV audits . . . is different from the documentation standard used to develop the Part C risk adjustment model," the Proposed Rule relies on the results of the CMS technical study. According to CMS, the study results "suggest[] that errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations."
- Inequities Between Audited and Unaudited Plans: CMS also asserts that "even if [it] had found that diagnosis error in FFS claims data led to systematic payment error in the MA program, we no longer believe that a RADV-specific payment adjustment would be appropriate. . . . Doing so would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans."

Below we discuss the limitations in the CMS technical study at length. In general, the CMS technical study fails to address the key issue of actuarial equivalence in the context of RADV audits. In addition, as the Milliman study points out, the level of the FFS adjuster depends in large part on the assumptions used. However, the CMS technical study contains multiple flaws and questionable assumptions that led to the calculation of artificially low error rates and, as a result, to CMS concluding that a FFS adjuster was not necessary. We reference the findings from the Milliman study where appropriate in each section on these limitations. After our discussion on the limitations of the CMS technical study, we discuss our strong disagreement with the rationale used to justify the inequities argument.

The limitations in CMS' study are as follows:

i. Limitation #1: An analysis of the systematic effects of the risk model does not address the actuarial equivalence question in the context of RADV audits

The question CMS identified in the 2012 RADV Notice related to how the FFS adjuster applies within the context of RADV, when recoveries are made if a medical record does not support a diagnosis code, but the risk model is developed based on claims and medical records that are not reviewed. This is the same issue addressed in the *UnitedHealthcare* case, where the court noted that "two figures are actuarially equivalent when they share the same set of actuarial assumptions. Different assumptions behind the elements of a calculation would, necessarily, result in actuarially non-equivalent results." *UnitedHealthcare*, 330 F. Supp. 3d at 186.

The Proposed Rule, however, makes no effort to address this meaning of "actuarial equivalence" in the context of RADV. As discussed in Section II.A.vi above, CMS did not even seek public comment on whether the statutory language mandating actuarial equivalence at section 42 U.S.C.

1395w–23(a)(1)(C) should be considered in the context of applying a FFS adjuster in the RADV audit methodology until the agency released additional data in June 2019. Instead, the Proposed Rule, through the CMS technical study, purports to ask and answer a different question: namely, whether diagnosis errors in FFS claims have a "systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore [a] systematic effect on the payments made to MA organizations."

This issue is irrelevant to the question of whether a FFS adjuster is needed to ensure actuarial equivalence in the context of RADV audits. That is, even assuming for the sake of argument that the CMS study actually supports the aggregate negative "systematic effect" conclusion for which it is cited (which in fact it does not), section 1853(a)(1)(C)(i) of the SSA imposes a mandatory duty on CMS to ensure actuarial equivalence. This mandatory duty was recognized in recent rulings by district courts in both the *UnitedHealthcare Ins. Co. v. Azar* and *Poehling* proceedings, as described above.

This requirement does not terminate when payment is made to an MA plan. The statute's use of the word "ensure" confirms that the actuarial equivalence requirement remains in effect through and including whatever post-payment audit process CMS may devise. The actuarial equivalence requirement is not met when CMS estimates the model on unaudited FFS data because it uses an audit methodology that applies a documentation standard drastically different from that applied to FFS claims. The use of these different documentation standards in model estimation and payment must therefore be addressed through the application of a FFS adjuster. Not doing so violates the fundamental standards of actuarial equivalence, which require consistency between the way a risk adjustment model is developed and how it is applied.

The continuing nature of the statutory duty imposed by section 1853(a)(1)(C)(i) of the SSA was at the heart of the decision in *UnitedHealthcare*. CMS stated before the court that the statute only imposed a duty regarding the manner in which the agency calculated initial payments made to MA plans. However, as Judge Collyer explained when questioning counsel for CMS during oral argument: "Their argument [referring to the *UnitedHealthcare* plaintiffs] is that by figuring the coefficients on unaudited files and then paying out but requiring repayment on anything that is not substantiated in a medical record is to start at the beginning as if it were actuarially equivalent, but set up a system whereby it no longer is. The beginning is arguably equivalent, the process is not." Hr'g Tr. 39:14–24, *UnitedHealthcare Ins. Co. v. Azar*, No. 1:16-cv-00157 (D.D.C. Aug. 9, 2018), ECF No. 73.

Therefore, even if errors in diagnosis coding under Medicare Parts A and B do not have a "systematic effect" on the aggregate risk scores used to calculate payments made to all MA plans, section 1853(a)(1)(C)(i) of the SSA requires CMS to take into account those diagnosis coding errors when determining how much, if anything, a particular MA plan may owe as the result of a RADV audit. This requires considering the particular enrollees included in the sample under review and, if contract-level extrapolation is deemed lawful, the particular enrollees included in the MA contract under review. The statute permits no construction—let alone a reasonable construction—that applies a different standard. *See, e.g.*, *Michigan v. EPA*, 135 S. Ct. 2699, 2708 (2015) ("*Chevron* allows agencies to choose among competing reasonable interpretations of a

statute; it does not license interpretive gerrymanders under which an agency keeps parts of statutory context it likes while throwing away parts it does not.").

ii. Limitation #2: The CMS technical study is based on inconsistent and arbitrary data

CMS uses three sources of input data for its technical study:

1) Calendar Year (CY) 2008 Comprehensive Error Rate Testing (CERT) audit data
2) 2004-2005 FFS claims data
3) Two million MA records sampled from the 2011 overpayment run, split evenly between RADV eligible and non-RADV eligible beneficiaries[26]

CMS does not explain why it chose each of these sources, in terms of the data or the time periods which the data represent. However, the data and time periods raise numerous questions. For example:

- More recent FFS claims data and MA records could have been used, rather than 2004-2005 FFS claims and 2011 MA data.
- By conducting its analysis using data sources from different years, the study may be inappropriately accounting for differences in health care treatment patterns between these different time periods.
- One-half of the MA records relate to beneficiaries who *are not eligible* to be included in RADV audits, which raises serious questions about whether the study could accurately assess the impact of removing diagnosis errors in a RADV audit of beneficiaries who *are eligible* to be included.
- CMS acknowledges on page 55037 of the Proposed Rule that the CMS-HCC model is "recalibrated approximately every 2 years to reflect newer treatment and coding patterns in Medicare FFS." Given this practice, it is unclear why CMS is relying on a point-in-time analysis of coding patterns from over 10 years ago.

The absence of any explanation for these data sources raises transparency concerns as commenters are left without an indication of the rationale for CMS' decision to use these data.

iii. Limitation #3: The CMS technical study is not a RADV-like review

In the 2012 RADV Notice, CMS states that the amount of the FFS adjuster would be "calculated by CMS based on a RADV-like review of records submitted to support FFS claims data." However, CMS did not conduct a RADV-like review of FFS claims data. In a RADV audit, CMS

[26] Per Section 1128J(d) of the SSA and the overpayment regulation 42 CFR §422.326, all MA plans are required to report and return overpayments. CMS recovers these overpayments on an annual basis by conducting "risk score reruns" for prior payment years within a six-year lookback period. From the data subsequently released by CMS in March 2019, we understand that CMS sampled MA records from those submitted for PY 2011 (2010 dates of service). However, CMS does not clarify that these data had been processed for overpayment recovery or specify during which calendar year the 2011 overpayment run took place (the most recent deadline for PY 2011 overpayment submission was July 6, 2018 and risk scores for 2011 were rerun for overpayment recovery purposes in payments made to MA plans on October 1, 2018).

randomly selects 201 beneficiaries from a MA contract in equal numbers across three strata based on risk score, determines whether the HCCs submitted for payment for each of these beneficiaries is substantiated based on a prescriptive medical record review, and then determines a payment error based on the difference between the original risk scores calculated for these beneficiaries and the corrected risk scores based on the medical record review. This payment error would then be extrapolated to determine a final recovery amount.

Instead of following the RADV methodology in reviewing FFS claims data, CMS designed its flawed study to determine the impact on the CMS-HCC risk model of diagnosis coding errors in FFS claims data. In addition, the RADV parameters were not strictly followed. For example:

- Instead of measuring diagnosis discrepancies using data sampled at the beneficiary level, CMS generated an estimate of these errors by using data sampled at the claims level. In its methodology, CMS commits a number of errors in assigning the beneficiary-level error rate based on this review of the sampled claims data. As a result, CMS' methodology is fatally flawed and does not represent an accurate representation of the beneficiary-level error rates.
    - Specifically, instead of selecting a random sample of FFS beneficiaries and reviewing the medical records to support each risk adjustment-eligible diagnosis reported for those beneficiaries, CMS reviewed a random sample of 8,630 FFS outpatient claims from the CERT audit data.
    - The CERT data do not resemble a RADV audit sample in any way, and CMS also admits that these data lack a large enough sample size for many HCCs to generalize error rates to the total population.
    - If the CERT audit data were somehow shown to be appropriate, which has not occurred, 2008 data predates the implementation of ICD-10 codes and therefore have questionable applicability to diagnosis coding trends in today's environment.
- CMS includes beneficiaries who are not eligible for inclusion in a RADV study. Given that one-half of the MA records used in the CMS technical study were not RADV eligible, the study does not represent a 'RADV-like' review of claims data, as CMS stated it would conduct to generate the FFS adjuster.
- The CMS methodology does not take into account the process plans must follow to validate HCCs in RADV medical record review, which allows submission of a specified number of medical records to substantiate an HCC.
- As noted in its addendum to the technical study, CMS "excluded claims where providers refused to submit medical records, or did not provide sufficient documentation" rather than determining the diagnoses on these claims were not supported, as would have occurred in a RADV audit.
- Instead of comparing original *risk scores* from a sample of beneficiaries to corrected risk scores based on medical record review, CMS calculated *coefficients* based on FFS claims data reflecting the simulated error rates and applied those coefficients to MA data.

As the technical analysis that CMS performed in no way resembled a "RADV-like review" – which the agency stated it would conduct in order to calculate the amount of the FFS adjuster –

and relies on statistical concepts not relevant to the key issue of actuarial equivalence, the study cannot be used to support a position that the FFS adjuster is not necessary.

iv. Limitation #4: CMS makes invalid statistical assumptions about claim independence

A critical assumption that allows CMS to find that a FFS adjuster is not necessary is that each Medicare claim is independent of one another. By making this assumption, CMS dramatically understates the likelihood that a beneficiary will have a diagnosis coding error corresponding to a given HCC. For example, in its review of the 2008 CERT data, CMS finds that among HCC 80 (Congestive Heart Failure), 156 claims out of 519 claims were discrepant, for an error rate of 30.1 percent. The agency further notes that an average enrollee with HCC 80 would have six claims, which leads to a probability that HCC 80 would be in error for a beneficiary of 0.301*6.1=0.8 percent. Not surprisingly, when CMS applies such low error rates to its data, the impact of removing diagnosis codes is minimal.

On page 9 of the CMS technical study appendix, CMS asserts – without any additional support – that "each enrollee HCC potentially has multiple claims with independent supportive medical records." In reality, coding errors will not be independent from one claim to the next, especially if the patient is seeing the same healthcare provider.

As pointed out in the Milliman study: "We believe it is more likely that a provider or medical coder would tend to make similar errors from one claim to the next based upon their work habits, training, office practices, and by looking at their own prior diagnosis coding when coding a subsequent claim; thus errors would be correlated to at least some degree. The assumption that providers code randomly must hold to assume independence." Further, Milliman points out: "This independence assumption can be expected to result in HCC-level error rates that are significantly lower than if providers or medical coders make errors that are related to each other, perhaps from copying diagnoses from a prior visit or from particular personnel repeatedly making the same type of error." Avalere makes a similar point in its study, noting that "it is probable that there are correlations in errors. For example, a healthcare provider submitting multiple claims for the same beneficiary might repeat the same coding or documentation error."

To summarize, CMS cannot multiply probabilities when the events are not independent. If the same provider has seen the enrollee, it is far more likely that the events are dependent. If there is a 50 percent chance that a provider will make an error when seeing an enrollee, that same probability applies regardless of how many visits the enrollee has to the provider. This assumption by CMS – which Milliman critiques in their analysis – is simply not credible.

v. Limitation #5: The average number of claims per beneficiary cannot be used to determine a beneficiary level error rate

Milliman notes that using an average number of claims per member in calculating a beneficiary level error rate ignores the fact that the number of claims per person will vary. Avalere makes a similar argument in its study.[27] That is, some beneficiaries have more than the average number of

[27] Op cit. 9

claims, and some have fewer. In addition, the data are not normally distributed, as noted in the Avalere study. That is, a small number of enrollees have a large number of claims, which skews the distribution of claims underlying the CMS study.

Milliman describes an example using HCC 55 (Major Depressive, Bipolar, and Paranoid Disorders), which CMS assumes has about a 50 percent error rate on a HCC basis. Milliman presents an illustrative example where two beneficiaries have HCC 55; one has two claims, while the other has 10. In this case, the error rate, assuming independence of diagnosis coding errors, is 0.5 ^ 2 = 0.25 for the first beneficiary and 0.5 ^ 10 = 0.0001 for the second. By averaging these error rates, Milliman finds the average error rate is 0.125. By contrast, CMS' methodology, which focused on an average number of claims for all beneficiaries, would result in an average error rate of 0.5 ^ 6 = 0.016. In other words, Milliman finds an average error rate in this example that is nearly eight times higher than the error rate calculated using CMS' approach.

In Milliman's analysis, they adjust for this methodological error by using the actual distribution of claims, rather than the average number of claims. Due to limitations in the data provided by CMS, Milliman used the 5 percent Limited Data Set (LDS) claims files for this analysis. The Avalere study also used the LDS files. Milliman's and Avalere's use of the actual number of claims represents a much more accurate depiction of how error rates can be applied to determine a FFS adjuster. By using the average number of claims instead of the actual number of claims, CMS calculated an inaccurate estimate of the audit miscalibration. Making this adjustment, as Milliman demonstrates, dramatically increases the level of the necessary FFS adjuster and proves that CMS' conclusion that a FFS adjuster is not necessary is flawed.

vi. Limitation #6: CMS does not properly "normalize" the risk adjustment model in its simulations

In its methodology, CMS excludes unsupported diagnosis codes in the calibration of the CMS-HCC model. However, when transforming the coefficients calculated by the risk model to relative factors used to determine a risk score – a process referred to as normalization, which ensures the overall risk score is 1.0 – CMS includes the unsupported diagnosis codes and therefore does not correctly normalize the model. As Milliman finds, this step leads CMS to its erroneous conclusion that a FFS adjuster is not necessary, when in fact adjusting for this error alone demonstrates that a FFS adjuster is necessary. In addition, the magnitude of the FFS adjuster is material (that is, non-zero) – even when using the average number of claims, which as noted above is not a valid assumption.

CMS, in their Addendum to the FFS study[28], provided additional information on the normalization process. This additional detail, however, does not correct for any of the flaws inherent in the agency's chosen methodology. In particular, CMS includes a mathematical "explanation" of their approach to "offset deletion bias". CMS also described the Inflated Post-Audit Risk Score (IPARS) adjustment that they made to "offset the bias that the deletion procedure itself creates in expenditures."

[28] Op cit. 3

Milliman reviewed the mathematical arguments put forward by CMS in the Addendum and found notable flaws in CMS' approach. In particular, Milliman notes the following:

> The mathematical explanation contains some errors. For example, step 2 defines I_{ji} as the complete matrix of all HCC disease indicators and further that the sumproduct of all coefficients and indicators is equal to the total FFS expenditure (E):
>
> $$\sum_{j=1}^{m}\sum_{i=1}^{p} b_{ji} I_{ji} = \sum_{j=1}^{m} E_j$$
>
> However, the disease indicators do not include demographic variables, which are included in the CMS HCC model and explain a significant portion of expenditures. Further, the use of averages to describe coefficient values in step 5 is inconsistent with Ordinary Least Squares (OLS) because it ignores the difference in weight and frequency of the coefficients and independent variables within the regression model.
>
> If regression concepts were considered rather than average coefficient values, then the removal of a disease indicator for a beneficiary with above average spend for that HCC would decrease, rather than increase (as CMS described in step 6), the coefficient value resulting from OLS.
>
> However, these mathematical problems with the CMS explanation should not be expected to invalidate the overall conclusion that, when the CMS HCC model is calibrated and normalized to produce the total FFS expenditures on separate sets of independent variables, the total always balances to the total FFS expenditure.

With respect to the IPARS, Milliman finds that CMS' calculation of the IPARS is itself evidence of the need for a FFS adjuster. IPARS represents an interim step in the methodology that was implicit in the description CMS provided in its technical appendix but made explicit in the Addendum – IPARS is the name CMS ascribes to the process through which the CMS-HCC model was normalized inconsistently in order for CMS to conclude that a FFS adjuster is not necessary. In particular, Milliman states that: "CMS calculates IPARS to be 0.9%. The CMS Addendum does not discuss the significance of IPARS; however, a non-zero IPARS demonstrates the need for a FFS adjuster. Further, the CMS IPARS calculation is consistent with our calculation of a payment discrepancy of 1.1% in the next section titled 'Adjustment of CMS technical approach.' As demonstrated in the examples and conceptual discussion, above, this difference in risk score and payment results is evidence of the need for a FFS adjuster in RADV audits. If the technical issues with CMS's estimated HCC error rates were resolved, IPARS would be dramatically larger, emphasizing the critical need for a FFS adjuster."

C. CMS' claim that a FFS adjuster would result in inequity among plans is not credible or reasonable

CMS provides an alternative rationale for not applying a FFS adjuster: even if the CMS technical study might otherwise support a FFS adjuster, the agency believes a FFS adjuster should not be applied because it would create inequities between audited and unaudited plans. We strongly disagree.

The FFS adjuster is needed to ensure compliance with the actuarial equivalence requirement in the statute. The issue of actuarial equivalence arises whenever CMS seeks to apply a documentation standard for payment (medical records) that differs from the standard used in developing the risk adjustment model (claims). Plans not subject to a RADV audit may still be subjected to different document standards if they face overpayment claims by the government, and two district courts have recently held that the actuarial equivalence requirement must be satisfied in the overpayment context. Thus, equity requires the application of a FFS adjuster to RADV audits. Further, unaudited plans that do not face payment recovery issues are not adversely affected by different documentation standards, and therefore the use of a FFS adjuster would not adversely affect them.

In addition, even assuming CMS was otherwise correct in identifying certain cases where there is a potential for different treatment, it would still be unreasonable for CMS to use the alternative rationale to avoid implementing a FFS adjuster. CMS seeks to justify not applying corrective action when such action is required to maintain actuarial equivalence for payments made to a specific MA plan undergoing a RADV audit, simply because no such corrective action will be taken by CMS with respect to MA plans not undergoing RADV audits. In other words, CMS wants to withhold fairness for some because the agency refuses to do justice to all. That interpretation is clearly not permitted under section 1853(a)(1)(C)(i) of the SSA. See *Global Tel*Link v. FCC*, 866 F.3d 397, 418 (D.C. Cir. 2017) (Silberman, J., concurring) ("*Chevron's* second step can and should be a meaningful limitation on the ability of administrative agencies to exploit statutory ambiguities, assert farfetched interpretations, and usurp undelegated policymaking discretion."). Moreover, the recent decision in *Poehling* confirms that the statute requires that CMS adjust payments to ensure actuarial equivalence. See *United States ex rel. Benjamin Poehling v. UnitedHealth Group, Inc.*, No. 16-08697, 2019 WL 2353125 (C.D. Cal. Mar. 28, 2019). CMS does not have the discretion to ignore that statutory requirement simply because it believes that requirement to be inequitable.

As a membership organization representing the MA industry, we can say without hesitation that our members support a FFS adjuster regardless of whether one of their contracts is selected for audit. We believe strongly that CMS is required to implement a FFS adjuster in payment recovery activities, and that such an adjustment is not only necessary to achieve actuarial equivalence but is equitable for both audited and unaudited plans in that context.

D. The FFS adjuster is required under the "same methodology" language in the statute

Section 1853(b)(4)(D) of the SSA requires that in computing expenditures for traditional Medicare, CMS must use the "same methodology as is expected to be applied in making payments to [MA plans]." CMS violates this statutory command if the "'methodology' applied in 'making payments' to [MA] insurers involves reconciliation based strictly on audited diagnosis codes for [MA] patients, in sharp contrast to unverified diagnosis codes for traditional Medicare patients from which payment rates were set." *UnitedHealthcare*, 330 F. Supp. 3d at 187. Just like the 2014 Overpayment Rule vacated in *UnitedHealthcare*, the Proposed Rule "fails to recognize a crucial data mismatch, and without correction, it fails to satisfy [1853(b)(4)(D)]." *Id*. A similar statutory interpretation – that this section of the statute is applicable to risk adjustment payments, and not just to CMS' annual reporting requirements as the Government had argued – was also recently upheld in the U.S. District Court for the Central District of California in its ruling in *United States ex rel. Benjamin Poehling v. UnitedHealth Group, Inc.:* "But the Court is unpersuaded that the statute is so limited [to CMS' annual reporting requirement], given that the face of the statute also requires '***computation*** [of] … [t]he average risk factor for the covered population . . . using the same methodology ***as is expected to be applied in making payments***' to MA plans." No. 16-08697, 2019 WL 2353125 at 5 (C.D. Cal. Mar. 28, 2019) (citing 42 U.S.C. § 1395w-23(b)(4)) (emphasis in original).

III. CMS' extrapolation proposal is procedurally defective, exceeds the Agency's statutory authority, and is arbitrary and capricious

A. The Proposed Rule fails to adequately reference the legal authority for extrapolation

CMS asserts that it may use contract-level extrapolation "based on longstanding case law and best practices from [the Department of Health and Human Services] and other federal agencies" (Preamble p. 54984). However, agency authority must be derived from statute, and the Proposed Rule never specifies what statute CMS believes grants it the authority to use extrapolation with respect to MA plans. As a result, the Proposed Rule violates the fundamental requirement imposed by the Administrative Procedures Act (APA) whereby a notice of proposed rulemaking must include "reference to the legal authority under which the rule is proposed."[29] The Proposed Rule also does not identify the "longstanding case law" referred to by the agency, thereby requiring the public to speculate regarding the decision(s) on which CMS might be relying. The APA's notice-and-comment requirements do not permit such an approach.

[29] 5 U.S.C. § 553(b)(2); *see also Attorney General's Manual on the Administrative Procedure Act* 29 (1947) ("The reference [to legal authority required by § 553(b)(2)] must be sufficiently precise to apprise interested persons of the agency's legal authority to issue the proposed rule.").

B. CMS does not have statutory authority to extrapolate RADV audit results

CMS does not have authority to use contract-level extrapolation against MA plans under the SSA. Most case law related to extrapolation does not address the threshold question of whether a federal agency has statutory authority to use extrapolation. Instead, it addresses the separate question of whether the use of extrapolation violates the constitutional right to due process.[30] The only appellate decision of which we are aware that addressed a somewhat similar statutory-authority question did so solely with respect to the use of extrapolation in FFS Medicare at a time when such extrapolation had already become a "long-standing and well-established practice" as applied to providers of services and suppliers under Medicare Parts A and B. *Chaves Cnty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 923 (D.C. Cir. 1991). Even in that instance, however, the D.C. Circuit openly acknowledged that the question of statutory authority to use extrapolation was "close." *Id.* at 923. The D.C. Circuit also found that nothing in the Medicare Act at the time spoke directly to the use of extrapolation. *See id.* at 916–18. However, after repeatedly noting that the appellants (three home health agencies) failed to challenge the statistical validity of the calculations at issue, the court found that the use of extrapolation in the particular context before it represented a reasonable interpretation of the "authority to recoup overpayments *from providers*," *Id.* at 916-17, 921-22 (emphasis added).

Yet much has changed since the D.C. Circuit's decision in *Chaves County*, the statutory-authority holding of which has essentially gone untested in any other circuit court of appeals. Not only has that holding been undermined by the Supreme Court's rejection of the "novel project" of "Trial by Formula,"[31] the government itself has acknowledged the need for legislation before proceeding as suggested in the Proposed Rule, explaining in testimony before Congress:

> The President's Budget includes seven legislative and administrative proposals that will strengthen efforts to fight Medicare and Medicaid fraud and abuse . . .
>
> *Legislative Proposals Included in the Budget*
>
> Extrapolate MA Plan Sample Error Rate to Entire Plan Payment in Risk Adjustment Audits: Historically, CMS has only recovered overpayments from risk adjustment

[30] *See, e.g., Ratanasen v. Cal. Dep't of Health & Human Servs.*, 11 F.3d 1467, 1469–71 (9th Cir. 1993) (addressing bankruptcy court's use of extrapolation with respect to amounts owed to state Medicaid program); *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 89–90 (2d Cir. 1991) (addressing state Medicaid agency's use of extrapolation); *Ill. Physicians Union v. Miller*, 675 F.2d 151, 154–56 (7th Cir. 1982) (same); *see also Mich. Dep't of Educ. v. U.S. Dep't of Educ.*, 875 F.2d 1196, 1204–06 (6th Cir. 1989) (addressing whether federal agency's use of extrapolation in recouping vocational-rehabilitation funds from State satisfied substantial-evidence standard); *Georgia ex rel. Dep't of Human Res. v. Califano*, 446 F. Supp. 404, 409–10 (N.D. Ga. 1977) (addressing whether federal agency's use of extrapolation in recouping Medicaid funds from State was arbitrary and capricious).

[31] *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367 (2011). Writing for the Supreme Court in *Dukes*, Justice Scalia found that it was improper to certify a class action on the premise that the defendant would only be able to litigate its defenses with respect to monetary claims asserted by a sample of class members, the outcome of which would then be extrapolated to the class as a whole. *See id.* The Supreme Court recently went further by limiting the use of extrapolation to those instances where statistical evidence would be relevant in adjudicating an individual claim of liability. *See Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016).

> errors found in the audited sample. This proposal would require that CMS recover risk adjustment overpayments by extrapolating sample error rates to all audited plans through risk adjustment validation (RADV) audits. The plan payment will only be adjusted on a statistically valid sample of beneficiaries . . .[32]

It would "strain[] credulity to suggest that" the government submitted such a request to Congress "without analyzing the relevant statutes." *U.S. House of Representatives v. Burwell*, 185 F. Supp. 3d 165, 186 (D.D.C. 2016).

Further, Congress has not stood silent with respect to the use of extrapolation. Instead, it has authorized CMS to use extrapolation, but only with respect to a limited universe of Medicare overpayments and only under carefully prescribed circumstances.

In 2003, Congress added section 1893(f) to the SSA, entitled "RECOVERY OF OVERPAYMENTS." The new subsection (f) combined together a collection of overpayment-related provisions specific to a "provider of services or supplier," which are terms of art that refer to physicians, hospitals, and other entities but do not include MA organizations. The list of overpayment-related provisions for a "provider of services or supplier" included the use of repayment plans; limitations on recoupment; the provision of supporting documentation; the use of consent settlements; notice of code overutilization; and payment audits.

Importantly, subsection (f)(3), entitled "LIMITATION ON USE OF EXTRAPOLATION," states:

> A [M]edicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless [CMS] determines that—
>
> (A) there is a sustained or high level of payment error; or
>
> (B) documented educational intervention has failed to correct the payment error.
>
> There shall be no administrative or judicial review under section 1869 [referring to appeal rights specific to Medicare Parts A and B], section 1878 [referring to additional appeal rights specific to certain providers of services under Part A], or otherwise, of determinations by [CMS] of sustained or high levels of payment errors under this paragraph.

The language of paragraph (3), which is included in the midst of a subsection focused entirely on overpayment issues related to providers and suppliers under Medicare Parts A and B, does not provide CMS with authority to use extrapolation with respect to anyone *other than* providers and suppliers under Medicare Parts A and B. "Statutory language cannot be construed in a vacuum. It

[32] *Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2011: Hearings Before the H.R. Comm. on Appropriations*, 111th Cong. pt. 7 at 14 (2010) (written statement of William Corr, Dep't Sec'y, Dep't of Health & Human Servs.); *see also* Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., *Fiscal Year 2011 Performance Budget* 177 (2010) (describing proposal that would "[c]larify in statute that CMS can extrapolate the error rate found in the risk adjustment validation (RADV) audits to the entire MA plan payment for a given year when recouping overpayments").

is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016) (internal quotation marks and citation omitted). Nor can CMS use Congress's specific grant of extrapolation authority with respect to Medicare Parts A and B as an implicit grant of such authority with respect to Medicare Part C. *See, e.g., Ry. Lab. Executives' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 670 (D.C. Cir. 1994) (en banc) ("Unable to link its assertion of authority to any statutory provision, the [agency's] position in this case amounts to the bare suggestion that it possesses *plenary* authority to act within a given area simply because Congress has endowed it with some authority to act in that area. We categorically reject that suggestion.").

Furthermore, even if one were to view section 1893(f)(3) in isolation, the Proposed Rule makes no effort to explain how the statute's prerequisites for the use of extrapolation—*i.e.*, a determination of a "sustained or high level of payment error" or "documented educational intervention [that] has failed to correct the payment error"—have been satisfied with respect to those MA plans selected to undergo RADV audits. *See also* H.R. Rep. No. 108-391, at 785 (2003) (Conf. Rep.) (explaining that "[e]xtrapolation is limited to those circumstances where there is a sustained or high level of payment error, as defined by [CMS] in regulation, or document[ed] educational intervention has failed to correct the payment error").

C. CMS extrapolation proposal creates an unlawful presumption

Even if CMS has statutory authority to use extrapolation under certain circumstances with respect to MA plans, it would not mean CMS has statutory authority to use extrapolation in any manner that it chooses. For example, decisions such as *Chaves County* speak to the use of extrapolation on a provider-specific basis, where it is at least plausible that a provider who is demonstrated to have submitted incorrect payment claims under certain circumstances with respect to certain patients did so with respect to other, similarly situated patients under the same provider's care during the same time period.

The Proposed Rule, in contrast, would establish a system whereby CMS reviews a sample of patients treated by certain healthcare providers under contract with an MA plan, determines whether those particular providers maintained (in CMS' view) adequate medical documentation to support the diagnoses they reported to the MA plan, and applies an error rate to a universe of diagnoses reported to the MA plan by thousands of other, unrelated providers simply because they, too, are under contract with the MA plan. In doing so, CMS would essentially establish a presumption that is impossible for an MA plan to rebut. The MA plan would have no way of establishing the existence of sufficient supporting medical documentation related to the extrapolated universe of cases because the total overpayment amount will not be tied to specific providers and specific patients.

The establishment of such a presumption exceeds CMS' statutory authority. "[A]n agency is not free to ignore statutory language by creating a presumption on grounds of policy to avoid the necessity for finding that which the legislature requires to be found." *United Scenic Artists v. NLRB*, 762 F.2d 1027, 1034 (D.C. Cir. 1985). The creation of such a presumption "is beyond the

[agency's] statutory authority." *Id.* at 1035. At a minimum, there must be a "sound factual connection . . . between the facts giving rise to the presumption and the facts then presumed." *Holland Livestock Ranch v. United States*, 714 F.2d 90, 92 (9th Cir. 1983) (internal quotation marks and citation omitted).

No such connection exists with respect to the presumption created by the extrapolation regime contained in the Proposed Rule, which avoids using the word "presumption" even though CMS has previously acknowledged that the use of statistical sampling and extrapolation does, in fact, create a presumption. *See, e.g.,* Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers, HCFA Ruling No. 86-1, at 11 (Feb. 20, 1986) ("Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment."). Just because a contracted provider maintained documentation that CMS, years after the fact, believes is insufficient to support diagnoses reported for a particular patient, does not logically suggest that the same is true of all patients treated by that provider, let alone that the same is true of all other providers under contract with the MA plan treating other patients. "The conclusion . . . simply does not follow from the premise," rendering the presumption beyond CMS' statutory authority. *United Scenic Artists*, 762 F.2d at 1035.

IV. CMS' published extrapolation methodology is so flawed that implementation would be arbitrary and capricious

AHIP commissioned a study by Wakely Consulting Group that examined the RADV sampling and extrapolation methodology applied in the contract-level audits conducted by CMS, but not finalized, for payment years 2011 to 2013.[33]

The Wakely study identified several significant areas of concern including:

- CMS' extrapolation approach is subject to a high degree of randomness and could result in inequitable treatment of similar contracts, because the application of the RADV process to contracts with similar average error rates may yield materially different payment penalties. The use of relatively small samples (201 enrollees), as well as the fact that coding errors can be rare, may result in erratic penalty results. To examine this issue, Wakely explored various scenarios of contract size and assumed coding error rates. For each scenario, Wakely ran 100,000 simulations of the RADV sampling process (selecting 201 enrollees). In one of the scenarios, Wakely assumed that 10 percent of HCCs are unsupported (coded but not supported by medical record), while 6 percent are supported but not reported (e.g., not coded but supported in medical record).[34] Wakely assumes a standardized bid of $850 per member per month (PMPM) for their simulations. They find wide variation in the penalties – from $0 PMPM to $67.07 PMPM – and note that "such variation in payment

[33] Murray, T., Morgan, E., Sauter, M. Medicare RADV: Review of CMS sampling and extrapolation methodology. Wakely Consulting Group. July 2018. Available at: https://www.ahip.org/wp-content/uploads/2018/07/Wakely-Medicare-RADV-Report-2018.07.pdf.

[34] Wakely also ran other scenarios based on different assumptions about the level of unsupported versus supported diagnoses – the assumption here is primarily used for illustrative purposes.

penalty for randomly chosen RADV samples from the same contract is obviously problematic."[35]

- The methodology is sensitive to which beneficiaries and conditions are included in the sample, because certain diseases can have a disproportionate impact on the payment error. As one example, based on a simulation of the RADV process, a single unsupported diagnosis of metastatic cancer could increase the payment penalty by 16.7 percent. Because the methodology does not take into account diagnosis-specific error rates, which are acknowledged by CMS to vary, penalties from one sample may be higher due to the "luck of the draw" for which diagnoses are selected (i.e., two different samples from the same plan could yield different payment penalties due to randomly selected diagnoses having a higher incidence of coding errors in the industry). Wakely notes that "random chance could drive material swings in extrapolated payment penalties" as a result.[36]
- The methodology could drive bias against higher enrollment contracts and contracts with low absolute risk scores. The sampling approach makes proportionally higher penalties more likely for larger enrollment contracts compared to smaller contracts. Wakely finds that "larger contract sizes are generally penalized by greater randomness in penalties."[37]
- The Proposed Rule explains that in choosing the enrollee population from which a sample will be taken for each MA contract selected for a RADV audit, CMS requires that enrollees have had "at least one diagnosis during the data collection year leading to at least one CMS-HCC assignment in the payment year." In other words, CMS excludes enrollees with no HCCs, thereby eliminating the possibility that such enrollees will be included in the sample from which CMS derives an overall payment error rate. Wakely notes that this practice "biases the sample payment error rate upwards." The report further explains: "Excluding non-HCC members from the RADV audit samples biases the observed payment error by removing potential supported but not reported codes for non-HCC members. This makes the expected observed payment error rate higher than the true payment error rate over the entire contract (RADV-eligible plus non-eligible)." In addition, the process for RADV that CMS uses for the exchange plans specifically considers the no-HCC population as its own stratum.[38]
- The methodology has a nonzero probability of yielding a payment penalty higher than the actual payment error, which is problematic even at very low probabilities. Such a penalty could yield a significant forfeiture of funding due to the randomness of the sampling methodology, and not due to coding accuracy.

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[35] Ibid., p. 11.
[36] Ibid., p. 12.
[37] Ibid.
[38] Centers for Medicare & Medicaid Services, Center for Consumer Information and Oversight. 2017 benefit year protocols: PPACA HHS risk adjustment data validation [Version 2.0]. August 10 2018. Available at: https://www.regtap.info/uploads/library/HRADV_2017Protocols_Updates_v2.0_081018_v1_5CR_081018.pdf. For example, CMS notes on page 28 of this document "With the No-HCC population, the risk score errors will likely be under-statements, meaning the No-HCC risk scores should be adjusted upward."… "Consequently, there is some risk that CMS may be understating the error rate, variance, and risk score assumptions for the No-HCC stratum."

Therefore, even assuming for the sake of argument that CMS has statutory authority to extrapolate RADV audit results, AHIP believes the extrapolation methodology is so flawed that, if it were finalized, it would amount to an arbitrary and capricious agency action. For example, the methodological flaws leading to random results that cause similarly situated MA plans to be treated differently is a hallmark of arbitrary agency action. *See, e.g.*, *Cnty. of L.A. v. Shalala*, 192 F.3d 1005, 1022 (D.C. Cir. 1999) ("A long line of precedent has established that an agency action is arbitrary when the agency offers insufficient reasons for treating similar situations differently.") (internal quotation marks, citations, and brackets omitted). Further, as noted in Section III.C above, CMS presumes that provider documentation practices are uniform throughout the universe of providers under contract with an MA plan, a presumption that appears clearly arbitrary without evidence, particularly given that, to our knowledge, CMS has never applied extrapolation on anything other than a provider- or supplier-specific basis throughout the history of Medicare Parts A and B.

V. CMS' retroactive application of the regulation is impermissible and not necessary or justified

Section 1871(e)(1) of the SSA specifies that a "substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under" title XVIII of the SSA shall not be applied retroactively to "items and services furnished before the effective date of the change" unless CMS makes one of two determinations. Either "such retroactive application is necessary to comply with statutory requirements;" or "failure to apply the change retroactively would be contrary to the public interest."

The Proposed Rule states that CMS intends to extrapolate RADV audit results beginning with payment year 2011. The Proposed Rule also states that even though the 2012 RADV Notice promised that CMS would apply the FFS adjuster in RADV audits beginning with those related to payment year 2011, CMS intends to break its promise with respect to past payment years. CMS solicits comment on whether applying the methodology to previous plan year audits would constitute retroactive rulemaking. However, CMS also indicates that even if doing so would constitute retroactive rulemaking, CMS will invoke authority under section 1871(e)(1)(A) to engage in such rulemaking.

The changes contained in the Proposed Rule clearly constitute retroactive rulemaking. We also believe the changes clearly exceed CMS' limited authority to engage in retroactive rulemaking.

A. <u>The Proposed Rule would constitute retroactive rulemaking</u>

"To determine whether a rule is impermissibly retroactive, [a court] first look[s] to see whether it effects a substantive change from the agency's prior regulation *or* practice." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 14 (D.C. Cir. 2011) (emphasis added) (internal quotation marks and citation omitted). The Proposed Rule does both.

The Proposed Rule significantly revises the regulations that govern MA plans. For example, CMS would amend 42 C.F.R. § 422.310(e) by adding new language, stating: "MA organizations must

remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings to Payment Year 2011 forward." Similarly, CMS would amend 42 C.F.R. § 422.311 by adding the following language: "Recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error extrapolation and recovery methodologies. CMS will apply extrapolation to plan year audits for payment year 2011 forward."

The 2012 RADV Notice promised that CMS "would apply a FFS Adjuster as an offset before finalizing the audit recovery." CMS attempts to use that notice as evidence that implementing the Proposed Rule "would not upset any settled interest" as it relates to the use of extrapolation generally (Preamble p. 55040). However, this is clearly incorrect given the reversal on the FFS adjuster.[39] Further, existing case law demonstrates that the 2012 RADV Notice cannot be used to thwart a claim of retroactivity. *See, e.g.*, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 215 (1988) (finding rule change impermissibly retroactive even though it had first been announced in a notice published years earlier in the *Federal Register*); *Nat'l Mining Ass'n v. Dep't of Lab.*, 292 F.3d 849, 868 (D.C. Cir. 2002) (rejecting agency's argument against retroactivity where past agency practice was "encapsulated only in a manual, not in a regulation promulgated pursuant to notice-and-comment rulemaking").

We note that retroactivity in this context is not limited to RADV audits already undertaken for plan years 2011-2013; it covers any periods before the final rule is implemented and includes audits for 2014 that CMS recently initiated. In other words, CMS can only apply changes in RADV methodology to payment years after publication of a final rule, and plans must have the ability to factor the RADV rules into their bids. Thus, even if CMS were to finalize a proposal on extrapolation in MA in 2019, the earliest it could apply would be CY 2021.

B. Retroactive application is not necessary to satisfy a statutory requirement

The Proposed Rule asserts in passing that in retroactively applying the proposed changes, "CMS would be acting in compliance with" the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA). However, choosing a course of action that the agency (mistakenly) believes to be "in compliance with" a particular statute is fundamentally different from the determination required by section 1871(e)(1)(A)(i): namely, a determination that "such retroactive application *is necessary* to comply with statutory requirements." CMS made no such

[39] Separate from the general question of authority for retroactive rulemaking, we believe a refusal to honor the promise of a FFS adjuster would be arbitrary and capricious. In explaining a changed position, an agency must be "cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). The Supreme Court has specifically cautioned agencies that "[i]t would be arbitrary and capricious to ignore such matters." *Fox Television*, 556 U.S. at 515. The entire MA community has reasonably relied on the 2012 RADV Notice, which CMS claimed at the time was a product of the agency "carefully review[ing] the more than 500 comments received on the draft methodology" that CMS published on its website in late 2010.

necessity determination in the Proposed Rule. Moreover, nothing in IPERIA *requires* CMS to engage in retroactive rulemaking in this context.

C. Retroactive application is not justified as being in the public interest

A public-interest determination under section 1871(e)(1)(A)(ii) is, at a minimum, subject to review under the arbitrary-and-capricious standard of the APA. *See, e.g.*, Sec'y Br. at 43, *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290 (D.C. Cir. 2018). The APA, in turn, requires that an agency "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (internal quotation marks and citation omitted). "In reviewing that explanation, [a court] must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (internal quotation marks and citations omitted). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

The public-interest determination is not justified in this case for several reasons.

First, if CMS could simply claim financial recovery as a basis, as it does here, CMS effectively would have almost limitless authority to implement changes retroactively. Essentially the public-interest exception would swallow the general rule against retroactive rules. And this interpretation would not be limited to RADV in the MA program; it in theory could apply to any one of the payment systems governing the traditional Medicare program.

Second, "agencies do *not* have free rein to use inaccurate data." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 56 (D.C. Cir. 2015). As the D.C. Circuit recently emphasized in a case involving CMS, an agency "is required to 'examine *the relevant data* and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *Id.* at 56–57 (quoting *State Farm*, 463 U.S. at 43) (emphasis supplied by D.C. Circuit). "If an agency fails to examine the relevant data—which examination could reveal, *inter alia*, that the figures being used are erroneous—it has failed to comply with the APA." *Id.* at 57.

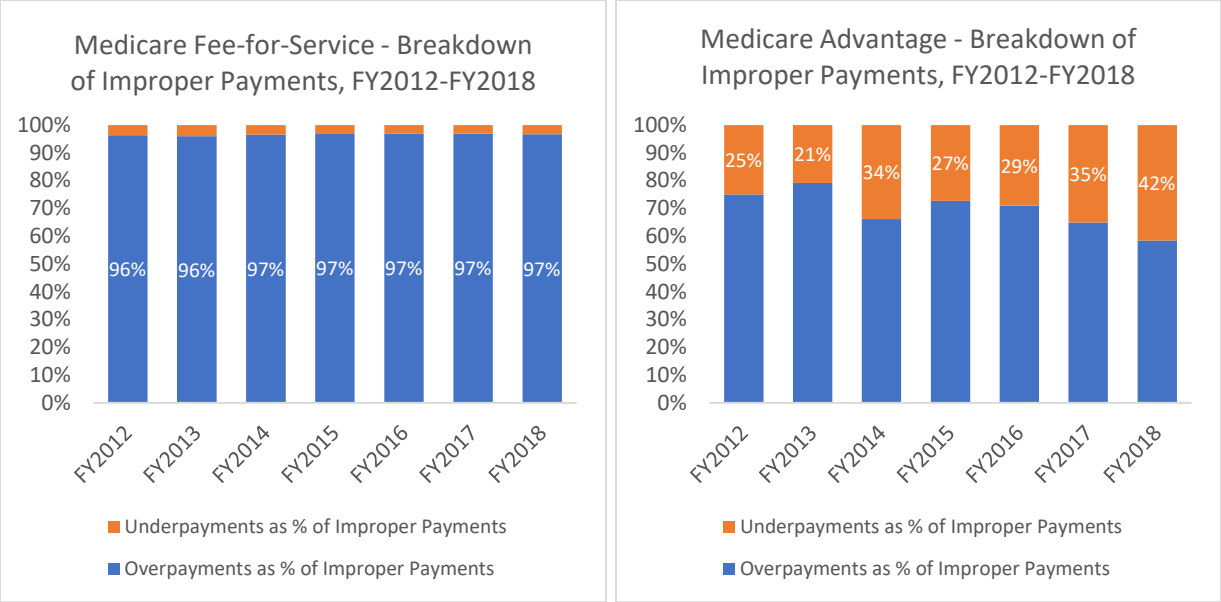
In this case, the public-interest determination is predicated on the assumption that extrapolation of RADV audit results in past payment years will result in the "recoupment of millions of dollars of public money improperly paid to private insurers." To arrive at these estimates, the Proposed Rule mischaracterizes the level of alleged MA improper payments. CMS asserts that MA plans have had "high levels of payment error in the Part C program" (Preamble p. 55039, footnote 27). CMS says the "amount of improper payments" identified under the MA program is $14.35 billion or 8.31 percent of total MA payments in FY 2017 (Preamble p. 55039).[40] However, this figure represents the "gross" improper payment rate, which is a combination of two payment error estimates: 1) 'overpayments' to MA plans, and 2) 'underpayments' to MA plans. An overpayment

[40] This figure comes from the annual National RADV audit, conducted in accordance with IPERIA.

is defined as an instance where a diagnosis code submitted for payment purposes was not supported by the beneficiary's medical record. An underpayment occurs when the medical record review identifies an additional diagnosis code that should have been submitted to CMS and used for payment. The gross improper payment rate represents the sum of overpayments and underpayments; the two numbers are not netted. Therefore, underpayments increase the gross improper payment rate to the same degree as overpayments.

Use of the gross improper payment rate vastly overstates the purported impact to the government of errors in the MA program. CMS' estimates show that underpayments for FY 2017 comprise 35 percent of the $14.35 billion estimate of improper payments.[41] And that level is increasing; in FY 2018, underpayments were 42 percent of total improper payments.[42] We also note CMS has consistently found that the MA program has a significantly lower net improper payment rate than the FFS Medicare program. Chart 1 below shows the difference in the FFS and MA program gross and net improper payment amounts over time.

Chart 1. Underpayments and Overpayments at a Percent of Improper Payments, FFS vs. MA (FY2012-2018)

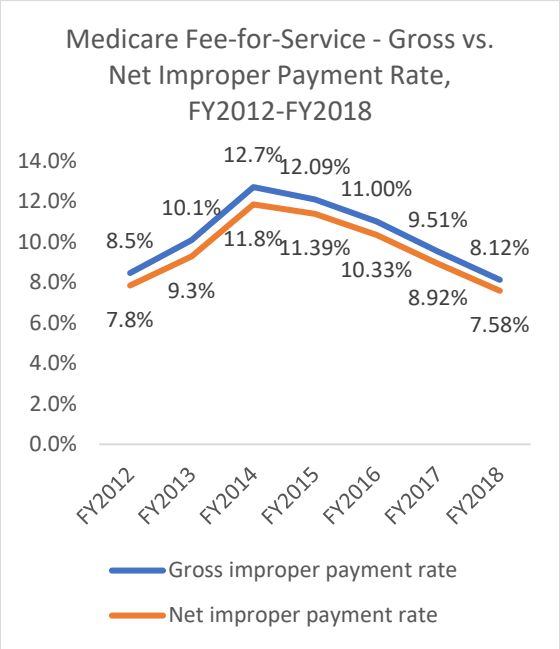


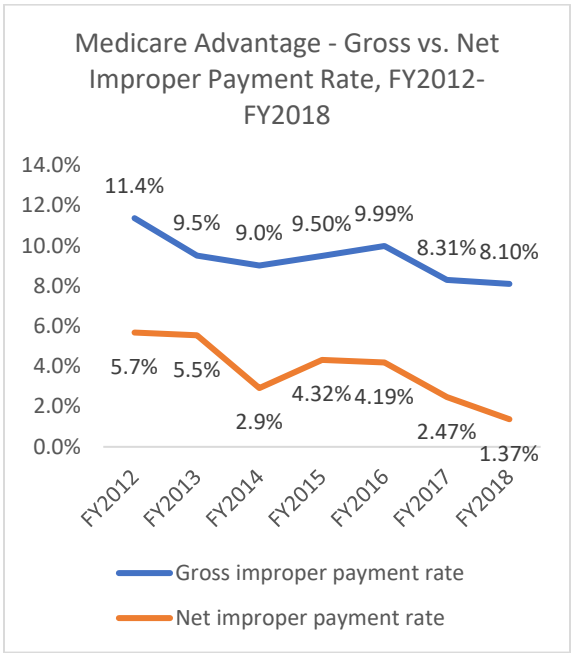
If the prevalence of underpayments in the MA program were properly considered, it would show a net improper payment rate of 1.37 percent or $2.6 billion in MA for FY 2018.[43] As shown in Chart 2 below, the MA net improper payment rate has decreased considerably since FY 2012, and in any event is much smaller than the FFS net improper payment rate. Accordingly, even if retroactive application of extrapolation were legally permissible in theory under the public-interest exception, we believe the relevant data demonstrates that the problem is small in relative

[41] Department of Health and Human Services. FY2017 Agency Financial Report. November 2017.
[42] Department of Health and Human Services. FY2018 Agency Financial Report. November 2018.
[43] Ibid.

terms, is shrinking, and therefore does not support a step as extraordinary as retroactive rulemaking.

Chart 2. Gross vs. Net Improper Payment Rates, FFS vs. MA (FY2012-2018)





Third, CMS' public-interest determination fails to consider the interest of finality, which is conspicuous for at least two reasons. CMS has long cited the interest of finality as a principal reason not to upset Medicare payment determinations. In addition, CMS has gone so far as to cite the interest of finality as a reason to engage in retroactive rulemaking under section 1871(e)(1)(A)(ii).[44]

The interest of finality serves more than just financial considerations. As CMS recently explained to the D.C. Circuit, the interest of finality also reflects "evidentiary and administrability considerations. Records grow stale, memories fade, personnel move on, and retention is costly."[45] This is especially true in the case of RADV audits. Such audits are predicated on the review of medical records related to services that may have been provided many years earlier.

These operational barriers to retroactive rulemaking are illustrated in the RADV audits for 2014 that CMS began earlier this year. Under these audits, plans must collect medical records from providers for services rendered in 2013. Because of the passage of time, medical records from 2013 may not exist or may be nearly impossible for plans to retrieve, for numerous reasons:

[44] *See* Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems, 78 Fed. Reg. 74,826, 75,165 (Dec. 10, 2013). In this rule, CMS asserted that not applying proposed regulatory changes retroactively would "undermine . . . the interests of both the Medicare program and Medicare providers in the finality of reimbursement determinations."

[45] Sec'y Br. at 47, *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290 (D.C. Cir. 2018).

- Solo practitioners have passed away, with no accessible repository for old medical records.
- Providers switched electronic medical record systems and have IT challenges in producing medical records prior to the switch (particularly for patients no longer seen by the provider and whose records were never migrated to the new system).
- Providers placed their records into off-site storage facilities whose personnel cannot locate the records in a timely fashion.
- Mental health providers are unwilling to provide data due to privacy concerns (that is, these providers will not release medical records without explicit beneficiary permission that may be difficult or impossible to obtain).

In addition to increasing the risk that records cannot be found to substantiate diagnoses, the long delay in the 2014 plan year audit will contribute to other documentation challenges for diagnoses. For example, provider signatures may be incomplete on some medical records, but if the providers can no longer be located to complete the attestations, CMS will not accept the records. In addition, since October 1, 2015, providers have used ICD-10 codes. However, the HCCs for the 2014 audit were based on ICD-9 codes which are no longer in use. Moreover, two different CMS-HCC risk adjustment models were used for payment in 2014. Even assuming plans still employ or can hire medical record reviewers who are knowledgeable about these outdated provisions, the situation lends itself to more disputes between plans and CMS.

Thus, if CMS is allowed to apply extrapolation retroactively, the agency will artificially inflate the number of cases identified as coding errors and the resulting amount of alleged overpayments. Diagnoses may be found unsubstantiated, not because the beneficiaries' clinical conditions did not exist, but because their medical records could not be obtained or validated (e.g., because providers are deceased or retired). These impacts stem directly from CMS' long delay in initiating the 2014 audits.

Fourth, we are concerned that CMS further justifies its proposal by failing to acknowledge the clinical importance of accurate diagnosis coding in MA. CMS states that "there is an incentive for plans to potentially over-report diagnoses so that they can increase their payment" (Preamble p. 55037). This statement fails to acknowledge that identifying accurate diagnoses is a crucial mechanism for understanding the health status of a patient. Due to the nature of capitated payments, MA promotes accurate diagnosis coding to support coordinated and integrated care because plans must consider the entire patient and how each of their clinical conditions interact. More accurate and detailed diagnosis coding helps plans identify and support the specific health care needs of their enrollees to ensure they receive integrated care coordination and chronic disease management.

Fifth, we note it would not be in the public interest to invoke section 1871(e)(1)(A)(ii) to retroactively "fix" CMS' failure to engage in notice-and-comment rulemaking with respect to the 2012 RADV Notice (see Section VI below). *Cf. Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987) ("The Secretary's suggestion that retroactive rulemaking is permissible to remedy a procedural defect in a rule would, if accepted, make a mockery of the provisions of the APA. Obviously, agencies would be free to violate the rulemaking requirements of the APA with

impunity if, upon invalidation of a rule, they were free to 'reissue' that rule on a retroactive basis."), *aff'd on other grounds*, 488 U.S. 204 (1988).

VI. Implementation of the RADV audit methodology would violate rulemaking requirements

The Proposed Rule is procedurally invalid because it fails to comply with the notice-and-comment provisions applicable to substantive rules under the Administrative Procedures Act (APA). *See* Section 5 U.S.C. 553. CMS, in addition, is bound by the Medicare-specific rulemaking requirements in the Medicare Act. Section 1871(a)(2) of the SSA states that "[n]o rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the payment for services . . . under this title shall take effect unless it is promulgated by the Secretary by regulation." The U.S. Supreme Court in *Azar v. Allina Health Services* recently upheld a D.C. Circuit Court opinion which invalidated how CMS calculated certain hospital payments under Medicare Part A because the methodology was not issued through regulation as required by section 1871(a)(2). 139 S. Ct. 1804 (2019). The Court noted that the policy "dramatically—and retroactively—reduced payments to hospitals serving low-income patients" and that "[b]ecause affected members of the public received no advance warning and no chance to comment first, and because the government has not identified a lawful excuse for neglecting its statutory notice-and-comment obligations" the agency's policy must be vacated. Id. at 1808.[46]

The Proposed Rule has components that are very similar to the policy invalidated in the *Allina* case. For example, the Proposed Rule applies extrapolation to 2011-2013 audits, a process that can result in "dramatically—and retroactively—reduced payments" to MA plans, using an extrapolation methodology never developed through rulemaking. CMS proposed its methodology for conducting RADV audits, including extrapolation, via the CMS website on December 20, 2010 instead of the Federal Register (Preamble p. 55038). The agency asked for comments 30 days after publication, and not 60 days, as is required under section 1871(b)(1). CMS then published the final methodology in the 2012 RADV Notice, which was essentially the same methodology that they had proposed, with one notable change – CMS acknowledged the need for the FFS adjuster, to adjust for different substantiation standards between MA payment and model development. Neither the 2010 proposal nor the 2012 RADV Notice had any discussion of alternatives considered, the impact on the industry, the rationale for the policy, or how the methodology fit with existing regulatory or statutory requirements.

The Proposed Rule attempts to justify the process for developing the 2012 RADV Notice, noting that "we invited public comment on this proposed methodology, and received more than 500 comments, which we carefully reviewed" (Preamble p. 55038). However, as summarized above,

[46] While the Court did not expressly endorse how the appeals court defined "substantive legal standard" under 1871(a)(2) or provide detailed guidance about how to interpret that phrase, the Court upheld the lower court because none of the Government's legislative history and policy-based arguments for avoiding the rulemaking requirement were persuasive. *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1814-16 (2019).

that process failed to incorporate key elements of a formal rulemaking process. Moreover, while CMS may have carefully reviewed 500 comments, they did not respond substantially or directly to any of them, including comments raised by AHIP, except as related to one item: the FFS adjuster. This prevented the public from having an opportunity to learn why the agency decided to make policy as it did, and how the agency would respond to concerns of affected stakeholders.[47]

We recognize CMS is now requesting comments through the Proposed Rule on the audit methodology. However, we understand the comment request does not affect audits already conducted from 2011 to 2013, because it would be entirely impractical to conduct new audits on those years given the passage of time.

In addition, the Proposed Rule states that CMS will develop a new RADV methodology for audit years after 2013. We believe this new RADV methodology would also reflect a change in a substantive legal standard governing payments and therefore require rulemaking under *Allina*. However, CMS clearly does not intend to provide stakeholders with the opportunity to meaningfully analyze and provide comments on the proposed methodology for audit years after 2013. For example, the Preamble states that "CMS is not required to set forth the methodology for calculating an extrapolated payment error through regulatory provisions." (Preamble p. 55038). While CMS says that in the "interest of transparency", it would describe its intent to develop a new RADV methodology, CMS' description of the methodology in the Proposed Rule for audit years after 2013 is far too vague to meet rulemaking requirements.[48] In addition, the agency is actively conducting audits for 2014, using a new methodology, before the comment period on the rule closed. This shows the agency has pre-judged the issues raised in the Proposed Rule.

Moreover, despite initiating audits for 2014, CMS has yet to provide the type of technical details that stakeholders need to understand CMS' methodology. For example, CMS held a training on April 2, 2019 limited to only those contracts selected for the 2014 audit. CMS provided limited details on the new methodology, including a two-tiered approach to sampling that reflects a sub-cohort methodology.[49] No information in the training was proposed for public comment prior to

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[47] *American College of Emergency Physicians v. Price*, 264 F.Supp.3d 89, 94 (D.D.C. 2017) ("Although an agency 'need not address every comment' made during the notice and comment period, 'it must respond in a reasoned manner to those that raise significant problems.'"(citations omitted))

[48] In a brief outline of the new methodology, CMS says that it "would calculate improper payments made on the audited MA contract for a particular sub-cohort or sub-cohorts in a given payment year." CMS further says that its methodology would be based on "statistically valid sampling and extrapolation methodologies." The agency also indicates that sub-cohorts could be "enrollees for whom a particular HCC or one of a related set of HCCs was reported." CMS "could often use a much smaller sample size" while generating "statistically significant recoveries." (Preamble p. 55039).

[49] In what CMS calls "Tier One", the sample would consist of 299 enrollees across 131 MA contracts. This cohort was based on the enrollees with "the highest predicted overpayment." CMS would not extrapolate results from Tier One audits. In what CMS calls "Tier Two", CMS would apply a sub-cohort methodology to enrollees with a high predicted overpayment rate – estimated through a regression model, the details for which have not been provided – and that have diabetes. Only 32 beneficiaries are being sampled per contract for this sub-cohort methodology, which is well below the sample size of 201 beneficiaries used in the 2011-2013 audits. CMS would extrapolate the results from Tier Two audits after the proposed regulation is finalized. Additionally, rather than auditing 30 contracts as CMS has historically selected (and suggested in its impact analysis of the Proposed Rule), CMS has selected 188 contracts for Tier Two audits.

being shared. This training has not been publicly posted on the CMS RADV website. Accordingly, the public has not had an opportunity to determine whether CMS' approach would be statistically valid or to otherwise adequately assess the proposal. Critical issues that are not addressed or left unclear include the following:

- The process for selecting sub-cohorts for audit purposes.
- The sizes needed to calculate a "statistically significant extrapolated recovery" or even what is meant by a "statistically significant extrapolated recovery."
- How CMS determines which contracts would be audited.
- How CMS would extrapolate the findings from these audits.

CMS has also not disclosed which contracts were selected for the 2014 RADV audit. However, CMS has a public document available on its website that lists every contract selected for RADV audit by year since 2007.[50] In addition to publicly releasing more detailed information about the audit methodology being used for the 2014 audit, we urge CMS to update this document with the list of contracts selected.

We also have serious concerns with the CMS statement in the Preamble that "we would make any future changes to that methodology (or those methodologies) through the Health Plan Management System." The agency is clearly stating an intent to use sub-regulatory guidance to issue RADV policy in the future, much as it did to establish the 2011 to 2013 audit methodology. We believe this is inconsistent with the SSA requirement for notice-and-comment rulemaking, as indicated in the *Allina* case. It also signals an unfortunate lack of CMS willingness to engage stakeholders on this critical issue.

VII. Other Issues

A. CMS's substantiation standards are insufficient for determining if the patient has the disease

On page 55037 of the Preamble of the Proposed Rule, CMS discusses the need for medical record documentation of diagnosis codes to support payment. The agency points to sub-regulatory guidance – none of which has ever been subject to notice-and-comment rulemaking – in which it has explained this requirement "since the beginning of the MA program." The only CMS RADV guidance that arguably satisfied the requirement was CMS' rule proposed in 2009 and finalized in 2010.[51,52]

Commenters to the 2009 rule expressed concern that the medical record requirement was overly proscriptive. It did not adequately consider the fundamental issue at stake – whether a person in

[50] Centers for Medicare & Medicaid Services. Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet (updated June 1, 2017). Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Fact-Sheet-2013.pdf
[51] Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule, 74 Fed. Reg. 54633 (2009).
[52] Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule, 75 Fed. Reg. 19677 (2010).

question actually has a disease. CMS noted such concerns, stating that "commenters contended that the one best medical record policy forces plans to omit relevant data that could be supported through documentation that CMS does not permit – such as prescription drug data and lab results."

However, CMS did not propose any changes to address these concerns. They responded instead that "the RADV risk adjustment model is based upon FFS claims data from specific risk adjustment provider types, and not alternative data sources, such as, prescription drug data or lab results. Therefore, the RADV audit process is based upon supporting medical record documentation from provider data sources that are used to calibrate the model."

If CMS were to finalize its proposal on extrapolation, we believe it would need to revisit its position on documentation. The purpose of the RADV program should be to determine if a person's diagnosis is correct. Absence of documentation in a RADV audit does not mean a person does not have the disease or is not being treated for it. Rather, it simply means that a medical record could not be located that supports the diagnosis code.

CMS has never adequately explained its continued refusal to consider other sources of information that could substantiate a diagnosis code. Medical records themselves are indications of what the person is being actively treated for, and not necessarily of what conditions the person has. For example, a person who has diabetes under control through medication may see a provider for a different condition. The medical record in this situation may not reflect that this person has diabetes, yet a simple check of prescription data for that person would show the person is taking insulin and therefore does, in fact, have diabetes. The person may also be receiving other services related to the diabetes. Because the HCC is meant to capture the incremental costs of an individual with diabetes, excluding the diagnosis code here would be inaccurate. Yet that is what CMS would do in the RADV audit by virtue of depending only on the medical record for proof that the person has diabetes.

CMS also seems to be under the impression that diagnosis coding is precise. In reality, coding is not an "exact science" and reasonable people can interpret the same medical record in different ways. Coding guidelines can be unclear and interpreted differently by different people. And while CMS references the ICD-10-CM guidelines, it did not publish the guidelines that it was using for the 2011 to 2013 RADV audits. In this sense, plans were completely in the dark about what guidelines CMS would use for these audits.

For these reasons, CMS should revisit its requirement that HCCs can only be supported by the medical record and should consider alternative sources of data to substantiate diagnosis codes.

B. Potential recovery based on OIG findings raises serious concerns

We strongly oppose the suggestion in the Preamble that MA organizations could be forced to remit payments based on findings from OIG audits. As CMS indicates in footnote 25 on page 55039, OIG "does not seek comment on its methodology for risk adjustment audit work that may lead to overpayment recoveries from MA organizations." Although OIG is required by statute to follow generally accepted government auditing standards, this requirement does not adequately

account for the necessary actuarial and statistical methodological principles at issue in the complex system of MA risk adjustment and payment recovery. Several MA organizations raised similar concerns about the potential for lack of consistency in methodology and audit process between CMS and OIG when CMS proposed to expand authority for conducting RADV audits in 2014.[53] At that time, CMS finalized its proposal to specify that OIG has the authority to conduct RADV audits but did not address these concerns.

Because OIG does not seek comment on its methodology and is not required to employ the same methodology as finalized by CMS after formal notice-and-comment rulemaking, it is possible that CMS and OIG could arrive at different conclusions about the payment accuracy of the same MA contract due to different methodologies. For example, CMS released the "Contract-Level Risk Adjustment Validation Medical Record Reviewer Guidance"[54] that would be used to determine whether a medical record supported a given diagnosis for any RADV audit that occurs after September 2017; however, OIG has never released the diagnosis coding guidelines that it is currently using or will use in the future to establish supporting documentation for a diagnosis in a medical record. In addition, CMS does not provide any additional information on what remedies would be available to plans that do not concur with audit findings by the OIG. For example, if plans were forced to remit payments based on OIG audit findings then they should have the same right to appeal those findings as to appeal CMS audit findings, and CMS in conjunction with OIG would need to establish such as an appeals process.

Therefore, MA organizations could be subject to conflicting RADV audit methodologies employed by different government agencies with possibly divergent diagnosis coding guidelines that potentially could have different appeal rights. In fact, unless CMS and OIG coordinate appropriately, it is possible an MA organization could be subject to conflicting results for the same people. From the perspective of an MA organization, it would be entirely arbitrary which government agency chose one of its contracts to audit. Furthermore, the regulations governing RADV audits apply to all RADV audits and do not distinguish between RADV audits conducted by CMS and those conducted by OIG or any other government agency.

Unless OIG is required to conduct RADV audits using the exact same methodology employed as CMS, we recommend that CMS rescind this proposal.

C. Further detail is needed on potential CMS RADV appeals proposal

CMS indicates that the agency is considering whether to explicitly expand MA organizations' appeal rights in RADV. It describes one option as adopting practices for MA plans to appeal the RADV payment error calculation methodology similar to those for providers and suppliers in Medicare FFS Parts A and B.

[53] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule, 79 Fed. Reg. 29843 (2014).
[54] This document was first released on September 27, 2017 for audits commencing after that date. On March 20, 2019, CMS released an updated document in effect as of that date but applied retrospectively for audits commencing after September 27, 2019.

As CMS has not made a specific proposal to expand MA organization appeal rights under RADV audit, it is not clear how the agency is considering applying the Medicare FFS appeals framework to the RADV program. We therefore are unable to provide specific feedback in response to CMS' invitation for comments on this point.

In addition, the RADV audit appeals process in 42 C.F.R. § 422.311 unnecessarily restricts the rights of MA organizations by allowing them to appeal only one medical record per HCC. We urge CMS to expand the number of medical records that can be appealed for each HCC audited, to allow a more complete review of key evidence that can substantiate a clinical diagnosis.

D. RADV guidance related to encounter data is needed

CMS points out that plans submit diagnoses through two systems – the Risk Adjustment Processing System (RAPS) and the Encounter Data System (EDS) (Preamble p. 55037). However, these two systems are quite different. In RAPS, plans pre-identify all diagnoses to be submitted to CMS. In EDS, plans submit all claims data – also known as encounter data – and CMS then identifies which diagnoses should be used for risk adjustment using what is known as the "filtering logic".

Nowhere in the Preamble does CMS address the application of RADV in an encounter data setting. Plans have submitted encounter data to CMS since 2012, and CMS has selected diagnoses from these data to calculate payment since 2015. By 2022, CMS anticipates that EDS will be the only source for diagnoses used for payment (Part I of the Advance Notice for 2019).[55] The EDS rules are such that plans are required to submit all data to CMS – regardless of whether these data are to be used for risk adjustment. And then, CMS determines through its own set of rules which diagnoses are allowed for risk adjustment.

We believe CMS needs to give serious consideration to potential changes that may be required in RADV to reflect the EDS process. The agency should collaborate closely with industry to develop that approach and address this issue through future rulemaking.

VIII. Recommendations

Based on the foregoing:

- We urge the agency to withdraw the RADV Proposed Rule.
- We ask that the agency affirm that it cannot apply regulations retroactively.
- The agency should acknowledge that, in the absence of recalibrating the HCC model using audited FFS diagnosis data, a FFS adjuster is required under statute whenever it attempts to determine the accuracy of risk adjusted payments to MA plans by auditing MA diagnosis data against the medical records, and improve the audit methodology.

[55] Centers for Medicare & Medicaid Services. Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model. December 27, 2017. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part1.pdf.

- We urge CMS to engage in meaningful, collaborative dialogue with the industry to develop RADV methodological changes going forward, and to ensure they are implemented solely through notice-and-comment rulemaking and on a prospective basis.

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TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
* * * * * * *	
Coffee, green beans	0.03
* * * * * * *	
Fennel, Florence, fresh leaves and stalk	20
* * * * * * *	
Kohlrabi	4
Leaf petiole vegetable subgroup 22B	20
Leafy greens subgroup 4–16A	40
* * * * * * *	
Papaya	1.5
* * * * * * *	
Peppermint, dried leaves	0.8
Peppermint, fresh leaves	0.6
* * * * * * *	
Spearmint, dried leaves	0.8
Spearmint, fresh leaves	0.6
Spice group 26	70
* * * * * * *	
Vegetable, *Brassica,* head and stem, group 5–16	4
* * * * * * *	
Vegetable, legume, bean, edible podded, subgroup 6–22A	4
Vegetable, legume, bean, succulent shelled, subgroup 6–22C	0.2
Vegetable, legume, pea, edible podded, subgroup 6–22B	4
Vegetable, legume, pea, succulent shelled, subgroup 6–22D	0.2
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E	0.7
* * * * * * *	

[1] There are no U.S. registrations.

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[FR Doc. 2023–02109 Filed 1–31–23; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS–4185–F2]

RIN 0938–AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule announces certain policies to improve program integrity and payment accuracy in the Medicare Advantage (MA) program. The purpose of this final rule is to outline our audit methodology and related policies for the contract-level MA Risk Adjustment Data Validation (RADV) program. Specifically, this final rule codifies in regulation that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018 and will not extrapolate RADV audit findings for PYs 2011 through 2017. We are also finalizing a policy whereby CMS will not apply an adjustment factor (known as a Fee-For-Service (FFS) Adjuster) in RADV audits. We are also codifying in regulation the requirement that MA organizations (MAOs) remit improper payments identified during RADV audits in a manner specified by CMS.

DATES: This final rule is effective on April 3, 2023.

FOR FURTHER INFORMATION CONTACT: Joseph Strazzire, 410–786–2775 or David Gardner, 410–786–7791.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Contract-level Risk Adjustment Data Validation (RADV) audits are our main corrective action for overpayments made to Medicare Advantage organizations (MAOs) when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. The purpose of this final rule is to outline our audit methodology and related policies for the contract-level RADV program. Specifically, this final rule codifies in regulation our approach to the use of extrapolation, our decision to not apply an FFS Adjuster in RADV audits, and the payment years in which these policies will apply.

We are finalizing that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings. We are not adopting any specific sampling or extrapolated audit methodology, but will rely on any statistically valid method for sampling and extrapolation that is determined to be well-suited to a particular audit. Rather than applying extrapolation beginning for payment year (PY) 2011 audits as we proposed,

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we are finalizing a policy whereby we will not extrapolate RADV audit findings for PYs 2011 through 2017 and will begin extrapolation with the PY 2018 RADV audit. As a result, CMS will only collect the non-extrapolated overpayments identified in the CMS RADV audits and Department of Health and Human Services Office of Inspector General (HHS–OIG) audits between PY 2011 and PY 2017, and will begin collection of extrapolated overpayment findings for any CMS and OIG audits conducted in PY 2018 and any subsequent payment year. We believe that this is an appropriate policy because it recognizes our fiduciary duty to protect taxpayer dollars from overpayments, and preserves our ability to collect on potentially significant amounts of overpayments made to plans beginning in PY 2018 using an extrapolation methodology. This final rule will also allow CMS to focus on conducting future RADV audits as soon as practicable after an MAO payment year concludes, which was the topic of significant public comment to the proposed rule. Lastly, we have determined that it is in the best interest of all parties to ensure that the contract-level RADV appeals process, which is also outlined in regulation, is able to successfully process all RADV appeals. By not using an extrapolation methodology prior to PY 2018, we expect to better control the total number of active appeals that are submitted in the first few years following finalization of this rule, which will alleviate burden on MAOs and CMS.

We are also finalizing a policy whereby CMS will not apply an FFS Adjuster in RADV audits because we have determined that an FFS Adjuster is not appropriate. As described at great length in this final rule, we have decided not to apply an FFS Adjuster in RADV audits because: (1) we believe, consistent with the D.C. Circuit's decision in *UnitedHealthcare* (*UnitedHealthcare Insurance Co.* v. *Becerra,* 16 F.4th 867 (D.C. Cir. August 13, 2021, reissued November 1, 2021), *cert. denied,* 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21–1140)), that the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to MAOs and not to the obligation of MAOs to return improper payments (for example, payments for unsupported diagnosis codes); and (2) it would not be reasonable to read the Social Security Act (the Act) as requiring a reduction in payments to MAOs by a statutorily-set minimum adjustment in the coding pattern adjustment, while at the same time prohibiting CMS from enforcing longstanding documentation requirements by requiring an offset to the recovery amounts calculated for CMS audits.

We are also codifying in regulation the requirement that MAOs remit improper payments identified during RADV audits in a manner specified by CMS. After the effective date of this final regulation, on a rolling basis (over a period of months, which will be communicated to MAOs by CMS), we will begin issuing the enrollee-level audit findings from the CMS RADV audits that have been completed, as well as recovering the enrollee-level improper payments identified in HHS–OIG audits.

Nothing in this rule changes the longstanding principle that a diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. *UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867, 869 (D.C. Cir. 2021) (''Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer.''). Nor does this rule change the longstanding obligation of an insurer to refund payments to CMS if it learns through any means that a diagnosis lacks support in the beneficiary's medical record. *Id.*

II. Background

A. General Overview of Risk Adjustment Payments in the MA Program

The Balanced Budget Act of 1997 (BBA), Public Law (Pub. L.) 105–33, established a new Part C of the Medicare program, known then as the Medicare+Choice (M+C) program, which became effective in January 1999. As part of the M+C program, the BBA authorized CMS to contract with public or private organizations to offer a variety of health plan options for Medicare beneficiaries. These health plans provide all Medicare Part A and Part B (also known as ''Original Medicare,'' or ''Medicare FFS'') benefits, and most offer additional benefits beyond those covered under the Medicare FFS program. The M+C program in Part C of Medicare was renamed the Medicare Advantage (MA) program under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted in December 2003. The MMA updated and improved the choice of plans for beneficiaries under Part C and changed the way benefits are established and payments are made. As of August 2022, over 29 million individuals receive their Medicare benefits through MA, which represents nearly half of the total Medicare beneficiary population.[1]

Section 1853(a)(1)(C) of the Act requires that CMS risk-adjust payments made to MAOs. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MAOs based on the health status and demographic characteristics of their enrolled beneficiaries, and that MAOs are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs). Making accurate payments to MAOs also ensures we are safeguarding Federal taxpayer dollars.

The current risk adjustment model employed to adjust MAO payments is known as the CMS Hierarchical Condition Category (CMS–HCC) model. This model functions by categorizing International Classification of Disease, Clinical Modification (ICD–CM)[2] diagnosis codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. There are approximately 9,875 diagnoses mapped to 86 HCCs in the CMS–HCC Risk Adjustment Model for 2022.[3] MA enrollee HCCs are assigned based on data submitted to CMS by MAOs. The HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee and the greater payment that is received by the MAO.

The CMS–HCC model was first used for payment in 2004 and has been recalibrated numerous times since then. When CMS recalibrates the CMS–HCC risk adjustment model, it uses data from Medicare FFS claims, using diagnoses in one year to predict the following year's expenditures. Claims data from beneficiaries enrolled in the Medicare FFS program are used to calibrate the CMS–HCC model, which produces a set of coefficients (also known as risk

[1] CMS, *CMS Fast Facts, August 2022 Edition,* pg.1, *https://data.cms.gov/sites/default/files/2022-08/4f0176a6-d634-47c1-8447-b074f014079a/CMSFastFactsAug2022.pdf.*

[2] The ICD–CM is a modification of the ICD, authorized by the World Health Organization, used as a source for diagnosis codes in the United States. The ICD–CM has been adopted by the Secretary as the standard medical data code set. *See* 45 CFR 162.1002.

[3] Source: *2022 Midyear Final ICD–10 Mappings* at *https://www.cms.gov/files/zip/2022-midyear-final-icd-10-mappings.zip.*

factors) that represent the marginal (additional) cost of each medical condition and demographic factor reported for a given beneficiary. (For additional information, see the Medicare Managed Care Manual, Ch. 7, section 70.1.[4]) Each beneficiary's risk coefficients are added together to form a risk score for that beneficiary that is used to adjust the insurer's base payment rate for that beneficiary.

The diagnosis data that MAOs submit to CMS do not undergo a validation review by CMS before being relied on by CMS to calculate each enrollee's risk score and make payments. Because there is an incentive for MAOs to potentially over-code diagnoses to increase their payments, that is, to code diagnoses not properly substantiated by medical record documentation, CMS conducts post-payment audits of MAO-submitted diagnosis data from a selection of MAOs for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. These audits are called contract-level Risk Adjustment Data Validation (RADV) program audits. While RADV audits are intended to identify improper risk adjustment payments, they are not specifically designed to detect fraud,[5] nor are they intended to identify all improper diagnosis submissions made by MAOs for risk adjustment payment.[6]

B. Purpose and Description of Contract-Level RADV Audits

The improper payment measurements conducted each year by CMS that are included in the HHS Agency Financial Report, as well as audits conducted by the HHS–OIG, have demonstrated that the MA program is at high risk of improper payments. In fiscal year (FY) 2021 (based on calendar year 2019 payments), we calculated that CMS made over $15 billion in Part C overpayments, a figure representing nearly 7 percent of total Part C payments.[7] The HHS–OIG has also released several reports over the past few years that demonstrate a high risk of improper payments in the MA program,[8] and for several years has identified the MA program as one of the top management and performance challenges facing HHS due to the high amount of improper payments.[9] The Medicare program, including MA, has also been identified by the Government Accountability Office (GAO) as a high-risk program due to the risk of substantial improper payments.[10]

RADV audits are our main corrective action for overpayments made to MAOs when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. We select MAOs for RADV audits using a risk-based approach that focuses on HCCs that are more likely to be in error as identified by prior RADV audits, Part C Improper Payment Measurements, and OIG findings, and other vulnerability analyses. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year and after CMS recalculates the risk factors for affected individuals to determine if payment adjustments are necessary, as described at 42 CFR 422.310(g).[11] RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MAOs in medical record documentation. RADV audits confirm the presence of the diagnoses related to the enrollee's HCC profile through the review of certain categories of medical records submitted by the MAOs for the purpose of a RADV audit; specifically, inpatient hospital, hospital outpatient facility, and physician/practitioner (excluding suppliers of durable medical equipment, prosthetics, orthotics, and supplies) medical records. Risk adjustment discrepancies are identified when an enrollee's HCCs used for payment, which are based on MAO self-reported data, differ from the HCCs assigned based on the medical record review performed by CMS through the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall level of payment error. In turn, payment error for a sample of contract enrollees can be used to calculate a total payment error estimate, for the larger universe of enrollees within an MAO contract from which a sample is drawn, within specified confidence intervals using statistical extrapolation.

C. History of the Contract-Level RADV Program

RADV audits have existed in various forms and approaches for over 20 years. RADV audits began for payment year (PY) 1999, when the amount of payment made to MAOs on a risk-adjusted basis was small (10 percent). During the audit period from PY 1999 until PY 2003, our RADV activity had an educational focus and was primarily intended to provide information that could be used by MAOs to improve the accuracy of the risk adjustment data submitted to CMS for payment. Payment adjustments (recoveries) were limited to enrollee-level adjustments for those enrollees sampled in the audits and were not extrapolated to the overall error of the

[4] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf.*

[5] For example, the Department of Justice is responsible for pursing potential violations of the False Claims Act, which includes certain elements of knowledge.

[6] CMS contract-level RADV audits focus on specific MAO contracts to determine and recoup improper payments. The HHS–OIG also undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions. CMS can collect the improper payments identified during those HHS–OIG audits, including the extrapolated amounts calculated by the OIG. CMS also oversees the Part C Improper Payment Measurement, previously referred to as ''national RADV,'' to determine a program-wide improper payment rate as required by the Payment Integrity Information Act of 2019 (Pub. L. 116–117). In addition to risk adjustment oversight conducted by CMS, HHS also oversees HHS–RADV, which was created by the Affordable Care Act to strengthen the integrity of the Affordable Care Act Marketplace by validating the accuracy of data submitted by issuers that is used to calculate the amount of funds transferred to insurers based on the actuarial risks of the individuals they enroll. Neither the Part C Improper Payment Measurement nor the HHS–RADV programs are subject to the provisions of this final rule.

[7] HHS, FY 2021 HHS Agency Financial Report, pg. 211, *https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf.* CMS made over $23 billion in total Part C improper payments. The improper payment measurement for the MA program in FY 2021included both overpayments ($15 billion) and underpayments ($8 billion).

[8] For example, see reports: Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. For example, see reports: Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, May 21, 2021, *https://oig.hhs.gov/oas/reports/region7/71901187.asp;* Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS, February 24, 2021, *https://oig.hhs.gov/oas/reports/region2/21801028.asp;* Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contact H3916) Submitted to CMS, September 29, 2022, *https://oig.hhs.gov/oas/reports/region3/31900001.asp;* Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS, July 18, 2022, *https://oig.hhs.gov/oas/reports/region2/22001009.asp;* Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS, February 3, 2022, *https://oig.hhs.gov/oas/reports/region7/71701169.asp;* Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS, April 19, 2021, *https://oig.hhs.gov/oas/reports/region7/71601165.asp.*

[9] For example, see OIG, 2021 Top Management and Performance Challenges Facing HHS, pg. 13, *https://oig.hhs.gov/reports-and-publications/top-challenges/2021/2021-tmc.pdf.*

[10] GAO, *Medicare Program & Improper Payments, https://www.gao.gov/highrisk/medicare-program-improper-payments.*

[11] *See* the May 23, 2014 final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule'' (79 FR 29843, at 29926) for a more detailed discussion of the timing and execution of the RADV audit and appeals process.

contract. As a result, for the few MA plans we audited, payment recovery amounts were small.

Risk adjustment payments using the CMS–HCC risk adjustment model began for the first time in PY 2004. Because of various risk adjustment payment methodology changes required in the BBA and the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), we provided a payment ''phase-in'' under the new risk adjustment methodologies from 2000 to 2007, when MAOs' payments were 100 percent risk-adjusted under the current methodology.[12] Under the new methodology that began in PY 2004, MAOs were required to submit diagnoses from multiple sites of care, which increased the administrative data burden on MAOs. Because of this burden and the associated phase-in of the new methodology, CMS considered PYs 2004 through 2006 as pilot years for the purpose of the RADV program and did not seek to recover improper payments for those payment years based on the audit results.

Improper payment recovery resumed for PY 2007, when we conducted two sets of RADV audits: (1) Pilot 2007, which involved 5 MA contracts; and (2) Targeted 2007, which involved 32 MA contracts. CMS began with the Pilot 2007 audit to test the methodology and make any needed changes before conducting the Targeted 2007 audit. CMS selected MA contracts after measuring the weighted average change in disease scores (risk scores) over the preceding 3-year period and grouping MAO contracts as high, medium, or low relative to other MA contracts that were eligible for a RADV audit. Through these two sets of audits, we recouped $13.7 million. Payment adjustments were again limited to enrollee-level adjustments for those enrollees sampled in the audits and not extrapolated to the overall contract error. After CMS' findings were reported to each MAO, any MAO that disagreed with CMS' determinations could challenge them through an administrative dispute and appeals process that was established by regulation (75 FR 19678). This dispute and appeals process, as subsequently amended (75 FR 32858 and 79 FR 29844), remains in effect and allows for the appeal of the medical record review determination and/or the payment error calculation through a three-level administrative review process, as outlined in 42 CFR 422.311. To date, CMS has not recovered based on RADV audit findings for audit years after PY 2007, as described more fully in this section of this rule.

1. Development of an Audit Methodology (PYs 2007 Through 2010)

After the RADV audits were conducted for PY 2007, CMS paused RADV audits for PYs 2008, 2009, and 2010. CMS used those years to continue refining the methodology for the RADV audits, including the consideration of statistical methods to calculate extrapolated improper payments based on the individual errors identified. The use of extrapolation would enable us to make contract-level payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample, as we had done previously.

On December 20, 2010, we published an informal proposal on the CMS website that outlined our intended RADV methodology for: (1) selecting a statistically valid sample of enrollees from each audited MA contract; and (2) calculating a contract-level payment adjustment by extrapolating the results of that sample. We invited public comment on this proposed methodology.

2. Informal Proposal Comments and the FFS Adjuster

In response to the December 2010 informal proposal, some MAOs suggested that CMS cannot lawfully enforce the requirement of medical record documentation for diagnosis codes while making payments at the published rates. These MAOs argued that there is a difference in auditing standards between Medicare FFS and MA diagnosis data because, in contrast to the MAO-submitted diagnoses data, Medicare FFS data is ''unaudited'' by CMS. This difference purportedly exists because most FFS payments are made on the basis of the item or service provided and not the beneficiary's diagnosis or diagnoses. For example, an office visit is paid based on whether the evaluation and management service billed met Medicare coverage and payment rules, not based on what diagnoses are listed on the claim or in the medical record. As a result, they argued, the Medicare FFS data used to calculate MAO payments will understate the cost of treating various conditions and, because erroneous diagnoses in the FFS claims data are used to calibrate the MA payment model, CMS must either adjust payment rates (by raising them) or adjust documentation standards (by loosening them) to resolve the alleged incompatibility between the payment rates and documentation standards. This proposed adjustment to the MAO payment rates and/or documentation standard is referred to as an ''FFS Adjuster.''

To understand the MAOs' argument about why an FFS Adjuster is needed, some background is important. These MAOs ground their arguments in section 1853(a)(1)(C)(i) of the Act, which requires the Secretary to adjust payments to MAOs for demographic and health-related risk factors so as to ensure ''actuarial equivalence.'' As described previously, the Act requires that we calculate risk-adjusted payments to MAOs to ensure that MAOs are paid appropriately based on the enrollees' health status and demographic characteristics. The current risk adjustment model does this by calculating plan enrollees' risk scores and, in turn, using them to adjust the MAOs' base payment rates, which are the rates for the average beneficiary.

This system of risk adjustment rests on two important principles. First, MAOs' payments are calculated using the CMS–HCC risk adjustment model, which is published each time it is updated (see section 1853(b) of the Act).[13] Second, an MAO may only report a diagnosis when that diagnosis is properly supported by the beneficiary's medical records. As we noted in our April 15, 2022 Health Plan Management System (HPMS) memorandum, *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data,* MAOs must submit data that conforms to all relevant national standards, including the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) Guidelines for Coding and Reporting requirement that diagnoses be documented in patients' medical records. (*See* 42 CFR 422.310(d)(1); 45 CFR 162.1002(c)(2) and (c)(3).) The diagnosis codes and other risk adjustment information that MAOs submit directly affect the calculation of CMS payments to the MAO. A diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. *UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867, 869, 877 (D.C. Cir. 2021). Medical records properly support a reported diagnosis when they comply with all CMS data and documentation requirements, which are described in current agency policy

[12] CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates,* 4–5 (March 28, 2003), *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2004.pdf.*

[13] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

documents, including the Medicare Managed Care Manual.[14] In their annual contracts with CMS, MAOs agree to operate in accordance with applicable Federal statutes, regulations, and policies, including policies described in the Medicare Managed Care Manual. MAOs are also required to submit a sample of medical records for the validation of this risk adjustment data, as required by CMS (see 42 CFR 422.310(e)).

3. The 2012 Methodology

The feedback received from industry in response to the informal proposal in 2010 was considered by CMS, and on February 24, 2012, we issued on our website [15] what we described as a final methodology for RADV contract-level payment error calculation, to begin with PY 2011 RADV audits (referred to herein as the ''2012 methodology''). That methodology described sampling techniques and a statistical calculation to extrapolate from the sample selected, as well as the use of an FFS Adjuster.[16] (Although the use of an FFS Adjuster beginning with PY 2011 RADV audits was included in the 2012 methodology, CMS has not issued final RADV audit results for PY 2011 audits or any subsequent year, and therefore, an FFS Adjuster has not been applied to any RADV audits issued by CMS to date.)

Sampling Technique: Under the 2012 methodology, up to 201 enrollees from each audited MA contract would be selected according to certain criteria. These criteria included, but were not limited to, the enrollee's: (1) continuous enrollment in the MA contract for the entire data collection year and January of the payment year; (2) lack of end-stage renal disease (ESRD) or hospice status for the entire data collection year and January of the payment year; (3) enrollment in Medicare Part B coverage for the entire data collection year; and (4) assignment of at least one CMS–HCC based on diagnoses submitted by the MAO for risk-adjustment payment. The RADV-eligible enrollees would then be ranked by risk score and divided into three equal strata (low risk score, average risk score, and high risk score), with an equal number of enrollees randomly selected from each stratum (for example, 67 enrollees per stratum in the case of an audit of 201 enrollees).

Payment Error Calculation: After medical records were reviewed, payment errors would be calculated for each selected enrollee based on the number of months the person was enrolled in the selected MA contract (and also was not in ESRD or hospice status) during the payment year. A payment error amount for each stratum would be calculated, which could include both RADV-identified overpayments and underpayments, and an overall payment error estimate for the audited contract would be derived, along with a 99 percent confidence interval around the payment error estimate.

FFS Adjuster: As part of the 2012 methodology, we also stated that we would apply an FFS Adjuster before finalizing audit recovery. The 2012 methodology stated that the actual value of the FFS Adjuster would be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

CMS subsequently conducted an extensive study regarding the impact of such errors in Medicare FFS claims data for the purpose of determining the appropriate value of an FFS Adjuster. This study found that, in fact, errors in Medicare FFS claims data did not have any systematic effect on the risk scores calculated by the CMS–HCC risk adjustment model and, therefore, did not have any systematic effect on the payments made to MAOs. On October 26, 2018, we published an Executive Summary and Technical Appendix of our FFS Adjuster study findings on the CMS website, which are available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html.* Additional information on this study can also be found in the November 2018 proposed rule.

4. The 2018 RADV Proposed Rule

In the 2018 proposed rule, to enhance transparency and provide ample notice to MAOs, we proposed to codify in regulation our methodological approach to RADV audits that would apply to all of the payment year audits that have not yet been finalized. These methodologies would apply to PY 2011 and subsequent years and include our proposals to use extrapolation and not apply an FFS Adjuster to our RADV audit findings.

5. Subsequent **Federal Register** Notices (2018, 2019, 2021, and 2022)

Since publication of the 2018 proposed rule, we have published several related notices to further enhance transparency and encourage robust public comment:

- On December 27, 2018, we announced in the **Federal Register** (83 FR 66661) an extension of the comment period for the proposed RADV provisions until April 30, 2019, as well as a plan to release data underlying the October 26, 2018, FFS Adjuster Study.[17]
- On March 6, 2019, we issued a notice in the **Federal Register** (84 FR 8069) announcing the release of additional data underlying the FFS Adjuster Study, both on the CMS website and to those organizations who established data use agreements (DUAs) with the CMS Office of Enterprise Data Analytics (OEDA).[18]
- On April 25, 2019, we posted updates to existing documentation related to the study data, as well as additional data on the CMS website.[19]
- On April 30, 2019, we issued a notice in the **Federal Register** (84 FR 18215) granting an additional extension of the comment period for the proposed RADV provisions until August 28, 2019. We also announced that we would be releasing additional data underlying the FFS Adjuster study, including data containing Protected Health Information (PHI), to all parties who entered an applicable DUA with CMS and paid the required fee.[20]
- On June 28, 2019, we issued a notice in the **Federal Register** (84 FR 30983) [21] that we replicated the FFS Adjuster Study and published a summary of that replication as an addendum to the study on the CMS website.[22] The purpose of this replication was to allow us to test our initial results and release a more complete set of underlying data. (Certain intermediate data elements, not saved as part of the implementation of the initial study, were preserved and published in the addendum.) The

[14] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS019326.*

[15] CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.*

[16] *Id.* at 4–5.

[17] *https://www.federalregister.gov/documents/2018/12/27/2018-28070/medicare-and-medicaid-programs-risk-adjustment-data-validation.*

[18] *https://www.federalregister.gov/documents/2019/03/06/2019-04052/medicare-program-release-of-data-underlying-risk-adjustment-data-validation-provisions.*

[19] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/NPRM-4185-Provisional-Data-Release-CPI-FFSA-Coefficients.xlsx.*

[20] *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/.*

[21] *https://www.federalregister.gov/documents/2019/06/28/2019-13891/medicare-and-medicaid-programs-risk-adjustment-data-validation.*

[22] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html.*

results of the replication were broadly consistent with the initial implementation of the study. In addition, the addendum contained further discussion of the study's assumptions and methodology. We also released the programming language used to implement the replication of the study, and a description of the technical requirements for use of that programming language.

• In the October 21, 2021 **Federal Register** (86 FR 58245), we issued a notice that provided a 1-year extension of the timeline for publication of the final rule.[23]

As part of this extension, we explained our determination that we were unable to meet the 3-year timeline for publication.[24] Based on extensive public comments received on the 2018 proposed rule and subsequent FFS Adjuster study and related data, along with delays resulting from the agency's focus on the COVID–19 public health emergency, we determined that additional time was needed to address the complex policy and operational issues that were raised. As such, we extended the timeline to publish the final rule from November 1, 2021 to November 1, 2022.

• In the November 1, 2022 **Federal Register** (87 FR 65723), we issued a notice that provided a 3-month extension of the timeline for publication of the final rule.[25] We explained that we were unable to meet the November 1, 2022, timeline for publication of the previously referenced RADV-audit related provisions. We explained that we continued to have ongoing delays resulting from the agency's focus on the COVID–19 public health emergency, and we determined that additional time continued to be needed to address the complex policy and operational issues that were raised. As such, we extended the timeline to publish the final rule from November 1, 2022, to February 1, 2023.

We received approximately 154 timely pieces of correspondence in response to the 2018 proposed rule and the subsequent notices and data releases. Summaries of the public comments that respond to the RADV provisions, and our responses to those public comments, are set forth in the discussion that follows. Additional public comments outside of the scope of the RADV proposed provisions were not considered and are not addressed in this final rule.

III. Provisions of the RADV Final Rule

A. Extrapolation of RADV Audit Findings

1. Use of Extrapolation in the Medicare Program

Extrapolation, or the act of estimating a value (such an overpayment amount for a Medicare provider) based on a statistically valid sample of units (such as Medicare claims), has historically been a standard part of auditing practice at CMS. There is significant guidance, including case law and best practices from HHS and other Federal agencies, stating that extrapolation may be utilized as a valid part of calculating improper payments. In particular, courts have held that sampling and extrapolation are a valid method of calculating improper Medicare payments, so long as statistically valid methods are used. *See United States* v. *Lahey Clinic Hosp., Inc.,* 399 F.3d 1, 18 n.19 (1st Cir. 2005) (noting that ''sampling of similar claims and extrapolation from the sample is a recognized method of proof'' for the United States in an affirmative case seeking recovery under a common-law theory). *See also Ratanasen* v. *California Dep't of Health Servs.,* 11 F.3d 1467, 1469–71 (9th Cir. 1993) (collecting cases in which sampling and extrapolation have been approved in the Medicaid context, and ''join[ing] other circuits in approving the use of sampling and extrapolation as part of audits in connection with Medicare and other similar programs''); *Chaves Cnty. Home Health Serv.* v. *Sullivan,* 931 F.2d 914, 917–23 (D.C. Cir. 1991). The authority to use sampling and extrapolation in Medicare audits is grounded in our statutory and regulatory authority to audit providers and recoup improper payments. *See Chaves,* 931 F.2d at 919 (interpreting the Medicare statute to allow for a ''sample adjudication procedure'' followed by extrapolation from that sample, which ''is reasonable given the logistical imperatives recognized by courts in other comparable circumstances'').

Sampling and extrapolation have been used to calculate improper payments in Medicare FFS (Part A and Part B) for decades. CMS formally approved of this technique in 1986 (HCFA Ruling 86–1), but Medicare Administrative Contractors (MACs), which are responsible for determining medical necessity and paying Medicare FFS claims, have been using it ''at least since 1972.'' *Chaves,* 931 F.2d at 921; *see id.* at 913 (explaining that ''sample adjudication has been used in previous instances involving post-payment review of 'coverage determinations' under Part A,'' and that HCFA Ruling 86–1 ''simply reiterated [the agency's] belief that it had the latitude to employ sample audits on post-payment review to efficiently recoup overpayments for non-covered services''). In 1991, the United States Court of Appeals for the District of Columbia Circuit, in *Chaves,* upheld the use of this audit methodology against arguments that the Medicare statute required individualized review of claims submitted by providers (*Id.* at 922).

The MMA imposed limits on the use of sampling and extrapolation in Medicare payment decisions in the context of Part A and Part B, when a settlement to resolve improper payments is not reached. Since 2003, Medicare Part A and Part B extrapolation under section 1893(f)(3) of the Act has been limited to instances in which the Secretary determines either that ''there is a sustained or high level of payment error'' or that ''documented educational intervention has failed to correct the payment error.'' No similar limitation applies to the MA program.

[23] *https://www.federalregister.gov/documents/2021/10/21/2021-22908/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

[24] Section 1871(a)(3)(A) of the Act requires the Secretary to ''establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.'' Section 1871(a)(3)(B) of the Act provides that ''[s]uch timeline . . . shall not be longer than 3 years except under exceptional circumstances.'' The Secretary therefore may not ''establish'' a ''regular timeline'' for the finalization of a proposal or interim final rule that exceeds three years, absent exceptional circumstances. Section 1871(a)(3)(B) of the Act authorizes the Secretary to ''vary such timeline''—that is, to alter the ''regular timeline'' initially ''establish[ed]'' for finalization—by publishing a timely notice in the **Federal Register** with ''a brief explanation of the justification for such variation.'' As we have said, ''[t]he Secretary may extend the initial targeted publication date of the final regulation, if the Secretary provides public notice including a brief explanation of the justification for the variation no later than the regulation's previously established proposed publication date.'' 69 FR 78443.

Under the plain text of the Act, no ''exceptional circumstances'' are required for the Secretary to extend the initial targeted publication date of the final regulation, but only ''a brief explanation of the justification'' for doing so. The Secretary has often extended such timelines without any reference to ''exceptional circumstances.'' (See 86 FR 50263; 85 FR 55385; 85 FR 52940; 85 FR 7; 79 FR 62356; 74 FR 8867; 72 FR 16794; 72 FR 13710.) But the Secretary has also said that the Act ''permits an extension of a published timeline under exceptional circumstances,'' 69 FR 78442, and has invoked ''exceptional circumstances'' in extending such timelines, including in the notices published in this rulemaking. For the reasons explained in this note, the Act has never required exceptional circumstances for such extensions—though exceptional circumstances have often been present, as they were here, when such timelines have been extended.

[25] *https://www.federalregister.gov/documents/2022/11/01/2022-23563/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

As previously discussed, sampling and extrapolation is a generally accepted audit technique in the Medicare context, and the Act does not apply any limits to the use of extrapolation in the MA program. Therefore, we believe that CMS has the authority to implement this audit methodology in RADV audits for any case in which a RADV audit identifies improper risk-adjusted payments. We also believe that this is a reasonable approach to our RADV audits, given the sustained and high level of risk adjustment payment error, as previously described.

2. Summary of Proposed Rule

In the 2018 proposed rule, CMS proposed to extrapolate contract-level RADV audit findings using statistically valid random sampling techniques. CMS proposed to extrapolate findings in PY 2011 and all subsequent payment years, but specifically sought comment on how to treat the audits for PYs 2011, 2012, and 2013. In the proposed rule, we explained that we had conducted RADV audits for PYs 2011–2013 according to the sampling and extrapolation methodology described in the 2012 methodology but that these audits were not yet finalized because we had not yet issued the audit findings to the MAOs.[26] For PYs 2011 through 2013, we estimated that audited MA contracts received $650 million in improper payments.

In the 2018 proposed rule, we stated that, given the amount of improper payments identified under the MA program, interest in determining an accurate recovery amount for each audited MA plan, and importance of protecting the overall integrity of the program, we believed that it was in the public interest for CMS to apply the RADV payment error methodology(ies) adopted through this rulemaking to PY 2011 and all subsequent years. We stated that CMS would be acting in compliance with the improper payment obligations under the Act (most recently updated as part of the Payment Integrity Information Act of 2019 (PIIA)), as well as our fiduciary responsibility to recover funds due to the Medicare Trust Funds. We also noted that our February 2012 publication put MAOs on notice that CMS expected to calculate a contract-level payment error for PY 2011 and subsequent payments years by extrapolating from its review of a statistically valid sample of enrollees, and that MAOs have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records.

We also proposed that MAOs would be required to remit extrapolated recovery amounts from RADV audit findings through CMS' payment system, the Medicare Advantage and Prescription Drug system (MARx), as offsets to MA plans' monthly capitation payments. In the event that the recovery amount exceeds the payment in one month, we proposed that the recovery would be spread across adjustments for multiple months until the full amount is recovered. We also proposed that CMS might likewise require MAOs to remit such recovery amounts based upon audit findings by the HHS–OIG.

We explained in the 2018 proposed rule that CMS is not required to set forth the methodology for calculating an extrapolated payment error through regulatory provisions. However, we explained that, in the interest of transparency, we were choosing to inform MAOs about our plans to use various sampling and extrapolation methodologies in RADV audits, as CMS deems appropriate, through rulemaking.

In addition to codifying in regulation our existing authority to use extrapolation techniques in the RADV context, we also used the 2018 proposed rule as a means to gather public feedback on sampling methodologies that could be employed for purposes of extrapolation. We explained that, in addition to the contract-level approach described in the 2012 RADV Methodology, we have identified other potential methodologies for sampling and extrapolation that are based on a particular sub-cohort or sub-cohorts in a given payment year. For example, a sub-cohort could be the enrollees for whom a particular HCC or one of a related set of HCCs (such as the three diabetes HCCs) was reported.

TABLE 1—DIABETES HCCS

HCC category description	HCC
Diabetes with acute complications ...	17
Diabetes with chronic complications	18
Diabetes without complication	19

After choosing an MA contract and a sub-cohort or sub-cohorts to audit, we would select a statistically significant sample of enrollees in the sub-cohort or sub-cohorts. After reviewing these enrollees' medical records that are submitted by the MAO, we would use statistical extrapolation to calculate and recoup the improper payments made to the audited MA contract for all enrollees in the sub-cohort or sub-cohorts in that payment year.

We noted in the 2018 proposed rule that using a sub-cohort methodology, such as one focused on enrollees with high-risk HCCs, could allow us to use a much smaller sample size to calculate a statistically valid extrapolated improper payment amount. This is possible because, when selecting a sample from a smaller population (that is, a sub-cohort of enrollees), one can still achieve an acceptable level of statistical confidence with that smaller sample size. This sub-cohort-based audit methodology would also allow us to spread our audit resources across a wider range of MA contracts and focus on cohorts of enrollees that raise programmatic concerns, while also reducing operational burden on both CMS and the MAOs due to the reduced sample size needed to calculate improper payments.

In the 2018 proposed rule, we invited comment on both the contract-level audit methodology published in February 2012 and our proposal for an extrapolated audit methodology based on sub-cohorts of enrollees. We also sought comment on whether there are particular situations in which one methodology may be preferable to the other. We emphasized that neither proposed methodology was meant to displace our longstanding authority to audit the medical records of particular enrollees who we believe may be associated with improper payments or to use any statistically valid audit methodology. We also stated that, if we finalize one or more sampling and extrapolation methodologies through this rulemaking, we would announce any future changes to that methodology (or those methodologies) through the Health Plan Management System (HPMS).

In addition, we stated that we may begin to conduct RADV audits for PYs 2014 and 2015 before finalizing the policies in the proposed rule, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup improper payments identified. We also sought comment on whether the use of sampling and extrapolation for certain payment years would require the exercise of our statutory authority to engage in retroactive rulemaking, as set out in section 1871(e)(1)(A) of the Act, which authorizes retroactive application of rules where ''failure to apply the change would be contrary to the public interest.''

We also discussed proposed changes to our RADV dispute and appeals regulations in 42 CFR 422.311 to conform with the finalized RADV provisions. Specifically, consistent with

[26] See 83 FR 55038.

our other proposed policies, we proposed to amend § 422.311 by adding language to clarify that recovery of improper payments from MAOs will be conducted according to the Secretary's payment error extrapolation and recovery methodologies, and that CMS will apply extrapolation to RADV audits beginning with PY 2011. We also requested comment on whether to explicitly expand the MAOs' RADV appeal rights, such as by permitting appeal of the RADV payment error calculation methodology used in a RADV audit, similar to practices in Medicare FFS. A summary of the comments received and our responses follow.

3. Summary of Public Comments

Comment: Several commenters supported CMS' proposal to use extrapolation in RADV audits, as well as our proposal to begin extrapolation for PY 2011 audits. Commenters indicated that this is the most effective way to address improper payments in MA.

Response: We thank commenters for their support. While we plan to finalize our proposal to apply extrapolation to RADV audits, we are making a change to the years in which to apply extrapolation to achieve what we believe is an appropriate final policy that still takes into consideration our obligation to address potentially significant improper payments in the MA program. Extrapolation will now begin with the PY 2018 RADV audits rather than PY 2011, as proposed. This change, as further described in this section of this rule, is being made due to our fiduciary duty to protect taxpayer dollars from overpayments, certain operational considerations, and public comments on the timeliness of RADV audits.

Comment: Several commenters opposed the use of extrapolation in RADV audits. Some commenters questioned whether we had the statutory authority to use sampling and extrapolation in RADV audits. These commenters suggested that, because section 1893(f)(3) of the Act grants CMS the authority to use sampling and extrapolation in certain circumstances when conducting audits in Medicare Part A and Part B, CMS cannot use those techniques in Part C audits without an equivalent grant of statutory authority.

Several commenters challenged the statistical and methodological validity of both the contract-level sampling and extrapolation techniques described in the 2012 methodology, as well as an approach based on sub-cohorts of enrollees. A commenter stated that it is more difficult for plans to determine results from extrapolation in MA than in Medicare FFS because RADV audits can include the review of multiple medical records to validate one diagnosis from various providers with ''disparate methods of documentation.''

Some comments focused on the application of extrapolation beginning in PY 2011. Several commenters asserted that increased liabilities of MAOs from retroactive application of an extrapolated payment error recovery would deter future participation by MAOs in the MA program and reduce benefits to beneficiaries. Several commenters expressed concern that extrapolation for past payment years will destabilize physician care. Specifically, the concern is that providers participating in risk-sharing contracts with MAOs that have not yet completed a final settlement may be at risk for losses. The same commenters believe that recovering improper payments when the audit methodology has been revised several times is inequitable to the MAOs.

Response: We appreciate these comments and considered them when finalizing the timing and content of these extrapolation policies. As discussed previously, CMS has the authority to use sampling and extrapolation in its RADV audits. Federal courts have held that sampling and extrapolation are a valid method of calculating improper Medicare payments, so long as statistically valid methods are used. The MMA added section 1893(f)(3) of the Act, which specifically applies to Medicare Part A and Part B and limits the use of extrapolation to determine overpayment amounts for recoupment under certain circumstances. This provision did not confer new authority to use extrapolation, but limited our preexisting audit authority in Medicare Part A and Part B. No similar limitation has been applied to audits in Medicare Part C. However, CMS will continue to focus its RADV efforts on MAOs identified as being at higher risk of improper payments.

In the implementation of this authority to use sampling and extrapolation in RADV, CMS will employ statistical methods to determine statistically valid sample sizes, accurately identify payment error, and extrapolate to the universe of enrollees from which the sample is selected. These statistically valid methods may include applying one or more RADV audit methodologies for any given RADV audit. In addition, while CMS views extrapolation as a statistically valid methodology for RADV audits, the agency may, at times, use its discretion to not utilize extrapolation in a particular instance. For example, there may be unforeseen circumstances in which the statistical validity of the sample is disturbed (such as the need to exclude a large number of cases from the sample due to the loss of medical records in a natural disaster) and extrapolation is no longer possible, despite the initial intent to do so. There may be other limited instances in which CMS seeks to collect overpayments associated only with enrollees in a given sample, or wishes to perform only a probe sample of RADV reviews without the use of a statistically valid sample and yet will seek to recover any identified, non-extrapolated overpayments. The OIG may also independently decide not to extrapolate for reasons outside the control of CMS, and CMS will still recover those overpayments in accordance with the provisions in this final rule. To account for this, we are finalizing § 422.311(a)(2) to read ''CMS *may* [emphasis added] apply extrapolation to audits for payment year 2018 and subsequent payment years,'' rather than ''CMS will apply extrapolation . . .'' as proposed. This language is not intended to signal that it would be a frequent occurrence to not extrapolate in PY 2018 and future audits; rather, extrapolation is expected to be the standard practice for RADV audits beginning in PY 2018.

As previously stated, we believe that it is in the best interest of the Federal Government and our efforts to protect taxpayer dollars to extrapolate in our RADV audits, given the substantial amount of improper payments in MA and the fact that RADV is CMS' main corrective action used to address the submission of inaccurate diagnosis data. However, we also have decided not to extrapolate for PY 2011 through 2017 audits, as originally proposed, due to certain operational considerations and public comments on the timeliness of RADV audits. The reasoning for this decision is discussed in greater detail later in this final rule.

In addition, we do not agree with the comment that RADV audits include the review of multiple medical records with ''disparate methods of documentation.'' We reemphasize that the policies we are finalizing in this rule do not impose new documentation requirements on providers. The core component of a RADV audit is ensuring that all diagnoses reported to CMS are properly supported by medical record documentation. CMS' existing regulatory documentation standards, 42 CFR 422.310(d)(1); 45 CFR 162.1002(c)(2) and (c)(3), including the RADV-specific authority to validate risk

adjustment data through the review of a sample of medical records at § 422.310(e), remain unchanged under this final rule and are described in current agency policy documents, including the Medicare Managed Care Manual (with which MAOs agree, in their MA contracts, to comply). MAOs are also already required to ensure that contracted providers meet MA documentation requirements.

We respectfully disagree with commenters' assertions that liabilities will increase. We are not imposing additional liabilities, penalties or retroactive application of new requirements or policy. We only seek to recover improper payments received by MAOs for HCCs that are not substantiated by enrollees' medical records. We continue to rely on existing program methods to establish auditing practices that encourage proper payment recovery consistent with established audit practices. We recognize that MAOs enter into agreements with providers, including those with a risk-sharing component, and we encourage all parties to those agreements to take steps to mitigate the submission of diagnosis codes that are not properly supported in the medical record.

We emphasize that nothing in this rule changes the longstanding principle that a diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. Nor does this rule change the longstanding obligation of an insurer to refund payments to CMS if it learns that a diagnosis lacks support in the beneficiary's medical record.

Comment: Many comments were received on the proposed extrapolation methodologies, mainly focused on our proposed sub-cohort approach. Some commenters requested clarity on the sub-cohort methodology, while others expressed support for this methodology with various suggestions to improve it. Commenters questioned whether the proposed sub-cohort methodology will replace the existing contract-level methodology, which utilizes a general, non-targeted sampling methodology, and how CMS will determine which HCC groups will be used in the identification of sub-cohorts. A commenter requested that CMS confirm whether RADV will consist of a single audit methodology or whether MAOs will be subject to multiple audit methodologies.

Some commenters believe that applying a sub-cohort extrapolation methodology of enrollees would produce inaccurate results in RADV audits because of differences between plans with regard to size and risk characteristics. For example, several commenters argued that plans with a higher than average risk score are at increased risk for RADV audit because high-risk enrollees are more likely to have more HCCs. Other commenters believe that a small sample size, which CMS sees as a benefit of a sub-cohort methodology, will result in inaccuracies. Others commented that an extrapolation methodology based on sub-cohorts of enrollees would violate the statutory mandate of ''actuarial equivalence'' between payments made under MA and Medicare FFS because it would generate recoveries based on random outcomes without regard to specific characteristics of MA plans' diagnostic mix, enrollment size, and risk scores. A commenter requested that, if CMS adopts a sub-cohort extrapolation methodology, it uses a pilot period first before implementing the program on a large scale and extrapolating results.

Other comments spoke to extrapolation methods more generally, including the appropriate confidence interval, potential for plans of certain sizes to be unduly chosen for RADV audits, and perceived inability to assess potential liability for RADV audits already performed if CMS abandons the extrapolation methodology set forth in the 2012 methodology.

Other comments on our proposed extrapolation methodologies were focused on the impact of underpayments. A commenter objected to the RADV audit sampling methodology, arguing that it results in a purported payment recovery bias against MAOs. The commenter believes the results of the RADV audit sample are ''asymmetric,'' thus incorrectly representing the improper payment rate. More specifically, the commenter asserted that ''[t]hough there is no upper limit for how high the payment recovery amount can be, there is no balancing negative recovery amount.'' In other words, the commenter objected that MAOs cannot receive a payment from CMS based on a RADV audit if, overall, the risk scores should have been higher because, for instance, there were more supported diagnoses that had not been submitted (that is more under-coding) than unsupported diagnoses that had been submitted (that is over-coding). Other commenters shared these concerns, as well as voiced concern that RADV audit samples do not account for the reported bias that exists for enrollees who have no diagnosis codes submitted during the year but have existing documentation to support a diagnosis that could have been submitted. The same commenters perceive the audit methodology as being random and indiscriminate, believing that the results will incorrectly estimate the risk profile of enrollees.

A commenter requested information related to the sampling methodology used to select enrollees for the PY 2014 RADV audit. Specifically, the commenter requested details on the development of the regression model used to predict payment error and on the sampling criteria from which the RADV audit currently extrapolates. This commenter also contended that the PY 2014 methodology appears to maximize the probability of selecting individuals with coding errors.

Response: As previously explained, extrapolation is an established auditing practice and remains a valid method for addressing audit recoveries. In this final rule, we are clarifying the scope of our authority to strengthen the integrity of the MA program by identifying improper payments. Our initiatives are designed to ensure fair and accurate recovery efforts by focusing on the areas at highest risk of improper payments. We will use statistically valid methodologies to extrapolate improper payment findings to the universe of enrollees from which a sample is selected. These statistically valid methodologies may include applying one or more RADV audit methodologies for any given RADV audit. As previously discussed, we may also determine that extrapolation will not be applied in certain limited instances. We emphasize that, in this final rule, we are not adopting either the contract-level sampling and extrapolation technique described in the 2012 methodology or a specific extrapolated audit methodology based on sub-cohorts of enrollees. Instead, for future RADV audits, CMS will rely on any statistically valid method for sampling and extrapolation that it determines to be well-suited to a particular audit. We described the sub-cohort methodology in the 2018 proposed rule to provide the industry with transparency on potential audit methodologies. In addition, while not required, CMS will continue to disclose our extrapolation methodology to MAOs through HPMS memos or other appropriate means, providing MAOs with the information sufficient to understand the means by which CMS extrapolated the improper payment determination.

Any sampling and extrapolation methodologies adopted by CMS for RADV audits will be focused on MAO contracts and enrollees' HCCs that, through statistical modeling and/or data

analytics, are identified as being at highest risk for improper payments. This is an appropriate approach to any Federal MA audit that seeks to recoup taxpayer dollars that have been inappropriately paid to MAOs for diagnoses that are not supported in the medical record. This approach was also recommended by the GAO in a 2016 report titled ''Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments.'' [27] The GAO recommended that CMS ''modify [its] selection of contracts for contract-level RADV audits to focus on those contracts most likely to have high rates of improper payments by taking actions such as the following: selecting more contracts with the highest coding intensity scores; excluding contracts with low coding intensity scores; selecting contracts with high rates of unsupported diagnoses in prior contract-level RADV audits; if a contract with a high rate of unsupported diagnoses is no longer in operation, selecting a contract under the same MAO that includes the service area of the prior contract; and selecting some contracts with high enrollment that also have either high rates of unsupported diagnoses in prior contract-level RADV audits or high coding intensity scores.'' [28]

We also note that the purpose of RADV audits is to validate that diagnoses submitted by MAOs for risk-adjusted payment are properly supported by medical record documentation. *See* 42 CRF 422.310(e). RADV audits are the main corrective action used to address the submission of inaccurate diagnosis data. Occasionally, upon review of these medical records, CMS will uncover ''additional'' diagnoses supported by the medical records that were not submitted for payment by MAOs during the data collection period for enrollees selected in the sample. Under current contract-level RADV policy, when CMS uncovers these additional diagnoses that map to CMS–HCCs during medical record review of audited CMS–HCC(s), these newly-discovered diagnosis codes are used to recalculate risk scores in certain circumstances, which may result in an updated (reduced) improper payment calculation.

MAOs are required by CMS regulations (§§ 422.503 and 422.504) and MAO contracts to establish compliance programs and processes to ensure accurate diagnosis coding and the submission of accurate diagnosis data. These processes should enable MAOs to identify not only instances where diagnoses submitted for risk-adjustment payment are not supported by the medical record, but also diagnoses that may not have been submitted to CMS. MAOs can submit additional diagnoses for risk-adjusted payment up until the final risk adjustment data submission deadlines described at § 422.310(g)(2)(ii). As with overpayment recoveries under the Affordable Care Act and CMS's Overpayment Rule, the purpose of RADV audits is not to reopen submission deadlines and for CMS to make additional payments.[29] RADV audits identify overpayments after the final risk adjustment data submission deadline.

Comment: Some comments were focused on the scope and number of plans selected for RADV audit. A commenter objected to an increase in the number of plans selected for the RADV audits. Another commenter requested an explanation of how sample sizes will be determined for Program of All-Inclusive Care for the Elderly (PACE) organizations, most of which have fewer than 500 enrollees.

Response: As previously described, any extrapolation methodology adopted by CMS for RADV audits will be focused on MAO contracts that, through statistical modeling and/or data analytics, are identified as being at highest risk for improper payments. Examples of MAO contracts that may be deemed higher risk for the purposes of RADV audit selection are discussed later in this section. This is also the best approach to ensure that MAOs that do not show indications of being at high risk of improper payments are not exposed to audit burden to the exclusion of higher-risk plans. In addition, as noted previously, such an approach was recommended by the GAO in its April 2016 report.[30] CMS does not currently subject PACE organizations to RADV audits and CMS' selection methodology for each year will describe any adjustments made for PACE or other low enrollment contracts.

Comment: Several commenters noted that implementing these proposed policies would lead to more audit burden for providers because of an increase in documentation standards for treating providers. For example, commenters believe that this is a ''more stringent audit expectation'' that will increase administrative burden at a time in which there is already a physician shortage, thereby impacting patients. Another commenter contended that our extrapolation methodology should reflect that certain HCCs are more difficult to substantiate in medical record documentation than others.

Response: RADV audits will not impose new documentation requirements on health care providers and, therefore, we believe there will be no additional audit impact on providers that contract with MAOs to provide services to MA plan enrollees. As previously stated, nothing in this rule changes the longstanding principle that a diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. In addition, there is a longstanding requirement under § 422.310(e), in place since the beginning of the MA program, that ''[MAOs] and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS,'' which is unaffected by this final rule. This requirement is consistent with longstanding requirements applicable to Medicare Part A and Part B providers that they furnish sufficient information to support payment. 42 U.S.C. 1395(g) (Effective July 7, 2004) (''[No]. . . . payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider . . .''); *Clinic Res. Mgmt.* v. *Burwell,* 2015 WL 3932657, at *2 (S.D. Tex. June 26, 2015) (''The provider is responsible for maintaining and submitting adequate information to substantiate medical necessity and entitlement to payment.'').[31]

[27] GAO, at 26, *https://www.gao.gov/assets/gao-16-76.pdf* (April 2016).

[28] *Id.*

[29] Section 6402 of the Affordable Care Act (Pub. L. 11–148) established section 1128J(d) of the Act. Under the Part C and D Overpayment Rule (79 FR 29844), which implemented section 6402 of the Affordable Care Act, MAOs are required to correct overpayments by self-reporting and returning payments associated with MAO diagnosis codes not supported by medical record documentation. Although MAOs are required to correct identified overpayments after the final risk adjustment data submission deadline in order for CMS to conduct reruns and recover the overpayments, MAOs are not permitted to submit additional diagnoses for payment after the submission deadline.

[30] GAO, at 26, *https://www.gao.gov/assets/gao-16-76.pdf* (April 2016).

[31] Under section 1853(a)(3) of the Act, the Secretary must require MAOs to submit data regarding inpatient hospital services and other services, as well as other information as the Secretary deems necessary to calculate MA risk adjustment payments. This authority has been implemented at § 422.310, which requires MAOs to submit ''data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner.'' § 422.310(b). MAOs must submit data that conforms to CMS' requirements for data equivalent to Medicare FFS

Comment: A commenter contested CMS' proposal to recover contract-level payment adjustments through a lump-sum reduction in the plans' monthly payments through MARx. The commenter noted that, for example, CMS currently makes retroactive, beneficiary-specific adjustments related to miscellaneous corrections to beneficiaries' status (such as eligibility, State and county of residence, date of death, etc.) outside of the RADV process. The commenter requested that CMS seek only beneficiary-level recoveries through RADV audits so as not to overlap with these non-RADV recoveries.

Response: While we appreciate the commenter's consideration of the other areas in which CMS may make adjustments to MA payments, we do not believe that current and proposed RADV efforts overlap with non-RADV adjustments. RADV audits only validate diagnoses associated with a beneficiary's medical record documentation, not a beneficiary's demographic characteristics. If an HCC cannot be validated with medical records, MAOs are not entitled to the risk-adjustment payment associated with that HCC.

Comment: Several commenters opposed the application of our extrapolation methodology to past payment years claiming that, pursuant to section 1853(b)(2) of the Act, this would be considered a retroactive application of policy and CMS must disclose our RADV audit methodology changes prior to any payment year RADV audit. Some commenters also asserted that the application of this rule to past payment years would alter the actuarial soundness of payments previously received by MA contracts, as existing contracts relied on the RADV audit methodology we announced in the 2012 RADV Methodology. Other commenters also characterized this approach as contrary to the Supreme Court's holding in *Azar* v. *Allina Health Servs.,* 139 S. Ct. 1804, 204 L. Ed. 2d 139 (2019), which emphasized that a substantive legal standard must go through a notice-and-comment process.

Response: First, as a fundamental concept, this policy does not impose any new requirements on MAOs that could be construed as retroactive. The 2012 RADV Methodology did not create a different ''documentation standard'' for MA plans than the standard that applies to traditional Medicare providers, nor did we state that an FFS Adjuster should set a permissible rate for the submission of erroneous codes. There is only one documentation standard for diagnosis coding, as discussed previously: proper medical record documentation is required for any reported diagnosis code to be valid. That is the consistent policy throughout the Medicare program (see previous discussion).

The RADV auditing methodology has not fundamentally changed the longstanding requirement that a diagnosis submitted to CMS by an MAO for payment must be properly supported by medical record documentation. See *UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867, 869, 877 (D.C. Cir. August 13, 2021, reissued November 1, 2021), *cert. denied,* 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21–1140). Rather, it only enforces the well-established regulatory requirement that MA diagnoses be validated under that longstanding documentation standard. (For additional information, see § 422.310(e); 83 FR 55037 (and authorities cited therein).)

We also noted in the 2018 proposed rule that we may begin to conduct RADV audits for additional payment years (specifically, 2014 and 2015) before this proposal is finalized, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup any improper payments identified.

Even if this methodology was determined to be a retroactive application of policy, a position with which we do not agree, it is still necessary to comply with statutory requirements and is in the public interest for CMS to apply extrapolation to past payment years, and, therefore, is authorized under the Act. CMS has the authority, in accordance with section 1871(e)(1)(A) of the Act, to apply retroactive changes in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability to items and services furnished before the effective date of the change, if the Secretary determines that ''such retroactive application is necessary to comply with statutory requirements or failure to apply the change would be contrary to the public interest.'' We believe that recovering extrapolated improper amounts is necessary to comply with statutory requirements and advances the public interest by protecting the overall integrity of the MA program. We have a statutory mandate under the PIIA to reduce improper payments and a fiduciary responsibility to recover funds due and owed to the Medicare Trust Funds.

As previously discussed, HHS and the GAO have identified a significant volume of improper payments in the MA program,[32] and RADV audits are the main way CMS ensures payment accuracy to MAOs. As further discussed in the Regulatory Impact Analysis section of this final rule, CMS estimates extrapolated improper payment recoveries of approximately $479 million per audit year beginning with the PY 2018 audit. We also believe that there will be an additional sentinel effect of RADV audits on the improper payment rate as MAOs improve their processes to report only those diagnoses that meet CMS requirements for risk adjustment payment.

In addition, as discussed previously, RADV audits will not impose new documentation requirements on health care providers. The core component of a RADV audit is ensuring that all diagnoses are properly supported by medical records. We only seek to recover improper payments received by MAOs for HCCs that are not substantiated by enrollees' medical records. MAOs have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records. Therefore, applying the rule under the public interest exception in section 1871(e)(1)(A) of the Act would not upset any settled or reasonable reliance interests. This all serves the public interest by reducing the improper allocation of taxpayer dollars that can otherwise be used for other purposes within the Federal Government, including solvency of the Medicare Trust Funds. Thus, applying the rule retroactively is necessary to comply with statutory requirements and in the public interest within the meaning of section 1871(e)(1)(A) of the Act.

Comment: Several comments provided input on the potential promulgation of rules permitting administrative appeals of RADV audit methodology. A commenter opined that such procedures were unnecessary because stakeholders had an opportunity to participate in the development of our methodology through the notice-and-comment

data, when appropriate, and to all relevant national standards. The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) Guidelines for Coding and Reporting is the existing national standard. (*See* § 422.310(d)(1); 45 CFR 162.1002(c)(2) and (c)(3)). This is consistent with obligations imposed on hospitals and providers in Medicare Parts A and B, who are required to furnish proper documentation and comply with the ICD Guidelines. See, for example, 42 U.S.C. 1395g and 1395n.

[32] For example, the FY 2021 HHS Agency Financial Report, pg. 211, *https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf,* states that Part C Improper Payment Measurement (IPM) estimated approximately $15 billion in overpayments for calendar year 2019 risk-adjusted payments to MAOs.

rulemaking process, and that permitting challenges to our methodology in the administrative appeals context would generate ''numerous unnecessary practical problems'' for us. Another commenter supported the expansion of RADV audit appeals to allow MAOs to demonstrate that alternative methodologies would be more accurate, and to show that cohorts sampled for RADV audits might not be representative of the contract population.

Response: We appreciate the commenters' input and concerns. We do not believe it would be appropriate to expand our appeals regulations to allow MAOs to appeal the RADV audit methodology, as revisions to the appeal regulations were not part of our proposed rule and stakeholders did not have the opportunity to provide comments on specific proposed policies. As such, MAOs will continue to be able to use the RADV appeals process currently set forth in § 422.311. Any future changes to our appeals process would occur through separate notice and comment rulemaking.

Comment: Several comments outside the scope of the proposed rule were received, including those related to the RADV program and other CMS programs. Out-of-scope comments pertaining to the RADV program included recommendations for changes to RADV documentation requirements and procedures; requests that CMS prohibit MAOs from auditing providers for patient records within the RADV cohort during the course of RADV audit; a request to expand the hardship exception to account for delays in acquiring medical records resulting from providers who are ''traveling, sick, or deceased;'' a request to implement a schedule whereby RADV audits would be performed within 2 years of the applicable dates of service; challenges in collecting medical records created several years before the RADV audit; and requests for clarification of how CMS treats ''non-unique'' diagnosis codes during RADV audits when, even if one code is in error, there may be one or more diagnoses that substantiate the same HCC.

Other out-of-scope comments pertained to the RADV dispute and appeals processes. These comments included requests for CMS to provide MAOs with more time to appeal a RADV audit finding; expand MAOs' appeal rights by removing the current limitation cited in § 422.311(c)(2)(iv) that allows MAOs, for each audited HCC, to appeal only one medical record that has undergone a RADV review; use an independent third party to reconsider disputed HCCs and/or payment error calculations; allow additional flexibility in disputing medical record interpretation during the appeals process and for MAOs to supplement medical records with documents that could not be obtained at the time of the audit; and allow MAOs to file complaints of underpayments by CMS.

Other comments were received unrelated to RADV, such as requests to make burden-reducing changes to the Medicare Part C Recovery Audit program requirements and requests for payment parity between MA and Medicare FFS.

Response: While we appreciate this feedback, these comments do not directly relate to the proposed changes to the RADV audit program, which is focused on our policies related to the use of extrapolation and the non-application of an FFS Adjuster, and are therefore outside of the scope of this final rule. Updated resources on RADV rules and methodologies are available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-andSystems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.* We also encourage stakeholders to engage with CMS throughout the course of an audit cycle and to provide feedback on programmatic improvements that can be considered outside of this rulemaking process.

4. Summary of Final Policies

After consideration of public comments, we are finalizing the use of extrapolation under the contract-level RADV program. However, we are modifying our proposed policy to extrapolate beginning in PY 2011. We are instead finalizing our ability to extrapolate beginning in PY 2018 due to considerations of appropriateness in light of public comments and certain operational concerns, as well as our obligations to protect the sustainability of the Medicare program. We are announcing, through this final rule, our interpretation of our statutory and regulatory authority as authorizing the use of sampling and extrapolation in RADV audits. We are not adopting any particular statistical sampling methodology in this final rule. As previously noted, CMS will use statistically valid methods for sampling and extrapolation that we determine to be well-suited to a particular RADV audit.

After reviewing comments and considering the matter further, we also believe that the use of sampling and extrapolation to calculate audit recoveries would not be retroactive within the requirements of section 1871(e)(1)(A) of the Act. The use of sampling and extrapolation for prior payment years is not retroactive because the substantive requirement of proper medical record documentation of all diagnoses submitted for payment remains unchanged, whether we calculate audit recoveries on an enrollee-by-enrollee basis or use a statistically valid sample of enrollees to extrapolate. Enrollee-level audit recoveries and extrapolated audit recoveries are simply two different ways of enforcing the same medical record documentation requirement under § 422.310(e).

While we believe that the use of sampling and extrapolation for prior payment years is not a retroactive application of policy, even if it was somehow interpreted as retroactive, we still believe that recovering extrapolated improper amounts is necessary to comply with statutory requirements and advances the public interest by protecting the overall integrity of the MA program. We have a statutory mandate under the PIIA to reduce improper payments and a fiduciary responsibility to recover funds due and owed to the Medicare Trust Funds. The RADV program was developed as one of the primary methods to address CMS' responsibility to recover improper payments in the MA program.

In addition, although we stated in the proposed rule that we intended to apply any finalized RADV payment error methodology or methodologies to PY 2011 and all subsequent years, we have decided to begin to exercise our authority to collect extrapolated recoveries with the PY 2018 RADV audit. Based on our review of a number of factors, CMS determined it is in the overall best interests of the RADV program and ultimately the Part C program itself to limit all RADV improper payment recoveries for PYs 2011 through 2017 to enrollee-level adjustments for those enrollees sampled in the payment validation audits. Our reasoning for this decision follows.

First, after careful consideration of the comments received, we believe that the most appropriate decision is to begin extrapolation with the PY 2018 audits. As a result, CMS will not collect extrapolated overpayments identified as a result of either CMS RADV or HHS–OIG audits for payment years prior to PY 2018, but will collect enrollee-level overpayments identified in those audits. As previously described, we believe that beginning extrapolation for PY 2018 RADV audits represents an appropriate policy because it recognizes our

fiduciary duty to protect taxpayer dollars from overpayments and preserves our ability to collect on significant (extrapolated) amounts of overpayments made to plans beginning in PY 2018. This final rule will also allow CMS to focus on conducting future RADV audits as soon as practicable after an MAO payment year concludes, which was the topic of significant public comment to the proposed rule.

Lastly, we have determined that it is in the best interest of all parties to ensure that the contract-level RADV appeals process, which is also outlined in regulation, is able to successfully process all RADV appeals. By not using an extrapolation methodology prior to PY 2018, we expect to better control the total number of active appeals that are submitted in the first few years following finalization of this rule, which will alleviate burden on MAOs and CMS. This includes appeals that result from CMS RADV audits, as well as CMS recoveries made based upon improper payments identified in HHS–OIG audits of MAOs. When this rule is finalized, we will begin issuing the enrollee-level audit findings from the CMS RADV audits that have been completed (that is, CMS RADV audits for PYs 2011 through 2013, followed eventually by PY 2014 and PY 2015 audits), as well as recovering enrollee-level improper payments identified in HHS–OIG audits. The release of these results in quick succession could result in an unprecedented influx of MAO appeals into the RADV appeals process. HHS' past experience with appeals backlogs, particularly for Medicare FFS claims, has demonstrated that proactive steps to avoid large volumes within an abbreviated period of time is key to ensuring the timely processing of all appeals. Depending upon the number of RADV audit appeals filed by plans, there may be a possible appeals backlog that could lead to significant burden on MAOs and CMS. It can also divert government resources away from other important activities that could also reduce MAO burden, such as finding ways that RADV audits can be performed in quicker succession to the conclusion of any payment year reconciliation period, resulting in future RADV audits being more contemporaneous, which was the topic of significant public comments to the proposed rule.

At the same time, this finalized policy also recognizes our fiduciary duty to protect taxpayer dollars from overpayments and preserves our ability to collect on significant (extrapolated) amounts of overpayments made to plans beginning in PY 2018. We understand that this decision means that certain amounts of improper payments will be left uncollected in those earlier payment years (PYs 2011 through 2017) because we will only be collecting the non-extrapolated improper payments identified for PYs 2011 through 2017 and not the extrapolated overpayments that we will be collecting for PY 2018 and subsequent payment years. However, for the reasons previously described, we believe that the overall long-term success of the RADV program and ultimately the Part C program requires us to consider several issues and balance the collection of extrapolated improper payments with the practical realities of the current RADV program.

We are finalizing our RADV regulations as proposed, with the exception of a change to the payment year in which extrapolation will begin. Specifically, we are—

- Revising § 422.300 to include ''collection of improper payments;''
- Amending § 422.310(e) to announce that extrapolation may be applied in RADV audits for PY 2018 forward and by adding a requirement for MAOs to remit improper payments based on RADV audits in accordance with a manner specified by CMS; [33] and
- Amending § 422.311 by clarifying that recovery of improper payments from MAOs will be conducted according to the Secretary's payment error extrapolation and recovery methodologies and that CMS may apply extrapolation to RADV audits for PY 2018 and subsequent payment years.

While we appreciate the comments received as to potential expansions of MAO appeals rights, we are not finalizing any other changes to the RADV appeals process as part of this final rule because no specific appeals-related policies were proposed.

B. Fee-For-Service Adjuster

1. Description of an FFS Adjuster

As previously described, risk adjustment ensures that MAOs are paid appropriately for their plan enrollees, and section 1853(a)(1)(C) of the Act requires that we calculate risk-adjusted payments to MAOs based on specific criteria, such as age, disability status, gender, institutional status, and health status. As discussed earlier, MAOs' payments are calculated using the CMS–HCC risk adjustment model, which is published each time it is updated (see section 1853(b) of the Act).[34] Additionally, an MAO may only report a diagnosis, and claim the associated payment, when that diagnosis is properly supported by the beneficiary's medical records. Medical records properly support a reported diagnosis when they comply with all CMS data and documentation requirements, which are described in current agency policy documents, including Chapter 7 of the Medicare Managed Care Manual.[35] Plans are also required to submit a sample of medical records for the validation of this risk adjustment data (see 42 CFR 422.310(e)).

Some MAOs have suggested that CMS cannot lawfully enforce the requirement of medical record documentation for diagnosis codes while making payments at the published rates. These MAOs argue that there is a difference in auditing standards between Medicare FFS and MA diagnosis data. In contrast to the MAO-submitted diagnosis data, these MAOs claim that Medicare FFS data is ''unaudited'' by CMS and presumably contains erroneous diagnosis codes not properly supported by beneficiaries' medical records. As a result, they argue, the Medicare FFS data used to calculate MAO payments will understate the cost of treating various conditions. To address the presence of erroneous diagnoses in the FFS claims data used to calibrate the MA payment model, MAOs argue that CMS must raise payment rates to MAOs or relax the documentation standard that CMS applies to reported medical diagnoses to ensure accurate payments. MAOs refer to this concept of a proposed adjustment to the payment rates and/or documentation standard for MAOs as an ''FFS Adjuster.'' These MAOs ground their arguments in section 1853(a)(1)(C)(i) of the Act, which requires the Secretary to adjust payments to MAOs for demographic and health related risk factors so as to ensure ''actuarial equivalence.'' According to these MAOs, an FFS Adjuster would either adjust payment rates (by raising them) or adjust documentation standards (by loosening them) to resolve the alleged incompatibility between the current rates and current documentation standards. In the 2012 methodology, using the term somewhat differently,

[33] See discussion regarding the use of ''may'' in § 422.310(e). This language is not intended to signal that it would be a frequent occurrence to not extrapolate in PY 2018 and future audits; rather, extrapolation is expected to be the standard practice for RADV audits beginning in PY 2018. This will allow CMS with flexibility to not extrapolate in certain limited instances the Agency determines to be appropriate.

[34] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[35] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf.*

CMS said that it would ''apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount'' calculated for RADV audits under that methodology.

2. Summary of 2018 Proposed Rule

In the 2018 proposed rule, we proposed not to include the FFS Adjuster described in the 2012 methodology in any final RADV payment error methodology. We stated that a study that we conducted found that errors in Medicare FFS claims data do not lead to systematic payment error in the MA program and that, even if there was evidence of systematic payment error, it would be inequitable to only correct payment errors made to audited contracts. We sought comment on our proposal not to use an FFS Adjuster. We also sought comment in our June 28, 2019 **Federal Register** notice and request for additional comment (84 FR 30983) regarding how the statutory minimum levels of the coding pattern adjustment set at section 1853(a)(1)(C)(ii) of the Act bear on the issue of whether or not to apply an FFS Adjuster.

3. Summary of Public Comments

We received numerous comments regarding our proposal to not include an FFS Adjuster in RADV.

Comment: Several commenters expressed support for CMS' proposal not to apply an FFS Adjuster, including the Medicare Payment Advisory Commission (MedPAC).[36] These commenters discussed the study results demonstrating that errors in FFS Medicare claims data do not systematically bias MA risk scores, and said that if such bias existed, applying an FFS Adjuster to RADV would not be the appropriate remedy to address that bias because only a small number of MA plans undergo RADV audits each year. These commenters further asserted that any potential bias from undocumented FFS diagnoses is negligible and that the application of an FFS Adjuster would require significant effort for negligible benefit.

Response: We thank these commenters for their support of not applying an FFS Adjuster to the RADV methodology. We agree with these comments for the reasons described throughout this final rule.

Comment: Some commenters contended that an FFS Adjuster is required to ensure ''actuarial equivalence'' between payments to MA plans and payments under the Medicare FFS program. Some commenters also contended that the ''same methodology'' provision of section 1853(b)(4)(D) of the Act requires the application of an FFS Adjuster in RADV. Other commenters argued that CMS needs to apply an FFS Adjuster to comply with the district court's holding in *UnitedHealthCare Insurance Co.* v. *Azar,* 330 F. Supp. 3d 173 (D.D.C. 2018), *rev'd sub nom. UnitedHealthcare Insurance Co.* v. *Becerra,* 16 F.4th 867 (D.C. Cir. August 13, 2021, reissued November 1, 2021), *cert. denied,* 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21–1140). A commenter requested that CMS suspend ongoing RADV audits and not begin any new RADV audits until an FFS Adjuster is developed for use in RADV audits and in MAOs' calculations of improper payments.

Response: As a general matter, we believe that it is in the best interest of the Federal Government and taxpayers for CMS to continue RADV audits for the purpose of addressing the high dollar amounts of improper payments, as well as to employ a RADV methodology that does not include the application of an FFS Adjuster. Further, the ''actuarial equivalence'' requirement under section 1853(a)(1)(C) of the Act and ''same methodology'' provision under section 1853(b)(4)(D) of the Act do not require the use of an FFS Adjuster. First, as described by the D.C. Circuit, these provisions do not apply to the obligation to return improper payments for MAO diagnosis codes that are unsupported by medical records. Although the D.C. Circuit did not address the RADV audit context in its decision in *UnitedHealthcare,* this position is consistent with the D.C. Circuit's reasoning in that case. (*See UnitedHealthcare,* 16 F.4th at 869, 891–92.) Second, it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits). (Section 1853(a)(1)(C)(ii) of the Act requires a minimum coding pattern adjustment to reduce the risk scores of all MA beneficiaries, and therefore, MA payment rates. Such a minimum coding pattern adjustment accounts for differences in coding patterns between MA and Medicare FFS, given that MAOs have a greater incentive than FFS providers to report diagnoses.) These points are further explained later in this section.

The first basis for our decision not to apply an FFS Adjuster is because we believe that the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to MAOs, and not to the obligation to return improper payments for diagnosis codes submitted by MAOs to CMS lacking medical record support. This position is consistent with the D.C. Circuit's decision in *UnitedHealthcare.* There, a group of MAOs challenged the Secretary's Part C Overpayment Rule (the ''Overpayment Rule'') (79 FR 29844), which implemented section 6402 of the Affordable Care Act and required MAOs to self-report and return payments associated with MAO diagnosis codes not supported by medical record documentation. The district court invalidated the Overpayment Rule. *UnitedHealthcare,* 330 F. Supp. 3d at 192.

However, the D.C. Circuit reversed the district court, holding that the actuarial equivalence provision applies only to how CMS risk adjusts the payments it makes to MAOs, and not to the obligation of MAOs to return improper payments for diagnosis codes, submitted by MAOs to CMS, lacking medical record support. (*See UnitedHealthcare,* 16 F.4th at 883–887.) The D.C. Circuit also held that even if the actuarial equivalence provision applied, plaintiffs' claims would still fail because they did not meet their burden in showing, either through empirical evidence or persuasive logic, that application of the Overpayment Rule would lead to systematic underpayment of MAOs. (*Id.* at 887 through 891.)

While the D.C. Circuit decision pertained only to the Overpayment Rule and declined to address RADV audits, its reasoning applies just as strongly in the RADV context and supports our conclusion that an FFS Adjuster is not appropriate in a RADV audit. ''The role of the actuarial-equivalence provision is to require CMS to model a demographically and medically analogous beneficiary population in traditional Medicare to determine the prospective lump-sum payments to [MAOs].'' (*Id.* at 870.) The RADV program, like the Overpayment Rule, applies after the fact to require MAOs to refund any payment to which they are not entitled, based on diagnoses that lack support in the medical record. The purpose of RADV audits is to recover payments that were made improperly based on diagnoses not supported by medical record documentation. If a payment is made to an MAO based on a diagnosis code not supported by

[36] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08122019_medpac_ma_radv_comment_v3_sec.pdf.*

medical record documentation, the entire payment for that code is in error and should be recovered in full because the payment standard has not been met. RADV audits only address issues relating to diagnoses that are not supported by valid medical record documentation.

Comment: Several commenters expressed concern that our proposal to extrapolate without applying an FFS Adjuster to payment recoveries achieved through RADV audits will overlap with coding pattern adjustments or create a double-recovery by CMS.

Response: Section 1853(a)(1)(C)(ii) of the Act requires the implementation of a minimum coding pattern adjustment to reduce risk scores of all MA beneficiaries, and therefore MA payment rates. This minimum coding pattern adjustment accounts for differences in coding patterns between MA and Medicare FFS, given that MAOs have a greater incentive than FFS providers to report diagnoses. To meet this requirement, each year, CMS has implemented an adjustment to offset the effects on MA risk scores of higher levels of coding patterns in MA relative to FFS. (See section 1853(a)(1)(C)(ii) of the Act.) Under section 1853(a)(1)(C)(ii)(III) of the Act, the minimum adjustment factor for 2019 and each subsequent year is 5.90 percent. CMS has, each year, implemented the minimum coding pattern adjustment reduction required by statute.

As CMS has explained in its annual MA advance notices and rate announcements, the coding pattern adjustment, unlike RADV, is not intended to address unsupported or inaccurate codes reported by MAOs in particular instances but only the general practice, relative to Medicare FFS, of reporting codes with greater intensity, including codes that are nonetheless accurate.[37] Contrary to some commenters' assertions, the coding pattern adjustment provision of the statute actually supports our decision not to apply an FFS Adjuster, and we rely on that conclusion here as a second basis for our decision not to apply an FFS Adjuster. We briefly review the history of that provision:

- The coding pattern adjustment was enacted as part of the Deficit Reduction Act of 2005. (Pub. L. 109–171 (February 8, 2006), codified at 42 U.S.C. 1395w–23(a)(1)(C)(ii)(I) and (II).)
- The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), section 1853(a)(1)(C)(ii) of the Act was amended to require that the adjustment be at least 4.71 percent in 2014, rising annually to at least 5.7 percent in 2019. (Pub. L. 111–152, tit. I, subtit. B, section 1102(e), 124 Stat. 1046.) (For payment years 2010 to 2013, CMS applied a 3.41 percent adjustment.[38])
- Section 1853(a)(1)(C)(ii)(III) of the Act was subsequently amended again in the American Taxpayer Relief Act of 2012 to require the Secretary to make a reduction of at least 4.91 percent in 2014, rising to at least 5.9 percent by 2019. (Pub. L. 112–240, tit. VI, subtit. C, section 639, 126 Stat. 2357.)

CMS audits reinforce longstanding documentation requirements. We believe it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits). To the contrary, because the Act requires CMS to reduce payments to MAOs by at least a specific minimum percentage, the only reasonable interpretation of the Act is that CMS would pay MAOs at those reduced rates, under the existing payment model,[39] and enforce the longstanding documentation requirements through CMS' audits.

Comment: Several comments disputed our suggestion that addressing any diagnosis error in FFS Medicare claims through a RADV FFS Adjuster would introduce inequities between plans that are audited and plans that are not audited. Specifically, commenters discussed that not applying an FFS Adjuster would be a disadvantage to the MA plans selected for RADV audits because the audited plans are held to a higher, inappropriate standard of medical documentation than unaudited plans.

Response: As we stated in the proposed rule, the purpose of RADV audits is to recover improper payments resulting from diagnoses that are not supported in the medical record documentation, which is a longstanding documentation standard that applies to all plans equally and regardless of whether the plan is subject to a RADV audit. The objective of an audit is to promote fair and impartial recovery of improper payments due to insufficient documentation in accordance with regulations. As we stated in the proposed rule, even if systematic error exists, it would be inequitable to correct such errors in the payments made only to audited plans through the application of an FFS Adjuster. We also do not intend for this conclusion to suggest that we believe an FFS Adjuster is appropriate or necessary outside of the RADV context.

Our position is consistent with the conclusion of the D.C. Circuit, which is that the actuarial-equivalence requirement is not an ''entitle[ment] . . . to a precise payment amount'' for a Medicare Advantage insurer, but only ''an instruction to the Secretary regarding the design of the risk adjustment model as a whole . . . describ[ing] the type of 'payment amount[s]' that the risk adjustment model should produce''; ''[i]t does not directly govern how CMS evaluates the validity of diagnoses or defines 'overpayment.' '' (*UnitedHealthcare,* 16 F.4th at 885–86).

Comment: Several commenters asserted that moving forward without an FFS Adjuster would render the RADV auditing requirements flawed, unclear, stringent and unrealistic, and increase the burden placed on providers to ensure accuracy as a result. Specifically, commenters believe this ''more stringent audit expectation'' during a physician shortage would not serve the public interest and would be detrimental to the MA program. A commenter argued that increased auditing requirements for MA providers would be contrary to CMS' other efforts focused on reducing unnecessary provider burden. Other commenters also noted burden for patients, while others believe that this policy will have a disproportionate impact on smaller, not-for-profit special needs plans with fewer resources to pay audit recoveries.

Response: This final rule does not impose a new documentation standard on MA providers, nor is there a distinction in the documentation standards between the MA and FFS Medicare programs. Section 1815(a) of the Act (Medicare Part A) states that ''no such payments shall be made to any

[37] Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 19 (April 5, 2010); *see also* Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 54 (April 4, 2016); Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 37–38 (April 4, 2011).

[38] Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies at 19–29 (April 6, 2009).

[39] Any changes to the CMS–HCC payment model are published in the annual payment notice.

provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period.'' Additionally, Section 1833(e) of the Act (Medicare Part B) states that ''[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.'' Section 1172 of the Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104–191) also requires both providers and health plans to use standard content, formats, and coding for health care transactions. In addition, the Secretary has adopted various organizations' formats and code sets, including the ICD–10 and the ICD Guidelines, which is the national standard for both FFS and MA. See 45 CFR 162.1002. CMS has always required proper medical record documentation in order for any reported diagnosis code or claim to be valid. (*See, for example, Becerra,* 16 F. 4th at 869 (''[n]either Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer'').) That is the consistent policy throughout the Medicare program, including MA and FFS.[40] (See 42 CFR 422.310 (''MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards.'').) As such, we do not believe that RADV audits impose any new level of burden on providers or violate any initiatives to reduce that burden.

This rule, rather than the 2012 methodology, will govern CMS' conduct of RADV audits. Nonetheless, we did not intend the 2012 methodology to suggest that contract-level RADV audits create a different ''documentation standard'' for MAOs than the standard that applies to traditional Medicare providers, or that any FFS Adjuster should set a permissible rate for the submission of invalid diagnosis codes. After a lengthy consideration of these issues, and more than a decade of additional experience with the Medicare Advantage program, we have decided not to apply an FFS Adjuster in RADV audits because: (1) we believe, consistent with the D.C. Circuit's decision in *UnitedHealthcare,* that the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to MAOs and not to the obligation of MAOs to return improper payments (that is, payments for unsupported diagnosis codes); and (2) it would not be reasonable to read the Act as requiring a reduction in payments to MAOs by a statutorily-set minimum adjustment in the coding pattern adjustment, while at the same time prohibiting CMS from enforcing longstanding documentation requirements by requiring an offset to the recovery amounts calculated for CMS audits.

Comment: A commenter opined that the cost to stakeholders of extrapolating payment error recoveries without an FFS Adjuster outweighed any benefits to the rule. The commenter noted that CMS' analysis of the regulatory impact in the proposed rule ignored changes in MA bids, including reduced or eliminated product availability, increased administrative costs to MAOs for auditing provider medical record documentation and coding, and the cost of responding to RADV audits. Other commenters argued that extrapolation, along with the elimination of the FFS Adjuster, would threaten the MA program more generally through consequences on the bidding process, reduced incentives for cost savings, reduced benefits to enrollees, and increased premiums. A commenter requested that CMS consider that selecting contracts that represent a disproportionate amount of an MAO's business for RADV audits may drive smaller organizations out of the MA program.

Response: It is our objective to strengthen the MA program by ensuring that the payments received by MAOs are accurate and that the Federal Government recovers any funds, representing taxpayer dollars, to which an MAO was not entitled. Our RADV audit methodology, which will not include an FFS Adjuster, should not have any material impact on MAOs' bidding practices or offerings because any funds recovered under RADV would be for payments to which the MAO was never entitled. Consistent with a prior GAO recommendation to focus on MAO contracts most likely to have high rates of improper payments, we have also shifted our RADV approach from a largely untargeted, random sampling from a universe of most of an audited MAOs' enrollees to a more targeted, risk-based approach that incorporates risk factors, such as HCCs that were more likely to be in error. This current approach enables the Federal Government to focus its limited auditing resources on areas where improper payments are more likely to be found, and reduces audit burden on those MAOs that are not at high risk of improper payments. We believe, for example, that MAOs that implement meaningful steps to reduce the reporting of unsupported diagnoses will be less likely in the future to be chosen for a CMS RADV audit because the indicators of potential improper payment risk will be greatly reduced in the risk adjustment data.

Comment: A commenter requested that CMS withdraw the proposed RADV provisions and develop a new audit procedure in concert with industry stakeholders. Several commenters noted that CMS has announced no plans to address FFS Medicare diagnosis errors in the original payments to plans. These commenters assert that CMS' failure to provide a general adjustment for payment bias does not justify our proposal not to apply an FFS Adjuster for audited plans.

Response: We believe these comments are outside the scope of the proposed rule's provisions. The RADV program enforces the longstanding medical record documentation regulatory requirement as it relates to risk adjustment, not the analyses performed to determine the risk adjustment coefficients used to calculate risk scores, and thus risk-adjusted payments. It would be inappropriate to address these determinations and calculations via this final rule's RADV payment error methodology.

Comment: Several commenters requested that we provide additional disclosures of information related to our FFS Adjuster study to enhance transparency, some arguing that the Information Quality Act (Pub. L. 106–554) requires disclosure of such materials. For example, a commenter requested copies of the medical records reviewed during the FFS Adjuster study and diagnostic coding protocols followed by reviewers, citing the Information Quality Act as the justification for this request. Another stated that additional data is needed in order to provide a meaningful response, such as the HCCs mapped from diagnoses on the claims from Medicare FFS data. A commenter argued that the RADV provisions violated the Administrative Procedures Act (APA) due to the disclosure of insufficient

[40] FFS Medicare claims are subject to error correction and payment adjustment when they are based on diagnosis codes not supported by the medical record. *See* Medicare Program Integrity Manual sections 3.3.1.1, 3.3.2.1, 3.6.2.4, 6.5.2, 6.5.3., *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS019033.*

methodology or data to support these policies. Another criticized the extension of the proposed rule comment period beyond 60 days as favoritism by CMS for MAOs as opposed to other stakeholders. Finally, a commenter asserted that the study was not compliant with actuarial professional standards because CMS did not identify a qualified actuary involved in the study and did not release information about how the study or proposed policy complied with the Actuarial Standards of Practice.

Response: Our approach after the release of the proposed rule was to ensure as much transparency as possible so that stakeholders could provide meaningful comment to our proposal not to apply an FFS Adjuster. To this end, we maximized data availability to the public and provided extended time for stakeholders to examine and opine on the data used in the study. As stated previously, since the publication of the FFS Adjuster Study on October 26, 2018, and the 2018 proposed rule on November 1, 2018, we published data and several related notices to further enhance transparency and to encourage robust public comment, including enhanced discussions of the methodology and assumptions used to conduct the study, extensions to the comment period of the proposed rule, and the release of the results of a replicated study. The data and methodology we disclosed should sufficiently allow for stakeholders to evaluate and comment on the study.

Comment: As part of the comments received, MAOs analyzed and assessed our FFS study and the data, assumptions, and methodology it relied on. Many of these comments provided lengthy analysis and critique, and some commenters performed counter-studies. Commenters criticized CMS' recalibration of the CMS–HCC model, the Inflated Post-Audit Risk Score (IPARS) adjustment, and the decision to convert claim-level discrepancy rates to beneficiary-level discrepancy rates.

Response: We appreciate the lengths that commenters went to examine and provide comment on our study, and we agree that any study that relies on assumptions, estimates, and projections has inherent limitations. However, the finalization of our proposal not to apply an FFS Adjuster does not depend on the results of our study. Even if systematic payment error exists, it does not impact the requirement that submitted diagnoses must be adequately supported by medical records. An adjustment factor to account for hypothetical systematic payment differences would not be appropriately applied in the RADV context, even if such systematic differences existed. Additionally, our decision relies on our reading of the coding pattern adjustment statutory provision and its minimum levels.

Further, although we are not relying on the empirical findings of our study as the basis for our decision not to apply an FFS Adjuster, we do not agree with those commenters who claim that our study or their counter-studies provide evidence that FFS errors systematically reduce payments to MAOs.

First, the magnitude of over-coding (diagnosis codes unsupported by medical records) in the Medicare FFS data is much smaller than some commenters have suggested. While some have claimed that the rate is as high as over 30 percent, our study calculated beneficiary-level discrepancy rates for each HCC that were on average only about 3 percent, with a median of 1.8 percent. The beneficiary-level error rate, and not the claim-level error rate, is the appropriate measure of inappropriate coding because an HCC is supported if just one claim in the relevant year for that beneficiary is supported.

Second, the FFS data contains significant under-coding (unreported diagnosis codes that have medical record support), which would likely offset the effects of FFS over-coding, to the extent any such effects exist. Although accurate coding supported by the medical record is required in Medicare FFS, Medicare FFS providers have less of an incentive to report all valid, supported codes because this does not increase their payments as directly as it does for MAOs in Part C. This is supported by the extant literature.[41] Significantly, the commenters' counter-studies purporting to show that Medicare FFS errors systematically reduce payments to MAOs do not adequately address the offsetting effects of Medicare FFS under-coding.

Third, the effects of Medicare FFS over-coding are also offset by the increased costs associated with that over-coding. As noted previously, Medicare FFS claims are subject to error correction and payment adjustment when they are based on diagnosis codes not supported by the medical record. (See Medicare Program Integrity Manual sections 3.3.1.1, 3.3.2.1, 3.6.2.4, 6.5.2, 6.5.3.) Thus, if CMS were to delete the unsupported Medicare FFS codes used to calibrate the risk adjustment model, it would also have to remove certain expenditures associated with those codes that should have been denied for payment. The purpose of the IPARS adjustment was to account for this relationship and the offsetting effects of costs associated with FFS over-coding.[42] The commenters' counter-studies did not adequately address these effects.

Fourth and finally, we note that the counter-studies purporting to prove that an FFS Adjuster in a specific amount is required employed widely differing methodologies and arrived at widely varying estimates for their FFS Adjuster. For example, one commenter claimed that an FFS Adjuster of 9 percent would be appropriate based on the analysis they conducted, while another claimed the appropriate amount would be 33 percent based on their analysis. The fact that these studies can be conducted in various different ways and produce such a wide range of results raises the question whether an FFS Adjuster is even a reasonable or practical means of addressing any risk adjustment coefficients that were too low and any that were too high, and if that was because of any over- and/or under-coding by FFS providers. It also further shows the complexity of the issues in measuring the effects of both under-coding and over-coding in FFS, and the fact that any related study must rely on assumptions, estimates, and projections,

[41] Kronick and Welch found that positive coding intensity in the MA risk scores increased faster than comparable FFS risk scores. Richard Kronick & Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program,* Medicare & Medicaid Research Review, 2014 Vol. 4, No. 2, at E1–E19. *https://www.cms.gov/mmrr/downloads/mmrr2014_004_02_a06.pdf.*

Frogner et al. examined the impact of incomplete FFS coding in the context of the CMS–HCC model and found that it biases payments to MAOs upwards. Bianca K. Frogner, Gerard F. Anderson, Robb A. Cohen & Chad Abrams, *Incorporating New Research Into Medicare Risk Adjustment,* 49 Medical Care 295 (2011). *https://journals.lww.com/lww-medicalcare/Fulltext/2011/03000/Incorporating_New_Research_Into_Medicare_Risk.11.aspx.*

Welch et al. found that regional variation of diagnostic coding in FFS was related to case-fatality. H.G. Welch, S.M. Sharp, D.J. Gottlieb, J.S. Skinner & J.E. Wennberg, *Geographic Variation in Diagnosis Frequency and Risk of Death Among Medicare Beneficiaries,* 305 JAMA 1113 (2011). That is, FFS Medicare enrollees have variable diagnostic coding. *https://jamanetwork.com/journals/jama/fullarticle/646152.*

Finally, MedPAC (1998) demonstrated that the persistence in diagnostic coding for FFS beneficiaries was low from year to year, even for conditions that were serious and permanent, documenting incomplete coding for FFS enrollees. Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, Vol. 1 at 32, Vol. 2 at 15–18 (1998).

[42] We note that applying the IPARS adjustment rather than directly studying this effect empirically is an inherent limitation of our study. As a result, our study's empirical findings are limited to the conclusion that attenuation bias, an effect described in the June 28, 2019 Addendum, does not systematically reduce payments to MAOs.

and will, therefore, have inherent limitations.

Thus, we do not agree with commenters who claim that our study or their counter-studies provide evidence that Medicare FFS errors systematically reduce payments to MAOs. For a complete discussion of the study methodology and all of its conclusions, see the November 1, 2018, proposed rule, the FFS Adjuster Study and Technical Appendix published on October 26, 2018, the study Addendum published June 28, 2019, and the other study documents previously described in this rule.

4. Summary of Final Policies

We are finalizing our proposal to not apply an FFS Adjuster to RADV audits because the ''actuarial equivalence'' and ''same methodology'' provisions do not apply to the obligation of an MAO to report and return improper payments for diagnoses lacking medical record support, including those improper payments identified during a RADV audit. We have also concluded that it would not be reasonable to interpret the Act as requiring a reduction in payments to MAOs by at least a statutorily-set minimum percentage pursuant to the coding pattern adjustment, while at the same time prohibiting CMS from enforcing longstanding documentation requirements by requiring an offset to the recovery amounts calculated for CMS audits.

While the D.C. Circuit's decision in *UnitedHealthcare* pertained to the Part C Overpayment Rule, its reasoning supports our conclusion that an FFS Adjuster is neither required nor appropriate in the context of RADV. ''The role of the actuarial-equivalence provision is to require CMS to model a demographically and medically analogous beneficiary population in traditional Medicare to determine the prospective lump-sum payments to [MAOs].'' (*UnitedHealthcare,* 16 F.4th at 870.) The RADV program, like the Overpayment Rule, applies after the fact to require MAOs to refund any payment to which they are not entitled, based on diagnoses that lack support in the medical record.

In the proposed rule, we also discussed a study that we conducted that concluded that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program. We also stated that, even if systematic error exists, it would be inequitable to correct such errors in the payments made to audited contracts only. Furthermore, in the interest of transparency, CMS publicly released additional data underlying the study cited in the proposed rule related to the FFS Adjuster, provided information on a replication of our original study, and extended the comment period to allow more time for stakeholders to review the data and provide comment.

Despite our discussion of the FFS Adjuster study in the proposed rule and efforts to achieve transparency, we are not relying upon the study to reach our conclusion that an FFS Adjuster is not appropriate in the RADV context. We recognize that any study that aims to demonstrate the impact of potential error in Medicare FFS diagnoses data on MA requires the use of certain assumptions, estimations, and projections, and that any theoretical study has natural limits that must account for those assumptions. However, that does not change our ultimate conclusion that, even if systematic payment error exists, an adjustment factor to account for this error would not be appropriately applied in the RADV context. We also do not intend for this conclusion to suggest that we believe an FFS Adjuster is appropriate or necessary outside of the RADV context.

Our position is consistent with the conclusion of the D.C. Circuit, which is that the actuarial-equivalence requirement is not an ''entitle[ment] . . . to a precise payment amount'' for a Medicare Advantage insurer, but only ''an instruction to the Secretary regarding the design of the risk adjustment model as a whole . . . describ[ing] the type of 'payment amount[s]' that the risk adjustment model should produce''; ''[i]t does not directly govern how CMS evaluates the validity of diagnoses or defines 'overpayment.''' (*UnitedHealthcare,* 16 F.4th at 885–86.)

IV. Collection of Information Requirements

As defined under 5 CFR 1320.3(b) and (c) of the Paperwork Reduction Act of 1995 (PRA's) (44 U.S.C. 3501 *et seq.*) implementing regulations, this final rule does not impose any new or revised ''collection of information'' requirements or related ''burden.'' More specifically, the utilization of extrapolation will not affect the existing process for MAOs submitting medical record documentation pursuant to RADV audits under § 422.310(e). The existing requirements for MAOs submitting medial record documentation are active and approved by OMB under control number 0938–1000 (CMS–10191). As this final rule is not imposing any new or revised ''collection of information'' requirements or related ''burden'', this rule is not subject to the requirements of the PRA.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule clarifies certain program integrity policies in the MA program, specifically, the recovery of improper payments identified during RADV audits, and aligns with the Administration's focus on the fiscal sustainability of the MA program and the interests of Medicare beneficiaries, providers, and MAOs.

The improper payment measurements conducted each year by CMS, which are included in the HHS Agency Financial Report, as well as audits conducted by the HHS–OIG, have demonstrated that the MA program is at high risk of improper payments. In FY 2021 (based on CY 2019 payments), we calculated that the agency made over $15 billion in erroneous overpayments.[43] (The improper payment measurements CMS conducts for all programs include both overpayments and underpayments.) The HHS–OIG has also released several reports over the past few years that also demonstrate a high risk of improper risk adjustment payments in the MA program,[44] and has identified the MA program as one of the top management and performance challenges facing HHS for several years due to the high rate of improper payments.[45] The Medicare program, including MA, has also been identified by the GAO as a high-risk

[43] HHS, FY 2021 HHS Agency Financial Report, *https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf.*

[44] For example, see reports: Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, May 21, 2021, *https://oig.hhs.gov/oas/reports/region7/71901187.asp;* Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS, February 24, 2021, *https://oig.hhs.gov/oas/reports/region2/21801028.asp;* Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contact H3916) Submitted to CMS, September 29, 2022, *https://oig.hhs.gov/oas/reports/region3/31900001.asp;* Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS, July 18, 2022, *https://oig.hhs.gov/oas/reports/region2/22001009.asp;* Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS, February 3, 2022, *https://oig.hhs.gov/oas/reports/region7/71701169.asp;* Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS, April 19, 2021, *https://oig.hhs.gov/oas/reports/region7/71601165.asp.*

[45] See OIG, 2021 Top Management and Performance Challenges Facing HHS, pg. 13, *https://oig.hhs.gov/reports-and-publications/top-challenges/2021/index.asp.*

program due to the risk of substantial improper payments.[46]

RADV audits are CMS' main corrective action for improper overpayments in the MA program made to MAOs when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. The RADV audits confirm the presence of the diagnoses related to the enrollee's HCC profile through the review of certain categories of medical records submitted by the MAOs for the purpose of a RADV audit. Risk adjustment discrepancies are identified when an enrollee's HCCs used for payment (which is, again, based on MAO self-reported data) differ from the HCCs assigned based on the medical record review performed by CMS through the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall amount of payment error for sampled enrollees. In turn, this payment error for the sample of contract enrollees can be extrapolated to calculate a payment error estimate for the universe of enrollees from which the sample is selected, within specified confidence intervals.

The policies in this final rule are essential to having an effective RADV program that protects taxpayer dollars and ensures oversight of the MA program.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Finally, in accordance with the provision of the Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This final rule would not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $165 million in any one year.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year. This final rule affects MAOs with a minimum threshold for small business size of $41.5 million (*see the Small Business Administration's website at http://www.sba.gov/content/small-business-size-standards*). This final rule additionally affects hospitals (NAICS subsector 622) and a variety of provider categories, including physicians and specialists (NAICS subsector 621).

To clarify the flow of payments between these entities and the Federal Government, note that MAOs submit bids (that is, proposed plan designs and projections of the revenue needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June for operation in the following contract year. These bids project payments to hospitals, providers, and staff as well as the cost of administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MAOs that pay providers and other stakeholders for their provision of covered benefits to enrollees in MA plans. Consequently, our analysis will focus on MAOs.

There are various types of Medicare health and drug plans, including MAOs, demonstrations, section 1876 cost plans, Part D prescription drug plans (PDPs), and PACE organizations. There are a variety of ways to assess whether MAOs meet the $41.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and/or projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MAOs fell below the $41.5 million threshold for small businesses. Additionally, an analysis of 2016 data shows that 32 percent of all MAOs fall below the minimum threshold for small businesses.

If a rule potentially has a significant impact on a substantial number of small entities, the rule must discuss steps taken, including alternatives, to minimize the burden on small entities. While some of the entities affected by this rule are not-for-profit organizations and small businesses, the impact is not significant. No changes are made to long-standing audit documentation standards as a result of this rule; therefore, there is no significant impact to small entities (or any entities). MAOs provide medical record documentation to CMS as a normal business practice pursuant to RADV audits. Consequently, the Secretary has certified that this final rule will not have a significant economic impact on a substantial

[46] *https://www.gao.gov/highrisk/medicare-program-improper-payments.*

number of small entities, and we have met the requirements of the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals, and as a result we are not preparing an analysis for section 1102(b) of the Act.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Because this final rule does not impose any substantial costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

C. Regulatory Review Cost

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are approximately 750 MA contracts (of which, 65 MA contracts include PDPs). We assume each entity will have one designated staff member who will review the entire rule. Other assumptions are possible and will be reviewed after the calculations.

Using the 2021 wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed for technical material of 200 words per minute, we estimate that it will take approximately 2 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore, $230.44 (2 hours * $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $172,830 ($230.44 * 750 reviewers).

Note that this analysis assumes one reader per contract. Some alternatives include assuming one reader per parent entity. Using parent organizations instead of contracts would reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this would reduce the total cost of reviewing by a third. However, we believe it is likely that reviewing will be performed at the contract level. The argument for this is that a parent organization might have local reviewers; even if that parent organization has several contracts that might have a reader for each distinct geographic region, to identify effects of provisions specific to that region.

D. Detailed Economic Analysis

This final rule creates regulations to govern the collection of extrapolated audit findings in MA. As we develop our approach to statistical sampling and extrapolation, we are taking account of the recommendations of the 2016 GAO report entitled, ''Fundamental Improvements Needed in CMS' Effort to Recover Substantial Amounts of Improper Payments.'' The GAO recommended that CMS select plans based on the risk for improper payments. Prior to the GAO report, CMS selected stratified random samples of enrollees during RADV audits, including our 2011 to 2013 audits for which we proposed to apply the policies in this rule. However, beginning with the 2014 audit year, CMS began incorporating the potential risk of improper payments to MAOs, based on past audit findings and other factors, into selecting enrollee samples for audits. Accordingly, CMS expects to be more effective in identifying improper payments in future audit years.

To clarify in more detail how the final rule impacts the recovery audit process, we note the following:

- The Part C Improper Payment Measurement audits are conducted annually to measure payment error in the Medicare Part C program. After defining the eligible population, a representative sample of beneficiaries from risk adjustment eligible contracts are selected for medical record review. MAOs submit medical record documentation to substantiate the CMS–HCCs payments sampled by CMS for each year's Part C Improper Payment Measurement. Certified coders code the medical records, and the findings are used to recalculate risk scores for each sampled beneficiary. The difference between the payment risk scores and the recalculated risk scores is termed Risk Adjustment Error. Validation results from the sample are extrapolated to the broader Part C population to produce payment error estimates that meet the PIIA requirements for the payment year. No recoveries are made through these audits.
- Findings from the Part C Improper Payment Measurement and contract-level audits are used to help identify cohorts of beneficiaries for which CMS may be most at risk for making improper payments to MAOs. While CMS has flexibility to decide how to focus audits, CMS intends to focus audits on such MAOs in the future, and has been taking a more focused approach on areas of high risk of improper payments starting with the PY 2014 RADV audits.
- By better targeting contract-level RADV audits based on MAOs' risk of receiving improper payments, CMS expects to have a sentinel effect and reduce the historical Part C improper payment rate over time.

1. Expected Impact of These Provisions

While we cannot fully estimate the quantitative impact of this provision, we can clearly identify certain components of impact. We start with some basic facts:

- With extrapolation applied to audit findings for payment years 2018 and later, we would realize a positive return on investment. The annual cost per year for the contract-level RADV audit program activities, with or without the changes finalized in this rule, is approximately $51 million.
- Extrapolating audit findings does not increase the cost burden on the plan. The cost to the plan of complying with a RADV audit is neither the subject of nor affected by this provision.
- We estimate that findings from audits of MAO contracts for PYs 2011, 2012, and 2013 will identify a total of $683.2 million in extrapolated improper payments. This $683.2 million represents a transfer from the Federal Government to insurers, because it reflects improper payments for human coding error which CMS paid to MAOs. Although we will not exercise our authority to seek extrapolated contract-level recoveries for these payment years, we refer to the $683.2 million in improper payments to estimate future expected recoveries from finalizing this rule.
- 30 contracts per year were audited in PYs 2011 through 2013.
- Approximately 80 percent of the audited contracts in 2011 through 2013 had findings of improper payments.

Using this data, we can conclude as follows:

- $683.2 million divided by 3 audit years is $227.7 million per audit year.
- $227.7 million per audit year divided by 24 contracts (30 contracts multiplied by 0.80) with audit findings

per year is approximately $9.5 million in findings per contract per year.

• As we are adopting GAO recommendations by focusing on contracts at higher risk for improper payments, if the average level of audit findings per contract, at a minimum, holds constant, the $9.5 million per contract with audit findings per year multiplied by 30 contracts with audit findings per year would produce approximately $285 million in improper payment recoveries per audit year.[47]

With extrapolation applied to audit findings beginning with 2018 payment year audits, the expected level of recovery in calendar year 2025 (the year in which we project to initiate improper payment recoveries for PY 2018 audits) would produce $428.4 million in net recovery (that is, $479.4 million minus the annual cost of the RADV program of $51 million). However, we note that while non-extrapolated recoveries would likely result in an average of $8.2 million in estimated improper payment recoveries associated with each audited payment year, the RADV audit program would not achieve positive net recoveries per year without the RADV rule (see Table 2).

• Improper payment recoveries in years 2025 and later increase based on projected rates of growth in MA spending. The 10-year impact of this final rule is estimated in Table 3. Estimating recovery amounts per year is difficult for the following reasons:

• The improper payment rate per year, as indicated in the reports of the CMS Chief Financial Officer, have been declining and are likely to continue to decline due to the impact that these RADV audits have on MAO efforts to reduce the reporting of unsupported HCCs.

• The aggregate amount paid to MAO contracts is increasing due to enrollment growth and other cost inflationary factors. The Office of the Actuary at CMS annually publishes a Trustees Report that contains projected annual MA enrollment in aggregate. All other things being equal, the increase in enrollment will cause nominal dollars in error to increase. The historical decline in the error rate may or may not offset the increase due to increasing enrollment, making a projection difficult.

• We previously indicated that acceptance of GAO recommendations would facilitate auditing contracts with cohorts of enrollees associated with higher degrees of risk for CMS making improper payments, and therefore assume there would be findings in all contract audits.

For the reasons cited previously in this section, we are increasing the annual estimate of recoveries of improper payments to the Medicare Trust Fund at the same rate as the projected growth in MA spending stated in the FY 2023 President's Budget, beginning with $479.4 million for 2025 (when we anticipate beginning to receive extrapolated recoveries). In 2023 and 2024, we estimate receiving approximately $13.1 million and $28.0 million, respectively, in non-extrapolated recoveries from 2011 through 2013 and 2014 and 2015 payment year audits. Accordingly, the result would be negative net recovery amounts of $37.9 million ($13.1 million minus the $51 million annual cost of the RADV audit program) in 2023 and $23 million ($28 million minus $51 million) in 2024.

In total, the estimated recovery amount from 2023 through 2032 is $4.7 billion (see Table 3). This money is a reduction in spending of the Medicare Trust Fund resulting mostly from recoveries (or transfers) from MAOs to the Federal Government; there will be no money transferred to enrollees.

The intent of this rule is to protect taxpayer dollars and ensure oversight of the MA program, in part by reducing the Part C improper payment rate.

2. Alternatives Considered

This rule includes transfers from MAOs to the Federal Government. The aggregate impact of each of these over 10 years is approximately $4.7 billion (see Table 3). Various alternatives to this rulemaking were considered, including the use and timing of extrapolation, as well as the application of an FFS Adjuster. These alternatives are described in this section of this rule.

a. Alternatives Related to the Extrapolation of RADV Findings

As an alternative to our decision to extrapolate our RADV audits beginning in PY 2018, we considered policies whereby we would not extrapolate and would only collect improper payments associated with sampled enrollees as a result of RADV audits. While such a policy would likely be favorably received by MAOs, it would result in a drastic reduction in potential recoveries and dilute the sentinel impact that the RADV program has on reducing the Part C improper payment rate. Specifically, annual net recoveries of improper payments (that is, estimated collections from past audits minus the estimated annual audit program costs) would be reduced from approximately $234 million[48] to negative $42.8 million (see Table 2). Given the overall cost of $51 million per year to administer the RADV program, this would result in a negative return on investment of approximately $6.2:1 (negative $51 million divided by $8.2 million). This would be in direct conflict with our responsibilities under the PIIA to reduce improper payments and fiduciary responsibility to recover improper payment from the Medicare Trust Funds, and therefore, this alternative was not an acceptable alternative to CMS.

We also considered whether to apply extrapolation beginning in PY 2011, as proposed, as well as other payment years after PY 2011. Beginning extrapolation in PY 2011 would result in the collection of approximately $2 billion in improper payments for PYs 2011 to 2017, in contrast to the $41.1 million in improper payments we estimate to collect for these years as a result of this final rule. While we believe that applying extrapolation to RADV findings beginning in PY 2011 (or other payment year after PY 2011) would be a supportable decision and consistent with our mandate to protect taxpayer dollars, we determined that the overall long-term success of the RADV program (and ultimately the MA program) requires us to consider the projected level of effort and likelihood of collecting improper payments along with other practical realities.

As previously described, we believe that beginning extrapolation for PY 2018 RADV audits represents an appropriate policy because it recognizes our fiduciary duty to protect taxpayer dollars from overpayments and preserves our ability to collect on significant (extrapolated) amounts of overpayments made to plans beginning in PY 2018. This final rule will also allow CMS to focus on conducting future RADV audits as soon as practicable after an MAO payment year concludes, which was the topic of significant public comment to the proposed rule. Lastly, we have determined that it is in the best interest of all parties to ensure that the contract-level RADV appeals process, which is also outlined in regulation, is able to

[47] The $285 million amount is a theoretical estimated amount for the audit of PY 2014; however, as we have previously explained, CMS will begin extrapolation with the PY 2018 RADV audits. The $285 million amount is the baseline amount from which CMS begins adjusting estimated improper payment recoveries for inflation beyond PY 2014. Note, if CMS conducts more than one payment year audit annually, savings estimates will be higher in subsequent years.

[48] $234 million in net recoveries is derived by subtracting $51 million (cost of administering the CMS RADV audit program) from the theoretical estimated amount of extrapolated recoveries ($285 million) that would have been collected if extrapolation was applied for the PY 2014 audits.

successfully process all RADV appeals. By not using an extrapolation methodology prior to PY 2018, we expect to better control the total number of active appeals that are submitted in the first few years following finalization of this rule, which will alleviate burden on MAOs and CMS.

b. Alternatives Related to the Application of an FFS Adjuster to RADV Improper Payment Determinations

As an alternative to our decision to not apply an FFS Adjuster to our RADV overpayment determinations, we considered whether to finalize a policy whereby we would apply an FFS Adjuster to RADV overpayment determinations. While we contemplated adoption of an FFS Adjuster as part of our 2012 Methodology, we believe that finalizing such an approach through regulatory or other means would be an unsupportable and unreasonable interpretation of the Act.

As previously described, we have determined that the ''actuarial equivalence'' and ''same methodology'' provisions do not apply to the obligation of an MAO to report and return overpayments that they have identified, including overpayments due to lack of medical record support for diagnoses, or their obligation to return overpayments identified based on a RADV audit. In *UnitedHealthcare,* the D.C. Circuit held that actuarial equivalence and same methodology do not apply to the MAOs' obligation to report and return overpayments that they have identified, including overpayments arising from the MAOs' submission of and payments based on diagnoses unsupported by their beneficiaries' medical records. Although *UnitedHealthcare* addressed the enforceability of the Part C overpayment regulation, its reasoning applies just as strongly in the RADV context and supports our conclusion that the use of an FFS Adjuster is neither required nor appropriate for an RADV audit.

We have also concluded that it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits). To the contrary, because the Act requires CMS to reduce payments to MAOs by at least a specific minimum percentage, the only reasonable interpretation of the Act is that CMS would pay MAOs at those reduced rates, under the existing payment model,[49] and enforce the longstanding documentation requirements through CMS' audits.

TABLE 2—EXPECTED NET RECOVERIES OF CMS RADV IMPROPER PAYMENTS PER YEAR WITHOUT EXTRAPOLATION

Label	Item	Amount ($ in millions)—non-extrapolated	Source or calculation
(A)	Estimated Non-Extrapolated Collections for 2011–2015 audits.	$41.1	
(B)	Number of years, 2011–2015	5	
(C)	Estimated Average Non-Extrapolated Collections per year.	$8.2	(C) = (A)/(B).
(D)	RADV audit programs costs per year	$51	Estimated costs of RADV program in which statistically valid samples are pulled to audit sub-cohorts of enrollees for a minimum of 30 contracts per year.
(E)	Estimated net recoveries of improper payments per year without extrapolation.	($42.8)	(E) = (C) − (D).

TABLE 3—IMPACT ON ESTIMATED COLLECTIONS OF IMPROPER PAYMENTS PER YEAR FROM RADV RULE

[$ in millions]

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total
Estimated Non-Extrapolated Collections Assumed Without RADV Final Rule Changes	13.1	28.0	11.6	10.9	12.7	13.5	14.4	15.4	16.4	17.5	153.5
Estimated Collections from Audits Completed in Prior Years With RADV Final Rule Changes	13.1	28.0	479.4	447.5	522.6	557.2	594.0	633.2	675.0	719.5	4,669.5
Additional Estimated Collections as a Result of RADV Final Rule	0.0	0.0	467.8	436.6	509.9	543.7	579.6	617.8	658.6	702.0	4,516.0

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), Table 4 shows the costs and transfers associated with the provisions of this final rule for calendar years 2022 through 2031.

[49] Any changes to the CMS–HCC payment model are published in the annual payment notice.

TABLE 4—ACCOUNTING STATEMENT—CLASSIFICATION OF ESTIMATED TRANSFERS

Category	Discount rate		Period covered
	7%	3%	
Transfers:			
Annualized Monetized Transfers ($ in Millions)	$410	$433	CYs 2023–2032.
From Whom to Whom	MAOs to Federal Government.		

We estimate that from 2022 through 2031 this final rule will generate Federal annualized monetized transfers of $410 million and $433 million, at the 7 percent and 3 percent discount rates respectively, from MAOs back to the Medicare Trust Fund.

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on January 24, 2023.

List of Subjects in 42 CFR Part 422

Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy Reporting and record keeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 422 as follows:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

Subpart G—PAYMENTS TO MEDICARE ADVANTAGE ORGANIZATIONS

■ 2. Section 422.300 is revised to read as follows:

§ 422.300 Basis and scope.

This subpart is based on sections 1106, 1128J(d), 1852, 1853, 1854, and 1858 of the Act. It sets forth the requirements for making payments to MA organizations offering local and regional MA policies, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, collection of improper payments and other payment rules. Section 422.458 specifies the requirements for risk sharing payments to MA regional organizations.

■ 3. Section 422.310 is amended by revising paragraph (e) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners are required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings for payment year 2018 and subsequent payment years.

* * * * *

■ 4. Section 422.311 is amended by revising paragraph (a) to read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

* * * * *

Dated: January 26, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–01942 Filed 1–30–23; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 230126–0026]

RIN 0648–BL75

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Amendment 23 to the Mackerel, Squid, and Butterfish Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This action implements approved measures for Amendment 23 to the Mackerel, Squid, and Butterfish Fishery Management Plan. Amendment 23 was developed by the Mid-Atlantic Fishery Management Council to establish a revised Atlantic mackerel rebuilding plan, set the 2023 Atlantic mackerel specifications including a river herring and shad catch cap for the Atlantic mackerel fishery, establish a recreational possession limit, and modify in-season closure measures. This action is necessary to prevent overfishing and rebuild the Atlantic mackerel stock based on a 2021 management track assessment that found that Atlantic mackerel stock remains overfished and overfishing is occurring. Amendment 23 is intended to ensure that Atlantic mackerel are sustainably managed to achieve optimum yield on a continuing basis. Additionally, this action approves the updated management goals and objectives of the Mackerel, Squid, and Butterfish Fishery Management Plan with the purpose of ensuring that management continues to reflect and address the current needs and condition of the mackerel, squid, and butterfish fisheries.

DATES: Effective February 1, 2023.

December 20, 2010

Medicare Advantage Risk Adjustment Data Validation (RADV)
Notice of Payment Error Calculation Methodology for Part C Organizations
Selected for Contract-Level RADV Audits
Request for Comment

Introduction

Section 1853(a)(3) of the Social Security Act requires that the Centers for Medicare & Medicaid Services (CMS) risk adjust payments to Medicare Advantage (MA) organizations. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, Ninth Revision Clinical Modification guidelines (ICD-9-CM) to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes are used to determine beneficiary risk scores, which in turn determine the risk adjusted reimbursement. MA enrollee risk scores are based on risk adjustment diagnoses that were present on Medicare Fee for Service (FFS) claims and/or submitted to CMS by MA organizations.

CMS annually selects MA organizations for RADV audits. Contract-specific MA organization RADV audits measure individual MA organization-level payment error-rates related to risk adjustment data for payment recovery. RADV audits confirm the presence of risk adjustment conditions based on supporting medical record documentation. As stated in the preamble of the new regulation on Risk Adjustment Data Validation –Dispute and Appeal Procedures at 42 CFR 422.311, CMS intends to provide an annual notice of the RADV payment error calculation methodology with the opportunity for MA organizations to comment on the methodology. This paper describes the sampling and error calculation methodology that CMS utilizes when conducting RADV audits. This sampling and error calculation methodology is used to calculate a payment error estimate and payment recovery amount for each MA contract selected for an audit.

Sampling

Once an MA contract has been selected for a RADV audit, CMS applies criteria for selecting the MA contract's enrollees.

Enrollee Selection

Enrollees are sampled from each selected MA contract for the purpose of estimating payment error related to risk adjustment. The enrollee sample for a RADV contract-level audit will be selected from the cohort of eligible Medicare beneficiaries who were enrolled in the contract (H-number, E-number, or R-number) in January of the payment year— based on monthly member enrollment files. The enrollees who are eligible for RADV sampling are those who were also:

1. Continuously enrolled in the same MA contract for all 12 months of the data collection year;
2. Non-End Stage Renal Disease (non-ESRD) status in or prior to the payment year;

3. Non-hospice between January of the data collection year and January of the payment year, and had less than 12 months of hospice during the payment year;

4. In Medicare Part B coverage for all twelve months during the data collection period (i.e., defined as full risk enrollees for risk adjusted payment); and had

5. At least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection period that led to at least one CMS-HCC assignment. These HCCs were present for risk adjusted payments, based on plan-submitted risk adjustment data, and are referred to as the validation HCCs for the sampled enrollees.

CMS will select up to 201 enrollees for medical record review from each contract selected for an audit.

Sample Stratification

Enrollee-based stratification will be used in the process of sampling enrollees. In order to derive the strata, the eligible enrollees, in each contract, will be ranked from lowest to highest based on their community risk score. The enrollees will then be divided into three equal groups based on the total number of eligible enrollees, where the first group will include the third of enrollees with the highest risk scores and the third group will include the third of enrollees with the lowest risk scores. The remaining enrollees will be in the middle stratum. In the case of 201 sampled enrollees, sixty-seven (67) enrollees will be randomly sampled from each group or stratum. The corresponding stratum-based enrollee weights will be computed as the number of RADV-eligible enrollees in the population grouping (or stratum) divided by the number of enrollees selected from that grouping for the sample (or N_h / n_h), where *h* represents the corresponding stratum. For example, if a contract has 3,000 enrollees, the enrollees would be ranked by risk score, then divided into three equal groups of 1,000 enrollees each (to represent high, medium, and low strata). An equal number of enrollees will be selected from each group. The weight for each enrollee will equal 14.925 (i.e., 1,000/67). The enrollee sampling weights will be used as multipliers to scale-up (or extrapolate) the sample payment error findings to the population which it represents.

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Payment Error Calculation

Enrollee-level Payment Error Calculation

The risk scores for each sampled enrollee will be corrected based on the HCCs that are supported by RADV medical record review findings for the enrollee. The RADV (or corrected) risk scores and payments will be calculated for each sampled enrollee. Enrollee-level payment errors will be defined as the difference between the original payment and the corrected payment (i.e., payment error = (original payment minus corrected payment)). The payment error for each enrollee will be either positive-- representing a net overpayment, or negative-- representing a net underpayment. A payment error will be calculated for each sampled enrollee based on the number of months the person was enrolled in the MA selected contract (and was not ESRD or hospice) during the payment year.

Payment Error Extrapolation Calculation

To derive the estimated payment error for each MA contract, the total payment error for each sampled enrollee will be multiplied by the enrollee's sampling weight (computed during the sampling phase as N_h/n_h for each stratum). The weighted enrollee payment errors will be summed across all enrollees in the sample to determine an estimated payment error for the MA contract. The payment recovery amount for each audited MA contract will be determined by the lower bound of the 99% confidence interval around the payment error estimate. The following is an example formula for computing a 99% confidence interval around the payment error estimate for one contract, assuming a sampling method containing three enrollee strata groupings.

The 99% confidence interval lower bound is computed as the estimated payment error (PE) minus (2.575 multiplied by the standard error) or (PE – (2.575 * SE)), whereby the standard error can be reproduced as follows:

1. Derive the variance, v_h, (standard deviation squared) of the unweighted enrollee payment errors across the sample enrollees within each of the three strata (*h*).

2. Calculate the variance of the estimated total (V_T), where N represents the number of enrollees in the RADV-eligible population of the h^{th} (1^{st}, 2^{nd}, 3^{rd}) stratum:

$$v_{\hat{T}} = \sum_{h=1}^{3} \frac{N_h^2}{67} v_h$$

3. The standard error is $se_{\hat{T}} = \sqrt{v_{\hat{T}}}$

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Request for Comment

CMS is pleased to invite public comment on this document. CMS will review all timely comments and may revise or modify the RADV sampling and payment error calculation methodology based on the comments received. Once all comments have been reviewed and considered, CMS will post a final version of the RADV sampling and payment error calculation methodology at https://www.cms.gov/HealthPlansGenInfo/.

Comments must be submitted in writing by Friday, January 21, 2011 to the following email address:

RADV@cms.hhs.gov

Please specify "Comment on RADV sampling and error calculation methodology" in the subject line of your email.

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
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202.778.3200
www.ahip.org



January 21, 2011

Cheri Rice
Acting Director, Medicare Plan Payment Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Rice:

I am writing on behalf of America's Health Insurance Plans (AHIP) in response to the "Invitation to Comment on Risk Adjustment Data Validation (RADV) Sampling and Payment Error-Calculation Methodology" issued by the Centers for Medicare & Medicaid Services (CMS) on December 22, 2010. AHIP is the national association representing 1,300 member companies providing health coverage to more than 200 million Americans. The methodology will have a direct impact on AHIP's member organizations many of which participate in the Medicare Advantage (MA) program.

The RADV audits currently underway address the Medicare Advantage (MA) program's CY 2007 payment year and are the first conducted under CMS' new audit approach. AHIP' member organizations have demonstrated a longstanding commitment to participation in the MA program and believe that the risk adjustment mechanism is an important feature of the MA payment methodology. We share CMS' interest in ensuring that risk adjusted payments are made accurately and understand CMS' responsibility for validating data submitted by MA organizations that are used for payment. However, we have serious concerns that the audit approach that is currently under development will not achieve the goal of ensuring payment accuracy.

Key shortcomings of CMS' approach include the agency's proposed use of the audit findings to determine payment adjustments based upon a calculation that is fundamentally inconsistent with the MA payment methodology. Further, CMS is applying the new audit design retroactively so that MA organizations have no opportunity to take this materially different approach into consideration in their bidding and compliance activities. In addition, the audit design focuses narrowly on how well medical records reflect documented diagnoses used for risk adjustment and ignores other information that would validate the enrollees' medical condition. As a result of these and other problematic aspects of the audit design, CMS' methodology would inappropriately penalize MA organizations and in doing so, destabilize the program for the beneficiaries who have chosen to enroll in MA plans potentially resulting in erosion of benefits, increases in premiums, and/or reduced plan choices. In our detailed comments below, we

discuss first critical issues and recommendations raised by CMS' proposed payment error calculation methodology, followed by important closely related issues and recommendations concerning the RADV audit design.

We believe it is particularly important to maintain the viability of the MA program through oversight that is both rigorous and fair, because MA organizations can play a key role in advancing national health care priorities. CMS is already actively engaged in activities that are designed to encourage formation of health care delivery systems that span the continuum of sites of care and offer coverage of comprehensive, coordinated, efficient health care services. These characteristics have long been hallmarks of health plans in both the public and private sectors. Accordingly, as CMS moves forward with establishment of the audit approach that has been initiated through CY 2007 RADV pilot audits and RADV targeted audits, we appreciate the opportunity to comment on the agency's proposed RADV sampling and payment error calculation that will be a key element of the audits, but also would like to offer our comments on the audit design as a whole. We believe that changes to the agency's approach are critical to establishing standards for MA organization accountability that are focused on maintaining the accuracy of the risk adjusted payment methodology.

We also believe it is critical that CMS make a full description of the RADV audit process available to all MA organizations, including those that have not yet been subject to audits under the new methodology and therefore have not been provided with a description of the audit design and have no experience with the audit process. We are also concerned that the lack of a comprehensive narrative description of the audit process has made it difficult for organizations undergoing CY 2007 RADV audits to ensure that they fully understand the audit process. To ensure transparency and promote uniform understanding of CMS' RADV audit process, we recommend that prior to selection of additional organizations for RADV audits, CMS issue detailed, comprehensive guidance describing the RADV audit design and payment error calculation methodology.

Further, because of the high level of interest and concern associated with CMS' RADV audit initiative, we believe it is critically important that when the agency issues the final version of the "Payment Error Calculation Methodology for Part C Organizations", CMS include the agency's response to the comments it has received. We believe that this proposed methodology is no less significant to MA organizations and the MA program than the annual Advance Notice of changes to the MA and Part D payment methodologies, and we note that CMS responds to comments on that notice each year in the final MA and Part D rate notice.

AHIP COMMENTS

CMS PROPOSED RADV PAYMENT ERROR CALCULATION

Sampling

Stratification

The CMS draft states that eligible enrollees enrolled under each audited contract will be divided into three equal strata and CMS will select up to 201 enrollees by randomly selecting an equal number from each stratum. The draft does not explain what method will be used to carry out the random selection (e.g., a random number generator). We recommend that CMS include this information in the final version of the document.

Payment Error Calculation

Enrollee-level Payment Error Calculation

The CMS draft states that, "The risk scores for each sampled enrollee will be corrected based on the HCCs that are supported by RADV medical record review findings for the enrollee." Under the CMS RADV audit process, we understand that MA organizations must select the "one best medical record" to support the diagnosis for each CMS-HCC being validated for enrollees in the audit sample. We have serious concerns that CMS consideration only of "one best medical record" provides an incomplete evaluation of the extent to which diagnoses for enrollees may be both over-reported and under-reported. This would produce an inaccurate net enrollee-level payment error determination and through extrapolation to the contract level, could lead to an inaccurate payment adjustment for the MA organization.

More specifically, our understanding of the CMS review process for the "one best medical record" is that the agency's contractors not only evaluate whether the record substantiates reported diagnoses but in the course of the review, may identify substantiated but previously unreported diagnoses. We believe that the CMS enrollee-level payment error determination reflects the net result of these findings and recommend that CMS explicitly confirm in the final document that this is the agency's practice. While we support use of a "net" determination, we believe that basing it on a partial picture of the enrollee's medical condition would lead to an inaccurate audit result that would compromise payment accuracy rather than promoting it.

Accordingly, we recommend that the audit design be revised to allow MA organizations to submit any medical records that could substantiate diagnoses for an enrollee in the audit sample.

Such an approach would provide a more complete basis for the enrollee-level payment error determination and contribute to a more accurate audit result. It would also be consistent with the principal goal of MA risk adjustment, which is to make MA payments more responsive to the mix of conditions that plan enrollees are expected to experience and to ensure that payments to MA organizations are adjusted fairly and accurately based on the demographics and risk status of their enrollees. Achieving this balance is essential to permit MA organizations to continue efforts to offer benefits that their enrollees value and to keep the cost of the benefits within their reach. We note that we understand CMS may be utilizing specific rules for determining when an additional diagnosis identified during the coding review can be taken into account under the RADV audits and recommend that CMS provide a narrative description of the agency's policy. To the extent that this policy may be inconsistent with our recommendation, we urge CMS to modify it as needed.

Payment Error Extrapolation Calculation

Payment Accuracy

As also discussed in our general comments below, we strongly urge CMS to incorporate an adjustment into the Payment Error Extrapolation Calculation that reflects the results of a RADV audit-comparable study to identify the underlying error in the Medicare fee-for-service (FFS) data used to calibrate the MA risk adjustment model. Due to the impact of this inherent error on the coefficients in the model, any payment adjustments that are not net of the value of this error would result in inaccurate payment to MA organizations compared to that called for under the MA risk adjusted payment methodology. In other words, the degree of error reflected in the MA risk adjustment methodology itself must also be reflected in any payment adjustment calculation in order to reach an accurate contract level payment amount.

Ensuring that these calculations are parallel is essential to maintaining the equivalence of the risk adjustment model required under actuarial Section 1853(a)(1)(C)(i) of the MA statute which states that

> The Secretary shall adjust the payment amount…for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3) so as to ensure actuarial equivalence.

It is also important to note that in discussing implementation of the coding intensity adjustment in the CY 2010 final MA rate announcement issued on April 6, 2009, CMS stated that



> Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustment to be valid. This means that MA organizations are coding 'accurately' when they are coding in a manner similar to fee-for-service coding used on beneficiaries to whom MA plan enrollees are being compared. [page 20]

The principle that "MA plans must code the same as Medicare Part A and Part B providers in order for risk adjustment to be accurate" is directly relevant to the RADV audit initiative as well as to the coding intensity adjustment.

To illustrate the impact on the accuracy of extrapolated RADV audit results of the Medicare FFS error, we offer the following simplified example:

+ Under the CMS-HCC model, diagnoses used in the model are sorted into groups based upon the similarity in Medicare fee-for-service costs of treating beneficiaries with each condition.

+ Factors are assigned to each HCC based upon the average costs for treating beneficiaries with the diagnoses in the category. If some diagnoses are miscoded in the medical records for beneficiaries in the Medicare FFS program, so that diagnoses appear to be more severe, the average costs for the diagnoses in the HCC would be lower than if all diagnoses were accurate and the risk factor for the HCC would also be lower.

+ If diagnoses reported by an MA organization contain the same degree of error that is reflected in the Medicare FFS data used to construct the MA risk adjustment model, the MA organization would receive the payment intended under the model. The MA organization would be paid accurately because the errors offset one another.

+ In contrast, if the MA organization reports diagnoses that have a lower degree of error than the Medicare FFS data used to calibrate the risk adjustment model, the payment calculation under the model would underpay the MA organization.

The implications of these interactions for the RADV audit payment error calculation would be:

+ If the error calculation for MA organizations is net of the Medicare FFS error inherent in the MA risk adjusted payments, the RADV audit payment adjustment to MA payments

would be in balance with the way payments to the organization are calculated under the payment methodology.

+ If the RADV error for MA organizations is determined without regard to the underlying Medicare FFS error in the payment methodology, applying a RADV audit payment adjustment would result in inaccurate payment to the MA organization that is not aligned with the MA payment methodology. In this case the MA organization could be inappropriately penalized.

As noted in our introductory comments, the impact of CMS' decision regarding the RADV payment error calculation on the viability of MA program participation is extremely serious. Stability in the rules for program participation is critically important because MA organizations accept full risk for covering all medical and administrative costs for serving their enrollees. They rely on the rules CMS establishes prior to bidding to estimate their costs and revenue needs and determine the benefits they will be able to offer to their enrollees. We have recently expressed a similar concern about CMS issuance of additional CY 2010 bidding requirements and criteria after the bid submission deadline.

The implications of the uncertainty surrounding the RADV audit methodology for MA organization bidding and therefore, for MA enrollees are grave. CMS has already established a precedent for alerting MA organizations to rules for evaluation of plan bids after the bid submission deadline. If, in addition, the agency adopts a RADV audit approach that signals the agency's willingness to alter materially the payment rules for prior years MA organizations will need to consider this risk in their bidding strategies, particularly at a time when the phase-in of the ACA changes to the MA payment methodology are expected over time to create significant challenges to sustain benefits valued by beneficiaries and program growth.

If the agency decides to continue CMS' plan to implement retroactively extrapolation of sample results to the contract level, we strongly urge CMS to incorporate a Medicare FFS adjustment into the RADV audit methodology and, apply a transition strategy until MA organizations can take action in response to the new audit approach.

Payment Error Extrapolation Calculation Formula

CMS is proposing that the "payment recovery amount" for each audited MA contract will be determined by the lower bound of the 99% confidence interval around the payment error estimate. While we continue to have serious concerns about CMS' use of extrapolation to derive an estimated payment error for impacted MA contracts, if the agency continues to use such an



approach, we support CMS' proposed use of the lower bound of the 99% confidence interval in this calculation.

The draft states that "The weighted enrollee payment errors will be summed across all enrollees in the sample to determine an estimate payment error for the MA contract." It is our understanding this means that for the purpose of extrapolation, the relevant population would be the eligible enrollees who are included in the population from which the audit sample was drawn. We request confirmation and recommend that CMS state the agency's intent with greater clarity in the final document.

In addition, we believe that the mathematical formula included in the CMS draft for computing the 99% confidence interval around the payment error estimate is unclear. For example, in step 1. of the calculation to reproduce the standard error, it is not clear whether the variance for each stratum is to be calculated using the sample variance formula or the population variance formula. However, it appears that the sample variance calculation would be more appropriate and that use of this formula is CMS' intent. We request confirmation that this understanding is correct. Further, to promote uniform interpretation of the formula by MA organizations and a consistent understanding of the proposed payment error extrapolation methodology, we recommend that when the final methodology is issued, CMS provide a detailed narrative that explains all terms in the formula for the Payment Error Extrapolation Calculation.

CRITICAL FEATURES OF RADV AUDIT DESIGN

As noted above in our introductory comments, we believe that key features of CMS audit design raise issues and concerns that are directly relevant to our comments regarding the payment error calculation methodology. These issues and our related recommendations are discussed below.

- **Determination of a Medicare FFS diagnosis error rate using an approach comparable to RADV audits of MA organizations.** As our comments above indicate, under the new CMS RADV audit approach, the relationship between coding error and payment error is more complex than a simple attribution of every medical record documentation discrepancy to a level of payment error. Unlike the previous CMS risk adjustment data review methodology that resulted in net payment adjustments for payments for each enrollee for whom data discrepancies were identified, the new approach under which audit results for a sample of records would be extrapolated to the contract level raises significant issues regarding how payment accuracy should be defined and payment adjustment methodologies should be designed. One complicating factor is the Medicare FFS data error that is inherent in the calibration of the MA risk adjustment

model. We have recommended that if CMS moves forward to use extrapolation to determine contract-level payment adjustments, a RADV audit-comparable study to determine a Medicare FFS error rate is essential. Since this study is critical to the utility and fairness of the resulting Medicare FFS error rate, we strongly recommend that CMS provide detailed information to MA organizations about the design of the study, including the methodology for evaluating the validity of the resulting Medicare FFS data error rate and ensure that the FFS adjustment methodology is transparent to MA organizations. In light of the importance of this element of the audit design, we would be interested in engaging in detailed discussions with CMS to contribute insights and expertise that could assist CMS in pursuing this initiative.

- **Retroactive changes to contract-level payments as a result of RADV audits are inconsistent with applicable bidding rules unless the adjustment methodology is issued prior to bid submission.** Applying a retroactive contract-level payment adjustment after CMS acceptance of MA organization bids alters the actuarial equivalence required of estimated risk adjusted payments and the actuarial bases underlying the estimated revenue needs under the bids. This is because key components of MA organizations' bids (including benefits and premiums) are affected by these projections, which are necessarily based upon what is known at the time of bid submission. A retrospective contract-level payment adjustment would materially alter the basis for prior year bids by introducing potential liability under a materially different audit and payment adjustment approach that could not have been accounted for in the bid assumptions. In addition to the implications for the CY 2007 payment year that is the subject of the current round of RADV audits, the retroactivity of the audit and adjustment policy raises the same concerns for CY 2008, CY 2009, and even CY 2010 since the details of the RADV audit methodology were not available prior to bid submission. We also note that starting with the CY 2009 payment year, CMS applied a coding intensity adjustment to MA organization risk scores to account for differences in coding patterns between MA and Medicare FFS. Accordingly, we recommend that CMS ensure that for the CY 2009 payment year and beyond, there will be no duplication in payment adjustments for MA organizations resulting from the RADV audit initiative and the application of the coding intensity adjustment.

  For these reasons, a critical principal underlying the integrity of the MA prospective payment and bidding system is that program rules for any year will be established in advance so that the impact on expected revenue and costs can be taken into consideration during the bid development process. Consistent with this principle, CMS has generally announced significant changes to program rules prior to bid submission (except during the CY 2011 bidding process an noted earlier), either through the Call Letter and/or in

separate, more detailed guidance. We recommend that CMS establish a transition strategy for implementation of the RADV audit and payment adjustment process until the anticipated impact of the audits can be taken into consideration in MA organization bids and the impact of efforts to improve performance in response to the audit and adjustment policy can begin to take effect.

This recommendation is further supported by the Department of Health and Human Services annual *Improper Payments Information Act (IPIA) Report*. FY 2009 was the baseline year for reporting the Part C error rate because the CY 2007 payment year, which was the basis for the error rate, was the first year of fully risk adjusted MA payments. The Department stated, "Program experience indicates that documentation will improve over time." This observation is consistent with the explanation included in the Office of Management and Budget's FY 2008 report on improper payments which pointed out that documentation under the Medicare fee-for-service program improved in the course of several years of reporting under the IPIA. It is also consistent with the FY 2010 HHS IPIA report, which reported a reduction in the Part C error rate from the 2007 to the 2008 payment year. As discussed below, we support CMS' ongoing efforts to bring about improvements to practitioner coding and medical record documentation for Medicare fee-for-service claims and believe it is essential for CMS and MA organizations to work together to promote improvements that can impact data reporting under the MA program.

- **Reliance on imperfect practitioner diagnosis coding and medical record documentation practices to validate risk adjustment data, which is derived primarily from claims and encounters, necessitates implementation of a Medicare-wide effort to improve these practices.** CMS requires that MA organizations submit risk adjustment data based upon diagnoses reported by physicians and certain other practitioners. The volume of diagnoses makes it impractical for MA organizations to review medical record documentation prior to submission of each diagnosis so that complying with the data submission requirement can only be achieved through reliance on claims and encounter data. This is also the case for the Medicare fee-for-service claims data used for calibration under the MA risk adjustment model.

  MA organizations are responsible for employing strategies to identify inappropriate practices and promote data accuracy and are committed to pursuing these activities. However, it is also critical for CMS to take steps to implement a coordinated strategy to improve all risk adjustment-related diagnostic data and to perform a study of Medicare fee-for-service data quality as it relates to MA risk adjustment requirements. CMS has instructed MA organizations to provide training for their contracted physicians, and many

MA organizations have implemented a variety of outreach and training strategies to improve these data. MA organizations have also instituted independent auditing and monitoring programs to help identify data quality issues and assist with targeted interventions. Despite these efforts, the size of the patient panel attributable to any single MA organization is typically far more limited than the number of patients served under the Medicare fee-for-service program, and MA organizations frequently are not able to exercise sufficient influence to change provider behavior on a scale that would meet the requirements of RADV.

We are interested in working with CMS to implement additional strategies to improve physician medical record documentation practices. As part of this effort, we recommend that CMS conduct vigorous outreach and training initiatives to supplement MA efforts and influence both the quality of data submitted under the Medicare fee-for-service program and data submitted by MA organizations. These efforts should be coupled with data analysis to determine rates of inaccuracies and studies of Medicare fee-for-service records to monitor improvements in Medicare fee-for-service practitioner coding and documentation that will be relevant to both the Medicare fee-for-service and MA programs.

Over time, CMS guidance has focused principally on the criteria for medical record documentation rather than practical issues related to data quality. We recognize the importance of MA organization accountability and are interested in working with the agency to identify problem areas as well as challenges and strategies for addressing them. In addition, we urge CMS to disseminate best practices for MA organizations and engage in intensive practitioner outreach and education about the importance of accurate coding and sound medical record documentation practices to satisfy requirements under the both Medicare fee-for-service and MA programs.

- **Audit requirements for documentation of diagnoses should not be limited to medical records within the data collection year, but to validate most accurately the presence of reported conditions, should include physician attestations and specified alternate sources.** CMS has required that diagnoses for MA risk adjustment can be validated only through medical record review. However, the challenges of ensuring accurate physician coding practices are well-known to CMS under the Medicare fee-for-service program. This is the case despite the agency's greater opportunities to influence physician practices, as discussed above, in contrast to MA organizations that in general provide reimbursement for a far smaller volume of services for each physician or practitioner. In light of these factors and since the purpose of risk adjustment data validation is to ensure that the enrollee has the medical condition at issue, we recommend that CMS revise the

audit criteria to permit diagnoses to be validated by alternate reliable sources of data under certain circumstances, such as the following.

+ ***Expand the circumstances for which physician attestation are permissible.*** We support CMS' decision to permit physician attestations to cure instances in which the medical record does not contain a legible physician signature or is not dated. We believe that CMS should also accept attestations when medical record coding is determined to be insufficient to support the submitted diagnosis. While physician coding may be deficient, an enrollee may nevertheless have the condition reported so that risk adjusted payment was appropriate under the payment methodology. In such circumstances, a payment adjustment resulting from the discrepancy would be unwarranted and to promote payment accuracy, which is the goal of the audit process, we recommend that the MA organization be permitted to seek an attestation from the physician to validate the diagnosis.

+ ***Permit substantiation of chronic conditions through alternate sources.*** In instances where a medical record is not available to validate the diagnosis of a chronic condition, the medical record documentation during the data collection year should not be sole source of permissible documentation. We recommend that CMS allow MA organizations to provide documentation from alternate sources such as a prior year medical record, information obtained through disease management programs, prescription drug data or a combination of these and other sources of information. We note that this recommendation is in addition to our comment above recommending that CMS permit MA organizations to submit multiple medical records rather than "one best medical record" to document fully the medical condition of enrollees in the audit sample.

+ ***Address situations in which medical records are unavailable.*** We also recommend that CMS provide a mechanism to ensure that MA organizations are not inappropriately disadvantaged in the event that it is not possible for the MA organization to obtain the medical records necessary to document or best document an HCC that CMS has identified for validation. Since the 2006 data year, a variety of events outside of an MA organization's control may have occurred that preclude access to a particular medical record. These circumstances include the death or retirement of a physician, natural disasters, or events such as fires in which medical records are destroyed. One approach to address this issue would be to utilize an oversampling approach so that an enrollee could be removed from the sample if a medical record is unavailable and another enrollee could be substituted to maintain the necessary sample size.

We have appreciated the opportunity to comment. Please contact me if additional information would be helpful or if you have questions about the issues we have raised. I can be reached at (202) 778-3209 or cschaller@ahip.org.

Sincerely,



Candace Schaller
Senior Vice President, Federal Programs

February 24, 2012

Notice of Final Payment Error Calculation Methodology for
Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits

Introduction

On December 21, 2010 the Centers for Medicare and Medicaid Services (CMS) posted on its website the "Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for RADV Audit – Request for Comment". CMS invited public comment on the proposed methodology, with such comments to be submitted in writing by Friday, January 21, 2011.

CMS carefully reviewed the more than 500 comments received on the draft methodology. This Notice responds to the analytic concerns raised relating to extrapolation and payment recovery and presents the final methodology for the RADV payment error calculation.

Following the background section, this Notice provides a general walkthrough of the RADV payment error calculation methodology in two sections: (A) sampling; and (B) payment error calculation.

This methodology will be applied to the next round of RADV contract-level audits, which will be conducted on payment year 2011. Payment year 2011 is the first year for which payment recovery based on extrapolated estimates will be conducted for Medicare Advantage (MA). Note that sampling for RADV audits will occur after the close of final reconciliation for the payment year being audited.

CMS' RADV audit initiative is the Agency's primary strategy to address the national payment error rate for the MA program, which is currently estimated to be 11 percent for FY 2011. In addition to recovery of overpayments through RADV audits, CMS also expects that these contract-level audits will have a sentinel effect on the quality of risk adjustment data submitted for payment by MA organizations.

Background

Section 1853(a)(3) of the Social Security Act requires that CMS risk adjust payments to Medicare Advantage (MA) organizations. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, Ninth Revision Clinical Modification guidelines (ICD-9-CM), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes submitted by MA organizations are used to determine beneficiary risk scores, which in turn determine the risk-adjusted reimbursement.

RADV audits determine whether the diagnosis codes submitted by MA organizations can be validated by supporting medical record documentation. This medical record documentation must meet certain criteria and standards specified in RADV materials that CMS provides to audited contracts. Diagnoses that cannot be validated contribute to a payment error rate. This document describes the sampling

methodology that CMS will use for RADV audits and the methodology for calculating the payment error for each audited Medicare Advantage contract.

A. Sampling

To conduct these audits, CMS selects a set of MA contracts for each RADV audit cycle. Enrollees are sampled from each selected MA contract for the purpose of estimating payment error related to risk adjustment.

Sampling Frame

First, CMS identifies all beneficiaries under each MA contract who are "RADV-eligible" because they meet the following criteria:

1. Enrolled in an MA contract (H-number, E-number, or R-number) in January of the payment year— based on CMS' monthly member enrollment files;
2. Continuously enrolled in the same MA contract (as identified in step (1) above) from January of the data collection year through January of the payment year;
3. Non-End Stage Renal Disease (non-ESRD) status from January of the data collection year through January of the payment year;
4. Non-hospice status from January of the data collection year through January of the payment year;
5. Enrolled in Medicare Part B coverage for all 12 months during the data collection year (i.e., defined as full risk enrollees for risk adjusted payment); and
6. Had at least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection year that led to at least one CMS-Hierarchical Condition Category (HCC) assignment for the payment year.

Sample Size and Strata

Next, CMS selects a sample of beneficiaries from each contract's cohort of RADV-eligible enrollees. Enrollee-based stratification will be used in the process of sampling enrollees. In order to derive the strata, the RADV-eligible enrollees in each contract will be ranked from lowest to highest based on their community risk score. The enrollees will then be divided into three equal groups based on the total number of eligible enrollees, where the first group will include the third of enrollees with the highest risk scores and the third group will include the third of enrollees with the lowest risk scores. The remaining enrollees will be in the middle stratum.

CMS will select up to 201 enrollees for medical record review from each contract selected for a contractlevel audit. For smaller contracts, i.e., those with fewer than 1,000 RADV-eligible enrollees, CMS will individually adjust their sample sizes by using the finite population correction factor. The sample sizes for these smaller contracts will be 201 or fewer enrollees.

To achieve a sample size of 201 enrollees per contract, sixty-seven (67) enrollees will be randomly sampled from each group or stratum. The corresponding stratum-based enrollee weights will be computed as the number of RADV-eligible enrollees in the population grouping (or stratum) divided by the number of enrollees selected from that grouping for the sample, i.e., N_h/n_h, where *h* represents the corresponding stratum.

For example, if a contract has 3,000 RADV-eligible enrollees, the enrollees would be ranked by risk score, then divided into three equal groups of 1,000 enrollees each (to represent high, medium, and low strata). An equal number of enrollees will be randomly selected from each group. The weight for each sampled enrollee will equal 14.925 (i.e., 1,000/67).

For small contracts with fewer than 1,000 RADV-eligible enrollees, the same enrollee-based stratification process will be applied; however, a proportionally smaller number of enrollees will be randomly sampled from each group or stratum.

The enrollee sampling weights will be used as multipliers to scale-up (or extrapolate) the sample payment error findings to the population it represents.

Once enrollees have been selected, the MA contract will be required to submit medical records to support all CMS-HCCs represented in the sampled beneficiaries' risk scores for the payment year.

Effective with the CY 2011 RADV audit, CMS will allow audited MA contracts to submit multiple medical records for each CMS-HCC being validated. All diagnoses will be abstracted from the first medical record that validates the CMS-HCC under review. The one best medical record policy will continue to apply to the RADV audit dispute and appeal processes outlined in 42 CFR §422.311. CMS will provide more detailed information in the RADV audit procedures that will be distributed to audited MA contracts.

B. Payment Error Calculation

Enrollee-level Payment Error Calculation

CMS will calculate each contract's payment error based on the validation results. For each sampled enrollee, the RADV-corrected risk score and corrected payment will be calculated based on the CMSHCCs that are supported by RADV medical record review findings for the enrollee. Enrollee-level payment errors will be defined as the difference between the original payment and the RADV-corrected payment (per member per month). The payment error for each enrollee will be either positive (representing a net overpayment), or negative (representing a net underpayment). An annual payment error amount will be calculated for each sampled enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year.

Payment Error Extrapolation Calculation

To derive the payment error estimate for each MA contract, the annual payment error for each sampled enrollee will be multiplied by the enrollee's sampling weight (computed for each stratum [h] during the sampling phase as N_h/n_h, where N represents the number of enrollees in the RADV-eligible population and n is the number of enrollees sampled). The weighted enrollee annual payment error will be summed across all enrollees in the sample to determine an estimated payment error for the MA contract (the "point estimate"). A 99 percent confidence interval (CI) will then be calculated for the estimated payment error for each audited MA contract.

The following formulas illustrate computation of a 99 percent CI around the payment error estimate for one contract, assuming a sample size of 201, with 67 enrollees selected from each of three strata groupings.

The lower bound of the 99 percent CI is computed as the estimated payment error for the contract (PE) minus (2.575 multiplied by the standard error), or (PE – (2.575 * SE)). The standard error (SE) can be calculated as follows:

1. Derive the variance, v_h, (standard deviation squared) of the unweighted enrollee payment errors across the sample enrollees within each of the three strata (*h*).
2. Calculate the variance of the estimated total ($V_{\hat{T}}$) payment error, where N represents the number of enrollees in the RADV-eligible population of the h^{th} (1^{st}, 2^{nd}, 3^{rd}) stratum:

$$= \sum_{h=1}^{3} \frac{N_h^2}{67} \; V_{\hat{T}} v_h$$

3. The standard error is $SE_{\hat{T}} = \sqrt{V_{\hat{T}}}$

Payment Recovery Amount and the Fee-For-Service Adjuster

If the CI for the point estimate includes zero or is below zero, the contract will have the payment recovery amount constrained to zero.

If the CI for the point estimate is above zero, the payment recovery amount for the contract will be determined as follows. First, a preliminary payment recovery amount will be set at the lower bound of the 99 percent CI for the contract's point estimate. Second, to determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. If the FFS Adjuster amount is greater than the preliminary recovery amount, the final recovery amount is equal to zero.

The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard

used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

Medicare Program Integrity Manual

Chapter 1 - Medicare Improper Payments: Measuring, Correcting, and Preventing Overpayments and Underpayments

Table of Contents
(Rev. 11032, 09-30-21)

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1.1- Overview of Program Integrity and Provider Compliance
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The term "Review Contractor" throughout the Program Integrity Manual refers to:

- Medicare Administrative Contractors (MACs)
- Comprehensive Error Rate Testing (CERT) contractors
- Recovery Auditors
- Unified Program Integrity Contractors (UPICs)
- Supplemental Medical Review Contractor (SMRC)

Review Contractors shall follow all sections of the PIM unless otherwise indicated as required by their applicable Statements of Work (SOW).

1.2 - Definitions
(Rev. 313; Issued: 11-20-09; Effective/Implementation Date: 12-21-09)

To facilitate understanding, the terms used in the PIM are defined in Exhibit 1.

1.3 – Medicare Improper Payment Reduction Efforts – Provider Compliance
(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

The Centers for Medicare & Medicaid Services (CMS) is the Federal agency that operates the Medicare program. Addressing improper payments in the Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for the CMS. Preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners including various Medicare contractors and providers. The CMS contracts with various types of contractors in its effort to fight improper payments and promote provider compliance in the Medicare FFS program:

- CERT contractors;
- MACs;
- Recovery auditors; and
- SMRC.

1.3.1 - Types of Contractors
(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

A. CERT Contractors

The CMS implemented the CERT program which establishes error rates and estimates of improper payments that is compliant with the Improper Payments Elimination and Recovery Improvement Act (IPERIA).

B. MACs

The MACs primarily use error rates produced by the CERT program and vulnerabilities identified through the Recovery Audit program to identify where to target their improper payment prevention efforts. The MACs analyze their internal data to determine which corrective actions would be best to prevent the CERT-identified and Recovery Auditor-identified vulnerabilities in the future. The CMS has determined that most improper payments in the Medicare FFS program occur because a provider did not comply with Medicare's coverage, coding, or billing rules. The cornerstone of the MACs' efforts to prevent improper payments is each contractor's Error Rate Reduction Plan (ERRP), which includes initiatives to help providers comply with the rules. These initiatives usually fall into one of three categories:

1. Targeted provider education to items or services with the highest improper payments,

2. Prepayment and postpayment claim review targeted to those services with the highest improper payments. In addition, in order to encourage providers to submit claims correctly, MACs can perform extrapolation reviews as needed, and

3. New or revised local coverage determinations, articles or coding instructions to assist providers in understanding how to correctly submit claims and under what circumstances the services will be considered reasonable and necessary.

See section 1.3.6, for information on quality of care and potential fraud issues.

C. Recovery Auditors

Although CMS, through the MACs have undertaken actions to prevent future improper payments, it is difficult to prevent all improper payments, considering that the Medicare FFS program processes more than 1 billion claims each year. The CMS uses the Recovery Audit program to detect and correct improper payments in the Medicare FFS program and provide information to CMS and review contractors that could help protect the Medicare Trust Funds by preventing future improper payments.

D. Supplemental MR Contractor (SMRC)

The Supplemental Medical Review Contractor's (SMRC) main tasks are to perform and/or provide support for a variety of tasks aimed at lowering the improper payment rates and increasing efficiencies of the medical review functions of the Medicare and Medicaid programs. Having a centralized medical review (MR) resource that can perform large volume MR nationally allows for a timely and consistent execution of MR review, activities and decisions. The focus of the reviews may include but are not limited to issues identified by CMS internal data analysis, the CERT program, professional organizations and other Federal agencies, such as the OIG/GAO and comparative billing reports.

1.3.2 - Improper Payment Prevention Goals

(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

The CMS strives in every case to pay the right amount to a legitimate provider, for covered, correctly coded and correctly billed services, provided to an eligible beneficiary. To achieve the goal of improving provider compliance and lowering the error rate, CMS follows three parallel strategies:

- Preventing improper payments through MACs and SMRC evaluation of program vulnerabilities and taking the necessary action to prevent the identified vulnerabilities in the future

- Correcting past improper payments through postpayment claim review by the Recovery Auditors

- Measuring improper payments and pinpointing the causes of improper payments by calculating service specific, provider type and contractor specific error rates by the CERT contractors

1.3.3 - Applicable Program Integrity Manual Sections

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

- The MACs, CERT, Recovery Auditors, UPICs, and SMRC shall follow all sections of the PIM unless otherwise indicated

- The MACs, CERT, Recovery Auditors, UPICs and SMRC shall follow the PIM to the extent outlined in their SOWs.

1.3.4 - Performance Metrics

(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

A. MAC MR Units Performance

The MAC MR Unit performance is measured by:

- **CERT**: CERT is a CMS program that measures a contractor's payment error rate.

- In addition, the MACs are measured by other measures listed in the MAC SOW.

B. Recovery Auditor Performance:

One key measure of Recovery Auditor performance is the Recovery Auditor accuracy rate. CMS will produce a Recovery Auditor accuracy rate for each Recovery Auditor on an annual basis. These rates will be released to the public through the annual Report to Congress.

C. CERT Performance

The CERT performance metrics are listed in the contractors' SOW. One key measure of CERT performance is the timely production of the national error rate each year.

D. SMRC

A performance measure of the SMRC contractor is the accuracy rate. This will be coordinated by CMS annually. Additional performance measures are listed in their SOW.

1.3.5 - Types of Claims for Which Contractors Are Responsible

(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

A. MACs

The MACs should, at their discretion perform medical review functions for all claims appropriately submitted to them.

Although they will continue to perform a number of quality functions, quality improvement organizations (QIOs) will no longer be performing the majority of utilization reviews for acute inpatient prospective payment system (IPPS) hospital and long-term care hospital (LTCH) claims. The review of acute IPPS hospital and LTCH claims (which, for the purposes of this section, also includes claims from any hospital that would be subject to the IPPS or LTCH PPS had it not been granted a waiver) is now the responsibility of the ACs and MACs. An exception occurs when a provider requests a higher-weighted diagnosis related group (DRG) review from the QIO. The QIO will continue to perform those reviews. QIOs will also continue to perform reviews related to quality of care and expedited determinations.

The MACs shall include claims for which they are responsible when performing data analysis to plan their medical review strategy. Amendments to plans and strategies shall be made as needed if analysis indicates adjustment of priorities.

B. CERT

The CERT review contractor is responsible for reviewing claims randomly selected by the CERT statistical contractor.

C. Recovery Auditors

In general, Recovery Auditors are responsible for reviewing claims where improper payments have been made or there is a high probability that improper payments were made.

D. SMRC

Medical review will be performed on Part A, Part B, and DME providers and suppliers as directed by CMS.

1.3.6 - Quality of Care Issues and Potential Fraud Issues

(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

Potential quality of care issues are not the responsibility of the MAC, CERT or Recovery Auditor, *UPIC*, and SMRC but they are the responsibility of the QIO, State licensing/survey and certification agency, or other appropriate entity in the service area. MACs, CERT, Recovery Auditor, *UPICs* and SMRC shall refer quality of care issues to the QIO, State licensing/survey and certification agency, or other appropriate entity in the service area. See chapter 3, section 3.1, for a discussion of how contractors should handle situations where providers are non-compliant with Medicare conditions of participation.

Contractors shall analyze provider compliance with Medicare coverage and coding rules and take appropriate corrective action when providers are found to be non-compliant. For repeated infractions, or infractions showing potential fraud or pattern of abuse, more severe administrative action shall be initiated. At any time, evidence of fraud shall result in referral to the *UPICs* for development. See chapter 4, section *4.9.4.2* for a discussion on benefit integrity interaction with QIOs.

1.3.7 - The MAC and SMRC Medical Review Program

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The MR program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, MACs are encouraged to automate this process; however it may require the evaluation of medical records and related documents to determine whether Medicare claims were billed in compliance with coverage, coding, payment, and billing policies.

The statutory authority for the MR program includes the following sections of the Social Security Act (the Act):

- Section 1833(e) which states, in part "...no payment shall be made to any provider... unless there has been furnished such information as may be necessary in order to determine the amounts due such provider ...;"

- Section 1842(a)(2)(B) which requires ACs and MACs to "assist in the application of safeguards against unnecessary utilization of services furnished by providers
  ...; "

- Section 1862(a)(1) which states no Medicare payment shall be made for expenses incurred for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member;"

- The remainder of Section 1862(a) which describes all statutory exclusions from coverage;

- Section 1893(b)(1) establishes the Medicare Integrity Program which allows contractors to review activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies. . .”

- Sections 1812, 1861, and 1832 which describe the Medicare benefit categories; and

- Sections 1874, 1816, and 1842 which provide further authority.

The regulatory authority for the MR program rests in:

- 42 CFR 421.100 for intermediaries.
- 42 CFR 421.200 for carriers.
- 42 CFR 421.400 for MACs.

The UPICs shall refer to chapter 4 for MR for BI purposes.

1.3.8 - Goal of MAC and SMRC MR Program

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The goal of the MAC and SMRC MR program is to reduce payment error by preventing the initial payment of claims that do not comply with Medicare’s with coverage, coding, payment, and billing policies. To achieve the goal of the MR program,

MACs:

- Identify provider noncompliance with coverage, coding, billing, and payment policies through analysis of data. (e.g., profiling of providers, services, or beneficiary utilization) and evaluation of other information (e.g., complaints, enrollment and/or cost report data). (Chapter 2 describes these activities in further detail.);

- Take action to prevent and/or address the identified improper payment; (chapter 3, describes these actions in further detail.); and

- Place emphasis on reducing the paid claims error rate by notifying the individual billing entities (i.e., providers, suppliers, or other approved clinician) of review findings identified by the ACs or by the MACs and making appropriate referrals to provider outreach and education (POE), and UPICs.

  SMRC:

- Identify provider noncompliance with coverage, coding, billing, and payment policies through the research and analysis of data related to assigned task. (e.g., profiling of providers, services, or beneficiary utilization)

- As directed by CMS, perform medical review

- As directed by CMS, perform extrapolation

- Notify the individual billing entities (i.e., providers, suppliers, or other approved clinician) of review findings identified and make appropriate recommendations for POE and UPIC referrals

1.3.9 – Provider Self Audits

(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

Providers may conduct self-audits to identify coverage and coding errors. The Office of Inspector General (OIG) Compliance Program Guidelines can be found at https://oig.hhs.gov/compliance/compliance-guidance/index.asp and the statistical guidelines in https://oig.hhs.gov/authorities/docs/selfdisclosure.pdf (if statistical sampling is utilized during the audit). The MACs shall follow chapter 4, section *4.2.2.8.1.3*, handling any voluntary refunds that may result from these provider self-audits.

Most errors do not represent fraud. Most errors are not acts that were committed knowingly, willfully, and intentionally. However, in situations where a provider has repeatedly submitted claims in error, the MACs shall follow the procedures listed in chapter 3, section 3.2.1. For example, some errors will be the result of provider misunderstanding or failure to pay adequate attention to Medicare policy. Other errors will represent calculated plans to knowingly acquire unwarranted payment. Per chapter 4, section 4.2.1, MACs shall take action commensurate with errors made. The MACs shall evaluate the circumstances surrounding the errors and proceed with the appropriate plan of correction.

1.3.10 – Coordination Among Contractors

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

A. Coordination among MACs and UPICs

The MAC MR staff shall coordinate and communicate with their associated UPIC to ensure coordination of efforts and to prevent inappropriate duplication of review activities. At any time, suspicion of fraud should result in referral to the UPIC for development.

B. Coordination among MACs and the Recovery Auditors

See Pub. 100-06, Financial Management Manual, chapter 4, section 100.1-100.15, for a description of the coordination efforts between MACs and Recovery Auditors. In addition, the MACs shall coordinate and communicate with the Recovery Auditors to

get the specifics on Recovery Auditor identified vulnerabilities for use in the MAC's data analysis and possible corrective actions.

C. SMRC

The SMRC shall make all recommendations for referrals through their CMS Contract Officer Representative (COR).

1.4 - Contractor Medical Director (CMD)

(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

MACs:

The MACs shall employ a minimum of two FTEs contractor medical director (CMD) and arrange for an alternate when the CMD is unavailable for extended periods. The CMD FTEs shall be composed of either a Doctor of Medicine or a Doctor of Osteopathy. All clinicians employed or retained as consultants shall be currently licensed to practice medicine in the United States, and the contractor shall periodically verify that the license is current. When recruiting CMDs, contractors shall give preference to physicians who have patient care experience and are actively involved in the practice of medicine. The CMD's duties are listed below.

Primary duties include:

- Leadership in the provider community, including:
  - Interacting with medical societies and peer groups;
  - Educating providers, individually or as a group, regarding identified problems or LCDs; and
  - Acting as co-chair of the Contractor Advisory Committee (CAC) (see chapter 13 §13.8.1.4 of this manual for co-chair responsibilities).
- Providing the clinical expertise and judgment to develop LCDs and internal MR guidelines:
  - Serving as a readily available source of medical information to provide guidance in questionable claims review situations;
  - Determining when LCDs are needed or must be revised to address program abuse;
  - Assuring that LCDs and associated internal guidelines are appropriate;
  - Briefing and directing personnel on the correct application of policy during claim adjudication, including through written internal claim review guidelines;

- Selecting consultants licensed in the pertinent fields of medicine for expert input into the development of LCDs and internal guidelines;
- Keeping abreast of medical practice and technology changes that may result in improper billing or program abuse;
- Providing the clinical expertise and judgment to effectively focus MR on areas of potential fraud and abuse; and
- Serving as a readily available source of medical information to provide guidance in questionable situations.

Other duties include:

- Interacting with the CMDs at other contractors to share information on potential problem areas;
- Participating in CMD clinical workgroups, as appropriate; and

Upon request, providing input to CO on national coverage and payment policy, including recommendations for relative value unit (RVU) assignments.

SMRC:

Primary duties include:

- Serving as a readily available source of medical information to provide guidance in questionable claims review situations
- Providing the clinical expertise and judgment to develop LCDs and internal MR guidelines
- Keeping abreast of medical practice and technology changes that may result in improper billing or program abuse
- Providing clinical expertise and judgment to effectively focus MR on areas of potential fraud and abuse
- Serving as a readily available source of medical information to provide guidance in questionable situations

1.5 - Medical Review Manager

(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

MACs:

An effective MR program begins with the strategies developed and implemented by senior management staff. The MACs shall name an MR point of contact referred to as the MR Manager who will act as the primary contact between the contractor and CMS concerning the contractor's MR program. The MR Manager will also have primary responsibility for the development, oversight and implementation of the contractor's MR Strategy, SAR, and quality assurance process. In addition, the MR Manager shall have the primary responsibility for ensuring the timely submission of required reports.

SMRC:

An effective Medical Review program begins with the senior management staff. The Contractor shall name a Medical Review point of contact referred to as the Medical Review Manager who will act as the primary contact between the Contractor and CMS concerning the SMRC medical review program. The MR Manager will also have primary responsibility for development, oversight and implementation of the Contractor's quality assurance process. In addition, the MR Manager shall have the primary responsibility for ensuring the timely submission of required reports. The MR Manager shall be a registered nurse. The MR Manager shall work collaboratively with their Project Manager and Contract Medical Director to plan, implement and evaluate all MR projects/tasks directed by CMS.

1.6 – Maintaining the Confidentiality of MR Medical Records and Documents

(Rev. 508; Issued: 03-07-14, Effective: 04-08-14, Implementation: 04-08-14)

A. Contractors to Which This Section Applies

This section applies to MACs, CERT, Recovery Auditors, and SMRC.

B. General

Contractors shall maintain the confidentiality of all MR medical records and documents before, during, and after the MR process. Similarly, contractors that use a subcontractor(s) to perform MR, to store MR documents, and/or to transport MR documents, are responsible for ensuring that the subcontractor(s) maintains the confidentiality of the MR documents that it handles. This responsibility applies to all contact with these documents by all parties and entities, however derived from the contractor. The responsibility is not limited or ended if the subcontractor allows an additional party or entity to have contact with these documents. Thus, just as the contractor shall assure that the subcontractor maintain confidentiality itself, so too shall the contractor assure that the subcontractor similarly assures that any third party or other entity, such as a sub to the subcontractor, which has contact with the documents, maintain confidentiality.

1.7 - Benefit Integrity

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

A. Contractors to Which This Section Applies

This section applies to UPICs only.

B. General

In addition to reducing improper payments, CMS strives to protect the program from potential fraud. CMS contracts with Unified Program Integrity Contractors (UPICs) to identify and stop potential fraud.

The primary task of UPICs is to identify cases of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any mistaken payments are identified. UPICs shall refer cases of potential fraud to the Department of Health and Human Services (HHS) Office of Inspector General (OIG) Office of Investigations (OI).

1.8 - Medical Review for Benefit Integrity (MR for BI)
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

A. Contractors to Which This Section Applies

This section applies to UPICs.

B. General

The goal of the MR for BI program is to address situations of potential fraud, waste, and abuse (e.g., looking for possible falsification).

Information on maintaining the confidentiality of MR documents can be found in this chapter, section 1.6.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R11032PI	09/30/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08	11/10/2021	12375
R10984PI	09/09/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08 - Rescinded and replaced by Transmittal 11032	11/10/2021	12375
R10365PI	10/02/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08-	08/27/2020	11884
R10228PI	07/27/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08 Rescinded and Replaced by Transmittal 10365	08/27/2020	11884
R508PI	03/07/2014	Supplemental Medical Review Contractor	04/08/2014	8578
R454PI	03/14/2013	Minor Changes to Chapter 1 of the Program Integrity Manual	04/01/2013	8205
R451PI	03/01/2013	Minor Changes to Chapter 1 of the Program Integrity Manual – Rescinded and replaced by Transmittal 454	04/01/2013	8205
R448PI	01/31/2013	Deletion of MR Operations Mailbox	03/04/2013	8187
R425PI	06/15/2012	Provider Self Audits	07/16/2012	7851
R313PI	11/20/2009	Program Integrity Manual (PIM) Reorganization Chapters 1, 2, and 7	12/21/2009	6546
R264PI	08/07/2008	Transition of Responsibility for Medical Review From Quality Improvement Organizations (QIOs)	08/15/2008	5849
R229PI	11/23/2007	Medical Review Strategy and Strategy Analysis Report	04/07/2008	5760
R220PI	08/24/2007	Various Medical Review Clarifications	09/03/2007	5550
R203PI	05/25/2007	Strategy Analysis Report	07/02/2007	5519
R174PI	11/17/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
R170PI	11/03/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
R163PI	09/29/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
R136PI	02/01/2006	Contractor Medical Director Requirements	03/01/2006	4105
R118PI	08/12/2005	Various Benefit Integrity (BI) Clarifications	09/12/2005	3896
R107PI	04/08/2005	Updated Chapter 1 to Reflect Changes in Program Requirements	05/09/2005	3754

R099PI	01/21/2005	Waivers Approved by the Regional Office (RO) by Replacing Regional Office with Central Office (CO)	02/22/2005	3646
R071PI	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
R065PI	01/30/2004	Requirement Removal of Fiscal Intermediary Medical Review on Long Term Care Hospitals	03/02/2004	2905
R040PIM	05/16/2003	Local Provider Education and Training Program	05/16/2003	2466
R033PI	11/01/2002	FY 2003 Budget Performance Requirement Revisions	11/01/2002	2407
R025PIM	04/25/2002	Types of claims for which Contractors are Responsible	07/01/2002	2122
R024PIM	04/05/2002	Removes the LMRP and related sections from Chap 1 and moves to Chap 13	10/01/2002	2061
R021PIM	02/28/2002	Inpatient Hospital Claims for Which Contractors are Responsible for Performing MR	04/01/2002	1969
R019PIM	02/08/2002	Benefit Integrity Unit Security Requirements	02/08/2002	1907
R017PIM	12/12/2001	Reorganizes chapter 3, sections 4, 5, and 6 and Removes reference to outdated MCM and MIM overpayment collection instructions and lists the more current CFR citations instead.	04/01/2002	1891
R016PIM	11/28/2001	Adds Various Program Memoranda for BI Requests for Information, Organizational Requirements, Unsolicited Voluntary Refund Checks, Anti-Kickback Statute Implications	11/28/2001	1732
R014PIM	09/26/2001	Local Medical Review Policy (LMRP) Format and Submission/Requirements	10/01/2001	1859
R010PIM	09/17/2001	Timeframe for Contractor Advisory Committees (CAC) Meetings	10/17/2001	1744
R009PIM	07/30/2001	LMRP Process	NA	1021
R008PIM	07/11/2001	Replaces PIM Chapter 1, Sections 2, 2.1, and sections 2.3 up through and including 2.3.4.	07/11/2001	1485
R006PIM	05/24/2001	Maintaining the Confidentiality of MR Records	05/24/2001	1581
R003PIM	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
R001PIM	06/2000	Initial Release of Manual	NA	931

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Medicare Program Integrity Manual

Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

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(Rev. 12633; Issued: 05-09-24)

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3.1 – Introduction

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

All references to Medicare Administrative Contractors (MACs) include Affiliated Contractors (ACs). Affiliated Contractors are FI's and Carriers.

A. Goals

This section applies to Medicare Administrative Contractors (MACs), Comprehensive Error Rate Testing (CERT), and Recovery Auditors, as indicated.

The Medicare Administrative Contractors (MACs) shall analyze claims to determine provider compliance with Medicare coverage, coding, and billing rules and take appropriate corrective action when providers are found to be non-compliant. The goal of MAC administrative actions is to correct the behavior in need of change and prevent future inappropriate billing. The priority for MACs is to minimize potential future losses to the Medicare Trust Funds through targeted claims review while using resources efficiently and treating providers and beneficiaries fairly.

For repeated infractions, MACs have the discretion to initiate progressively more severe administrative action, commensurate with the seriousness of the identified problem. (Refer to PIM chapter 3, §3.7.1). MACs shall deal with serious problems using the most substantial administrative actions available, such as 100 percent prepayment review of claims. Minor or isolated inappropriate billing shall be remediated through provider notification or feedback with reevaluation after notification. When medical review (MR) notification and feedback letters are issued, the MAC MR staff shall ensure that Provider Outreach and Education (POE) staff has access to copies of the letters in case a provider requests further education or POE determines that future education is needed. While program savings are realized through denials of payment for inappropriate provider billing, the optimal result occurs when compliance is achieved and providers no longer incorrectly code or bill for non-covered services.

The Medicare Fee For Service Recovery Audit program is a legislatively mandated program (Tax Relief and Health Care Act of 2006) that utilizes Recovery Auditors to identify improper payments paid by Medicare to fee-for-service providers. The Recovery Auditors identify the improper payments, and the MACs adjust the claims, recoup identified overpayments and return underpayments.

MAC, CERT and Recovery Auditor staff shall not expend Medicare Integrity Program (MIP)/ MR resources analyzing provider compliance with Medicare rules that do not affect Medicare payment. Examples of such rules include violations of conditions of participation (COPs), or coverage or coding errors that do not change the Medicare payment amount.

The COPs define specific quality standards that providers shall meet to participate in the Medicare program. A provider's compliance with the COPs is determined by the CMS

Regional Office (RO) based on the State survey agency recommendation. If during a review, any contractor believes that a provider does not comply with conditions of participation, the reviewer shall not deny payment solely for this reason. Instead, the contractor shall notify the RO and the applicable State survey agency.

When a potential underpayment or overpayment is identified, certain steps are normally followed to determine if a payment error exists. These steps are referred to as the claims development process. The reviewer generally does the following:

- Investigates the claims and associated documentation;
- Performs appropriate research regarding liability, benefit categories, statutory requirements, etc.;
- Determines if a payment error exists and the nature of the error;
- Notifies the beneficiary and provider/supplier; and
- Starts the payment reconciliation process.

B. New Provider/New Benefit Monitoring

This section applies to the MACs.

The MACs shall analyze data to identify patterns of billing aberrancies of providers new to the Medicare program. The MACs have the option of performing prepayment or postpayment review of claims submitted by new providers as needed. The CMS encourages the MACs to perform these reviews on a prepayment basis to have the greatest chance of identifying and reducing the error rate of new providers. When MACs review the claims of a new provider, the MACs shall perform a limited review of generally 20-40 claims in order to evaluate accurate billing.

The MACs shall also monitor for provider use of new statutory benefits and to ensure correct coverage, coding, and billing from the beginning. New benefit edits shall continue until the MAC is satisfied that the new benefits are being used and billed appropriately or until the MAC determines that resources would best be spent on other types of review.

3.2 – Overview of Prepayment and Postpayment Reviews

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

This section applies to MACs, CERT, RACs, SMRCs, and Unified Program Integrity Contractors (UPICs), as indicated.

A. Prepayment and Postpayment Review

Prepayment review occurs when a reviewer makes a claim determination before claim payment has been made. Prepayment review always results in an "initial determination". Postpayment review occurs when a reviewer makes a claim determination after the claim has been paid. Postpayment review results in either no change to the initial determination or a "revised determination" indicating that an overpayment or underpayment has occurred.

B. Prepayment Edit Capabilities

Prepayment edits shall be able to key on a beneficiary's Medicare beneficiary identifier (Mbi), National Provider Identifier (NPI) and specialty code, service dates, and diagnosis or procedure code(s) (i.e., Healthcare Common Procedure Coding System [HCPCS] and/or International Classification of Diseases diagnoses codes), Type of Bill (TOB), revenue codes, occurrence codes, condition codes, and value codes.

The MAC systems shall be able to select claims for prepayment review using different types of comparisons. At a minimum, those comparisons shall include:

- Procedure to Procedure -permits contractor systems to screen multiple services at the claim level and in history.
- Procedure to Provider - permits selective screening of services that need review for a given provider.
- Frequency to Time- permits contractors to screen for a certain number of services provided within a given time period.
- Diagnosis to Procedure- permits contractors to screen for services submitted with a specific diagnosis. For example, the need for a vitamin B12 injection is related to pernicious anemia, absent of the stomach, or distal ileum. Contractors must be able to establish edits where specific diagnosis/procedure relationships are considered in order to qualify the claim for payment.
- Procedure to Specialty Code or TOB- permits contractors to screen services provided by a certain specialty or TOB.
- Procedure to Place of Service- permits selective screening of claims where the service was provided in a certain setting such as a comprehensive outpatient rehabilitation facility.

Additional MAC system comparisons shall include, but are not limited to the following:

- Diagnoses alone or in combination with related factors.

- Revenue linked to the health care common procedure coding system (HCPCS).
- Charges related to utilization, especially when the service or procedure has an established dollar or number limit.
- Length of stay or number of visits, especially when the service or procedure violates time or number limits.
- Specific providers alone or in combination with other parameters.

The MR edits are coded system logic that either automatically pays all or part of a claim, automatically denies all or part of a claim, or suspends all or part of a claim so that a trained clinician or claims analyst can review the claim and associated documentation (including documentation requested after the claim is submitted) in order to make determinations about coverage and payment under Section 1862(a) (1) (A) of the Act.

Namely, the claim is for a service or device that is medically reasonable and necessary to diagnose or treat an injury or improve the functioning of a malformed body member. All non-automated review work resulting from MR edits shall:

- Involve activities defined under the MIP at §1893(b)(1) of the Act;
- Be articulated in the MAC's medical review strategy;
- Be designed in such a way as to reduce the MAC's CERT error rate or prevent the MAC's CERT error rate from increasing, or;

Prevent improper payments identified by the RACs.

3.2.1 – Setting Priorities and Targeting Reviews
(Rev. 399, Issued: 11-04-11, Effective: 12-05-11, Implementation: 12-05-11)

This section applies to MACs and Recovery Auditors, as indicated. Recovery Auditors perform targeted reviews consistent with their statements of work (SOWs).

The MACs have the authority to review any claim at any time, however, the claims volume of the Medicare Program doesn't allow for review of every claim. The MACs shall target their efforts at error prevention to those services and items that pose the greatest financial risk to the Medicare program and that represent the best investment of resources. This requires establishing a priority setting process to assure MR focuses on areas with the greatest potential for improper payment.

The MACs shall develop a problem-focused, outcome-based MR strategy and Strategy Analysis Report (SAR) that defines what risks to the Medicare trust fund the MAC's MR

programs will address and the interventions that will be implemented during the fiscal/option year as addressed in PIM chapter 7.

The MACs shall focus their edits where the services billed have significant potential to be non-covered or incorrectly coded. Medical review staff may decide to focus review on problem areas that demonstrate significant risk to the Medicare program as a result of inappropriate billing or improper payments. The MACs shall have in place a program of systematic and ongoing analysis of claims and data from Recovery Auditors and CERT, among other sources, in order to focus intervention efforts on the most significant errors.

The MACs shall initiate a targeted provider-specific prepayment review only when there is the likelihood of sustained or high level of payment error. MACs are encouraged to initiate targeted service-specific prepayment review to prevent improper payments for services identified by CERT or Recovery Auditors as problem areas, as well as, problem areas identified by their own data analysis.

The MACs have the discretion to select target areas because of:

- High volume of services;
- High cost;
- Dramatic change in frequency of use;
- High risk problem-prone areas; and/or,
- Recovery Auditor, CERT, Office of Inspector General (OIG) or Government Accounting Office (GAO) data demonstrating vulnerability. Probe reviews are not required when targeted areas are based on data from these entities.

In an effort to identify the claims most likely to contain improper billing, MACs are encouraged to use prepayment and postpayment screening tools or natural language coding software. MACs shall not deny a payment for a service simply because the claim fails a single screening tool criterion. Instead, the reviewer shall make an individual determination on each claim. MACs have the discretion to post the screening tools in use to their Web site or otherwise disclose to the provider community. Recovery Auditors shall use screening tools and disclose their use to the provider community consistent with the requirements in their statements of work (SOWs).

MACs and Recovery Auditors shall NOT target a provider for review solely based on the provider's preferred method of maintaining or submitting documentation. For example, a MAC or Recovery Auditor shall NOT choose a provider for review based only on the fact that the provider uses an electronic health record or responds to documentation requests using the Electronic Submission of Medical Documentation (esMD) mechanism. (More information about esMD can be found in Section (3.2.3.5)

3.2.2 - Provider Notice

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, RACs, UPICs, and SMRC as indicated.

Because the CERT contractors select claims on a random basis, they are not required to notify providers of their intention to begin a review.

Providers may submit unsolicited documentation to the MAC when submitting a claim. Providers are to list the PWK 02 Report Transmission Code (PWK (paperwork) modifier) on the claim when submitting this documentation. MACs should inform the providers that they are NOT required to submit unsolicited documentation (and the corresponding PWK modifier) and that the absence or presence of PWK modifier does not mean that their claim will be reviewed. MACs should, at their discretion, consider posting to their website or sending letters to providers informing them of what additional documentation is needed to make a determination on the claim.

A. Notice of Provider-Specific Review

When MAC data analysis indicates that a provider-specific potential error exists that cannot be confirmed without requesting and reviewing documentation associated with the claim, the MAC shall review a sample of representative claims. Before deploying significant medical review resources to examine claims identified as potential problems through data analysis, MACs shall take the interim step of selecting a small "probe" sample of generally 20-40 potential problem claims (prepayment or postpayment) to validate the hypothesis that such claims are being billed in error. This ensures that medical review activities are targeted at identified problem areas. The MACs shall ensure that such a sample is large enough to provide confidence in the result, but small enough to limit administrative burden. The CMS encourages the MACs to conduct error validation reviews on a prepayment basis in order to help prevent improper payments.

MACs shall select providers for error validation reviews in the following instances, at a minimum:

- The MAC has identified questionable billing practices (e.g., non-covered, incorrectly coded or incorrectly billed services) through data analysis;
- The MAC receives alerts from other MACs, Quality Improvement Organizations (QIOs), CERT, RACs, OIG/GAO, or internal/external components that warrant review;
- The MAC receives complaints; or,
- The MAC validates the items bulleted in §3.2.1.

Provider-specific error validation reviews are undertaken when one or a relatively small number of providers seem to be experiencing similar/recurrent problems with billing. The MACs shall document their reasons for selecting the provider for the error validation

review. In all cases, they shall clearly document the issues noted and cite the applicable law, published national coverage determination, or local coverage determination.

For provider-specific problems, the MAC shall notify providers in writing that a probe sample review is being conducted. MACs shall consider sending letters to providers informing them of what additional documentation is needed to make a determination on the claim. MACs have the discretion to use a letter similar to the letters in Exhibit 7 of the PIM when notifying providers of the probe review and requesting documentation. MACs have the discretion to advise providers of the probe sample at the same time that medical documentation or other documentation is requested.

Generally, MACs shall subject a provider to no more than one probe review at any time; however, MACs have the discretion to conduct multiple probes for very large billers as long as they will not constitute undue administrative burden.

MACs

The MACs shall notify selected providers prior to beginning a provider-specific review by sending an individual written notice. MACs shall indicate whether the review will occur on a prepayment or postpayment basis. This notification may be issued via certified letter with return receipt requested. MACs shall notify providers of the specific reason for selection. If the basis for selection is comparative data, MACs shall provide the data on how the provider varies significantly from other providers in the same specialty, jurisdiction, or locality. Graphic presentations help to communicate the perceived problem more clearly.

RACs

The RACs are required to post a description of all approved new issues to the RAC's Web site before correspondence is sent to the provider. After posting, the RAC should issue an additional documentation request (ADR) to the provider, if warranted.

Unified Program Integrity Contractor (UPIC)

The UPICs shall notify selected providers prior to beginning a provider-specific review by sending an individual written notice. UPICs shall indicate whether the review will occur on a prepayment or postpayment basis. UPICs shall maintain a copy of the letter and the date it was mailed. This notification shall be mailed the same day that the edit request is forwarded to the MAC. Refer to Exhibit 45 for the letter to be sent.

B. Notice of Service-Specific Review

This section applies to MACs, RACs and SMRC as indicated.

Service-specific reviews are undertaken when the same or similar problematic process is noted to be widespread and affecting one type of service (e.g., providing tube feedings to

home health beneficiaries across three (3) states).

MACs

Web site postings

The MACs shall provide notification prior to beginning a service-specific review by posting a review description on their Web site. MACs should, at their discretion, state what additional documentation is needed from providers to make a claim determination on their Web site. MACs shall keep the Web site current by posting active reviews.

MACs should, at their discretion, create an archive for old review topics that are no longer under active review. Active review is defined as the time period during which ADRs are sent, determinations are made and findings are communicated to the providers. MACs should categorize the active review topics by provider type.

Individual written notices

MACs have the discretion to also notify providers about a service-specific review by sending individual notices to the affected providers. MACs have the discretion to issue the notice separately or include it in the ADR. MACs should, at their discretion, state what additional documentation is needed from providers to make a claim determination in the written notices.

RACs

Before beginning widespread service-specific reviews, RACs shall notify the provider community that the RAC intends to initiate review of certain items/services through a posting on the RAC Web site describing the item/service that will be reviewed.

Additionally, for medical record reviews, the RACs shall send ADRs to providers that clearly articulate the items or services under review and indicate the appropriate documentation to be submitted.

Unified Program Integrity Contractors (UPICs)

The UPICs shall provide notification prior to beginning a service-specific review by sending individual written notices to the affected providers. This notification shall be mailed the same day that the edit request is forwarded to the MAC. The UPICs shall maintain a copy of the letter and the date it was mailed. Refer to Exhibit 45 for the letter to be sent.

SMRC

The SMRC shall operate/maintain a public Web site that displays what types of issues are under review. For each area, the SMRC shall include a link to the relevant OIG/GAO or

other reports available. In addition to the Web site, the SMRC shall notify providers about a service-specific review by sending an ADR. The SMRC shall state what additional documentation is needed from providers to make a claim determination in the ADR.

3.2.2.1 - Maintaining Provider Information

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

This section applies to MAC.

A. Provider Tracking System (PTS)

The MACs shall have a PTS in place to identify and track all individual providers currently under action plans to correct identified problems, such, as not reasonable and necessary, incorrect coding, and inappropriate billing. MACs shall use the provider tracking system (PTS) to coordinate contacts with providers such as MR notifications, telephone calls directly related to probe reviews, and referrals to POE. The MACs shall ensure that if a provider is to be contacted as a result of more than one problem, redundant contacts are minimized. The MACs shall also coordinate corrective action information with the UPICs to ensure contacts are not in conflict with benefit integrity related activities. The MAC PTS shall contain the date a provider is put on a provider-specific edit. The MAC shall reassess all providers on provider-specific prepayment or postpayment review on a quarterly basis to determine whether the behavior has improved. The MAC shall note the results of these quarterly assessments in the PTS. If the behavior has improved sufficiently and the edit was turned off, note that date as well in the PTS. When a MAC becomes aware that the provider has appealed a medical review determination to an Administrative Law Judge (ALJ), the MAC should send a letter to the ALJ and describe the information in the PTS to demonstrate the corrective actions that have been taken by the MAC.

B. Recovery Auditor Case Files

The Recovery Auditor shall maintain case files following the guidelines in the Recovery Auditor SOW.

C. Provider Addresses

This section applies to MACs, CERT, and Recovery Auditors, as indicated.

The MACs, CERT and Recovery Auditors shall mail the ADR to the best known address for the provider. MACs are encouraged to indicate the procedure a provider can follow to update address information in their ADRs and on their Web sites. If a provider wishes to have ADRs sent to one address but demand letters sent to a different address, MACs are encouraged to accommodate this request.

Note: Providers and suppliers must complete and submit a Medicare enrollment application (either the paper CMS-855 or a submission via Internet-based Provider Enrollment, Chain & Ownership [PECOS] to change existing information in the Medicare enrollment record.)

D. When the Provider or Supplier No Longer Occupies a Physical Address

This section applies to MACs and UPICs, as indicated.

When the MACs and UPICs become aware that the provider or supplier no longer occupies a physical address, any future correspondence shall reference only the claim control numbers and not list the individual beneficiary data (e.g., names and Medicare beneficiary identifiers). This process is contingent on current automated system limits.

The following are situations where the MAC and UPIC can assume the provider or supplier no longer occupies the last known location. This list is not exhaustive and the MACs and UPICs should use other means to confirm addresses, at their discretion.

- The MAC and UPIC receive mail that has been returned by the post office indicating no known address;
- An onsite visit has confirmed the address is vacant or is occupied by another occupant; or,
- A beneficiary complaint(s) is on record stating the provider or supplier is no longer at the address and follow up confirms the complaint.

In the above situations, correspondence from the MACs and UPICs shall only contain the claim control number and advise the provider or supplier to contact them for a list of the specific claims associated with the overpayment. This process will prevent the potential compromise of Medicare beneficiary names and/or Medicare beneficiary identifiers being sent to an abandoned address (or a location with a new occupant). If the letter is returned from the post office, maintain the notification on file for evidence.

3.2.3 - Requesting Additional Documentation During Prepayment and Postpayment Review

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, RACs, and UPICs, as indicated.

A. General

In certain circumstances, the MACs, CERT, RACs, and UPICs may not be able to make a determination on a claim they have chosen for review based upon the information on the claim, its attachments, or the billing history found in claims processing system (if applicable) or the Common Working File (CWF). In those instances, the reviewer shall solicit documentation from the provider or supplier by issuing an additional documentation request (ADR). The term ADR refers to all documentation requests associated with prepayment review and postpayment review. MACs, CERT, RACs, and UPICs have the discretion to collect documentation related to the beneficiary's condition before and after a service in order to get a more complete picture of the beneficiary's clinical condition. The MAC, RAC, and UPIC shall not deny other claims submitted before or after the claim in question unless appropriate consideration is given to the actual additional claims and associated documentation. The CERT contractor shall solicit documentation in those circumstances in accordance with its Statement of Work (SOW).

The term "additional documentation" refers to medical documentation and other documents such as supplier/lab/ambulance notes and includes:

- Clinical evaluations, physician evaluations, consultations, progress notes, physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation is maintained by the physician and/or provider.

- Supplier/lab/ambulance notes include all documents that are submitted by suppliers, labs, and ambulance companies in support of the claim (e.g., Certificates of Medical Necessity, supplier records of a home assessment for a power wheelchair).

- Other documents include any records needed from a biller in order to conduct a review and reach a conclusion about the claim.

NOTE: Reviewers shall consider documentation in accordance with other sections of this manual.

The MAC and UPIC have the discretion to deny other "related" claims submitted before or after the claim in question, subject to CMS approval as described below. If documentation associated with one claim can be used to validate another claim, those claims may be considered "related." Approved examples of "related" claims that may be denied as "related" are in the following situations:

- When the Part A Inpatient surgical claim is denied as not reasonable and necessary, the MAC may recoup the surgeon's Part B services.

For services where the patient's history and physical (H&P), physician progress notes or other hospital record documentation does not support the medical necessity for performing the procedure, postpayment recoupment may occur for the performing physician's Part B service.

- Reserved for future approved "related" claim review situations. The MAC shall report to their BFL and COR prior to initiating denial of "related" claims situations.

The MAC and UPIC shall await CMS approval prior to initiating requested "related" claim(s) review. Upon CMS approval, the MAC shall post the intent to conduct "related" claim review(s) to their Web site within 1 month prior to initiation of the approved "related" claim review(s). The MAC shall inform CMS of the implementation date of the "related" claim(s) review 1 month prior to the implementation date.

If "related" claims are denied automatically, MACs shall count these denials as automated review. If the "related" claims are denied after manual intervention, MACs shall count these denials as non-medical record review.

The RAC shall utilize the review approval process as outlined in their SOW when performing reviews of "related" claims.

The MAC, RAC, and UPIC are not required to request additional documentation for the "related" claims before issuing a denial for the "related" claims.

Contactors shall process appeals of the "related" claim(s) separately.

B. Authority to Collect Medical Documentation

Contractors are authorized to collect medical documentation by the Social Security Act. Section 1833(e) states "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period." Section 1815(a) states "…no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period."

The OMB Paperwork Reduction Act collection number for prepayment medical review is 0938-0969. MACs shall use this number on every additional documentation request or any other type of written request for additional documentation for prepayment medical review. It can be in the header, footer or body of the document. CMS suggests the information read "OMB #: 0938-0969" or OMB Control #: 0938-0969." Postpayment medical review does not require an OMB control number.

C. PWK (Paperwork) Modifier

MAC medical review departments are only required to review unsolicited documentation when the claim suspends for a medical review edit/audit. MACs shall not send an ADR request for a claim with a PWK modifier until after review of the PWK unsolicited documentation or the waiting days have elapsed without receipt of documentation.

MACs shall allow 7 calendar "waiting days" (from the date of receipt of the claim) for additional unsolicited documentation to be submitted or 10 calendar "waiting" days for the unsolicited documentation to be mailed. Contractors serving island territories shall have the flexibility to adjust "waiting days" as is necessary. CMS expects that any adjustment from the core 7/10 days will be discussed with and approved by your contracting officer prior to implementation. When the documentation is received, the contractor has 30 calendar days to make a determination on the claim. If the contractor cannot make a determination on the claim after reviewing the unsolicited documentation submitted, they shall request additional documentation using their normal business procedures for ADR that are outlined in Chapter 3 of the Program Integrity Manual.

3.2.3.1 - Additional Documentation Requests (ADR)

(Rev.933; Issued: 01-10-20; Effective: 02- 03- 20; Implementation: 01-06- 20)

This section applies to MACs, Recovery Auditors, CERT and UPICs, as indicated.

The MACs, CERT, Recovery Auditors, and UPICs shall specify in the ADR only those individual pieces of documentation needed to make a determination. When reviewing documentation, the reviewer shall give appropriate consideration to all documentation that is provided in accordance with other sections of this manual.

The MACs and the RACs shall also support soliciting documentation from the provider or supplier via Electronic Submission of Medical Documentation (esMD). The contractors shall send an Electronic Medical Documentation Request (eMDR) via esMD to those providers/suppliers that have registered to receive the request electronically. The contractors are encouraged to explore other ways to send eMDRs electronically (For example, using direct exchange, clearinghouses, state Health Information Exchange (HIEs)).

Providers interested in submitting documentation via esMD can find information on the CMS esMD website at http://www.cms.gov/esMD.

A. Outcome Assessment Information Set (OASIS)

Medicare's Home Health PPS Rate Update for CY 2010 final rule, published in the November 10, 2009 Federal Register, includes a provision to require the submission of the OASIS as a condition of payment, that is codified in regulations 42 CFR§484.210(e).

Beginning January 1, 2010, home health agencies (HHAs) are required to submit an OASIS as a condition for payment. The MACs shall deny the claim if providers do not meet this regulatory requirement. The assessment must be patient specific, accurate and reflect the current health status of the patient. This status includes certain OASIS elements used for calculation of payment. These include documentation of clinical needs, functional status, and service utilization.

B. Plan of Care (POC)

Comprehensive care planning is essential to good patient care under the Medicare program. In fact, it is specifically written into the coverage and/or certification requirements for a number of healthcare settings. For purposes of the Part A benefit for home health, inpatient rehabilitation facility and hospice, the Social Security Act describes criteria and standards used for covering these services. This includes establishing an individualized POC.

The POC identifies treatment goals and coordination of services to meet patient needs as set forth in CFR §418.200 requirement for coverage. The POC must be established by a physician(s). However, in the case of a hospice, in addition to the physician, an interdisciplinary group shall establish a POC.

Section 1814(a)(2)(C), Part B 1835(a)(2)(A) of the Act, and CFR §409.43 state that a POC established by a treating physician must contain all pertinent information, such as, the patient history, initial status, treatment goals, procedures/services duration, and progress notes.

CFR§412.622 requires an individualized POC by a rehabilitation physician that meets the requirements listed in the regulation. MACs shall deny the claim as not meeting statutory requirements under the Social Security Act when the provider of services fails to comply with the POC requirements.

Pursuant to 42 CFR §489.21, a provider of services shall not charge a beneficiary for services that have been denied for the reasons stated above.

3.2.3.2 - Time - Frames for Submission

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, RACs, CERT, SMRC, and UPICs, as indicated.

In certain circumstances, the MACs, CERT, SMRC, RACs, UPICs and other contractors may not be able to make a determination on prepayment or post-payment claims they have chosen for review based upon the information on the claim, its attachments, or the billing history found in claims processing system (if applicable) or the Common Working File (CWF). In those instances, the reviewer shall solicit documentation from the provider or supplier by issuing an ADR.

Contractors are authorized to collect medical documentation by the Social Security Act (the Act).

Section 1815(a) of the Act states that "…no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period."

Section 1833(e) of the Act states that "[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

In addition, Contractors are required to ensure that payment is limited to those items and services that are reasonable and necessary.

Section 1862(a)(1)(A) of the Act states that "[n]otwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services— which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Contractors are required, when authoring correspondence related to ADRs, to cite sections 1815(a), 1833(e), and 1862(a)(1)(A) of the Act exclusively when referring to the authority for requiring submission of documentation.

A. Prepayment Review Time Frames

When requesting documentation for prepayment review, the MACs and UPICs shall notify providers when they expect documentation to be received. The reviewer should not grant extensions to providers who need more time to comply with the request. Reviewers shall deny claims when the requested documentation to support payment is not received by the expected timeframe.

B. Post-payment Review Time Frames

When requesting documentation for post-payment review, the MACs, CERT, SMRC, UPICs and RACs shall notify providers when they expect documentation to be received. MACs, CERT, SMRC, UPICs and RACs have the discretion to grant extensions to providers who need more time to comply with the request.

The MACs, CERT, SMRC, UPICs and RACs shall deny claims when the requested documentation to support payment is not received by the expected timeframe (including any applicable extensions).

C. For esMD submissions

The esMD review contractor shall use the Enterprise File Transfer (EFT) system receipt date as the date the documentation was received. If the EFT receipt date is outside of the contractors normal business hours, the following business day shall be used as the receipt date. Contractors shall pull for esMD files at least every 4 hours (business hours) daily; including a mandatory pulling between the hours of 6-7pm EST daily. If unforeseeable circumstances occur, in which contractors are not technically capable of retrieving documentation in a timely manner due to issues outside of their control, contractors are to notify the esMD Team and can use the date documentation was available to be retrieved once issues have been resolved in the EFT system.

3.2.3.3 - Third-party Additional Documentation Request

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, RACs, CERT and UPICs, as indicated.

Unless otherwise specified, the MAC, RAC and UPIC shall request information from the billing provider/supplier. The treating physician, another clinician, provider, or supplier should submit the requested documentation. However, because the provider selected for review is the one whose payment is at risk, it is this provider who is ultimately responsible for submitting, within the established timelines, the documentation requested by the MAC, CERT, RAC and UPIC.

The CERT reviewer shall request medical record documentation from the referring provider as submitted/identified by National Provider Identifier/Unique Physician Identification Number on the claim when such information is not sent in by the billing supplier/provider initially and after a request for additional documentation fails to produce medical documentation necessary to support the service billed and supported by the Local and National Coverage Determinations.

The MAC, UPIC and RAC have the discretion to send a separate ADR to third- party entities involved in the beneficiary's care. They shall not solicit documentation from a third party unless they first or simultaneously solicit the same information from the billing provider or supplier. The following requirements also apply:

- The MACs, UPICs and RACs shall notify the third party and the billing provider or supplier that they have 30 calendar days to respond for a prepayment review or 45 calendar days for a postpayment review for MACs and RACs and 30 calendar days for UPICs.

- For prepayment review, the MACs and UPICs shall pend the claim for 45 calendar days. This 45 day time period may run concurrently

as the 45 days that the billing provider or supplier has to respond to the ADR letter;

- The MACs and UPICs have the discretion to issue as many reminder notices as they deem appropriate to the third party via email, letter or phone call prior to the 30th or 45th calendar day, as discussed above;

- When information is requested from both the billing provider or supplier and a third party and a response is received from one or both that fails to support the medical necessity of the service, the MACs and UPICs shall deny the claim, in full or in part, using the appropriate denial code. Contractors shall count these denials as medical record reviews.

- Contractors shall include language in the denial notice reminding providers that beneficiaries cannot be held liable for these denials unless they received proper liability notification before services were rendered, as detailed in CMS Pub.100- 04, Medicare Claims Processing Manual, chapter 30.

- Refer to§3.2.3.7 for ADR to ordering providers for lab services.

3.2.3.4 - Additional Documentation Request Required and Optional Elements

(Rev. 557, Issued: 11-26-14, Effective: 12-29-14, Implementation: 12-29-14)

This section applies to Medicare Administrative Contractors (MAC), Recovery Auditors, Comprehensive Error Rate Testing (CERT), and Supplemental Medical Review Contractors (SMRC), as indicated.

- The MAC shall use discretion to ensure that the amount of medical documentation requested does not negatively impact the provider's ability to provide care.

- The Recovery Auditors shall issue Additional Documentation Requests (ADR) in accordance with limits established by their Contracting Officer's Representative (COR) for each calendar year.

- The MACs, CERT, SMRCs, and Recovery Auditors, shall request records related to the claim(s) being reviewed and have the discretion to collect documentation related to the beneficiary's condition before and after a service.

- The MACs, Recovery Auditors, and SMRCs have the discretion to issue as many reminder notices as they deem appropriate. Reminder notices can be issued via email, letter, or phone call.

- The CERT shall issue reminder notices in accordance with its SOW.

- The MACs, Recovery Auditors, and SMRCs shall not target their ADRs to providers based solely on the provider's electronic health record status or chosen method of submitting records.

When requesting documentation for postpayment medical review, the MACs, CERT, SMRCs and Recovery Auditors shall use the unified postpayment ADR letter format. Contractors shall maintain the format of the letter, but have the discretion to insert case-specific information. In other words, contractors shall not change the order of the sections on the letter, but should modify the text underneath each section to provide detailed information and accurately reflect the information specific to the subject of the letter. The detailed text in the Exhibit 46 templates serves only to provide an example of what types of information belong under each section heading. The templates show the format and order contractors shall use when constructing postpayment ADR letters.

If any of the elements are lengthy, contractors have the discretion to utilize an attachment to provide the details. If a contractor does not have attachments, but has supplementary information to provide in the text of the letter, the contractor should insert the text beneath the section title "Attachments / Supplementary Information").

The MACs, CERT, SMRCs and Recovery Auditors shall include the following elements in their ADRs and shall use the appropriate templates provided in Exhibit 46:

A. Introductory Paragraph

- CMS as the government agency making the request;
- The program making the request (e.g. the MAC program, the SMRC program, the Recovery Audit Program, the CERT program); and
- The regulations and/or laws that apply to the request.

The first paragraph in the ADR may identify the following:

- The program purpose;
- Where additional information about the program and regulations can be found, for example, a website reference; and
- Additional program information that may be helpful to the provider or supplier.

B. Reason for Selection

The reason the provider or supplier was sent the ADR letter and notes about the claims under review.

C. Action

The action(s) the provider or supplier shall take as a result of receiving the ADR letter.

D. When
The date a provider/supplier shall reply to the ADR letter and submit the documentation to the contractor.

E. Consequences
The consequences if the provider or supplier fails to submit the requested documentation.

F. Instructions
Instructions and notes that will help the provider or supplier respond to the ADR letter.

G. Submission Methods
The methods the provider or supplier can submit the requested documentation.

H. Questions
Contractor contact information for provider inquiries related to the ADR.

I. Attachments / Supplementary Information

- If there are attachments or other supplementary information associated with the ADR, provide a listing of the attachment titles or provide the supplementary information.

3.2.3.5 - Acceptable Submission Methods for Responses to ADRs

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, Recovery Auditors, CERT, and UPICs, as indicated.

Reviewers shall be clear in their ADR letters about what documentation submission methods they will accept from a provider or Health Information Handler (HIH). The MACs, CERT, and Recovery Auditors shall accept documents via paper, fax, CD/DVD, and electronic submission of medical documentation (esMD).

A. Paper

The MACs, CERT, and Recovery Auditors are encouraged to state in the ADRs that paper medical documentation can be mailed by any means including US Postal Service, FedEx, UPS, or certified mail. To facilitate delivery of documentation, MACs, CERT and Recovery Auditors should provide a physical mailing address instead of a P.O. Box.

B. Fax

If the MACs, CERT, or Recovery Auditors have the capability to offer fax confirmation, they are encouraged to send such confirmations with every successfully received fax.

C. Imaged Medical Documentation File(s) Sent on CD/DVD

The MACs and CERT shall state in the ADR that imaged medical documentation files on CD/DVD may be mailed by any means. Recovery Auditor ADRs shall provide a Web site link or phone number that provides information regarding the requirements for submitting imaged documentation on CD or DVD.

D. Medical Documentation Sent via Electronic Submission of Medical Documentation (esMD) Transmission

Electronic Submission of Medical Documentation (esMD) is a system that allows providers/HIHs to submit medical documentation over secure electronic means. Information about the esMD system can be found at www.cms.gov/esMD.

MACs and CERT are encouraged to state in their ADRs how providers can get more information about submitting medical documentation via the esMD mechanism.

Any time a new esMD service or document type is being offered, and any contractor wants to publish a public announcement (Web posting, list serve, tweet, etc.) the contractor must clear the announcement with CMS.

3.2.3.6 - Reimbursing Providers and HIHs for Additional Documentation

(Rev. 786, Issued: 04-13-18, Effective: 05-14-18, Implementation: 05-14-18)

A. General

1. Rules for MACs, SMRC, CERT, and UPICs

- The MACs, SMRC, CERT, and UPICs are not required to pay for medical documentation for either prepayment or post payment review.

2. Rules for RACs

- RACs performing post payment review of hospital inpatient prospective payment system (PPS) and long term care facilities are required to pay the providers for submitting requested medical records. RACs shall pay according to the payment rate schedule listed in section B below.

- RACs performing post payment review of provider types other than hospital inpatient PPS and long term care facilities are required to pay the providers for submitting requested medical records, according to the payment rate schedule listed in section B below.

- Providers under a Medicare reimbursement system (such as Critical Access Hospitals) receive no reimbursement for submitting medical records.

- RACs shall pay a maximum of $15.00 per record, including first class postage if applicable, for requested documents submitted via mail/fax/CD/DVD.

- RACs shall pay a maximum of $27.00 per record, including a transaction fee of $2.00/case, for requested documents submitted via esMD.

- Payments will not be made for blank pages or documents/records that are not related to the claim being reviewed.

- RACs shall issue documentation submission payments on at least a monthly basis and shall issue all photocopying payments within 45 calendar days of receiving the documentation.

  RACs shall honor all requests from providers to issue photocopying payments to HIHs. RACs should gather, from the provider, all necessary information, such as, the HIH's name, phone number and bank routing number, etc.

- Providers interested in submitting documentation via esMD can find information on the CMS esMD website at http://www.cms.gov/esMD.

B. Payment Schedule for Requested Medical Records

	Hospital Inpatient Prospective Payment System (PPS) Facilities and Long Term Care Facilities	**Non-PPS Institutions and Practitioners**
Documentation sent via mail, fax, CD/DVD	- 12 cents per page - Plus first class postage, if applicable - $15.00 maximum per record	- 15 cents per page - Plus first class postage, if applicable - $15.00 maximum per record
Documentation sent via esMD	- 12 cents per page - Plus $2.00 transaction fee, per record - $27.00 maximum per record	- 15 cents per page - Plus $2.00 transaction fee, per case

		- $27.00 maximum per record

*Note: Providers under a Medicare reimbursement system (such as Critical Access Hospitals) receive no reimbursement for submitting medical records. Also, payments will not be made for blank pages or documents/records that are not related to the claim being reviewed.

3.2.3.7 - Special Provisions for Lab Additional Documentation Requests
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, RACs, UPICs, and SMRC as indicated.

ICD-10-CM is used for diagnoses on inpatient discharges and for other services provided upon implementation of ICD-10. ICD-9-CM is used for discharges and other services before that implementation.

When the MACs, CERT, RACs, and UPICs send an ADR for a lab service, the following documentation shall be requested from the billing lab:

- The order for the service billed (including sufficient information to allow the reviewer to identify and contact the ordering provider);
- Verification of accurate processing of the order and submission of the claim; and
- Diagnostic or other medical information supplied to the lab by the ordering provider, including any diagnosis codes or narratives.

The contractor shall deny the claim if a benefit category, statutory exclusion, or coding issue is in question, or send an ADR to the ordering provider in order to determine medical necessity. The contractor shall review information from the lab and find it insufficient before the ordering provider is contacted. The contractor shall send an ADR to the ordering provider that shall include sufficient information to identify the claim in question.

If the documentation received does not demonstrate that the service was reasonable and necessary, the contractor shall deny the claim. These denials count as medical record reviews. Contractor denial notices shall remind providers that beneficiaries cannot be held liable for these denials unless they have received proper liability notification before services were rendered, as detailed in CMS Pub. IOM 100-04, chapter 30.

3.2.3.8 - No Response or Insufficient Response to Additional Documentation Requests

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, RACs, CERT, SMRC, and UPICs, as indicated.

A. Additional Documentation Requests

The reviewer authority to request that documentation be submitted, to support claims payment, is outlined in Section 3.2.3.2 of this chapter.

If information is requested from both the billing provider or supplier and/or a third party and no response is received within the expected timeframes (or within a reasonable time following an extension), the MACs, RACs, SMRC, and UPICs shall deny the claim, in full or in part, as not reasonable and necessary. Contractors shall use Group Code: CO - Contractual Obligation and Claim Adjustment Reason Code (CARC) 50 - these are non-covered services because this is not deemed a "medical necessity" by the payer and Remittance Advice Remark Code (RARC) M127 - Missing patient medical record for this service.

MACs shall count these denials as automated review or non-medical record review depending whether the denial is automated or requires manual intervention. For claims that had a PWK modifier, and the unsolicited documentation was reviewed, the review shall be counted as medical record review.

B. No Response

During prepayment review, if no response is received within the expected timeframes, the MACs and UPICs shall deny the claim.

During post-payment review, if no response is received within the expected timeframes (or extension), the MACs, RACs, UPICs and SMRC shall deny the claim as not reasonable and necessary. These contractors shall cite sections 1815(a), 1833(e), and 1862(a)(1)(A) of the Act exclusively when referring to the authority for requiring submission of documentation, when denying claims for no response within the expected timeframes. The MACs shall count these denials as non-medical record reviews.

C. Insufficient Response

If the MAC, CERT, RAC, SMRC, or UPIC requests additional documentation to verify compliance with a benefit category requirement, and the submitted documentation lacks evidence that the benefit category requirements were met, the reviewer shall issue a benefit category denial. If the submitted documentation includes defective information (the documentation does not support the physician's certification), the reviewer shall deny the claim as not meeting the reasonable and necessary criteria.

3.2.3.9 - Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

Contractors shall make available general reopening process information via their website, in their ADR letters, or through remittance advice notices.

If the MACs receive the requested information from a provider or supplier after a denial has been issued but within a reasonable number of days (generally 15 calendar days after the denial date), they have the discretion to reopen the claim. MACs who choose to reopen a specific claim shall notify the provider or supplier of their intent to reopen that claim. Notification to the provider/supplier of the intent to reopen a specific claim shall be completed through any of the following mechanisms: Interactive Voice Response (IVR), contractor website portal, telephone contact, by letter, fax, email or secure messaging within 3 business days of identification of the request to reopen or receipt of medical record documentation. MR will make an MR determination on the lines previously denied due to failure to submit requested documentation, and do one of the following, within 60 calendar days of receiving documentation in the mailroom:

- For claims originally selected for postpayment review, the reviewer shall issue a new letter containing the revised denial reason and the information required by PIM chapter 3 §3.6.4;

- For claims originally selected for prepayment review, the MAC shall enter the revised MR determination into the shared system, generating a new Medicare Summary Notice (MSN) and remittance advice with the new denial reason and appeals information;

- The workload, costs, and savings associated with this activity shall be allocated to the appropriate MR activity (e.g., MR reopenings);

In cases where the MAC or UPIC denied a claim and the denial is appealed, the appeals entity will send the claim to the contractor's MR department for reopening in accordance with CMS Pub. IOM 100-04, chapter 34, § 10.3. The claim sent back to the contractor's MR department must have been denied using Group Code: CO - Contractual Obligation and Claim Adjustment Reason Code (CARC) 50 - these are non-covered services because this is not deemed a "medical necessity" by the payer and Remittance Advice Remark Code (RARC) M127 - Missing patient medical record for this service.

The MR department of the contractor (AC, MAC, or UPIC) who initiated the prepayment edit shall be responsible for conducting the reopening.

- The MACs who choose not to reopen claims when documentation is received past the deadline shall retain the information (hardcopy or electronic) in a location where it can be easily accessed.

If the RAC receives requested documentation from a supplier after a denial has been issued they shall not reopen the claim.

- If a RAC receives documentation after the submission deadline, but before they have issued a demand letter, the RAC shall review and consider the late documentation when making a claim determination;

- If the RAC receives a late response to a documentation request after they have issued a demand letter, the RAC shall retain the documentation so that it is available for review during the appeal process.

For information on how CERT handles late documentation, please refer to Chapter 12, Section 12.3.9.

3.2.3.10 - Record Retention and Storage
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The MACs, CERT, and UPICs shall abide by all documentation retention requirements listed in all litigation holds issued via Joint Signature Memoranda or Technical Direction Letters (JSM/TDL). Recovery Auditors shall comply with the record retention requirements in its SOWs.

3.2.4 - Use of Claims History Information in Claim Payment Determinations
(Rev. 802; Issued: 06-22-18; Effective: 07-24-18; Implementation: 07-24-18)

A. Contractors to Which This Section Applies

This section applies to MACs, CERT, SMRC, and RACs.

B. General

In certain circumstances it may be appropriate for medical reviewers to use relevant and accessible claims history to assist in making medical record review determinations. Examples of when this may be used for payment purposes, include, but are not limited to:

1. Reviewers have the discretion to use beneficiary payment history to identify other providers, other than the billing entity, who may have documentation to support payment of a claim. MAC, CERT and RAC reviewers have the discretion to contact identified providers for supporting documentation. Example: A diabetic beneficiary may have an order from a family practitioner but is also seeing an endocrinologist. The documentation from the family practitioner does not support the level of diabetic testing, but medical records from the endocrinologist do support the level of testing.

2. Reviewers have the discretion to use claims history information to document an event, such as a surgical procedure, that supports the need for a service or item billed in limited circumstances. In some cases, this event occurs a number of years prior to the date of service on the claim being reviewed, making it difficult to collect medical record documentation. If repeated attempts to collect medical record of the event are unsuccessful, contractors have the discretion to consider claims history information as documentation of the event. Contractors shall document their repeated attempts to collect the medical record if they chose to consider claims history information as documentation of the event. Example: A beneficiary is eligible for immunosuppressant drugs only if they received an organ transplant. Patients generally remain on these life-saving drugs for the rest of their life so it is possible for the transplant to have occurred many years prior to the date of service being reviewed. If there was no record of the transplant in the medical documentation provided by the ordering physician, the contractor may use claims history to validate the transplant occurred.

3. Reviewers shall use claims history information to verify that the frequency or quantity of supplies provided to a beneficiary do not exceed policy guidelines.

4. Reviewers shall use claims history information to identify duplication and overutilization of services.

3.2.5 - Targeted Probe and Educate (TPE)

(Rev. 10132; Issued: 05-15-2020; Effective: 06-16-2020; Implementation: 06-16-2020)

This section applies to MACs.

A. Overview

The purpose of Targeted Probe and Educate (TPE) is to decrease provider burden, reduce appeals, and improve the medical review/education process.

This section describes requirements that MACs shall follow when performing medical review as part of TPE.

TPE reviews can be either prepayment or postpayment and involve MACs focusing on specific providers/suppliers that bill a particular item or service.

A round of TPE typically involves the review of 20-40 claims, per provider/supplier, per service/item, and corresponding education. In rare circumstances, CMS may approve a probe sample of other than 20-40 claims. This process is typically repeated for up to three rounds, but may involve additional rounds at CMS direction. MACs discontinue the process if/when providers/suppliers become compliant. Providers/suppliers who remain non-compliant after three rounds of TPE are referred to CMS for further action.

B. Provider Selection

The MACs shall initiate a provider-specific, prepayment or postpayment review based upon data analysis, as discussed in §3.2.1. MACs shall also initiate targeted, provider-specific, prepayment or postpayment review upon referral from the Recovery Auditor Contractor (RAC), Comprehensive Error Rate Testing (CERT), Unified Program Integrity Contractor (UPIC), Office of Inspector General (OIG), or Government Accountability Office (GAO) when directed by CMS. MACs shall target providers/suppliers who have historically high claim denial rates, who have billing practices that vary from their peers, or when evidence suggests that there is a potential risk to the Medicare Trust Fund.

Probe Selection

The MACs shall select probe samples of typically 20-40 claims. Probe samples of different sizes may be deemed appropriate on a case-by-case basis, with approval by CMS.

Provider Notification Letter

The MACs shall send a notification letter to providers/suppliers being targeted for review that:

- Outlines the targeted probe & educate process,
- Explains the process by which providers/suppliers will be able to receive one-on-one education and the types of education that will be available,
- Notifies providers/suppliers that MACs shall have the option to refer providers/suppliers to the RAC or UPIC as a result of non-response to Additional Development Requests (ADRs), and
- Includes the following language to remind providers of 42 CFR §424.535

"In addition, we remind you that the regulation at 42 CFR §424.535 authorizes us to revoke Medicare billing privileges under certain conditions. In particular, we note that per 42 CFR §424.535(a)(8)(ii), CMS has the authority to revoke a currently enrolled provider or supplier's Medicare billing privileges if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements."

C. TPE One-On-One Education

For the TPE process, one-on-one education is defined as teleconference calls, face-to-face visits, electronic visits using webinar technology, or other similar technologies that enable direct communication between the MAC educator and the provider/supplier. MACs shall record these activities in monthly reporting to CMS as well as document and maintain the results of the education, and/or attempts for education, for data analysis and possible future reporting.

Intra-Probe Education

The MAC may identify errors in the claim(s) that can be easily resolved during the course of provider's/supplier's probe reviews. Easily curable errors include, but are not limited to, missing documentation that can be resolved through the submission of additional documentation and missing signatures that can be resolved with a signature attestation. When the MAC identifies an easily curable error, the MAC shall contact the provider to address the error and allow the provider to submit missing documentation, etc.

Post-Probe Education

The MAC shall contact the provider/supplier via telephone (or face-to-face, electronic visits using webinar technology, or other similar technologies as they become available) to offer a one-on-one educational session after each round of probe review. If the provider/supplier declines the offer for one-on-one education, MACs shall maintain a record of the effort and the reason for denial. The purpose of this one-on-one education is to:

1) Alert the provider of errors identified and how they may be resolved for future claim submissions; and
2) Provide education regarding the review topic to help prevent new issues from arising during future rounds of review. This post-probe one-on-one education should be individualized, claims-specific, and conducted in a format that is interactive, allowing the provider/supplier to ask questions as needed.

The MAC shall provide a minimum of 45 days after each post-probe educational session, before selecting new claims for review, to allow time for the provider/supplier to cure identified errors.

D. Post-Probe Activity

Final Results Letter

The MAC shall send the provider/supplier a letter detailing the results of the claims reviewed at the conclusion of each round of review. The MAC shall include details regarding the provider's/supplier's specific claim errors. For providers/suppliers who will be released from review due to meeting the established error rate goal, results letters shall indicate that the provider is being released from review for one year, with the caveat that additional review may occur at any time should the MAC identified changes in billing pattern. For providers/suppliers who continue to have high error rates after three rounds of TPE review, results letters shall indicate that they have not met the established goal error rate and will be referred to CMS for additional action, which may include additional rounds of TPE review, 100 percent prepayment review, extrapolation, referral to a Recovery Auditor, and/or referral for revocation. Additionally, the letter shall include the following language to remind providers of 42 CFR §424.535.

> "In addition, we remind you that the regulation at 42 CFR §424.535 authorizes us to revoke Medicare billing privileges under certain conditions. In particular, we note that per 42 CFR §424.535(a)(8)(ii), CMS has the authority to revoke a currently enrolled provider or supplier's Medicare billing privileges if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements."

Determining the Need for Additional TPE

The MAC shall calculate the provider/supplier claim error rate and payment error rate at the conclusion of each round of TPE. The MAC shall use the provider/supplier error rate to determine whether an additional round of TPE is appropriate.

Closure and Monitoring

A provider/supplier may be removed from TPE after any round if they demonstrate low error rates or sufficient improvement in error rates, as determined by the MAC. MACs shall use data analysis to monitor the providers/suppliers who have been discontinued from the TPE process. MACs shall conduct follow-up review in one year or sooner if data analysis indicates changes in billing patterns or when potential risk to the Medicare Trust Fund is identified.

E. Referrals

If a provider/supplier continues to have a high error rate at the conclusion of three rounds of TPE, the MAC shall refer to CMS for further action. Referrals shall include details regarding the reason the provider/supplier was selected for TPE review, TPE review results, results of appealed denials (to the extent available at the time of referral), any education provided (or offered and refused), and any other relevant information that may be helpful in determining appropriate next steps.

The MAC shall refer suspected fraudulent providers to the UPIC at any time during the TPE process.

F. Next Steps

Once the MAC refers a provider/supplier to CMS, details are reviewed to determine if additional action must be taken by the MAC. Additional actions that may be required include, but are not limited to, additional rounds of TPE review, 100 percent prepayment review, extrapolation, referral to a Recovery Auditor, and/or referral for revocation. If CMS directs the MAC to conduct an additional round of TPE review, the MAC shall send the provider/supplier a notification letter indicating that an additional round of review is required. These reviews shall be of claims with dates of service at least 45 days after the prior round's post probe education and after the provider/supplier has received the aforementioned notification letter.

3.3 – Policies and Guidelines Applied During Review
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors, Supplemental Medical Review Contractors (SMRCs) and UPICs, as indicated.

A. Statutes, Regulations, the CMS' Rulings, National Coverage Determinations, Coverage Provisions in Interpretive Medicare Manuals, and Local Coverage Determinations

The primary authority for all coverage provisions and subsequent policies is the Social Security Act. In general, MACs, CERT, Recovery Auditors, SMRCs, and UPICs shall apply the provisions of the Act according to the following hierarchy of documents in effect at the time the item(s) or service(s) was provided to make medical review decisions:

Social Security Act
Code of
Federal Regulations CMS'
Rulings
National Coverage Determination (NCDs)
Coverage provisions in Interpretive Manuals or Internet Only Manuals (IOM) which includes Medical Review Guidance in the Medicare Program Integrity Manual
CMS coding policies
Technical Direction Letters (TDLs)* The relevant MAC's Local Coverage Determination (LCDs) The relevant MAC's local articles
AHA Coding Clinics.

*TDLs that contain MR guidance may provide an exception to this hierarchy.

B. Coding Guidelines

The MACs, CERT, Recovery Auditors, and UPICs shall apply coding guidelines to services selected for review. All contractors shall determine that an item/service is correctly coded when it meets all the coding guidelines listed in the Current Procedural Terminology-4 (CPT) book, International Classification of Diseases Guidelines (ICD), CMS HCPCS or ICD policy or guideline requirements, LCDs, or MAC articles.

C. Internal Medical Review Guidelines

The MAC, CERT, Recovery Auditor, and UPIC staffs have the discretion to develop detailed written review guidelines to guide staff during claim reviews. Internal MR guidelines shall specify the information to be reviewed by reviewers and the appropriate resulting determination. Recovery Auditors are required to develop written review

guidelines in accordance with their SOW. The MACs, CERT, Recovery Auditors, and UPICs shall make their internal MR guidelines available to their staff, as needed. Internal MR Guidelines shall not create or change the CMS policy.

3.3.1 - Types of Review: Medical Record Review, Non-Medical Record Review, and Automated Review

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, SMRC, and UPICs, as indicated.

A. General

Most of the claim review activities completed for the purpose of identifying inappropriate billing and avoiding improper payments are divided into three distinct types: Medical Record Review, Non-Medical Record Review, and Automated Review.

The chart below indicates which contractors perform which types of review:

	Prepayment			Postpayment	
Contractor Type	Medical Record Review	Non-Medical Record Review	Automated Reviews	Medical Record Review	Non-Medical Record review
MACs	Yes	Yes	Yes	Yes	Yes
CERT	No	No	No	Yes	No
RACs	No	No	No	Yes	No
SMRC	No	No	No	Yes	Yes
UPIC	Yes	No	No	Yes	Yes

3.3.1.1 - Medical Record Review

(Rev. 11529; Issued: 07-28-2022; Effective: 08-30-2022; Implementation: 08-30-2022)

This section applies to MACs, CERT, RACs, Supplemental Medical Review Contractor(s) and UPICs, as indicated.

A. Definition

Medical record review involves requesting, receiving, and reviewing medical documentation associated with a claim.

Medical record review, for the purpose of determining medical necessity, requires a licensed medical professional to use clinical review judgment to evaluate medical record documentation.

B. Clinical Review Judgment

Clinical review judgment involves two steps:

1. The synthesis of all submitted medical record information (e.g. progress notes, diagnostic findings, medications, nursing notes, etc.) to create a longitudinal clinical picture of the patient; and

2. The application of this clinical picture to the review criteria is to make a reviewer determination on whether the clinical requirements in the relevant policy have been met. MAC, CERT, RAC, and UPIC clinical review staff shall use clinical review judgment when making medical record review determinations about a claim.

   Clinical review judgment does not replace poor or inadequate medical records. Clinical review judgment by definition is not a process that MACs, CERT, RACs and UPICs can use to override, supersede or disregard a policy requirement. Policies include laws, regulations, the CMS' rulings, manual instructions, MAC policy articles attached to an LCD or listed in the Medicare Coverage Database, national coverage decisions, and local coverage determinations.

C. Credentials of Reviewers

The MACs, MRAC, and CERT shall ensure that medical record reviews for the purpose of making coverage determinations are performed by licensed nurses (RNs), therapists or physicians. Current LPNs may be grandfathered in and can continue to perform medical record review. The MACs, MRAC, and CERT shall not hire any new LPNs to perform medical record review. UPICs, RACs and the SMRC shall ensure that the credentials of their reviewers are consistent with the requirements in their respective SOWs.

During a medical record review, nurse and physician reviewers may call upon other health care professionals (e.g., dieticians or physician specialists) for advice. The MACs, MRAC, and CERT, shall ensure that services reviewed by other licensed health care professionals are within their scope of practice and that their MR strategy supports the need for their specialized expertise in the adjudication of particular claim type (i.e., speech therapy claim, physical therapy). RACs and the SMRC shall follow guidance related to calling upon other healthcare professionals as outlined in their respective SOWs.

RACs shall ensure that a licensed medical professional will perform medical record reviews for the purpose of determining medical necessity, using their clinical review judgment to evaluate medical record documentation. Certified coders will perform coding determinations. CERT and MACs are encouraged to make coding determinations by using certified coders. UPICs have the discretion to make coding determinations using certified coders.

D. Credential Files

The MACs, MRAC, CERT, RACs, and UPICs shall maintain a credentials file for each reviewer (including consultants, contract staff, subcontractors, and temporary staff) who performs medical record reviews. The credentials file shall contain at least a copy of the reviewer's active professional license.

E. Quality Improvement (QI) Process

The MACs, CERT, RACs, and SMRCs shall establish a Quality Improvement (QI) process that verifies the accuracy of MR decisions made by licensed health care professionals. The MACs, CERT, RACs, and SMRCs shall attend the annual medical review training conference as directed by the CMS and/or their SOW. The MACs, CERT, RACs, and SMRCs shall include inter-rater reliability assessments in their QI process and shall report these results as directed by CMS.

F. Advanced Beneficiary Notice (ABN)

The MACs, CERT, RACs, UPICs, and SMRCs shall request as part of the ADR, during a medical record review, a copy of any mandatory ABNs, as defined in Pub. 100- 04, Medicare Claims Processing Manual Chapter 30 section 50.3.1. If the claim is determined not to be reasonable and necessary, the contractor will perform a face validity assessment of the ABN in accordance with the instructions stated in Pub. 100-04 Medicare Claims Processing Manual chapter 30 section 50.6.3.

The Face Validity assessments do not include contacting beneficiaries or providers to ensure the accuracy or authenticity of the information. Face Validity assessments will assist in ensuring that liability is assigned in accordance with the Limitations of Liability Provisions of section 1879 of the Social Security Act.

G. MAC Funding Issues

The MAC-medical record review work performed by medical review staff for purposes other than MR (e.g., appeals) shall be charged, for expenditure reporting purposes, to the area requiring medical review services.

All medical record review work performed by MACs shall:

- Involve activities defined under the Medicare Integrity Program (MIP) at Section 1893(b)(1) of the Act;
- Be articulated in its medical review strategy; and
- Be designed in such a way as to reduce its Comprehensive Error Rate Testing (CERT) error rate or prevent the contractor's error rate from increasing.

The MACs shall be mindful that edits suspending a claim for medical review to check for

issues other than inappropriate billing (i.e. completeness of claims, conditions of participation, quality of care) are not medical review edits as defined under Section 1893(b)(1) of the Act and cannot be funded by MIP. Therefore, edits resulting in work other than that defined in Section1893 (b) (1) shall be charged to the appropriate Program Management activity cost center. Activities associated with claims processing edits shall not be charged to MIP.

H. Review Timeliness Requirements

Prepayment Review Requirements for MACs

When a MAC receives requested documentation for prepayment review within 45 calendar days of the date of the ADR, the MAC shall do the following within 30 calendar days of receiving the requested documentation: 1) make and document the review determination and 2) enter the decision into the Fiscal Intermediary Shared System (FISS), Multi-Carrier System (MCS), or the VIPS Medicare System (VMS). The 30 calendar day timeframe applies to prepayment non-medical record reviews and prepayment medical record reviews. The 30 calendar day timeframe does not apply to prepayment reviews of Third Party Liability claims. The MACs shall make and enter a review determination for Third Party Liability claims within 60 calendar days.

Counting the 30 Calendar Day Timeframe

The MACs and RACs shall count day one as the date each new medical record is received in the mailroom. The MACs and RACs shall give each new medical record received an independent 30 day review time period.

Prepayment Review Requirements for UPICs

When a UPIC receives all documentation requested for prepayment review within 45 calendar days of the date of the ADR, the UPIC shall make and document the review determination and notify the MAC of its determination within 60 calendar days of receiving all requested documentation. Medical review for the purpose of fraud, waste, or abuse requires 60 days to allow for the integration of information from the investigative process. This information may be a result of recent/concurrent investigative actions such as beneficiary/provider/supplier interviews, site visits and/or receipt of additional internal/external information.

Post-payment Review Requirements for MACs

The MAC shall make a review determination, and mail the review results notification letter to the provider within 60 calendar days of receiving the requested documentation.

For claims associated with any referrals to the UPIC for program integrity investigation, MACs shall stop counting the 60-day time period on the date the referral is made. The 60-day time period will be restarted on the date the MAC received requested input from

the UPIC or is notified by the UPIC that the referral has been declined.

For claims sent to MR for reopening by the contractor appeals department, in accordance with Pub. 100-04, chapter 34, §10.3, begin counting the 60 days from the time the medical records are received in the MR department.

Post-payment Review Requirements for RACs

When a RAC receives requested documentation for review within 45 calendar days of the date of the ADR, the RAC shall do the following within 30 calendar days of receiving the requested documentation: 1) make and document the review determination, and 2) communicate the results to the provider.

State Laws that Affect Prepayment Review Timeliness Requirements

The MACs shall adhere to state laws that require an evidentiary hearing for the beneficiary before any denials are processed. The MAC shall review the claim within 30 days, allow the time required for the evidentiary hearing, and then continue with the processing of the claim on the next business day.

Post-payment Review Requirements for UPICs

To promote the timeliness of the investigative process, the UPICs shall complete post-payment medical review and provide the lead investigator with a final summary of the medical review findings that includes reference to the allegations being substantiated/not substantiated by medical review, reasons for denials, and any observations or trends noted within 60 calendar days, unless otherwise directed by CMS. The counting for the 60-day time period begins when all of the documentation is received by the UPIC. The UPIC shall have a HIPAA compliant process to receive this documentation that includes the application of the date the documents are received at the UPIC's designated mailing address for all methods described in section 3.2.3.5 of this chapter. The medical review unit shall communicate the medical review findings in a summary document to the investigative lead within 60 calendar days of receiving all of the requested documentation. Medical review for the purpose of fraud, waste, or abuse requires 60 days to allow for the integration of information from the investigative process. This information may be a result of recent/concurrent investigative actions such as beneficiary/provider/supplier interviews, site visits and/or receipt of additional internal/external information.

If the UPIC is unable to complete the post-payment medical review in 60 days, they shall document this and the reason for the delay in the UCM, and communicate this to their COR.

3.3.1.2 - Non-Medical Record Review

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, SMRC, and UPICs, as indicated.

A. Definition

Non-medical record reviews uses manual intervention, but only to the extent a reviewer can make a determination based on information on a claim. It does not require clinical judgment in review of medical record documentation. Contractors shall only perform a non-medical record review for denials of related claims and/or no receipt of ADR documentation where such denials cannot be automated.

3.3.1.3 - Automated Review

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

A. Definition

A medical review is considered automated when a payment decision is made at the system level, using available electronic information, with no manual intervention.

CERT refers to all reviews where no documentation was requested as "T-claim review." T-claims are a particular category of claim reviewed by CERT. T-claims are claims that were automatically denied by the MAC.

B. Basis for Automated Reviews

The MAC, RAC, CERT, SMRC, and UPIC shall ensure that automated prepayment and postpayment denials are based on clear policy that serves as the basis for denial; or a Medically Unlikely Edit (MUE); or occurs when no timely response is received to an ADR.

When a clear policy exists (or in the case of a MUE), MACs, RACs, SMRC, and UPICs have the discretion to automatically deny the services without stopping the claim for manual review, even if documentation is attached or simultaneously submitted. Reviewers shall still make a determination based on the liability limitations of §1879 of the Act. The term "clear policy" means a statute, regulation, NCD, coverage provision in an interpretive manual, coding guideline, LCD or MAC article that specifies the circumstances under which a service will always be considered non-covered, incorrectly coded, or improperly billed.

A MUE is a unit of service (UOS) edit for a Healthcare Common Procedure Coding system (HCPCS)/Current Procedural Terminology (CPT) code for services rendered by a single provider/supplier to a single beneficiary on the same date of service. The ideal MUE is the maximum UOS that would be reported for a HCPCS/CPT code on the vast majority of appropriately reported claims. The MUE program provides a method to report medically reasonable and necessary UOS in excess of a MUE.

Automated edits can be used for apparent typographical errors (e.g., 10,000 blood

cultures for the same beneficiary on the same day).

MACs shall implement automated prepayment review whenever appropriate.

The RACs refer to all reviews where no documentation was requested as "automated review."

3.3.2 - Medical Review Guidance
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors, and UPICs, as indicated.

This section describes the requirements that MACs, CERT, Recovery Auditors, and UPICs shall follow when reviewing submitted documentation. Additional requirements for UPICs are located in PIM chapter 4. When UPIC staff is performing benefit integrity reviews, their focus is different than that of MACs, CERT, and Recovery Auditors. For example, UPIC staff looks for some of the following situations when reviewing documentation:

- Possible falsification or other evidence of alterations including, but not limited to: obliterated sections; missing pages, inserted pages, white out; and excessive late entries;
- Evidence that the service billed for was actually provided; or,
- Patterns and trends that may indicate potential fraud.

3.3.2.1 - Documents on Which to Base a Determination
(Rev. 802; Issued: 06-22-18; Effective: 07-24-18; Implementation: 07-24-18)

This section applies to MACs, CERT, RACs, SMRC and UPICs, as indicated.

The MACs, CERT, RACs, SMRC, and UPICs shall review any information necessary to make a prepayment and/or postpayment claim determination, unless otherwise directed in this manual. This includes reviewing any documentation submitted with the claim and any other documentation subsequently requested from the provider or other entity when necessary. In certain circumstances it may be appropriate for medical reviewers to consider relevant and accessible billing history or other information obtained from the Common Working File (in limited circumstances), outcome assessment and information set (OASIS), or the minimum data set (MDS), among others. For Medicare to consider coverage and payment for any item or service, the information submitted by the supplier or provider must corroborate the documentation in the beneficiary's medical documentation and confirm that Medicare coverage criteria have been met.

3.3.2.1.1 - Progress Notes and Templates
(Rev. 833; Issued: 10-12-18; Effective: 11-13-18; Implementation: 11-13-18)

A. Definitions

For the purposes of Section 3.3.2.1.1, the following definitions apply:

1. "Progress Notes" -- visit notes, encounter notes, Evaluation and Management documentation, office notes, face-to-face evaluation notes or any other type of record of the services provided by a physician or other licensed/certified medical professional (LCMP) in the medical record. Progress notes may be in any form or format, hardcopy or electronic.

2. "Template" -- a tool/instrument/interface that assists in documenting a progress note. Templates may be paper or electronic.

Electronic records may involve any type of interface including but not limited to:

simple electronic documents,

sophisticated graphical user interfaces (GUIs) with clinical decision and documentation support prompts, or

electronic pen capture devices.

“Licensed/Certified Medical Professional (LCMP)” – Medical professional licensed or certified to practice in the state in which services are rendered. For the purposes of documenting DMEPOS items, the physician or LCMP must not have a financial relationship with the DMEPOS supplier.

B. Guidelines Regarding Which Documents Review Contractors Will Consider

The review contractor shall consider all medical record entries made by physicians and LCMPs. See PIM 3.3.2.5 regarding consideration of Amendments, Corrections and Delayed Entries in Medical Documentation.

The amount of necessary clinical information needed to demonstrate that all coverage and coding requirements are met will vary depending on the item/service. See the applicable National and Local Coverage Determination for further details.

CMS does not prohibit the use of templates to facilitate record-keeping. CMS also does not endorse or approve any particular templates except for the clinical templates it publishes on its website. A physician/LCMP may choose any template to assist in documenting medical information. Contractors shall consider information captured in templates when conducting medical review.

Some templates provide limited options and/or space for the collection of information such as by using "check boxes," predefined answers, limited space to enter information, etc. CMS discourages the use of such templates. Claim review experience shows that that limited space templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met.

Physician/LCMPs should be aware that templates designed to gather selected information focused primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. This is often because these documents generally do not provide sufficient information to adequately show that the medical necessity criteria for the item/service are met.

If a physician/LCMP chooses to use a template during the patient visit, CMS encourages them to **select one that allows for a full and complete collection of information** to demonstrate that the applicable coverage and coding criteria are met.

Certificates of Medical Necessity (CMN), DME Information Forms (DIF), supplier prepared statements and physician attestations by themselves do NOT provide sufficient documentation of medical necessity, even if signed by the signed by the ordering physician.. See PIM §5.7 for additional information on documentation.

C. Financial Liability

The physician/LCMP should be aware that inadequate medical record documentation can lead to a financial liability for the Beneficiary and/or Supplier, should the reviewer determine that a claim is not supported.

In addition, the physician/LCMP should be aware that when ordering an item or service that will be furnished by another entity, Section 1842(p)(4) of the Social Security Act requires that adequate documentation supporting medical necessity be provided to the entity at the time that the item or service is ordered. Physicians/LCMPs who fail submit documentation upon a supplier's request may trigger increased MAC or RAC review of the physician/LCMP's evaluation and management services.

3.3.2.1.2 –DMEPOS Orders

(Rev. 10190; Issued: 06-19-2020, Effective: 01-01-2020; Implementation: 07-01-2020)

Totality of the Record

All DMEPOS items require a Standard Written Order (SWO) from the treating practitioner as a condition of payment. Medicare contractors shall consider the totality of the medical record when reviewing for compliance of the SWO elements. This will allow contractors to account for the dynamic nature of electronic medical record documentation systems, and give them additional discretion when they believe the entirety of the record demonstrates compliance with our order requirements. For example, a contractor may

nonetheless support payment when an order has a missing or flawed element that is clearly documented elsewhere in the record.

Contractors acting as a secondary reviewer shall grant deference to the initial reviewer's discretion, if such an initial decision resulted in a reasonably prudent decision that aligns with Medicare coverage and coding instructions.

3.3.2.2 - Absolute Words and Prerequisite Therapies
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors, and UPICs, as indicated.

The MACs, CERT, Recovery Auditors, and UPICs shall not deviate from coverage provisions if absolute words such as "never" or "only if" are used when making claim determinations where a regulation, CMS ruling, NCD, LCD, or MAC policy article exists. In these cases, reviewers shall not make any exceptions or give individual consideration.

Requirements for prerequisite therapies shall be followed when deciding whether to cover a service if listed in coverage provisions in interpretive manuals (e.g., "conservative treatment has been tried, but failed").

3.3.2.3 - Mandatory Policy Provisions
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, Recovery Auditors, CERT and UPICs, as indicated.

CERT contractors select claims for review on a random basis and do not select claims that are suspect. The CERT reviewers shall review every line on the randomly selected claim that affects payment to determine if the following types of requirements are met:

- Coding requirements;
- Benefit category requirements;
- The reasonable and necessary requirements of the NCDs and LCDs, among others.

The MACs and UPICs select claims to prevent or identify an improper payment. They are only required to review the suspect line and not every line on the selected claims. The selected line does not need to be completely reviewed. Along with reviewing the line for coding accuracy, the MACs should review for medical necessity if the provider has been notified that both types of review will occur. The UPICs shall use discretion in notifying the provider.

3.3.2.4 - Signature Requirements
(Rev. 12633; Issued: 05-09-24: Effective: 06-10-24; Implementation: 06-10-24)

This section is applicable for Medicare Administrative Contractors (MACs), Unified Program Integrity Contractors (UPICs), Supplemental Medical Review Contractors (SMRCs), Comprehensive Error Rate Testing (CERT), and Recovery Audit Contractors (RACs), as indicated.

For medical review purposes, Medicare requires that the person(s) responsible for the care of the beneficiary*, including providing/ordering/certifying items/services for the beneficiary, be identifiable as such in accordance with Medicare billing and coverage policies, such as the Social Security Act §1815(a) and §1833(e). Medicare contractors shall consider the totality of the medical record when reviewing for compliance with the above.*

Signatures are required upon medical review for two distinct purposes:

1. *To satisfy specific signature requirements in statute, regulation, national coverage determination (NCD) or local coverage determination (LCD); and*
2. *To resolve authenticity concerns related to legitimacy or falsity of the documentation.*

*If a signature **is** required per statute, regulation, NCD or LCD:*

- *Contractors shall use the totality of the record to determine if the signature requirement, as outlined in statute, regulation, NCD, LCD is met.*
- *If the signature requirement is not met, and it is not an instance in which the statute, regulation or NCD/LCD policy indicate that a signature must be in place prior to a given event or a given date, the attestation process may be used to try and resolve the issue. If the attestation process does not resolve the issue, the contractor may pursue a denial and/or any other appropriate corrective actions.*
- *If the signature requirement is not met because the signature is illegible, the signature log process may be used to try and resolve the issue.*

*If signature **is not** required per statute, regulation, NCD, or LCD:*

- *Contractors shall determine if the signature is necessary to identify the author of the record for the purposes of authenticity.*
    - *If not, the contractor shall disregard the missing or illegible signature and continue their review of all medical documentation to determine if the claim meets coverage, coding, and billing requirements.*
    - *If there is not an explicit signature requirement, but in the Contractor's review of the totality of the record they have authenticity concerns related to the legitimacy or falsity of the*

documentation, they shall pursue the attestation, signature log, denial, and/or fraud referral process, as appropriate.

NOTE: If review contractors find reasons for denial unrelated to signature requirements, the reviewer need not proceed to signature authentication.

NOTE: When a scribe is used by a provider in documenting medical record entries (e.g., progress notes), CMS does not require the scribe to sign/date the documentation. The treating physician/non-physician practitioner's (NPP's) signature on a note indicates that the physician/NPP affirms the note adequately documents the care provided.

NOTE: Conditions of participation (COP) are not conditions of payment.

A. Handwritten Signature

A handwritten signature is a mark or sign by an individual on a document signifying knowledge, approval, acceptance, or obligation.

***NOTE**: Stamped signatures are not typically acceptable. CMS permits use of a rubber stamp for signature in accordance with the Rehabilitation Act of 1973 in the case of an author with a physical disability that can provide proof to a CMS contractor of his/her inability to sign their signature due to their disability. By affixing the rubber stamp, the provider is certifying that they have reviewed the document.*

B. Electronic Signatures

Providers using electronic systems shall recognize there is a potential for misuse or abuse with alternate signature methods. For example, providers need a system and software products that are protected against modification, etc., and should apply adequate administrative procedures that correspond to recognized standards and laws. The individual whose name is on the alternate signature method and the provider bear the responsibility for the authenticity of the information for which an attestation has been provided. Physicians are encouraged to check with their attorneys and malpractice insurers concerning the use of alternative signature methods.

C. Signature Log

Providers will sometimes include a signature log in the documentation they submit that lists the typed or printed name of the author associated with initials or illegible signature. The signature log might be included on the actual page where the initials or illegible signature are used or might be a separate document. Reviewers should encourage providers to list their credentials in the log. However, reviewers shall not deny a claim for a signature log that is missing credentials. Reviewers shall consider all submitted signature logs regardless of the date they were created. Reviewers are encouraged to file signature logs in an easily accessible manner to minimize the cost of future reviews where the signature log may be needed again.

D. Signature Attestation Statement

Providers will sometimes include an attestation statement in the documentation they submit. *T*o be considered valid for Medicare medical review purposes, an attestation statement must be signed and dated by the author of the medical record entry and must contain sufficient information to identify the beneficiary.

Should a provider choose to submit an attestation statement, they may choose to use the following statement:

"I, [print full name of the physician/practitioner], hereby attest that the medical record entry for [date of service] accurately reflects signatures/notations that I made in my capacity as [insert provider credentials, e.g., M.D.] when I treated/diagnosed the above listed Medicare beneficiary. I do hereby attest that this information is true, accurate and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact may subject me to administrative, civil, or criminal liability."

Although this format is acceptable, the CMS currently neither requires nor instructs providers to use a certain form or format. A general request for signature attestation shall be considered a non-standardized follow-up question from the contractors to the providers.

In situations where the contractor identifies the need for an attestation (to fulfill a requirement or for authenticity purposes), the contractor shall ask if the billing entity would like to submit an attestation statement or signature log within 20-calendar days. (We note that this timeframe does not apply to the CERT contractor(s)). The 20-calendar day timeframe begins on the date of the telephone contact with the provider or on the date the request letter is received by the provider. Note: if sent via a mail courier without receipt notification, the contractor shall use the sent date plus anticipated mail processing timeframes to calculate. If the biller submits a signature log or attestation that resolves the signature issue, the reviewer shall consider the contents of the medical record entry.

In cases where a reviewer has requested a signature attestation or log, the time for completing the review is extended by 15-calendar days. (We note that this timeframe does not apply to the CERT contractor(s)). This extension starts upon receipt of the signature attestation or log.

The review contractors shall document all contacts with the provider and/or other efforts to authenticate the signature.

Note: *Contractors* shall NOT consider attestation statements where there is no associated medical record entry. Reviewers shall NOT consider attestation statements from someone

other than the author of the medical record entry in question (even in cases where two individuals are in the same group, one should not sign for the other in medical record entries or attestation statements). Reviewers shall consider all attestations that meet the above requirements regardless of the date the attestation was created, except in those cases where the regulations or policy indicate that a signature must be in place prior to a given event or a given date. For example, if a *statute, regulation, NCD or LCD* states the physician must sign the plan of care before therapy begins, an attestation can be used to clarify the identity associated with an illegible signature. However, such attestation cannot be used to "backdate" the plan of care.

E. Signature Dating Requirements

For medical review purposes, if the relevant *statute,* regulation, NCD, *and* LCD are silent on whether the signature must be dated, the *review contractors* shall ensure that the documentation contains enough information for the reviewer to determine the date on which the service was performed/ordered.

Example:

> The claim selected for review is for a hospital visit on October 4*th*. The ADR response is one page *in length and comes* from the hospital medical record containing three (3) entries. The first entry is a *physical therapy note* dated October 4*th*. The second entry is a physician visit note that is undated *and t*he third entry is a nursing note dated October 4*th*. The reviewer should conclude that the physician visit was conducted on October 4*th*.

F. Potential Fraud Referrals

At any time, suspected fraud shall result in a referral to the UPIC for development. If MAC, RAC, SMRC or CERT reviewers identify missing/illegible signature*(s) that raise legitimacy or falsity concerns, the reviewer shall consider referring* to the appropriate UPIC for further development *and may consider referring to the Regional Office and State Agency.*

3.3.2.5 - Amendments, Corrections and Delayed Entries in Medical Documentation

(Rev. 12633; Issued: 05-09-24: Effective: 06-10-24; Implementation: 06-10-24)

This section applies to MACs, CERT, *RACs*, SMRC and UPICs, as indicated.

All services provided to beneficiaries are expected to be documented in the medical record at the time they are rendered. Occasionally, certain entries related to services provided may not be properly documented. In this scenario, the documentation may need to be amended, corrected, or entered after rendering the service. The date and author of any amendment,

correction or delayed entry should be identifiable, and the change/addenda should be clearly and permanently denoted. Contractors shall review any amendment, correction, or delayed entry in accordance with section 3.3.2.4 of this chapter.

If the MACs, CERT, SMRC or *RACs* identify medical documentation with potentially fraudulent entries, the reviewers shall refer the cases to the UPIC and may consider referring to the RO and State Agency.

3.3.2.6 - Psychotherapy Notes

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors or UPICs, as indicated.

Psychotherapy notes are defined in 45 CFR§164.501 as "notes recorded by a mental health professional which document or analyze the contents of a counseling session and that are separated from the rest of a medical record." The definition of psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of administered treatment, results of clinical tests, and any summary of diagnosis, functional status, treatment plan, symptoms prognosis, ongoing progress and progress to date. This class of information does not qualify as psychotherapy note material. Physically integrating information excluded from the definition of psychotherapy notes and protected information into one document or record does not transform the non-protected information into protected psychotherapy notes.

Under no circumstances shall the MACs, CERT, Recovery Auditors or UPICs request that a provider submit psychotherapy notes defined in 45 CFR §164.501. The refusal of a provider to submit such information shall not result in the automatic denial of a claim.

If the medical documentation includes any of the information included in the definition of psychotherapy notes in §164.501, as stated above, the provider is responsible for extracting information required to support that the claim is for reasonable and necessary services. MACs, Recovery Auditors, CERT or UPICs shall review the claim using the supporting documentation submitted by the provider. If the provider does not submit information sufficient to demonstrate that services were medically necessary, the claim shall be denied. Beneficiaries cannot be held liable for these denials unless they received proper liability notification before services were rendered, as detailed in CMS Pub. IOM, 100-04 chapter 30, §30.1.

3.3.2.7 - Review Guidelines for Therapy Services

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

Financial limitations on therapy services (therapy caps) were originally initiated by the Balanced Budget Act of 1997 and have been implemented at times without an exceptions process. During a time when no exceptions process exists, contractors shall deny claims for Part B occupational, physical, and speech-language pathology therapy services, except for hospital outpatient therapy services, which exceed the therapy cap. There is no therapy cap for hospital outpatient therapy services.

Automatic Process for Exception from the Therapy Cap

Section 1833(g)(5) of the Social Security Act provides that contractors shall, at the request of the individual enrolled under the Part B benefit or a person acting on behalf of that individual, grant an exception to the therapy cap in certain circumstances.

For therapy services provided during a time when a therapy cap exceptions process is in effect, the contractor shall presume the beneficiary to be excepted from the therapy cap without submission of request for exception or supporting documentation if:

- The beneficiary meets specific conditions listed in CMS Pub.100-04, chapter 5, §10.2 for exception from the therapy cap, or

- The beneficiary does not meet the specific criteria in CMS Pub.100-04, chapter 5, §10.2, but has a need for medically necessary therapy services above the therapy cap.

In both of these situations, the contractor shall require that the therapist maintain on file, necessary documentation to support the medical necessity of therapy services. Documentation requirements are found in CMS Pub.100-02, chapter 15, section 230.3.

Request for Exception from Therapy Caps

Contractors shall not require providers to submit written requests for exception from the therapy cap. Instead, the placement of the KX modifier on the claim shall be interpreted as a request for exception from the cap. For beneficiaries who the clinician believes will require therapy treatment days in excess of those payable under the therapy cap, and who meet the above bulleted criteria for automatic exception, the Medicare contractor shall require the provider to maintain sufficient documentation on file to support the medical necessity for this service. Use of the KX modifier shall be interpreted as the therapist's attestation that services provided above the cap are medically necessary.

The contractor shall require the provider to maintain on file documentation in accordance with CMS Pub.100-02, chapter 15, section 220.3 and CMS Pub.100-04, chapter 5, sections 10.2 and 20 with the request for treatment days in excess of those payable under the therapy cap.

If the clinician attests that the requested services are medically necessary by using a KX modifier on the claim line, the contractor may make the determination that the claim is medically necessary. That determination is binding on the contractor in the absence of:

- potential fraud; or
- evidence of misrepresentation of facts presented to the contractor, or
- A pattern of aberrant billing by a provider.

Should such evidence of potential fraud, misrepresentation, or aberrant billing patterns by a provider be found, claims are subject to medical review regardless of whether the KX modifier was used on the claim.

Progressive corrective action (PCA) and medical review have a role in the therapy exception process. Although the services may meet the criteria for exception from the cap due to condition or complexity, they are still subject to review to determine that the services are otherwise covered and appropriately provided. The exception is granted on the clinician's assertion that there is documentation in the record justifying that the services meet the criteria for reasonable and necessary services. For example, the documentation must accurately represent the facts, and there shall be no evidence of patterns of aberrant billing of the services by the provider/supplier. Services deemed medically necessary are still subject to review related to fraud or abuse. An example of inappropriate use of the process is the routine use of the KX modifier on every claim for a patient that has an excepted condition or complexity, regardless of the impact of the condition on the need for services above the cap.

3.3.2.8 - MAC Articles

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs.

A. General

The MACs have the discretion to publish articles communicating certain information to providers, such as any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. The MACs are required to enter articles that address LCDs, coding or medical review-related billing and claims considerations into the Medicare Coverage Database (MCD).

For the purposes of this manual, the term "publish" will be used to describe any form of dissemination including posting on a Web site, distributing at a seminar, e-mailing, or printing in a hardcopy bulletin. The MAC Medical Review Departments are responsible for the development of articles associated with new or revised LCDs and for entering those articles into the Medicare Coverage Database. Other widespread educational articles shall not be charged to MR.

The MAC medical review departments shall send articles to the appropriate department

within the MAC for publishing. All newly created articles shall be posted on the MAC's Web site where duplicate copies can be obtained by providers/suppliers.

When NCDs or other coverage instructions issued by the CMS include specific conditions or parameters for covered services, the MACs have the discretion to develop and publish a list of covered codes associated with the coverage provision. MACs have the discretion to automate denials for codes not included on the list without the development of a LCD if the NCD indicates or states that no other condition or parameters will be covered.

MACs also have the discretion to:

- Publish definitions of procedure codes, lists of items that may be billed under a particular code, or minimum requirements that providers must meet in order to bill using a certain code.

- Publish a product classification list that instructs providers about which specific products meet the definitional requirements of a particular HCPCS code. Developing or revising an LCD for this article is unnecessary.

- Explain which off-labeled uses of the Food and Drug Administration (FDA) approved drugs are considered reasonable and necessary within the diagnosis codes that reflect such uses.

- Explain the benefit category decisions and publish a list of drugs/biologicals that are considered usually self-administered. MACs should enter their self- administered medication exclusion list into the Medicare Coverage Database. This database can be accessed at www.cms.gov/mcd.

- MACs have the discretion to explain which HCPCS code or group of codes properly describes a particular service.

- MACs have the discretion to publish State non-physician licensure information that governs services billed by the physician under the "incident to" provision.

The MACs shall ensure that articles do not conflict with NCDs, LCDs, policy, or coverage provisions in interpretive manuals. Although a comment and notice process is not required, MACs are encouraged to consult with stakeholders in the provider community when developing articles. MACs shall monitor comments about articles from clinician providers and respond to their concerns, as needed, by issuing revised or clarifying articles.

NOTE: Nothing in this section precludes the MACs or UPICs from making individual

claim determinations, even in the absence of an article or LCD.

3.3.3 - Reviewing Claims in the Absence of Policies and Guidelines
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The MACs, CERT, Recovery Auditors, and UPICs have the discretion to review claims, in the absence of polices, whether a NCD, coverage provision in an interpretive Medicare manual, or LCD exists for that service. When making individual claim determinations, they shall determine that the service in question is covered based on whether the service meets all of the conditions listed in section 3.6.2.1.

3.4 - Prepayment Review of Claims
(Rev.902, Issued: 09-27-19, Effective: 10-28-19, Implementation: 10-28-19)

This section applies to MACs and UPICs.

A. General

Non-random (targeted) review is defined as review conducted with a specific reason or logic to substantiate the cause for review. MACs are encouraged to initiate non-random service-specific prepayment review to prevent improper payments for services identified by CERT or Recovery Auditors or other sources.

The MACs shall initiate targeted provider-specific prepayment review only when there is the likelihood of a sustained or high level of improper payments.

B. 100% Prepayment Review and Random Review Instructions

Section 1302 of the Health Care and Education Reconciliation Act (HCERA) repealed section 1874A (h) of the Social Security Act which had placed restrictions on prepayment medical review. CMS review contractors shall comply with Section 1 random review and Section 2 100% prepayment review.

1. Random Review

Random review is defined as review conducted without a specific reason or logic to substantiate the cause for review. MACs have the discretion to conduct random reviews of services; however, CMS does not recommend random reviews. MACs shall notify the CMS Contracting Officer's Representative (COR), Regional Office Technical Monitor (TM), and Business Function Lead (BFL) of its intent to conduct random review. The MAC shall describe what the intended result of the random review will be, an estimate of the number of claims to be reviewed randomly and the rationale as to why random review would be more effective than targeted review.

2. 100% Prepayment Review

100% prepayment review is defined as review of every claim submitted by a targeted provider for a specific code (i.e., DRG, CPT, HCPCs). 100% prepayment review also includes review of every claim submitted by the targeted provider.

MACs have the discretion to conduct 100 % prepayment review of providers. CMS considers 100 % prepayment review to be appropriate when a provider has a prolonged time period of non-compliance with CMS policies. Any MAC that plans to conduct 100 % prepayment review shall inform the CMS COR, Regional Office TM, and BFL in advance about any provider being placed on 100 % prepayment review. In addition, the MAC shall provide

- The background information on attempts to educate the provider.
- The historical improper payment rate of the provider before beginning 100% prepayment review.
- The length of time the provider is expected to be on 100 % prepayment reviews.
- The estimated number of claims and the dollar value of claims expected to be reviewed per month.
- The criteria for removing the provider from 100 % prepayment review.

3. UPIC Initiated Prepayment Reviews

No UPIC shall initiate a 100% prepayment review without CMS approval, except 100% prepayment reviews associated with a Payment Suspension. Therefore, the UPIC shall provide its COR and IAG BFL a summary of the investigation, any prior history (if applicable) with the provider/supplier in question, and any other relevant information in a format agreed upon by the COR and IAG BFL.

If the COR and IAG BFL agree that 100% prepayment review is appropriate, the UPIC shall include the case on the next case coordination meeting agenda for discussion and final approval. During the case coordination meeting, the UPIC may receive additional guidance from CMS related to subsequent actions related to these investigations. If the UPIC has subsequent questions following the case coordination meeting, the UPIC shall coordinate with its COR and IAG BFL.

3.4.1 - Electronic and Paper Claims

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

This section applies to MACs.

The Administrative Simplification Compliance Act (ASCA, Section 3 of Pub. L, 107-105, 42 CFR 424.32) requires that all Medicare claims be submitted electronically using the ASC X12 837 institutional or professional claim formats with few exceptions. MACs

shall not require providers to submit paper claims when they are targeted for prepayment medical record review. The MACs shall allow providers that qualify for an ASCA mandatory electronic billing exception to submit paper claims when they are targeted for prepayment review (See IOM Pub.100-04, chapter 24, §90 for exceptions).

3.4.1.1 - Linking LCD and NCD ID Numbers to Edits
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The MACs shall ensure that any edit that could result in a denial based on a LCD or NCD includes the LCD or NCD ID number(s) associated with the denial. The MACs shall ensure that any edit that could result in a denial based on a lab negotiated NCD includes the NCD ID number(s) associated with the denial.

3.4.1.2 - Not Otherwise Classified (NOC) Codes
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

The MAC MR staff should assist claims processing staff in making coverage and pricing determinations on NOC HCPCS/CPT codes. The claims processing staff will need information from the MR staff so that they can price the service in accordance with CMS pricing methodologies described in the Claims Processing Manual (IOM Pub. 100-04). MACs shall keep track of pricing determinations for frequently billed services so that the claims processing staff can price future claims using established MR pricing guidelines for that service.

3.4.1.3 - Diagnosis Code Requirements
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs and UPICs, as indicated.

ICD-10-CM is used for diagnoses on inpatient discharges and for other services provided on and after the implementation of ICD-10-CM. ICD-9-CM is used for discharges and other services before the implementation of ICD-10-CM.

Section 1833(e) of the Act states that no payment should be made "under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person…." MACs and UPICs should require submission of information, in accordance with the requirements below, that they deem necessary to make a claim determination and determine appropriate payment. Some provider types are required to submit diagnosis codes on all claims while other provider types are required to submit diagnosis codes only if such information is required by a LCD.

A. Claims Submitted by Physicians or Certain Non-Physician Practitioners Must Contain Diagnosis Codes.

Section 1842 (p) (1) of the Act states that for each claim submitted by physicians or certain non-physician practitioners (defined in 1842(b) (18) (C) of the Act) "shall include the appropriate diagnosis code (or codes)…." For claims submitted with invalid, truncated, or missing diagnosis codes, MACs and UPICs shall classify the claim as rejected as unprocessable within the MCS. See the Claims Processing Manuals IOM Pub.100-04.

B. Claims Submitted by All Other Provider Types Must Contain Diagnosis Codes if required by a LCD

During a service-specific review to address potential abuse or overutilization, MACs and UPICs should require that diagnosis codes be submitted with each claim for the targeted service. The diagnosis information is used to determine if the services are covered and correctly coded. MACs and UPICs should require that ICD diagnosis codes be submitted by all non-physician billers with every claim for a targeted service only if such a requirement appears in a LCD for that service. This outreach shall occur via Web site, bulletin articles, etc.

For provider-specific reviews, MACs and UPICs have the discretion to require submission of diagnosis codes to support that the reasonable and necessary criteria has been met on all claims submitted by individual non-physician providers who have been targeted because of unusual billing practices, fraud referrals, etc., even if no LCD exists requiring such codes. For claims submitted with invalid, truncated, or missing diagnosis codes, reviewers shall classify the claim as unable to be processed, and return the claim to the provider (RTP). See the Claims Processing Manual IOM Pub.100-04.

C. Requirements for Lab Claims

The American Medical Association's (AMA) 1998 edition of the Current Procedural Terminology (CPT) established three new and one revised Organ and Disease Oriented laboratory panels. Since these panels are composed of clinically relevant groupings of automated multichannel tests there is a general presumption of medical necessity. If there is data or reason to suspect abuse of the panel codes, contractors may review these claims. Should contractors determine the need to develop a LCD for laboratory panel codes the MAC shall develop these policies at the panel code level. In some instances of perceived abuse of the panel codes, the contractors may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

3.4.1.4 - Prepayment Review of Claims Involving Utilization Parameters

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

This section applies to MACs.

A. For Non-lab Claims

The MACs shall implement prepayment edits that will prevent payment to providers who have a pattern of billing for items or services that are not covered, incorrectly coded or inappropriately billed. The MACs shall respond quickly when they identify providers who seem to have egregious overutilization of a non-lab item or service and who bill for egregious amounts. The identification of, and response to these providers shall be within the context of the MAC's MR Strategy and prioritization of review targets.

B. Utilization Denials

The MACs have the discretion to establish edits to automatically deny services when overutilization of a non-lab service is identified and clear policy serves as the basis for denial.

The MACs shall establish medical record review edits and make individual claim determinations when overutilization of a non-lab service is identified and there is not clear policy to serve as the basis for denial.

The MACs shall establish medical record review edits that do not involve utilization parameters and make individual claim determinations when overutilization of a lab service is identified and there is no clear policy to serve as the basis for denial. For example, if the problem is limited to a few laboratory providers, the MAC could develop a provider-specific prepayment edit to suspend payment for all of the lab services in question from the problem providers. If the problem is widespread, the MAC could develop a service-specific edit to suspend payment for all of the lab services in question or all of the services in question for a particular diagnosis or revenue code. Based on data analysis within each MAC jurisdiction, the MACs shall focus the edit by provider, diagnosis, procedure code, or in any other way except by use of a utilization parameter.

3.4.1.5 - Prepayment Review Edits

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

A. Automated Edits

Automated prepayment edits, designed by MAC staff, are put in place to prevent payment for non-covered, incorrectly coded, or inappropriately billed services. Most automated payment edits will be service-specific. The MAC will rarely install a provider-specific automated prepayment edit.

B. Limits on Automated Prepayment Review

The MACs shall not install edits that result in the automatic denial of payment for items or services based solely on the diagnosis of a progressively debilitating disease when treatment may be reasonable and necessary. The appearance of a progressively debilitating disease on a claim or history does not permit automated denials that presume a stage of that disease that negates the effectiveness of treatment. Likewise, when a

beneficiary with a progressively debilitating disease experiences an illness or injury unrelated to his or her progressively debilitating disease, the provider should submit a claim with a primary diagnosis that most accurately reflects the need for the provided item or service. For instance, a claim for treatment for an acute urinary tract infection cannot be denied by automatic edit just because the beneficiary has a diagnosis of multiple sclerosis.

3.4.2 – Prepayment Medical Record Review Edits

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

This section applies to MACs.

The MACs shall focus prepayment medical record review edits to suspend only claims with a high probability of aberrant billing practices. Focused edits reduce provider burdens and increase the efficiency of MR activities. The MACs shall ensure that edits are specific enough to identify only the services that they determine to be questionable based on data analysis. MACs are encouraged to ensure that most MR edits are located in the table driven portion of the system and are not hard coded. It is important to have the flexibility to modify MR edits based on workload demands and changes in provider behavior.

The MACs have the discretion to establish prepayment medical record review edits that are either service-specific or provider-specific. Provider-specific edits can suspend all claims from a particular provider or focus on selected service(s), place of service, or other parameters.

3.5 - Postpayment Medical Record Review of Claims

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The MACs shall initiate targeted provider-specific or service-specific postpayment medical record review only when there is the likelihood of a sustained or high level of payment error. RACs, UPICs, and SMRC shall perform postpay review of claims as outlined in their SOW.

3.5.1 - Re-opening Claims

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, RACs, SMRC and UPICs, as indicated.

The MACs, CERT, RACs, SMRC, and UPICs shall adhere to the rules found in CFR 405.980 through 986 when conducting automated or postpayment medical record reviews. High error rate and/or potential overutilization, identified by data analysis, are reasons to perform postpayment review and represent sufficient cause to reopen claims in accordance with 42 CFR 405.986. See Pub. 100-04, chapter 34 for more information on good cause for reopening.

3.5.2 - Case Selection

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, SMRC, and UPICs, as indicated.

Case review and development provisions:

The MACs and the SMRC shall not perform postpayment review of unassigned claims. A claim submitted for a service or supply by a provider who has not accepted the Medicare fee schedule is an unassigned claim.

- The MACs, SMRC, and UPICs have the discretion to select cases for postpayment review on a claim-by-claim basis or use statistical sampling for overpayment estimation.
    - When MACs, SMRC, and UPICs conduct claim-by-claim postpayment review, they shall only collect or refund the actual overpayment or underpayment amount.
    - When MACs, SMRC, and UPICs conduct statistical sampling for overpayment estimation as specified in PIM chapter 8, they shall extrapolate the sampling results to the known universe of similar claims when calculating the projected overpayment or underpayment amount.
- The MACs, RACs, SMRC, and UPICs have the discretion to conduct the postpayment review onsite at the provider or supplier's location.
- MAC staff shall review their provider tracking system, using RAC Data Warehouse (RACDW) data, and consult with the UPICs to ensure non- duplication during the process of selecting providers for postpayment review.
- To prevent duplicate claim reviews, the MACs, SMRC, and RACs shall use the RACDW to identify, and exclude from review, claims that were previously reviewed, or that are under current review, by another contractor.
- CERT shall duplicate another contractor's review, when appropriate, if those claims are chosen as part of a statistically valid random sample to measure the improper payment rate.
- This instruction does not prevent the UPICs from reviewing a claim that has been reviewed by another contractor in order to support their

case development or other administrative action.

- When the MACs, CERT, RACs, SMRC and UPICs choose to send the provider an ADR for a postpayment review, they shall do so in accordance with PIM chapter 3, §3.2.3.2. The contractors may grant an extension of the submission timeframes at their discretion or in accordance with their SOWs.

- The MACs, CERT, RACs, SMRC and UPICs make coverage, coding, and/or other determinations when re-adjudicating claims.

- The MACs, CERT, RACs, SMRC and UPICs shall document all incorrectly paid, denied, or under-coded (e.g., billed using a procedure/supply or other code that is lower than what is supported by medical documentation) items or services.

- Services newly denied as a result of re-adjudication shall be reported as positive values.

- Services that were denied, but are reinstated as a result of re-adjudication shall be reported as negative values.

- The MACs, CERT, RACs, SMRC and UPICs shall document the rationale for denial and include the basis for revisions in each case (important for provider appeals). MACs, CERT, and UPICs should include copies of the NCD, coverage provisions from interpretive manuals, or LCD and any applicable references needed to support individual case determinations. RACs and the SMRC shall include detailed rationale as outlined in their SOWs.

- The MACs have the discretion to deny payment without the review of the claim with a medically unlikely service edit.

3.5.3 - CMS Mandated Edits

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

In past years, CMS created mandated edits that suspend certain claims for medical review coverage and coding review. However, more recently, CMS has given the contractors the discretion to prioritize workload to effectively lower the error rate. CMS is now in the process of removing such mandated coverage and coding review edits from CWF, pricer, grouper, fee schedules, etc.

Contractors may override CMS mandated edits that suspend for medical review coverage and coding review without performing review if one or more of the following conditions apply:

1. The contractor does not have MR responsibility for the claim, or

2. The contractor's data analysis/priority setting/ MR strategy does not indicate this service is a problem in their jurisdiction, or

3. It is not a skilled nursing facility (excluding swing beds) or a home health demand bill (these demand bills must be reviewed).

3.5.4 - Tracking Medicare Contractors' Prepayment and Postpayment Reviews

(Rev. 11933; Issued: 03-30-23; Effective: 04-01-23; Implementation: 04-03-23)

Shared System Maintainers shall create a pre-payment claim file that is automatically uploaded to the RACDW by the VDC. Medicare Administrative Contractors (MACs) shall input all postpayment complex reviews into the Recovery Audit Data Warehouse. All claims chosen for review by the MAC where an additional documentation request letter was issued to the provider before or after payment was made shall be included. MACs shall include all reviews, even those that did not result in an improper payment.

Claims may be manually uploaded into the data warehouse or submitted by flat file. The Shared System Maintainers and MACs shall use the file layout provided by CMS for claims uploaded to the Recovery Audit Data Warehouse. Postpayment claims shall be submitted to the Recovery Audit Data Warehouse by the 20th day of every month for the previous month. Prepayment claims shall be submitted to the Recovery Audit Data Warehouse daily.

MAC staff who need access to the Data Warehouse shall contact RAC@cms.hhs.gov.

3.6 - Determinations Made During Review

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors, and UPICs, as indicated.

A. General

The MACs, CERT, Recovery Auditors, and UPICs shall be able to differentiate the type of determination made, ensuring that limitation of liability determinations are appropriate.

When the MAC determines, through prepayment data analysis or postpayment review, that an inappropriate claim has been submitted; or the Recovery Auditor determines, in post-payment review, that an improper payment has been made, the MAC and Recovery Auditor shall verify that the error represents an unacceptable practice and not just an explainable aberrancy. Some legitimate reasons for anomalous data include:

- The provider may be associated with a medical school, research center, or may be a highly specialized facility, for instance, the facility may be a Medicare- dependant hospital or CAH, which might skew the type of claims submitted; or

- The community in which the provider practices may have special characteristics such as socio-economic level or a concentration of a specific age group that leads to an apparent aberrancy in the use of certain services.

The MACs, CERT, Recovery Auditors, and UPICs have the discretion to make other determinations during the review of a claim to avoid or identify improper payments for such things as duplicate claims, etc. Other examples are listed below:

Example 1: A Medicare policy states that when three (3) procedures are performed during the same operative session, Medicare pays 100 percent for the first, 50 percent for the second and 25 percent for the third. A claim is identified where all three (3) procedures were paid at 100 percent.

Example 2: A claim was paid using the fee schedule from the prior year.

Example 3: A Medicare payment policy states that in order to pay for a capped rental item, consideration shall be given to whether the item was in "continuous use" by the beneficiary for a specified time period. A claim is found to have been paid out of compliance with this policy provision.

If, at any time, the medical review detects potential fraud, MACs, CERT, and Recovery Auditors, shall refer the issue to the appropriate UPIC.

3.6.1 - Determining Overpayments and Underpayments
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, and UPICs. It does not apply to CERT or Recovery Auditors.

A. General

The results of the re-adjudication are used to determine the overpayment or underpayment amount for each claim. Re-adjudicating claims may not result in a payment correction. Where statistical sampling for overpayment estimation is used, refer to instructions in the PIM chapter 8, §8.4 and to Exhibits 9, 10, 11 and 12 for projection methodologies based on FFS claims. For claims paid under PPS rules, MACs and UPICs shall develop projection methodologies in conjunction with their statisticians that are consistent with the requirements found in PIM chapter 8, §8.4. MACs and UPICs shall net out the dollar amount of services underpaid during the cost accounting period, meaning that amounts owed to providers are balanced against amounts owed from

providers.

Amounts of the following overpayments are to be included in each provider's or supplier's estimate for the reviewed sample:

- According to the provisions of §1879 of the Act, the provider or supplier is liable for the overpayment of initially paid claims that were later denied on re- adjudication if :

  (1) The basis for denial is by reason of §1862(a) (l) or (9) of the Act

  (2) The provider or supplier knew or could reasonably have been expected to know that the items or services were excluded from coverage, and

- For denials of non-assigned claims make a§1842(l) determination on denials for §1862(a)(1)

- The provider or supplier was not without fault for the overpayment as defined in §1870 of the Act.

For appeal purposes, overpayment estimations applicable under §1879 of the Act will be identified separately from denials in which §1879 of the Act does not apply. Where both types of denials occur in the sample, MACs and UPICs calculate and document separate under/overpayments for each type of denial. For recovery purposes, however, both denial results are combined.

3.6.2 - Verifying Errors

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, and UPICs, as indicated.

Understanding the characteristics of the service area of the provider is a key element of claim data analysis. The areas selected for review by the contractor (e.g., providers, services) must be deemed high priority and contractors must be able to document the rationale for selection.

3.6.2.1 - Coverage Determinations

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The MACs, CERT, Recovery Auditors, and UPICs shall deny an item or service if it does not meet any of the conditions listed below:

- The item or service does not fall into a Medicare benefit category.
- The item or service is statutorily excluded on grounds other than §1862(a) (1) (A) of the Act.
- The item or service is not reasonable and necessary under §1862(a) (1) (A) of the Act.
- The item or service does not meet other Medicare program requirements for payment.

3.6.2.2 - Reasonable and Necessary Criteria

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors, and UPICs, as indicated.

CMS issues national coverage determinations (NCDs) that specify whether certain items, services, procedures or technologies are reasonable and necessary under §1862(a) (1) (A) of the Act. In the absence of an NCD, Medicare contractors are responsible for determining whether services are reasonable and necessary. If no local coverage determination (LCD) exists for a particular item or service, the MACs, CERT, Recovery Auditors, and UPICs shall consider an item or service to be reasonable and necessary if the item or service meets the following criteria:

- It is safe and effective;
- It is not experimental or investigational; and
- It is appropriate, including the duration and frequency in terms of whether the service or item is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the beneficiary's medical needs and condition;
    - Ordered and furnished by qualified personnel; and,
    - One that meets, but does not exceed, the beneficiary's medical need.

There are several exceptions to the requirement that a service be reasonable and

necessary for diagnosis or treatment of illness or injury in order to be considered for payment. The exceptions appear in the full text of §1862(a) (l) (A) of the Act. See also PIM chapters 13, §5.1 and 7.1.

3.6.2.3 - Limitation of Liability Determinations

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors, and UPICs, as indicated.

Section 1879(a)-(g) of the Act limits the financial liability of beneficiaries, providers, and suppliers by permitting Medicare payments, or requiring refunds, for certain services and items for which Medicare payment would otherwise be denied. The purpose of this provision is to protect beneficiaries from liability in certain cases of denied services. The limitation of liability provisions apply only to claims for services not statutorily excluded, that are denied for the following reasons:

- The service or item did not meet the reasonable and necessary criteria;
- The beneficiary or provider did not know, or could not have been reasonably expected to know that the service or item would not be covered; and
- The beneficiary receives certain screening tests and preventive services in excess of the guidelines.

(See IOM Pub. 100-04, chapter30, §20 for more information).

The MACs, CERT, and UPICs shall first examine benefit categories and statutory exclusions to determine if a service or item is covered. Recovery Auditors shall examine categories and exclusions as outlined in their SOW. If the item or service meets the requirements of the appropriate benefit category and is not excluded by statute, the next consideration is whether the service was reasonable and necessary. When a claim is denied, in full or in part, because an item or service is not reasonable and necessary, MACs, CERT, Recovery Auditors, and UPICs shall make and document determinations as appropriate to §§1879, 1870, and 1842(l) of the Act. Because the determinations can be appealed, it is important that the rationale for the determination be documented initially and at each level of appeal.

Limitations of liability provisions do not apply if there is a statutory exclusion, even if the service meets the reasonable and necessary criteria.

3.6.2.4 - Coding Determinations

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, SMRC, Recovery Auditors, and UPICs, as indicated.

ICD-10-CM is used for diagnoses on inpatient discharges and for other services provided on and after the implementation of ICD-10-CM.. ICD-9-CM is used for discharges and other services before that date.

The MACs, CERT, SMRC, Recovery Auditors, and UPICs shall determine that an item/service is correctly coded when it meets all the coding guidelines listed in the Current Procedural Terminology-4 (CPT-4), Coding Clinic for ICD, Coding Clinic for HCPCS, and any coding requirements listed in CMS manuals or MAC articles.

In certain situations, it is appropriate for contractors to up code or down code a claim (or items or services on a claim) and adjust the payment. When the medical record supports a higher or lower level code, the MACs, SMRC, CERT, UPICs and Recovery Auditors shall not deny the entire claim but instead shall adjust the code and adjust the payment.

The MACs, SMRC, CERT, UPICs and Recovery Auditors shall up code or down code when it is possible to pay for the item or service actually provided without making a reasonable and necessary determination or if otherwise specified in applicable CMS medical review instructions. The MACs, SMRC, CERT, UPICs and Recovery Auditors shall not substitute the payment amount of one item or service for a different item or service based on a reasonable and necessary determination.

Example situations where it is appropriate to up code or down code a claim are:

1. CBC with diff was ordered and billed but CBC without diff was provided;

2. X-ray with contrast was ordered and billed but X-ray without contrast was provided;

3. E&M level 3 was billed but the medical record supports level 2 (or other level);

4. PPS (DRG/RUG/HHRG) code was billed but the medical records supports a different code; and

5. Quantity of diabetic test strips exceeds limits; for example, quantity was provided for insulin treated but the patient was not insulin treated.

3.6.2.5 - Denial Types

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

This section applies to MACs, CERT, RACs, and UPICs, as indicated.

A. Distinguishing Between Benefit Category, Statutory Exclusion and Reasonable and Necessary Denials

The MACs, CERT, RACs, and UPICs shall be cognizant that the denial type may affect the financial liability of beneficiaries. They shall ensure that benefit category denials take precedence over statutory exclusion and reasonable and necessary denials. They shall ensure that statutory exclusion denials take precedence over reasonable and necessary denials. MACs, CERT, and UPICs shall use the guidelines listed below in selecting the appropriate denial reason. RACs shall follow denial reason guidance outlined in their SOW.

- If additional documentation was requested from the provider or other entity for any MR reason (benefit category, statutory exclusion, reasonable/necessary, or coding), and the information is not received within 45 calendar days or a reasonable time thereafter, the MACS, CERT, and UPICs shall issue a reasonable and necessary denial, in full or in part.

- If additional documentation was requested because compliance with a benefit category requirement is questioned and the documentation received fails to support compliance with the benefit category, the MACs, CERT, and UPICs shall issue a benefit category denial.

- If additional documentation was requested because compliance with a benefit category requirement is questioned and the received documentation shows evidence that the benefit category requirement is present but is defective, the MACs, and UPICs shall issue a reasonable and necessary denial.

EXAMPLE 1: A MAC is conducting a review of partial hospitalization (PH) claims from a provider who has a pattern of failing to comply with the benefit category requirement that there be a signed certification in the medical record. In the first medical record, the MAC finds that there is no signed certification present in the medical record. The MAC shall deny all PH services for this

beneficiary under §1835(a) (2) (F) of the Act (a benefit category denial). However, in the second medical record, the MAC determines that a signed certification is present in the medical record, but the documentation does not support the physician's certification, the services shall be denied under §1862(a) (1) (A) of the Act (a reasonable and necessary denial) because the certification is present but defective.

Example 2: The MAC performs a medical record review on a surgical procedure claim and determines that the procedure was cosmetic in nature and was not reasonable and necessary; the denial reason would be that the service is statutorily excluded since statutory exclusion denials take precedence over reasonable and necessary denials.

The MACs, CERT, RACs, and UPICs shall deny payment on claims either partially (e.g., by down coding or denying one line item on a multi-line claim) or in full, and provide the specific reason for the denial whenever there is evidence that a service:

- Does not meet the Benefit Category requirements described in Title XVIII of the Act, NCD, or coverage provision in an interpretive manual;
- Is statutorily excluded by other than §1862(a)(1) of the Act;
- Is not reasonable and necessary as defined under §1862(a) (1) of the Act. MACs, CERT, RACs, and UPICs shall use this denial reason for all non-responses to documentation requests;
- Was not billed in compliance with the national and local coding, payment or billing requirements; and/or
- Was not delivered or provided to the beneficiary, or not provided as billed.

The denial explanation needs to be more specific than merely repeating one of the above bullets. The general exception to the need for a full denial explanation is in the event of a clerical error, for example, the billing entity transposes two digits in the Medicare beneficiary identifier on a claim. The claim is quickly returned, usually electronically, to the provider for correction. In the case of dual-eligible beneficiaries where there is a State-specific policy, see CMS IOM Pub. 100-04, chapter 30, §60.5 A for a detailed explanation of handling administrative denials.

3.6.3 - Beneficiary Notification

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, RACs, and UPICs, as indicated.

A. General

If a claim is denied through prepayment or postpayment review, the MAC shall notify the beneficiary consistent with the requirements in PIM chapter 3, §3.6.2.3. The MAC shall include limitation of liability and appeals information. Notification can occur via Medicare Summary Notice (MSN). The CERT, RACs, and UPICs are not required to issue beneficiary notices for claims they deny. Instead, CERT, RACs, and UPICs shall communicate sufficient information to the MAC to allow the MAC to develop an appropriate beneficiary notice.

The MACs are required to give notice to Medicare beneficiaries when claims are denied in part or in whole based on application of a LCD. All denials that result from LCDs shall provide the MSN message 15.19 in addition to the current applicable message. Message 15.19 states (IOM Pub. 100-04, chapter 21):

> "A local coverage determination (LCD) was used when we made this decision. A LCD provides a guide to assist in determining whether a particular item or service is covered by Medicare. A copy of this policy is available from your local intermediary, carrier or (Medicare Administrative Contractor) by calling the number in the customer service information box on page one. You can compare the facts in your case to the guidelines set out in the LCD to see whether additional information from your physician would change our decision."

The MACs shall make these messages available in Spanish where appropriate. The 15.19 portion of the MSN message states:

> Una Determinación de Cobertura Local (LCD, por sus siglas en inglés) fue utilizada cuando se tomó esta decisión. La LCD es una guía que ayuda a determinar si un artículo o servicio en particular está cubierto por Medicare. Una copia de esta póliza está disponible en su intermediario, local o en su empresa de seguros Medicare, o en su Contratista Administrative de Medicare, al llamar al número que aparece en la información de Servicios al Cliente en la página uno. Usted puede comparar los datos de su caso con las reglas establecidas en la LCD para ver si obteniendo información adicional de su médico pudiera cambiar nuestra decisión.

The MACs shall use the above message in every instance of a prepayment denial where a LCD was used in reviewing the claim. Use this message, and message 15.20 (now for FISS MACs, and when 15.20 is fully implemented for contractors on the MCS/VMS systems) on both full and partial denials, whether the denial was made following automated, non-medical review, or medical record review. MACs shall not use this message on denials not involving LCDs. For claims reviewed on a postpayment basis,

include the language exactly as contained in the MSN message above if sending the beneficiary a new MSN. If sending a letter, include the language exactly as contained in the MSN message above. Message 15.20 currently states:

"The following policies [insert LCD ID# and NCD#] were used when we made this decision."(Pub.100-04, chapter 21).

The MACs shall continue to use 15.19 in conjunction with the MSN message 15.20, where 15.19 is applicable. MACs should, at their discretion, combine these messages if necessary, but 15.19 shall not be deleted.

In the case where the results of claims sampling are extrapolated to the universe, only those beneficiaries in the sample need to be notified. In RAC cases, the RAC and MAC Joint Operating Agreement (JOA) shall specify what information the RAC will supply to allow the MAC to notify the beneficiary when re-adjudication results in a change to the initial determination.

3.6.4 - Notifying the Provider

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to, MACs, RACs, and UPICs, as indicated.

A. General

At the conclusion of postpayment review, the MACs shall send a Review Results Letter to the provider even if no overpayment determination is made. If the MACs choose to send a Review Results Letter separately from the demand letter they shall do so within the timeframes listed in PIM chapter 3, §3.3.1.1F. Likewise, the RACs shall issue a Review Results Letter for all audits as outlined in their SOW requirements.

UPICs shall comply with the requirements listed below when issuing Review Results Letters. Each Review Results Letter shall include:

- Identification of the provider or supplier—name, address, and NPI;
- Reason for conducting the review or good cause for reopening;
- A narrative description of the overpayment situation that states the specific issues involved in the overpayment as well as any recommended corrective actions;
- The review determination for each claim in the sample, including a specific explanation of why any services were determined to be non-covered, or incorrectly coded and if others were payable;

- A list of all individual claims that includes the actual non-covered amount, the reason for non-coverage, the denied amounts, under/overpayment amounts, the §1879 and §1870 of the Act determinations made for each specific claim, along with the amounts that will and will not be recovered from the provider or supplier;

- Any information required by PIM chapter 8, §8.4 for statistical sampling for overpayment estimation reviews;

- Total underpayment amounts;

- Total overpayment amounts that the provider or supplier is responsible for;

- Total overpayment amounts the provider or supplier is not responsible for because the provider or supplier was found to be without fault;

- MACs shall include an explanation that subsequent adjustments may be made at cost settlement to reflect final settled costs;

- An explanation of the procedures for recovery of overpayments including Medicare's right to recover overpayments and charge interest on debts not repaid within 30 days (not applicable to RACs or UPICs);

- The provider's or supplier's right to request an extended repayment schedule (not applicable to RACs or UPICs);

- The MACs and UPICs shall include limitation of liability and appeals information in the provider notices;

- The MACs shall include appeals information in the provider notices;

- The MACs shall include the provider or supplier financial rebuttal rights under PIM chapter 3, §3.6.5; and

- For MAC Review Results Letter only, a description of any additional corrective actions or follow-up activity the MAC is planning (i.e., prepayment review, re- review in 6 months).

If a claim is denied through prepayment review, the MACs and UPICs are encouraged to issue a notification letter to the provider but may use a remittance notice to meet this requirement. However, if a claim is denied through postpayment review, the MAC and

RAC shall notify the provider by issuing a notification letter to meet this requirement. The UPIC shall use discretion on whether to issue a notification letter.

The CERT contractor is NOT required to issue provider notices for claims they deny. Instead, the CERT contractor shall communicate sufficient information to the MAC to allow the MAC to develop an appropriate provider notice.

B. MACs

The MACs need provide only high-level information to providers when informing them of a prepayment denial via a remittance advice. In other words, the shared system remittance advice messages are sufficient notices to the provider. However, for medical record review, the provider should be notified through the shared system, but the MAC shall retain more detailed information in an accessible location so that upon written or verbal request from the provider, the MAC can explain the specific reason the claim was denied as incorrectly coded or otherwise inappropriate.

C. RACs

For overpayments detected through medical record review, the RAC shall send a review results letter as indicated in the RAC SOW. In addition, the RAC shall communicate sufficient information to the MAC so that the MAC can send a remittance advice to the provider and collect the overpayment.

For underpayments, the RAC shall notify the provider as indicated in the RAC SOW. In addition, the RAC shall communicate sufficient information to the MAC so that the MAC can send a remittance advice to the provider and pay back the underpayment.

D. UPICs

For overpayments detected through medical record review, and after coordination between the UPIC and OIG, the UPIC shall send a review results letter (the MAC sends the demand letter). In addition, the UPIC shall communicate sufficient information to the MAC so that the MAC can send a demand letter to the provider and collect the overpayment. The UPIC shall use discretion on whether to send the review results letter.

E. Indicate in the Denial Notice Whether Records Were Reviewed

For claims where the MAC or UPIC had sent an ADR letter and no timely response was received, they shall issue a denial and indicate in the provider denial notice, that the denial was made without reviewing the documentation because the requested documentation was not received or was not received within the allowable time frame (§1862(a) (1) of the Act). This information will be useful to the provider in deciding whether to appeal the decision. When denying the claims, contractors shall use Group Code: CO - Contractual Obligation and Claim Adjustment Reason Code (CARC) 50 - these are non-covered services because this is not deemed a “medical necessity” by the

payer and Remittance Advice Remark Code (RARC) M127 - Missing patient medical record for this service.

For claims where the reviewer makes a denial following medical record review, the reviewer has the discretion to indicate in the denial notice, using Group Code: CO - Contractual Obligation and Claim Adjustment Reason Code (CARC) 50 - these are non-covered services because this is not deemed a "medical necessity" by the payer that the denial was made after review of submitted documentation. This includes those claims where the provider submits documentation along with the claim and the reviewer selects that claim for review.

3.6.5 - Provider Financial Rebuttal of Findings

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to the MACs. It does not apply to Recovery Auditors, CERT, and UPICs.

A. General

Providers or suppliers have the right to submit a financial rebuttal statement in accordance with 42 CFR 405.370-375 following receipt of the review results letter and prior to recoupment of the overpayment. The rebuttal statement and any accompanying evidence must be submitted within 15 calendar days from the date of the results letter unless the MAC staff find cause to extend or shorten the time frame.

B. Review of Financial Rebuttal Statement(s)

Within 15 calendar days of receipt of a financial rebuttal, MAC staff shall consider the statement and any evidence submitted to reach a determination regarding whether the facts justify the recoupment. However, the MAC shall not delay recovery of any overpayment beyond the date indicated in the review results letter in order to review and respond to the rebuttal statement even if the principal of the debt is modified after reviewing the rebuttal statement (See 42 CFR 405.375(a)). The MAC shall provide a copy of the rebuttal request and a copy of the MAC's response on the rebuttal outcome to the UPICs.

C. Cost Report Issues

Because of the cost report relationship to the overpayment, it is important to note that the projected overpayment recovered from a provider as a result of a postpayment review using statistical sampling for overpayment estimation is based on the interim payment rate in effect at the time of the review.

3.6.6 - Review Determination Documentation Requirements

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs, CERT, Recovery Auditors, and UPICs, as indicated.

For each claim denied, in full or in part, the MACs, CERT, and UPICs shall carefully document the basis for the denial in the internal claim record. If there are several reasons for denial they shall document each reason in the internal claim record. In addition, the internal claim record should document the date and content of the provider notice of review (§ 3.2.2), additional documentation requests (§3.2.3), and third party documentation requests and response (§3.2.3.3).

In verifying an overpayment, MACs, CERT, Recovery Auditors, and UPICs shall carefully document claims for services not furnished or not furnished as billed so that the denials are more likely to be sustained upon appeal and judicial review.

3.7 - Corrective Actions

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

This section applies to MACs.

The MACs shall take corrective actions they deem necessary based upon their findings during or after a review. These actions may include payment suspension, imposition of civil money penalties, institution of prepayment or postpayment review, additional edits, etc.

Providers/suppliers who show a pattern of failing to comply with requests for additional supporting documentation for any claims submitted to CMS may be subject to medical record review for all claims. This paragraph applies to both providers and suppliers and to instances in which CMS or its contractors request documentation directly from these entities to support services billed on the claim. This paragraph does not change or diminish the provider's or supplier's responsibility to provide required documentation. For purposes of this paragraph, a pattern is two or more ADRs that have gone unanswered.

3.7.1 - Progressive Corrective Action (PCA)

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs.

The MACs shall ensure that actions imposed upon Medicare providers or suppliers for failure to meet Medicare rules, regulations and other requirements are appropriate given the level of non-compliance.

When an error has been validated through MR, the corrective action imposed by the MACs should match the severity of the error. PCA is a means of evaluating the relative risk of the error and assigning appropriate corrective actions. The principles of PCA are:

- It is data-driven. Errors are validated by prepayment and postpayment claims review. (See below).
- Hypotheses and edits are tested prior to implementation to determine facility, utility, and return on investment.
- Workloads are targeted, specific, and prioritized.
- Money is collected when errors are validated.
- Referrals for potential fraud are made when necessary.
- Provider feedback and education are mandatory.
- Medical review resources should be used efficiently.

For each provider data identifies as being at risk, the potential error is validated with prepayment or postpayment review of generally 20-40 potentially erroneous claims. Payments are either denied or recouped. Any underpayments by Medicare will be netted out during the financial reconciliation process. Corrective actions are then implemented based on whether the error represents a minor, moderate, or major concern.

For potentially risky services, errors are validated by prepayment and postpayment review of generally up to 100 potential problem claims for that service from a representative sample of providers. Service-specific errors may require more widespread education for providers and may require the implementation of service-specific prepayment edits.

An example of a minor concern would be a provider with a low error rate and no pattern of errors who has made a relatively minor error with low financial impact. Education and collection of the overpayment may be sufficient corrective actions.

For moderate concerns, where a provider with a low error rate has made an error with substantial financial impact, some level of prepayment review should be considered. The prepayment review should be tracked and adjusted or eliminated according to the provider's response.

A major concern would be a provider with a high error rate who has made a high-dollar error with no mitigating circumstances, indicating the need for stringent administrative action. A high level prepayment review should be considered along with possible payment suspension and referral to the UPICs.

3.7.1.1 - Provider Error Rate

(Rev. 738; Issued: 08-18-17; Effective Date: 09-19-17; Implementation Date: 09-19-17)

This section applies to MACs.

If the MAC identifies a provider-specific problem, the provider error rate is an important consideration in deciding how to address the problem. For instance, a provider with a low error rate with no history of patterns of errors may require a fairly minor corrective action plan such as education with recoupment of overpayment. Other factors such as the total dollar value of the problem and the past history of the provider also deserve consideration. The MAC assesses the nature of the problem as minor, moderate or major and uses available tools such as data analysis and evaluation of other information to validate the problem.

A. Provider Error Rate Formula

The MACs shall include claims denied due to no response to ADRs when calculating the provider error rate.

The MACs shall use the following formula for prepayment review to calculate the provider's service specific error rate:

Total Dollar amount of allowable** charges for services billed in error as determined by MR***
Total Dollar amount of allowable** charges for services subject to a medical review documentation request

For postpayment review, the MACs shall use the following formula to calculate the provider's service specific error rate:

Total Dollar amount of services paid in error as determined by MR***
Total Dollar amount of services subject to a medical review documentation request

**If allowable charges are not available, submitted charges may be used until system changes are made.

***Net out (subtract) the dollar amount of charges under billed

3.7.1.2 - Vignettes

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

The following vignettes provide guidance on how the MACs shall characterize and respond to varying levels of confirmed errors. These are examples of results from medical review accompanied by suggested corrective actions. This information should only be used as a guide and is not meant to be a comprehensive list of vignettes nor an inclusive list of administrative actions. The MAC MR department shall include communication and follow-up with provider outreach and education (POE) throughout

the PCA process to coordinate efforts toward problem resolution. The MACs shall monitor trends indicating widespread educational need and shall ensure that POE staff has access to copies of all MR provider notification and feedback letters so they are prepared for provider requests for education (See IOM Pub. 100-04, chapter 20, §3.4.2, for further information).

1. Twenty claims from one provider are reviewed. Once claim is denied because a physician signature is lacking on the plan of care. The denial reflects 7 percent of the dollar amount of claims reviewed. Judicious assessment of medical review resources indicates no further review is necessary at this time. The MAC uses data analysis to determine where to target medical review activities in the future.

2. Forty claims from one provider are reviewed. Twenty claims are for services determined to be not reasonable and necessary. These denials reflect 50 percent of the dollar amount of claims reviewed. One hundred percent prepayment review is initiated due to the high number of claims denied and the high dollar amount denied. The MAC provides notification to the provider about specific errors made and makes a priority referral to POE to inform them of the severity of the problem.

3. Forty claims from one provider are reviewed. Thirty-five claims are denied. These denials reflect 70 percent of the dollar amount of claims reviewed. Payment suspension is initiated due to the high denial percentage and the Medicare dollars at risk. The MAC provides notification to the provider about the specific errors made and makes a priority referral to POE to inform them of the severity of the problem.

4. Forty claims from one provider are reviewed. Thirty-three claims are denied. These denials reflect 25 percent of the dollar amount of the claims reviewed. The MAC provides notification to the provider about the specific errors made. The MAC initiates a moderate amount (e.g., 30 percent) of prepayment medical review to ensure proper billing.

5. Thirty-five claims from one provider are reviewed. Thirty claims are denied representing 75 percent of the dollar amount of the claims reviewed. Many of the denials represent services provided to beneficiaries who did not meet the Medicare eligibility requirements. The MAC provides notification to the provider about specific errors made and makes a priority referral to POE to inform them of the severity of the problem. A consent settlement offer is made but declined by the provider. A postpayment review of statistical sampling for overpayment estimation is performed and an overpayment is projected to the universe of similar claims from the provider. Overpayment collection is initiated.

6. Twenty-five claims from one supplier are reviewed. Five claims representing 5 percent of the dollar amount of the claims are denied. This supplier is known to the DME MAC as one who has a significant decrease in billing volume when

targeted medical review is initiated. The DME MAC is concerned that this supplier may be selectively submitting bills when placed on medical review and chooses to continue some level of prepayment medical review despite the low error rate.

7. Twenty claims from one provider are reviewed. Ten claims are denied for incomplete physician orders representing 65 percent of the dollar amount of the claims. The MAC issues a letter to inform the home health agency (HHA) about the denials and the reason for the denials. In response to the notification letter, the agency owner initiated a mandatory training program for select staff. The HHA was put on 30 percent prepayment medical review. Results of the review indicated an improvement in the error rate to 30 percent (based on dollars denied divided by dollars reviewed). On appeal, most of the denials were overturned. The MAC consults with the ALJ to understand why the cases are being overturned and consults with the RO on appropriate next steps.

3.7.1.3 - Provider Notification and Feedback
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

Direct communication between the MAC and the provider is an essential part of solving problems. This process is carried out through written communication or by telephone as a result of specific claims or a group of reviewed claims. The overall goal of providing notification and feedback is to ensure proper billing practices and appropriate consideration of coverage criteria so claims will be submitted and paid correctly.

The MACs shall include an offer to provide individualized education in the notification letter along with contact information for POE. When inquiries are received in response to a provider notification or feedback letter, only responses to those inquiries directly related to a specific claim or group of claims reviewed on probe or targeted medical review shall be charged to medical review. This charge must be in the appropriate activity code or applicable SOW section for the type of review performed.

3.7.2 - Comparative Billing Reports (CBRs)
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

The MACs have the discretion to develop and issue comparative billing reports in the following three (3) situations**:**

1. **Provider-specific CBRs for providers with aberrant billing patterns.**

The MACs have the discretion to give provider-specific comparative billing reports to providers with the highest utilization for the services they bill in order to address

potential over-utilization. The MACs have the discretion to send the CBRs based solely on data analysis, without further review or CBRs may be included in the feedback and notification information issued as a result of probe and targeted medical review. These reports shall provide comparative data on how the provider varies from other providers in the same specialty payment area or locality. MACs should not charge a fee for providing these reports.

2. Provider-specific or specialty-specific CBRs requestors.

To provide good customer service, MACs have the discretion to provide specific reports to providers or provider associations who request such a report. They may charge a fee for providing these discretionary reports. However, any money collected shall be reported as a credit in the appropriate activity code or the applicable SOW section and be accompanied with a rationale for charging the fee. Revenues collected from these discretionary activities shall be used only to cover the cost of these activities, and shall not be used to supplement other MAC activities. If the MACs choose to make such reports available, the MACs shall describe on their Web site the mechanism by which a provider or provider association can request the report and state the associated fee.

3. CBRs for service-specific problems

When widespread problems are verified, MACs shall refer that information to their POE department for possible Web site posting. For example, data analysis may reveal that home health providers in a particular state bill three (3) times more of a particular code than do home health providers in other surrounding states. The MACs shall not charge a fee for posting these reports.

The MACs shall ensure that POE staff has ready access to copies of all MR provider notification and feedback letters so that they will have this information available in the event that a provider contacts POE requesting education. If the problem identified by MR is of medium or high priority, the MAC shall make a priority referral to POE, alerting POE staff to the degree of severity and educational need.

3.7.3 - Evaluating the Effectiveness of Corrective Actions

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs.

The MACs shall evaluate the effectiveness of their corrective actions on targeted providers or problem areas at least every three (3) months until there is evidence that the poor practice has been corrected. MACs shall establish a method to determine the disposition of educational referrals made to POE to ensure coordination of efforts and resolution of identified problems. MACs have the discretion to use the PTS to perform this function, but are not mandated to do so. MACs shall use the PTS to coordinate contacts with providers regarding MR activities. MACs shall also coordinate this

information with the UPICs to ensure contacts are not in conflict with fraud related activities.

3.7.3.1 - Evaluation of Prepayment Edits
(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

This section applies to MACs.

The MACs shall develop prepayment edits based on the findings of data analysis, followed by identification and prioritization of identified problems. The MACs shall evaluate all service-specific and provider-specific prepayment edits as follows:

- Automated edits shall be evaluated annually, and
- Non-medical record review or medical record review edits shall be evaluated quarterly.

The edit evaluations are to determine their effectiveness on the provider or service area while assessing the effect of the edit tasks on workload. The MACs shall consider an edit to be effective when it has a reasonable rate of denial relative to suspensions and a reasonable dollar return on cost of operation or potential to avoid significant risk to beneficiaries. The MACs shall revise or replace edits that are ineffective. Edits may be ineffective when payments or claims denied are very small in proportion to the volume of claims suspended for review. It is appropriate to leave edits in place if sufficient data are not available to evaluate effectiveness, for instance, a measurable impact is expected, or a quarter is too brief a time period to observe a change. The MACs shall analyze prepayment edits in conjunction with data analysis to confirm or re-establish priorities. The MACs should replace existing effective edits to address problems that are potentially more costly, if appropriate.

3.7.3.2 - Evaluating Effectiveness of Established Automated Edits
(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs.

MACs shall consider the following factors when looking at edit effectiveness for established automated edits:

- Time and staffing needs for review and appeal reviews. MACs shall implement mechanisms (e.g., manual logs, automated tracking systems) to allow the appeals unit to communicate to the MR unit information such as when denial categories are causing the greatest impact on appeals, the outcome of the appeal, and

- MACs shall maintain and make available to the appropriate CMS staff documentation demonstrating that they consider appeals in their edit evaluation process; and specificity of edits in relation to

identified problem(s).

The MACs should note that even an automated edit that results in no denials may be effective as long as the presence of the edit is not preventing the installation of other automated edits. The MAC shall provide the claims data necessary to the UPIC to evaluate the effectiveness of edits implemented at UPIC request. The MACs shall provide this report on a monthly basis by the 15th business day of each month. This requirement could also be met by the UPICs retrieving claim data necessary directly from the EDC if available.

A. Edit Effectiveness for all Other Edits

The MACs shall consider the following factors when looking at edit effectiveness for all other edits:

- Time and staffing needs for review and appeal reviews. MACs shall implement mechanisms (e.g., manual logs, automated tracking systems) to allow the appeals unit to communicate to the MAC MR unit and the UPIC just specific to UPIC edits information such as which denial categories are causing the greatest impact on appeals, and the outcome of the appeal. MACs shall maintain and make available to CMS documentation demonstrating that appeal outcomes are considered in their edit evaluation process;

- Specificity of edits in relation to identified problem(s);

- Demonstrated change in provider behavior, i.e., the MAC can show a decrease in frequency of services per beneficiary, the decrease in the number of beneficiaries receiving the services, the service is no longer billed, or another valid measure can be used to reflect a change in provider behavior over time;

- Impact of educational or deterrent effect in relation to review costs; and

- The relative priorities or competing edits in terms of the number of claims/days/charges.

The MACs shall test each edit before implementation to verify that the edit accomplishes the objective of efficiently selecting claims for review and to determine the edit's impact on workload.

3.7.3.3 - Evaluation of Postpayment Review Effectiveness

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs.

The MACs shall determine if any other corrective actions are necessary such as:

- Uncovering potential fraud in the course of MR postpayment review activities. The MR unit shall refer these cases to the UPIC. If it is believed that the overpayment resulted from potential fraud, a refund may not be requested from the provider until the potential fraud issue is resolved.

- Initiating provider or supplier specific edits to focus prepayment view on the problem provider or supplier or group of providers or suppliers, if appropriate ;

- Working with the CMS Central Office Division of Benefit Integrity Management Operations (DBIMO) Fraud and Abuse Suspensions and Sanctions (FASS) Team to suspend payment to the provider or group of providers;

- Referring provider certification issues to the State survey agency through CMS staff;

- Referring quality issues involving inpatient hospital services to the RO and QIO; and

- Coordinating with the QIO and MAC on interrelated billing problems

The MACs periodically perform a follow-up analysis of the provider(s) or supplier(s) for as long as necessary to determine if further corrective actions are required. In some cases, it may be feasible and timely to perform the follow-up analysis of the provider or supplier after the three (3) month time period. The MACs shall continue to monitor the provider(s) or supplier(s) until there is a referral to the UPICs for potential fraud, evidence that the utilization or billing problem is corrected, or data analysis indicating resources would be better utilized elsewhere.

3.7.4 - Tracking Appeals

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

The MACs shall track and evaluate the results of appeals. It is not an efficient use of medical review resources to deny claims that are routinely reversed upon appeal. When such outcomes are identified, MACs shall take steps to understand why hearing or

appeals officers viewed the case differently from them, and discuss appropriate changes in policy, procedure, outreach or review strategies with the regional office.

3.7.5 - Corrective Action Reporting Requirements

(Rev.: 10100; Issued: 05-08-2020; Effective: 06-09-2020; Implementation: 06-09-2020)

A. General

This section applies to MACs.

The CMS will provide information to the MACs regarding CMS Recovery Audit Contractor (RAC), and OIG-identified issues via Technical Direction Letters (TDLs). The TDLs will be sent to the MACs on a quarterly basis. Each MAC shall report corrective actions by the dates stated in the TDLs.

B. Corrective Action Reporting on CMS and OIG-Identified Issues

The CMS will provide MACs with a list of issues on an Excel spreadsheet template (Corrective Actions Taken on CMS and OIG-Identified Issues). These issues may be uncovered by the RAC, OIG audits, internal CMS analysis, or other means. The MACs shall review the spreadsheet, type precise responses on the template (see interim and final reportable action statement samples below), and upload the excel file or flat file to the RAC Data Warehouse (RAC DW).

For each of the issues, MACs shall report interim actions, final actions, and action dates (see interim and final reportable action statement examples below). The common factor between all reportable actions is quantifiability. The distinguishing factor between the two types of reportable actions is intervention implementation. Interim reportable actions generally indicate in-progress reviews of issues prior to the initiation of final actions. Final reportable actions indicate specific interventions completed to prevent future improper payments.

Examples of interim reportable action statements:

- MAC is planning a 50% post-payment review (to be performed between 08/01/2014 – 08/31/2014) of 200 claims (with dates of service between 01/01/2012 – 12/31/2012).
- MAC performed a 100% pre-payment review for DRG numbers ### – ### on 02/14/2014 (with dates of service between 01/01/2012 – 12/31/2012).
- MAC performed a pre-payment widespread review using a 100 claim probe on 03/26/2014 (with dates of service between 01/01/2012 – 12/31/2012).
- MAC performed a provider-specific pre-payment review on 04/17/2014 (with dates of service between 01/01/2012 – 12/31/2012).
- Due to resource limitations, not yet able to fully research issue (with dates of service between 01/01/2012 – 12/31/2012).

Examples of final reportable action statements:

- MAC held a provider seminar for 500 chiropractors regarding documentation requirements on 11/12/2013.
- MAC published an article regarding billing for nebulizer drugs on 02/27/2014 that explained the coverage policy for nebulizer drugs.
- MAC installed an automated edit and validated functionality on 03/19/2014 for codes ### – ###.
    - If readily available, please provide edit effectiveness as defined in PIM section 3.7.3.1 – Evaluation of Prepayment Edits. <Please insert cost savings and number or percentage of claims denied.>

- MAC performed a provider -specific review resulting in a provider education activity. <Comparative Billing Report, letter, one-on-one telephone explanation,…>…on 05/19/2014.
- Based on analysis, this is not an issue within jurisdiction X.

Interim and final reportable action statement rationales:

- In the additional comments section of the TDL template, MACs shall provide brief supplementary rationales for the reported actions. o For example, rationales may state that analysis produced no significant findings due to low volume, claims paid, lower risk and lower priority ranking when compared with other issues.

- The MACs have the discretion to also utilize the additional comments section to briefly explain pertinent background information regarding the MACs processes for specific issues. The MACs may also utilize the space to communicate suggestions for CMS to consider regarding possible future actions.

The MACs shall use the format (Corrective Actions Taken on CMS and OIG-Identified Issues) located in Exhibit 18, section A for reporting purposes. The MACs shall use the prescribed format, acceptable to the RAC DW. The MACs shall upload the file by the date specified in the TDL. If the due dates fall on a weekend or a federal holiday, the MAC shall upload the file on the closest business day after the weekend or holiday. A TDL may occasionally provide an exception to the submission criteria described in the PIM and the exception will be stated within the text of the memorandum.

Updates to previous reportable actions

The MACs shall keep CMS informed of any updates or changes to interim or final reportable actions on top issues from past TDL responses. The format located in Exhibit 18, Section A will included a column titled ‘Updated Responses.’ The MACs shall enter the following information, in a single cell, for each update:

- The New Issue number being updated
- The Issue Label
- The fiscal year and quarter that the responses were first provided
- The type of response originally provided [Interim or Final]
- The type of response being provided in the update [Interim or Final]
- The response statement in the format described above

The MACs should leave this section blank if they have no updates for the quarter.

C. Overpayment Recovery Reporting

The CMS will provide the MACs with specific claims information from Office of the Inspector General (OIG) audits on a quarterly basis via TDLs. These specific claims have not been reviewed by the OIG and overpayments have not yet been identified. The MACs have the discretion to review these specific OIG-identified claims. The MACs shall report overpayment recoveries pertaining to the specific OIG-identified claims to the CMS on a quarterly basis. If the MAC does not plan on conducting review or cannot conduct review on the specific OIG-identified claims, the MAC shall indicate that no medical review will be conducted and shall also indicate the reason why no medical review and/or overpayment recovery will be conducted on the particular claims set. The reporting shall include the Medicare contractor number, the OIG audit number (e.g. A-01-08-00528, OEI-01-04-0060) and the cumulative amount collected on the overpayments resulting from the specific set of OIG-identified claims. The cumulative amount shall include appeals. The CMS will indicate the "final reporting date" in the reporting document when the recovery process has been completed for a specific set of OIG-identified claims. CMS will indicate when the report shall be closed. The MACs have the discretion to report on overpayments that have been referred or are uncollectable at this time resulting from the specific set of OIG-identified claims.

The MACs shall submit their response to CMS on or before March 1, June 1, September 1, and December 1. If the due dates fall on a weekend or a federal holiday, the MACs shall submit the report on the closest business day after the weekend or holiday. The MACs shall submit their response in Excel via email to the CMS contact indicated in the most recent TDL from CMS which includes the claim information and report number. The MACs shall use the format titled "Overpayment Recovery on OIG Claims Format" located in Exhibit 18 for reporting purposes. The MAC has the discretion to readjust the format for use in Excel. The MAC shall complete all fields in the format except for the one optional column. The MACs have the discretion to complete the column titled "Overpayments referred or uncollectable (in dollars)."

3.8 - Administrative Relief from MR During a Disaster

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

This section applies to MACs and Recovery Auditors. UPICs refer to the PIM chapter 4.

A. General

When a disaster occurs, whether natural or man-made, MACs and Recovery Auditors shall anticipate both an increased demand for emergency and other health care services, and a corresponding disruption to normal health care delivery systems and networks. In disaster situations, MACs should do whatever they can to ensure that all Medicare beneficiaries have access to the emergency or urgent care they need. MACs are encouraged to let providers know (via Web site, responses to provider calls, etc.) that the provider's first responsibility, as in any emergency, is to provide the needed emergency or urgent service or treatment. The MACs should assure providers they will work with providers to ensure that they receive payment for all covered services. The administrative flexibility available to MACs and Recovery Auditors is discussed below. These actions will prevent most inappropriate denials and subsequent appeals.

B. Definition of Disaster

A disaster is defined as any natural or man-made catastrophe (such as hurricane, tornado, earthquake, volcanic eruption, mudslide, snowstorm, tsunami, terrorist attack, bombing, fire, flood, or explosion) which causes damage of sufficient severity and magnitude to partially or completely destroy medical records and associated documentation that could be requested by the MACs and Recovery Auditors in the course of a Medicare audit, interrupt normal mail service (including US Postal delivery, overnight parcel delivery services, etc.), and/or otherwise significantly limit the provider's daily operations.

A disaster may be widespread and impact multiple structures (e.g., a regional flood) or isolated and impact a single site only (e.g., water main failure). The fact that a provider is located in a presidentially declared disaster area under the power of the Stafford Act is not sufficient in itself to justify administrative relief, as not all structures in the disaster area may have been subject to the same amount of damage. Damage must be of sufficient severity and extent to compromise retrieval of medical documentation.

C. Basis for Providing Administrative Relief

In the event of a disaster, MACs and Recovery Auditors shall grant temporary administrative relief to any affected providers for up to 6 months (or longer with good cause). Administrative relief is to be granted to providers on a case-by-case basis in accordance with the following guidelines:

- The MACs and Recovery Auditors shall make every effort to be responsive to providers who are victims of the disaster and whose medical documentation may be partially or completely destroyed.

- Providers must maintain and submit verification upon contractor request by the MAC or Recovery Auditor that (1) a disaster has occurred and (2) medical record loss resulted from this disaster to the point where administrative relief from medical review

requirements is necessary to allow the provider sufficient time to retrieve copies of, or restore damaged, medical documentation.

Verification of the disaster and the resultant damage should include but is not limited to:

(1) Copies of claims filed by the provider with his/her insurance and liability company; and
(2) Copies of police reports filed to report the damage, (3) copies of claims submitted to FEMA for financial assistance, (4) copies of tax reports filed to report the losses, or (5) photographs of damage. MACs and Recovery Auditors shall not routinely request providers to submit verification of damage or loss of medical record documentation.

D. Types of Relief

Providers Directly Affected By Disaster

The MACs and Recovery Auditors shall stop sending ADR letters to providers who have been directly affected for at least 60 calendar days. The MACs and Recovery Auditors shall allow up to an additional six months beyond the original due date for the submission of requested records. Requests for extensions beyond this date can be granted with good cause at the discretion of the MAC or Recovery Auditor.

In the case of complete destruction of medical records where no backup records exist, MACs and Recovery Auditors shall accept an attestation that no medical records exist and consider the services covered and correctly coded. In the case of partial destruction, MACs and Recovery Auditors should instruct providers to reconstruct the records as much as possible with whatever original records can be salvaged. Providers should note on the face sheet of the completely or partially reconstructed medical record: "This record was reconstructed because of disaster."

Providers Indirectly Affected By Disaster

For providers that are indirectly affected by a disaster (e.g., an interruption of mail service caused by a grounding of US commercial air flights), MACs and Recovery Auditors shall take the following actions:

For ADRs, extend the parameter that triggers denial for non-receipt of medical records from 45 calendar days to 90 calendar days. ADRs shall reflect that the response is due in 90 calendar days rather than 45 calendar days. This action will prevent most inappropriate denials and unnecessary increases in appeals workload.

If the MAC or Recovery Auditor receives the requested documentation after a denial has been issued but within a reasonable number of days beyond the denial date, the MAC or Recovery Auditor has the discretion to reopen the claim and make a medical review determination. Many reviewers follow a standard 15 calendar days although MACs and

Recovery Auditors shall make these decisions on a case-by-case basis. The MACs and Recovery Auditors shall allocate the workload, costs and savings to the appropriate MR activity.

The MACs and Recovery Auditors shall review reopened claims retroactively to the date of the disaster. The MAC's data analyses shall take into consideration the expected increase in certain services in disaster areas.

E. Impact on MAC Performance Evaluations

During performance evaluations, CMS will consider a waiver to all MAC MR requirements, as necessary, to allow MACs the flexibility to handle issues that arise in the aftermath of a disaster. Examples of such waived requirements include workload targets and any other MR administrative rules. MACs shall retain documentation of how their MR operations were affected during the disaster and make it available to Performance Evaluation Teams and other CMS Staff, upon request.

3.9 - Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings

(Rev. 853, Issued: 01-04-19; Effective: 02-05-19; Implementation: 02-05-19)

This section in its entirety applies to MACs. This section applies to Recovery Auditors, CERT, UPICs, and the SMRC, as indicated in their SOWs.

Overview:

Effective March 20, 2017 several changes were made to the regulations that outline the activities related to contractor participation in ALJ hearings. Under the new regulations, CMS contractors are limited to 3 roles in an ALJ hearing: a Participant, a Party, or a Witness (defined in detail below). These changes are outlined in 42 CFR §405.1010 and 42 CFR §405.1012.

A physician overseeing participation shall be a current Contractor Medical Director (CMD), a contractor employed physician or any combination thereof. Nurses and other staff may assist the physician with the tasks described in this section. While the physician is generally the primary individual overseeing and/or taking party or participant status, a contractor may elect to have an attorney or clinician take party or participant status, or another experienced qualified individual if approved by their COR. In either situation, the contractor must be prepared to discuss details related to the facts of each claim under appeal, the relevant coverage policies and payment requirements, including any clarification required on decisions made earlier in the appeals process. For post-pay audit/overpayment cases, the contractor must be prepared to discuss the background on how the provider/supplier was selected for review, results of the sample case adjudications, as well as matters related to the extrapolation methodology and/or processes.

This section establishes expectations related to the contractor's participation and associated coordination activities, although CMS may provide additional guidance and direction as needed. Further rules and procedures related to the ALJ hearing process are contained in 42 CFR §405.1000.

The MAC shall capture and report the ALJ participation and party data in their monthly status report to CMS. Contractors shall record the frequency of their support as a witness in the narrative field of the monthly status reports. Contractors shall ensure that JOAs are sufficient to support the ALJ hearing process and related coordination activities.

Role of the Participant:

In accordance with the revised regulation under 42 CFR Part §405.1010(c) and (d), all contractors' participation as a participant (i.e., non-party) shall be limited to submitting written testimony and/or position papers (except in those instances when non-party participants are able to provide testimony to clarify factual or policy issues in the case—as noted in the scenario below).

The regulations do not prohibit multiple CMS contractors and/or related entities from participating in the ALJ hearing as a participant. However, if no contractor or CMS invokes party status, then the first entity to submit their election to participate as a non-party participant to the ALJ may participate in the oral hearing (limited to clarification of factual or policy issues, as requested by the ALJ). All other entities may participate, but are precluded from the hearing and may only submit written testimony and/or position papers as indicated in 42 CFR §405.1010(d)(1) and (2). If the contractor is able to participate in the hearing, they shall be adequately prepared to respond to questioning by the ALJ regarding all issues related to the claims under appeal. Because participation status does not include the same rights as full party status, the contractor may not call witnesses or cross-examine witnesses of another party, as indicated in 42 CFR §405.1010(c)(1).

(Note: At this time, CMS would not expect contractors to be responsible for clarifying factual or policy issues for cases/claims outside of their jurisdiction.)

Role of the Party:

Contractors shall invoke party status in ALJ hearings in accordance with the regulatory provisions in 42 CFR § 405.1012 and the CMS-prescribed prioritization process, described below, for cases or items/services of interest to CMS. Under 42 CFR §405.1012(d)(1), the first contractor to invoke party status with the ALJ is made the party to the hearing. All other contractors who invoke party status for that particular hearing are made participants and are precluded from the hearing (See Role of the Participant section above).

Note: At this time, CMS would not expect contractors to be responsible for representing cases/claims outside of their jurisdiction.

If the contactor is interested in a particular case, but is precluded from invoking party status based on the CMS-prescribed prioritization of cases or otherwise, the contractor may request 'leave' from the ALJ in accordance with 42 CFR §405.1012(d)(2). The request for 'leave' process occurs outside of the Administrative Qualified Independent Contractor (AdQIC) portal, described below. In submitting a request for 'leave' to the ALJ, the contractor is formally requesting that the ALJ grant the contractor the right to be a secondary party to the hearing. Requests for 'leave' to the ALJ shall also include the reason(s) why the contractor believes that their presence as a secondary party in the ALJ Hearing is necessary. The ALJ shall make the determination as to whether the contractor is granted 'leave.' If this is approved, the contractor shall become a secondary party to the hearing. Alternatively, if denied, the contractor may participate as a participant or as a witness, based on the circumstance. (See Role of Witness section for additional information).

As a party, the contractor is able to orally participate in the hearing and may file position papers, call witnesses, and/or cross-examine witnesses of other parties. The contractor shall submit any position paper or additional evidence requested by the ALJ in accordance with 42 CFR §405.1012(c)(2)(i) and (ii). The contractor shall be adequately prepared to respond to questioning by the ALJ or other parties regarding all issues related to the claims under appeal. As a party to the hearing, contractors are subject to discovery by the other party to the hearing in accordance with 42 CFR §405.1037.

For Notice of Hearings (NOHs) received that include issues deemed significant by CMS or the contractor, the contractor shall, at a minimum:

- Invoke party status in ALJ cases per volume of ALJ cases funded for this activity;
- Participate in any pre-ALJ hearing conference calls, as needed, with other contractors (as facilitated by the appropriate Qualified Independent Contractor (QIC));
- Coordinate with Medical Director(s) or related personnel from other contractors intending to participate as consultants/expert witnesses, as necessary, in accordance with 42 CFR §405.1010(d)(3). In addition, the MAC shall coordinate with other contractors for those hearings in which they do not invoke party status, but decide to participate as a consultant/expert witness; and/or,
- Participate in the hearings as a party via telephone, video teleconferencing, or in-person.

Role of the Witness:

If the ALJ declines the request for contractor 'leave' on a particular hearing, the contractor may be called as a 'witness' by CMS or another CMS contractor that is a party

to the hearing. A determination regarding the need for a 'witness' by the participating party shall be determined by the party and communicated to the contractor prior to the hearing. Contractors should, at their discretion, participate as a 'witness' in any case in which another CMS contractor and/or CMS has requested their support in a hearing. Contractors shall notify the requesting party no later than 10 days prior to the scheduled hearing in those instances in which contractors are unable to support the hearing as a 'witness.' As a 'witness,' contractors shall be tasked with supporting the party to the hearing in responding to policy or factual issues related to a particular case through direct examination and is subject to cross examination by the opposing party.

Note: Contractors who are interested in acting as a witness may indicate their interest via the AdQIC Portal. CMS contractors may indicate interest in participating as a witness without first making a request for 'leave' with an ALJ. Additionally, in accordance with 42 CFR §405.1020, witness designations/elections shall be made during the coordination of interest/role selection process, as described below, and shall be included in the response to a given NOH.
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3.9.1 - Election of Status

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The contractor shall establish a process for assessing the NOHs received to determine which cases should be selected for participation, as well as the type of participation (participant, party, or witness) to be employed. Factors to be examined should include, but not be limited to: originator of initial denial, policy implications, dollars at issue, program integrity matters, and the extent to which a particular issue is, or has been, a recurring issue at the ALJ level of appeal.

Contractors shall, for those cases in which they were the medical reviewer issuing the denial subject to appeal, have a prioritized ability to invoke party status (in lieu of other appeals support contractors). This process is further described below.

A. Election of Participation Status Prior to Receipt of a Formal NOH

The election to participate as a participant shall be made consistent with 42 CFR §405.1010 and can be done either prior to receipt of a formal NOH or after the receipt of a formal NOH.

The regulations allow CMS contractors to elect to participate as a participant before issuance and/or receipt of the formal NOH. See section of 42 CFR §405.1010(b)(1) for additional information. If the contractor elects to participate before the receipt of the NOH, it shall send written notice of its intent to the assigned ALJ or attorney adjudicator, or the designee of the Chief ALJ, if no contact assigned yet, and to all parties on the reconsideration (per the prescribed OMHA process) within 30 calendar days after notification that a request for hearing had been filed. In accordance with the regulations, a position paper or written testimony must either be submitted within 14 calendar days of

an election to participate, if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing, if a hearing is scheduled, unless the ALJ grants additional time to submit the position paper or written testimony. Contractors should note that there is a risk that the case may be later resolved by the ALJ, or an Attorney Adjudicator within the OMHA, without a hearing.

B. Election of Participation or Party Status Following Receipt of the Formal NOH

The election to be a participant or a party to a hearing after receipt of the formal NOH shall be made consistent with 42 CFR §405.1010(b) or 42 CFR §405.1012, respectively, and the CMS-prescribed prioritization process, described below. If through the CMS-prescribed prioritization process it is determined that the contractor may act as either the party or a participant to a hearing, elections of participation must be sent by the Contractor within 10 calendar days of receipt of the NOH at the AdQIC to all parties listed on the NOH. Submission of a position paper, written testimony, and/or evidence must be submitted no later than five calendar days before the date of the scheduled hearing. Copies of these items must also be sent to those parties listed on the NOH in accordance with 42 CFR §405.1010(c)(3)(ii) and 42 CFR §405.1012(c)(2)(ii).

C. CMS-prescribed Prioritization Process and AdQIC Portal for Providing a Response to the Formal NOH

As the AdQIC is tasked with coordinating contractor interest in participation among the related CMS contractors and/or CMS, all NOHs will be sent directly to the AdQIC from the OMHA. The AdQIC, within two (2) calendar days of receipt of the formal NOH from OMHA, will create a record in the AdQIC portal that will generate an email notification to all applicable CMS contractors (e.g., DME MAC, A/B MAC, UPIC, SMRC, and/or RAC) notifying them that a hearing has been scheduled.

Upon receipt of the formal NOH e-mail alert, all applicable CMS contractors shall log onto the AdQIC website, https://participation.q2a.com, to access the NOH information. All applicable CMS contractors shall make their elections, via the AdQIC website, within five (5) calendar days of the formal NOH e-mail sent date. To make an election, contractors must sign-in on the website (see above), and a dashboard will be available listing all appeals for the respective contractor that they may choose to participate in.

Users can also search for appeals based on the information provided in the notification email. Next, the contractors shall select the applicable NOH identifier and complete/submit the CMS Contractor Participation Form indicating for each appeal whether they would like to participate as a party, participant, or witness, and/or if they would like to call a witness if made a party to the hearing. CMS contractors that fail to sign-in to the AdQIC system and make their respective participation role selections, in the required timeframe, may be precluded from the prioritization process.

Note: Users will not be able to view the actual NOH document on the site. The web-

site/dashboard will allow contractors to view all scheduled hearings for which they received an NOH.

For all NOH communications (e.g., NOHs received from OMHA, NOH email alerts) received after standard business hours (e.g., 4:00 p.m., ET) and/or during weekends or business Holidays, as defined by the respective entity, the AdQIC portal is programmed to calculate the response time beginning with the next applicable business day [e.g., if the AdQIC receives the formal NOH on a Friday at 4:00 pm, the five (5) calendar day timeframe begins on Monday (with Monday being day zero (0))].

The AdQIC portal will evaluate all submissions received and determine which entity shall have the primary opportunity to participate as a 'party,' and which entities can participate as 'participants' or 'witnesses' based on CMS' prioritization logic.

The anticipated prioritization for the role of party status is as follows:

1) Primary opportunity for the 'party' role in an ALJ hearing will be granted to the entity that conducted the initial claim denial (e.g., UPIC, RAC, SMRC or medical review unit within the MAC).
2) If the entity that issued the initial claim denial does not have interest in participating as a party (due to workload considerations or otherwise) the QIC will have the primary opportunity to participate as a party.
3) If no CMS contractors and/or CMS wish to invoke 'party' status in a hearing and multiple entities wish to be a participant, the primary participant shall be the entity that conducted the initial claim denial (e.g., UPIC, RAC, SMRC, or medical review unit within the MAC).
4) If the entity that identified/conducted the initial claim denial does not wish to be the 'primary' participant on the case, the QIC will have the next opportunity to assume this role.

The AdQIC portal will review and prioritize contractor roles in a respective ALJ hearing (i.e., which contractor shall be the 'party', 'participants,' etc.), within 2 calendar days of receipt of the completed Contractor Participation forms. The website will automatically calculate the contractor's Participation Form response due date and each contractor's role determination, and prioritize participation elections on the next calendar day after the contractor response timeframe expires. Participation/role designations will be sent via a system-generated email notification to any contractors who expressed interest in participation. The status of elections for a given NOH will be available on the AdQIC's website once determinations have been made and notifications have been sent to the applicable CMS contractors.

On rare occasion, the QIC may need to facilitate a call with the CMS and the related contractors to determine the roles and/or responsibilities on a particular hearing.

Within 10 calendar days from the initial NOH receipt date, the AdQIC will reply on behalf of all applicable CMS contractors to the NOH and OMHA with a consolidated response. The consolidated response shall include a Notice of Election form for each applicable CMS contractor for a given NOH.

In the event that OMHA issues an amended NOH, the amended NOH email will be sent from OMHA directly to the AdQIC. The AdQIC will alert all applicable CMS contractors of the amended NOH within 2 calendar days of receipt of the amended NOH email from OMHA. CMS contractor participation roles, as determined via the prioritization process in the response to the original NOH and submitted to OMHA via a Notice of Intent (NOI), shall remain intact following issuance of an amended NOH by OMHA. However, if a CMS contractor wishes to change their method of participation following the receipt of an amended NOH, then the CMS contractor shall notify/work with the AdQIC and OMHA, as applicable (e.g., if another CMS contractor was designated as the Party and the QIC was made a non-party Participant, but now the QIC wishes to serve as a Party following the receipt of an amended NOH, then the QIC must request 'leave' with the ALJ and notify the AdQIC if the request for 'leave' is approved).

D. Communications Outside of the Portal/AdQIC Process

While the AdQIC and its prioritization portal provide useful vehicles for assessing information transcribed from the notices of hearing received from OMHA and providing formal response, contractors are reminded of regulatory communications that occur outside of this process.

Contractors are reminded that the AdQIC portal and prioritization process is initiated by receipt of an NOH from OMHA. Therefore, Contractors electing status prior to receipt of an NOH shall follow the regulatory process (outlined in 42 CFR §405.1010) to alert OMHA and other parties that were sent a copy of the notice of reconsideration of their intent to participate, which occurs outside of the portal.

In accordance with section of 42 CFR §405.1010(b)(2) and (3), if a contractor elects to participate in an ALJ hearing, the contractor (not the AdQIC) shall provide written notice of its intent to participate to the parties who were sent a copy of an NOH. Failure to notify the other parties to the appeal, of the intent to participate, may result in the ALJ determining the contractor's election for a given NOH invalid. This requirement remains applicable in the event of an amended NOH, and contractors shall ensure compliance. All pertinent information (e.g. party names, mailing address) will be available in the portal for a given NOH.

Additionally, CMS contractors participating or taking party status shall provide copies of all submitted position papers, written testimony, and/or evidence to the ALJ and other appropriate parties within the time frames as set forth in 42 C.F.R. sections 405.1010, 405.1012, or 423.2010, as applicable. Failure to provide copies of submitted position papers, written testimony, and/or evidence within the required timeframe will result in the

submissions not being considered by the respective ALJ. Providing copies of all submitted position papers, written testimony, and/or evidence to the appropriate parties remains applicable in the event an amended NOH is issued and contractors shall ensure compliance.

If a contractor requests 'leave' to the ALJ, or formally requests the ALJ to grant the contractor the right to be a secondary party to the hearing, this process occurs outside of the portal.

The ALJ sets the hearing date, time, and method by video teleconferencing (VTC), telephone, or in-person if VTC is not available or special circumstances exist. A party may object in writing to the time and place of the hearing, as soon as possible before the originally scheduled time but no later than 5 calendar days prior to the hearing, and include the reason for the objection along with a proposed alternative date and time. In addition, a party may request an in-person hearing by notifying the ALJ in writing and following the same procedures noted above for an objection to the time/place of the hearing. The ALJ may reschedule if good cause is established per 42 CFR §405.1020(f) or (g).

3.9.2 - Coordination of the ALJ Hearing

(Rev. 748, Issued: 10-13-17; Effective: 11-14-17; Implementation: 11-14-17)

As needed, if multiple entities are participating in a hearing as a party, participant, or witness, the QIC will set up a brief pre-hearing conference call to discuss the respective entity's participation in the case, roles and responsibilities, etc. Examples in which this may be necessary include high dollar cases, extrapolated overpayments, policy implications, and/or fraud related cases, etc.

Pre-hearing briefing topics may include: coordination with OMHA on scheduling matters, the manner of participation, coordination on position papers or other written testimony submitted, and lessons learned from participation in the ALJ process.

There may be cases in which testimony from another contractor is necessary. The contractor may call those entities as a witness only if the contractor has declared party status. However, if the contractor submits a position paper as a participant, the contractor may collaborate with other contractors and document their views on the case in the paper—although only one contractor may typically participate via the hearing.

The contractor shall establish a single point of contact for ALJ offices on administrative matters involving notifications, scheduling, information sharing, and other coordination necessary between the ALJ, the appellant, and other contractors.

3.10 – Prior Authorization

(Rev. 876; Issued: 04-12-19; Effective: 05-13-19; Implementation: 05-13-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare

beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

A. Overview

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item or service is furnished to the beneficiary and before the claim is submitted for processing. It is a process that permits the submitter (e.g., provider, supplier, beneficiary, etc.) to send in medical documentation in advance of providing and billing for an item or service, to verify its eligibility for Medicare claim payment. Contractors shall, at the direction of CMS or other authorizing entity, conduct prior authorizations and alert the submitter of any potential issues with the information, as submitted.

For any item or service to be covered by Medicare it must:

- Be eligible for a defined Medicare benefit category,
- Be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and
- Meet all other applicable Medicare coverage, coding and payment requirements.

Contractors shall communicate to the submitter (and beneficiary upon request) their prior authorization decision and the assigned unique tracking number (UTN), which indicates that the submitter requested a prior authorization, for corresponding claim submissions.

For certain prior authorization programs, the requirement to prior authorize is a condition of payment, as further described in the sections below.

Absent any explicit CMS instruction to the contrary, submitters may correct identified issues with their prior authorization request(s) and resubmit their request(s) for prior authorization without restriction. Contractors shall conduct prior authorization reviews within the timeframes defined by CMS in the corresponding prior authorization program operational instruction(s).

The prior authorization process is further described in following sections.

B. Condition of Payment

Contractors shall determine if the requirement to prior authorize a particular item or service is a condition of payment, as specified in the individual operational instruction(s). If prior authorization is a condition of payment, claims submitted without an indication

that the submitter made a prior authorization request (i.e., UTN) shall be denied upon receipt.

C. Outreach and Education

Contractors shall educate stakeholders each time a new prior authorization program is launched for a particular item or service, the requisite information and timeframes for prior authorization submissions, and the vehicle(s) for submitting such information to the contractor for assessment. Contractors shall make sure submitters are aware of the timeframes for contractors to render prior authorization decisions, for each individual prior authorization program.

Each prior authorization program will have an associated Operational Guide and will be available on the CMS website. Contractors shall, at a minimum, provide public access to agency-developed prior authorization operational guides, by posting the link(s) on their website.

Contractors shall hold group or individualized training sessions, as appropriate, to notify the stakeholders of upcoming prior authorization programs and to make sure there is ongoing understanding of the specific requirements for those applicable prior authorization programs.

D. Prior Authorization Submission

Contractors shall assess the information/documentation included in the prior authorization submission for completeness. Requisite information for individualized prior authorization programs will be included in the operational guides, and shall be available on the CMS website.

Requisite information may include, but is not limited to:

- Beneficiary Information (i.e., name, Medicare beneficiary identifier, date of birth)
- Physician/Practitioner Information (i.e., name, provider identification number, address)
- Supplier Information (i.e., name, national supplier clearinghouse (NSC) number, identification number, address)
- Documentation from the medical record to support the medical necessity of the item or service, and
- Any other relevant documents as deemed necessary by the contractor to process the prior authorization.

E. Prior Authorization Decisions

Contractors shall notify the submitter if their prior authorization submission results in a provisional affirmative, or non-affirmative decision.

- A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the item or service likely meets Medicare's coverage, coding, and payment requirements.

- A non-affirmative decision is a finding that the submitted information/documentation does not meet Medicare's coverage, coding, and payment requirements, and if a claim associated with the prior authorization is submitted for payment, it would not be paid. Contractors shall provide notification of the reason(s) for the non-affirmation, if a request is non-affirmative, to the submitter. If a prior authorization request receives a non-affirmative decision, the prior authorization request can be resubmitted an unlimited number of times, unless otherwise specified.

Contractors shall send detailed decision letters to submitters. As appropriate for the given prior authorization program, contractors shall send detailed decision letters to other stakeholders (e.g., beneficiaries) using their official address on file. In addition, there may be certain prior authorization programs that require the contractors to notify the appropriate entity by other means, such as telephone.

If a claim is submitted for payment without an affirmative prior authorization decision on file, contractors shall use their existing processes to either suspend claims for additional review or to process claims as denials, based on each individualized prior authorization program, as detailed in the operational instruction.

F. Expedited Request

For certain items or services, delays in receipt of a prior authorization decision could jeopardize the life or health of the beneficiary. Contractors shall, for such items or services, expedite their decisions based on the operational instruction.

If the claim processing systems would unavoidably delay the delivery of the UTN in an expedited fashion, contractors shall nonetheless render an affirmative or non-affirmative decision to the submitter within the mandated, expedited timeframe. Contractors shall alert the submitter that the decision is being provided as expediently as possible, so that the item or service may be provided, but that the submitter should hold their claim and not submit it until such time as the UTN is received (in order to avoid a claims payment denial).

3.10.1 - Prior Authorization Program for Certain DMEPOS

(Rev. 937; Issued: 01-31-20; Effective: 03-02-20; Implementation: 03-02-20)

A prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization is described in 42 CFR §405 and §414.234. Among other things, these sections establish a Master List of certain DMEPOS items meeting inclusion criteria and potentially subject to prior authorization. CMS will select Healthcare Common Procedure Coding System (HCPCS) codes from the Prior Authorization Master List that shall require prior authorization, at its discretion. In selecting HCPCS codes, CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis, and may implement prior authorization nationally or locally.

The Prior Authorization Master List is the list of DMEPOS items that have been identified using the inclusion criteria described in 42 CFR 414.234. The Master List can be found on the CMS website.

The Required Prior Authorization List is the items selected from the Prior Authorization Master List to be implemented in the Prior Authorization Program. The Required Prior Authorization List can be found on the CMS website, and will be updated as additional codes are selected for prior authorization.

CMS may elect to exempt suppliers from prior authorization program upon demonstration of compliance with Medicare coverage, coding, and payment rules.

The CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rulemaking. CMS provides notification of the suspension of the prior authorization requirements via—(i) Federal Register notice; and (ii) Posting on the CMS prior authorization Web site.

3.10.1.1- Voluntary Prior Authorization (PA) for DMEPOS Accessories
(Rev: 12056; Issued: 05-25-23; Effective: 06-26-23; Implementation: 06-26-23)

The 2019 ESRD and DMEPOS final rule (84 Fed. Reg. 60648 (Nov. 8, 2019)) permits CMS to develop a program to allow suppliers to voluntarily include certain accessories on prior authorization requests submitted for items on the Required Prior Authorization List. These accessories may receive a prior authorization decision for operational simplicity, even if the accessory itself is not on the Required Prior Authorization List. Voluntarily submitting a prior authorization request for accessories does not create a condition of payment and is not mandatory.

Prior authorization requests for accessories must include a corresponding item on the Required Prior Authorization List; otherwise, the prior authorization request for the accessory will be rejected. Accessories submitted on a prior authorization request where the corresponding item on the Required Prior Authorization List is non-affirmed will also be non-affirmed.

The list of DME items that require prior authorization can be found on Required Prior

Authorization List, and the list of selected accessories that can be voluntarily added to prior authorization requests can be found on the Voluntary Prior Authorization List. The Required Prior Authorization List and the Voluntary Prior Authorization List will be updated as additional codes are selected.

For more information, please see the CMS DMEPOS Prior Authorization website.

3.10.2 - Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services

(Rev. 937; Issued: 01-31-20; Effective: 03-02-20; Implementation: 03-02-20)

A prior authorization process for certain hospital OPD services is described in 42 CFR §§419.80 through 419.89 as a method for controlling unnecessary increases in the volume of covered services. These sections establish requirements for the submission of a prior authorization request (PAR), the timeframes for the review of a PAR, and the process for CMS to exempt providers from prior authorization requirements.

The list of hospital OPD services requiring prior authorization will be updated through formal notice-and-comment rulemaking. Technical updates to the list of services, such as changes to the name of the service or the HCPCS code, will be published on the CMS website.

The CMS may elect to exempt a provider from this prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules after semiannual assessments. Providers must reach a prior authorization provisional affirmation threshold of 90 percent or greater to be eligible for exemption.

The CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on the CMS website.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R12633PI	05/09/2024	Medical Review Policies for Signature Requirements	06/10/2024	13556
R12056PI	05/25/2023	Update to Chapter 3 of Publication (Pub.) 100-08 (Program Integrity Manual (PIM)) for the Voluntary Prior Authorization (PA) Process for Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) Accessories	06/26/2023	13185
R11933PI	03/30/2023	Update to Process and Responsibility for Tracking Medicare Contractors' Prepayment and Post Payment Reviews in the RAC Data Warehouse (RACDW)	04/03/2023	12281
R11697PI	11/09/2022	Update to Process and Responsibility for Tracking Medicare Contractors' Prepayment and Post Payment Reviews in the RAC Data Warehouse (RACDW)- Rescinded and Replaced by Transmittal 11933	04/03/2023	12881
R11529PI	07/28/2022	Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Post-Payment Review Process, and Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor Suspects Additional Improper Claims	08/30/2022	12827

Rev #	Issue Date	Subject	Impl Date	CR#
R11032PI	09/30/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08	11/10/2021	12375
R10984PI	09/09/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08 - Rescinded and Replaced by Transmittal 11032	11/10/2021	12375
R10365PI	10/02/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08	08/27/2020	11884
R10228PI	07/27/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08 Rescinded and Replaced by Transmittal #10365	08/27/2020	11884
R10197PI	06/26/2020	Publication (Pub.) 100-08 Chapter 3 Updates to Section 3.2.3.2 (Timeframes for Submission) and Section 3.2.3.8 (No Response or Insufficient Response to Additional Documentation Requests (ADRs))	07/27/2020	11730
R10190PI	06/19/2020	Revising Chapters 3 and 5 of Publication (Pub.) 100-08, to Reflect the Recent Final Rule CMS-1713-F	07/01/2020	11599
R10171PI	06/12/2020	Updates to Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) and Ambulance Certification Signature Requirements	07/13/2020	11763
R10132PI	05/15/2020	Revising Subsection 3.2.5, Targeted Probe and Educate (TPE), in Chapter 3 of Publication (Pub.) 100-08	06/16/2020	11695
R10100PI	05/08/2020	Revision to Language in Chapter 3, Section 3.7.5 (Corrective Action Reporting Requirements) of Publication (Pub.) 100-08	06/09/2020	11756
R937PI	01/31/2020	Updates to the Prior Authorization (PA) Guidance Within Publication (Pub.) 100-08	03/02/2020	11633
R933PI	01/10/2020	Update to Chapter 3, Section 3.2.3.1 Additional Documentation Requests (ADR) of Publication (Pub) 100-08	01/06/2020	10828
R912PI	10/18/2019	Medicare Administrative Contractor (MAC) Verification of Potential Errors and Corrective Actions Taken	11/19/2019	11463
R907PI	10/04/2019	Update to Chapter 3, Section 3.2.3.1	01/06/2020	10828

Rev #	Issue Date	Subject	Impl Date	CR#
		Additional Documentation Requests (ADR) of Publication (Pub) 100-08- Rescinded and Replaced by Transmittal #933		
R902PI	09/27/2019	Updates to Chapters 3, 4, 8, 15, and Exhibits of Publication (Pub.) 100-08	10/28/2019	11425
R876PI	04/12/2019	Update to Publication (Pub.) 100-08 to Provide Language-Only Changes for the New Medicare Card Project	05/13/2019	11109
R853PI	01/04/2019	Updates to the Appeals Prioritization Process	02/05/2019	10641
R833PI	10/12/2018	Templates in Medical Review	11/13/2018	10930
R825PI	09/21/2018	Credentials of Reviewers (This Change Request (CR) Rescinds and Fully Replaces CR 10157.)	10/22/2018	10909
R819PI	08/17/2018	Adding a Targeted Probe and Educate (TPE) Sub-Section Into Section 3.2 of Chapter 3 in Publication (Pub.) 100-08	09/17/2018	10876
R796PI	05/11/2018	Intent to Reopen	08/13/2018	9855
R802PI	06/21/2018	Use of Accessible and Applicable Claims History During Medical Review	07/24/2018	10640
R791PI	04/27/2018	Restoring Section 3.2.3 B. and Section 3.2.3 C. to Chapter 3 of Publication (Pub.) 100-08 in the Internet Only Manual (IOM)	05/29/2018	10505
R786PI	04/13/2018	Reimbursing Providers and Health Information Handlers (HIHs) for Additional Documentation	05/14/2018	10529
R768PI	02/08/2018	Post-Payment Review Timeliness Requirements	04/01/2018	9990
R755PI	11/09/2017	Tracking Medicare Contractors' Prepayment and Postpayment Reviews	12/11/2017	10177
R751PI	10/20/2017	Clarifying Signature Requirements	11/20/2017	10322
R748PI	10/13/2017	Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings	11/14/2017	10226
R738PI	08/18/2017	Provider Error Rate Formula	09/19/2017	10210
R732PI	07/21/2017	Clarifying the Instructions for Amending or Correcting Entries in Medical Records	08/22/2017	10120
R721PI	06/09/2017	Elimination of Routine Reviews Including Documentation Compliance Reviews and Instituting Three Medical Reviews	07/11/2017	9809
R713PI	05/05/2017	Scribe Services Signature Requirements	06/06/2017	10076

Rev #	Issue Date	Subject	Impl Date	CR#
R698PI	01/20/2017	The Process of Prior Authorization	02/21/2017	9940
R674PI	09/02/2016	Duplicate Postpayment Claim Reviews	11/04/2016	9665
R663PI	07/15/2016	Denial Codes for Missing or Insufficient Documentation	08/16/2016	9690
R657PI	06/17/2016	Special Provisions for Lab Additional Documentation Requests (ADRs)	07/18/2016	9670
R634PI	01/22/2016	Reviewers' Credentials, Notifying the Provider, CARC Code Update	04/22/2016	9333
R628PI	12/04/2015	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)	01/06/2016	9438
R620PI	10/16/2015	Pub. 100-08 Chapter 3 Updates: Section 3.2.3.2 Timeframes for Submission and Section 3.2.3.8 - No response to Additional Documentation Requests – Rescinded and not replaced	11/17/2015	9226
R617PI	10/09/2015	Update to Chapter 3 of Pub. 100-08	11/10/2015	9303
R615PI	10/02/2015	Signature Requirements	11/02/2015	9332
R613PI	09/25/2015	Postpayment Review Requirements	10/26/2015	9323
R608PI	08/14/2015	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/14/2015	8747
R604PI	07/24/2015	Signature Requirements	08/25/2015	9225
R585PI	04/03/2015	Coding Determinations	05/04/2015	8937
R568PI	02/04/2015	Review Timeliness Requirements for Complex Review	03/01/2015	8443
R567PI	02/04/2015	New Timeframe for Response to Additional Documentation Requests	04/06/2015	8583
R566PI	01/07/2015	New Timeframe for Response to Additional Documentation Requests – Rescinded and replaced by Transmittal 567	04/06/2015	8583
R565PI	12/31/2014	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)	02/02/2015	9012
R557PI	11/26/2014	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.4 (Additional Documentation Request Required and Optional Elements)	12/29/2014	8948

Rev #	Issue Date	Subject	Impl Date	CR#
R554PI	11/14/2014	New Timeframe for Response to Additional Documentation Requests – Rescinded and replaced by Transmittal 566	04/06/2015	8583
R547PI	10/17/2014	Review Timeliness Requirements for Complex Review – Rescinded and replaced by Transmittal 566	02/24/2015	8443
R543PI	09/26/2014	Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings	10/27/2014	8501
R541PI	09/12/2014	Claims that are Related	09/08/2014	8802
R540PI	09/04/2014	Claims that are Related – Rescinded and replaced by Transmittal 541	09/08/2014	8802
R534PI	08/08/2014	Claims that are Related – Rescinded and replaced by Transmittal 540	09/08/2014	8802
R527PI	07/03/2014	Provider Notice on MAC Web sites	09/05/2014	8690
R523PI	04/20/2014	Update to CMS Pub. 100-08, Chapter 3 – Rescinded and not replaced	07/22/2014	8791
R512PI	04/18/2014	Revision to the Program Integrity Manual, Chapter 3 Section 3.3	05/19/2014	8716
R505PI	02/05/2014	Removing Prohibition - Rescinded	03/06/2014	8425
R501PI	01/09/2014	Complex Medical Review	10/07/2013	8429
R500PI	12/27/2013	Third-party Additional Documentation Request CERT Update	01/28/2014	8547
R498PI	12/27/2013	Notifying the Provider of Postpayment Review Results	01/28/2014	8541
R496PI	12/12/2013	Tracking Medicare Contractors' Postpayment Reviews	10/03/2013	8362
R489PI	10/18/2013	100% Prepayment Review and Random Review Instructions	11/19/2013	8427
R488PI	09/20/2013	Acceptable Submission Methods for Responses to ADRs	10/21/2013	8436
R487PI	09/13/2013	Tracking Medicare Contractors' Postpayment Reviews	10/03/2013	8362
R486PI	09/06/2013	Complex Medical Review – Rescinded and replaced by Transmittal 501	10/07/2013	8429
R485PI	08/21/2013	Program Safeguard Contractor (PSC) and Zone Program Integrity Contractor (ZPIC) Provider Notification	01/29/2013	8079
R484PI	08/21/2013	OMB Collection Number	05/21/2012	7750

Rev #	Issue Date	Subject	Impl Date	CR#
R477PI	08/02/2013	Tracking Medicare Contractors' Postpayment Reviews – Rescinded and replaced by Transmittal 487	10/03/2013	8362
R465PI	05/17/2013	Use of a Rubber Stamp for Signature	06/18/2013	8219
R464PI	05/17/2013	Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information	06/18/2013	8267
R458PI	04/12/2013	EsMD RC Public Announcement	05/13/2013	8208
R455PI	03/15/2013	Progress Notes and Forms	12/10/2012	8033
R453PI	03/13/2013	Progress Notes and Forms – Rescinded and replaced by Transmittal 455	12/10/2012	8033
R447PI	01/18/2013	Medical Review Timeliness Requirements	02/19/2013	8131
R446PI	12/28/2012	Program Safeguard Contractor (PSC) and Zone Program Integrity Contractor (ZPIC) Provider Notification – Rescinded and replaced by Transmittal 485	01/29/2013	8079
R442PI	12/07/2012	Update for Amendments, Corrections and Delayed Entries in Medical Documentation	01/08/2013	8105
R438PI	11/09/2012	Progress Notes and Forms – Rescinded and replaced by Transmittal 453	12/10/2012	8033
R426PI	06/15/2012	Process for Handling Electronic Submission of Medical Documentation (esMD)	07/16/2012	7835
R422PI	05/25/2012	Request Records Related to the Claim Being Reviewed	06/26/2012	7837
R418PI	04/20/2012	OMB Collection Number – Rescinded and replaced by Transmittal 484	05/21/2012	7750
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Medicare Program Integrity Manual
Chapter 6 - Medicare Contractor Medical Review Guidelines for Specific Services

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6.1 – Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Claims

(Rev. 924; Issued: 11-15-19; Effective: 10-01-19; Implementation: 12-17-19)

In 1998, Medicare began paying skilled nursing facilities (SNFs) under a Prospective Payment System (PPS). PPS payments are per diem rates based on the patient's condition and determined through a CMS prescribed case-mix model and payment classification system. This classification is done by the use of a clinical assessment tool, the Minimum Data Set (MDS), and is required to be performed periodically according to an established schedule for purposes of Medicare payment. Each MDS represents the patient's clinical status based on an Assessment Reference Date (ARD) and established look-back periods for the covered days associated with that MDS. Medicare expects to pay at the rate based on the most recent clinical assessment (i.e., MDS), for all covered days associated with that MDS. Medical review decisions are based on documentation provided to support the coding and medical necessity of services recorded on the MDS for the claim period billed. Medicare contractors focus on the unique, individualized needs, characteristics and goals of each patient, in conjunction with CMS payment policies, to determine the appropriateness of the case-mix classifier billed.

All Medicare contractors are to review, in accordance with their medical review strategies, SNF PPS services covered by the consolidated billing policy. SNF services excluded from consolidated billing are identified in §4432(a) of the BBA and regular updates which can be accessed by contractors at: http://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html.

"Rules of thumb" in the Medical Review (MR) process are prohibited. Medicare contractors must not make denial decisions solely on the reviewer's general inferences about beneficiaries with similar diagnoses or on general data related to utilization. Any "rules of thumb" that would declare a claim not covered solely on the basis of elements, including but not limited to, lack of restoration potential, ability to walk a certain number of feet, or degree of stability, is unacceptable without individual review of all pertinent facts to determine if coverage may be justified. Medical denial decisions must be based on a detailed and thorough analysis of the beneficiary's total condition and individual need for care.

The goal of medical review is to determine whether the services are reasonable and necessary, delivered in the appropriate setting, and coded correctly, based on appropriate documentation. Under PPS, beneficiaries must continue to meet the regular eligibility requirements for a SNF stay as described in Pub. 100-02, Medicare Benefit Policy Manual, chapter 8, §§20ff, such as the 3-day medically necessary hospital stay and admission to a participating SNF within a specified time period (generally 30 days) after discharge from the hospital.

6.1.1 - Skilled Nursing Facility Qualifying Inpatient Stay
(Rev. 924; Issued: 11-15-19; Effective: 10-01-19; Implementation: 12-17-19)

Under the SNF PPS, beneficiaries who are admitted (or readmitted) directly to a SNF after a qualifying hospital stay are presumed to meet the level of care requirements of 42 CFR 409.31 up to and including the assessment reference date (ARD) for the initial Medicare assessment (commonly referred to as the "5-day" assessment) prescribed in 42 CFR 413.343(b), when correctly assigned to one of the more intensive case-mix classifiers that is designated (in the annual publication of Federal prospective payment rates described in 42 CFR 413.345) as representing the required level of care. If the beneficiary is not admitted (or readmitted) directly to a SNF after a qualifying hospital stay, the administrative level of care presumption does not apply. For a further explanation of the administrative presumption of coverage, please refer to §6.1.4 of this chapter, and to Pub. 100-02, Medicare Benefit Policy Manual, chapter 8, §30.1 (including item 3 of that section for a discussion of a rehospitalization that exceeds the 3-day interruption window specified under the SNF PPS's interrupted stay policy).

Medicare contractors shall:

- Use the Common Working File (CWF) to validate the presence of an inpatient hospital claim that was paid by Medicare. Because the entire medical record from the inpatient hospital stay is not received for a SNF claim, it is difficult to determine if the medical record and the CWF conflict. Therefore, it is assumed that the dates of service for the inpatient hospital claim in CWF are correct for purposes of establishing the 3-day prior inpatient hospital claim dates. If the CWF is silent as to an associated 3-day inpatient hospital claim, confirm that the beneficiary had a 3-day inpatient hospitalization outside the Medicare system (for example, the Veteran's Administration hospital system). If such is the case, the medical record from the inpatient hospitalization can be used to establish inpatient hospitalization dates. This documentation need not be signed for this purpose.

- Presume medical necessity of the qualifying inpatient hospitalization. If, during the normal claims review process, evidence that the hospitalization may not have been medically necessary emerges, the Medicare contractors shall fully develop the case in accordance with the directions contained in Pub. 100-02, chapter 8, § 20 and 20.1.

- Verify that the extended care services were for an ongoing condition that was also present during the prior hospital stay (even if not the main reason for that stay), or for a new condition that arose while the beneficiary was receiving treatment in the SNF for the ongoing condition. In this context, the ongoing condition need not have been the principal diagnosis that actually precipitated the beneficiary's admission to the hospital, but could be any one of the conditions present during the qualifying hospital stay. The Medicare contractors may use a hospital discharge summary or any additional

documentation from the inpatient hospital to make this verification. This documentation need not be signed for this purpose.

6.1.2 - Types of SNF PPS Review

(Rev. 924; Issued: 11-15-19; Effective: 10-01-19; Implementation: 12-17-19)

A. Targeted Probe and Educate Medical Review

Medicare Administrative Contractors (MACs) shall follow the instructions described in Chapter 3 of Pub. 100-08, the Medicare Program Integrity Manual, when conducting medical review.

B. Demand Bills

MACs must conduct MR of all patient-generated demand bills with the following exception:

> Demand bills for services to beneficiaries who are not entitled to Medicare or do not meet eligibility requirements for payment of SNF benefits (i.e., no qualifying hospital stay) do not require MR. A denial notice with the appropriate reasons for denial must be sent.

Demand bills are bills submitted by the SNF at the beneficiary's request because the beneficiary disputes the provider's opinion that the bill will not be paid by Medicare and requests that the bill be submitted for a payment determination. The demand bill is identified by the presence of a condition code 20. The SNF must have the proper liability notice consistent with Section 1879 of the Social Security Act signed by the beneficiary unless the beneficiary is deceased or incapable of signing. In this case, the beneficiary's guardian, relative, or other authorized representative may make the request (see 42 CFR 424.36, Signature requirements). In the case where all covered services are being terminated, the SNF provider is also required to have issued an expedited determinations notice, as detailed in Pub. 100-04, Medicare Claims Processing Manual, chapter 30, section 260, and on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-Expedited-Determination-Notices.html.

When determining eligibility for Medicare coverage, the MAC shall review the demand bill and the medical record to determine that both technical and clinical criteria are met. If all technical and clinical criteria are met, and the reviewer determines that some or all services provided were reasonable and necessary, use the MDS QC System Software, as necessary, to determine the appropriate case-mix classifier. Further instruction on the use of this software for adjustment of SNF claims is found in section 6.1.3 below. If the reviewer determines that no services provided were medically necessary, the MAC shall deny the claim in full.

The Health Insurance Prospective Payment System (HIPPS) code and revenue code

0022 must be present on the demand bill. There may be cases where the MAC receives a demand bill for which no associated MDS (or other required Medicare assessment) was transmitted to the repository because the provider did not feel that the services were appropriate for Medicare payment. In these cases, if the Medicare contractor determines that coverage criteria are met (see § 6.1.4 B.), and medically necessary skilled services were provided, the Medicare contractor shall pay the claim at the default rate for the period of covered care for which there is no associated MDS in the repository.

C. Claims Submitted for Medicare Denial Notices

Providers may submit claims for a denial from Medicare for Medicaid or another insurer that requires a Medicare denial notice. These claims are identified by condition code 21. The SNF is required to issue a notice of noncoverage to the beneficiary that includes the specific reasons the services were determined to be noncovered. A copy of this notice must be maintained on file by the SNF in case the Medicare contractor requests a copy of the notice. See Pub. 100-04, Medicare Claims Processing Manual, chapter 1, §60.1.3 for further details.

6.1.3 - Bill Review Requirements

(Rev. 924; Issued: 11-15-19; Effective: 10-01-19; Implementation: 12-17-19)

Medicare contractors must conduct review of SNF PPS claims in accordance with these instructions and all applicable Pub. 100-08, Medicare Program Integrity Manual sections, including but not limited to, Medicare contractor standard operating procedures for soliciting additional documentation, time limitations for receipt of the solicited documentation, claim adjudication, and recoupment of overpayment. Minimum requirements of a valid SNF PPS claim are:

- Revenue Code 0022 must be on the claim. This is the code that designates SNF PPS billing.

- A HIPPS code must also be on the claim. This is a five-character code. The first character represents the patient's physical therapy (PT) component and occupational therapy (OT) component classification. The second character represents the patient's speech-language pathology (SLP) component classification. The third character represents the patient's nursing component classification. The fourth character represents the patient's non-therapy ancillary (NTA) component classification. The fifth character represents the assessment indicator (AI) code. See Pub. 100-04, chapter 6, §30.1 for valid codes and assessment indicators.

6.1.4 - Medical Review Process

(Rev. 924, Issued: 11-15-19; Effective: 10-01-19; Implementation: 12-17-19)

A. Obtain Medical Records and MDS

Medicare contractors shall obtain documentation necessary to make a MR determination. Medical records must be requested from the provider and the MDS data must be obtained from the national repository. Medicare contractors are to use the MDS as part of the medical documentation used to determine whether the HIPPS codes billed were accurate and appropriate. Medicare contractors shall use the QIES (Quality Improvement & Evaluation System) Business Intelligence Center (QBIC) Fiscal Intermediary (FI) Extract Reports to obtain the MDS data from the National Reporting repository.

Additional information about the use of the FI Extract Reports can be found in the QBIC User's Guide.

Information (QBIC documentation & training) can be found at https://qtso.cms.gov. (Search for 'QBIC' when accessing the webpage.) Once the clinical reviewer has utilized the FI Extract Reports to obtain the MDS(es) corresponding to the period being reviewed, the reviewer will import the MDS data into the MDS QC Software System to convert it into a readable format to be used, in conjunction with review of the medical record, for the adjustment of the SNF claim.

Once the clinical reviewer has used the FI Extract Tool to obtain the MDS corresponding to the period being reviewed, the reviewer will import the MDS QC Software System to convert it into a readable format to be used, in conjunction with review of the medical record for the adjustment of the SNF claim. The MDS QC System Software and Reference Manual can be requested at MDSQC@nerdvana.fu.com. The MDS QC Tool contractor will contact CMS for approval of the request prior to sending out the MDS QC System Software and Reference Manual by FedEx.

Medicare contractors shall also request documentation to support the HIPPS code(s) billed, including notes related to the ARD, documentation relating to the look-back periods which may fall outside the billing period under review, and documentation related to the claim period billed. Since the ARD for each MDS marks the end of the look-back period (which may extend back 30 days), the Medicare contractor must be sure to obtain supporting documentation for up to 30 days prior to the ARD if applicable. The requested documentation may include hospital discharge summaries and transfer forms; physician orders and progress notes; patient care plans; nursing and rehabilitation therapy notes; and treatment and flow charts and vital sign records, weight charts and medication records.

Clinical documentation that supports medical necessity may be expected to include: physician orders for care and treatments, medical diagnoses, rehabilitation diagnosis (as appropriate), past medical history, progress notes that describe the beneficiary's response to treatments and his/her physical/mental status, lab and other test results, and other documentation supporting the beneficiary's need for the skilled services being provided in the SNF.

During the review process, if the provider fails to respond to a Medicare contractor's Additional Documentation Request (ADR) within the prescribed time frame, the Medicare contractor shall deny the claim. See Pub. 100-08, Medicare Program Integrity Manual, chapter 3, section 3.2.3.8 for information on denials based on non-response to

ADRs and section 3.2.3.9 for handling of late documentation. If the provider furnishes documentation that is incomplete/insufficient to support medical necessity, adjust the bill in accordance with §1862(a)(1)(A) of the Act.

B. Make a Coverage Determination

For all selected claims, the Medicare contractor shall review medical documentation and determine whether the following criteria are met, in order to make a payment determination:

- The services must not be statutorily excluded--Determine whether the services are excluded from coverage under any provision in §1862(a) of the Act other than
  §1862(a)(1)(A).

- MDS must have been transmitted to the state repository - The Medicare contractor shall require that the provider submit the claim with the case-mix classifiers obtained from the "Grouper" software, as instructed in Pub. 100-04, Medicare Claims Processing Manual, chapter 6, § 30.1. Claims for which MDSs have not been transmitted to the repository should therefore not be submitted to Medicare for payment, and shall be denied. An exception to that instruction occurs in the case where the beneficiary is discharged or dies on or before day 8 of the SNF admission or readmission, as described in Chapter 2 of the MDS 3.0 RAI manual. In that specific case, Medicare contractors shall pay claims at the default rate, provided that level of care criteria were met and skilled services were provided and were reasonable and necessary. In all other cases, the Medicare contractor shall deny any claim for which the associated MDS is not in the repository.

- SNF must have complied with the assessment schedule - In accordance with 42 CFR §413.343, in those instances when the assessment is not completed timely, the contractor shall pay at the default rate for any days of care prior to the assessment reference date of the required assessment.

  The Interim Payment Assessment (IPA) is an optional assessment that providers may complete to report a change in the patient's classification. If an IPA has been completed, medical reviewer will examine the medical documentation as described in this section.

- Services are Reasonable and Necessary--Determine whether the services are reasonable and necessary under §1862(a)(1)(A) of the Act. When making

reasonable and necessary determinations, contractors shall determine whether the services indicated on the MDS were rendered and were reasonable and necessary for the beneficiary's condition as reflected by medical record documentation. If the reviewer determines that none of the services provided were reasonable and necessary or that none of the services billed were supported by the medical record as having been provided, the Medicare contractor shall deny the claim in full.

- Level of care requirement must be met--Determine whether the services met the requirements according to 42 CFR §409.31.

  - Under PPS, the beneficiary must meet level of care requirements as defined in 42 CFR §409.31. The SNF PPS includes an administrative presumption in which a beneficiary who is correctly assigned one of the designated case-mix classifiers on the initial Medicare ("5-day") PPS assessment is presumed to meet the SNF level of care through the assessment reference date (ARD). This effectively creates a presumption of coverage for the period from the first day of the Medicare covered services up to, and including, the ARD for that assessment, which must be set for no later than the eighth day of the SNF stay. The 5-day assessment may trigger a presumption of coverage only when the SNF admission directly follows discharge from a prior qualifying hospital stay. See Pub. 100-02, Medicare Benefit Policy Manual, chapter 8, §30.1 for further explanation of the administrative presumption of coverage.

  - In the case described above, where the administrative presumption of coverage exists, Medicare contractors shall review the claim and supporting medical information specifically to confirm the correctness of the case-mix classifier assignment that triggered the presumption. To determine if the beneficiary was correctly assigned to a case-mix classifier, Medicare contractors shall verify that the billed case-mix classifier is supported by the associated provider documentation. Medicare contractors shall consider all available information in determining coverage. This includes the MDS, the medical records including physician, nursing, and therapy documentation, and the beneficiary's billing history.

  - A beneficiary who is not assigned one of the case-mix classifiers designated as representing the required level of care on the 5-day assessment prescribed in 42 CFR 413.343(b) IS NOT automatically classified as either meeting or not meeting the SNF level of care definition. Instead, the beneficiary must receive an individual level of care determination using existing administrative criteria and procedures, so documentation must support that these beneficiaries meet the level of care requirements.

  - For days after the assessment reference date of the 5-day assessment, determination of the continued need for, and receipt of, a skilled level of

care will be based on the beneficiary's clinical status and skilled care needs for the dates of service under review.

- The level of care requirement includes the requirement that the beneficiary must require skilled nursing or skilled rehabilitation services, or both on a daily basis. Criteria and examples of skilled nursing and rehabilitation services, including overall management and evaluation of the care plan and observation of a patient's changing condition, may be found at 42 CFR §§409.32 and 409.33.

- An apparent interruption in daily skilled services should not be interpreted to signal an end to daily skilled care. Rather, consideration should be given to the provision of observation and assessment and management and evaluation of the care plan during the review of medical records.

C. Review Documentation and Enter Correct Data into the MDS QC Software When Appropriate.

If the reviewer determines that coverage criteria are met and services are not statutorily excluded, but some services provided were not reasonable and necessary or were not supported in the medical record as having been provided as billed, the current MDS QC System Software must be used to calculate appropriate payment. Medicare contractors shall pay claims according to the case-mix classifier value calculated using the MDS QC tool, regardless of whether it is higher or lower than the case-mix classifier billed by the provider. If none of the services provided were reasonable and necessary, the Medicare contractor shall deny the claim in full.

Medicare contractors shall use the most current version of MDS QC System Software to review and calculate appropriate payment for SNF claims. The medical reviewer will examine the medical documentation to make a determination as to whether it supports the data entered into the MDS assessment completed by the provider and extracted from the repository. If a discrepancy is noted, the reviewer shall enter the correct data reflected in the medical record, according to the instructions in the MDS QC System Software Reference Manual. The reviewer shall consider all available medical record documentation in entering data into the software. This includes physician, nursing, and therapy documentation, and the beneficiary's billing history. Review of the claim form alone does not provide sufficient information to make an accurate payment determination.

D. Outcome of Medical Record Review

The Medicare contractor shall take action to pay the claim appropriately, for the days on which the SNF was in compliance with the assessment schedule (pay the default rate for the days on which the SNF provided covered care, but was not in compliance with the assessment schedule), as described in each of the following situations—

Services are Reasonable and Necessary as Documented on the MDS Submitted to the Repository:

- If no discrepancies are noted between the MDS submitted to the repository and the patient's medical record, during the relevant assessment period for the timeframe being billed, the Medicare contractor shall verify that the case-mix classifier submitted on the claim matches the case-mix classifier on the MDS imported from the repository into the MDS QC tool, and:
    - If the facility case-mix classifier obtained through the MDS QC tool matches the case-mix classifier submitted on the claim, the Medicare contractor shall pay the claim as billed for all covered days associated with that MDS, even if the level of therapy changed during the payment period.
    - If the facility case-mix classifier obtained through the MDS QC tool DOES NOT match the case-mix classifier submitted on the claim, the Medicare contractor shall pay the claim at the appropriate level based on the case-mix classifier level on the MDS submitted to the repository (and subsequently obtained through the MDS QC tool) for all covered days associated with that MDS, even if the services provided changed during the payment period.

Some Services are Reasonable and Necessary but Not Supported as Billed in Patient Medical Record:

- If some skilled services were appropriate, but some services provided were not reasonable and necessary or were not supported by the medical record as having been provided as billed, and the reviewer determines (based on data entered from the medical record into the MDS QC System Software) that:
    - The discrepancies are such that they do not result in a change in the case-mix classification level as calculated by the MDS QC tool, during the relevant assessment period for the timeframe being billed, the Medicare contractor shall accept the claim as billed for all covered days associated with that MDS, even if the level of skilled care changed during the payment period.
    - There is another case-mix classifier for which the beneficiary qualifies, the Medicare contractor shall pay the claim according to the correct case-mix classifier calculated using the MDS QC System Software for all covered days associated with that MDS, and recoup any overpayments as necessary.

Need For Skilled Care Ends:

- If the reviewer determines that the beneficiary falls to a non-skilled level of care at some point during the period under review, the Medicare contractor shall deny the claim from the date on which the beneficiary no longer meets level of care criteria.

General Information for All HIPPS Codes

- No Skilled Care Needed or Provided--If the reviewer determines that none of the services furnished were reasonable and necessary and that no skilled care is needed or provided, the Medicare contractor shall deny the claim from the date that skilled care ended.

- Services Billed But Not Furnished--If the reviewer determines that any of the services billed were not furnished, deny the claim in part or full and, if applicable, the Medicare contractor shall apply the fraud and abuse guidelines in Pub 100-08, Medicare Program Integrity Manual, chapter 4.

A partial denial is defined as either the disallowance of specific days within the stay or reclassification into a lower case-mix classifier.

For any full or partial denials made, adjust the claim accordingly to recoup the overpayment. A partial denial based on classification into a new case-mix classification code or a full denial because the level of care requirement was not met are considered reasonable and necessary denials (§1862(a)(1)(A)) and are subject to appeal rights.

It is important to recognize the possibility that the necessity of some services could be questioned and yet not impact the case-mix classification. The case-mix classification may not change because there are many clinical conditions and treatment regimens that qualify the beneficiary for the case-mix classifier to which he or she was assigned.

When reviewing bills, if the reviewer suspects fraudulent behavior, e.g., a pattern of intentional reporting of inaccurate information for the purpose of payment or the billing for services which were not furnished or quality of care concerns, it is the Medicare contractor's responsibility to refer the provider to the appropriate entity for further investigation.

6.1.5 - Workload

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

All Medicare contractors must review some level of SNF PPS bills based on data analysis. These are medical record reviews and should be reviewed by professionals, i.e., at a minimum, by LPNs. Workload projections are to be addressed through the annual Budget Performance Requirements process.

6.2 - Medical Review of Home Health Services

(Rev. 10184; Issued: 06-19-2020; Effective: 07-21-2020; Implementation: 07-21-2020)

This section applies to Unified Program Integrity Contractors (UPIC), Medicare Administrative Contractors (MAC), Supplemental Medical Review Contractor (SMRC),

Recovery Audit Contractors (RAC) and the Comprehensive Error Rate Testing (CERT) contractor.

6.2.1 - Physician Certification of Patient Eligibility for the Medicare Home Health Benefit

(Rev.603, Issued: 07-21-15, Effective: 08-11-15, Implementation: 08-11-15)

A physician certification/recertification of patient eligibility for the Medicare home health benefit is a condition for Medicare payment per sections 1814(a) and 1835(a) of the Social Security Act (the "Act"). The regulations at 42 CFR 424.22 list the requirements for eligibility certification and recertification. The requirements differ for eligibility certification and recertification; however, if the requirements for certification are not met, then claims for subsequent episodes of care, which require a recertification, will be non-covered—even if the requirements for recertification are met.

Home health agencies (HHAs) should obtain as much documentation from the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) as they deem necessary to assure themselves that the Medicare home health patient eligibility criteria for certification and recertification have been met and must be able to provide it to CMS and its review entities upon request. Per the regulations at 42 CFR 424.22(c), if the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

Therefore, for all medical necessity reviews, the Medicare review contractors shall review the certification documentation for any episode initiated with the completion of a start-of-care Outcome and Assessment Information Set (OASIS) assessment. This means that if the subject claim is for a subsequent episode of care, the HHA must submit all certification documentation as well as recertification documentation. The review contractor shall send a documentation request to the billing HHA requesting the supporting documentation from the certifying physician and/or the acute/post-acute care facility if the patient was directly admitted to home health from such setting (as defined in 42 CFR 424.22) that substantiates the patient's eligibility for the Medicare home health benefit.

For medical review purposes, the referring /certifying physician's initial order for home health services for a patient initiates the establishment of a plan of care as part of the certification of patient eligibility for the Medicare home health benefit. The physician's initial order must specify the medical treatment(s) to be furnished and does not eliminate the need for the plan of care as required in 42 CFR 409.43.

If the review contractor finds that the documentation in the certifying physician's medical record for that patient used as the basis for the certification of eligibility, which includes subsequent supporting documentation from the HHA (if incorporated into the certifying physician's or acute/post-acute care facility's medical record for that patient), is

insufficient to demonstrate the patient is or was eligible to receive services under the Medicare home health benefit, the review contractor shall deny payment (in the case of prepayment review) or shall initiate an overpayment demand letter (in the case of post payment review).

The review contractor shall only consider a plan of care and the certification or recertification for home health services from physicians who do not have a financial relationship with the HHA. The review contractor shall only consider documentation of the face-to-face encounter from physicians or allowed non-physician practitioners, as defined in 42 CFR 424.22, who do not have a financial relationship with the HHA (see 6.2.3).

CMS does not require a specific form or format for the certification as long as a physician certifies that the five certification requirements, outlined in 42 CFR 424.22(a)(1) and section 6.2.1.1, are met.

6.2.1.1 – Certification Requirements

(Rev. 704, Issued: 03-17-17, Effective: 04-17-17, Implementation: 04-17-17)

When conducting a medical necessity review, the review contractor shall determine whether the supporting documentation addresses each of the following criteria for which a physician certified (attested to):

1. Homebound. Home health services are or were required because the individual is or was confined to the home per the criteria below (as defined in sections 1835(a) and 1814(a) of the Social Security Act).

   a. Criteria-One:

   The patient must--

   - Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence

   OR

   - Have a condition such that leaving his or her home is medically contraindicated.

   If the patient meets one of the Criteria-One conditions, then the patient must ALSO meet two additional requirements defined in Criteria-Two below.

   b. Criteria-Two:

   - There must exist a normal inability to leave home;

   AND

- Leaving home must require a considerable and taxing effort.

In determining whether the patient meets criterion two of the homebound definition, the clinician needs to take into account the illness or injury for which the patient met criterion one and consider the illness or injury in the context of the patient's overall condition. The clinician is not required to include standardized phrases reflecting the patient's condition (e.g., repeating the words "taxing effort to leave the home") in the patient's chart, nor are such phrases sufficient, by themselves, to demonstrate that criterion two has been met. For example, longitudinal clinical information about the patient's health status is typically needed to sufficiently demonstrate a normal inability to leave the home and that leaving home requires a considerable and taxing effort. Such clinical information about the patient's overall health status may include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.

2. Skilled Care. The patient needs or needed intermittent skilled nursing care (other than solely venipuncture for the purposes of obtaining a blood sample), physical therapy, and/or speech language pathology services as defined in 42 CFR 409.42(c).

NOTE: Where a patient's sole skilled service need is for skilled oversight of unskilled services (management and evaluation of the care plan as defined in 42 CFR 409.42(c)), the physician must include a brief narrative describing the clinical justification of this need as part of the certification, or as a signed addendum to the certification. The physician must sign immediately following the narrative.

3. Plan of Care. A plan for furnishing the services has been established and is, or will be, periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine (a doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under state law). If the physician's orders for home health services meet the requirements specified in 42 CFR 409.43 Plan of Care Requirements, this meets the requirement for establishing a plan of care as part of the certification of patient eligibility for the Medicare home health benefit.

4. Under Physician Care. Home health services will be or were furnished while the individual is or was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

5. Face-to-Face Encounter. A face-to-face patient encounter occurred no more than 90 days prior to the home health start of care date or within 30 days after the start of the home health care, was related to the primary reason the patient requires home health services, and was performed by an allowed provider type

defined in 42 CFR 424.22(a)(1)(v). The certifying physician must also document the date of the encounter as part of the certification.

While the face-to-face encounter must be related to the primary reason for home health services, the patient's skilled need and homebound status can be substantiated through an examination of all submitted medical record documentation from the certifying physician, acute/post-acute care facility, and/or HHA (see below). The synthesis of progress notes, diagnostic findings, medications, nursing notes, etc., help to create a longitudinal clinical picture of the patient's health status.

6.2.2 – Physician Recertification

(Rev. 603, Issued: 07-21-15, Effective: 08-11-15, Implementation: 08-11-15)

At the end of the 60-day episode, a decision must be made whether or not to recertify the patient for a subsequent 60-day episode. The plan of care must be reviewed and signed by the physician at least every 60 days when there is a need for continuous home care unless the beneficiary transfers to another HHA or the beneficiary is discharged and subsequently re-admitted (these situations trigger a new certification, rather than a recertification).

6.2.2.1 – Recertification Elements

(Rev. 870, Issued: 03-22-19, Effective: 04-22-19, Implementation: 04-22-19)

Recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode. Recertification should occur at the time the plan of care is reviewed, and must be signed and dated by the physician who reviews the plan of care. Recertification is required at least every 60 days unless there is a—

(i) Beneficiary elected transfer; or
(ii) Discharge with goals met and/or no expectation of a return to home health care.

Medicare does not limit the number of continuous episode recertifications for beneficiaries who continue to be eligible for the home health benefit. The physician certification may cover a period less than but not greater than 60 days. Because the updated home health plan of care must include the frequency and duration of visits to be made, the physician does not have to estimate how much longer skilled services will be needed for the recertification.

The recertification statement must indicate the continuing need for services. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. In this case reviewers will look for documentation substantiating the need for continued

occupational therapy when the needed skilled nursing care or physical therapy or speech therapy that were initially needed, are no longer needed.

If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the reviewer will look for the physician's brief narrative describing the clinical justification of this need. If the narrative is part of the recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately following the narrative in the addendum.

As mentioned earlier in this section, the reviewer will confirm that all elements of the certification are included in the documentation sent for the recertification claim review. If the submitted certification documentation (submitted with the recertification documentation) does not support home health eligibility, the claim associated with the recertification period will not be paid.

6.2.3 – The Use of the Patient's Medical Record Documentation to Support the Home Health Certification

(Rev. 704, Issued: 03-17-17, Effective: 04-17-17, Implementation: 04-17-17)

As mentioned in section 6.2.1.1 – Certification Requirements, for home health services to be covered by Medicare, the certifying physician's and/or the acute/post-acute care facility's medical record for the patient must contain sufficient documentation of the patient's medical condition(s) to substantiate eligibility for home health services. The information may include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.

The physicians'/acute/post-acute care facility's medical records can always stand alone in substantiating eligibility for home health services. The physician's/acute/post-acute care facility's record, in conjunction with appropriately incorporated HHA documentation (e.g., Form 485/Plan of Care, OASIS, etc.), may also substantiate the certification of eligibility for home health services. The HHA's generated medical record documentation for the patient, by itself, is not sufficient in demonstrating the patient's eligibility for Medicare home health services.

As noted earlier, per 42CFR424.22 (a) and (c) it is the patient's medical record held by the certifying physician and/or the acute/post-acute care facility that must support the patient's eligibility for home health services. Therefore, any documentation used to support certification that was generated by the home health agency must be signed off by the certifying physician and incorporated into the medical record held by the physician or the acute/post-acute care facility's medical record. Any information

provided to the certifying physician by the HHA and incorporated into the patient's medical record held by the physician or the acute/post-acute care facility's medical record (if the patient was directly admitted to home health) must corroborate the rest of the patient's medical record. This means that the HHA information, along with the certifying physician's and/or the acute/post-acute care facility's medical record, creates a clinically consistent picture that the patient is eligible for Medicare home health services. This could include, but is not limited to, the plan of care required per 42 CFR 409.43, the initial and/or the comprehensive assessment of the patient required per 42 CFR 484.55, the inpatient discharge summary or multi-disciplinary clinical notes, etc., which must correspond to the dates of service being billed and not contradict the certifying physician's and/or the acute/post-acute care facility's own documentation or medical record entries. Once incorporated into the certifying physician's medical record for the patient, the HHA information can be used to support the patient's homebound status and need for skilled care, the reviewer shall consider all documentation from the HHA that has been signed off in a timely manner and incorporated into the physician/hospital record when making its coverage determination. HHA documentation that is used to support the home health certification is considered to be incorporated timely when it is signed off prior to or at the time of claim submission. See section 6.2.6 Examples of Sufficient Documentation Incorporated into a Physician's Medical Record.

It is important to apply the review process to the entire patient's medical record that is received by the reviewer. Doing so assures that the reviewer is establishing that the HHA generated medical record documentation corroborates other patient medical records received and used to support the patient's eligibility for home health services. Therefore, the HHA generated documentation does not necessarily need to restate pertinent facts or conditions, but instead the HHA generated medical records for the patient should be in alignment with and not contradict other patient records. The HHA generated medical record for the patient together with other medical records received must lead the reviewer to confirm that the patient is eligible for home health services as established in 42 CFR 424.22(a)(1).

6.2.4 - Coding

(Rev. 603, Issued: 07-21-15, Effective: 08-11-15, Implementation: 08-11-15)

If the patient's comprehensive assessment or recertification assessment was signed off and incorporated into the certifying physician's medical record for the patient (or the acute/post-acute care facility's medical record if the patient was directly admitted to home health), contractors shall use it to determine whether the Home Health Resource Group (HHRG) codes billed were accurate and appropriate. In addition, if the comprehensive assessment is incorporated into the certifying physician's record for the patient and is used to support that the patient meets the home health eligibility criteria,

then the diagnoses and conditions listed on the start of care assessment must be corroborated by information in the certifying physician's and/or the acute/post-acute care facility's own medical record documentation.

The contractor shall use the web regrouping program provided by CMS to recode claims as appropriate.

6.2.5 - Medical Necessity of Services Provided

(Rev. 603, Issued: 07-21-15, Effective: 08-11-15, Implementation: 08-11-15)

In addition to certification and recertification requirement documentation, contractors shall also review the medical record documentation to determine whether services provided were medically necessary. Again, home health generated information must be reviewed, signed off by the certifying physician and incorporated into the certifying physician medical record for the patient or the acute/post-acute care facility's medical record for the patient (if the patient was directly admitted to home health) if used to support certification/recertification.

6.2.6 - Examples of Sufficient Documentation Incorporated Into a Physician's Medical Record

(Rev. 603, Issued: 07-21-15, Effective: 08-11-15, Implementation: 08-11-15)

To be eligible for Medicare home health services, a patient must have Medicare Part A and/or Part B and, per §1814(a)(2)(C) and §1835(a)(2)(A) of the Act:

- Be confined to the home;
- Need skilled services;
- Be under the care of a physician;
- Receive services under a plan of care established and reviewed by a physician; and
- Have had a face-to-face encounter with a physician or allowed non-physician practitioner (NPP).

EXAMPLE 1:

Does the below submitted documentation support the certification statement stating that the patient meets the eligibility criteria for home health benefit certification? Yes.

Records received by the reviewer for a HHA claim for dates of service starting on 4/15/2015:

1. Patient was admitted to the hospital with a right-sided femur fracture sustained from a fall requiring surgery. A discharge summary dated April 14, 2015, signed by the inpatient attending physician. Included in the summary was a description of the patient's injury, DME required, non-weight-bearing status, and the name of and appointment date for the community orthopedic physician who would

continue to follow-up with patient, and the notation of the order for home physical therapy for home safety evaluation, gait training and strengthening 2-3 times per week for 6 weeks to be delivered by an HHA.

Meets requirements for a face-to-face encounter (occurred within the required timeframe, was performed by an allowed provider type, and related to the primary reason the patient requires home health). Identifies the need for skilled services and alludes to the fact that the patient is most likely homebound because of the non-weight-bearing status and the order for DME. Identifies physician who will be providing care while patient is receiving home health services. Plan of care established with physician orders.

2. HHA generated comprehensive assessment (admission OASIS) dated 04/15/2015 along with physical therapy progress notes. PT progress note documents patient is non-weight bearing on right leg and requires use of a two-handed device to walk alone on a level surface, and requires assistance to negotiate stairs or steps or uneven surfaces. The HHA assessment with progress notes has been signed by the community orthopedic certifying physician.

   PT progress note further supports that patient is confined to the home.

3. The community orthopedic physician-signed certification statement for HH services for start of care date of April 15, 2015.

Certification statement signed by certifying physician.

4. HHA generated plan of care, which specifies the type, frequency and goals for therapies. The plan of care includes the signature of the certifying physician.

   Supports that plan of care has been established and reviewed by the certifying physician.

EXAMPLE TWO:

Does the below submitted documentation support the certification statement stating that the patient meets the eligibility criteria for home health benefit certification? Yes.

Records received by the reviewer for a HHA claim for dates of service starting on February 1, 2015:

1. Primary care physician progress note dated November 15, 2014. States reason for visit is patient has a non-healing left foot diabetic foot ulcer measuring 1 cm x1 cm x 0.5 cm. Patient instructed on wound care with hydroactive gel dressing to be changed every 3 days. Patient able to return demonstrate application of dressing without difficulties.

Meets requirements for a face-to-face encounter (occurred within the required timeframe, was performed by an allowed provider type, and related to the primary reason the patient requires home health).

2. Clinical note in physician record states that patient called primary care physician (PCP) on January 30th stating that the wound has gotten larger and there is copious purulent drainage causing the dressing to be saturated. She states she is unable to adequately change the dressing and keep it in place because of the size of the wound and the amount of drainage. Patient just recovering from pneumonia and she says she is unable to come into the physician's office because she cannot drive. PCP made referral to HHA for skilled nursing services to evaluate the wound.

Identifies the need for skilled services.

3. HHA generated comprehensive assessment (admission OASIS) dated 02/01/2015 along with skilled nursing notes which includes wound measurements, condition of wound, and documentation of physician phone call to report findings and receipt of verbal orders for daily wound care for 3 weeks, monitor and teach on signs and symptoms of infection and initiation of oral antibiotics twice a day for 14 days. Nursing notes also states that the patient is significantly deconditioned, as a result of recent pneumonia, requires the use of a walker to ambulate from chair to bathroom with frequent stops to rest.

HHA skilled nursing notes further support that patient needs skilled services to initiate new wound care regimen, monitor for infection and that the patient is confined to the home. Physician's verbal orders for daily wound care establish the plan of care.

4. The primary care physician-signed certification statement for HH services for start of care date of February 1, 2015.

Certification statement signed by certifying physician.

5. HHA generated plan of care, which specifies the wound care orders, frequency of skilled nursing visits and goals for home health services. The plan of care includes the signature of the certifying physician.

Supports that plan of care has been established and reviewed by the certifying physician.

6.2.7 - Medical Review of Home Health Demand Bills

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

As a result of litigation settlements, A/B MACs (A) must perform medical record reviews on 100% of the home health demand bills.

6.3 – Medical Review of Certification and Recertification of Residents in SNFs

(Rev. 823; Issued: 10-05-18; Effective: 11-06-18; Implementation: 11-06-18)

The Medicare conditions of payment require a physician certification and (when specified) recertification for SNF services. This requirement is explicitly stated in §1814(a)(2) of the Social Security Act. 42 CFR 424.20 details the required contents of the certification and re-certifications and 42 CFR 424.11 specifies that "no specific procedures or forms are required for certification and recertification statements," and that "the provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form" (emphasis added). Further, 42 CFR § 424.11(b) specifies that information contained in other provider records, such as physicians' progress notes, need not be repeated in the certification or recertification statement itself. Recent decisions by administrative law judges, that CMS believes are fully consistent with law and regulations, reinforce the need for MACs to consider documentation in the beneficiary's medical record beyond a discrete certification or recertification form to determine if the required elements for certification are present.

Contractors shall deny claims for failure to comply with the certification or re-certification content requirements in 42 CFR 424.20 and not for the failure to use a separate certification form or particular format.

6.4 - Medical Review of Rural Air Ambulance Services

(Rev. 102, Issued: 02-01-05, Effective: 01-01-05, Implementation: 02-14-05)

6.4.1 – "Reasonable" Requests

(Rev. 308, Issued: 10-30-09, Effective: 11-30-09, Implementation: 11-30-09)

Rural air ambulance transport shall be considered reasonable and necessary when a physician or other qualified medical personnel orders or certifies the air transport service. A physician or other qualified medical personnel must certify or determine that the individual's condition requires air transport due to time or geographical factors. The following should be considered to be personnel qualified to order air ambulance services:

- Physician,
- Registered nurse practitioner (from the transferring hospital),
- Physician's assistant (from transferring hospital),
- Paramedic or EMT (at the scene), and
- Trained first responder (at the scene).

6.4.2 – Emergency Medical Services (EMS) Protocols

(Rev. 308, Issued: 10-30-09, Effective: 11-30-09, Implementation: 11-30-09)

Per Section 415 of the Medicare Modernization act of 2003, the reasonable and necessary requirement for rural air transport may be "deemed" to be met when the service is provided pursuant to an established State or regional emergency medical services (EMS)

agency protocol. CMS defines "established" to mean those protocols, which have been reviewed and approved by State EMS agencies or have been developed according to State EMS umbrella guidelines. Additionally, the protocol must be recognized or approved by the Secretary.

The information on the FI, carrier, or MAC Web site must inform rural air ambulance providers that if they anticipate transport based upon the contents of such a protocol (either State or regional) they must submit that protocol in advance to the fiscal intermediaries, carriers, or MACs for review and approval. Include instructions on the Web site for submitting the protocol. The contractor will review the protocol to ensure that the contents are consistent with statutory requirements at 1862(a)(1)(A), which direct that all services paid for by Medicare must be reasonable and necessary for the diagnosis or treatment of an illness or injury. The contractor shall make a determination regarding the protocol and/or subsequent revisions and notify the rural air ambulance provider of their determination within 30 days of receipt of the protocol.

Approval of a protocol does not exempt the provider from requirements in the Act at 1861(s)(7) and regulatory requirements at 42 CFR 424.106 which outlines the criteria for determining whether the hospital was the most accessible. Regardless of protocol instructions regarding transport locations Medicare payment can be made only to the closet facility capable of providing the care needed by the beneficiary.

6.4.3 – Prohibited Air Ambulance Relationships

(Rev. 102, Issued: 02-01-05, Effective: 01-01-05, Implementation: 02-14-05)

Do not apply the "deemed" reasonable and necessary determination if there is a financial or employment relationship between the person requesting the air ambulance service and the entity furnishing the service; an entity under common ownership with the entity furnishing the service; or a financial relationship between an immediate family member of the person requesting the service and the entity furnishing the service. Only one exception is available for this provision. When the referring hospital and the entity furnishing the air ambulance services are under common ownership, the above limitation does not apply to remuneration by the hospital for provider based physician services furnished in a hospital, reimbursed under Part A and the amount of the remuneration is unrelated directly or indirectly to the provision of air ambulance services.

6.4.4 – Reasonable and Necessary Services

(Rev. 308, Issued: 10-30-09, Effective: 11-30-09, Implementation: 11-30-09)

When data analysis indicates, fiscal intermediaries, carriers, or MACs may perform medical review of rural air ambulance claims in those instances noted in the above paragraph where there is financial or employment relationship between the person requesting an air ambulance transport and the person providing the service. The fiscal intermediaries, carriers, or MACs may also conduct medical review of rural air ambulance claims with "deemed" medical necessity status when there are questions as to

whether the transport was made pursuant to a protocol which has been approved by the Secretary; or questions as to whether the transport was inconsistent with an approved protocol. Medicare payment can be made only to the closest facility capable of providing the care needed by the beneficiary irrespective of whom orders the transport.

6.4.5 – Definition of Rural Air Ambulance Services

(Rev. 102, Issued: 02-01-05, Effective: 01-01-05, Implementation: 02-14-05)

For purposes of this section the term "rural air ambulance service" means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in Section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725).

6.5 - Medical Review of Inpatient Hospital Claims for Part A Payment

(Rev. 716, Issued: 05-12-17, Effective: 06-13-17, Implementation: 06-13-17)

6.5.1 - Screening Instruments

(Rev. 264; Issued: 08-07-08; Effective Date: 08-01-08; Implementation Date: 08-15-08)

The reviewer shall use a screening tool as part of their medical review of acute IPPS and LTCH claims. CMS does not require that you use a specific criteria set. In all cases, in addition to screening instruments, the reviewer applies his/her own clinical judgment to make a medical review determination based on the documentation in the medical record.

The following shall be utilized as applicable, for each case:

- Admission criteria;
- Invasive procedure criteria;
- CMS coverage guidelines;
- Published CMS criteria
- DRG validation guidelines;
- Coding guidelines; and
- Other screens, criteria, and guidelines (e.g., practice guidelines that are well accepted by the medical community)

Contractors shall consult with physician or other specialists if necessary to make an informed medical review determination.

6.5.2 - Conducting Patient Status Reviews of Claims for Medicare Part A Payment for Inpatient Hospital Admissions

(Rev. 10184; Issued: 06-19-2020; Effective: 07-21-2020; Implementation: 07-21-2020)

This section applies to Unified Program Integrity Contractors (UPIC), Medicare Administrative Contractors (MAC), Supplemental Medical Review Contractor (SMRC), Recovery Audit Contractors and the Comprehensive Error patient Rate Testing (CERT) contractor.

For purposes of determining the appropriateness of Medicare Part A payment, Medicare contractors shall conduct reviews of medical records for inpatient acute IPPS hospital, Critical Access Hospital (CAH), Inpatient Psychiatric Facility (IPF) and Long Term Care Hospital (LTCH) claims, as appropriate and as so permitted by CMS, based on data analysis and their prioritized medical review strategies. Review of the medical record must indicate that hospital care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the beneficiary at any time during the stay, and that the stay was appropriate for Medicare Part A payment.

A. Determining the Appropriateness of Part A Payment

The term “patient status review” refers to reviews conducted by Medicare contractors to determine a hospital’s compliance with Medicare requirements to bill for Medicare Part A payment. Medicare contractors shall conduct such reviews in accordance with two distinct, but related, medical review policies: a 2-midnight presumption, which helps guide contractor selection of claims for medical review, and a 2-midnight benchmark, which helps guide contractor reviews of short stay hospital claims for Part A payment. “Patient status reviews” may result in determinations that claims are not properly payable under Medicare Part A; “patient status reviews” do not involve changing a beneficiary’s status from inpatient to outpatient.

Per the 2-midnight presumption, Medicare contractors shall presume hospital stays spanning 2 or more midnights after the beneficiary is formally admitted as an inpatient are reasonable and necessary for Part A payment. Medicare contractors shall not focus their medical review efforts on stays spanning 2 or more midnights after formal inpatient admission absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption.

Per the 2-midnight benchmark, hospital stays are generally payable under Part A if the admitting practitioner expects the beneficiary to require medically necessary hospital care spanning 2 or more midnights, and such reasonable expectation is supported by the medical record documentation. Medicare Part A payment is generally not appropriate for hospital stays expected to span less than 2 midnights. If a stay is not reasonably expected to span 2 or more midnights, Medicare contractors shall assess the claim to determine if an exception exists that would nonetheless make Part A payment appropriate, including:

- If the procedure is on the Secretary's list of "inpatient only" procedures (identified through annual regulation);

- If the procedure is a CMS-identified, national exception to the 2-midnight benchmark; or

- If the admission otherwise qualifies for a case-by-case exception to the 2-midnight benchmark because the medical record documentation supports the admitting physician/practitioner's judgment that the beneficiary required hospital care on an inpatient basis despite the lack of a 2- midnight expectation. Medicare contractors shall note CMS' expectation that stays under 24 hours would rarely qualify for an exception to the 2- midnight benchmark.

Hospital treatment decisions for beneficiaries are based on the medical judgment of physicians and other qualified practitioners. The 2-midnight rule does not prevent such practitioners from providing any service at any hospital, regardless of the expected duration of the service. Rather, it provides a benchmark to help guide consistent Part A payment decisions.

I. Reviewing Hospital Claims for Patient Status: The 2-Midnight Benchmark

A. Determine if the stay involved an "Inpatient Only" procedure

When conducting patient status reviews, assuming all other coverage requirements are met, the Medicare review contractor shall determine Medicare Part A payment to be appropriate if a medically necessary procedure classified by the Secretary as an "inpatient only" procedure is performed. "Inpatient only" procedures are so designated per 42 C.F.R. § 419.22(n), and are detailed in the annual Outpatient Prospective Payment System (OPPS) regulation.

Medicare contractors shall review the medical documentation and make an initial determination of whether a medically necessary inpatient only procedure is documented within the medical record. If so, and if the other requisite elements for payment are present, then the Medicare review contractor shall deem Medicare Part A payment to be appropriate, without regard to the expected or actual length of stay.
If the Medicare review contractor does not identify an inpatient only procedure during the initial review, the claim should be assessed in accordance with the 2-midnight benchmark.

B. Calculating Time Relative to the 2-Midnight Benchmark

Per the 2-midnight benchmark, Medicare contractors shall assess short stay (i.e., less than 2 midnights after formal inpatient admission) hospital claims for their appropriateness for Part A payment. Generally, hospital claims are payable under Part A if the contractor identifies information in the medical record supporting a reasonable expectation on the

part of the admitting practitioner at the time of admission that the beneficiary would require a hospital stay that crossed at least two midnights.

Medicare review contractor reviews shall assess the information available at the time of the original physician/practitioners' decision. The expectation for sufficient documentation is well rooted in good medical practice. Physician/practitioners need not include a separate attestation of the expected length of stay; rather, this information may be inferred from the physician/practitioner's standard medical documentation, such as his or her plan of care, treatment orders, and progress notes. Medicare contractors shall consider the complex medical factors that support both the decision to keep the beneficiary at the hospital and the expected length of the stay. These complex medical factors may include, but are not limited to, the beneficiary's medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk (probability) of an adverse event occurring during the time period for which hospitalization is considered.

For purposes of determining whether the admitting practitioner had a reasonable expectation of hospital care spanning 2 or more midnights at the time of admission, the Medicare contractors shall take into account the time the beneficiary spent receiving contiguous outpatient services within the hospital prior to inpatient admission. This pre-admission time may include services such as observation services, treatments in the emergency department (ED), and procedures provided in the operating room or other treatment area. If the beneficiary was transferred from one hospital to another, then for the purpose of determining whether the beneficiary satisfies the 2-midnight benchmark at the recipient hospital, the Medicare contractors shall take into account the time and treatment provided to the beneficiary at the initial hospital. That is, the start clock for transfers begins when the care begins in the initial hospital. In the event that a beneficiary was transferred from one hospital to another, the Medicare review contractor shall request documentation that was authored by the transferring hospital to support the medical necessity of the services provided and to verify when the beneficiary began receiving hospital care. Medicare contractors will generally expect this information to be provided by the recipient hospital seeking Part A payment.

Medicare contractors shall continue to follow CMS' longstanding instruction that Medicare Part A payment is prohibited for care rendered for social purposes or reasons of convenience that are not medically necessary. Therefore, Medicare contractors shall exclude extensive delays in the provision of medically necessary care from the 2-midnight benchmark calculation. Factors that may result in an inconvenience to a beneficiary, family, physician or facility do not, by themselves, support Part A payment for an inpatient admission. When such factors affect the beneficiary's health, Medicare contractors shall consider them in determining whether Part A payment is appropriate for an inpatient admission.

NOTE: While, as discussed above, the time a beneficiary spent as an outpatient before being admitted as an inpatient is considered during the medical review process for purposes of determining the appropriateness of Part A payment, such time does not

qualify as inpatient time. (See Pub. 100-02, Ch. 1, Section 10.2 for additional information regarding the formal order for inpatient admission.)

C. Unforeseen Circumstances Interrupting Reasonable Expectation

The 2-midnight benchmark is based on the expectation at the time of admission that medically necessary hospital care will span 2 or more midnights. Medicare contractors shall, during the course of their review, assess the reasonableness of such expectations. In the event that a stay does not span 2 or more midnights, Medicare contractors shall look to see if there was an intervening event that nonetheless supports the reasonableness of the physician/practitioner's original judgment. An event that interrupts an otherwise reasonable expectation that a beneficiary's stay will span 2 or more midnights is commonly referred to by CMS and its contractors as an unforeseen circumstance. Such events must be documented in the medical record, and may include, but are not limited to, unexpected: death, transfer to another hospital, departure against medical advice, clinical improvement, and election of hospice in lieu of continued treatment in the hospital.

D. Stays Expected to Span Less than 2 Midnights

When a beneficiary enters a hospital for a surgical procedure not specified by Medicare as inpatient only under 42 C.F.R. § 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for less than 2 midnights, the services are generally inappropriate for inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the beneficiary used a bed.

The Medicare review contractor shall assess such claims to see if they qualify for a general or case-by-case exception to this generalized instruction, which would make the claim appropriate for Medicare Part A payment, assuming all other requirements are met.

E. Exceptions to the 2-Midnight Rule

1. Medicare's Inpatient-Only List

As discussed above, inpatient admissions where a medically necessary Inpatient-Only procedure is performed are generally appropriate for Part A payment regardless of expected or actual length of stay.

2. Nationally-Identified Rare & Unusual Exceptions to the 2-Midnight Rule

If a general exception to the 2-midnight benchmark, as identified by CMS, is present within the medical record, the Medicare review contractor shall consider the inpatient admission to be appropriate for Part A payment so long as other requirements for Part A payment are met.
CMS has identified the following national or general exception to the 2-midnight rule:

Mechanical Ventilation Initiated During Present Visit

CMS believes newly initiated mechanical ventilation to be rarely provided in hospital stays less than 2 midnights, and to embody the same characteristics as those procedures included in Medicare's inpatient–only list. While CMS believes a physician will generally expect beneficiaries with newly initiated mechanical ventilation to require 2 or more midnights of hospital care, if the physician expects that the beneficiary will only require one midnight of hospital care, but still orders inpatient admission, Part A payment is nonetheless generally appropriate.

3. Physician-Identified Case-by-Case Exceptions to the 2-Midnight Rule

For hospital stays that are expected to span less than 2 midnights, an inpatient admission may be payable under Medicare Part A on a case-by-case or individualized basis if the medical record supports the admitting physician/practitioner's judgment that the beneficiary required hospital care on an inpatient basis despite the lack of a 2-midnight expectation. Medicare contractors shall consider, when assessing the physician's decision, complex medical factors including, but not limited to:

- The beneficiary history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

Medicare contractors shall note CMS' expectation that stays under 24 hours would rarely qualify for an exception to the 2- midnight benchmark, and as such, may be prioritized for medical review.

A. Determining Whether Covered Care Was Given at Any Time During a Stay in a PPS Hospital

Medicare contractors shall utilize the medical record to determine whether procedures and diagnoses were coded correctly. If the medical record supports that they were, pay the claim as billed. If the medical record supports that they were not, then utilize ICD-9-CM or ICD-10-CM coding guidelines to adjust the claim and pay at the appropriate DRG. See section 6.5.4 of this chapter for further details on DRG validation review. When you determine that the beneficiary did not, at the time of admission, have an expected length of stay of 2 or more midnights, or otherwise meet CMS standards for payment of an inpatient admission, but that the beneficiary's condition changed during the stay and Part A payment became appropriate, you shall review the case in accordance with the following procedures:

- The first day on which inpatient care is determined to be medically necessary is deemed to be the date of admission;

- The deemed date of admission applies when determining cost outlier status (i.e., days or services prior to the deemed date of admission are excluded for outlier purposes); and
- The diagnosis determined to be chiefly responsible for the beneficiary's need for covered services on the deemed date of admission is the principal diagnosis.
- Adjust the claim according to the diagnosis determined to be responsible for the need for medically necessary care to have been provided on an inpatient basis.

When you determine that the beneficiary did not meet the requirements for Part A payment at any time during the admission, deny the claim in full.

6.5.3 - DRG Validation Review

(Rev. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

The contractor shall perform DRG validation on PPS, as appropriate, reviewing the medical record for medical necessity and DRG validation. The purpose of DRG validation is to ensure that diagnostic and procedural information and the discharge status of the beneficiary, as coded and reported by the hospital on its claim, matches both the attending physician's description and the information contained in the beneficiary's medical record. Reviewers shall validate principal diagnosis, secondary diagnoses, and procedures affecting or potentially affecting the DRG.

NOTE: For PPS waived/excluded areas, review shall be performed appropriate to your area.

A. Coding

The contractor shall use individuals trained and experienced in ICD coding to perform the DRG validation functions. The validation is to verify the accuracy of the hospital's ICD coding of all diagnoses and procedures that affect the DRG.

The contractor shall base DRG validation upon accepted principles of coding practice, consistent with guidelines established for ICD coding, the Uniform Hospital Discharge Data Set data element definitions, and coding clarifications issued by CMS. The contractor shall not change these guidelines or institute new coding requirements that do not conform to established coding rules.

The contractor shall verify a hospital's coding in accordance with the coding principles reflected in the ICD Coding Manual. Contractors shall use the ICD version in place at the time the services were rendered, and the official National Center for Health Statistics and CMS addenda, which update the ICD Manual annually. The annual addenda are effective on October 1 of each year and apply to discharges occurring on or after October 1. The contractor shall use only ICD Manual volumes based on official ICD Addendum and updates when performing DRG validation.

Hospitals are not required to code minor diagnostic and therapeutic procedures (e.g., imaging studies, physical, occupational, respiratory therapy), but may do so at their discretion.

B. Diagnoses

Contractors shall ensure that the hospital reports the principal diagnosis and all relevant secondary diagnoses on the claim. The relevant diagnoses are those that affect DRG assignment. The hospital must identify the principal diagnosis when secondary diagnoses are also reported. When a comorbid condition, complication, or secondary diagnosis affecting the DRG assignment is not listed on the hospital's claim but is indicated in the medical record, insert the appropriate code on the claim form. If the hospital already reported the maximum number of diagnoses allowed on the claim form, delete a code that does not affect DRG assignment, and insert the new code.

The contractor is not required to code additional diagnoses on the claim as long as all conditions that affect the DRG are reflected in the diagnoses already listed, and the principal diagnosis is correct and properly identified. The hospital can list the secondary diagnoses in any sequence on the claim form because the GROUPER program will search the entire list to identify the appropriate DRG assignment.

- Principal Diagnosis -The contractor shall determine whether the principal diagnosis listed on the claim is the diagnosis which, after study, is determined to have occasioned the beneficiary's admission to the hospital. The principal diagnosis (as evidenced by the physician's entries in the beneficiary's medical record) (see 42 CFR 412.46) must match the principal diagnosis reported on the claim form. The principal diagnosis must be coded to the highest level of specificity. For example, a diagnosis from "Symptoms, Signs, and Ill-defined Conditions," may not be used as the principal diagnosis when the underlying cause of the beneficiary's condition is known.

- Inappropriate Diagnoses -The contractor shall exclude diagnoses relating to an earlier episode that have no bearing on the current hospital stay. Delete any incorrect diagnoses and revise the DRG assignment as necessary.

C. Procedures

The contractor shall ensure that the hospital has reported all procedures affecting the DRG assignment on the claim. If there are more procedures performed than can be listed on the claim, verify that those reported include all procedures that affect DRG assignment, and that they are coded accurately. See section 6.5.4 below for further detail on reviewing procedures.

6.5.4 – Review of Procedures Affecting the DRG

(Rev. 475, Issued: 07-19-13, Effective Date: 08-19-13; Implementation Date: 08-19-13)

The contractor shall determine whether the performance of any procedure that affects, or has the potential to affect, the DRG was reasonable and medically necessary. If the admission and the procedure were medically necessary, but the procedure could have been performed on an outpatient basis if the beneficiary had not already been in the hospital, do not deny the procedure or the admission.

When a procedure was not medically necessary, the contractor shall follow these guidelines:

If the admission was for the sole purpose of the performance of the non-covered procedure, and the beneficiary never developed the need for a covered level of service, deny the admission;

If the admission was appropriate, and not for the sole purpose of performing the procedure, deny the procedure (i.e., remove from the DRG calculation), but approve the admission;

If performing a cost outlier review, in accordance with Pub. 100-10, chapter 4, §4210 B, and the beneficiary was in the hospital for any day(s) solely for the performance of the procedure or care related to the procedure, deny the costs for the day(s) and for the performance of the procedure; and

If performing a cost outlier review, and the beneficiary was receiving the appropriate level of covered care for all hospital days, deny the procedure or service.

See Pub. 100-02, Chapter 1, §10 for further detail on payment of inpatient claims containing non-covered services.

6.5.5 – Special Review Considerations

(Rev. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

Refer to Pub. 100-04, chapter 3, §20 C. for information regarding handling of claims with DRG 468. This DRG represents a discharge with valid data but where the surgical procedure is unrelated to the principal diagnosis.

Refer to 100-04, chapter 3, §20.2.1, subsection D.9. for a description of questionable admission diagnosis codes. A/B MACs (A) may wish to consider including these diagnoses in their data analysis.

For a listing of diagnosis codes identified as “questionable admission” codes see the Medicare Code Editor (MCE) Web site at:
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/01_overview.asp

Refer to 100-04, chapter 3, §20.2.1, subsection D.9 for a description of diagnoses which are acceptable only when coded with a secondary diagnosis. A/B MACs (A) may wish to include these diagnoses in their data analysis as the MCE will not reject them when they are billed with a secondary diagnosis.

For a listing of diagnosis codes that are acceptable only when coded with a secondary diagnosis see the MCE Website at:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY_14_Definition_of-Medicare_Code_Edits_V_31_Manual.pdf

6.5.6 - Length-of-Stay Review

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The contractor shall determine whether the length-of-stay for PPS cost outlier claims and specialty hospital/unit claims, when selected for medical review, is appropriate and medically necessary. Identify cases of potential delayed discharge. For example, the beneficiary was medically stable, and continued hospitalization was unnecessary, or nursing home placement or discharge to home with home care would have been appropriate in providing needed care without posing a threat to the safety or health of the beneficiary (see §4110).

If Medicare payment is applicable to only part of the stay, review the covered portion of the stay and enough of the rest of the medical record (if necessary) to answer any specific questions that may arise from review of the covered part of the stay. If a beneficiary became Medicare eligible during a hospital stay, review enough of the medical record prior to the initiation of Medicare benefits to acquire sufficient information to make a determination. Do not perform lengthy reviews of non-covered care. In PPS waived/excluded areas, length-of-stay review is performed for all inpatient admissions that are selected for medical review.

The contractor shall determine whether the length of stay was appropriate for claims selected for medical review that represent PPS cost outliers. However, the contractor shall not include days on which care is determined not to have been medically necessary in the calculation of outlier payments. Where it is determined that a beneficiary's stay was unnecessarily long, and potentially represents fraud or abuse, the contractor shall make a referral to the *UPIC*.

6.5.7 - Reserved for Future Use

(Rev. 475, Issued: 07-19-13, Effective Date: 08-19-13; Implementation Date: 08-19-13)

6.5.8 - Reserved for Future Use

(Rev. 475, Issued: 07-19-13, Effective Date: 08-19-13; Implementation Date: 08-19-13)

6.5.9 - Circumvention of PPS

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

If you suspect, during review of a claim associated with a transfer or readmission, that a provider of Medicare services took an action with the intent of circumventing PPS (as described in §1886(f)(2) of the Act) and that action resulted in unnecessary admissions, premature discharges and readmissions, multiple readmissions, or other inappropriate medical or other practices with respect to beneficiaries or billing for services, you shall make a referral to your *Unified Program Integrity Contractor (UPIC)*.

6.6 - Referrals to the Quality Improvement Organization (QIO)

(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)

The MACs shall only refer Quality of (Health) Care Concerns to the QIOs. A Quality of (Health) Care Concern is defined as "a concern that care provided did not meet a professionally recognized standard of health care." The Contractor shall follow the referral process as agreed upon in the QIO-MAC Joint Operating Agreement. The QIOs will retain their responsibility for performing expedited determinations, Hospital-Issued Notices of Non-Coverage (HINN) reviews, quality reviews, transfer reviews, readmission reviews and, provider-requested higher-weighted DRG reviews.

The Circumvention of PPS will continue to be reported to your UPIC. The quality initiatives associated with payment for performance are now the reporting source for Readmission Reviews and Transfer Review data to the QIOs. Non-covered benefits/services are not to be reported to the QIO.

All initial payment determinations and claim adjustments are required to be performed by the MAC.

All MACs are to turn off all automated edits/processes that generate a referral to the QIOs prior to a medical record review of the claim. Referrals to the QIO shall be limited to Quality of Health Care issues as defined above and shall result from a clinician's medical record review of a provider's medical documentation.

If during the medical record review process, "a concern that care provided did not meet a professionally recognized standard of health care," the MAC shall issue a payment determination and/or adjustment for the claim, complete the QIO referral form, and forward the completed referral form and file(s) to the QIO. If the referral form is not complete, the QIO will return the file to the MAC and request that the MAC provide the missing information prior to the QIO performing a review.

A non-covered service and/or procedure shall not be automatically referred to the QIO. The MAC shall make the initial payment determination and/or claim adjustment for a non-covered service or procedure in accordance with the Medicare IOM 100-04, Claims Processing Manual and IOM 100-02, Benefit Policy Manual.

If during the medical record review process, "a concern that care provided did not meet a professionally recognized standard of health care," such as a medically unnecessary procedure, the claim shall be referred to the QIO for quality review after payment determination and/or claim adjustment is made.

The MACs shall not instruct providers, suppliers, or beneficiaries to refer payment issues to the QIO. If the provider or supplier does not agree with the payment and/or claim adjustment decision, the MAC shall communicate their options to follow the current process in IOM 100-08, requesting a reopening or an appeal. If the beneficiary disagrees with the payment decision and makes a request for re-evaluation/redetermination, this will be considered a demand bill and is the responsibility of the MAC.

6.7 - Medical Review of Inpatient Rehabilitation Facility (IRF) Services

(Rev. 10184; Issued: 06-19-2020; Effective: 07-21-2020; Implementation: 07-21-2020)

This section applies to Unified Program Integrity Contractors (UPIC), Medicare Administrative Contractors (MAC), Supplemental Medical Review Contractor (SMRC), Recovery Audit Contractors (RAC) and the Comprehensive Error Rate Testing (CERT) Contractor, as indicated.

6.7.1 – Reviewing for Intensive Level of Rehabilitation Therapy Services Requirements

(Rev. 10184; Issued: 06-19-2020; Effective: 07-21-2020; Implementation: 07-21-2020)

When reviewing IRF claims, the UPIC, MAC, SMRC, CERT and RAC shall verify that the IRF documentation requirements are met in accordance with IOM 100-02, Medicare Benefit Policy Manual, Chapter 1, Section 110.

The UPIC, MAC, SMRC, CERT and RAC shall not make absolute claim denials based solely on a threshold of therapy time not being met. When the current industry standard of generally 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics) per day at least 5 days per week or at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period is not met, the claim shall undergo further review.

The UPIC, MAC, SMRC, CERT and RAC shall use clinical review judgment to determine medical necessity of the intensive rehabilitation therapy program based on the individual facts and circumstances of the case, and not on the basis of any threshold of therapy time. The standard of care for IRF patients is individualized (i.e., one-on-one) therapy. Group and concurrent therapy can be used on a limited basis within the current industry standard of generally 3 hours of therapy per day at least 5 days per week or at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period. In those instances in which group therapy better meets the patient's needs on a limited basis, the situation/rationale that justifies group therapy should be specified in the patient's

medical record at the IRF. However, MAC, SMRC, CERT and RAC shall not deny solely because the situation/rationale that justifies group therapy is not submitted in response to an ADR.

6.8 – Medical Review of Evaluation and Management (E/M) Documentation

(Rev.808; Issued: 07-13-18; Effective: 08-14-18; Implementation: 08-14-18)

This section applies to MACs, RACs, UPICs, SMRC and CERT.

6.8.1 – Medical Review of E/M Documentation Provided by Student

(Rev.808; Issued: 07-13-18; Effective: 08-14-18; Implementation: 08-14-18)

The Medicare Claims Processing Manual, Chapter 12, Section 100.1.1 (B) states the teaching physician must personally perform (or re-perform) the physical exam and medical decision making activities of the E/M service being billed, but may verify any student documentation of them in the medical record rather than re-documenting this work. If the teaching physician chooses to rely on the medical student documentation and chooses not to re-document the E/M service, contractors shall consider this requirement met if the teaching physician signs and dates the medical student's entry in the medical record.

6.9 – Medical Review of Diagnostic Tests

(Rev. 850, Issued: 12-14-18; Effective: 12-17-18; Implementation: 12-17-18)

This section applies to MACs, RACs, UPICs, SMRC and CERT.

6.9.1 – Medical Review of Diagnostic Laboratory Tests

(Rev. 850, Issued: 12-14-18; Effective: 12-17-18; Implementation: 12-17-18)

42 CFR §410.32 states that all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary and that tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

Pub. 100-02, Chapter 15, Section 80.6.1 states that while a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed.

Contractors shall consider order requirements for diagnostic laboratory tests met if there is:

1. A signed order or signed requisition listing the specific test; or
2. An unsigned order or unsigned laboratory requisition listing the specific tests to be performed AND an authenticated medical record that supports the

physician/practitioner's intent to order the tests (e.g. "order labs", "check blood", "repeat urine"); or

3. An authenticated medical record that supports the physician/practitioner's intent to order the specific tests.

See Pub. 100-08, Chapter 3, Section 3.3.2.4 for authentication requirements.

Regardless of how the order requirements are met, contractors shall verify that the supporting authenticated medical record documentation contains sufficient information supporting the ordered/provided tests are reasonable and necessary per 42 CFR §410.32.

Note: As noted in Pub. 100-02, Chapter 15, Section 80.6.1, if the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R10365PI	10/02/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08	08/27/2020	11884
R10228PI	07/27/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08 Rescinded and replaced by Transmittal 10365	08/27/2020	11884
R10184PI	06/19/2020	Updates to Chapters 4, 6, and 8 of Publication (Pub.) 100-08	07/21/2020	11812
R924PI	11/15/2019	Updates to the Medical Review Instructions Related to Skilled Nursing Facilities (SNF)	12/17/2019	11520
R870PI	03/22/2019	Manual Updates Related to Home Health Certification and Recertification Policy Changes	04/22/2019	11104
R850PI	12/14/2018	Medical Review of Diagnostic Laboratory Tests	12/17/2018	10908
R836PI	10/19/2018	Medical Review of Diagnostic Laboratory Tests	11/21/2018	10908
R832PI	10/05/2018	Modification to Chapter 6, Section 6.3 (Medical Review of Certification and Recertification of Residents in SNFs) of Publication (Pub.) 100-08	11/06/2018	10921
R808PI	07/13/2018	Medical Review of Evaluation and Management (E/M) Documentation	08/14/2018	10627
R771PI	02/23/2018	Clarification of Instructions Regarding the Intensive Level of Rehabilitation Therapy Services Requirements	03/23/2018	10482
R721PI	06/09/2017	Elimination of Routine Reviews Including Documentation Compliance Reviews and Instituting Three Medical Reviews	07/11/2017	9809
R716PI	05/12/2017	Clarifying Medical Review of Hospital Claims for Part A Payment	06/13/2017	10080
R704PI	03/17/2017	Home Health (HH) Language in Pub. 100-8	04/17/2017	10006
R656PI	06/15/2016	Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Bills	06/28/2016	9571
R651PI	05/27/2016	Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Bills – Rescinded and replaced by Transmittal 656	06/28/2016	9571

Rev #	Issue Date	Subject	Impl Date	CR#
R608PI	08/14/2015	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/14/2015	8747
R603PI	07/21/2015	Medical Review of Home Health Services	08/11/2015	9189
R602PI	07/10/2015	Medical Review of Home Health Services – Rescinded and replaced by Transmittal 603	08/11/2015	9189
R601PI	07/02/2015	Review of Home Health Claims	08/03/2015	9240
R475PI	07/19/2013	PIM Chapter 6 MR Guidelines 6.54-6.5.7 Update	08/19/2013	8379
R308PI	10/30/2009	Rural Air Ambulance	11/30/2009	6682
R264PI	08/07/2008	Transition of Responsibility for Medical Review From Quality Improvement Organizations (QIOs)	08/15/2008	5849
R196PI	03/30/2007	Medical Review of Skilled Nursing Facility (SNF) Claims Using the MDS QC System Software	04/30/2007	5418
R174PI	11/17/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
R171PI	11/03/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 174	10/06/2006	5275
R163PI	09/29/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 170	10/06/2006	5275
R102PI	02/01/2005	Medical Review of Rural Air Ambulance Services	02/14/2005	3571
R093PI	01/14/2005	Medical Review of Rural Air Ambulance Services - Replaced by Transmittal 102	02/14/2005	3571
R082PI	07/23/2004	Home Health Demand Bills	08/23/2004	3266
R074PI	04/23/2004	SNF Certification and Recertification	05/24/2004	3150
R071PI	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
R042PI	06/20/2003	Intermediary Medical Review Guidelines	07/01/2003	2720
R026PIM	04/27/2002	Deletes Section 1.7 Quality Issues in SNF and Referral to other Agencies	N/A	2100
R023PIM	03/18/2002	Revises and clarifies HHAs Certification and Plan of Care Data	05/02/2002	1981
R020PIM	02/21/2002	Revises Terminology used in Chap 6,sec 12 MR of Ambulance Services	04/01/2002	1974

Rev #	Issue Date	Subject	Impl Date	CR#
R018PIM	01/17/2002	Manualizes PM A-00-08, Revises the existing SNF MR guidelines	N/A	1064
R015PIM	10/29/2001	MR of Partial Hospitalization Claims,	12/13/2001	1831
R003PIM	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
R002PIM	9/15/2000	Intermediary MR Guidelines for Specific Services	NA	882
R001PIM	06/2000	Initial Release of Manual	NA	931

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Part C Improper Payment Measure (Part C IPM)
Fiscal Year 2022 (FY 2022) Payment Error Rate Results

For fiscal year 2022 (FY 2022), CMS reported an Improper Payment Measurement (IPM) for the Part C program based on calendar year 2020 (CY 2020) payments.[1] The CY 2020 Part C IPM payment error rate of 5.42% is not comparable to prior years because of refined policy and methodology enhancements that CMS implemented, as described below.

The CY 2020 estimated gross payment error for Part C is approximately $13.94 billion and the estimated net payment error is approximately $11.43 billion. **Table 1** presents the CY 2020 Part C Payment Error Estimate results.

Table 1: CY 2020 Part C Payment Error Estimates for FY 2022 Reporting

Type of Estimate	Part C Payment Error
Overpayments	$12,686,060,323
Underpayments	$1,254,763,569
Gross Payments in Error (error rate numerator)	$13,940,823,901
Part C Denominator (total Part C expenditures)	$257,174,116,535
Improper Payment Error Rate	5.42%
Net Payment in Error	$11,431,296,764
Net Payment Error Rate	4.44%
Portion of improper payments due to missing documentation*	$486,637,274
Portion of improper payments in Error Due to Missing Documentation	0.19%

*Missing documentation indicates no medical records were submitted to support the payments. Missing documentation is a subset of total overpayments.

Change to Part C IPM Error Rate Calculation Methodology for FY 2022

In FY 2022, CMS finalized its policy regarding treatment of spontaneous "additionals" in the improper payment rate calculation.[2] Diagnoses that were not submitted to the United States

[1] Information on the Part C Improper Payment Measure is available in the U.S. Department of Health and Human Services Agency Financial Report for FY 2022, and prior years' data are available at https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html.

[2] There are two major categories of "additionals": (1) new, or spontaneous, "additionals" identified as an artifact of CMS' IPM review and were not originally submitted by the Medicare Advantage (MA) Organization for payment purposes and (2) "additionals" within the same hierarchy as the audited CMS-Hierarchical Condition Categories (CMS-HCCs). "Additionals" occur during the medical record review process when the medical record submitted by the MA Organization supports a CMS-HCC that was never submitted for payment, or the medical record supports a more severe diagnosis within the same hierarchy as the CMS-HCC submitted for payment. Spontaneous "additionals" do not meet the definition of improper payment and are excluded under HHS' FY 2022 methodology.

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(U.S.) Department of Health and Human Services (HHS) for payment have been excluded from the payment error calculation to get a true measure of payment error. In previous years, these potential payments were reflected in the underpayment rate and overall payment error calculation; however, including the spontaneous "additionals" in the gross underpayment portion resulted in an overstatement of the overall improper payment rate. The implemented policy for FY 2022 contributed to a decrease in the projected Part C improper payment rate, representing a new baseline improper payment rate for Part C and is not directly comparable with prior reporting years. Moreover, FY 2021 also represented a baseline due to various methodology changes, most significantly, a refined denominator calculation.

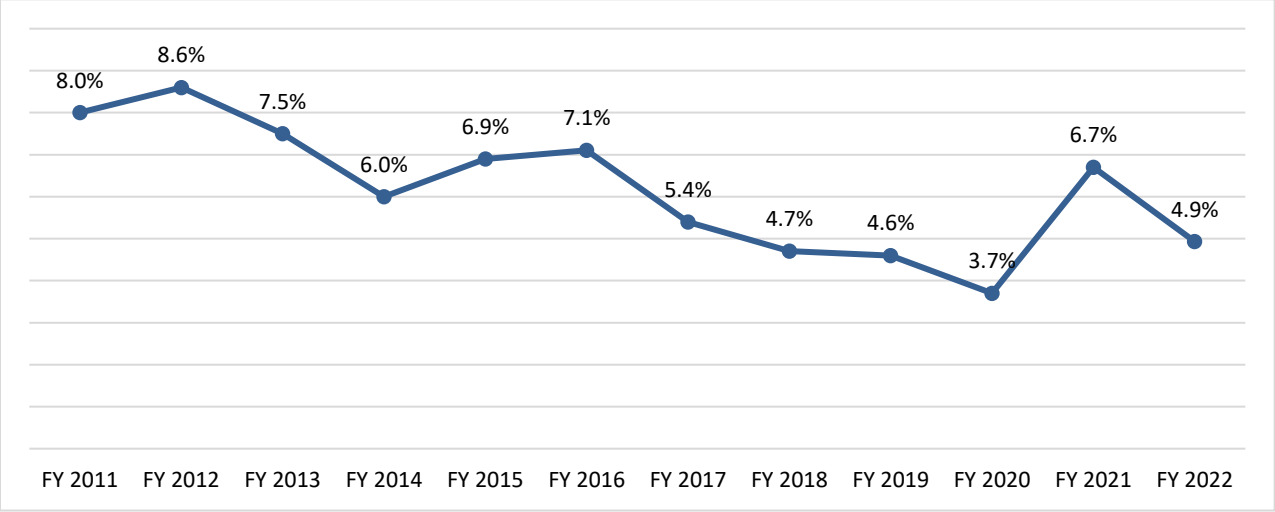
Findings on Overpayments

When Medicare Advantage (MA) Organizations report diagnoses to the CMS Encounter Data System (EDS) or the Risk Adjustment Processing System (RAPS) for payment, CMS uses the CMS Hierarchical Condition Category (CMS-HCC) Risk Adjustment model to assign CMS-HCCs and calculate a risk score for each enrollee. Overpayments occur when CMS-HCCs originally reported to EDS or the RAPS for payment are not supported by the medical record or are identified during medical record review as lower manifestations within the disease hierarchies of the CMS-HCC risk adjustment model. Overpayments also reflect instances when missing or insufficient documentation was provided to validate the CMS-HCC.

The primary overpayment category of FY 2022 Medicare Part C IPM consists of medical record discrepancies (4.74 percent) and a smaller portion of unknown payments resulting from missing or insufficient documentation to determine whether payment was proper or improper (0.19 percent).

Figure 1 presents the percentage of the payment error attributed to overpayments for FY 2011 through FY 2022.

Figure 1: Part C Population Error (%) from Overpayments, FY 2011 – FY 2022



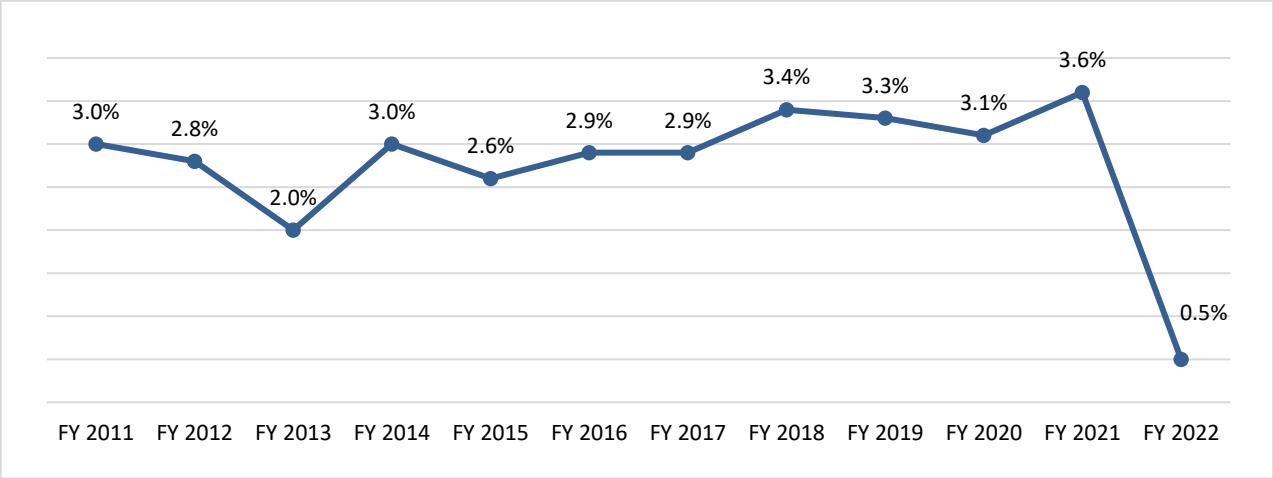
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Findings on Underpayments

Underpayments occur when CMS-HCCs of higher manifestations of the audited CMS-HCCs, in the same disease hierarchies of the CMS-HCC risk adjustment model, are identified during medical record review. The underpayments category of FY 2022 Medicare Part C IPM consists of medical record discrepancies (0.49 percent in underpayments).

Figure 2 presents the percentage of the payment error attributed to underpayment for FY 2011 through FY 2022.

Figure 2: Part C Population Error (%) from Underpayments, FY 2011 – FY 2022



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-18-3621

In the case of	Claim for
McLaren Regional Medical Center (Appellant)	Hospital Insurance Benefits (Part A)
[redacted] (Beneficiary)	XXX-XX-[redacted] (HIC Number)
Wisconsin Physicians Service (Contractor)	1-2412938126 (ALJ Appeal Number)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated January 12, 2018, because the decision is not consistent with the preponderance of the evidence in the administrative record. *See* 42 C.F.R. § 405.1110(c)(1). The ALJ concluded the appellant-provider (appellant) was entitled to Medicare Part A payment for inpatient hospital services that it furnished to the beneficiary from November 13, 2009, through November 20, 2009, at the original Diagnosis Related Group (DRG) assignment of 981 instead of the subsequently down-coded DRG of 480.

By memorandum dated March 12, 2018, the Centers for Medicare & Medicaid Services (CMS) asks the Council to review the ALJ's decision. CMS seeks Council own-motion review on the basis that the ALJ's decision contains a material error of law and is not supported by the preponderance of the evidence in the administrative record. CMS's referral memorandum is admitted into the administrative record as Exhibit (Exh.) MAC-1. The Council sent the appellant a copy of CMS's memorandum but the appellant has not filed any exceptions to it.

We have carefully considered the administrative record, including the appellant's contentions that it presented during the lower levels of the appeals process. For the reasons set forth below, the Council agrees with CMS and finds the ALJ's decision is not supported by the preponderance of the evidence in the administrative record. Therefore, we reverse the ALJ's decision.

BACKGROUND

The instant appeal concerns inpatient hospital services that the appellant furnished to the beneficiary from November 13, 2009, through November 20, 2009. Exh. 1 at 85. The appellant billed Medicare for these services using DRG code 981, listing a principal diagnosis of atrial flutter (HCPCS[1] code 427.32) and a secondary diagnosis of hip fracture (code 820.21). *Id.* at 22, 85. Medicare originally paid these services as billed. *Id.* at 85. A recovery audit contractor (RAC) subsequently determined that the record did not support payment for the services as billed and assessed an overpayment against the appellant for the difference in Medicare payment between the two DRG codes. Specifically, the RAC deemed that "the medical documentation supplied does not support the assignment of Atrial flutter, 427.32 as the principal diagnosis." *Id.* The RAC resequenced the claim with hip fracture as the principal diagnosis and atrial flutter as the secondary diagnosis, resulting in a new DRG of 480 and a lower Medicare reimbursement amount. *Id.* at 22, 85.

Both the contractor and Qualified Independent Contractor (QIC) agreed with the RAC that hip fracture was the principal diagnosis and that the DRG code had properly been adjusted to 480. *Id.* at 11; Exh. 3 at 5-6. In finding that atrial flutter was not the principal diagnosis, the QIC explained that "[t]he beneficiary was noted to have atrial flutter that was treated, but the principal reason for the admission was the hip fracture that was treated with ORIF after medical clearance." Exh. 3 at 6.

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[1] The Centers for Medicare & Medicaid Services (CMS), the federal agency that administers the Medicare program, has established a coding system for screening, processing, identifying, and paying Medicare claims - the Healthcare Common Procedure Coding System (HCPCS). *See* 42 C.F.R. §§ 414.2, 414.40. The HCPCS incorporates codes developed by the American Medical Association, Current Procedure Terminology (CPT) codes, to identify and describe medical services and items.

Following a hearing, at which the appellant as well as the QIC participated, the ALJ ruled that the readjustment of the DRG code was improper because there was sufficient evidence that atrial flutter was the principal diagnosis. Dec. at 6. The ALJ found that:

> Per ICD-9-CM Official Guidelines for Coding and Reporting, when two or more diagnoses equally me[e]t the definition for principal diagnosis, anyone of the diagnoses may be sequenced first. There is sufficient evidence in the record to support the principal diagnosis code of 427.32 (Atrial flutter). As discussed above, there is evidence that the Beneficiary was treated for atrial fibrillation during her inpatient admission. Specifically, the History and Physical revealed that the Beneficiary was assessed with atrial flutter with rapid ventricular response that was noted as a new onset problem.

Id.

Before the Council, CMS asserts that the ALJ's decision contains a material legal error and that the preponderance of the evidence in the administrative record does not support a finding that atrial flutter met the definition as the principal diagnosis in this case. Exh. MAC-1 at 2-3. CMS asserts that the ALJ legally erred by not considering "whether the atrial flutter was the diagnosis established after study to be chiefly responsible for causing the beneficiary's admission as inpatient," as required in assessing the validity of a DRG code. *Id.* at 14. According to CMS, hip fracture rather than atrial flutter was the diagnosis that was chiefly responsible for the beneficiary's hospital admission. *Id.* at 3. As such, the claim should not have been billed with atrial flutter as the principal diagnosis and was properly resequenced by the RAC to a DRG with hip fracture as the principal diagnosis. *See id.* at 2-3.

DISCUSSION

As a preliminary matter, the Council concurs with CMS that the ALJ's decision is not supported by the preponderance of the evidence in the administrative record. *See* 42 C.F.R. § 405.1110(c)(1). Because a CMS contractor participated in the proceedings before the ALJ, we do not consider whether the ALJ's decision also contains a material error of law. *See id.*

Payment

As explained in the Medicare Claims Processing Manual (MCPM), "[p]ayment for inpatient hospital services is made on the basis of a rate per discharge that varies according to the MS-DRG to which a beneficiary's stay is assigned." Pub. 100-04, Ch. 3, § 20 (Rev. 1571 Effective Aug. 15, 2008). In turn, the DRG code to which a beneficiary's stay is assigned varies based on the beneficiary's principal diagnosis. The regulations define principal diagnosis as "the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital." 42 C.F.R. § 412.60(c)(1). Echoing the regulations, the Medicare Program Integrity Manual (MPIM) provides that the principal diagnosis "is the diagnosis which, after study, is determined to have occasioned the beneficiary's admission to the hospital" and that the principal diagnosis reflected in the beneficiary's medical records must match the principal diagnosis reported on the claim form. Pub. 100-08, Ch. 6, § 6.5.3 (Rev. 264 Effective Aug. 15, 2008).

Applying these regulations and guidelines, the Council finds that the ALJ's decision is contrary to the preponderance of the evidence because the medical records indicate that hip fracture rather than atrial flutter was the beneficiary's principal diagnosis.

There is no dispute that the beneficiary required and received treatment at the hospital for atrial flutter. We also recognize that it may very well have been the case that her atrial flutter caused the beneficiary to fall and fracture her hip. Nonetheless, the medical records show that, at least during the inpatient hospital stay in question, hip fracture was the principal diagnosis. *See* 42 C.F.R. § 412.60(c)(1). Notably, the medical records primarily focus on the surgery for the beneficiary's hip fracture. In contrast, there is considerably less attention paid to the beneficiary's atrial flutter. For example, hip fracture is listed first on the Assessment and Plan section of a hospital History & Physical document whereas atrial flutter is listed fourth. Exh. 2 at 37. Likewise, the November 13, 2009, admission orders designate hip fracture as the first diagnosis and atrial flutter is listed as the second diagnosis. *Id.* at 182. In addition, we note that the medical records indicate that the beneficiary's heart rate was "fairly controlled" by November 15, 2009, and that the beneficiary underwent surgery the next day, November 16, 2009. *Id.* at 94, 96. These events reasonably support a conclusion that the

treatment of the beneficiary's atrial flutter was merely a precursor to stabilizing the beneficiary for hip surgery and was not the primary reason for the beneficiary's hospital admission.

Based on the evidence in the administrative record discussed above, the Council disagrees with the ALJ that atrial flutter was the principal diagnosis and finds that the principal diagnosis for the beneficiary's hospital admission was for a hip fracture. In turn, we find that the RAC properly down-coded the originally assigned DRG from 981 to 480 and also correctly assessed an overpayment against the appellant to account for the reduced Medicare payment due to the down-coded DRG.

Waiver of Overpayment

Because we uphold the overpayment assessed by the RAC, the Council must next address whether the appellant is entitled to a waiver of that overpayment under § 1870 of the Social Security Act (Act).

Section 1870 of the Act allows for Medicare's recovery of an overpayment to be waived if a provider is "without fault" in incurring the overpayment. The applicable Medicare Financial Management Manual (MFMM) explains that a provider is not without fault where it submitted claims for payment that it knew, or should have known, would not be covered by Medicare. MFMM, Pub. 100-06, Ch. 3, § 90 (Rev. 29, effective Jan. 2, 2004).

As a provider who participates in the Medicare program, the appellant knew, or at the very least should have known, about the published Medicare coverage requirements and billing guidelines for hospital inpatient services. Thus, the appellant could reasonably have been expected to know that Medicare would not pay for the services at issue that were billed under DRG 981. 42 C.F.R. § 411.406; CMS Ruling 95-1; MCPM, Ch. 30, §§ 40.1, 40.1.2. Therefore, Council finds the appellant is not without fault in submitting the claims that resulted in the overpayment, and the appellant is not entitled to a waiver of the overpayment.

(Continued on next page)

DECISION

For these reasons, the Council finds the ALJ's decision is not supported by the preponderance of the evidence in the administrative record. We also find that Medicare Part A properly pays for the inpatient hospital services furnished to the beneficiary from November 13, 2009, through November 20, 2009, with a down-coded DRG of 480 instead of the originally assigned DRG of 981. In addition, we find the appellant is not entitled to a waiver of the overpayment that was assessed as a result of the adjusted DRGs.

Therefore, the ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL

Stephen M. Godek
Administrative Appeals Judge

Stanley I. Osborne, Jr.
Administrative Appeals Judge

Date: JUN - 7 2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
Medicare Appeals Council
Docket No. M-15-8503
(formerly M-15-2801 and M-13-2309)

Zoll Lifecor Corporation, Appellant
ALJ Appeal No. 1-1189749795R1

DECISION

The underlying claim concerns Medicare coverage for a rental automatic external defibrillator (code K0606) furnished to the beneficiary by the appellant on January 26, 2010, and February 26, 2010. The Council had remanded the case to the Administrative Law Judge (ALJ) under Docket No. M-13-2309 (Oct. 17, 2013), because the hearing recording was inaudible. The ALJ subsequently held another hearing and issued a new decision dated July 27, 2015. In the new decision, the ALJ addressed claims for four beneficiaries, including the beneficiary at issue. Relevant here, the ALJ found that the automatic external defibrillator furnished to the beneficiary at issue did not meet Medicare coverage requirements and was not covered by Medicare. The ALJ also held the appellant liable for the non-covered charges under § 1879 of the Social Security Act (Act).

The appellant subsequently submitted a timely-filed request for review, appealing the ALJ's unfavorable decision for the beneficiary at issue. The Council then remanded the case to the ALJ under Docket No. M-15-2801 (April 10, 2017), because the Council was unable to obtain the claim file despite repeated efforts. Following our remand, the Council received the missing claim file. Accordingly, the Council now vacates our remand order under Docket No. M-15-2801, and considers the appellant's request for review.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council admits the appellant's request for review into the administrative record as Exhibit (Exh.) MAC-1. The Council admits a copy of our remand order under Docket No. M-15-2801 into the administrative record as Exh. MAC-2.

As set forth below, the Council adopts the ALJ's decision.

DISCUSSION

Coverage

The appellant has not satisfied the coverage requirements for the automatic external defibrillator furnished to the beneficiary at issue. The ALJ referenced Local Coverage Determination (LCD) L13877 and stated that an automatic external defibrillator (HCPCS code K0606) is covered for patients if they meet one of the following four criteria:

1) Documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia; or
2) Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
3) Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
4) A previously implanted defibrillator now requires explantation.

ALJ No. 1-1189749795R1, Dec. at 3; LCD L13877. The ALJ found that although the record showed that the beneficiary had a qualifying ejection fraction, the record did not show that the beneficiary had a qualifying diagnosis of dilated cardiomyopathy or myocardial infarction confirmed by electrocardiogram (EKG) or cardiac enzyme testing. *Id.* at 6. The ALJ therefore concluded that the coverage requirements were not met. *Id.*

In the request for review, the appellant argues that the record supports a diagnosis of dilated cardiomyopathy. Exh. MAC-1 at 2. On this point, the appellant notes that the stress test report, the EKG, the office notes, and the physician's order, taken together, show that the beneficiary has a diagnosis of dilated cardiomyopathy. *Id.* The appellant also argues that the record supports a diagnosis of prior myocardial infarcation. *Id.* On this point, the appellant notes that the stress test and the testimony of the appellant's medical director show that the beneficary has prior myocardial infarcation. *Id.;* Exh. 6 at 8. The appellant also notes that the LCD does not require evidence of a myocardial infarcation be presented on an EKG. Exh. MAC-1 at 2. The appellant further argues that a claim for a different date of service for the beneficiary was fully favorable at the reconsideration level based on the same medical records. *Id.*; Exh. 3 at 6-7.

The Council has carefully reviewed the documentation in the record, including the ALJ's decision, the hearing testimony, and the appellant's request for review. We find the record does not support that the coverage requirements for the automatic external defibrillator furnished to the beneficiary at issue are met. As the ALJ noted, the applicable LCD L13877 (Effective Sept. 1, 2009) provides that an automatic external defibrillator (HCPCS code K0606) is covered if one of the four criteria listed in the LCD is met. The ALJ's analysis and the appellant's arguments in the request for review concern whether the third criterion in the LCD is met, namely there must be "[e]ither documented prior myocardial infarction (ICD-9 410.00-410.92, 412) or dilated cardiomyopathy (ICD-9 425.0-425.9) and a measured left ventricular ejection fraction less than or equal to 0.35". LCD L13877; Exh. MAC-1 at 2; ALJ No. 1-1189749795R1, Dec. at 6. The appellant does not otherwise argue that the beneficiary meets the other three criteria in the LCD as an alternative basis for coverage in this case; therefore, we limit our

review to whether the third criterion in the LCD is met. 42 C.F.R. §§ 405.1112(b), 405.1112(c); Exh. MAC-1 at 1-3.

The record does not support that the third criterion in the LCD is met. Although the treating physician's written order in the record checked off the qualifying diagnosis of dilated cardiomyopathy, the Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 5, § 5.7 (Rev. 242, Effective March 1, 2008), makes clear that there must be information in the medical record that substantiates the information in the written order. Exh. 3 at 11. The contemporaneous medical evidence includes a stress test report dated February 27, 2009, and a physician's office visit note dated January 22, 2010, both showing that the beneficiary was diagnosed with ischemic cardiomyopathy. *See* Exh. 3 at 15, 17. LCD L13877 limits the qualifying diagnosis of dilated cardiomyopathy to diagnosis codes 425.0 through 425.9, but the physician's office visit note lists the beneficiary's diagnosis of ischemic cardiomyopathy as diagnosis code 414.9, which does not meet the LCD's requirements. *See* Exh. 3 at 17. The Council has also considered the EKG dated January 22, 2010, referenced in the appellant's request for review. *See* Exh. MAC-1 at 2; Exh. 3 at 16. Although this EKG lists an indication of cardiomyopathy, it does not state a specific type of cardiomyopathy. Therefore, this EKG does not document the qualifying diagnosis of dilated cardiomyopathy as required by the LCD.

The stress test report dated February 27, 2009, shows that the radiologist found that the beneficiary has a "[f]ixed inferior defect" in the INTERPRETATION section of the report, and an "[i]nferior wall infarct" in the IMPRESSION section of the report. Exh. 3 at 15. However, there is no evidence in the medical record that a "fixed inferior defect" and "inferior wall infarct" are synonymous with prior myocardial infarction. *Id.* Additionally, there is no contemporaneous evidence that the beneficiary's treating physician had concurred with the radiologist's findings in the stress test report. In fact, the treating physician left the diagnosis of myocardial infarction unchecked in the written order. *Id.* at 11. The Council has also considered the appellant's argument that a claim for a different date of service for the beneficiary was fully favorable at the reconsideration level based on the same medical records. Exh. MAC-1 at 2. However, prior decisons of ALJs and contractors are not precedential, nor are they binding on the Council. As such, we find no merit in the appellant's argument on this issue.

In sum, we agree with the ALJ that the appellant has not satisfied the documentation requirements for coverage of the rental automatic external defibrillator furnished to the beneficiary on January 26, 2010 and February 26, 2010. LCD L13877; 42 C.F.R. § 405.1062.

Liability

The appellant is liable for the non-covered items under § 1879 of the Act. The ALJ held the appellant liable for the non-covered charges under § 1879 of the Act. Dec. at 7. In its request for review, the appellant asserts that it reasonably believed that the item would be covered by Medicare. Exh. MAC-1 at 2. In support, the appellant asserts that another claim for this beneficiary was fully favorable at the reconsideration level, and that the record supports that the beneficiary has a qualifying diagnosis and ejection fraction. Exh. MAC-1 at 2; Exh. 3 at 6-7. Section 1879 of the Act may limit a party's liability if a party knew or should have known that Medicare would not have covered the services or items. As we discussed above, the evidence in

the administrative record does not substantiate that the beneficiary has a qualifying diagnosis of prior myocardial infarction or dilated cardiomyopathy. Further, prior decisions are not precedential, nor are they binding; therefore, the appellant's reliance on a favorable reconsideration decision in a similar claim for this beneficiary is misplaced. We find that the appellant is a supplier who participates in the Medicare program and has access to the coverage guidelines discussed above; therefore, the appellant could reasonably have been expected to know that the item would not be covered. Accordingly, the Council agrees with the ALJ that the appellant is financially liable for the non-covered costs of the item under § 1879 of the Act.

DECISION

The Council adopts the ALJ's decision. Medicare does not cover the rental automatic external defibrillator (HCPCS code K0606) furnished to the beneficiary on January 26, 2010 and February 26, 2010. The appellant remains financially liable for the non-covered costs.

MEDICARE APPEALS COUNCIL

Deborah S. Samenow
Administrative Appeals Judge

Date: DEC 6 2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
Medicare Appeals Council
Docket No. M-20-40

Desert Valley Hospital, Inc., Appellant
ALJ Appeal No. 1-2996618146

DECISION

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated August 19, 2019, because the ALJ's decision contains an error of law material to the outcome of the claim, and because the decision is not consistent with the preponderance of the evidence of record. 42 C.F.R. § 405.1110. The ALJ concluded the appellant-provider (appellant) was entitled to Medicare Part A payment for inpatient hospital services that it furnished to the beneficiary on January 8, 2011, at the original Diagnosis Related Group (DRG) assignment of 682 billed instead of the subsequently down-coded DRG of 391.

By memorandum dated October 7, 2019, the Centers for Medicare & Medicaid Services (CMS) asks the Council to review the ALJ's decision. CMS seeks Council own-motion review on the basis that the ALJ's decision contains a material error of law and is not supported by the preponderance of the evidence in the administrative record. CMS's referral memorandum is admitted into the administrative record as Exhibit (Exh.) MAC-1. CMS sent a copy of its referral memorandum to the appellant, but we have not received a response.

For the reasons set forth below, the Council agrees with CMS that the ALJ's decision contains an error of law material to the outcome of the claim, and the decision is not consistent with the preponderance of the evidence of record. Therefore, we reverse the ALJ's decision.

BACKGROUND

The instant appeal concerns inpatient hospital services that the appellant furnished to the beneficiary on January 8, 2011. *See* Exh. 2 at 1, 28-29. The appellant billed Medicare for these services using DRG 682, listing a principal diagnosis of hypertensive chronic kidney disease stage V or end stage renal disease, unspecified benign or malignant (ICD-9 code 403.91). *Id.* at 72. Medicare originally paid these services as billed, but a recovery auditor contractor (RAC) subsequently assessed an overpayment after

down-coding the inpatient hospital claim from DRG 682 to DRG 391. Exh. 1 at 51. Specifically, the RAC replaced the principal diagnosis to intractable nausea and vomiting (ICD-9 code 787.01). *Id.*

At the lower appeal levels, the appellant argued that the principal diagnosis of hypertensive kidney disease unspecified with ESRD (end-stage renal disease) was substantiated in the record and was correctly billed. The appellant did not dispute that nausea and vomiting were the principal reasons for admission, as set forth in admission and discharge documents, but asserted that the underlying cause of this condition was ESRD, which should thus be the principal diagnosis. Exh. 1 at 19-20, 39-40; Exh. 3 at 6-8; Exh. 4 at 1-4. On redetermination and reconsideration, the contractor and the Qualified Independent Contractor (QIC) respectively upheld the down-coding of the claim to DRG 391 and the resulting overpayment. Exh. 1 at 30-34, 1-5.

Following a hearing, at which the appellant and the QIC participated, the ALJ issued a favorable decision for the appellant, finding that the originally billed DRG 682 was appropriate. ALJ Decision (Dec.) at 10-11. Specifically, the ALJ found:

> The original codes billed by the Appellant are supported by the medical records in evidence. The primary diagnosis code of 403.91 - hypertensive chronic kidney disease stage V or end-stage renal disease is supported by the fact that the Beneficiary is in dialysis due to this condition. In addition, according to Dr. [R.'s] testimony, the Beneficiary was admitted due to an elevated Troponin level which was due in part to the Beneficiary's end-stage renal disease. Therefore, the Appellant properly billed the inpatient care under DRG 682.

Id. at 10.

Before the Council, CMS first asserts that the ALJ's decision contains an error of law material to the outcome of the claim. Exh. MAC-1 at 12-13. On this point, CMS asserts that the ALJ did not correctly apply Medicare policy in the Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 6 § 6.5.3.B, which provides that a principal diagnosis listed on a claim is the diagnosis which, after study, is determined to have occasioned the beneficiary's admission to the hospital and that "other diagnoses," defined by the Uniform Hospital Discharge Data Set (UHDDS) as "all conditions that coexist at the time of the admission, that develop subsequently, or that affect the treatment received and/or the length of stay," may not be used as the "principal diagnosis" for purposes of DRG billing. *Id.* at 13.

Next, CMS argues that the ALJ's decision is not consistent with the preponderance of the evidence of record, because the record does not support a principal diagnosis of ESRD,

which CMS asserts is a "coexisting condition." Exh. MAC-1 at 13. On this point, CMS states:

> The beneficiary came to the ED [emergency department] on January 7, 2011, with nausea, vomiting, and abdominal pain. The beneficiary was found to have elevated troponin. The beneficiary was admitted as an inpatient the following day, on January 8, 2011. The assessment completed on January 8, 2011, the date of admission, *and* the general admission order both listed the following diagnoses (in order): (1) Elevated troponin, rule out myocardial infarction, (2) Nausea and vomiting, intractable, (3) End-stage renal failure, (4) Hyperglycemia/diabetes, (5) Elevated D-dimer, (6) Elevated BNP, (7) Anemia, normocytic, and (8) Leukocytosis. The beneficiary voluntarily left the hospital against the advice of the physician on the same day as inpatient admission, January 8, 2011. The circumstances of this admission were that a beneficiary was admitted as inpatient on January 8, 2011, and left the hospital on the same day. The circumstances of the beneficiary's hospital stay included treatment of his gastrointestinal symptoms and monitoring of his elevated troponin level.

Id. at 13-14 (internal citations omitted).

DISCUSSION

Payment

The Council agrees with CMS that the ALJ's decision contains an error of law material to the outcome of the claim and is not consistent with the preponderance of the evidence of record.

CMS has established a classification of inpatient hospital discharges by DRGs and, in general, the contractor initially pays for inpatient hospital services on the basis of a rate per discharge that varies according to the DRG to which a beneficiary's stay is assigned. 42 C.F.R. § 412.60(a)-(c). Each DRG represents the average resources required to care for a case in that particular DRG, relative to the national average of resources consumed per case. Medicare Claims Processing Manual, Ch. 3, § 20.2.2 (Rev. 2028; Effective Jan. 1, 2011). The assignment of the appropriate DRG requires a consideration of various factors that not only include the principal diagnosis, but also age, sex, secondary diagnoses, procedures performed, and discharge status, in accordance with 42 C.F.R. § 412.60(c)(1).

The ALJ erred as a matter of law by not correctly applying Medicare policies relevant in determining the assignment of appropriate DRGs for inpatient hospital services or explaining his reasons for declining to follow the applicable policies. 42 C.F.R.

§ 405.1062(a), (b). Here, the ALJ concluded that the primary diagnosis of ESRD was supported because, *inter alia*, the beneficiary was in dialysis for this condition at the time of admission. Dec. at 10. However, the regulations define principal diagnosis as "the diagnosis established *after study* to be chiefly responsible for causing the patient's admission to the hospital." 42 C.F.R. § 412.60(c)(1)(emphasis added). Consistent with the regulations, the MPIM provides that the principal diagnosis "is the diagnosis which, after study, is determined to have occasioned the beneficiary's admission to the hospital" and that the principal diagnosis reflected in the beneficiary's medical records must match the principal diagnosis reported on the claim form. MPIM, Ch. 6, § 6.5.3 (Rev. 264, Effective Aug. 15, 2008); *see also* 50 Fed. Reg. 31038, 31039 (July 31, 1985), available at https://www.govinfo.gov/content/pkg/FR-1985-07-31/pdf/FR-1985-07-31.pdf (last visited Dec. 23, 2019)(UHDDS definition of "other diagnoses" as including "all conditions that coexist at the time of admission. . . .").

Applying these guidelines, we find that the down-coding of the claim was appropriate, because the preponderance of the evidence of record does not support a principal diagnosis of hypertensive chronic kidney disease stage V or end stage renal disease, unspecified benign or malignant, that the appellant used to bill DRG 682. Exh. 2 at 72. Here, the emergency room records show that the beneficiary arrived at the hospital by ambulance on January 7, 2011, with chief complaint abdominal pain of sudden onset and pain of 8/10. *Id.* at 23. Review of the beneficiary's gastrointestinal system (GI) was positive for abdominal pain, nausea, and vomiting, with all other systems reviewed and negative. *Id.* The emergency department summary reflects stated complaint as "high troponin r/o MI/NV intractable/high D-DIMER." *Id.* at 3. Triage and nursing GI assessments throughout the night reflect pain in the lower abdomen with nausea and vomiting. *Id.* at 3-17. The beneficiary was admitted as an inpatient at 05:35 on January 8, 2011, with chief complaint abdominal pain and description of symptoms "had dialysis c/o abd pain." *Id.* at 27, 36. History of present illness on inpatient admission states, in relevant part, as follows:

> He was brought in by ambulance from dialysis center. He complained of abdominal pain at dialysis center, but denies pain at this time. He continues to be nauseous. The patient states that his medications may have upset his stomach. He reports that he was in [another hospital] with myocardial infarction one week ago.

Id. at 28. Impression on admission, in part and in sequence, was (1) elevated troponin, rule out myocardial infarction; (2) nausea and vomiting, intractable; and (3) end-stage renal failure. *Id.* at 29. The plan was admission to the intensive care unit, with cardiology and nephrology consultations. *Id.* Hospital records indicate that the beneficiary left the hospital at 09:45 on January 8, 2011, against medical advice. *Id.* at 42.

We recognize the appellant's argument that the beneficiary's ESRD caused the nausea and vomiting that was the main reason for hospital admission; therefore, justifying the principal diagnosis of ESRD. Exh. 1 at 20. However, the appellant cited to no medical evidence to support its contention that the cause and effect relationship between the nausea and vomiting and the beneficiary's ESRD occasioned this admission. *See* Exh. 3 at 6-7; Exh. 4 at 1-4. Finally, the record supports that the beneficiary's elevated troponin level is discussed in relation to ruling out myocardial infarction, following the beneficiary's recent hospitalization for myocardial infarction and cardiac catheterization, not in relation to ESRD. Exh. 2 at 3, 29, 30. Considering the record as a whole, we find insufficient evidence that the beneficiary's ESRD was chiefly responsible for causing the beneficiary's admission to the hospital after study. 42 C.F.R. § 412.60(c)(1); MPIM, Ch. 6, § 6.5.3.

In sum, we find that the preponderance of the evidence of record does not support a principal diagnosis of hypertensive chronic kidney disease unspecified or ESRD (ICD-9 403.91), as originally billed. Therefore, we find that the RAC correctly replaced the principal diagnosis to intractable nausea and vomiting, which resulted in a down-coding of the claim to DRG 391 and the overpayment assessment.

Liability and Waiver of Recovery

In the appellant's briefing to the ALJ, the appellant argues that it is not liable for the non-covered charges under section 1879 of the Act, and that it is entitled to waiver of recovery under section 1870 of the Act, because "[t]here is no specific guidance provided to have put the provider on notice that this particular service would be denied." Exh. 4 at 3. However, the limitation on liability provisions of section 1879 of the Act do not apply to a denial based on DRG down-coding, which is a payment methodology revision based on the average resources used to care for a patient, rather than a denial based on medical necessity for which the limitation on liability under section 1879 of the Act would apply.

Regarding waiver of recovery, section 1870(b) of the Act allows for Medicare's recovery of an overpayment to be waived if a provider is "without fault" in incurring the overpayment. We find that, as a provider who participates in the Medicare program, the appellant knew, or at the very least should have known, about the published Medicare coverage requirements and billing guidelines for hospital inpatient services. Thus, the appellant could reasonably have been expected to know the Medicare policies in 42 C.F.R. § 412.60 and the MPIM, Ch. 6, § 6.5.3, which instruct providers, such as the appellant, on the correct reporting of the principal diagnosis that affect the DRG assignment. Further, in this case, the appellant knew, or should have known, that the medical record does not support a principal diagnosis of hypertensive chronic kidney disease or ESRD, when the record consistently documents nausea and vomiting as the principal reason for the beneficiary's hospital visit. Therefore, the Council finds that the appellant is not without fault for the overpayment under section 1870(b) of the Act, as

interpreted in the Medicare Financial Management Manual, CMS Pub. 100-06, Ch. 3, §§ 90-90.1 (Rev. 29, Effective Jan. 2, 2004). Accordingly, recovery of the overpayment is not waived.

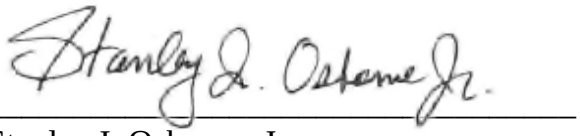
DECISION

The Council finds that the RAC correctly down-coded the claim from DRG 682 to DRG 391, and that recovery of the overpayment is not waived under section 1870 of the Act. Therefore, the ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL



Debbie K. Nobleman
Administrative Appeals Judge



Stanley I. Osborne, Jr.
Administrative Appeals Judge

Date: December 27, 2019

HCFA Rulings

Department of Health and Human Services

Health Care Financing Administration

Ruling No. 86-1 Date: February 20, 1986

USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENTS TO MEDICARE PROVIDERS AND SUPPLIERS

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex statutes or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, HCFA contractors, the Provider Reimbursement Review Board, and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This ruling, HCFAR-86-1, is the first to be issued in a format separate from the bound HCFA Rulings booklet or a Federal Register notice. HCFA is currently in the process of transferring all HCFA Rulings that have been issued into a looseleaf booklet form. This ruling, which is effective on the date of issuance, will be incorporated into that looseleaf booklet.

SECTION 1815(a), 1842(a), and 1861(v)(1)(A)(ii) (42 U.S.C. 1395g(a), 1395u(a), and 1395x(v)(1)(A)(ii)).--HOSPITAL INSURANCE AND SUPPLEMENTARY MEDICAL INSURANCE--USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENTS TO PROVIDERS AND SUPPLIERS

HCFAR-86-1

HCFA and its Medicare contractors may use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible.

The provider billed and was paid by Medicare for services to beneficiaries from September 1982 through July 1985. As a result of a subsequent audit of the provider's Medicare claims, the intermediary discovered a large number of bills for medically unnecessary services. The intermediary also determined that the provider knew or should have known that the services were not covered and, therefore, was not entitled to have payment made to it for the services.

The intermediary considered conducting a case-by-case review in order to determine the amount the provider has been overpaid for the services. This would have entailed an examination of all of the provider's beneficiary records for the period in question in order to identify those beneficiaries who had received unnecessary services. It also would have been necessary to tabulate the total amount that

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Medicare had paid the provider for each beneficiary. The intermediary decided that this method of determining the amount of the overpayment was not administratively feasible, given the volume of records involved and the cost of retrieving and reviewing all the beneficiary records for the period in question. The cost of identifying and calculating each individual overpayment itself would constitute a substantial portion of the amount the intermediary might reasonably be expected to recover. Further, the allocation of sufficient staff to reexamine all individual claims for the period in question would interfere with current claims processing activities to an unacceptable degree.

The intermediary notified the provider that, because of the volume of records and the costs of retrieving and reviewing all records for the period as discussed above, it intended to project the overpayment by reviewing a statistically valid sample of beneficiary records and that if it were determined that the provider had been overpaid for the sample cases, it would project the results (again using statistically valid methods) to the entire population of cases from which the sample had been drawn. This would result in a statistically accurate estimate of the total amount the provider had been overpaid for services to these beneficiaries.

The provider objected to the intermediary's use of sampling to project the overpayment on the following grounds:

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1. There is no legal authority in the Medicare statute or regulations for HCFA or its intermediaries to determine overpayments by projecting the findings of a sample of specific claims onto a universe of unspecified beneficiaries and claims.
2. Section 1879 of the Social Security Act, 42 U.S.C. 1395pp, contemplates that medical necessity and custodial care coverage determinations will be made only by means of a case-by-case review.
3. When sampling is used, providers are not able to bill individual beneficiaries not in the sample group for the services determined to be noncovered.
4. Use of a sampling procedure violates the rights of providers to appeal adverse determinations.
5. The use of sampling and extrapolation to determine overpayments deprives the provider of due process.

(The succeeding presentation of our decision and supporting facts is applicable also to the use of sampling to project overpayments to suppliers (including physicians)

whose claims are processed by Medicare carriers when 100 percent readjudication would be excessively costly or impractical.)

4

The Supreme Court has long recognized that the Federal Government possesses an inherent right to recover monies illegally or erroneously paid out. United States v. Carr, 132 U.S. 644, 650 (1890); Wisconsin Cent. R.R. v. United States, 164 U.S. 190, 212 (1896). This right exists independent of statute. See United States v. Wurts, 303 U.S. 414, 416 (1938); Grand Trunk W. Ry. v. United States, 252 U.S. 112, 121 (1920). The Government may enforce its right of recoupment by reasonable means, and it may exercise that right without resorting to litigation by offsetting the amount against sums otherwise due. United States v. Munsey Trust Co., 332 U.S. 234, 239-240 (1947). Offsets against current or subsequent obligations may be used to prevent a recipient of Federal funds from retaining monies that are later found to have been unauthorized by the terms and conditions under which they were received. Wisconsin Cent. R.R. v. United States, supra, 164 U.S. at 211-212.

The Government's common law right of recoupment, and its corollary power of recovery by offset, are based on strong considerations of public policy. All funds at the disposal of the Government belong to the public. As custodian of these funds, a Federal agency has the fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. Accordingly, if the public's money has been expended in a manner not authorized by statute, the agency's obligation requires it to take

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administrative actions necessary to prevent an unjust enrichment by the recipient at the expense of the Federal treasury. See United States v. Wurts, supra, 303 U.S. at 415-416; Grand Trunk W. Ry. v. United States, supra, 252 U.S. at 120-121.

The common law right to recover Federal funds has been specifically recognized as being fully applicable to the Medicare program. Mt. Sinai Hospital v. Weinberger, 517 F.2d 329 (5th Cir. 1975); Wilson Clinic and Hospital, Inc. v. Blue Cross, 494 F.2d 50 (4th Cir. 1974). Moreover, the courts have also recognized that extrapolation based on a sample is a valid audit technique in cases arising under the Social Security Act. Illinois Physicians Union v. Miller, 675 F.2d 151 (7th Cir. 1982); State of Georgia v. Califano, 446 F. Supp. 404 (N.D. Ga. 1977); New Jersey Welfare Rights Organization v. Cahill, 349 F. Supp. 501 (D.N.J. 1972); Rosado v. Wyman, 322 F. Supp. 1173 (E.D. N.Y. 1970), aff'd 402 U.S. 991 (1971). In view of the enormous logistical problems in determining massive overpayments in social welfare programs, sampling is the only feasible method available. State of Georgia v. Califano, supra; Illinois Physicians Union v. Miller, supra.

Congress has affirmed the Government's right to recover Medicare Trust Funds by reasonable means from those who have no right to retain them. Section 1815(a) of the Social Security Act, 42 U.S.C. 1395g(a), authorizes "necessary

adjustments on account of previously made overpayments or underpayments" under Medicare Part A. Similarly, as to Part B of Medicare, section 1842(a), 42 U.S.C. 1395u(a), provides that carriers make determinations as to the amount of payments to be made to providers of services and other persons, and authorizes such audits of the records as may be necessary to assure that proper payments are made. In addition, section 1861(v)(1)(A)(ii) of the Act, 42 U.S.C. 1395x(v)(1)(A)(ii), provides for the "making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive." These statutory requirements, in effect, would be abrogated if sampling were not available to determine Medicare overpayments. The imposition of such a result would be inconsistent with the settled principle that, when Congress creates a statutory right, the existence of appropriate remedies to enforce that right will be presumed in the absence of a clear indication of a contrary congressional intent. Texas & N.O.R.R. v. Brotherhood of Railway & Steamship Clerks, 281 U.S. 548, 569-570 (1939); Sullivan v. Little Hunting Park, Inc., 396 U.S. 229, 239 (1969).

Since HCFA's contractors process vast numbers of Medicare claims (for example, in fiscal year 1985, intermediaries received over 59.5 million Medicare claims and carriers

received over 270.8 million Medicare claims), an interpretation that title XVIII of the Act mandates that a 100 percent review of cases be conducted before HCFA or its contractors can determine that providers or suppliers have been overpaid would make it virtually impossible for HCFA to implement these statutory provisions in many cases. A case-by-case review could require a significant diversion of staff from the ongoing claims process, and the cost of determining the amount of an overpayment would be prohibitively high unless a sampling method were used. To fulfill the congressional intent, HCFA must adopt realistic and practical auditing procedures. The alternative is to conclude that the intent of Congress was that, if case-by-case overpayment determinations are not administratively feasible, the Medicare Trust Funds must forego restitution of funds improperly obtained by providers and suppliers. We do not believe that was Congress' intent.

We also do not believe that the statutory provisions limiting provider or beneficiary liability preclude the use of sampling. In instances where Medicare coverage is denied because items or services furnished are not "medically necessary" or constitute "custodial" care, section 1879 of the Act, 42 U.S.C. 1395pp (42 CFR 405.330), authorizes a limitation of the beneficiary's liability when the beneficiary did not know, and could not reasonably be expected to have known, that the items or services were not

"medically necessary" or that they constituted "custodial" care. The Medicare program will make payments to the provider when both the beneficiary and the provider were without the requisite knowledge. When the beneficiary did not have such knowledge, but the provider did, liability for the denied services rests with the provider and the beneficiary's liability is waived. The beneficiary will be indemnified by the Medicare program if he or she has already paid the provider. See 42 U.S.C. 1395pp. Liability will rest with the beneficiary only when he or she knew or could have been expected to know that the items or services furnished were not "medically necessary" or were "custodial" in nature.

The use of sampling to determine overpayments for medically unnecessary services or custodial care does not deprive a provider of its right to bill those beneficiaries who knew or should have known that they were receiving these services. Under the governing regulation, 42 CFR 405.334, a beneficiary is presumed not to have had such knowledge unless he or she was notified in writing by the provider, the intermediary, or the Peer Review Organization (PRO). For example, when a beneficiary who is receiving a course of treatment has received a previous denial notice stating that similar items or services were not covered, the previous denial notice would constitute evidence that the beneficiary

did or should have had knowledge of noncoverage. See 42 CFR 405.334 for examples of acceptable written notice to a beneficiary. The operation of this provision effectively serves to resolve most limitation of liability questions in the beneficiary's favor. However, a provider that wishes to bill individual beneficiaries not included in the sample can identify those individuals who were previously informed that they were receiving noncovered services by inquiring of the intermediary or PRO as to whether it sent a notice to the individual. (The provider presumably did not give notice to the beneficiary that the services were not covered because, if it had, it is unlikely that it would have billed Medicare for the services.)

Even if we assume that a provider is effectively precluded from billing a beneficiary in certain cases, this assumption would not bar the Government from its fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. As between the provider and the Government, strong considerations of public policy favor recovery. On the other hand, the provider had the responsibility to know and should have known that the services furnished were not medically necessary. Moreover, as the United States Court of Appeals for the Fifth Circuit recognized in Mt. Sinai Hospital of Greater Miami v. Weinberger, 517 F.2d 329 (5th Cir. 1976), the provider assumes substantial responsibility for overpayments.

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> ... [the hospital] is not a neutral, innocent party in this three-way transaction between HEW, Medicare beneficiary and Medicare provider. The decision to provide a service is made by the individual attending physician, who is far better informed on both the medical issue and the scope of Medicare coverage than is the patient-beneficiary. The physician is either an employee of the hospital or a doctor with staff privileges. Whatever else the granting of staff privileges may connote, it is clear to us that it involves a delegation by the hospital of authority to make decisions on utilization of its facilities. 534 F.2d at 338.

In reimbursing providers, HCFA has to balance the need to process billings rapidly in order that a provider's liquidity needs do not suffer and the need to verify that the claims submitted are for services covered by the Act. Mixed into this balance is the volume of claims which must be reviewed. Considering the volume of claims (as cited earlier to be over 330.3 million for fiscal year 1985), it is virtually impossible to examine each bill submitted by a provider or supplier in sufficient detail to assure before payment in every case that only medically necessary services have been provided. Therefore, as a practical matter, HCFA and its contractors must depend on the provider to submit claims for services that are covered by the Act. In most cases, this reliance is justified. However, if HCFA or its contractors later have reason to make an indepth and careful review of claims for services which had been previously paid and discover that medically unnecessary services have been provided, a provider cannot cry "foul" when these payments (to which they were never legally entitled) are recovered.

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Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

The provisions of the statutes and regulations provide a constitutionally sufficient means by which the provider may challenge an overpayment determination. In cases of denials made through sampling which are based on medical necessity or custodial care, section 1879 of the Act, 42 U.S.C. 1395pp, permits the provider to assert the same appeal rights that an individual has under the statute when the individual does not exercise his rights to appeal. Under Part A, these rights

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include an opportunity for reconsideration (42 CFR 405.710-405.716), an oral evidentiary hearing by an administrative law judge (42 CFR 405.720-405.722), Appeals Council Review (42 CFR 405.701(c) and 405.724), and finally judicial review if the amount in controversy is $1,000 or more (42 CFR 405.730; 42 U.S.C. 1395ff(b)(2)). In cases which do not involve medical necessity or custodial care, 42 CFR 405.370, et seq. sets out the applicable procedures through which current payments may be suspended (offset) to recover an overpayment under the Medicare program. Under 42 CFR 405.371, a provider is given notice as to the basis for the overpayment and an opportunity to respond before an intermediary may suspend current Medicare reimbursement. 42 CFR 405.372, in conjunction with 42 CFR 405.370(b), forestalls any suspension pending consideration of any statement by the provider in opposition to the notice of suspension. Finally, if it is determined that a suspension should go into effect, written notice of the determination will be sent to the provider or other supplier. The notice will contain specific findings on the conditions upon which the suspension was based and an explanatory statement for the final decision. Thus, the administrative scheme provides sufficient means for a provider to challenge overpayment determinations that are made on the basis of sampling.

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Under Part B, suppliers who accept assignment may request a Medicare carrier to review a payment determination with which the supplier disagrees (42 CFR 405.807). If the supplier is dissatisfied with the carrier's review determination, the supplier may request a hearing before a carrier hearing officer if the amount in controversy is $100 or more (42 CFR 405.820). There are no further appeals available under Part B. In U.S. v. Erika, Inc., 456 U.S. 201 (1982), the Supreme Court ruled unanimously that, under current law, the Part B hearing is rightfully the final step in the Part B appeals process.

In summary, the use of sampling is a reasonable and cost effective method of projecting overpayments under Medicare. It is not unfair to a provider or supplier to hold it accountable for the receipt of Medicare funds to which it is not entitled under the statute. To the contrary, allowing a provider or supplier improperly to retain large sums of program funds would be unfair to the intended beneficiaries of Medicare and to the taxpayers who contribute to the trust funds. As the Supreme Court held in Richardson v. Perales, 402 U.S. 389 (1971), the system must not only be fair, but it must work.

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Accordingly, it is held that the use of statistical sampling to project an overpayment is consistent with the Government's common law right to recover overpayments, the Medicare statute, and the Department's regulations, and does

not deny a provider or supplier due process. Neither the statute nor regulations require that a case-by-case review be conducted in order to determine that a provider or supplier has been overpaid and to determine the amount of overpayment.

DATED: 2/20/86

/s/ Henry R. Desmarais
Acting Administrator, Health
Care Financing Administration

U.S. GOVERNMENT PRINTING OFFICE: 1986 - 491 – 264/42028



Medicare & Medicaid Program Integrity

Annual Report to Congress

CMS Nondiscrimination Notice & Notice of Availability of Auxiliary Aids & Services and Language Assistance Services

The Centers for Medicare & Medicaid Services (CMS) does not exclude, deny benefits to, or otherwise discriminate against any person on the basis of race, color, national origin, disability, sex or age in admission to, participation in, or receipt of the services and benefits under any of its programs and activities. The non-discrimination policy applies whether carried out by CMS directly or through a contractor or any other entity with which CMS arranges to carry out its programs and activities.

CMS is committed to making its programs, benefits, services, facilities, information, and technology accessible in accordance Section 504 (42 U.S.C. § 794) and Section 508 (42 U.S.C. § 794(d)) of the Rehabilitation Act of 1973 and Section 1557 of the Patient Protection and Affordable Care Act of 2010 and their respective implementing regulations. Section 504 prohibits discrimination on the basis of disability in Federal programs and activities, and Section 508 requires Federal agencies to ensure that their electronic and information technology is accessible to individuals with disabilities. CMS provides various auxiliary aids and services, including written information in alternate formats (large print, audio, accessible electronic formats, other formats), relay services, and qualified interpreters for individuals with disabilities at no cost to communicate effectively with people with disabilities. In addition, CMS provides free language services to people whose primary language is not English, such as qualified interpreters for individuals with limited English proficiency and information written in other languages.

To request an auxiliary aid or service:

1. For Medicare publications, call 1-800-MEDICARE.
   TTY users should call 1-877-486-2048.
2. For all other CMS publications, you can:
   - Call 1-844-ALT-FORM (1-844-258-3676). TTY users should call 1-844-716-3676.
   - Send a fax to 1-844-530-3676.
   - Send an email to AltFormatRequest@cms.hhs.gov.
   - Send a letter to:

     Centers for Medicare & Medicaid Services
     Office of Equal Employment Opportunity & Civil Rights (OEOCR)
     7500 Security Boulevard, Room N2-22-16
     Baltimore, MD 21244-1850
     Attn: CMS Alternate Format Team

Note: Your request for CMS publications should include:

- Your name, phone number, and the mailing address where we should send the publications.
- The publication title and CMS Publication No., if available.
- The format you need, like Braille, large print, compact disc (CD), audio CD, or a qualified reader.

If you believe you have been subjected to discrimination in a CMS program or activity, there are three ways to file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights:

- **Online** at https://www.hhs.gov/ocr/complaints/index.html.
- By phone: Call 1-800-368-1019. TDD users should call 1-800-537-7697.
- **By Mail:** Send information about your complaint to:

  Centralized Case Management Operations
  U.S. Department of Health and Human Services
  200 Independence Avenue, S.W.
  Room 509F HHH Bldg.
  Washington, D.C. 20201

- **By Email**: Send information to:

  OCRComplaint@hhs.gov

  For additional information, email AltFormatRequest@cms.hhs.gov.

Executive Summary

The Annual Report to Congress on the Medicare and Medicaid Integrity Programs for Fiscal Year (FY) 2019 fulfills requirements in sections 1893(i)(2) and 1936(e)(5) of the Social Security Act (the Act). These provisions require the Centers for Medicare & Medicaid Services (CMS) to report annually about the use of appropriated funds and the effectiveness of the use of such funds for Medicare and Medicaid program integrity activities.[1]

CMS's mission for program integrity is to detect and combat fraud, waste, and abuse of the Medicare and Medicaid programs. CMS achieves this mission by making the correct payment to the right entity for services covered under CMS programs. CMS also works with providers, states, and other stakeholders to support proper enrollment and accurate billing practices. This work focuses on protecting patients while also minimizing unnecessary burden on providers and states.

As federal health programs are quickly evolving, CMS's program integrity strategy must keep pace addressing emerging challenges. CMS developed a five-pillar program integrity strategy intended to modernize the Agency's approach and protect its programs for future generation.[2] This strategy focused on stopping bad actors, preventing fraud, mitigating emerging program risks, and reducing provider burden, and leveraging new technology.

Medicare Program Integrity

Medicare processes over one billion Fee-for-Service FFS claims a year.[3] To do this properly – to "pay it right" – Medicare contractors must determine whether the claim is submitted by a legitimate provider or supplier for an item or services that is covered, reasonable and necessary, and properly documented in the medical record.[4]

In FY 2019, CMS's program integrity activities, including both the prevention and recovery of improper payments, saved Medicare an estimated $13.8 billion and produced a

[1] Please note that not all Medicare program integrity-related activities are funded under section 1893 of the Act and not all Medicaid program integrity activities are funded under section 1936 of the Act. As such, this report includes other Medicare and Medicaid program integrity activities to provide a more complete view of CMS's program integrity activities. For example, where applicable in this report, we have described activities conducted by the program integrity units of the states that enhance the overall integrity of the Medicaid program, even if they are not funded under section 1936 of the Act. In addition, for the purposes of this document, the term "provider" may refer to a provider, supplier, physician, or non-physician practitioner, and the term may represent an individual or an organization.

[2] https://www.cms.gov/newsroom/press-releases/fiscal-year-fy-2019-medicare-fee-service-improper-payment-rate-lowest-2010-while-data-points and https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2019-11-27

[3] https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2019.pdf at page 2.

[4] https://www.cms.gov/About-CMS/Components/CPI/Downloads/Center-for-Program-Integrity-Future-of-PI-RFI.pdf

return on investment of $9.7 to 1 (see Table 3 for activity-specific savings).[5] These activities help strengthen the integrity and sustainability of the Medicare program, while promoting quality and the efficient delivery and financing of health care.

In addition to the estimated savings and ROI cited above, CMS's program integrity efforts have contributed to a reduction in the improper payment rate in recent years. The Medicare FFS estimated improper payment rate decreased to 7.25 percent in FY 2019, from 8.12 percent in FY 2018, the third consecutive year the Medicare FFS improper payment rate has been below the 10 percent threshold for compliance established by the Improper Payments Elimination and Recovery Act of 2010. Progress in a number of important areas drove the FY 2019 decrease:[6]

- Home health claims corrective actions, including policy clarification and Targeted Probe and Educate for home health agencies, resulted in a significant **$5.32 billion decrease** in estimated improper payments from FY 2016 to FY 2019.
- Other Medicare Part B services (e.g., physician office visits, ambulance services, lab tests, etc.) saw a $1.82 billion reduction in estimated improper payments in FY 2019 due to clarification and simplification of documentation requirements for billing Medicare.
- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) improper payments decreased an estimated $1.29 billion from FY 2016 to FY 2019 due to various corrective actions implemented over the years.

Medicaid and Children's Health Insurance Program (CHIP) Program Integrity

States and the Federal Government share mutual obligations and accountability for the integrity of Medicaid and the Children's Health Insurance Program (CHIP). This includes the application of effective safeguards to ensure the proper and appropriate use of both federal and state dollars and the provision of quality care to some of the nation's most vulnerable populations. While the responsibility for making proper payments in Medicaid primarily lies with the states, CMS plays a significant role in supporting state efforts to meet high program standards. **In FY 2019, federal and state collaborative program integrity efforts for Medicaid and CHIP resulted in estimated federal share[7] savings of $1.1 billion (see Table 4 for activity-specific savings).**

CMS recently took a significant step by releasing the FYs 2019-2023 Comprehensive Medicaid Integrity Plan (CMIP) that seeks to protect taxpayer dollars and is based on the three pillars of

[5] CMS periodically updates the methodologies for Medicare savings metrics due to program and/or data source changes; thus, some Medicare savings amounts may not be directly comparable to amounts in previous reports. Appendix B provides information regarding which savings metrics underwent methodological changes.

[6] https://www.cms.gov/newsroom/press-releases/fiscal-year-fy-2019-medicare-fee-service-improper-payment-rate-lowest-2010-while-data-points

[7] The federal government and states jointly fund the Medicaid program. The federal government pays states for a specified percentage of program expenditures, called the Federal Medical Assistance Percentage (FMAP). Therefore, program-integrity-related activities in Medicaid result in savings for both states and the federal government. CMS highlights the federal share (instead of the combined federal and state shares) of Medicaid savings for reporting consistency across savings metrics.

flexibility, accountability, and integrity. The CMIP includes stronger audit and oversight functions, increased beneficiary eligibility oversight, and enhanced enforcement of state compliance with federal rules.[8]

Collaboration with Law Enforcement in Program Integrity

CMS coordinates closely with a variety of other partners to meet its program integrity objectives, including, but not limited to the Department of Health and Human Services Office of Inspector General (HHS-OIG); the Department of Justice (DOJ); State law enforcement officials, including those from the state Medicaid Fraud Control Units (MFCUs); and other federal, state and local agencies. Specifically, since FY 2018, CMS coordinates a Major Case Coordination initiative, providing an opportunity for Medicare and Medicaid policy experts, law enforcement officials, clinicians, and fraud investigators to collaborate before, during, and after the development of fraud leads. Highlights of the Major Case Coordination in FY 2019 include:

- In April 2019, CMS implemented administrative actions as part of "Operation Brace Yourself," a joint effort with HHS-OIG and DOJ to target fraudulent DMEPOS suppliers. As part of this effort, CMS implemented payment suspensions on 130 DMEPOS suppliers totaling $74 million as of August 2019. CMS implemented payment suspensions on an additional seven DMEPOS suppliers subsequent to those initial actions. Forty suppliers under payment suspension voluntarily withdrew from the Medicare program and 45 suppliers were revoked from Medicare since that activity.
- CPI suspended Medicare payments to eight enrolled providers and revoked four providers in order to support the April 2019 coordinated law enforcement actions of the Appalachian Regional Prescription Opioid Strike Force (ARPO).
- In September 2019, CMS took administrative action in support of a federal law enforcement action involving five federal districts against 35 defendants associated with dozens of telemedicine companies and cancer genetic testing laboratories.[9]
  Also in September 2019, CMS participated in a coordinated health care fraud enforcement action in the northeastern United States, involving more than $800 million and the distribution of over 3.25 million pills of opioids in "pill mill" clinics. This takedown also included the second phase of "Operation Brace Yourself", where DOJ announced charges in that DMEPOS fraud case against defendants around the country, for their alleged participation in a massive DMEPOS telemarketing fraud scheme back on April 9, 2019.

[8] https://www.cms.gov/files/document/comprehensive-medicaid-integrity-plan-fys-2019-2023.pdf

[9] https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against

Program Integrity Public/Private Partnerships

The Healthcare Fraud Prevention Partnership (HFPP) is a voluntary public/private partnership between the Federal Government, state and local agencies, law enforcement entities, private health insurance plans, employer organizations, and health care anti-fraud associations. The purpose of the partnership is to exchange data and information between the partners to help improve capabilities to fight fraud, waste, and abuse in the health care industry. In FY 2019, the HFPP reached a membership level of 144 Partner organizations.[10] Collectively, these organizations represent more than 215 million covered lives, equivalent to more than three out of four insured Americans. Thirty-four of the current partners are actively submitting claim level data, representing 100 million individuals, or more than one in three insured Americans.

During FY 2019, the HFPP completed a number of studies using multiple partner data to address fraud, waste, and abuse. The HFPP also held quarterly Regional Information Sharing Sessions throughout FY 2019, allowing partners to participate in case sharing sessions, listen to panel discussions, receive updates from law enforcement, and collaborate with members from across the Partnership. In the summer of 2019, the HFPP published an issue paper to the Partnership titled "Fraud & Abuse in Recovery Treatment Services for Substance Use Disorders: An Issue Paper by the Healthcare Fraud Prevention Partnership." In September 2019, the HFPP also hosted its annual Executive Board meeting, which expanded participation to include Partner executive leadership, and provided an opportunity for attendees to review HFPP successes and strategies.

[10] The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control (HCFAC) Program Annual Report for Fiscal Year 2019 (The FY 2019 HCFAC Report) at page 10.

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1. Introduction

The Report to Congress on the Medicare and Medicaid Integrity Programs for Fiscal Year (FY) 2019 fulfills requirements in sections 1893(i)(2) and 1936(e)(5) of the Social Security Act (the Act). These provisions require the Centers for Medicare & Medicaid Services (CMS) to report annually about the use of appropriated funds and the effectiveness of the use of such funds for activities conducted under the Medicare and Medicaid Integrity Programs.

CMS is the agency within the Department of Health and Human Services (HHS) responsible for administering the Medicare program consistent with title XVIII of the Act. CMS is also responsible for providing direction and guidance to, and oversight of, state-operated Medicaid programs and Children's Health Insurance Programs (CHIP), consistent with titles XIX and XXI of the Act, respectively, in addition to other federal health care programs and activities. The Medicare and Medicaid Integrity Programs help protect Medicare and Medicaid against fraud, waste and abuse.

The Medicare and Medicaid programs provide coverage for a large proportion of Americans each year. Medicare enrollment has increased from 19 million beneficiaries in 1966 to approximately 60 million beneficiaries in FY 2019, while Medicaid enrollment has increased from 11 million beneficiaries in 1966 to about 75 million beneficiaries.[11]

The CMS Center for Program Integrity (CPI) is primarily responsible for implementation of the Medicare Integrity Program and the Medicaid Integrity Program. While other areas of CMS also engage in program integrity-related activities,[12] this report focuses on the program integrity activities led, or that had significant involvement, by CPI.

During FY 2019, CMS's comprehensive program integrity efforts resulted in estimated Medicare savings of $13.8 billion and estimated Medicaid and CHIP federal share[13] savings of $1.1 billion. This commitment to fiscal integrity allows CMS to focus on efforts to better serve patients and ensure that providers render high-quality care. Section 1.3 of this report provides activity-specific Medicare, Medicaid, and CHIP savings, and Appendix B provides detailed methodologies for all savings metrics.

CMS Program Integrity Strategy

CMS's mission for program integrity is to detect and combat fraud, waste, and abuse of the Medicare and Medicaid programs. CMS makes sure it is paying the right entity the right amount for services covered under our programs. This work includes providers, states, and other

[11] The 2019 CMS Agency Financial Report can be found at https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2019.

[12] For example, the Office of Financial Management, the Center for Medicaid and CHIP Services, and the Center for Medicare also perform program integrity activities, such as the Medicare Secondary Payer (MSP) program and certain improper payment measurement programs.

[13] The Medicaid program is jointly funded by the Federal Government and states. The Federal Government pays states for a specified percentage of program expenditures, called the Federal Medical Assistance Percentage (FMAP). Therefore, program-integrity-related activities in Medicaid result in savings for both states and the Federal Government. CMS highlights the federal share (instead of the combined federal and state shares) of Medicaid savings for reporting consistency across savings metrics.

stakeholders to support proper enrollment and accurate billing practices, and focuses on protecting patients while also minimizing unnecessary burden on providers and states.

CMS developed a five-pillar program integrity strategy[14] intended to modernize the Agency's approach and protect its programs for future generations:

1. **Stop Bad Actors.** CMS works with law enforcement agencies to identify and take action on those who defraud federal health programs. This collaboration allows CMS to maximize efforts to identify, investigate, and pursue providers who might otherwise endanger program beneficiaries or commit fraud on federal programs.

2. **Prevent Fraud.** CMS continues to focus on moving away from an expensive and inefficient "pay and chase" model to preventing fraud, waste and abuse on the front end. This focus includes making system changes to avoid similar fraudulent activities in the future, as well as developing policies, regulations, and processes to prevent the exploitation of vulnerabilities before claims payment.

3. **Mitigate Emerging Programmatic Risks**. CMS recognizes the need to be vigilant in monitoring new and emerging areas of risk, and developing methods to address these risks. This includes maintaining flexibility to respond to future data and trends, tailor strategies accordingly, and use new approaches for high vulnerability services. CMS is also exploring ways to identify and reduce program integrity risks related to value-based payment programs by looking to experts in the health care community for lessons learned and best practices.

4. **Reduce Provider Burden.** While CMS strengthens program integrity, the Agency also takes steps to ensure that these efforts do not create unnecessary time and cost burden on providers. Efforts in this area include targeted medical review with individualized education to assist rather than punish providers who make good faith claim errors. CMS is also working to make access to our coverage and payment rules more easily accessible to providers, as well as streamlining and reducing documentation requirements that are duplicative or unnecessary. Additionally, CMS is exploring ways to centralize provider screening and provider monitoring across payers.

5. **Leverage New Technology**. CMS is looking to leverage new, innovative strategies and technologies, perhaps involving artificial intelligence and/or machine learning, to modernize and automate our program integrity efforts. This new technology could allow the Medicare program to review compliance on more claims with less burden on providers and less cost to taxpayers. CMS could use these innovations in both our current payment models, as well as in new payment models.

CMS organized this report around these strategic goals, with each section detailing specific aspects of CMS's program integrity efforts. Appendices at the end of this report provide additional information and references.

[14] https://www.cms.gov/blog/future-medicare-program-integrity

1.1 Reporting Requirements

As required by sections 1893(i)(2) and 1936(e)(5) of the Act, CMS must report to Congress the use of appropriated funds and the effectiveness of the use of such funds for activities conducted under the Medicare and Medicaid Integrity Programs.[15] Section 1893(h)(8) of the Act also requires an annual report to Congress concerning the effectiveness of the Recovery Audit Programs under Medicare and Medicaid in identifying underpayments and overpayments and recouping overpayments, including an evaluation of the comparative performance of such contractors including the savings to the program.

This report fulfills the reporting requirements with respect to the Medicare and Medicaid Integrity Programs, the Medicare Fee-for-Service (FFS) Recovery Audit Contractors (RACs), the Medicare Advantage (MA or Part C) and Medicare Prescription Drug Part D Program (Part D) RACs, and the Medicaid RACs.[16]

1.1.1 Medicare Program Integrity Funding

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[17] established mandatory funding for the Medicare Integrity Program, which provided a stable funding source for Medicare program integrity activities not subject to annual appropriations. The Patient Protection and Affordable Care Act[18] increased the base funding level and applied an annual inflationary adjustment to that base funding level. This funding supports program integrity functions performed across CMS, including: Audits, Medicare Secondary Payer (MSP), Medical Review, Provider Outreach and Education, Benefit Integrity, and Provider Enrollment.

CMS receives additional mandatory funding under the Deficit Reduction Act of 2005 (DRA)[19] and the Patient Protection and Affordable Care Act, as well as discretionary Health Care Fraud and Abuse Control (HCFAC) program funding, subject to annual appropriation. CMS obligated a total of $1.3 billion in FY 2019 for the Medicare Integrity Program.

Appendix A provides further information on the obligations for program integrity activities for both Medicare and Medicaid. Please note that this report includes activities funded outside of the Medicare or Medicaid Integrity Programs. Activities such as CMS Innovation Center models, the Medicare Shared Savings Program (MSSP), and the DMEPOS Competitive Bidding are included to provide a more complete discussion of CMS's efforts to address program integrity

[15] Please note that not all Medicare program integrity-related activities are funded under section 1893 of the Act and not all Medicaid program integrity activities are funded under section 1936 of the Act. As such, this report includes other Medicare and Medicaid program integrity activities to provide a more complete view of CMS's program integrity activities. For example, where applicable in this report, we have described activities conducted by the program integrity units of the states that enhance the overall integrity of the Medicaid program.

[16] CMS is subject to other requirements to report to Congress, such as on the use of Health Care Fraud and Abuse Control program funds. This report details activities that may also be subject to other reporting requirements.

[17] Public Law 104-191.

[18] Public Law 111-148 and Public Law 111-152 collectively constitute the Patient Protection and Affordable Care Act.

[19] Public Law 109-171.

1.1.2 Medicaid Program Integrity Funding

The DRA added section 1936 to the Act to establish the Medicaid Integrity Program and provided CMS with dedicated funding to operate the program. Under section 1936 of the Act, Congress appropriated funds for the Medicaid Integrity Program beginning in FY 2006 and authorized these funds to remain available until expended. Beginning in FY 2011, the Patient Protection and Affordable Care Act amended the Act to increase this funding authorization each year by the Consumer Price Index for all urban consumers.[20] CMS obligated a total of $84.4 million in FY 2019 for the Medicaid Integrity Program. In addition, CMS obligated a total of $90.2 million in FY 2019 for Medicaid program integrity activities using discretionary HCFAC funds.

Appendix A provides further information on the obligations for program integrity activities for both Medicare and Medicaid. Please note that this report includes activities funded outside of the Medicare or Medicaid Integrity Programs. Activities such as CMS Innovation Center models, the Medicare Shared Savings Program (MSSP), and the DMEPOS Competitive Bidding are included to provide a more complete discussion of CMS's efforts to address program integrity.

1.2 Program Integrity in Medicare and Medicaid

As the largest purchaser of health care in the world, CMS maintains the nation's largest collection of health care data. Based on the latest 2019 projections, Medicare and Medicaid (including state funding) represent 37 cents of every dollar spent on health care in the United States (U.S.)—or looked at from three different perspectives: 54 cents of every dollar spent on nursing homes, 44 cents of every dollar received by U.S. hospitals, and 34 cents of every dollar spent on physician services.[21]

Medicare processes over one billion FFS claims a year, and accounts for approximately 15 percent of the federal budget. Since 1966, Medicare enrollment has increased from 19 million to over 60 million beneficiaries.[22]

States and the Federal Government jointly fund the Medicaid program, as CMS provides specified matching payments to the states and territories for Medicaid program expenditures and related administrative costs. Medicaid is the primary source of health care for more than 75 million beneficiaries. Approximately 12.3 million people are dually eligible and covered by both Medicare and Medicaid.[23]

As required by law, CMS and state Medicaid agencies procure contractors to conduct certain program integrity activities in the Medicare and Medicaid programs. Table 1 below summarizes each contractor and its distinct role and responsibility.

[20] 42 U.S.C. 1396u-6(e)(1)(D).

[21] CMS Financial Report Fiscal Year 2019, at page 2. https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2019.

[22] *Id.* at page 2.

[23] https://www.cms.gov/files/document/medicaremedicaiddualenrollmenteverenrolledtrendsdatabrief.pdf

Table 1: Program Integrity Contractors

Contractor	Program	Program Integrity Responsibilities
Unified Program Integrity Contractors (UPICs) [24]	Medicare FFS and Medicaid	• Investigate leads generated by the Fraud Prevention System (FPS) and complaints from beneficiaries and a variety of other sources • Perform proactive data analysis to identify cases of suspected fraud, waste, and abuse in Medicare and Medicaid • Make recommendations to CMS or states for appropriate administrative actions (i.e., revocations and suspensions) to protect the Medicare Trust Funds and Medicaid dollars • Implement administrative actions (i.e., payment suspensions, prepayment edits, auto-denial edits) in coordination with the Medicare Administrative Contractors • Conduct medical review for Medicare and Medicaid program integrity purposes • Identify and investigate incidents of potential fraud, waste, or abuse that exist in Medicare and Medicaid • Make referrals to law enforcement for potential prosecution • Provide support for ongoing law enforcement investigations • Provide feedback and support to CMS to improve the Unified Case Management System • Identify improper payments to be recovered within Medicare and Medicaid
Medicare Administrative Contractors (MACs)	Medicare FFS	• Determine proper payment amounts, process and pay providers, suppliers, and individuals • Perform provider and supplier screening and enrollment • Audit the Medicare cost reports upon which CMS bases part of Medicare payments to institutional providers, such as hospitals and skilled nursing facilities • Conduct prepayment, post-payment medical review, and prior authorization • Analyze claims data to identify providers and suppliers with patterns of errors or unusually high volumes of particular claims types • Develop and implement prepayment edits • Provide beneficiary, provider, and supplier education, outreach, and technical assistance • Collect overpayment amounts identified through prepayment and post-payment review conducted by the MACs and other review contractors
Supplemental Medical Review Contractor (SMRC)	Medicare FFS	• Conducts nationwide medical review as directed by CMS • Notifies CMS and the MACs of identified improper payments and noncompliance with documentation requests

Contractor	Program	Program Integrity Responsibilities
Medicare FFS Recovery Audit Contractors (RACs)	Medicare FFS	• Conduct post-payment audits to identify a wide range of improper payments • Correct improper payments by collecting identified overpayments and restoring identified underpayments • Make recommendations to CMS about how to reduce improper payments in the Medicare FFS program
Coordination of Benefits & Recovery (COB&R) Contractors	Medicare FFS Secondary Payer	• Identify, develop, and recover Group Health Plan and Non-Group Health Plan debts • Provide customer service to beneficiaries, providers, attorneys, insurers, and employers • Perform data collection and electronic data interchange • Conduct business analysis, quality assurance activities, and outreach and education to stakeholders • Provide system development and data center support for all coordination of benefits and recovery information systems
National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC)	Medicare Part C and Part D	• Conduct data analyses of Part C and Part D issues leading to potential identification of improper payments and regulatory compliance • Coordinate Part C and Part D program integrity outreach activities for stakeholders, including plan sponsors and law enforcement entities • Support CMS enforcement of Part C and Part D through Program Integrity focused audits of plan sponsors.
Investigations Medicare Drug Integrity Contractor (I-MEDIC)	Medicare Part C and Part D	• Detect, prevent, and proactively deter fraud, waste, and abuse (FWA) for high risk prescribers/pharmacies in Medicare Parts C and D • Conduct complaint intake and response, data analysis, investigative activities, referrals to law enforcement partners, and law enforcement support which includes RFIs
Part D RAC	Medicare Part D	• Conduct post-payment reviews of reconciled Part D Prescription Drug Events (PDEs) data to identify a wide range of improper payments
State Medicaid RACs	Medicaid FFS and Managed Care	• Contract with state Medicaid agencies (SMAs) to identify and recover overpayments, and identify underpayments made to Medicaid providers

1.3 Measuring Program Integrity Success

1.3.1 Improper Payment Rates

As required by the Improper Payments Information Act of 2002 (IPIA), as amended,[25] CMS calculates an improper payment rate for Medicare FFS, Part C, and Part D; Medicaid; and CHIP. Table 2 provides the gross improper payment rates (including both overpayments and

[25] Public Law 107-300, Public Law 111-204, and Public Law 112-248, respectively.

underpayments) and summarizes trends in the improper payment rates since 2013. Section 4.1 of this report provides specific information on how each program measures improper payment.

Table 2: Reported Improper Payment Rates Trend for Reporting Years 2015-2019

Program	2015	2016	2017	2018	2019
Medicare FFS	12.1%	11.0%	9.5%	8.1%	7.25%
Part C	9.5%	10.0%	8.3%	8.1%	7.87%
Part D	3.6%	3.4%	1.7%	1.7%	0.75%
Medicaid	9.8%	10.5%	10.1%	9.8%	14.9%
CHIP	6.8%	8.0%	8.6%	8.6%	15.83%

While this report discusses many of the ways that CMS works to reduce the improper payment rates for Medicare, Medicaid, and CHIP, the FY 2019 HHS Agency Financial Report (AFR) also includes a comprehensive overview of the improper payment rates for CMS programs, as well as the corrective actions implemented in FY 2019 to reduce improper payments.[26]

1.3.2 Medicare Program Integrity Savings

In FY 2019, CMS's Medicare program integrity activities saved an estimated $13.8 billion.[27] This represents a return on investment of $9.7 to 1.[28] CMS provides activity-specific Medicare program integrity savings in Table 3,[29] programmatic highlights in subsequent sections of this report, and detailed savings metric methodologies in Appendix B.

As a particular highlight in FY 2019, CMS and its law enforcement partners orchestrated multiple takedowns of fraudulent providers, and CMS's administrative actions on these providers resulted in significant savings. Of the savings reported in Table 3, a total of $750.5 million came from takedown-related actions, as well as concurrent and ensuing administrative actions (e.g., from CMS's provider enrollment operations), on providers involved in DMEPOS, genetic testing, and home health fraud schemes.

Table 3: Medicare Savings

Type of Medicare Savings [a]	FY 2019 Savings (in millions)
Prevention Savings	
Automated Actions	

[26] HHS FY 2019 Agency Financial Report, at page 189. https://www.hhs.gov/sites/default/files/fy2019-hhs-agency-financial-report-final.pdf.

[27] CMS periodically updates the methodologies for Medicare savings metrics due to program and/or data source changes; thus, some Medicare savings amounts may not be directly comparable to amounts in previous reports. Appendix B provides information regarding which savings metrics underwent methodological changes.

[28] CMS calculates the fiscal year return on investment for the Medicare Integrity Program by dividing the total Medicare savings by the total Medicare obligations.

[29] In addition to the savings provided in Table 3, CMS's program integrity activities may result in other benefits that are difficult to quantify, e.g., potential sentinel effects from CMS's pre-claim review and prior authorization initiatives.

Type of Medicare Savings [a]	FY 2019 Savings (in millions)
National Correct Coding Initiative (NCCI) Procedure-to-Procedure Edits	$251.2
NCCI Medically Unlikely Edits	$366.0
Ordering and Referring Edits	$122.3
Fraud Prevention System Edits	$69.4
MAC Automated Medical Review Edits	$1,011.4
UPIC Automated Edits	$36.2
Prepayment Review Actions	
Medicare Secondary Payer (MSP) Operations	$6,397.7
MAC Non-Automated Medical Reviews	$69.6
UPIC Non-Automated Reviews	$20.7
Provider Enrollment Actions	
Revocations	$407.9
Deactivations	$101.3
Other Actions	
Payment Suspensions	$654.4
Medicare Part D Reconciliation Data Reviews	-$5.6
Total Prevention Savings [b]	**$9,502.4**
Recovered Savings	
Overpayment Recoveries	
MSP Operations	$2,919.7
MSP Commercial Repayment Center	$167.3
MAC Post-Payment Medical Reviews	$5.3
Medicare FFS RAC Reviews	$119.9
SMRC Reviews	$57.4
UPIC Post-Payment Reviews	$113.6
Overpayments from Retroactive Revocations	$1.4
Overpayments Related to Risk Adjustment Data	$46.1
Medicare Part D Plan Sponsor Audits	$3.8
Medicare Part D RAC Reviews	$0.0
Cost Report Payment Accuracy	
Provider Cost Report Reviews and Audits	$453.2
Cost-Based Plan Audits	$42.4
Plan Penalties	
Medicare Part C and Part D Program Audits	$0.6
Medical Loss Ratio Requirement	$222.1
Other Actions	
Party Status Appeals	$10.7
Law Enforcement Referrals	
UPIC Law Enforcement Referrals	$72.3
I-MEDIC Part C and Part D Law Enforcement Referrals	$18.5
Total Recovered Savings [b]	**$4,254.2**
Total Savings (Prevention and Recovered) [b]	**$13,756.6**

[a] Appendix B provides detailed methodologies for all metrics listed in this table.
[b] Savings values may not add to totals due to rounding.

1.3.3 Medicaid and CHIP Savings

States and the Federal Government share mutual obligations and accountability for the integrity of Medicaid and CHIP. This includes the application of effective safeguards to ensure the proper and appropriate use of both federal and state dollars and the provision of quality care to some of the nation's most vulnerable populations. CMS quantifies the federal share of Medicaid and CHIP program integrity savings stemming from Medicaid and CHIP financial management and state-reported Medicaid overpayment recoveries due to collaborative federal-state programs and state-level initiatives. **In FY 2019, these efforts resulted in estimated federal share savings of $1.1 billion.** CMS provides activity-specific Medicaid and CHIP federal share savings in Table 4,[30] programmatic highlights in subsequent sections of this report, and detailed savings metric methodologies in Appendix B.

Table 4: Medicaid and CHIP Savings

Type of Medicaid and CHIP Savings [a]	FY 2019 Federal Share Savings (in millions)
Medicaid and CHIP Financial Management	
Averted Medicaid and CHIP Federal Financial Participation	$257.7
Recovered Medicaid and CHIP Federal Financial Participation	$370.4
State-Reported Medicaid Overpayment Recoveries	
UPIC Recoveries	$17.8
State Medicaid RAC Recoveries	$78.4
Office of Inspector General Compliant False Claims Act Recoveries	$9.3
Other State Program Integrity Recoveries	$352.2
Total Savings [b]	**$1,085.8**

[a] Appendix B provides detailed methodologies for all metrics listed in this table.
[b] Savings values may not add to totals due to rounding.

[30] Medicaid savings may differ in the HHS Agency Financial Report compared to the Report to Congress on the Medicare and Medicaid Integrity Programs because CMS pulls the data from Form CMS-64 at different times.

2. Stop Bad Actors

2.1 Partnership and Collaboration with Law Enforcement

2.1.1 Major Case Coordination

CMS coordinates closely with a variety of other partners to meet its program integrity objectives, including but not limited to the Department of Health and Human Services Office of Inspector General (HHS-OIG), DOJ; and other federal agencies.

CMS's Major Case Coordination initiative provides an opportunity for Medicare and Medicaid policy experts, law enforcement officials, clinicians, and fraud investigators to collaborate before, during, and after the development of fraud leads. This level of collaboration has contributed to several successful coordinated law enforcement actions and helped CMS better identify national fraud trends and program vulnerabilities. As a result of the work performed in the Major Case Coordination initiative, there has also been a marked increase in the number and quality of law enforcement referrals. In FY 2019, CPI conducted 42 Major Case Coordination meetings that included participants from CMS and law enforcement partners, including the Medicare Fraud Strike Force,[31] resulting in 540 referrals to law enforcement and 125 referrals to the Strike Force. Since implementation, there have been over 1,400 case reviews and 800 law enforcement referrals made as a result of Major Case Coordination.

Highlights of Major Case Coordination outcomes in FY 2019 include:

- In April 2019, CMS, along with our Federal and State law enforcement partners, participated in the largest ever prescription opioid law enforcement operation. The Appalachian Regional Prescription Opioid Surge Takedown resulted in charges against 60 individuals, including 53 medical professionals, for their alleged participation in the illegal prescribing and distributing of opioids and other dangerous narcotics and for health care fraud schemes. The charges involved over 350,000 prescriptions for controlled substances and over 32 million pills in West Virginia, Ohio, Kentucky, Alabama, and Tennessee. Law enforcement activity affected more than 24,000 patients in the region, who received prescriptions from these medical professionals over the past two years. CPI suspended Medicare payments to eight providers and revoked four providers in order to support coordinated law enforcement actions of the Appalachian Regional Opioid Strike Force.
- Also in April 2019, CMS implemented administrative actions as part of "Operation Brace Yourself," a joint effort with HHS-OIG and DOJ to target fraudulent DMEPOS suppliers. As part of this effort, CMS implemented payment suspensions on 130 DMEPOS suppliers in an amount that totaled $74 million as of August 2019. CMS implemented payment suspensions on an additional seven DMEPOS suppliers subsequent to those initial actions. Forty suppliers under payment suspension voluntarily withdrew from the Medicare program, and 45 suppliers were revoked from Medicare since that activity.

[31] The Medicare Fraud Strike Force is a key component of the joint HHS and DOJ Health Care Fraud Prevention and Enforcement Action Team, known as "HEAT."

- In September 2019, CMS took administrative action in support of a federal law enforcement action involving five federal districts against 35 defendants associated with dozens of telemedicine companies and cancer genetic testing laboratories.
- Also in September 2019, CMS participated in a coordinated health care fraud enforcement action in the northeastern United States, involving more than $800 million and the distribution of over 3.25 million pills of opioids in "pill mill" clinics. This takedown also included the second phase of "Operation Brace Yourself", where DOJ announced charges in that DMEPOS fraud case against defendants around the country, for their alleged participation in a massive DMEPOS telemarketing fraud scheme back on April 9, 2019.

2.1.2 Command Center

The CMS Command Center opened in July 2012 and provides a venue for Medicare and Medicaid policy experts, law enforcement officials, clinicians, and CMS fraud investigators to collaborate in real time before, during, and after the development of fraud leads. These collaborative activities enable CMS to more quickly and efficiently take administrative actions such as revocations of Medicare billing privileges and payment suspensions. In FY 2019, CPI conducted 42 Major Case Coordination meetings in the Command Center that included participants from CMS and law enforcement partners.

2.2 Provider Enrollment

Provider enrollment is the gateway to the Medicare and Medicaid programs, and careful and appropriate provider enrollment screening techniques are the key to preventing ineligible providers and/or suppliers from entering either program. Payments to potentially fraudulent providers, either directly via FFS arrangements, or through managed care plans, divert Medicare and Medicaid funds from their intended purpose, may deprive beneficiaries of needed services, and/or might harm beneficiaries who receive unnecessary care. Identifying overpayments due to fraud—and recovering those overpayments from providers that engaged in the fraud—is resource-intensive and can take several years. By contrast, keeping ineligible entities and individuals from enrolling as providers in Medicare and state Medicaid programs allows the programs to avoid paying inappropriate claims to such parties and then later having to attempt to identify and recover those overpayments, which often is a burdensome and costly process. Provider screening identifies such individuals and entities before they are able to enroll and start billing.

CMS's role in the provider and supplier enrollment process differs between the Medicare and Medicaid programs. CMS directly administers Medicare and oversees the provider enrollment and screening process for providers and suppliers participating in the Medicare FFS program. CMS uses provider and supplier enrollment information in a variety of ways, such as claims payment and fraud prevention programs. States directly oversee the provider screening and enrollment process for their Medicaid programs, and CMS provides regulatory guidance and technical assistance to states.

2.2.1 Medicare Provider Screening and Site Visits

As required by law,[32] CMS established three levels of provider and supplier enrollment risk-based screening: "limited"; "moderate"; "high"; and a classification by provider- and supplier-types, subject to upward adjustment in certain circumstances. [33]

Providers and suppliers designated in the "limited" risk category undergo verification of licensure and a wide range of database checks to ensure compliance with all provider- or supplier-specific requirements. Providers and suppliers designated in the "moderate" risk category are subject to unannounced site visits in addition to all the requirements in the "limited" screening level. Providers and suppliers in the "high" risk category are subject to fingerprint-based criminal background checks (FCBCs) in addition to all of the requirements in the "limited" and "moderate" screening levels. In FY 2019, CMS denied approximately 771 enrollments and revoked 11 enrollments because of the FCBCs or a failure to respond to a request for fingerprints.

The Advanced Provider Screening (APS) system automatically screens all current and prospective providers and suppliers against a number of data sources, including provider and supplier licensing and criminal records, to identify and highlight potential program integrity issues for proactive investigation by CMS. APS continuously monitors all providers and suppliers against external licensure and criminal data sources to alert CMS of any actionable changes to licensure information or of any criminal flags. In FY 2019, APS conducted more than 6.3 million screenings. The number of screenings increased due to more frequent federal rescreening of providers, bulk screening of providers for preclusion list and additional screenings for Medicaid state pilot. These screenings generated more than 46,000 License Continuous Monitoring alerts and more than 3,000 Criminal Continuous Monitoring alerts, which resulted in approximately 85 revocations due to felony convictions and over 77 revocations due to licensure issues.

Site visits are a screening mechanism used to prevent questionable providers and suppliers from enrolling or maintaining enrollment in the Medicare program. The CMS-authorized site visit contractors validate that the provider or supplier complies with Medicare enrollment requirements during these visits. In FY 2019, there were 30,668 site visits conducted by the National Site Visit Contractor, which conducts site visits for most Medicare FFS providers and suppliers, and 26,438 conducted by the National Supplier Clearinghouse, which conducts site visits for Medicare DMEPOS suppliers. This work resulted in about 232 revocations due to non-operational site visit determinations for all providers and suppliers.

CMS's provider screening and enrollment efforts in Medicare have had a significant impact on removing ineligible providers and suppliers from the program. In FY 2019, **CMS deactivated over 150,679 enrollments and revoked about 2,556 enrollments**.[34] The site visit and

[32] Sec. 6401 Public Law 111–148

[33] 76 FR 5862 (Feb. 2, 2011).

[34] We note that revalidation results are point-in-time results, as deactivated providers could reactivate over time with updated practice information or after showing evidence of proper licensing.

revalidation requirements[35] have contributed to the deactivation[36] and revocation[37] of more than one million enrollment records since CMS started implementing these screening and enrollment requirements.

2.3 Provider Revalidation

DMEPOS suppliers are required to revalidate every three years and all other providers and suppliers are required to revalidate every five years. These efforts ensure that only qualified and legitimate providers and suppliers can provide health care items and services to Medicare beneficiaries. Similarly, states are also required to revalidate Medicaid providers at least every five years. States may rely on Medicare revalidation results in order to meet revalidation requirements for dually participating providers and suppliers.

In FY 2019, CMS continued its revalidation efforts, which includes regular revalidation cycles for all existing two million Medicare providers and suppliers. In FY 2019, CMS initiated revalidation for more than 245,000 providers and suppliers. In this same time period, close to 200,000 providers and suppliers have successfully completed revalidation and approximately 45,000 providers and suppliers have been deactivated.

[35] Revalidation requires providers and suppliers to resubmit and recertify the accuracy of their enrollment information to maintain their Medicare billing privileges and for reevaluation under new screening guidelines.

[36] Deactivation means the provider's or supplier's billing privileges are stopped but can be restored upon the submission of updated information. See 42 CFR § 424.540.

[37] Revocation means the provider's or supplier's billing privileges are terminated. See 42 CFR § 424.535.

3. Prevent Fraud

3.1 Unified Program Integrity Contractors

One way CMS investigates instances of suspected fraud, waste, and abuse in Medicare and Medicaid is through the UPICs. The UPICs develop investigations and take actions to prevent making inappropriate payments to Medicare and Medicaid providers and suppliers. Actions taken by the UPICs include provider and beneficiary interviews and site visits, the initiation of appropriate administrative actions (e.g., prepayment edits, payment suspensions, revocations), and program integrity reviews of medical records. While a variety of other contractors also perform medical review, UPIC reviews are uniquely focused on fraud detection and investigation. For example, the UPICs look for possible falsification of documents that may be associated with an attempt to defraud the Medicare and Medicaid programs.

Various UPIC administrative actions result in Medicare savings, including automated edit claim denials, non-automated review claim denials, provider revocations and deactivations, payment suspensions, overpayment recoveries, and law enforcement referrals.

The Fraud Prevention System (FPS) is one source of leads for UPICs. The FPS is a predictive analytics technology required by the Small Business Jobs Act of 2010, and it runs sophisticated algorithms against Medicare FFS claims nationwide. When FPS models identify aberrant activity or patterns, the system automatically generates and prioritizes leads for further review and investigation by UPICs. Based on the results of all information collected, the UPICs coordinate with CMS and the MACs in taking appropriate administrative action to recover improper payments and prevent future loss of funds, or the UPICs refer the case to law enforcement.

3.2 Integrated Data Repository and the One Program Integrity Portal

The Integrated Data Repository (IDR) contains Medicare Part A; Part B (including DMEPOS); MA (encounter); and Part D PDE, beneficiary, and provider data. This robust data warehouse supports program integrity analytics, such as the development of FPS models. CMS uses the IDR to provide broad, easy access to data and enhanced data integration while strengthening and supporting CMS's analytical capabilities.

CMS augments the data available in the IDR to provide a comprehensive view of Medicare and Medicaid data including claims, beneficiary data, and prescription drug information. For example, CMS has added Shared Systems location data for pre-adjudicated claims, claims submitter, and medical review utilization data.

CMS is also working to incorporate state Medicaid data into the IDR through standard Transformed Medicaid Statistical Information System (T-MSIS) data formats, while also working with states to improve the quality and /consistency of the data from each state.

CMS uses the One Program Integrity (One PI) web-based portal in conjunction with the IDR to provide access to robust business intelligence analytical tools and to facilitate data sharing with program integrity contractors and law enforcement. One PI provides a single access point to the data within the IDR, as well as analytic tools to review the data.

3.3 Part C and D Program Integrity

3.3.1 Medicare Part C and Part D Program Oversight

In FY 2019, CMS continued to strengthen Part C and Part D oversight. As part of the program integrity oversight of Part C and Part D programs, CMS evaluates plan sponsors' operations for compliance with federal regulations and guidance. All Part C and Part D plan sponsors are required to have an effective program to prevent, detect, and correct non-compliance and fraud, waste, and abuse. These programs consist of written policies, procedures, and standards that articulate the organizations' commitment to complying with all applicable federal and state standards, including the prevention and detection of fraud and abuse in the Part C and Part D programs. Specifically, Part C and Part D plan sponsors must have a properly trained compliance officer vested with the daily operations of the compliance program, provisions for internal monitoring and auditing, and oversight of their first-tier downstream and related entities, as well as other requirements. Plan sponsors' compliance programs must include measures to prevent, detect, and correct noncompliance with CMS's program requirements, as well as fraud, waste, and abuse. In FY 2019, CMS continued to enhance its data analytic capabilities and improved coordination with law enforcement to provide a more comprehensive assessment of program integrity activities in the Part C and Part D programs.

3.3.2 Medicare Drug Integrity Contractors

In FY 2019, HHS split the Medicare Part C and Part D program integrity initiatives between two contractors, the National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC)[38] and the Investigations MEDIC (I-MEDIC). The NBI MEDIC has a national focus related to plan oversight pertaining to the following Medicare Part C and Part D program integrity initiatives, including identification of program vulnerabilities, data analysis, health plan audits, outreach and education, and law enforcement support. The primary purpose of the I-MEDIC is to detect, prevent, and proactively deter fraud, waste, and abuse for high-risk prescribers or pharmacies in Medicare Part C and Part D by focusing primarily on complaint intake and response, data analysis, investigative activities, referrals to law enforcement partners, and law enforcement support.

As part of its work, the NBI MEDIC conducts analyses to identify trends, anomalies, and questionable provider and pharmacy practices, including aberrant opioid prescriptions. Examples include:

- Quarterly Pharmacy Risk Assessment, which categorizes pharmacies as high, medium, or low risk
- Quarterly Outlier Prescriber Assessment, which provides a peer comparison of the prescribing of Schedule II controlled substances
- Pill Mill Doctor Project/Pill Mill Prescriber 2.0, which identifies prescribers with a high risk of fraud, waste and abuse in prescribing Schedules II-IV controlled substances

[38] At the end of FY 2019, the NBI MEDIC was re-named the Plan Program Integrity (PPI) MEDIC.

- Improper payments for drugs inappropriately paid under the Part D program without a medically accepted indication (e.g., Transmucosal Immediate Release Fentanyl[39])

In January 2019, CMS launched a voluntary tool, Analytics and Investigations Collaborative Environment-Fraud, Waste and Abuse (AICE-FWA), in the Health Plan Management System (HPMS). AICE-FWA is designed to assist MA and Part D plan sponsors in identifying and addressing potential fraud, waste, and abuse, as well as to encourage information sharing between plan sponsors, law enforcement, states, and CMS. By providing users with monthly-updated national Part D summary information, AICE-FWA yields an overall picture of provider activity and allows users to identify suspicious pharmacies and providers, and overcomes the constraint of plan sponsors being limited to only their drug claims processing information. In addition, AICE-FWA provides plan sponsors with the opportunity to report their administrative and investigative actions taken against subjects, which serves to alert other plan sponsors to questionable activity. Examples of actions entered into AICE-FWA include terminations, payment suspensions, post-payment reviews, and referrals to law enforcement. CMS's federal law enforcement partners also use AICE-FWA.

3.3.3 Medicare Part C and Part D Marketing Oversight

CMS takes compliance action against Part C and Part D plan sponsors, Section 1876 Cost Plans,[40] and Medicare-Medicaid Plans that fail to send timely and accurate Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents to Medicare enrollees. The ANOC provides a description of changes in the enrollee's existing coverage, costs, or service area that will become effective the following January. The EOC details health care benefits covered by the plan, available services, and cost sharing. Both documents provide Medicare enrollees with vital information that can influence their ability to make informed choices concerning their Medicare health care and prescription drug options.

CMS performs annual timeliness reviews of ANOC documents and accuracy reviews of ANOC and EOC documents to ensure that Medicare enrollees receive accurate information within specified deadlines. CMS issues notices, such as Notices of Non-Compliance, Warning Letters, and Ad-Hoc Corrective Action Plans, to Part C and Part D plan sponsors for sending late and/or inaccurate ANOC and EOC documents. CMS may determine a civil money penalty (CMP) should be imposed when a Part C or Part D plan sponsor substantially fails to comply with program and/or contract requirements involving ANOC and EOC documents.[41]

[39] *CMS Opioid Misuse Strategy 2016*, available at https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.

[40] Section 1876 cost plans are operated by a legal entity licensed as an HMO in accordance with a Medicare managed care risk or cost reimbursement contract under Section 1876 of the Social Security Act and Title 42, Part 417 of the Code of Federal Regulations

[41] The FY 2019 HCFAC Report at page 76.

3.3.4 Medicare Part C and Part D Audits

CMS conducts program audits of Part C and Part D plan sponsors, as well as organizations offering Medicare-Medicaid plans, to evaluate their delivery of health care items, services, and drugs to beneficiaries. Routine program audits occur at the parent organization level, whereby all plan contracts owned and operated by the parent organization are included in the audit scope, to maximize Agency resources. Plans subject to routine audits have all program areas reviewed, except where a protocol was not applicable to their operation.[42]

The audits in FY 2019 evaluated sponsor compliance in the following program areas:

- Compliance Program Effectiveness
- Part D Formulary and Benefit Administration
- Part D Coverage Determinations, Appeals, and Grievances
- Part C Organization Determinations, Appeals, and Grievances
- Special Needs Plans Model of Care
- Medicare-Medicaid Plan – Service Authorization Requests, Appeals and Grievances
- Medicare-Medicaid Plan - Care Coordination and Quality Improvement Program Effectiveness

In 2019, CMS cited an average of 11 conditions of noncompliance per sponsor audited, which was similar to 2018 where CMS cited an average of 13 conditions per audited sponsor. Plan sponsors are required to correct cited deficiencies and undergo validation to ensure compliance before the program audit is closed.

In addition to the program audits performed above, Sections 1857(d)(1) and 1860D-12(b)(c) of the Act require the HHS Secretary to provide for the annual audit of financial records of at least one-third of the Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs) and Program of All-inclusive Care for the Elderly (PACE) organizations. The one-third financial audit program examines the health plans' financial records, data relating to costs, Medicare utilization, and the computation of plan bids.

In general, program and financial audits give CMS reasonable assurance that Part C and Part D plan sponsors deliver benefits in accordance with the terms of their contract and plan benefit package. CMS also has authority to take compliance and enforcement actions, up to and including termination, if warranted, for findings that involve direct beneficiary harm or the potential to result in such harm. During FY 2019, CMS completed 218 audits of MAOs and PDPs for the contract year 2017.

3.3.5 Medicare Part D Reconciliation Data Reviews

Part D plan sponsors receive monthly prospective payments from CMS. During benefit-year-end reconciliation, CMS compares its prospective payments to a plan with the plan's actual cost data,

[42] For example, if a plan sponsor does not operate a Special Needs Plan then it would not have a Model of Care audit performed. Likewise, a stand-alone prescription drug plan does not have the Part C Organization Determinations, Appeals, and Grievances protocol applied because it does not offer the Part C benefit.

submitted through prescription drug event (PDE) records and direct and indirect remuneration (DIR) reporting, to settle any residual payments required between CMS and the plan sponsor. CMS also determines any risk corridor payments, which limit each plan's overall losses or profits if actual spending is much higher or lower than anticipated. Risk corridors provide a cushion for plans in the event of large, unforeseen aggregate drug spending. To promote accuracy in the plan-reported data, CMS validates both PDE and DIR data in advance of reconciliation and works with the plans to resolve any issues.

3.3.6 Medical Loss Ratio Requirement

A medical loss ratio (MLR) represents the percentage of revenue a health insurance issuer uses for patient care or activities that improve health care quality, as opposed to other expenses that do not directly impact patient care or quality (e.g., marketing, profits, salaries, administrative expenses, and agent commissions). The minimum MLR requirement may create incentives for Part C and Part D plan sponsors to reduce overhead expenses, and ensure that taxpayers and enrolled beneficiaries receive value from Medicare plans. Part C and Part D plan sponsors must report the MLR for each contract they have with CMS.

A contract must have a minimum MLR of at least 85 percent to avoid financial and other penalties. If a Part C or Part D plan sponsor has a MLR for a contract year that is less than 85 percent, meaning that a plan sponsor uses less than 85 percent of its revenue for patient care or quality improvement, then Part C or Part D plan sponsor owes a remittance to CMS. CMS deducts the remittance from the regular monthly plan payments to the Part C or Part D sponsor. Further MLR-related sanctions may include a prohibition on enrolling new members after three consecutive years and contract termination after five consecutive years of failing to meet the minimum MLR requirement.

3.3.7 Compliance Enforcement in Medicare Part C and Part D

CMS has the authority to take enforcement or contract actions when it determines that a Part C or Part D plan sponsor either:

- Substantially fails to comply with program and/or contract requirements
- Carries out its contract with CMS in a manner inconsistent with the efficient and effective administration of the Part C and Part D program requirements, or
- No longer substantially meets the applicable conditions of the Part C and Part D programs

Enforcement and contract actions may include CMPs, intermediate sanctions (e.g., suspension of marketing, enrollment, and payment), or contract terminations.

In FY2019, CMS issued six CMPs to Part C and Part D plan sponsors, placed three Part C plan sponsors and one Part D plan sponsor under enrollment sanctions, and terminated the contract of one Part C plan sponsor.[43]

[43] Medicare Part C and Part D enforcement notices are available at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.html.

3.4 Healthcare Fraud Prevention Partnership

The Healthcare Fraud Prevention Partnership (HFPP) is a voluntary, public-private partnership between the federal government, state agencies, law enforcement, private health insurance plans, employer organizations, and health care anti-fraud associations. The purpose of the partnership is to exchange data and information between the partners to help improve capabilities to fight fraud, waste, and abuse in the health care industry.[44] The HFPP aims to foster a proactive approach to detect and prevent health care fraud through data and information sharing. The HFPP works to provide:

- An unparalleled data source – The HFPP represents a full spectrum of health care payers that provide claims data that supports sophisticated data analytics
- Collaboration & strategic partnerships – HFPP Partners participate and guide the Partnership, have the opportunity to establish strategic collaborations across diverse stakeholders, and share critical time-sensitive information
- Material outcomes – The HFPP's most important goal is generating comprehensive approaches, strategies, and leads that materially impact each Partner's effort to combat health care fraud, waste, and abuse

To achieve its objectives, the HFPP uses a "Trusted Third Party" (TTP), a CMS contractor, to act as a "common data aggregator" under the HIPAA Privacy Rules. Under this model, the TTP is able to conduct cross-payer data aggregation and analysis services to identify potential fraud across payers, while ensuring that each Partner only has access to its own claims data.

Cross-payer studies enable the HFPP to proactively identify vulnerabilities in real time, significantly increasing the value of membership to all Partner organizations. The HFPP is currently using professional and institutional claims but is planning to expand to collect, pharmacy, and dental claims in the future. The HFPP uses a diverse variety of approaches to identify vulnerabilities in Partner data. These methods include:

- Standard searches to detect anomalies that may indicate the existence of fraud, waste, and abuse
- Scanning of incoming claims information against existing data sets, such as lists of deactivated providers
- Creation of reference files that list providers that may be suspect based on known risks
- Creation of informational content to support stakeholders in addressing vulnerabilities (e.g., white papers)

In FY 2019, the HFPP reached a membership level of 144 Partner organizations that included 48 state and local government agencies, 71 private payers, 12 federal agencies and 13 associations representing more than 215 million covered lives, which is equivalent to more than 3 in 4 insured Americans. Thirty-four of the current partners are actively submitting claim level data, representing 100 million individuals, or more than 1 in 3 insured Americans.[45]

[44] The FY 2019 HCFAC Report, page 10.

[45] The FY 2019 HCFAC Report, page 10.

In addition, in FY 2019, partners submitted over 9.9 billion professional claim lines for conducting cross-payer analyses and, by the end of FY 2019, the HFPP commenced or completed more than 25 studies since program inception.

Example of studies developed or executed in FY 2019 include the identification of:

- Services billed under an "impossible day" scenario (including evaluation and management services, psychotherapy services, and physical and occupational therapy services)
- Deactivated providers that continue to submit claims for payment
- Providers that submitted claims after the ordering/referring provider was deactivated
- Abnormalities (such as billing for services more frequently than would normally be expected) pertaining to specific service areas including chronic care management, electroencephalograms, urine drug testing, and sleep studies

The HFPP also held quarterly Regional Information Sharing Sessions throughout FY 2019. These sessions allow Partners to participate in case sharing sessions, listen to panel discussions, receive updates from law enforcement, and have the opportunity to collaborate with members from across the Partnership.

In FY 2019, the HFPP published an issue paper entitled "Fraud and Abuse in Recovery Treatment Services for Substance Use Disorders: An Issue Paper by the Healthcare Fraud Prevention Partnership." Issues related to substance use treatment fraud and abuse are significant and of high interest to Partners. The paper provides Partners with information that characterizes the key elements of substance use treatment fraud and abuse and supports Partner's efforts to detect and deter those issues.

3.5 Medicare Beneficiary Education

CMS undertakes various activities to inform Medicare beneficiaries about the importance of guarding their personal information against identity theft and how they can protect against and report suspected fraud. In FY 2019, CMS communicated key fraud prevention messages in beneficiary channels, including the *Medicare & You* handbook and other beneficiary education materials, through 1-800-MEDICARE, and via Medicare.gov. CMS disseminated similar messages through a wide range of beneficiary touch points, including the Medicare Summary Notice, the MyMedicare.gov Message Center, social media, direct-to-beneficiary emails, and response letters to beneficiary inquiries.

Medicare Beneficiary Identifiers and the New Medicare Card

Beginning in August 2017, CMS conducted a national "Guard Your Card" advertising campaign to alert beneficiaries about scams to obtain their Medicare number and the importance of protecting their number to prevent identify theft and Medicare fraud. The campaign also noted that Medicare would mail new Medicare cards to people with Medicare starting in early 2018 to help prevent personal identity theft. Earned and social media outreach and other promotional efforts continued into the fall to remind beneficiaries to protect their Medicare number and warning them about the types of scams that occur during the Medicare open enrollment period.

While new Medicare cards were being mailed out(April 2018 - January 2019), CMS ramped up outreach to beneficiaries making fraud prevention messaging more prominent in all channels we traditionally use to communicate with this audience. Key messages served to remind beneficiaries:

- they were getting a new card with a new, unique and more secure Medicare number
- they did not have to take action to get their new card
- the new card is free of charge
- once they received their new card, they must securely destroy their old card

CMS launched an aggressive localized earned media campaign to reach beneficiaries in each of the mailing waves when card mailing began in their states and territories. CMS continued this targeted strategy of ramping up outreach in the states and territories where a wave was about to begin, to help ensure beneficiaries were primed and engaged just before the new card hit their mailbox.

CMS proactively communicated through CMS's multiple existing beneficiary channels (Medicare.gov, local and national partnerships, social media, etc.) as well as constantly monitored feedback from our call center, regional offices, information intermediaries, etc. making adjustments as necessary to our fraud prevention messaging and outreach tactics as card mailing progressed and waves ended.

In January 2019, CMS announced that it finished mailing new cards to approximately 61 million people with Medicare, across all mailing waves before our April 2019 statutory deadline. Through national press, CMS reminded beneficiaries about the importance of protecting their new card against health care fraud and continued to share this message throughout 2019.

Unlike with the previous use of Social Security Numbers, CMS now has the ability to re-issue an individual's Medicare Beneficiary Identifier (MBI). Following the major takedowns related to DMEPOS, genetic testing, and home health fraud, CMS identified and reissued approximately 220,000 MBIs that were compromised in these fraud schemes, providing a safeguard for an estimated $1.1 billion at risk.

3.6 National Correct Coding Initiative

3.6.1 Medicare National Correct Coding Initiative

Given the volume of claims processed by Medicare each day, and the cost associated with conducting medical review of an individual claim, CMS uses automated edits to help prevent improper payment without the need for manual intervention. CMS developed the National Correct Coding Initiative (NCCI) to promote national correct coding methodologies and to control improper coding that leads to inappropriate payment of Part B claims. NCCI Procedure-to-Procedure (PTP) edits prevent inappropriate payment for billing code pairs that in general should not be reported together by the same provider for the same beneficiary for the same date of service. NCCI Medically Unlikely Edits (MUEs) prevent payment for a potentially

inappropriate quantity of the same service rendered by the same provider for the same beneficiary on the same date of service. NCCI edits are refined and updated quarterly.[46]

3.6.2 Medicaid National Correct Coding Initiative

Section 1903(r) of the Act requires states to implement NCCI methodologies into their Medicaid Management Information Systems (MMIS) in order to process applicable Medicaid claims using the national NCCI methodologies, including the PTP edits and MUEs. CMS maintains a technical guidance manual and provides assistance to State Medicaid Agencies (SMAs) in the use of NCCI methodologies in their Medicaid programs. Similar to that for Medicare, the Medicaid NCCI edits are refined and updated quarterly.[47]

3.7 Medicare-Medicaid Data Match

The Medicare-Medicaid Data Match (Medi-Medi) activities support the integration of Medicaid and Medicare investigations and audits where possible. Medi-Medi functionality matches Medicaid and Medicare claims and other data to identify improper billing and utilization patterns. Analyses performed in the Medi-Medi program can reveal trends that are not evident in each program's claims data alone, making it an important tool in identifying and preventing aberrant billing practices and other schemes across both programs. CMS analyzes matched data to identify potential fraud, waste, and abuse patterns, and shares the results with the state. Participation in these activities is optional for the states. Each state's participation in Medi-Medi activities is designed to accommodate the individual complexity of that state's Medicaid program and associated program integrity efforts. During FY 2019, CMS collaborated with nineteen states that account for most of the expenditures in Medicaid.

CMS's Medi-Medi data matching activity has produced various law enforcement referrals on a variety of subjects, including individual health care providers, opioid prescribers, clinical labs, and hospitals. In certain instances, law enforcement cases have produced significant results from the support CMS has provided.

[46] See sections 1.1 and 1.2 of Appendix B for further information regarding NCCI PTP edits and MUEs.

[47] These Medicaid NCCI edits and other resources are located on the Medicaid website (https://www.medicaid.gov/medicaid/program-integrity/ncci/index.html).

4. Mitigate Emerging Programmatic Risks

4.1 Improper Payment Rate Measurement

An improper payment occurs when a payment should not have been made, federal funds go to the wrong recipient, the recipient receives an incorrect amount of funds, or the recipient uses the funds in an improper manner. In addition, improper payments cited do not necessarily represent expenses that should not have occurred. For example, instances where there is no or insufficient documentation to support the payment as proper or improper are cited as improper payments. The Improper Payments Information Act of 2002, as amended by the Improper Payments Elimination and Recovery Act of 2010, and the Improper Payments Elimination and Recovery Improvement Act of 2012 requires federal agencies to review their programs and activities to identify programs that may be susceptible to significant improper payments, and for high risk programs, to estimate the amount of improper payments and develop and implement corrective actions. CMS works to better prevent, detect, and reduce improper payments through close review of our programs and activities using sound risk models, statistical estimates, and internal controls.[48]

In FY 2019, CMS continued its requirements to measure improper payments, as required under law, as well as its efforts to reduce and recover improper payments in its programs. Results of CMS's efforts are outlined herein.

4.1.1 Medicare Fee-for-Service

CMS uses the Comprehensive Error Rate Testing (CERT) program to estimate the Medicare FFS improper payments. The CERT program reviews a stratified random sample of Medicare FFS claims to determine if CMS properly paid claims under Medicare coverage, coding, and billing rules. The Medicare FFS improper payment estimate also includes improper payments due to insufficient or no documentation.[49]

The CERT program considers improper payments to be:

- Any claim payment that should have been denied or was made in the wrong amount, including overpayments and underpayments. The claim counts as either a total or partial improper payment, depending on the error;
- Improper payments of all dollar amounts (i.e., there is no dollar threshold under which errors will not be cited); and
- Improper payments caused by policy changes as of the new policy's effective date (i.e., there is no grace period permitted).

CMS sampled approximately 50,000 claims during the FY 2019 report period. The improper payment rate estimated from this sample reflects all claims processed by the Medicare FFS program during the report period across four claim types:

[48] https://www.hhs.gov/sites/default/files/fy2019-hhs-agency-financial-report-final.pdf

[49] *Id.* at 200.

- Part A claims, excluding hospital Inpatient Prospective Payment System (IPPS) (e.g., home health, inpatient rehabilitation facility (IRF), skilled nursing facility (SNF), and hospice
- Part A hospital IPPS claims
- Part B claims (e.g., physician, laboratory, and ambulance services)
- DMEPOS

The national Medicare FFS estimated improper payment rate for FY 2019 was 7.25 percent, representing $28.91 billion in gross improper payments. The FY 2019 improper payment rate decreased from the prior year's reported 8.12 percent due to reduced improper payments for home health, Part B, and DMEPOS claims. Although the improper payment rate for these services and the gross Medicare FFS improper payment rate decreased, improper payments for SNF, hospital outpatient, IRF, and home health claims continued to be major contributing factors to the FY 2019 Medicare FFS improper payment rate, comprising 36.01 percent of the overall estimated improper payment rate. While the factors contributing to improper payments are complex and vary by year, the primary causes of improper payments continue to be insufficient documentation and medical necessity errors.[50]

4.1.2 Medicaid and CHIP

CMS uses the Payment Error Rate Measurement (PERM) program to estimate national improper payment rates in Medicaid and CHIP. The improper payment rates are based on reviews of the FFS, managed care, and eligibility components of Medicaid and CHIP in the fiscal year under review. CMS measures Medicaid and CHIP improper payment rates using three 17-state cycles so that each state is reviewed once every three years. The FY 2019 national Medicaid improper payment rate estimate was 14.90 percent, representing $57.36 billion in improper payments. The FY 2019 national CHIP improper payment rate estimate was 15.83 percent, totaling $2.74 billion in improper payments.

While the Medicaid and CHIP improper payment rates increased between FY 2018 and FY 2019, these results are not comparable because the measurement has changed significantly. Most notably, FY 2019 was the first year in which CMS reintegrated the PERM eligibility component into the measurement, which is a driver of Medicaid and CHIP improper payments, as described below. CMS will complete the review of the remaining 33 states and the District of Columbia under the new eligibility requirements over the next two years and establish a baseline in FY 2021 once all states are measured under the new requirements.

Medicaid and CHIP eligibility improper payments in FY 2019 were mostly due to insufficient documentation to verify eligibility, related primarily to income or resource verification. There were both situations where the required verification was not done at all and where there is indication the verification was initiated but there was no documentation to validate the verification process was completed, and non-compliance with eligibility redetermination requirements. The CHIP improper payment rate was also driven by claims where the beneficiary was incorrectly determined eligible for CHIP, but upon review was found eligible for Medicaid, mostly related to beneficiary income calculation. Continued non-compliance with provider

[50] *Id*. at 201

enrollment, screening, and National Provider Identifier requirements, including compliance with newer requirements for provider revalidation of enrollment and rescreening, was also a driver of improper payments.

CMS works closely with states to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating the effectiveness of their plans, with assistance and oversight from CMS.[51]

4.1.3 Medicare Part C and Part D Programs

In the Medicare Part C and Part D programs, CMS makes prospective, monthly per-capita payments to MA organizations and Part D plan sponsors. Each per-person payment is based in part on a bid amount, approved by CMS, that reflects the plan's estimate of average revenue required to provide coverage of original Medicare (Part A and Part B) benefits to an enrollee with an average risk profile. CMS risk-adjusts these payments to take into account the cost associated with treating individual beneficiaries based on the individual enrollee's health status and demographic factors.[52] In addition, certain Part D prospective payments are reconciled against actual costs, and risk-sharing rules set in law are applied to further mitigate plan risk.

For FY 2019, the Part C improper payment estimate was 7.87 percent, representing $16.73 billion in improper payments. This represents a decrease from the FY 2018 rate of 8.10 percent, representing $15.55 billion in improper payments, and was driven primarily by MA organizations submitting a greater number of accurate medical records validating the diagnoses for which they were paid.[53]

For Part D, CMS measures the inconsistencies between the information reported on prescription drug events (PDEs) and the supporting documentation submitted by Part D sponsors, including prescription record hardcopies (or medication orders, as appropriate) and detailed claims information. Based on these reviews, each PDE in the audit sample is assigned a gross drug cost error, which is applied to a representative sample of beneficiaries to determine the Part D improper payment estimate.

For FY 2019, the Part D improper payment estimate is 0.75 percent, or $610 million in improper payments. This represents a decrease from the FY 2018 estimate of 1.66 percent, or $1.32 billion in improper payments, and was driven primarily by errors being smaller in magnitude than in the previous years.[54]

[51] https://www.hhs.gov/sites/default/files/fy-2020-hhs-agency-financial-report.pdf

[52] Under MA, CMS may also make payments of rebates to plans that bid below the benchmark for their services area(s).

[53] https://www.cms.gov/newsroom/fact-sheets/2019-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs

[54] https://www.cms.gov/newsroom/fact-sheets/2019-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs

4.2 Recovery Audit Programs

4.2.1 Medicare Fee for Service (FFS)

Section 1893(h) of the Act requires the establishment of a nationwide Medicare FFS Recovery Audit Program, and Recovery Audit Program contractors are known as RACs. The mission of the Medicare FFS Recovery Audit Program is to identify and correct overpayments made on claims for health care items and services provided to beneficiaries, to identify underpayments to providers, and to provide information that allows CMS to implement corrective actions that will prevent future improper payments.

As required by section 1893(h), RACs are paid on a contingency fee basis. The amount of the contingency fee is a percentage of the improper payment recovered from, or reimbursed to, providers. The RACs negotiate their contingency fees at the time of the contract award. The RAC must return the contingency fee if an improper payment determination is overturned at any level of appeal.

Results

Table 5 breaks out overpayments collected, underpayments restored, and amounts overturned on appeal in the FFS RAC regions in FY 2019, including both old and new.

Table 5 RAC Performance

FFS RAC Region/Name	Collected Overpayments (in millions)	Restored Underpayments (in millions)	Overturned on Appeal[a] (in millions)
1/ Performant	14.07	0.71	0.81
2/ Cotiviti	39.85	3.65	5.73
3/ Cotiviti	25.45	2.54	3.95
4/ HDI/HMS	61.46	2.19	10.91
5/ Performant	14.73	0.26	0.23
Unknown/Old Contracts[55]	6.46	8.96	2.20
Totals[b]	**162.03**	**18.30**	**23.83**

Note: Payments made to providers under the Hospital Appeal Settlement process resulted in reduced collected overpayments. Because these reductions could not always be offset by other collected amounts, some resulted in an overall negative amount being reported.

[55] The original FFS RACs (Regions A, B, C, and D) stopped reviewing new claims as of July 31, 2016. Per the FFS RAC Statement of Work (SOW), from August 2016 until January 31, 2018, the original FFS RACs were in their "contract closeout and reconciliation" period, which involved administrative activities only (no reviews). These activities included CMS recoupment of funds from providers on improper payments, RAC invoicing for contingency payments on eligible claims, allowing the RACs to support the appeal process, and allowing CMS to recoup contingency fees from overturned appeals. New FFS RAC contracts (Regions 1, 2, 3, 4, and 5) were awarded on October 31, 2016.

FFS RAC Region/Name	Collected Overpayments (in millions)	Restored Underpayments (in millions)	Overturned on Appeal[a] (in millions)

[a] Overturned amounts include collected overpayments from previous FYs.
[b] Savings values may not add to totals due to rounding.

In FY 2019, the program identified approximately $219.98 million in overpayments and recovered $162.03 million, before taking into account appeal dispositions. Additional results and analysis of Recovery Audit Program data are available for download at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Resources.

FFS RAC Appeals

Providers who disagree with a RAC's improper payment determination may utilize the multilevel administrative appeals process under section 1869 of the Act. RAC appeals follow the same appeal process as other Medicare claim determinations. Throughout the first four levels of the appeals process, in FY 2019, there were 34,001 appeal decisions rendered for claims with overpayments identified by the RACs. Claims may have had initial overpayment determinations made prior to FY 2019 and appealed claims may be counted multiple times if the claim had appeal decisions rendered at multiple levels during FY 2019. For example, if a claim was appealed to the first level and received a decision in FY 2018, then appealed to the second level and received a decision in FY 2019, both decisions are counted.

Of the 34,001 total appeals decided in FY 2019, 18,449 decisions, or 54 percent were overturned with decisions in the provider's favor (see Table 6). While the percentage of appeals decisions overturned seems high, the figure is misleading. When compared to the total number of claims (143,734) that were corrected by the RACs in FY 2019, the total number of appeal decisions (34,001) is equal to 23 percent. The resulting overturns then represent only 12.7 percent of the total number of claims corrected by the RAC, which is significantly less than the 54 percent referenced as overturned in the provider's favor.

It is also worth noting that Table 6 reflects claim decisions, not claims. Therefore, the same claim may be counted more than once. For example, a claim appealed to the MAC which was upheld (favorable to the RAC) and then also appealed to the QIC, with decisions both in FY 2019, would count twice against the total. The majority of overturns that occur at the MAC level are due to the submission of documents on appeal that were not initially submitted to the RAC. Therefore, the initial RAC decision was based on incomplete documentation.

Table 6. RAC Appeals

Appeal Level	Total Decisions in FY 2019	Favorable/ Partially Favorable Decision	Percent Overturned
1 (MAC)	18,795[56]	11,041	59%
2 (QIC)	1,971[57]	735	37%
3 (ALJ)	13,205[58]	6,671	51%
4 (Departmental Appeals Board (DAB))	30[59]	2	7%
Totals	34,001	**18,449**	**54%**

Oversight

CMS believes that regular contractor oversight is essential to the success of the Recovery Audit Program and CMS regularly evaluates the RACs' performance and adherence to program requirements. Staff members go on location to observe medical reviews, information technology systems, and customer service areas. In addition to onsite visits, CMS conducts desk audits on claims to confirm that all aspects of the review process were correctly completed and documented. CMS also uses an independent validation contractor to perform accuracy and validation reviews for all RAC regions. These monthly accuracy reviews include randomly selected samples of claims for which the RAC has determined there was an improper payment. These samples include all claim and provider types that were reviewed by the RACs. The validation contractor calculates an accuracy rate for each RAC region. The RACs also engage in regular meetings with the MACs, provider groups, and other stakeholders to discuss review topics and issues. If there are performance concerns, CMS notifies the RAC and requires a corrective action plan. The results of these regular evaluations are consolidated annually in the Contractor Performance Assessment Reporting System (CPARS) for an overall performance rating for the year. These results are available to all federal agencies that wish to procure contracts with these entities.

4.2.2 Part C and Part D

Section 1893(h) of the Act expands the RAC program to Medicare Part C and Part D. Despite the success of RACs in Medicare FFS, however, CMS has found that the use of RACs in Medicare Part C and Part D has not been an effective oversight mechanism. RAC vendors have reported that Medicare Part C and Part D are an unattractive business model for overpayment identification and collection because of differing payment structures, a narrow scope of payment error, and unlimited appeal timeframes. As a result, there is little incentive for RACs to perform

[56] Total MAC Decisions does not include 938 dismissed claims.

[57] Total QIC Decisions does not include 145 dismissed claims.

[58] Total ALJ Decisions does not include 47 remanded claims and 4,932 dismissed claims.

[59] Total DAB Decisions does not include 4 remanded claims and 491 dismissed/withdrawn claims.

the audits in Part C and Part D, and CMS has realized little return on investment for these activities.

The Part C RAC objectives (i.e., identifying and recouping overpayments) are being met through contract-level Risk Adjustment Data Validation (RADV) audits conducted by CMS with the use of non-RAC contractors that perform medical review, payment error calculations, and other supportive tasks. The contract-level RADV audit program is the primary corrective action to reduce the Part C improper payment rate through the identification and collection of overpayments. Through contract-level RADV audits, medical records are reviewed and MAOs are held financially accountable when the MAO-submitted diagnostic data for risk adjustment purposes does not conform to program rules.

In April 2019, CMS launched the payment year 2014 RADV audit and held a training webinar for MA organizations selected for audits. The payment year 2015 RADV audit launched in September 2019 and a training webinar was conducted in December 2019. The purpose of the trainings was to prepare the MA industry for the selection of audited MA organizations for RADV audits. The payment year 2014 RADV audit medical record submission phase is complete.

In a similar circumstance to the Part C RAC, the Part D RAC objectives (i.e., identifying and recouping overpayments) are currently being met by the NBI-MEDIC, a non-RAC contractor. The NBI-MEDIC's workload is substantially like that of the Part D RAC, and the NBI-MEDIC has a robust program to identify improper payments. After the NBI-MEDIC identifies improper payments, CMS requests that plan sponsors delete PDE records that are associated with potential overpayments. Subsequently, CMS validates whether plan sponsors delete the PDEs and do not resubmit such PDEs for payment. As noted previously, the NBI-MEDIC's responsibilities relate to plan oversight and pertain to specific initiatives like data analysis, health plan audits, outreach and education, and law enforcement support. In FY 2019, the NBI-MEDIC continued audits that identified potentially improper payments and conducted education and outreach for Part D plan sponsors.

4.2.3 Medicaid

Section 1902(a)(42) of the Act requires states to establish Medicaid RAC programs. Each state has the flexibility to tailor its RAC program, where appropriate, with guidance from HHS. In FY 2019, 31 states had CMS-approved exceptions to Medicaid RAC implementation due to high managed care penetration and issues related to procurement. Seventeen states and the District of Columbia had operational RAC programs in FY 2019.

4.3 Medicare Fee-for-Service Medical Review

Consistent with sections 1815(a), 1833(e), 1862(a)(1), and 1893 of the Act, CMS is required to protect the Medicare Trust Funds by taking corrective actions to prevent and reduce improper payments. CMS contracts with a variety of medical review contractors, including the MACs and

SMRC, to perform medical review for claims paid by the Medicare FFS program.[60] Medical review involves both automated and manual processes to ensure that only claims for items and services that meet all Medicare coverage, payment, and coding requirements are paid. Medical review activities concentrate on areas identified through a variety of means, including targeted data analysis, Comprehensive Error Rate Testing (CERT) results, and oversight agency findings that indicate questionable billing patterns. CMS incorporates provider feedback processes, such as one-on-one education and detailed medical review results notifications to encourage proper billing.

4.3.1 Targeted Probe and Educate

CMS's Targeted Probe and Educate (TPE) program helps providers and suppliers reduce claim denials and appeals through one-on-one education by the MACs. As part of TPE, the MACs focus on providers/suppliers who have the highest claim denial rates or who have billing practices that vary significantly from their peers. Under the TPE strategy, MACs conduct up to three rounds of review of 20-40 claims per round, with one-on-one education provided at the conclusion of each round. Providers/suppliers are also offered individualized education during each round of review to more efficiently fix simple problems. The goal of TPE is to help providers and suppliers meet Medicare's payment policy requirements. TPE also reduces burden on those providers and suppliers who, based on data analysis, are already submitting claims that are compliant with Medicare policy.[61]

Since inception, the MACs have reviewed approximately 13,000 providers and suppliers resulting in the review of over 435,000 claims. During the same time period, MACs have also made 90,000 educational contacts to assist providers and suppliers with the TPE audits and future billing.[62]

4.3.2 Supplemental Medical Review (Post-payment)

The role of the SMRC is to perform and/or provide support for a variety of tasks aimed at reducing improper payments in the Medicare FFS program. One of the SMRC's primary tasks is conducting nationwide medical review of Medicare Part A, Part B and DMEPOS claims, as directed by CMS. The focus of the reviews may include, but are not limited to, issues identified by CMS internal data analysis; the CERT program; professional organizations; and other Federal agencies, such as the OIG and GAO. Medical records and related documents are reviewed to determine whether claims were billed in compliance with Medicare's coverage, coding, and payment rules.

In FY 2019, the traditional SMRC medical review activities continued on a small scale to facilitate contract closure and the procurement and award of a new contract. The SMRC

[60] The UPICs also perform medical review, as discussed in section 3.1, as well as the Recovery Audit Contractors, as discussed in section .3.3.

[61] *Targeted Probe and Educate Qs & As* can be found at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/TPE-QAs.pdf

[62] The general numbers reported here are publicly available in the TPE Q&A document: https://www.cms.gov/files/document/updated-tpe-qas.pdf. See questions 14, 15 and 16.

performed post-payment reviews on multiple areas, such as positive airway pressure device replacements, DME provided to patients during a SNF stay, emergency ambulance services, hospice services, non-emergency ambulance services, spinal cord stimulators, providers who ordered DME, and IRF services. CMS uses the reviewers' results to improve billing accuracy. Results are shared with providers through detailed review results letters and possible overpayment determinations. These letters include educational information regarding what was incorrect in the original claim billing.

The scope of the new SMRC contract was expanded in FY 2019 to provide support to a variety of CPI initiatives, including medical review activities to support our fraud-fighting functions and to review issues identified through the Healthcare Fraud Prevention Partnership (HFPP).

4.4 Medicare Provider Cost Report Audits

Auditing of cost reports is one of CMS's primary instruments to safeguard payments made to institutional providers, such as hospitals, SNFs, and end-stage renal dialysis facilities. Although many of these providers have most of their claims paid through a prospective (bundled) payment system, reimbursement of several items continues on an interim basis, subject to final payment after a cost reconciliation process. These providers submit an annual Medicare cost report that, after the settlement process, forms the basis for reconciliation and final payment to the provider. The cost report includes calculations of the final payment amount for items such as graduate medical education, disproportionate share hospital (DSH) payments, and Medicare bad debts.

The cost report audit process provides a method to detect improper payments, as well as reasons these improper payments have occurred. These reasons for improper payments provide insight into potential payment vulnerabilities, the recognition of which can strengthen and focus the program integrity response. The audit process includes the timely receipt and acceptance of provider cost reports, the performance of desk reviews, audits of those cost reports, and the final settlement of the provider cost reports. The audit/settlement process determines whether providers have been paid properly, in accordance with CMS regulations and instructions. During FY 2019, the MACs received and accepted approximately 54,113 Medicare cost reports. This included initial cost report filings as well as amended filings. Approximately 31,310 cost reports were tentatively settled and approximately 39,675 cost reports were desk reviewed. In addition, the MACs completed approximately 478 audits.

4.5 Medicare Shared Savings Program

The Medicare Shared Savings Program (Shared Savings Program) is a voluntary program that facilitates coordination and cooperation among providers and suppliers to improve the quality of care for Medicare fee-for-service beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). When an ACO succeeds both in delivering high-quality care and reducing Medicare expenditures, the ACO may share in the savings it achieves for the Medicare program. If the

ACO participates in a two-sided risk track under the Shared Savings Program, it may be liable for a portion of any losses incurred by Medicare.[63]

CMS has developed a streamlined provider and supplier screening process to enhance program integrity efforts for the Shared Savings Program that relies in part on safeguards associated with Medicare FFS enrollment. These provider screenings are facilitated by the electronic capture and exchange of provider information including, but not limited to enrollment status, reassignment details, current/previous Medicare Exclusion Database sanctions, payment suspensions, and FPS alerts. CMS also coordinates a screening process with law enforcement for additional checks of program integrity issues. CMS may deny an ACO's application, reject the addition of a provider, supplier, or ACO participant, or impose additional safeguards on ACO participants whose screening reveals a history of program integrity issues or affiliation with individuals or entities that have a history of program integrity issues. CMS monitors ACO participant and SNF affiliate[64] Medicare enrollment on a biannual basis and will remove from the Medicare Shared Savings Program any ACO Participants and SNF affiliates that are no longer enrolled in Medicare.

Additionally, CMS conducts monitoring to ensure that ACOs are in compliance with the program integrity requirements of the Shared Savings Program. For example, CMS conducts monitoring to verify that any changes to the governing body of an ACO or changes in ACO participants meet regulatory requirements. CMS also audits the accuracy of reported quality data and recalculates risk adjusted historical benchmarks as necessary to maintain the integrity of financial benchmarks used to determine whether the ACO has generated shared savings or shared losses.

4.6 Medicare Appeals and Party Status

When Medicare beneficiaries, providers of services, or suppliers disagree with a coverage or payment decision made by CMS or a CMS contractor, they have the right to appeal; there are similar appeal rights when an enrollee, a health care provider, or prescriber disagrees with a coverage or payment decision by an MA plan or Part D plan.[65] Although CMS continues to strengthen Medicare program integrity to combat all improper payments, including fraud, waste, and abuse, the Agency remains equally committed to protecting the rights of Medicare beneficiaries, providers, and suppliers through the Medicare appeals process.

The Act and implementing regulations adopted by CMS establish five levels to the Medicare appeals process:

[63] For more information, please visit the Medicare Shared Savings Program webpage at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram

[64] ACO SNF affiliates are associated with those ACOs that are approved to use the Shared Savings Program SNF 3-Day Rule Waiver.

[65] https://www.hhs.gov/about/agencies/omha/the-appeals-process/index.html; https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/index; https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/index; and https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index

- Level 1: In Medicare FFS, a redetermination by a MAC; in MA, a reconsideration by a MA plan; or for Part D, a redetermination by a Part D plan sponsor
- Level 2: In Medicare FFS, a reconsideration by a Qualified Independent Contractor (QIC); in MA, an automatic reconsideration by an Independent Review Entity (IRE); or for Part D, a reconsideration by an IRE requested by an enrollee. [66]
- Level 3: A hearing by an Administrative Law Judge (ALJ) in the HHS Office of Medicare Hearings and Appeals (OMHA) or review by an attorney adjudicator in certain circumstances
- Level 4: Review by the Medicare Appeals Council in the HHS Departmental Appeals Board (DAB)
- Level 5: Judicial review in U.S. District Court

The reviews at Levels 1 and 2 in the Medicare FFS, MA and Part D programs are governed by separate and different regulations. Level 3 and 4 reviews are generally governed by many of the same regulations for the Medicare FFS and MA programs (with some differences to account for different statutory requirements and the different roles of the QIC and the MA plan). Level 3 and 4 reviews for the Part D program are governed by separate and different regulations.

For the FFS program, CMS regulations at 42 CFR §§ 405.1010-1012 allow QICs, which are responsible for conducting Level 2 appeals, to participate in ALJ hearings either as a party participant, a "non-party" participant, or as a witness, and CMS provides funding for such activities.

In FFS appeals, while "non-party" participation limits the QIC to submitting written position papers and providing testimony to clarify factual or policy issues, participation as a party allows the QIC additional opportunities to represent its position related to its decision-making by providing the QIC the right to call witnesses, cross-examine witnesses, and present evidence. In Part D appeals, the IRE or the Part D plan sponsor may request "non-party" participation in an ALJ hearing but not participation as a party. Non-party participation by the IRE or Part D plan sponsor may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee.

Generally, the QICs will invoke party status when there is a significant amount in controversy at issue, there are national policy implications, or there are areas of particular interest for CMS. When CMS uses program integrity funding for a QIC to participate as a party and the ALJ either fully upholds the prior decision or dismisses the case, CMS considers the estimated amount in controversy as savings. FFS data shows ALJ overturn rate is lower in cases in which the QIC participates as a party.[67]

[66] Beginning in plan year 2021, adverse at-risk redeterminations made by a Part D plan under its drug management program must be automatically forwarded to the Part D IRE.

[67] In FY 19, the overall adjudicated reversal rate by the ALJ was 43.7 percent. However, in that same period, in cases in which the QIC participated as a Party, the adjudicated reversal rate was 25.9 percent. In sum, when the QIC participated as a Party in an ALJ hearing, the overturn rate was 17.8 percentage points lower.

CMS also actively participates in an HHS intra-agency appeals workgroup. CMS and our HHS partners are implementing initiatives with the goal of improving the efficiency of the appeals process.

4.7 Medicare Secondary Payer

The Medicare Secondary Payer (MSP) program ensures that when Medicare is a secondary payer (the provider of coverage that pays after another "primary" insurance), Medicare does not pay, or recovers Medicare funds that were paid conditionally, once another individual or entity is determined to be primarily responsible for payment. Sections 1862(b)(7) and (8) of the Act, as added by section 111 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Extension Act of 2007 (MMSEA),[68] added mandatory reporting requirements with respect to Medicare beneficiaries who have coverage under Group Health Plan (GHP) arrangements as well as for Medicare beneficiaries who receive settlements, judgments, awards or other payment from liability insurance (including self-insurance), no-fault insurance, or workers' compensation, collectively referred to as Non-Group Health Plan (NGHP) or NGHP insurance. The mandatory insurer reporting requirements continue to be the primary source of new MSP information reported to CMS from group health plans and other insurers, and the annual number of new MSP records posted to CMS's systems remains more than twice the number posted before this provision's implementation.

Commercial Repayment Center (CRC) Recovery Auditors

The Commercial Repayment Center (CRC) Recovery Auditor recovers Part A and Part B payments made by the Medicare program when another entity had primary payment responsibility. There are two broad situations where the CRC makes recoveries. The first is when a beneficiary has or had coverage through an employer-sponsored GHP. The CRC generally recovers Medicare's mistaken payments in this situation from employers. The second situation is the recovery of certain conditional payments where an applicable plan (a non-GHP entity such as a liability insurer, no-fault insurer, or workers' compensation entity) had primary payment responsibility. In this situation, the CRC recovers Medicare payments from the applicable plan.

4.8 Medicaid Program Integrity

The Medicaid program is a federal-state partnership, and that partnership is central to the program's success. While states have primary responsibility for direct oversight of their programs, CMS plays a critical role in ensuring that states are compliant with federal statute and regulations. As a result, CMS undertakes a wide array of activities to oversee and support states' Medicaid program integrity efforts.

Section 1936(d) of the Act directs the Secretary of HHS to establish, on a recurring 5-fiscal year basis, a comprehensive plan for ensuring the integrity of the Medicaid program by combatting fraud, waste, and abuse. CMS released the most recent Comprehensive Medicaid Integrity Plan

[68] Public Law 110-173.

(CMIP), which sets forth CMS's strategy to safeguard the integrity of the Medicaid program for FYs 2019-2023.[69]

The CMIP is shaped by the following themes:

- **Patients First**: CMS's overarching strategy is built upon the goal of putting patients first because fraud, waste, and abuse not only result in loss of program funds but can directly harm beneficiaries when Medicaid is billed for unnecessary or undelivered services.
- **Federal-State Partnership**: Medicaid program integrity efforts can only succeed when CMS and states work in partnership. To facilitate and improve the federal-state partnership, CMS is adjusting its Medicaid oversight in ways that are more mindful of the uniqueness of each state's size, resources, delivery systems, and level of risk.
- **Flexibility, Accountability, and Integrity** are the three key principles that ground CMS's vision for transforming the Medicaid program. CMS applies these principles in its program integrity work to achieve: (1) greater flexibility in program integrity approaches to empower individual states to create innovative programs; (2) stronger accountability for cost-effective program integrity outcomes and reducing improper payments; and (3) enhanced program integrity, employing new and evolving initiatives to work in partnership with state.

Building upon CMS's existing program integrity efforts, this CMIP includes new and enhanced Medicaid program integrity initiatives that CMS announced in the Medicaid Program Integrity Strategy that was released in June 2018.[70] Highlights of the program integrity elements from the CMIP that CMS engaged in during FY 2019 are described in greater detail in the following sections.

4.8.1 Eligibility and Payment Integrity

A large driver of the Medicaid and CHIP improper payment rates in FY 2019 was state noncompliance with various beneficiary eligibility requirements and processes. Making accurate beneficiary eligibility determinations helps make sure that only truly eligible individuals are enrolled in Medicaid and CHIP, which protects the integrity of the Medicaid program and CHIP, as well as taxpayer dollars. In FY 2019, CMS conducted several oversight activities of states' beneficiary eligibility determinations.

The Medicaid Eligibility Quality Control (MEQC) Program

Under the Medicaid Eligibility Quality Control (MEQC) program, states design and conduct pilots to evaluate the processes that determine an individual's eligibility for Medicaid and CHIP benefits. These MEQC pilots are conducted during the two-year intervals ("off-years") that occur between their triennial PERM review years, allowing states to implement prospective improvements in eligibility determination processes prior to their next PERM review. Consistent with federal requirements, states have great flexibility in designing pilots to focus on vulnerable or error-prone areas as identified by the PERM program and by the state. However, CMS may

[69] https://www.cms.gov/files/document/comprehensive-medicaid-integrity-plan-fys-2019-2023.pdf

[70] CMS announces initiatives to strengthen Medicaid program integrity, press release, June 26, 2018

require states to target specific areas of vulnerability in states that have consecutive PERM eligibility improper payment rates over 3 percent. In addition, states are required to devote part of their MEQC pilots to reviews of improper denials or terminations, which are not addressed through PERM reviews. For cases where individuals were erroneously determined eligible, states are also required to assess the financial implications of the errors during the 3-month period after the effective date of the erroneous eligibility determination. States will be required to return the federal share of any such overpayments made as a result of these erroneous eligibility determinations through their quarterly expenditure reports.

Audits of Beneficiary Eligibility Determinations

To ensure compliance with the eligibility determination requirements for the adult group, CMS began new eligibility audits in FY 2019 in several states (New York, Kentucky, Louisiana, and California) in which the HHS-OIG and State Auditors previously identified vulnerabilities in the states' eligibility systems. CMS audits in these high-risk states focused on: (1) identifying whether the state determined Medicaid eligibility for individuals in the adult group in accordance with federal and state eligibility requirements and claimed the appropriate FMAP; (2) comparing current review findings to similar findings of the HHS-OIG to ensure those identified findings had been appropriately addressed; (3) identifying and assessing the impact of any changes to Medicaid eligibility policy due to the ACA; and (4) determining whether the adult group eligibility and enrollment process impacted other eligibility categories in the state. CMS is also calculating the amounts inappropriately paid, if any, to the states due to improper eligibility determinations.

4.8.2 Review of State Program Integrity Activities

Conducting oversight of states' program integrity activities is an important component of CMS's plan to protect the integrity of the Medicaid program. Specifically, CMS conducts state program integrity reviews and oversight of states' PERM Corrective Active Plans (CAPs) to ensure states are complying with federal rules and requirements.

State Program Integrity Reviews

CMS conducts focused reviews on high-risk areas, such as managed care, new statutory and regulatory provisions, nonemergency medical transportation, and personal care services. Focused program integrity reviews include onsite state visits to assess the effectiveness of each state's program integrity oversight functions and to identify areas of regulatory non-compliance and program vulnerabilities. In FY 2019, CMS continued to conduct focused reviews of high-risk program integrity areas, such as managed care and personal care services in selected states. In addition to the focused reviews, CMS also conducted desk reviews of states' program integrity activities to increase the number of states and topics that are assessed each year. Beginning in FY 2019, CMS also conducted desk reviews related to states' responses to the opioid crisis and completion of corrective actions from previous program integrity reviews. Additional areas for future desk reviews may include terminated providers that should no longer be billing Medicaid and compliance with Medicaid payment suspension requirements.

Corrective Actions to Reduce Payment Errors

In an intensive effort to solve the root causes of payment errors identified by the PERM program, CMS provides support and technical assistance to states as they develop and implement PERM

CAPs, and CMS will monitor and evaluate their effectiveness. CMS works directly with states to help identify vulnerabilities and overcome barriers that prevent resolution of identified deficiencies with the goal of eliminating repeat findings. Along with increased support, CMS will hold states accountable for reducing their improper payment rates. CMS requires states to meet more stringent PERM CAP requirements if they have consecutive PERM eligibility improper payment rates exceeding the 3 percent national standard, pursuant to section 1903(u) of the Act. Under current regulations, CMS will pursue disallowances for states that fail to demonstrate a good faith effort by satisfying PERM CAP and MEQC pilot requirements.[71]

4.8.3 Medicaid Managed Care Medical Loss Ratio (MLR) Reviews

The 2016 Medicaid managed care final rule[72] strengthens the fiscal integrity in Medicaid and CHIP managed care by requiring more transparency in the managed care rate setting process and adding standards for the calculation and reporting of MLRs and encounter data submissions. The final rule stipulates that states must require managed care plans to submit financial and other data supporting service encounters, the actuarial soundness of capitation rates, and reported MLRs. In FY 2019, CMS conducted a review of California's Medicaid managed care plans' financial reporting, focusing on MLRs and rate setting. Released in June 2020, CMS's review verified whether California's managed care plans' expenditures for providing health care services were reported accurately and supported capitation rates specified in managed care plans' contracts.[73] California previously conducted its own review of its managed care plans' MLR reporting, resulting in recoupments from managed care plans amounting to $2.56 billion. CMS's review determined that California correctly identified findings and overpayments. CMS did not identify any new findings; however, CMS identified several areas for improvement when California calculates and reviews each managed care plan's MLR in the future.

4.8.4 State Access to Medicare Data

Approximately 12.3 million Americans are dually enrolled in Medicare and Medicaid, and providers and managed care plans that serve Medicaid patients often participate in Medicare as well. This overlap means that Medicare program integrity data offers the potential to greatly enhance state Medicaid program integrity efforts. Analyzing both Medicare and Medicaid claims data enables CMS and states to detect duplicate and other improper payments for services billed to both programs. Sharing information among federal and state investigators about aberrant providers or plans can improve the identification of improper billing and optimize investigative resources. Through the State Data Resource Center (SDRC), state Medicaid agencies may request Medicare data, free of charge, for individuals who are dually enrolled in Medicare and Medicaid to support care coordination and program integrity functions, such as preventing duplicate payments by Medicare and Medicaid. A state Medicaid agency may request Medicare eligibility and enrollment data, Medicare Parts A and B claims, and Part D pharmacy claims. The SDRC offers frequent

[71] See 42 CFR Part 431.1010

[72] 81 FR 27497, May 6, 2016

[73] https://www.cms.gov/files/document/california-medical-loss-ratio-examination-report.pdf

webinars on a variety of topics such as linking Medicare and Medicaid databases and program integrity data requests.

CMS also administers the Medicare-Medicaid Data Match (Medi-Medi) program, through which Medicare and Medicaid claims for dually enrolled beneficiaries are matched at the provider and beneficiary level to check for duplications. State participation is voluntary; as of December 2019, 19 states participate in the Medi-Medi program. CMS's Unified Program Integrity Contractors perform analyses of Medicare-Medicaid matched data and collaborate with state Medicaid agencies to conduct investigations and audits. CMS also provides states access to Medicare data sources in a data warehouse environment, upon request. These Medicare data sources include Medicare Parts A and B claims, Part D pharmacy claims, and Medicare-Medicaid matched data. CMS reaches out to states to inform them of opportunities to access these data sources and provides states with guidance on using these data sets and applying advanced analytics. CMS and states are able to identify duplicate Medicare and Medicaid payments and other types of improper payments for services billed to both programs.

4.8.5 Strengthen Medicaid Data Analytics and Audits

Strong data collection and analysis will enable smarter efforts to tackle fraud, waste, and abuse. CMS is enhancing data sharing and collaboration to tackle program integrity efforts in both the Medicare and Medicaid programs.

Transformed Medicaid Statistical Information System (T-MSIS) Data Use

Continuous T-MSIS data quality review and improvement is an essential and ongoing task, which CMS expects states to maintain as a permanent and ongoing process of their operations. CMS outlined expectations for states to address T-MSIS data quality issues by identifying 12 top priority items that states were expected to either resolve by February 2019 or submit corrective action plans, followed by additional guidance to states regarding T-MSIS state compliance in March 2019. In FY 2019, CMS continued efforts to address T-MSIS data quality and use, which included validating the quality and completeness of T-MSIS data for program integrity purposes. CMS's ongoing goal is to use advanced analytics and other innovative solutions to both improve T-MSIS data and maximize the potential for program integrity purposes. This will allow CMS to identify instances like a beneficiary receiving more hours of treatment than hours in a day or other flags that necessitate further investigation. CMS's Unified Program Integrity Contractors and our other program integrity analytics contractors have begun testing T-MSIS data and will submit state-specific reports and recommendations to CMS regarding the use of T-MSIS data for program integrity going forward. As T-MSIS data quality meets required criteria, CMS will incorporate T-MSIS data into both Medicaid-specific and multi-program analytics to allow states, CMS, and other stakeholders the ability to observe and address trends or patterns indicating potential fraud, waste, and abuse in Medicaid.

Data Analytics Pilots

CMS remains committed to utilizing advanced analytics and other innovative solutions to both improve Medicaid eligibility and payment data and maximize the potential for the data to be used for program integrity purposes. CMS is a national leader in the use of predictive analytics to identify program integrity vulnerabilities. The CMS Fraud Prevention System (FPS) streams Medicare Part A and Part B claims on a national basis, running claims against multiple algorithms that identify

patterns of fraud, waste, and abuse. Claims may be automatically denied based upon edits, and alerts (or leads) are created for additional investigation when the FPS identifies claims and other data that suggest aberrant billing. CMS will share its extensive knowledge, gained from analyzing large, complex Medicare data sets, to support states in analyzing Medicaid claims data to identify potential program integrity issues based on state and CMS priorities. CMS anticipates that continuing to work with states to improve the quality of T-MSIS data will enable states and CMS to perform analyses useful for program integrity and program management. Through forums, such as the Medicaid Integrity Institute, CMS will share FPS algorithms and provide data analytic support as necessary to assist states with their program integrity efforts.

4.8.6 Provider Screening and Enrollment

As part of its oversight role in Medicaid, CMS works closely with state Medicaid agencies to provide regulatory guidance, technical assistance, and other support with respect to provider screening and enrollment.

Provider Screening Data Sources

CMS has significantly expanded data sources available to states for provider screening and enrollment over the past few years and continues to enhance the usability of these data sources through ongoing work with state partners. By the end of FY 2018, CMS completed transitioning state access to these databases to a new online portal, the Data Exchange (DEX) system, to provide states with enhanced data formats and an improved user interface. DEX allows CMS to share Medicare revocation data with the Medicaid programs of every state, which in turn use DEX to share terminated Medicaid and CHIP provider information with CMS and other states. By March 2019, all 50 states and Puerto Rico had access to DEX.

CMS will continue to work with states to ensure adoption of the DEX system and to determine the need for future enhancements that may benefit states. DEX provides enhanced functionality for the exchange of the following types of data for provider screening and enrollment:

- Provider Terminations: States must deny or terminate the enrollment of any provider that is terminated for cause under Medicare or under the Medicaid program or CHIP of any other state.[45] DEX is CMS's centralized online mechanism for sharing reciprocal Medicare and Medicaid/CHIP provider revocation and termination data.
- Death Master File: DEX provides states with access to the Social Security Administration's Death Master File (DMF), which states are required to check as part of provider screening and revalidation to ensure that identities of deceased providers are not used fraudulently to bill Medicaid. Complete access to the DMF was previously available to states only through a paid subscription, which some states had identified as a challenge.
- Provider Enrollment, Chain and Ownership System (PECOS): To provide state access to key Medicare provider enrollment information, CMS has provided states with training and direct access to the Medicare provider enrollment system known as PECOS since 2012, regular data extracts from PECOS since 2013, and enhanced usability to assist states' Medicaid provider screening since 2014. These improved PECOS data extracts are now available to states to download through DEX. Additionally, CMS launched the PECOS States' page in January 2017, which included provider enrollment information

such as Medicare enrollment status, site visit information, fingerprint results, ownership information, reassignments, Medicare risk levels, and more.

- Medicare Exclusion Database (MED) Extracts: CMS also provides states with access through DEX to the MED, which contains the HHS-OIG's data regarding individuals and entities excluded from federally funded health care programs, which states are required to check as part of Medicaid provider screening and revalidation.

In addition, some states have faced challenges implementing the required activities to comply fully with enhanced provider screening requirements. As a result, non-compliance with provider screening requirements has been a primary driver of improper Medicaid and CHIP payments since FY 2014. To reduce the burden of conducting screening for new enrollments and revalidation of Medicaid providers, CMS allows states to use provider screening results from Medicare, CHIP, or other State Medicaid agencies. To assist in this work, CMS currently offers a data compare service for provider screening that allows a state to rely on Medicare's screening in lieu of conducting state screening. This service reduces state burden, particularly for provider revalidation, because it allows states to remove dually enrolled providers from their revalidation workload. Using the data compare service, a state provides a list of Medicaid providers to CMS and then CMS returns information indicating for which providers the state can rely on Medicare's screening. As of June 2019, 26 states and territories had participated in the data compare service. CMS will continue to work with states on an ongoing basis to promote the advantages of the data compare service to work toward the goal of expanding use of the service to all states.

Provider Enrollment: Guidance and Technical Assistance

To help states strengthen their provider screening and enrollment processes, CMS has significantly enhanced guidance and technical assistance to states. As part of this ongoing effort, CMS continues to update guidance and expand these services to all states through the following activities:

- CMS published the first edition of the Medicaid Provider Enrollment Compendium (MPEC) in March 2016—a culmination of sub-regulatory guidance to assist states in the implementation of provider screening and enrollment requirements. CMS published updates to the MPEC in FY 2018, which focused on applying new screening and enrollment requirements to Medicaid managed care network providers.
- CMS provider enrollment experts and a State Assessment contractor conduct onsite visits and follow-up visits to provide direct, individualized technical assistance to states in strengthening their provider screening and enrollment processes to meet federal requirements. CMS along with the State Assessment contractor, assess state compliance with enrollment requirements, work to reduce state burden by helping states leverage Medicare screening and enrollment data, conduct a gap analysis, and develop strategic blueprints to help states improve their enrollment processes. In FY 2019, CMS and the State Assessment contractor visited and worked with 32 states. CMS will expand its work by providing assistance to additional states until all states have had the opportunity to meet.
- Going forward, CMS will also continue monthly calls with states to understand challenges or barriers states currently face, to facilitate the exchange of noteworthy practices among states, and to respond to questions regarding guidance or other provider

enrollment issues. CMS has also dedicated an additional monthly call focused entirely on provider enrollment and screening issues in Medicaid managed care.

Screening Medicaid Providers

As part of the Medicaid Program Integrity Strategy, CMS began piloting a centralized process to screen Medicaid-only providers on behalf of states on an opt-in basis, similar to the current process in place for Medicare. The purpose of this effort is to explore whether centralization of Medicaid provider screening can reduce state and provider burden, better ensure providers are screened appropriately based on categories of risk, and address a major source of improper payments. CMS has recruited two states, Iowa and Missouri, and began screening their Medicaid-only providers through databases for valid licenses, criminal background checks, and the federal Treasury's Do Not Pay portal in late FY 2019. Iowa and Missouri are currently evaluation screening results. CMS will evaluate the results and impact of the pilot and assess the value of expanding the service to more states in the future.

4.8.7 Medicaid Integrity Institute

Since 2008, CMS has offered training to state program integrity staff at no cost to states through the Medicaid Integrity Institute (MII), which provides both residential classroom training and distance learning webinars to enhance the professional qualifications of state Medicaid integrity staff across the nation. The MII offers a program of courses and examinations for the Certified Program Integrity Professional designation, which is recognized by the American Association of Professional Coders and the National Health Care Anti-Fraud Association. Courses at the MII also provide opportunities to discuss emerging trends, support new initiatives, and strengthen collaboration among state and federal partners. In FY 2019, CMS updated and expanded MII training for state program integrity staff to meet new state challenges and federal priorities. CMS hosted 18 courses in FY 2019, with emphasis on beneficiary eligibility and fraud, provider enrollment, HFPP, UPIC and State collaboration, and Medicaid managed care. CMS also took steps to integrate MII training more closely with follow-up technical assistance when state staff return to their respective agencies to facilitate applying lessons learned at MII to solving problems at the state level.

4.9 Durable Medical Equipment, Prosthetics, Orthotics and Supplies

4.9.1. DMEPOS Investigations

DMEPOS suppliers have historically posed a high risk of fraud to the Medicare program and CMS has undertaken an aggressive strategy to address this risk. In FY 2019, UPICs continued conducting site visits and interviews of DMEPOS suppliers, providers, and beneficiaries receiving DMEPOS items in high billing areas.

4.9.2 Competitive Bidding[74]

The DMEPOS Competitive Bidding Program was mandated by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which requires that Medicare replace the previous fee schedule payment methodology for select DMEPOS items with a competitive bid process.

Under the DMEPOS Competitive Bidding Program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items to people with Medicare living in, or visiting, competitive bidding areas. Medicare payment is not made for claims for items subject to the program that are submitted by entities other than contract suppliers and certain exempted suppliers, thereby reducing the ability of entities to commit fraud and allowing for better oversight of suppliers receiving payment.[75]

The savings experienced as a result of the DMEPOS Competitive Bidding Program predominantly come from lower payments and decreased unnecessary utilization.[76]

The Medicare DMEPOS Competitive Bidding Program works with other fraud, waste, and abuse initiatives and is currently saving over $2 billion per year without negatively impacting health outcomes.[77]

The DMEPOS Competitive Bidding Program has been an essential tool to help Medicare set market-based payment rates for DMEPOS items, save money for beneficiaries and taxpayers, and limit fraud and abuse in the Medicare program. The program has saved billions of dollars since implementation, while ensuring access to quality items and services.[78]

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[74] The DMEPOS Competitive Bidding Program was initially required under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) [Public Law 108-173], modified by Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) [Public Law 110-275], and expanded by the Patient Protection and Affordable Care Act. It is an administrative program and is neither a specific program integrity activity nor is it funded from program integrity obligations. The program is mentioned in this report because it represents CMS's proactive approach to preventing improper payments.

[75] On March 7, 2019, CMS announced plans to consolidate the competitive bidding areas (CBAs) included in the Round 2 Recompete and Round 1 2017 DMEPOS Competitive Bidding Program into a single round of competition named Round 2021. Round 2021 contracts are scheduled to become effective on January 1, 2021, and extend through December 31, 2023., therefore they will be reported in those fiscal years in which they are effective.

[76] All DMEPOS Competitive Bidding Program contracts expired on December 31, 2018. As of January 1, 2019, there is a temporary gap in the entire DMEPOS Competitive Bidding Program that CMS expects will last until December 31, 2020. During the temporary gap, any Medicare enrolled DMEPOS supplier may furnish DMEPOS items and services to people with Medicare.

[77] https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/DMEPOS_Toolkit.html

[78] "DMEPOS Competitive Bidding Round 2021". Fact Sheet (March 8, 2019): https://www.cms.gov/newsroom/fact-sheets/dmepos-competitive-bidding-round-2021

4.9.3 DMEPOS Prior Authorization

CMS issued a DMEPOS prior authorization final rule in FY 2016 that establishes a prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization.[79] The rule defines unnecessary utilization as "the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules." The rule also establishes a list of DMEPOS items that could be subject to prior authorization before items or services are provided and payment is made.

In FY 2017, CMS began implementing prior authorization for two types of group 3 power wheelchairs (HCPCS codes K0856 and K0861) in a staggered approach. In March 2017, prior authorization began in Illinois, Missouri, New York, and West Virginia, which was followed by a nationwide expansion in July 2017. On September 1, 2018, CMS implemented prior authorization nationwide for 31 types of PMDs that were previously included in the PMD Demonstration.[80] On July 22, 2019, CMS implemented prior authorization for seven additional power wheelchairs (HCPCS codes K0857, K0858, K0859, K0860, K0862, K0863, and K0864) nationwide. In addition to the power wheelchairs, CMS implemented prior authorization on July 22, 2019 for five pressure reducing support surfaces (HCPCS codes E0193, E0277, E0371, E0372, and E0373) in California, Indiana, New Jersey, and North Carolina.

4.10 Demonstrations and Models

CMS conducts a number of innovative demonstrations and models designed to test improved methods for the prevention and identification of potential fraud, waste and abuse, with the goal of reducing program expenditures while preserving or enhancing the quality of care.[81]

4.10.1 Demonstrations

Section 402(a)(1)(J) of the Social Security Amendments of 1967[82] authorizes the Secretary to conduct demonstrations designed to develop or demonstrate improved methods of the investigation and prosecution of fraud in the provision of care or services provided under the Medicare program.

Review Choice Demonstration for Home Health Services

In FY 2019, CMS implemented the Review Choice Demonstration for Home Health Services, based on stakeholder feedback on CMS's previous Pre-Claim Review Demonstration.[83] The demonstration offers providers increased flexibility and choice, as well as risk-based changes to reward providers who show compliance with Medicare home health policies. The demonstration gives providers in the demonstration states an initial choice of three options – pre-claim review,

[79] CMS–6050–F, 80 FR 81674 (Dec. 30, 2015).

[80] 83 FR 25947 (June 5, 2018)

[81] While these demonstrations and models contribute towards CMS's program integrity objectives, they are not part of the Medicare or Medicaid Integrity Programs. These demonstrations and models are supported by other sources and authorities.

[82] Public Law 90-248.

[83] 83 FR 25012 (May 31, 2018)

post payment review, or minimal post payment review with a 25 percent payment reduction for all home health services. A provider's compliance with Medicare billing, coding, and coverage requirements determines the provider's next steps under the demonstration.

The demonstration applies to Home Health and Hospice Medicare Administrative Contractor (HH/H MAC) Jurisdiction M (Palmetto GBA) providers operating in Illinois, Ohio, Texas, North Carolina, and Florida for five years, with the option to expand to other states in the Palmetto/JM Jurisdiction. CMS implemented the demonstration in Illinois on June 1, 2019 and in Ohio on September 30, 2019. This demonstration will assist in developing improved methods to identify, investigate, and prosecute potential fraud in order to protect the Medicare Trust Funds, potentially reduce the rate of improper payments, and improve provider compliance with Medicare rules and requirements.

4.10.2 Models

Section 1115A of the Act authorizes the Secretary, through the Center for Medicare and Medicaid Innovation, to test innovative payment and service delivery models in order to reduce program expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

Prior Authorization for Repetitive, Scheduled Non-Emergent Ambulance Transport
In FY 2019, CMS continued implementing a Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. This began as a three-year model on December 1, 2014 for transports occurring on or after December 15, 2014 in Pennsylvania, New Jersey, and South Carolina.[84] Then, as required by section 515 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),[85] beginning January 1, 2016, five additional states (North Carolina, Virginia, West Virginia, Maryland, and Delaware) and the District of Columbia were included in the model.[86] CMS announced that it will expand the model nationwide, as the model has met all expansion criteria under section 1834(l)(16) of the Act (as added by section 515(b) of MACRA (Pub. L. 114-10)).[87]

Expenditure data reflects that, in the model's first four years, average spending in the initial three states decreased from $18.9 million to $6.2 million per month, while data from the first three years of the model for the additional states reflects that average spending decreased from $5.7 million to $2.9 million per month.[88]

4.11 Federally-Facilitated Exchanges

To the extent permitted by states, licensed agents and brokers may assist consumers to determine their eligibility for insurance affordability programs, including those offered

[84] 79 FR 68271 (Nov. 14, 2014)

[85] PL 114-10.

[86] 80 FR 64418-19 (Oct. 23, 2015)

[87] 85 FR 74725 (Nov. 23, 2020)

[88] FY 2019 HHS Agency Financial Report https://www.hhs.gov/sites/default/files/fy-2019-hhs-agency-financial-report.pdf (Nov. 13, 2019)

through the Federally-Facilitated Exchange (FFE). These agents and brokers offer information to consumers on advance payments of the premium tax credit and help enroll them in qualified health plans (QHPs). Due to the financial incentives involved and agent/broker access to consumers' personal information, this can create opportunities for fraud, waste and abuse.

CPI continued refining program integrity operations for the FFE during FY 2019. The Marketplace Complaints Review Contractor (MCRC) reviewed and categorized more than 10,000 consumer complaints, escalating the most urgent consumer harm cases for urgent handling when necessary. The Marketplace Program Integrity Contractor (MPIC) then triaged the complaints, using statistics and other data analytics, and conducted investigations of potential misconduct and fraud by insurance agents and brokers. The MPIC also continued refining high-risk data indicators to help support complaint-driven investigations and to initiate data-driven investigations of entities exhibiting unusual patterns of behavior. The MPIC also used state Departments of Insurance databases to verify the licensure status of thousands of insurance agents and brokers actively assisting consumers on the FFE.

In FY 2019, CMS greatly reduced the amount of time needed, from months to weeks, for resolving consumer complaints alleging unauthorized or fraudulent enrollments into FFE plans that they either did not know about or did not give consent. CMS works with health plan issuers to research and cancel fraudulent health insurance policies in order to alleviate unwarranted tax liabilities for consumers. In FY 2019, CMS cancelled more than 3,400 unauthorized enrollments due to suspected fraud.

Other fraud allegations come to CPI from health plan issuers whose own data analytics reveal potentially fraudulent enrollments, such as those associated with sober home schemes. In FY 2019, CMS approved the cancellation (i.e., rescission) of more than 150 health insurance policies. Rescinding policies associated with fraud schemes protects issuers from high dollar fraudulent claims, which in turn helps safeguard the integrity of health plans participating in the FFE.

CMS also continued to support law enforcement agencies around the country, investigating possible fraud impacting consumers and issuers participating in the FFE, by servicing requests for FFE data and program information. When necessary, CMS refers cases to law enforcement and/or regulatory agencies, such as states' Departments of Insurance, for investigation or to take actions within their jurisdictions.

4.12. Open Payments

The Open Payments program is a statutorily required, national disclosure program that promotes transparency and accountability by making information about the financial relationships between

the health care industry (reporting entities)[89] and providers (covered recipients)[90] available to the public.

The Open Payments data includes payments and other transfers of value made by reporting entities to covered recipients, along with ownership and investment interests held by physicians or their immediate family members in the reporting entities. Payments are reported across three main categories:

- General Payments: Payments or other transfers of value that are not in connection with a research agreement or research protocol. General payments may include, but are not limited to honoraria, gifts, meals, consulting fees, and travel compensation.
- Research Payments: Payments or other transfers of value made in connection with a formal research agreement or research protocol.
- Physician Ownership Information: Information about the ownership or investment interests those physicians or their immediate family members have in the reporting entities.

In FY 2019, CMS published Program Year 2018 data, completing the fifth full year of data reported to Open Payments. This included the publication of 11.4 million payment records, transfers of value, or instances of ownership/investment interest reported during calendar year 2018. These financial transactions totaled $9.35 billion. In addition to the publication of Program Year 2018 data, all previous program years were refreshed and republished[91] to reflect any updates made by reporting entities during the 2018 program year cycle.

Disclosure of the financial relationships between the reporting entities and covered recipients does not signify an inappropriate relationship, and Open Payments does not prohibit such transactions. Reporting entities, after giving providers an opportunity to review and dispute the data, self-report the data displayed on the Open Payments website. The public can search, download, and evaluate the reported data found on the Open Payments website (https://openpaymentsdata.cms.gov/). The Open Payments search tool is a crucial component of the program as it is the vehicle that provides the public access to the Open Payments data. CMS continues to maintain the search tool and make updates for optimal user experience and accessibility. The following are the notable enhancements to the search tool throughout 2019:

- **Query Builder Tool** –The new Query Builder tool allows users to build their own queries to search the vast Open Payments data.

[89] Reporting entities refers to applicable manufacturers and group purchasing organizations (GPOs) required to report payments or transfers of value to covered recipients under the Open Payments Program (42 USC §1320a-7h).

[90] Covered recipients are any physicians (excluding medical residents) who are not employees of the applicable manufacturer that is reporting the payment; or teaching hospitals that receive payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available.

[91] Refreshed and republished data includes data corrections made to reported payments since the initial publication of data that were submitted by applicable manufacturers and GPOs.

- **Homepage Autocomplete Search Update** – An auto-complete function was added to the homepage search to enable faster and more successful searches.
- **All Years Data View** – An "All Years" view of the data was added to entity profiles and across several applications for users to see a sum of data for all available years instead of only viewing data for a single year at a time.
- **Search Tool Survey** – A simple question survey was added to the search tool site during designated periods of time. The survey was available three different times throughout FY 2019 and results showed consistent positive user experience. CMS publishes financial data for each program year.[92]

In FY 2019, Open Payments continued compliance efforts focused on improving the timeliness, accuracy, and completeness of the reported data. These efforts resulted in the inclusion of previously unreported data and the correction of errors in approximately 2.97 million records with an associated value of about $679 million.

Partner engagement and outreach efforts are a priority for CMS. Open Payments stakeholders, including medical college faculty, teaching hospital employees, industry professional groups, physicians, attorneys, and compliance professionals, received Open Payments outreach throughout FY 2019.

[92] The program year coincides with the calendar year. In this case, the program year is the calendar year ended December 31, 2017.

5. Reduce Provider Burden

5.1 Outreach and Education – Medicare Fee-for-Service

One of the goals of provider outreach and education in the Medicare FFS program is to reduce improper payments by ensuring that providers have timely and accurate information they need to bill correctly the first time. The MACs educate Medicare providers, suppliers, and their staff about Medicare policies and procedures, including local coverage determinations; significant changes to the Medicare program; and issues identified through review of provider inquiries, claim submission errors, medical review data, CERT program data, and other relevant sources. Medicare contractors use a variety of strategies and communication channels to offer Medicare providers and suppliers a broad spectrum of information about the Medicare program, including CMS-developed materials and MAC-developed materials.

CMS-developed materials include Medicare Learning Network® (MLN) educational products, information, and resources for the health care professional community. For example, MLN Matters articles provide content from clinicians, billing experts, and CMS subject matter experts that explains Medicare policies and the latest changes to CMS programs. Other MLN products, such as webinars, fact sheets, and listserv messages are also used to provide educational messages to CMS stakeholders. MAC-developed materials include education on local coverage determinations and listserv messages tailored to the relevant MAC jurisdiction. CMS receives significant positive feedback from providers and suppliers on the value of these educational materials.

5.2 Outreach and Education – Medicare Part C and Part D

In FY 2019, CMS continued the sharing of educational training tools for MA and Part D plans on the Health Plan Management System (HPMS). MA and Part D plans are able to access educational presentations, fact sheets, and booklets on the same HPMS platform where CMS makes available other pertinent information such as CMS communications, operational information, and policy materials.

CMS also led the development of multiple training events in FY 2019, pertaining to current Medicare Parts C and Part D fraud schemes; fraud prevention techniques; and anti-fraud, waste, and abuse activities. The training events consisted of the following:

- Two smaller in-person events, involving approximately 30 to 40 individuals, at the CPI Command Center where participants were educated about the latest trends in Medicare Part C and Part D fraud, waste and abuse. Attendees included participants from Medicare Parts C and Part D plans, law enforcement and the NBI MEDIC. Attendees reported an overwhelmingly positive experience, and also provided feedback about topics for future training events that were considered for the larger offsite training event.
- A larger offsite training event was held with 177 attendees, including Medicare Part C and Part D plan sponsors, law enforcement, NBI MEDIC and CMS staff. The event included group discussions, highly interactive information-sharing exercises, and presentations and panel discussions that featured active question-and-answer segments. The audience reacted positively to the overall event, reporting that the information shared will be useful for their work in combating FWA.

- Two opioid missions with eight plan sponsors. These are collaborative educational meetings to review the monitoring and educating of high-volume, Schedule II opioid analgesic prescribers to ensure that opioid analgesics used by Medicare beneficiaries are prescribed at safe dosages, not used concurrently in combinations with increased overdose risk to beneficiaries, and are for medically necessary use. Attendees included, plans sponsors, NBI MEDIC, I-MEDIC and law enforcement.

5.3 Program Integrity Annual Meeting

In FY 2019, CMS held an in-person, three-day conference onsite at CMS Headquarters, designed to promote collaboration between CMS and our stakeholders to address potential vulnerabilities, strengthen our program integrity efforts, and minimize unnecessary administrative burden for providers. The Program Integrity Annual Meeting had 373 attendees from CMS, DOJ, HHS-OIG, MACs, UPICs, NBI MEDIC, RACs, CERT contractor, Medical Review Accuracy Contractor (MRAC), and other PI support contractors. Speakers presented ways to detect fraud and reduce improper payments, while also contributing to CMS's goal of reducing provider burden. Topics covered included data analysis, provider enrollment, fraud prevention, stakeholder engagement, medical review, and burden reduction.

5.4 Medicaid Educational Toolkits

CMS uses an online resource for Medicaid program integrity education, which provides public access to educational toolkits covering a variety of topics, such as dental compliance and beneficiary card sharing.[93] These toolkits include print and electronic media, train-the-trainer guides, webinars, videos, and other innovative strategies for promoting successful practices and enhancing awareness of Medicaid fraud, waste, and abuse. In 2019, CMS began the process to review and update the educational material that is available for state Medicaid Agencies, and is redesigning the Medicaid educational webpages for enhancements.

State Medicaid Program Integrity units also have access to the Regional Information Sharing System (RISS). The MII supports this Medicaid program integrity workspace, which is a secure, web-based portal for collaboration, and dissemination where all states can exchange documents, tips, and best practices about Medicaid program integrity under the auspices of the DOJ Office of Legal Education. Educational material, including course material from the MII as well as the NCCI Medicaid code sets, is maintained on RISS.

5.5 Open Door Forums

Open Door Forums (ODFs) are calls that are held on a regular basis, where CMS connects with providers on various topics of interest. Among other purposes, CMS uses these ODFs to share information and answer questions on the programs and projects in which program integrity is involved. For example, CMS has provided updates to the public on the new Medicare cards, (see

[93] Medicaid Program Integrity online toolkits are available at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html.

Section 3.5). CMS also hosts Special ODFs throughout the year to discuss our program integrity initiatives more in depth, such as new prior authorization programs, or the Documentation Requirements Lookup Service. CMS makes Open Door Forums and other presentations available as an audio podcasts, free of charge.[94]

5.6 Provider Compliance Focus Groups

Focus groups are a way for providers and CMS to meet in-person or via the web to share ideas and collect feedback and opinions on a number of program integrity programs and projects CMS runs. CMS held focus groups in October 2018 and July 2019. The October 2018 focus group had 288 individuals registered for attendance. The July 2019 focus group had 228 registered individuals. Topics discussed included: telehealth, comparative billing reports, the QIC Appeals Demonstration, TPE, documentation requirements, electronic submission of medical documentation (esMD) and updates to questions asked at previous focus group meetings. All focus group meetings include an Open Mic session during which participants are encouraged to ask questions and provide feedback about Medicare FFS compliance topics. Participants are encouraged to ask questions and be actively engaged throughout the half-day events.

5.7 In-Person Provider Enrollment Conferences

In March 2019, April 2018 and September 2017, CMS hosted National Provider Enrollment conferences, where provider enrollment experts from CMS and providers and their support staff met to discuss challenges, explore opportunities for collaboration, and exchange ideas to improve provider enrollment.

The March 2019 conference was held in Nashville, Tennessee and included the following subjects:[95]

- Provider Enrollment 101
- Medicare Effective Dates
- Medicaid Provider Enrollment
- DMEPOS Enrollment
- Maintaining Compliance and the Appeals Process
- Provider Enrollment, Chain, and Ownership System (PECOS) 101
- Federally Qualified Health Centers Enrollment

5.8 National Provider Compliance Conference

The in-person inaugural National Provider Compliance Conference was held in FY 2019. The event provided compliance professionals with informative presentations and discussions focused on the efficient and effective submission of Part A and Part B claims, including home health, hospice, and DMEPOS claims. The conference was designed to encourage interactive

[94] https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts

[95] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Provider-Enrollment-Events

communication and offered learning opportunities in the form of individual presentations, panel discussions, and subject matter breakouts, in addition to forums for meaningful stakeholder engagement. A total of 241 attendees participated in the 1-1/2-day conference. Of the total attendees, 87 percent of respondents stated that they would attend this conference again, while 88 percent of respondents stated they will be implementing improvements to their work as a result of something they have learned at this conference.

5.9 Victimized Provider Project

CMS works with providers who claim to be victims of identity theft and who have suffered financial liabilities in the form of Medicare overpayments or debts through the Victimized Provider Project (VPP). The VPP attempts to validate and remediate a provider's claims as an identity theft victim. CMS wants to ensure that no provider is re-victimized through the wrongful assignment of debts.[96]

5.10 Central Repository for Requirements Documentation

CMS is striving toward the development of a central repository of documentation requirements for all programs and all payers that is easily accessible within the electronic health record (EHR) in order to minimize improper payments and reduce provider and supplier burden. A recent key focus of this effort is the development of a prototype Medicare FFS Documentation Requirements Lookup Service (DRLS). The DRLS will allow providers and suppliers to identify Medicare FFS prior authorization and documentation requirements within their EHR or integrated practice management system, reducing provider and supplier burden while simultaneously addressing a leading cause of improper payments – missing or incomplete documentation. We are also working with the DaVinci project, a private-sector initiative led by Health Level 7 (HL7®), a standards development organization focused on accelerating the adoption of HL7® Fast Health Interoperability Resources (FHIR®) as the standard to support and integrate the exchange of value-based care data.[97]

[96] https://www.cms.gov/About-CMS/Components/CPI/VictimizedProviderProject

[97] https://www.cms.gov/About-CMS/Components/CPI/Downloads/Center-for-Program-Integrity-Future-of-PI-RFI.pdf

6. Leverage New Technology

6.1 Provider Enrollment Systems

6.1.1 Provider Enrollment, Chain and Ownership System (PECOS) Improvements

PECOS is the Internet-based system that providers and suppliers use to enroll, revalidate, or make changes to their enrollment information in the Medicare FFS program. CMS made significant improvements to the system to make it easier for providers and suppliers to access and use the system. In FY 2019, CMS engaged providers and suppliers regularly to better understand the challenges users face and prioritized the improvements based upon the information learned through:

- Sponsoring quarterly focus groups with providers and suppliers
- Organizing the National Provider Enrollment Conference
- Conducting education and outreach through listservs, CMS.gov, PECOS homepage, Medicare Learning Network® (MLN) Matters Articles, change requests, and national provider calls

In FY 2019, CMS made significant changes to PECOS to simplify access, improve the usability and enhance the security of the system, including the following changes:

- Added initial features necessary to facilitate the future implementation of Multi-Factor Authentication
- Implemented the enhancements necessary to ensure all enrollment data that flows to the claims system comes directly from PECOS
- Continued enhancing and streamlining the process that expedites the enrollment processing for users by allowing digital upload of the signature pages
- Implemented enhancements to the Provider Enrollment Process to support the Program Integrity Enhancements to the Provider Enrollment Process Final Rule (CMS-6058-FC)[98]
- Implemented a Medicare ID Search tool in the provider interface to ease the process of finding the Medicare billing numbers to assist the provider community with any inquiries

6.1.2 National Plan and Provider Enumeration System (NPPES) Improvements

The National Plan and Provider Enumeration System (NPPES) supplies the NPI numbers to health care providers, maintains their NPI record, and publishes the records online. In FY 2019, CMS made changes to the NPPES security and enhanced features for managing and enumerating NPIs. The enhancements include:

- Streamlined and enhanced the bulk upload and bulk enumeration process for large organizations

[98] 84 Fed. Reg. 47794 (Sept. 10, 2019)

- Strong focus on security enhancement, including groundwork necessary to implement multi-factor authentication
- Focus on user experience ease and simplifying the process of submitting NPI requests

6.2 Medicaid and CHIP Business Information Solutions

The Medicaid and CHIP Business Information Solutions (MACBIS) is a CMS enterprise-wide initiative to ensure the Medicaid and Children's Health Insurance Program (CHIP) data infrastructure and automated tools are commensurate to the programs' role in the United States healthcare system. This initiative creates a more robust and comprehensive information management strategy—a "transformed data state"—to integrate Medicaid and CHIP operational, quality, and performance data for the first time. MACBIS consists of several product development efforts aimed at delivering an integrated set of modern digital products focused on ensuring CMS delivers on the following objectives:

- CMS will advance innovation in state Medicaid Programs by implementing changes that decrease burden while increasing accountability for outcomes.
- CMS will use data to accelerate quality improvement and drive accountability for results.
- CMS will ensure that every federal dollar is spent with integrity.
- CMS is the model for customer service and efficiency with states.

The "business" operations of Medicaid and CHIP take place across a continuum beginning with policy formulation (often in the form of legislation and/or regulation) and then continues to implementation to monitoring and financial management to evaluation. In an ideal world, these processes inform each other and flow seamlessly. This continuum requires a modern and robust set of automated tools, all working together to accomplish the CMS mission

Current MACBIS products and services include:

Table 7: MACBIS Products and Services

Product	Description
T-MSIS (Transformed Medicaid Statistical Information System)	The purpose of the T-MSIS product is to ensure that accurate, complete, and timely Medicaid and CHIP is available to enable powerful data analytics for policy research, policy decisions, and improved healthcare outcomes for Medicaid and CHIP populations.
Data Quality Operations and Services	This product and services offering from the MACBIS team is aimed at ensuring that states have timely and actionable feedback about the quality of the data they submit to CMS, along with technical assistance and support to improve data quality.
MACPro/Workflow	MACPro is a suite of products designed to enhance the Federal-State partnership in Medicaid & CHIP through automated workflows, structured data and document management to replace legacy, paper based process for SPAs, Waivers, APDs and other state-reported data.

MACPro/eAPD	As a core function of the MACPro suite, the eAPD system will serve as a singular, streamlined portal for state, federal, and associated partners to develop, review, track, analyze, and share APD, contract submissions, and data to improve accountability and outcomes associated with the State's Medicaid business needs.
MACFin (Medicaid and CHIP Financials)	MACFin will be a modern, integrated product suite that will replace the current Medicaid Budget and Expenditure System (MBES) and incorporate and improve other existing business processes related to Medicaid and CHIP financial management.
MDP (Medicaid Drug Program)	Medicaid Drug Programs (MDP) administers the mission-critical Medicaid pharmacy systems which resulted in Federal and State rebate revenues of approximately $35 billion in FFY 2019 and $34.7 billion in FFY 2018. Medicaid Drug Programs (MDP) is essential to ensure the accuracy of the Medicaid Drug Program data. MDP is currently under new design and development to improve workflows and ensure better accuracy for the entire Medicaid drug program.
AREMAC (Analytic and Reporting Environment for Medicaid & CHIP)	AREMAC's mission is to unleash the power of data to improve the lives of Medicaid and CHIP beneficiaries. AREMAC aims to be the trusted one-stop shop for all Medicaid and CHIP data. Currently, AREMAC is building reports and dashboards to support CMCS make data-driven program and policy decisions. Longer-term, AREMAC intends to enable users to develop self-service proficiency and expertise in their data domain.

CMS will use MACBIS data to support detection of fraudulent patterns in state Medicaid programs, as well as to conduct comparative analytics across state lines and between the Medicare and Medicaid programs. States will be able to analyze their own program data along with other information in the CMS data repositories, including certain Medicare data pertaining to beneficiaries in their states, in order to identify potential anomalies for further investigation. As appropriate CMS will take action to incorporate data from T-MSIS, as it is received from states, into both Medicaid-specific and multi-program analytics.

T-MSIS is currently the primary source for Medicaid and CHIP data around beneficiary eligibility and enrollment, providers, claims and managed care encounters, and financials. All states have been reporting T-MSIS data monthly as of early 2018. Data quality has also been a significant focus since 2017 to improve the overall data set given its importance to Medicaid and CHIP. In August 2018, CMS issued State Health Official (SHO) letter 18-008[99] informing states of T-MSIS data quality expectations. SHO 18-008 provided information regarding the steps CMS will be taking to assess, improve, and maintain T-MSIS data quality, and advised states to consider T-MSIS data quality efforts a permanent and ongoing part of their state T-MSIS operations. In March 2019, CMS issued an Information Bulletin[100] conveying CMS priorities for T-MSIS data quality as well as a timeline for assessing state T-MSIS reporting. States that did

[99] https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO18008.pdf

[100] https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib031819.pdf

not meet requirements were at risk for reduced enhanced Federal Financial Participation for operational costs of systems. State specific data quality assessment letters were sent in April and in the fall of 2019.

As a result of state data quality improvements, a significant milestone was achieved in the fall of 2019 whereby the first set of T-MSIS data called Research Identifiable Files (RIFs) were publicly released.

The following represent some of the major milestones achieved in FY 2019:

- Issued state-specific letter regarding T-MSIS data quality and addressing minimum data quality requirements to avoid potential compliance actions
- MACFin first functional delivery of software within 7 months of contract award – DSH allotments, incremental legacy improvements
- MDP delivered FDA data verifications and Drug Utilization Review Survey
- AREMAC (data warehouse) delivered first production use by users (and received authority to operate)
- Publicly released T-MSIS Research Identifiable Files (RIFs)
- Produced objective measures for T-MSIS data quality and "missingness" reports (data usability)[101]
- Implemented several enhancements to the TMSIS operations dashboard, incorporating an executive view and improved data quality summaries
- T-MSIS data generated more than 7 leads for program integrity.
- Published first Substance Use Disorder (SUD) Data Book as required by the SUPPORT Act

[101] For data usability, CMS created the DQ Atlas, which presents state-level data quality assessments via comparisons to benchmarks across key topics for all data years. One common measure is missingness, in which CMS flags states that are missing high amounts of data, either in lieu of or in combination with an external benchmark – this varies by state. The purpose of DQ Atlas is to help data users decide what data is suitable for their analyses. States also use the Operations Dashboard and Data Quality Tool to review and improve T-MSIS Data Quality or related missingness measures and rules.

Appendix A – Program Integrity Obligations

CMS Program Integrity Obligations (amounts in thousands)[102]	FY 2019 Actual Amounts (in thousands)
Audits & Appeals	
Audits	$251,352
Appeals Initiatives	$4,219
Audits & Appeals Subtotal	$255,571
Medical Review	
Medical Review Subtotal	$231,266
Medicare Secondary Payer	
Medicare Secondary Payer Subtotal	$110,425
PI Investigation, Systems & Analytics	
Benefits Integrity	$186,721
PI Modeling & Analytics	$33,626
Systems	$74,267
Exchange Program Integrity[103]	$14,873
PI Investigation, System & Analytics Subtotal	$309,488
Technical Assistance, Outreach & Education	
Outreach and Education – Medicare	$47,549
Outreach and Education – Medicaid	$15,769
Healthcare Fraud Prevention Partnership	$15,867
Senior Medicare Patrol	$18,000
Technical Assistance, Outreach & Education Subtotal	$97,185
Provider Enrollment & Screening	
Provider Enrollment, Chain and Ownership System (PECOS)	$56,282
Advanced Provider Screening	$35,251

[102] This table represents total obligations for the CMS Center for Program Integrity, Medicare Integrity Program, and Medicaid Integrity Program for FY 2019 (10/1/2018 through 9/30/2019, inclusive).

[103] These Exchange activities are funded with discretionary HCFAC resources.

CMS Program Integrity Obligations (amounts in thousands)[102]	FY 2019 Actual Amounts (in thousands)
National Supplier Clearinghouse	$17,219
Section 6401 Provider Screening/Other Enrollment[104]	$4,438
Provider Enrollment & Screening Subtotal	$113,189
Error Rate Measurement[105]	
Error Rate Measurement Subtotal	$72,013
Provider & Plan Oversight	
Open Payments	$14,812
Parts C & D	$25,429
Medicaid	$11,862
Provider & Plan Oversight Subtotal	$52,103
Program Support & Administration	
Program Support & Administration Subtotal	$287,827
Recovery Audit Contractors[106]	
Recovery Audit Contractors Subtotal	$77,768
Total CMS Program Integrity Obligations[107]	$1,606,835

[104] This amount includes funding from sources other than HCFAC or DRA.

[105] In addition to Medicare and Medicaid, this includes Exchange activities funded with discretionary HCFAC resources.

[106] The Medicare Recovery Audit Program is not a budget appropriation. RACs receive payment through contingency fees based on the amounts recovered from their audit activity. In addition, RACs receive payment for identifying underpayments.

[107] This total includes amounts for the Medicare Recovery Audit Program, which are not obligations under the budget authority.

Appendix B-1 – Medicare Savings Methodology

Introduction

CMS measures its program integrity return on investment (ROI) based on Medicare savings achieved through program-integrity-funded activities that prevent or recover improper payments. Savings represent the numerator of the ROI, while the Medicare program integrity obligations represent the denominator. This appendix provides the methodologies used to determine the Medicare savings amounts presented in the FY 2019 Report to Congress on the Medicare and Medicaid Integrity Programs, *Table 3: Medicare Savings*.

Prevention Savings

CMS calculates prevention savings attributable to prepayment administrative actions in the Medicare fee-for-service (FFS) program (also known as Medicare Part A and Part B) and the Medicare prescription drug benefit program (Part D). Prevention savings are the estimated amounts Medicare would have paid providers[108] or plan sponsors in the absence of these actions. The following table lists CMS's prevention activities.

Prevention Activities	Medicare Program
Automated Actions	
National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits	FFS
NCCI Medically Unlikely Edits (MUEs)	FFS
Ordering and Referring (O&R) Edits	FFS
Fraud Prevention System (FPS) Edits	FFS
Medicare Administrative Contractor (MAC) Automated Medical Review Edits	FFS
Unified Program Integrity Contractor (UPIC) Automated Edits	FFS
Prepayment Review Actions	
Medicare Secondary Payer (MSP) Operations	FFS
MAC Non-Automated Medical Reviews	FFS
UPIC Non-Automated Reviews	FFS
Provider Enrollment Actions	
Revocations	FFS
Deactivations	FFS
Other Actions	
Payment Suspensions	FFS
Medicare Part D Reconciliation Data Reviews	Part D

[108] For the purpose of this document, the term "provider" may refer to a provider, supplier, physician, or non-physician practitioner, and the term may represent an individual or an organization.

1 Automated Actions

Automated actions prevent improper payments without the need for manual intervention. Automated actions occur as the result of edits, or sets of instructions, that are coded into a claims processing system to identify and automatically deny or reject all or part of a claim exhibiting specific errors or inconsistency with Medicare policy. CMS calculates automated action savings from the following edits of Medicare FFS claims:

- National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits
- NCCI Medically Unlikely Edits (MUEs)
- Ordering and Referring (O&R) Edits
- Fraud Prevention System (FPS) Edits
- Medicare Administrative Contractor (MAC) Automated Medical Review Edits
- Unified Program Integrity Contractor (UPIC) Automated Edits

1.1 National Correct Coding Initiative Procedure-to-Procedure Edits

Savings:	The estimated amount Medicare FFS did not have to pay for all unique claim lines denied or reduced in payment due to a PTP edit, accounting for any subsequently paid claim lines.
Data Source:	Multi-Carrier System (MCS) and Fiscal Intermediary Shared System (FISS) claims data in the CMS Integrated Data Repository (IDR)

CMS developed NCCI edits to promote national correct coding practices and reduce inappropriate payments from improper coding in Medicare Part B claims. The coding decisions for these edits are based on coding conventions defined in the American Medical Association's *Current Procedural Terminology (CPT) Manual*, Medicare policies, coding guidelines developed by national societies, and standards of medical and surgical practice. NCCI edit tables are refined and updated quarterly to address changes in coding guidelines and additions, deletions, and modifications of Healthcare Common Procedural Coding System (HCPCS)/CPT codes.[109] NCCI edits apply to services rendered by the same provider for the same beneficiary on the same date of service (DOS).

NCCI PTP edits prevent inappropriate payment when incorrect code combinations are billed for the same provider, beneficiary, and DOS. Each PTP edit applies to a specific pair of HCPCS/CPT codes. CMS uses PTP edits for pairs of codes where one code, in general, should not be reported with another code for a variety of reasons; for example, one code may represent a component of a more comprehensive code, or the codes may be mutually exclusive due to anatomic, gender, or temporal reasons. One code in each edit pair is defined as eligible for payment. If the two codes of an edit pair are billed for the same provider, beneficiary, and DOS, the edit automatically allows

[109] When billing Medicare, health care providers use HCPCS/CPT codes to define medical services performed on patients.

payment for the claim line containing the eligible code and denies payment for the claim line containing the other code.

NCCI PTP edits are used to adjudicate claims for practitioner, ambulatory surgical center, outpatient hospital, outpatient therapy, and some home health services. Practitioner and ambulatory surgical PTP edits occur in MCS, and outpatient hospital and outpatient therapy services edits occur in FISS. These edits occur before claims are sent to the Common Working File (CWF).

For every incoming claim line, PTP edits test for edit code pairs between the reported HCPCS/CPT code and all other codes submitted at the same time or in the claims history for the same provider, beneficiary, and DOS. Thus, it is possible to trigger an NCCI PTP edit by billing a code after payment of a different code from a PTP edit for the same provider, beneficiary, and DOS. If the code on the current claim line is the non-payable code in the edit pair, it is automatically denied. If the code on the current claim line is the payable code in the edit pair, in most cases, the claims processing system automatically reduces the allowed payment for the payable code by the amount previously allowed for its non-payable code pair (referred to as a cutback in this document).[110]

When justified by clinical circumstances and documented in the medical record, providers may append an NCCI-PTP-associated modifier to some codes to bypass certain PTP edits. If there are no clinical circumstances under which a pair of services should be paid at the same encounter, the PTP edit for that pair cannot be bypassed with any modifiers. After a PTP edit denial/cutback, a provider could resubmit the service with corrected information that makes the claim payable. Providers also have the right to appeal PTP edit denials/cutbacks through the Medicare FFS appeals process.

CMS calculates savings attributable to PTP edits in three steps: 1) identifying PTP edit denials/cutbacks, 2) pricing these denials/cutbacks, and 3) accounting for subsequent payment of previously denied/cutback services.

1. Identifying PTP Edit Denials and Cutbacks

System logic in MCS or FISS automatically appends a specific reduction/audit or reason code to claim lines that fail one of the PTP edits. During processing, claim lines may be denied for multiple errors. CMS attributes savings to PTP edits only when a PTP edit code is the system's highest priority reason for denying or reducing payment for a claim line.[111]

When a claim line is denied/cutback, a provider might try to submit another claim for that service without additional or corrected information necessary to pass the edit logic, thus resulting in multiple denials for the same service, provider, beneficiary, and DOS. CMS only counts savings from the earliest, or unique, PTP edit denial/cutback of claim lines that share the same claim type code, HCPCS code, provider, beneficiary, and DOS.

2. Pricing PTP Edit Denials and Cutbacks

[110] The PTP edits savings metric includes the cutback amounts from such claim lines in MCS only, as reduced allowed payments almost never occur in conjunction with PTP edit denials in FISS.

[111] Because claims can be denied at the claim- and/or claim-line level in FISS, CMS considers PTP-denied claim lines in PTP edit savings *only if* there is no claim-level denial for a non-PTP-edit reason.

In order to quantify what Medicare did not have to pay for each denial, CMS uses pricing methodologies specific to each claims processing system:

- *MCS:* In MCS, most denied/cutback claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been fully payable. When a system-generated price for a claim line is unavailable in MCS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit of service using claim lines paid in the same quarter for the same HCPCS code and other matching characteristics, including the claims processing contractor, locality, place of service, and pricing modifier.[112] For each unique denial, CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.[113, 114] For each unique cutback, CMS first determines the cutback amount by subtracting the allowed payment amount from the system-generated or average price. CMS then multiplies the cutback amount by 80 percent to estimate what Medicare did not have to pay.

- *FISS*: Unlike MCS, FISS does not store the priced amount of denied claim lines; thus, CMS approximates the price for each PTP denial based on the applicable pricing mechanism.[115] CMS uses a combination of claim attributes to determine if the denied claim line would have been subject to 1) the Hospital Outpatient Prospective Payment System (OPPS), 2) reasonable cost payment, or 3) a fee schedule. CMS then calculates the price by replicating the specific pricing formula. If the claim line would have been subject to coinsurance, CMS removes the estimated beneficiary coinsurance from the replicated price. CMS does not count any savings from PTP denied claim lines that were packaged under OPPS, since such claim lines would not have received separate pricing or payment.

3. Accounting for Subsequent Payment

To determine savings, CMS accounts for providers who successfully appeal or resubmit previously denied/cutback services. Specifically, where there are any subsequently paid claim lines for a previously denied/cutback service, CMS subtracts the allowed payment amount of those subsequently paid claim lines from a) the priced amount of the earliest denial, up to that priced amount, or b) the cutback amount of the earliest cutback, up to that cutback amount. Subsequently paid claim lines include those that were processed on or after the date of the earliest denial/cutback

[112] For a small number of HCPCS codes, there may not be a paid claim line in the calendar year corresponding to the current claim's DOS. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

[113] In the methodology for this and other edits involving Part B services, CMS uses 80 percent as a conservative estimate of what Medicare did not have to pay a provider. There may be denied services for which Medicare would have paid 100 percent or the beneficiary would have paid 100 percent as part of his/her deductible.

[114] In the methodology for this and other edits across MCS, FISS, and the Viable Information Processing Systems (VIPS) Medicare System (VMS), CMS multiplies savings estimates by 98 percent to account for sequestration.

[115] CMS uses the provider-billed amount to estimate the price in the following situations: 1) when pricing indicators are unavailable and 2) for claim lines priced under the fee schedule where the calculated amount using CMS's pricing methodology is greater than the billed amount.

and that share the same claim type code, HCPCS code, provider, beneficiary, and DOS. All amounts used in these steps have the estimated beneficiary coinsurance removed, where appropriate.

For a given PTP denied/cutback claim line, CMS reports savings in the fiscal year during which the DOS for that claim line occurred. The calculation of PTP edits savings uses claims data captured 90 days after the end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.[116]

1.2 National Correct Coding Initiative Medically Unlikely Edits

Savings:	The estimated amount Medicare FFS did not have to pay for all unique claim lines denied due to an MUE, accounting for any subsequently paid units of service.
Data Source:	MCS, Viable Information Processing Systems (VIPS) Medicare System (VMS), and FISS claims data in the IDR

First implemented in 2007, NCCI MUEs prevent payment for billing an inappropriate quantity of the same service[117] rendered by the same provider for the same beneficiary on the same DOS. An MUE for a given service defines the maximum units of that service that a provider would report under most circumstances for the same beneficiary on the same DOS. MUEs are adjudicated either as claim line edits or DOS edits. If the MUE is adjudicated as a claim line edit, the units of service (UOS) on each claim line are compared to the MUE value for the HCPCS/CPT code on that claim line. If the UOS exceed the MUE value, all UOS on that claim line are denied. If the MUE is adjudicated as a DOS edit, the MUE value is compared to the sum of all UOS for the same HCPCS/CPT code, provider, beneficiary, and DOS on claim lines of the current claim and paid claim lines of previously submitted claims. If the sum of all UOS exceeds the MUE value, all UOS for that HCPCS/CPT code and DOS are denied on the current claim.

NCCI MUEs apply to claims for hospital outpatient services; practitioner services; ambulatory surgery center services; and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Before claims are sent to CWF, practitioner and ambulatory surgical MUEs are implemented in MCS, DMEPOS MUEs are implemented in VMS, and hospital outpatient service MUEs are implemented in FISS.

If a HCPCS/CPT code has an MUE adjudicated as a claim line edit, and when justified by clinical circumstances documented in the medical record, providers may use specific modifiers to report the same HCPCS/CPT code on separate claim lines in order to receive payment for medically necessary services in excess of the MUE value. After an MUE denial, a provider could resubmit the service

[116] A provider has up to one year to submit a claim and, thereafter, a specified period to file an appeal if the claim is denied. There may be a small percentage of claim line denials and appeals for a given fiscal year that are not included in the savings calculation. This is due to claims submission, adjudication, and appeal decisions after the data capture. This applies to all metrics that use claims data captured 90 days after the end of the fiscal year.

[117] For the purpose of this document, the term “service” generally refers to an item or service.

with corrected information that makes the claim payable. Providers also have the right to use the Medicare FFS appeals process to appeal denials due to either claim line or DOS MUEs.

CMS calculates savings attributable to MUEs in three steps: 1) identifying MUE denials, 2) pricing these denials, and 3) accounting for subsequent payment of previously denied services.

1. Identifying MUE Denials

System logic in MCS, VMS, and FISS automatically appends a specific reduction/audit, action, or reason code, respectively, to claim lines that fail an MUE. During processing, claim lines may be denied for multiple errors. CMS attributes savings to MUEs only when an MUE code is the system's highest priority reason for denying a claim line.[118]

When a claim line is denied, a provider might try to submit another claim for that service without additional or corrected information necessary to pass the edit logic, thus resulting in multiple denials for the same service, provider, beneficiary, and DOS. CMS only counts savings from the earliest, or unique, MUE denial of claim lines that share the same claim type code, HCPCS code, provider, beneficiary, and DOS.

2. Pricing MUE Denials

In order to quantify what Medicare did not have to pay for each denial, CMS uses pricing methodologies specific to each claims processing system:

- *MCS:* In MCS, most denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in MCS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit of service using claim lines paid in the same quarter for the same HCPCS code and other matching characteristics, including the claims processing contractor, locality, place of service, and pricing modifier.[119] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *VMS:* In VMS, most MUE denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in VMS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit using paid claim lines with the same HCPCS code and other matching characteristics, including the ZIP code, quarter, and equipment modifier categories (e.g., capped rentals, items requiring frequent servicing, new

[118] Because claims can be denied at the claim- and/or claim-line level in FISS, CMS considers MUE-denied claim lines in MUE savings *only if* there is no claim-level denial for a non-MUE reason.

[119] For a small number of HCPCS codes, there may not be a paid claim line in the calendar year corresponding to the current claim's DOS. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price, in the rare cases that the billed amount is less than the system-generated or average price.

or used equipment, etc.).[120] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *FISS:* Unlike MCS and VMS, FISS does not store the priced amount of denied claim lines; thus, CMS approximates the price for each MUE denial based on the applicable pricing mechanism.[121] CMS uses a combination of claim attributes to determine if the denied claim line would have been subject to 1) the Hospital OPPS, 2) reasonable cost payment, or 3) a fee schedule. CMS then calculates the price by replicating the specific pricing formula. If the claim line would have been subject to coinsurance, CMS removes the estimated beneficiary coinsurance from the replicated price. CMS does not count any savings from MUE denied claim lines that were packaged under OPPS, since such claim lines would not have received separate pricing or payment.

3. Accounting for Subsequent Payment

To determine savings, CMS accounts for providers who successfully appeal or resubmit previously denied services. First, CMS removes any savings from denied claim lines where the provider was subsequently paid for UOS above the MUE value, which may be due to medical necessity. Specifically, CMS does not count an MUE denial toward savings if the total paid UOS for claim lines with the same claim type code, HCPCS code, provider, beneficiary, and DOS as that denial exceed the MUE value. Second, CMS subtracts the allowed payment amount for any subsequently paid claim lines with UOS below the MUE value. Specifically, for claim lines with the same claim type code, HCPCS code, provider, beneficiary, and DOS and total paid UOS below the MUE value, CMS subtracts the allowed payment amount for the subsequently paid UOS from the priced amount for the earliest denial, up to that priced amount, to obtain the remaining savings. Subsequently paid claim lines include those that were processed on or after the date of the earliest denial. All amounts used in these steps have the estimated beneficiary coinsurance removed.

For a given MUE denied claim line, CMS reports savings in the fiscal year during which the DOS for that claim line occurred. The calculation of MUE savings uses claims data captured 90 days after the end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.

1.3 Ordering and Referring Edits

Savings:	The estimated amount Medicare FFS did not have to pay for all unique claim lines denied or rejected due to an O&R edit, accounting for any subsequently paid units of service.

[120] For a small number of HCPCS codes, there may not be paid claim lines with matching characteristics. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price, in the rare cases that the billed amount is less than the system-generated or average price.

[121] CMS uses the provider-billed amount to estimate the price in the following situations: 1) when pricing indicators are unavailable and 2) for claim lines priced under the fee schedule where the calculated amount using CMS's pricing methodology is greater than the billed amount.

Data Source: MCS, VMS, and FISS claims data in the IDR

Physicians or other eligible professionals must be enrolled in or validly opted out of the Medicare program to order or refer certain items or services for Medicare beneficiaries. In addition, only physicians and certain types of non-physician practitioners are eligible to order or refer such items or services for Medicare beneficiaries. CMS implemented O&R edits to validate Part B clinical laboratory and imaging, DMEPOS, and home health claims that require identification of the ordering/referring provider.[122] O&R edits prevent inappropriate payment for items or services when the ordering/referring provider: 1) does not have an approved Medicare enrollment record or a valid opt-out affidavit and a valid National Provider Identifier (NPI) or 2) is not eligible to order or refer items or services for Medicare beneficiaries.[123] Part B clinical laboratory and imaging, DMEPOS, and home health O&R edits are implemented in MCS, VMS, and FISS, respectively, before claims are sent to CWF.

If a claim or claim line does not pass the ordering/referring provider requirements, the O&R edit logic automatically denies or rejects the claim or claim line. This prevents payment to the billing provider, i.e., the provider who furnished the item or service based on the order or referral. CMS regularly updates a public ordering/referring data file containing the NPIs and names of physicians and eligible professionals who have approved Medicare enrollment records or valid opt-out affidavits on file and are of a type/specialty that is eligible to order and refer. Billing providers may reference this information to ensure that the physicians and eligible professionals from whom they accept orders and referrals meet Medicare's criteria.

After an O&R edit denial/rejection, a provider could resubmit the service with corrected information that makes the claim payable. Providers may also have the right to appeal O&R edit denials through the Medicare FFS appeals process.

CMS calculates savings attributable to O&R edits in three steps: 1) identifying O&R edit denials/rejections, 2) pricing these denials/rejections, and 3) accounting for subsequent payment of previously denied/rejected services.

1. Identifying O&R Edit Denials and Rejections

System logic in MCS and VMS automatically appends a specific reduction/audit or action code, respectively, to claim lines that fail an O&R edit. During processing, claim lines may be denied for multiple errors. CMS attributes savings to O&R edits only when an O&R edit code is the system's highest priority reason for denying or rejecting a claim line.

In FISS, CMS identifies O&R denials/rejections at the claim level to ensure appropriate attribution of savings. When a home health claim fails an O&R edit, system logic automatically appends a

[122] The term ordering/referring provider denotes the person who ordered, referred, or certified an item or service reported in a claim.

[123] CMS calculates savings from Phase 2 O&R edits, which were fully implemented in January 2014. See MLN Matters® article #SE1305 "Full Implementation of Edits on the Ordering/Referring Providers in Medicare Part B, DME and Part A Home Health Agency (HHA) Claims" for additional information. CMS also includes savings from a previously-implemented edit that identifies claims missing the required matching NPI for the ordering/referring provider.

specific reason code to the claim, indicating that the O&R edit was the reason for denying or rejecting the entire claim.

When a claim or claim line is denied or rejected, a provider might try to submit another claim for that service without additional or corrected information necessary to pass the edit logic, thus resulting in multiple denials/rejections for the same service, provider, beneficiary, and DOS. CMS only counts savings from the earliest processed O&R denial/rejection among matching claims or claim lines. In MCS and VMS, CMS considers matching claim lines as those that share the same HCPCS code, rendering provider, beneficiary, and DOS. In FISS, CMS considers matching claims as those that share the same claim type code, beneficiary, provider, and DOS (i.e., the start date of the home health episode of care).

2. Pricing O&R Edit Denials and Rejections

In order to quantify what Medicare did not have to pay for each denial/rejection, CMS uses pricing methodologies specific to each claims processing system:

- *MCS:* In MCS, most denied/rejected claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in MCS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit of service using claim lines paid in the same quarter for the same HCPCS code and other matching characteristics, including the claims processing contractor, locality, place of service, and pricing modifier.[124] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *VMS:* In VMS, few O&R edit denied/rejected claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in VMS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit using paid claim lines with the same HCPCS code and other matching characteristics, including the ZIP code, quarter, and equipment modifier categories (e.g., capped rentals, items requiring frequent servicing, new or used equipment, etc.).[125] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

[124] For a small number of HCPCS codes, there may not be a paid claim line in the calendar year corresponding to the current claim's DOS. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price, in the rare cases that the billed amount is less than the system-generated or average price.

[125] For a small number of HCPCS codes, there may not be paid claim lines with matching characteristics. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price, in the rare cases that the billed amount is less than the system-generated or average price.

- *FISS:* FISS does not store the priced amount of denied/rejected claims; thus, CMS approximates the price for each O&R denial/rejection by replicating the home health prospective payment system (PPS) pricing formula.

3. Accounting for Subsequent Payment

To determine savings, CMS accounts for providers who successfully appeal or resubmit previously denied/rejected services. Specifically, where there are any subsequently paid claims or claim lines for a previously denied/rejected service, CMS subtracts the allowed payment amount of those subsequently paid claims or claim lines from the priced amount of the earliest denial/rejection, up to that priced amount. Subsequently paid claim lines include those that were processed on or after the date of the earliest denial/rejection and that share the same attributes. In MCS and VMS, these attributes are the same HCPCS code, rendering provider, beneficiary, and DOS as the denial. In FISS, these attributes are the same claim type code, beneficiary, provider, and DOS as the denial. Amounts used in these steps have the estimated beneficiary coinsurance removed, when applicable.

For a given O&R denied or rejected claim or claim line, CMS reports savings in the fiscal year during which the DOS for that claim or claim line occurred. The calculation of O&R edits savings uses claims data captured 90 days after the end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.

1.4 Fraud Prevention System Edits

Savings:	The estimated amount Medicare FFS did not have to pay for all unique claim lines denied or rejected due to an FPS edit, accounting for any subsequently paid claim lines.
Data Source:	1) FPS and 2) CWF claims data

The FPS is capable of evaluating claims for episodes of care that span different service types or providers (e.g., inpatient care, outpatient and practitioner services, and DME) as well as those that span multiple visits over a period of time. Because of its integrated potential fraud identification capabilities, CMS implements both edits and analytical models in the FPS to address vulnerabilities for fraud, waste, and abuse on a national level. When a vulnerability is identified, CMS conducts a rigorous assessment to determine if an FPS edit is an appropriate and effective action against that vulnerability, or if other approaches, such as an FPS model[126] or provider education, are better suited for the issue. CMS continuously develops new FPS edits and updates existing edits.

FPS edits screen Medicare FFS claims prior to payment. FPS edits automatically reject or deny claim lines for non-covered, incorrectly coded, or inappropriately billed services not payable under Medicare policy. FPS edits occur after NCCI, prepayment, and local MAC edits but prior to some CWF edits. Providers have the right to appeal FPS edit denials through the Medicare FFS appeals

[126] FPS models look for aberrant billing patterns in post-payment claims data. When FPS models identify egregious, suspect, or aberrant activity, the system automatically generates and prioritizes leads for further review and investigation by UPICs.

process. Unlike for denials, providers may not appeal FPS rejections, but they are allowed to resubmit their claims with additional or corrected information.

When a claim line is denied or rejected, a provider might try to submit another claim for that service without additional or corrected information necessary to pass the edit logic, thus resulting in multiple denials for the same service, provider, beneficiary, and DOS. CMS only counts savings from the earliest, or unique, FPS denial or rejection of claim lines that share the same HCPCS code, provider, beneficiary, and DOS. For most denied or rejected claim lines, FPS automatically generates the price, i.e., the amount Medicare would have paid for that claim line. The pricing data fields are the Medicare payment amount for Part A claims and the provider reimbursement amount for Part B claims. Both amounts exclude the beneficiary cost share. A small number of claim lines do not have a priced amount and are not included in savings.

To estimate actual costs avoided, CMS subtracts any subsequently paid resubmissions from the priced amount of the earliest denial or rejection, up to that priced amount. Paid resubmissions include paid claim lines that were processed on or after the earliest denial or rejection and that share the same HCPCS code, provider, beneficiary, and DOS.

For a given FPS denied or rejected claim line, CMS reports savings in the fiscal year during which the claim line was processed. The calculation of FPS edits savings uses claims data captured 90 days after the end of the fiscal year to allow time for appeals.

1.5 Medicare Administrative Contractor Automated Medical Review Edits

Savings:	The estimated amount Medicare FFS did not have to pay for claims or claim lines denied by MAC automated medical review edits, accounting for subsequently paid claims or claim lines.
Data Source:	MCS, VMS, and FISS claims data in the IDR

The MACs serve as the primary operational contact between the Medicare FFS program and the health care providers enrolled in the program. CMS awards a geographic jurisdiction to each MAC to process and pay Medicare Part A and Part B medical claims[127] or DME claims. The MACs perform a variety of operational functions, but this document focuses on MAC activities in support of program integrity.

CMS works with each MAC to develop improper payment reduction strategies, based on vulnerabilities identified by the Comprehensive Error Rate Testing (CERT) program,[128] the Government Accountability Office (GAO), the Department of Health and Human Services Office of Inspector General (HHS-OIG), the Medicare FFS Recovery Audit Contractors (RACs), and other sources. The MACs' medical review efforts focus on reducing payment errors; thus, the MACs refer cases of potential fraud to UPICs. The MACs conduct most of their medical review activities

[127] CMS contracts with four of the A/B MACs to also process home health and hospice claims across the nation.

[128] Through the CERT program, CMS annually calculates the Medicare FFS improper payment rate by determining if claims in a statistically-valid random sample were properly paid under Medicare coverage, coding, and billing rules.

prior to payment using both automated and non-automated, or manual, methods (see Appendix B-1 Section 2.2 for non-automated medical reviews that occur prior to payment and Appendix B-1 Section 5.3 for post-payment medical reviews).

CMS generally considers medical review as automated when a payment decision is made at the system level with no manual intervention. The MACs develop and implement automated medical review edits in MCS, VMS, and FISS to automatically deny payment for non-covered, incorrectly coded, or inappropriately billed services. The MACs must base these automated denials on clear policy, such as a local coverage determination. Another type of automated medical review edit automatically denies claims or claim lines that had been suspended for non-automated review but the provider did not respond in a timely manner to an additional documentation request (ADR). Providers have the right to appeal MAC automated medical review edit denials through the Medicare FFS appeals process.

CMS calculates savings attributable to MAC automated medical review edit denials in three steps: 1) identifying MAC automated medical review edit denials, 2) pricing these denials, and 3) accounting for subsequent payment of previously denied services.

1. Identifying MAC Automated Medical Review Edit Denials

System logic in MCS and VMS automatically appends a specific Program Integrity Management Reporting (PIMR) activity code[129] to claim lines that fail an automated medical review edit. In MCS, CMS identifies automated medical review denials as those denied claim lines tagged with the MAC-specific automated PIMR activity code and a medical review suspense audit code indicated as the system's highest priority reason for denying the claim line. In VMS, CMS identifies automated medical review denials as those denied claim lines with a combination of the MAC-specific automated PIMR activity code and a medical review edit code in the automated range provided by each MAC.[130]

Unlike MCS and VMS, FISS reimburses services at either the claim (e.g., for Part A inpatient services) or claim line level (e.g., for outpatient services). Accordingly, CMS identifies MAC automated medical review denials as those denied claims or claim lines with a MAC-specific medical review code as the denial reason and a MAC-specific edit reason code or PIMR code indicative of automated review.[131] For services subject to claim-level reimbursement, CMS

[129] CMS previously maintained a PIMR system, which interfaced with the claims processing systems and provided system-generated reports of cost, savings, and workload data related to each MAC's medical review unit. Although CMS retired the PIMR system in 2012, it retained the PIMR data fields in the claims processing systems for the MACs' continued use.

[130] CMS does not currently have a comprehensive way to determine if a MAC medical review denial is the system's highest priority reason for denying the claim line in VMS. Partially to this end, CMS excludes from savings those claim lines denied as duplicates, since that is a higher priority reason over MAC medical review denials.

[131] The MACs annually provide CMS with lists of edit and denial reason codes used for medical review. CMS also includes the cross-contractor reason code 56900 (failure to comply with an ADR) as a MAC-specific code, when other claim attributes indicate a MAC reviewed the applicable claim/claim line. In some cases, MAC-denied claims/claim lines do not have an edit reason code or PIMR code to indicate automated or non-automated medical review. CMS counts these cases as automated medical review savings because MAC denials without an edit reason code most frequently have an automated PIMR code.

identifies denials at the claim level. For services subject to claim-line-level reimbursement, CMS identifies denials at either the claim[132] or claim line level.[133]

When a claim or claim line is denied, a provider might try to submit another claim for that service without additional or corrected information necessary to pass the edit logic, thus resulting in multiple denials for the same service, provider, beneficiary, and DOS. CMS only counts savings from the earliest processed medical review edit denial among matching claims or claim lines. In MCS and VMS, CMS considers matching claim lines as those that share the same HCPCS code, rendering provider, beneficiary, and DOS. In FISS, CMS considers matching claims as those that share the same claim type code, beneficiary, provider, and DOS or admission date, and it considers matching claim lines as those that share the same claim type code, beneficiary, provider, HCPCS code, and DOS.

2. Pricing MAC Automated Medical Review Edit Denials

In order to quantify what Medicare did not have to pay for each denial, CMS uses pricing methodologies specific to each claims processing system:

- *MCS:* In MCS, most MAC medical review denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in MCS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit of service using paid claim lines from the same quarter that share the same HCPCS code and other matching characteristics, including claims processing contractor, locality, place of service, and pricing modifier.[134] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *VMS:* In VMS, the majority of MAC medical review denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in VMS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit using paid claim lines with the same HCPCS code and other matching characteristics, including the ZIP code, quarter, and equipment modifier categories (e.g., capped rentals, items requiring frequent servicing, new or used equipment, etc.).[135] CMS

[132] For services reimbursed at the claim line level, if CMS identifies a MAC denial at the claim level, CMS excludes from savings any claim lines with non-MAC-specific denial reason codes.

[133] CMS considers MAC-denied claim lines in MAC medical review savings *only if* the claim-level denial reason code is 1) a MAC or UPIC-specific medical review code (and the claim status is paid or rejected), 2) missing, or 3) an administrative code indicating that all lines on the claim were individually denied or rejected by line-level edits.

[134] For a small number of HCPCS codes, there may not be a paid claim line in MCS in the calendar year corresponding to the current claim's DOS. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

[135] For a small number of HCPCS codes, there may not be a paid claim line in VMS with matching characteristics. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *FISS:* Unlike MCS and VMS, FISS does not store the priced amount of denied claims or claim lines; thus, CMS approximates the price for each automated medical review denial based on the applicable pricing mechanism.[136] CMS uses a combination of claim attributes to determine if the denied claim or claim line would have been subject to 1) a PPS, 2) reasonable cost payment, or 3) a fee schedule. CMS then calculates the price by replicating the specific pricing formula. If the claim or claim line would have been subject to coinsurance, CMS removes the estimated beneficiary coinsurance from the replicated price.

3. Accounting for Subsequent Payment

To determine savings, CMS accounts for providers who successfully appeal or resubmit previously denied services. Specifically, where there are any subsequently paid claims or claim lines for a previously denied service, CMS subtracts the allowed payment amount of those subsequently paid claims or claim lines from the priced amount of the earliest denial, up to that priced amount. Subsequently paid claims or claim lines include those that were processed on or after the date of the earliest denial and that share the same attributes. In MCS and VMS, these attributes are the same HCPCS code, rendering provider, beneficiary, and DOS as the denial. In FISS, claim-level attributes are the same claim type code, beneficiary, provider, and DOS or admission date as the denial, and the claim-line-level attributes are the same claim type code, beneficiary, provider, HCPCS code, and DOS as the denial. Amounts used in these steps have the estimated beneficiary coinsurance removed, when applicable.

For a given denied claim or claim line, CMS reports savings in the fiscal year during which the DOS or admission date for that claim or claim line occurred. The calculation of MAC automated medical review edit savings uses claims data captured 90 days after the end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.

1.6 Unified Program Integrity Contractor Automated Edits

Savings:	The estimated amount Medicare FFS did not have to pay for claims or claim lines denied by UPIC-initiated automated edits, accounting for subsequently paid claims or claim lines.
Data Source:	MCS, VMS, and FISS claims data in the IDR

The primary goal of UPICs is to identify cases of suspected fraud, waste, and abuse; develop cases thoroughly and in a timely manner; and take immediate action to ensure that Medicare funds are not inappropriately paid. UPICs have teams of investigators, data analysts, and medical reviewers to

[136] CMS was unable to replicate the price for a small number of claims and claim lines in FISS. For claim lines where CMS cannot determine the applicable fee schedule, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS excludes from savings claims or claim lines missing key information to replicate the applicable PPS or reasonable cost pricing formula.

perform program integrity functions for the Medicare FFS program and the Medicare-Medicaid Data Match Program. CMS has established geographic program integrity jurisdictions to cover the nation, and each UPIC operates in a specific jurisdiction. UPICs receive leads about potential fraud from several sources, including complaints, MACs, FPS, CMS, and HHS-OIG. UPICs also conduct their own proactive data analysis to look for aberrant billing patterns.

During investigations, UPICs may request and review medical records from providers; analyze data; conduct interviews with beneficiaries, providers, or other medical personnel; and conduct onsite visits to provider locations. Based on the findings and CMS's approval, UPICs initiate appropriate administrative actions, such as denying or suspending payment that should not be made to a provider due to reliable evidence of fraud or abuse.[137]

Automated edits are among the administrative actions a UPIC may initiate. A UPIC may request that the MAC within its jurisdiction implement automated edits[138] to address program integrity issues and prevent the loss of future Medicare funds. In most cases, the MACs must comply with UPICs' requests to install automated edits in the relevant local claims processing system. Depending on the issue, these UPIC-initiated edits may automatically deny payment for 1) non-covered, incorrectly coded, or inappropriately billed services, 2) services submitted by suspicious providers, or 3) certain types of services for beneficiaries identified as part of a fraud scheme. Another type of UPIC automated edit denies claim lines that had been suspended for non-automated review but the provider did not respond in a timely manner to an ADR. Providers have the right to appeal UPIC automated edit denials through the Medicare FFS appeals process.

CMS calculates savings attributable to UPIC automated edits in three steps: 1) identifying UPIC automated edit denials, 2) pricing these denials, and 3) accounting for subsequent payment of previously denied services.

1. Identifying UPIC Automated Edit Denials

System logic in MCS and VMS automatically appends a specific PIMR activity code to claim lines that fail an automated edit. In MCS, CMS identifies UPIC automated edit denials as those denied claim lines tagged with the UPIC-specific automated PIMR activity code and a medical review suspense audit code indicated as the system's highest priority reason for denying the claim line. In VMS, CMS generally identifies automated edit denials as those denied claim lines with the UPIC-specific automated PIMR activity code and a medical review edit code in the ranges allocated by each MAC for UPIC use.[139]

[137] The administrative actions that may result from UPIC investigations include automated edits, non-automated reviews (Appendix B-1 Section 2.3) provider enrollment revocations and deactivations (Appendix B-1 Section 3), payment suspensions, post-payment reviews (Appendix B-1 Section 5.6), and referrals to law enforcement (Appendix B-1 Section 9.1).

[138] Depending on the jurisdiction, a UPIC may install DME automated edits in VMS, the system that processes DME claims.

[139] CMS does not currently have a comprehensive way to determine if a UPIC denial is the system's highest priority reason for denying the claim line in VMS. Partially to this end, CMS excludes from savings those claim lines denied as duplicates, since that is a higher priority reason over UPIC automated edit denials.

Unlike MCS and VMS, FISS reimburses services at either the claim (e.g., for Part A inpatient services) or claim line level (e.g., for outpatient services). Accordingly, CMS identifies UPIC automated denials as those denied claims or claim lines with a UPIC-specific code as the denial reason and a UPIC-specific edit reason code or PIMR code indicative of automated review.[140] For services subject to claim-level reimbursement, CMS identifies denials at the claim level. For services subject to claim-line-level reimbursement, CMS identifies denials at either the claim[141] or claim line level.[142]

When a claim or claim line is denied, a provider might try to submit another claim for that service without additional or corrected information necessary to pass the edit logic, thus resulting in multiple denials for the same service, provider, beneficiary, and DOS. CMS only counts savings from the earliest processed automated edit denial among matching claims or claim lines. In MCS and VMS, CMS considers matching claim lines as those that share the same HCPCS code, rendering provider, beneficiary, and DOS. In FISS, CMS considers matching claims as those that share the same claim type code, beneficiary, provider, and DOS or admission date, and it considers matching claim lines as those that share the same claim type code, beneficiary, provider, HCPCS code, and DOS.

2. Pricing UPIC Automated Edit Denials

In order to quantify what Medicare did not have to pay for each denial, CMS uses pricing methodologies specific to each claims processing system:

- *MCS:* In MCS, most UPIC automated edit denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in MCS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit of service using paid claim lines from the same quarter that share the same HCPCS code and other matching characteristics, including claims processing contractor, locality, place of service, and pricing modifier.[143] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

[140] The MACs annually provide CMS with lists of edit and denial reason codes used for UPICs. CMS also includes the cross-contractor reason code 56900 (failure to comply with an ADR) as a UPIC-specific code, when other claim attributes indicate a UPIC reviewed the applicable claim/claim line. In some cases, UPIC-denied claims/claim lines do not have an edit reason code or PIMR code to indicate automated or non-automated review. CMS counts these cases as automated review savings.

[141] For services reimbursed at the claim line level, if CMS identifies a UPIC denial at the claim level, CMS excludes from savings any claim lines with non-UPIC-specific denial reason codes.

[142] CMS considers UPIC-denied claim lines in UPIC savings *only if* the claim-level denial reason code is 1) a UPIC-specific code (and the claim status is paid or rejected), 2) missing, or 3) an administrative code indicating that all lines on the claim were individually denied or rejected by line-level edits.

[143] For a small number of HCPCS codes, there may not be a paid claim line in MCS in the calendar year corresponding to the current claim's DOS. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

- *VMS:* In VMS, the majority of the UPIC automated edit denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in VMS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit using paid claim lines with the same HCPCS code and other matching characteristics, including the ZIP code, quarter, and equipment modifier categories (e.g., capped rentals, items requiring frequent servicing, new or used equipment, etc.).[144] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *FISS:* Unlike MCS and VMS, FISS does not store the priced amount of denied claims or claim lines; thus, CMS approximates the price for each automated denial based on the applicable pricing mechanism.[145] CMS uses a combination of claim attributes to determine if the denied claim or claim line would have been subject to 1) a PPS, 2) reasonable cost payment, or 3) a fee schedule. CMS then calculates the price by replicating the specific pricing formula. If the claim or claim line would have been subject to coinsurance, CMS removes the estimated beneficiary coinsurance from the replicated price.

3. Accounting for Subsequent Payment

To determine savings, CMS accounts for providers who successfully appeal or resubmit previously denied services. Specifically, where there are any subsequently paid claims or claim lines for a previously denied service, CMS subtracts the allowed payment amount of those subsequently paid claims or claim lines from the priced amount of the earliest denial, up to that priced amount. Subsequently paid claims or claim lines include those that were processed on or after the date of the earliest denial and that share the same attributes. In MCS and VMS, these attributes are the same HCPCS code, rendering provider, beneficiary, and DOS as the denial. In FISS, claim-level attributes are the same claim type code, beneficiary, provider, and DOS or admission date as the denial, and the claim-line-level attributes are the same claim type code, beneficiary, provider, HCPCS code, and DOS as the denial. Amounts used in these steps have the estimated beneficiary coinsurance removed, when applicable.

For a given denied claim or claim line, CMS reports savings in the fiscal year during which the DOS or admission date for that claim or claim line occurred. The calculation of UPIC automated edit savings uses claims data captured 90 days after the end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.

[144] For a small number of HCPCS codes, there may not be a paid claim line in VMS with matching characteristics. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

[145] CMS was unable to replicate the price for a small number of claims and claim lines in FISS. For claim lines where CMS cannot determine the applicable fee schedule, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS excludes from savings claims or claim lines missing key information to replicate the applicable PPS or reasonable cost pricing formula.

2 Prepayment Review Actions

Some claims may require manual examination before they are paid to ensure that providers complied with Medicare policy. This document uses the broad category of prepayment review actions to describe program integrity activities involving manual processing prior to an initial claim determination. CMS calculates prepayment review action savings from the following activities for Medicare FFS claims:

- Medicare Secondary Payer (MSP) Operations[146]
- MAC Non-Automated Medical Reviews
- UPIC Non-Automated Reviews

2.1 Medicare Secondary Payer Operations

Savings:	The amount Medicare FFS would have paid as the primary payer, minus Medicare's secondary payment (as applicable), for all instances of MSP records available during prepayment claims processing.
Data Source:	1) Contractor Reporting of Operational and Workload Data (CROWD) system and 2) CMS records of Workers' Compensation Medicare Set-Aside Agreements (WCMSAs)

MSP is the term used to describe the set of provisions governing primary payment responsibility when a beneficiary has other health insurance or coverage in addition to Medicare. Over the years, Congress has passed legislation that made Medicare the secondary payer to certain primary plans in an effort to shift costs from Medicare to the appropriate private sources of payment. If a beneficiary has Medicare and other health insurance or coverage that may be expected to pay for medical expenses, coordination of benefits rules determine which entity pays first, second, and so forth.

The types of other health insurance or coverage that may have primary payment responsibility for a beneficiary's claim include the following:

- Group health plan (GHP)[147]

[146] MSP operations involve the collection and identification of MSP occurrences and the application through automated edits and manual examination of claims.

[147] A GHP is a health insurance plan offered by an employer or other plan sponsor (e.g., union or employee health and welfare fund). A Medicare beneficiary may be eligible for GHP employee/family coverage if he/she or a spouse is currently working, or for continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Specific situations, including employer size and the beneficiary's status (e.g., age 65 or older, disabled, and/or end-stage renal disease), determine whether Medicare or the GHP has primary payment responsibility. Some Medicare beneficiaries have retiree GHP coverage through a former employer. For these beneficiaries, Medicare is always the primary payer, and the retiree GHP is the secondary payer.

- Liability insurance (including self-insurance)[148]
- No-fault insurance[149]
- Workers' compensation (WC)[150]

In situations when Medicare is not the primary payer, providers must bill the primary payer(s) before billing Medicare. If services are not covered in full by the primary payer(s), Medicare may make secondary payments for the services, as Medicare coverage allows. When a beneficiary does not have other health insurance or coverage for a claim, Medicare remains the primary payer.

CMS's MSP operations involve prevention of erroneous primary payments as well as recovery of mistaken or conditional payments made by Medicare (see Appendix B-1 sections 5.1 and 5.2 for additional information about recovery efforts). CMS collects information about Medicare beneficiaries' other health insurance or coverage through a variety of methods. These methods include mandatory reporting by other insurers regarding covered Medicare beneficiaries, beneficiary self-reporting of other coverage, and claims investigations. In addition, Medicare providers are obligated to ask Medicare beneficiaries about other coverage and submit that information with Medicare claims.

In order to prevent erroneous primary payments, CMS records MSP information for beneficiaries in the CWF, which is the system that maintains beneficiary claims history and entitlement information. Incoming claims are automatically checked against MSP records. System logic built into the CWF 1) allows Medicare to pay correctly when incoming claims are correctly billed to Medicare as a secondary payer and 2) enables the CWF to automatically deny or reject a claim that is erroneously billed to Medicare as the primary payer.

Some MSP-related claims may require manual intervention by the MACs. A claims examiner reviews the claim and information about other coverage. Depending on the findings regarding payment responsibility, the claim may be adjusted such that Medicare only makes a secondary payment, or the claim may be rejected or denied. The MACs then attribute costs avoided to the associated MSP records.[151]

Providers may appeal or resubmit a denied/rejected claim and provide additional information to support receiving payment. If the primary payer is not expected to promptly pay the claim, a provider may receive a conditional payment from Medicare (see Appendix B-1 Section 5.1). If the primary payer denies the claim or makes an exhausted benefits determination, a provider may bill Medicare and include documentation of the primary payer's denial or determination. Medicare may make a payment, as Medicare coverage allows.

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[148] Liability insurance may pay for medical expenses resulting from negligence, such as inappropriate action or inaction that causes injury. Examples of liability insurance types include automobile, uninsured/underinsured motorist, homeowners', product, and malpractice.

[149] No-fault insurance may pay for medical expenses resulting from injury in an accident, regardless of who is at fault for causing the accident. Examples of no-fault insurance types include automobile, homeowners', and commercial.

[150] WC refers to a law or plan requiring employers to cover employees who get sick or injured on the job.

[151] The MACs' MSP-related claims processing efforts are not currently included in the MSP program obligations in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs.

To determine savings, the amount Medicare would have paid as the primary payer is based on the Medicare fee schedule and Medicare coverage of items and services. What Medicare pays as the secondary payer is subtracted from this amount. In general, savings are reported in the fiscal year during which the dates of service or dates of discharge for the applicable claims occurred.[152] For WCMSAs,[153] the full amount set aside is reported in the fiscal year during which the agreement is set up. Because Medicare does not receive ongoing WC claims, yearly savings due to WCMSAs cannot be determined.

2.2 Medicare Administrative Contractor Non-Automated Medical Reviews

Savings:	The estimated amount Medicare FFS did not have to pay for claims or claim lines denied prior to payment by MAC non-automated medical reviews, accounting for subsequently paid claims or claim lines.
Data Source:	MCS, VMS, and FISS claims data in the IDR

In addition to automated medical review edits (see Appendix B-1 Section 1.5), the MACs conduct non-automated, or manual, medical reviews where there is risk for improper payment. In MCS, VMS, and FISS, the MACs implement non-automated medical review edits, which suspend all or part of a claim possessing the targeted criteria for review. The MACs may request additional documentation from providers (i.e., through an ADR), and specific time frames apply to providers' submission of documentation and the MACs' completion of reviews. Each MAC has a medical review staff of trained clinicians and claims analysts, who review claims and associated documentation in order to make coverage and payment determinations. Claim lines that are inconsistent with Medicare policy are denied payment or, in certain situations, are up- or down-coded for adjusted payment. The MACs also offer providers education to resolve errors and improve future accuracy.[154] Providers have the right to appeal MAC non-automated medical review denials through the Medicare FFS appeals process.

CMS calculates savings attributable to MAC non-automated medical review denials in three steps: 1) identifying MAC non-automated medical review denials, 2) pricing these denials, and 3) accounting for subsequent payment of previously denied services.

[152] For full details of the savings methodology, please see CMS Publication 100-05: Medicare Secondary Payer Manual, Chapter 5 - Contractor Prepayment Processing Requirements.

[153] A workers' compensation settlement may provide for funds to be set aside to pay for future medical and/or prescription drug expenses related to an injury, illness, or disease. A WCMSA may be set up for using these funds. Medicare will not pay for any medical expenses related to the injury, illness, or disease until all of the set-aside funds are used appropriately.

[154] Effective FY 2018, CMS implemented Targeted Probe and Educate (TPE), a national medical review strategy that focuses on providers who have the highest claim denial rates or who have billing practices that vary significantly from their peers. TPE involves up to three rounds of prepayment or post-payment claim review combined with individualized provider education. See Appendix B-1 Section 5.3 for information about MAC post-payment medical reviews.

1. Identifying MAC Non-Automated Medical Review Denials

In MCS and VMS, the MACs set up processes to append a characterizing PIMR activity code that captures the category of medical review edit that fired on a given claim line.[155] In MCS, CMS identifies non-automated medical review denials as those denied claim lines tagged with a MAC-specific non-automated review PIMR activity code and a medical review suspense audit code indicated as the system's highest priority reason for denying the claim line. In VMS, CMS generally identifies non-automated medical review denials as those denied claim lines with a combination of a MAC-specific non-automated review PIMR activity code and a medical review edit code in the non-automated ranges provided by each MAC.[156]

Unlike MCS and VMS, FISS reimburses services at either the claim (e.g., for Part A inpatient services) or claim line level (e.g., for outpatient services). Accordingly, CMS identifies MAC non-automated medical review denials as those denied claims or claim lines with a MAC-specific medical review code as the denial reason and a MAC-specific edit reason code or PIMR code indicative of non-automated medical review.[157] For services subject to claim-level reimbursement, CMS identifies denials at the claim level. For services subject to claim-line-level reimbursement, CMS identifies denials at either the claim[158] or claim line level.[159]

CMS only counts savings from the earliest processed medical review edit denial among matching claims or claim lines. In MCS and VMS, CMS considers matching claim lines as those that share the same HCPCS code, rendering provider, beneficiary, and DOS. In FISS, CMS considers matching claims as those that share the same claim type code, beneficiary, provider, and DOS or admission date, and it considers matching claim lines as those that share the same claim type code, beneficiary, provider, HCPCS code, and DOS.

2. Pricing MAC Non-Automated Medical Review Denials

In order to quantify what Medicare did not have to pay for each denial, CMS uses pricing methodologies specific to each claims processing system:

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[155] The MAC non-automated PIMR categories include manual routine review, prepayment complex manual review, and prepayment complex manual probe review.

[156] For VMS, CMS notes two methodological items related to attribution. First, for the rare cases where a claim line has a category mismatch between the PIMR activity code and the medical review edit code (e.g., an automated PIMR activity code and a medical review edit code in the non-automated range), CMS categorizes the denial based on the medical review edit code. Second, CMS does not currently have a comprehensive way to determine if a MAC medical review denial is the system's highest priority reason for denying the claim line. Partially to this end, CMS excludes from savings those claim lines denied as duplicates, since that is a higher priority reason over MAC medical review denials.

[157] The MACs annually provide CMS with lists of edit and denial reason codes used for medical review.

[158] For services reimbursed at the claim line level, if CMS identifies a MAC denial at the claim level, CMS excludes from savings any claim lines with non-MAC-specific denial reason codes.

[159] CMS considers MAC-denied claim lines in MAC medical review savings *only if* the claim-level denial reason code is 1) a MAC or UPIC-specific medical review code (and the claim status is paid or rejected), 2) missing, or 3) an administrative code indicating that all lines on the claim were individually denied or rejected by line-level edits.

- *MCS:* In MCS, most MAC medical review denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in MCS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit of service using paid claim lines from the same quarter that share the same HCPCS code and other matching characteristics, including claims processing contractor, locality, place of service, and pricing modifier.[160] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *VMS:* In VMS, the majority of MAC medical review denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in VMS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit using paid claim lines with the same HCPCS code and other matching characteristics, including the ZIP code, quarter, and equipment modifier categories (e.g., capped rentals, items requiring frequent servicing, new or used equipment, etc.).[161] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *FISS:* Unlike MCS and VMS, FISS does not store the priced amount of denied claims or claim lines; thus, CMS approximates the price for each non-automated medical review denial based on the applicable pricing mechanism.[162] CMS uses a combination of claim attributes to determine if the denied claim or claim line would have been subject to 1) a PPS, 2) reasonable cost payment, or 3) a fee schedule. CMS then calculates the price by replicating the specific pricing formula. If the claim or claim line would have been subject to coinsurance, CMS removes the estimated beneficiary coinsurance from the replicated price.

3. Accounting for Subsequent Payment

To determine savings, CMS accounts for providers who successfully appeal or resubmit previously denied services. Specifically, where there are any subsequently paid claims or claim lines for a previously denied service, CMS subtracts the allowed payment amount of those subsequently paid claims or claim lines from the priced amount of the earliest denial, up to that priced amount. Subsequently paid claims or claim lines include those that were processed on or after the date of the earliest denial and that share the same attributes. In MCS and VMS, these attributes are the same

[160] For a small number of HCPCS codes, there may not be a paid claim line in MCS in the calendar year corresponding to the current claim's DOS. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

[161] For a small number of HCPCS codes, there may not be a paid claim line in VMS with matching characteristics. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

[162] CMS was unable to replicate the price for a small number of claims and claim lines in FISS. For claim lines where CMS cannot determine the applicable fee schedule, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS excludes from savings claims or claim lines missing key information to replicate the applicable PPS or reasonable cost pricing formula.

HCPCS code, rendering provider, beneficiary, and DOS as the denial. In FISS, claim-level attributes are the same claim type code, beneficiary, provider, and DOS or admission date as the denial, and the claim-line-level attributes are the same claim type code, beneficiary, provider, HCPCS code, and DOS as the denial. Amounts used in these steps have the estimated beneficiary coinsurance removed, when applicable.

For a given denied claim or claim line, CMS reports savings in the fiscal year during which the DOS or admission date for that claim or claim line occurred. The calculation of MAC non-automated medical review savings uses claims data captured 90 days after the end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.

2.3 Unified Program Integrity Contractor Non-Automated Reviews

Savings:	The estimated amount Medicare FFS did not have to pay for claims or claim lines denied by UPIC non-automated reviews, accounting for subsequently paid claims or claim lines.
Data Source:	MCS, VMS, and FISS claims data in the IDR

In addition to automated edits (see Appendix B-1 Section 1.6), a UPIC may request that the MAC in their jurisdiction implement non-automated prepayment review edits in the local claims processing system[163] to identify and suspend claims for medical review prior to payment.

To initiate non-automated review, the MAC sends an ADR to the provider under review. In that notice, the provider is instructed to provide the necessary medical record documentation to the UPIC for further review. In accordance with CMS guidance, the provider must submit the necessary documentation to the UPIC within 45 calendar days or the claims are denied.[164] Once the documentation is received, the UPIC examines the medical records for compliance with Medicare policy while determining if there is evidence of fraud, waste, or abuse. When the medical documentation does not support the services billed by the provider, the UPIC denies or adjusts payment for the claims. Providers have the right to appeal UPIC non-automated review denials through the Medicare FFS appeals process.

CMS calculates savings attributable to UPIC non-automated review denials in three steps: 1) identifying UPIC non-automated review denials, 2) pricing these denials, and 3) accounting for subsequent payment of previously denied services.

1. Identifying UPIC Non-Automated Review Denials

[163] Depending on the jurisdiction, a UPIC may install DME prepayment review edits in VMS, the system that processes DME claims.

[164] CMS Publication 100-08: Medicare Program Integrity Manual, Chapter 3 – Verifying Potential Errors and Taking Corrective Actions, § 3.2.3.2 – Time Frames for Submission.

In MCS and VMS, the MACs set up processes to append a characterizing PIMR activity code that captures the category of medical review edit that fired on a given claim line.[165] In MCS, CMS identifies UPIC non-automated review denials as those denied claim lines tagged with a UPIC-specific non-automated review PIMR activity code and a medical review suspense audit code indicated as the system's highest priority reason for denying the claim line. In VMS, CMS identifies non-automated review denials as those denied claim lines with a UPIC-specific non-automated review PIMR activity code and a medical review edit code in the ranges allocated by each MAC for UPIC use.[166]

Unlike MCS and VMS, FISS reimburses services at either the claim (e.g., for Part A inpatient services) or claim line level (e.g., for outpatient services). Accordingly, CMS identifies UPIC non-automated review denials as those denied claims or claim lines with a UPIC-specific code as the denial reason and a UPIC-specific edit reason code or PIMR code indicative of non-automated review.[167] For services subject to claim-level reimbursement, CMS identifies denials at the claim level. For services subject to claim-line-level reimbursement, CMS identifies denials at either the claim[168] or claim line level.[169]

CMS only counts savings from the earliest processed non-automated review denial among matching claims or claim lines. In MCS and VMS, CMS considers matching claim lines as those that share the same HCPCS code, rendering provider, beneficiary, and DOS. In FISS, CMS considers matching claims as those that share the same claim type code, beneficiary, provider, and DOS or admission date, and it considers matching claim lines as those that share the same claim type code, beneficiary, provider, HCPCS code, and DOS.

2. Pricing UPIC Non-Automated Review Denials

In order to quantify what Medicare did not have to pay for each denial, CMS uses pricing methodologies specific to each claims processing system:

- *MCS:* In MCS, most UPIC non-automated review denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in MCS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit of service using paid claim lines from the same quarter that share the same HCPCS code and other matching characteristics, including claims processing contractor, locality,

[165] The program integrity contractor non-automated PIMR categories include manual routine review, prepayment complex probe review, prepayment complex provider-specific review, and prepayment complex manual review.

[166] CMS does not currently have a comprehensive way to determine if a UPIC non-automated review denial is the system's highest priority reason for denying the claim line in VMS. Partially to this end, CMS excludes from savings those claim lines denied as duplicates, since that is a higher priority reason over UPIC review denials.

[167] The MACs annually provide CMS with lists of edit and denial reason codes used for UPICs.

[168] For services reimbursed at the claim-line level, if CMS identifies a UPIC denial at the claim level, CMS excludes from savings any claim lines with non-UPIC-specific denial reason codes.

[169] CMS considers UPIC-denied claim lines in UPIC savings *only if* the claim-level denial reason code is 1) a UPIC-specific code (and the claim status is paid or rejected), 2) missing, or 3) an administrative code indicating that all lines on the claim were individually denied or rejected by line-level edits.

place of service, and pricing modifier.[170] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *VMS:* In VMS, most of UPIC non-automated review denied claim lines contain a system-generated price, specifically the Medicare-approved charge if the claim line had been payable. When a system-generated price for a claim line is unavailable in VMS, CMS approximates the price. Specifically, CMS calculates an average allowed payment amount per unit using paid claim lines with the same HCPCS code and other matching characteristics, including the ZIP code, quarter, and equipment modifier categories (e.g., capped rentals, items requiring frequent servicing, new or used equipment, etc.).[171] CMS multiplies the system-generated or average price by 80 percent to remove the beneficiary coinsurance and estimate what Medicare did not have to pay the provider.

- *FISS:* Unlike MCS and VMS, FISS does not store the priced amount of denied claims or claim lines; thus, CMS approximates the price for each non-automated review denial based on the applicable pricing mechanism.[172] CMS uses a combination of claim attributes to determine if the denied claim or claim line would have been subject to 1) a PPS, 2) reasonable cost payment, or 3) a fee schedule. CMS then calculates the price by replicating the specific pricing formula. If the claim or claim line would have been subject to coinsurance, CMS removes the estimated beneficiary coinsurance from the replicated price.

3. Accounting for Subsequent Payment

To determine savings, CMS accounts for providers who successfully appeal or resubmit previously denied services. Specifically, where there are any subsequently paid claims or claim lines for a previously denied service, CMS subtracts the allowed payment amount of those subsequently paid claims or claim lines from the priced amount of the earliest denial, up to that priced amount. Subsequently paid claims or claim lines include those that were processed on or after the date of the earliest denial and that share the same attributes. In MCS and VMS, these attributes are the same HCPCS code, rendering provider, beneficiary, and DOS as the denial. In FISS, claim-level attributes are the same claim type code, beneficiary, provider, and DOS or admission date as the denial, and the claim-line-level attributes are the same claim type code, beneficiary, provider, HCPCS code, and DOS as the denial. Amounts used in these steps have the estimated beneficiary coinsurance removed, when applicable.

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[170] For a small number of HCPCS codes, there may not be a paid claim line in MCS in the calendar year corresponding to the current claim's DOS. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

[171] For a small number of HCPCS codes, there may not be a paid claim line in VMS with matching characteristics. In such cases, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS also uses the provider-billed amount to estimate the price in the rare cases that the billed amount is less than the system-generated or average price.

[172] CMS was unable to replicate the price for a small number of claims and claim lines in FISS. For claim lines where CMS cannot determine the applicable fee schedule, CMS uses the provider-billed amount multiplied by 70 percent to estimate the price. CMS excludes from savings claims or claim lines missing key information to replicate the applicable PPS or reasonable cost pricing formula.

For a given denied claim or claim line, CMS reports savings in the fiscal year during which the DOS or admission date for that claim or claim line occurred. The calculation of UPIC non-automated review edit savings uses claims data captured 90 days after the end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.

3 Provider Enrollment Actions

Providers must enroll in the Medicare FFS program to be paid for covered services they furnish to Medicare beneficiaries. In order to enroll, providers must submit a paper CMS-855 enrollment application or a corresponding online application through the Provider Enrollment, Chain, and Ownership System (PECOS) and then undergo risk-based screening. If a prospective provider does not meet eligibility requirements, CMS denies enrollment. Once enrolled, providers are responsible for keeping their enrollment information (e.g., address, practice location, adverse legal actions, etc.) up-to-date. CMS may revoke or deactivate a currently enrolled provider's Medicare billing privileges if the provider's behavior triggers one or more of the 14 revocation reasons or three deactivation reasons.

A provider may have multiple enrollments (e.g., enrollments per state or specialty), and CMS's administrative actions occur at the individual enrollment level. Depending on the circumstances, CMS may deny, revoke, or deactivate one or more of a provider's enrollments. If CMS applies an administrative action to all of a provider's enrollments, the provider cannot bill Medicare. If CMS applies an administrative action to only a subset of a provider's enrollments, the provider can continue to bill Medicare through its remaining active enrollments, as appropriate.

CMS estimates savings in Medicare FFS due to provider revocations and deactivations. The methodology uses each revoked or deactivated provider's claims history to project avoided costs assuming a revoked or deactivated provider would have continued the same billing patterns.

3.1 Revocations

Savings:	The projected amount Medicare FFS did not pay fully revoked providers during each provider's re-enrollment bar, based on a weighted moving average of each provider's historically paid claims and adjusted to exclude estimated amounts from expected billing by active providers for like services as previously billed by revoked providers for the same beneficiaries.
Data Source:	1) PECOS, 2) Previous 18 months of CWF claims data for each revoked provider, and 3) Cost avoidance adjustment factor

CMS has 14 regulatory reasons upon which to revoke a provider's Medicare FFS billing privileges. Examples include non-compliance with Medicare enrollment requirements, certain felony convictions, submission of false or misleading application information, determination that the provider is non-operational, abuse of billing privileges, failure to comply with enrollment reporting requirements, and termination of Medicaid billing privileges. Depending on the revocation reason, CMS bars a provider from re-enrolling in Medicare for one to three years.

If the revocation reason is non-compliance with Medicare enrollment requirements, a provider may submit a corrective action plan (CAP) for CMS's consideration. If CMS approves the CAP, the provider's revocation is rescinded. If CMS denies the CAP, the provider cannot appeal that decision but may continue through the appeals process for the revocation determination.

For all revocation reasons, a provider may appeal a revocation determination by requesting reconsideration before a CMS hearing officer. The reconsideration is an independent review conducted by an officer not involved in the initial determination. If the provider is dissatisfied with the reconsideration decision, the provider may request a hearing before an HHS Administrative Law Judge (ALJ) within the Departmental Appeals Board (DAB). Thereafter, a provider may seek DAB review and then judicial review.

CMS calculates costs avoided for fully revoked providers at the professional identifier and provider type level.[173] As the professional identifier, CMS uses the NPI for individual providers and the Employer Identification Number (EIN) for provider organizations. CMS defines a full revocation as an NPI or EIN by provider type that has no approved enrollments and for which the latest action was a revocation within the fiscal year.[174] To calculate savings, CMS captures PECOS enrollment data and CWF claims data as of 90 days after the end of the fiscal year to allow time for revocation appeals as well as for claims submission, adjudication, and appeals/resubmission.

CMS estimates the amount that Medicare did not pay fully revoked providers in two steps: 1) projecting costs avoided and 2) accounting for billing picked up by active providers.

1. Projecting Costs Avoided

CMS projects what Medicare would have paid a fully revoked provider based on the earliest 12 months of claims history in the 18 months preceding the provider's full revocation date.[175] Using the paid claims in this 12-month period and placing higher weights on previous months of billing, CMS calculates the weighted moving average for each month of the revoked provider's re-enrollment bar to project the Medicare payments that provider would have received. The sum of the payment projections for each month represents the costs avoided for the revoked provider during the length of its re-enrollment bar.

2. Accounting for Billing Picked Up by Active Providers

CMS uses provider-type-specific adjustment factors to account for beneficiaries receiving care from other providers after their original provider is revoked. Each adjustment factor estimates the percentage of a revoked provider's previous billing not expected to be shifted to other active providers. Thus, an adjustment factor represents the proportion of projected costs avoided that CMS

[173] CMS uses the following provider types: Medicare Part B organization, Medicare Part B individual practitioner, DME supplier, home health agency, hospice, skilled nursing facility, and other Medicare Part A provider.

[174] In FY 2019, CMS implemented this updated definition of a fully revoked provider to better characterize revocation actions within fiscal year reporting periods.

[175] CMS uses the earliest 12 months in the 18 months preceding the provider's revocation date because a provider may change its billing practices closer to the revocation date, especially if the provider becomes aware of CMS conducting a review or investigation of its claims.

expects Medicare to realize as savings due to a revocation. To estimate savings due to fully revoking a provider, CMS multiplies the projected costs avoided for that provider by the appropriate provider-type-specific adjustment factor.

CMS developed the provider-type-specific adjustment factors by analyzing the change in service utilization by the beneficiaries of a historical sample of fully-revoked providers.[176] For each fully-revoked provider in the sample, CMS identified the beneficiaries and which services they received from that provider in the 180 days before the revocation became effective. CMS then calculated the following amounts:

- *Pre-revocation payments to the revoked provider*: Payments to the revoked provider for services rendered to the identified beneficiaries during the 180 days preceding the provider's revocation
- *Pre-revocation payments to all providers*: Payments to any provider, including the revoked provider, for the same types of services furnished to the beneficiaries identified above (i.e., those who appeared in the revoked provider's billing) during the 180 days preceding the revoked provider's revocation
- *Post-revocation payments to all providers*: Payments to any provider for the same types of services furnished to the same beneficiaries identified above during the 180 days following the revoked provider's revocation

For each provider type, CMS summed each of the amounts—i.e., the pre-revocation payments to a revoked provider, the pre-revocation payments to all providers, and the post-revocation payments to all providers—that it calculated for each fully-revoked provider in that provider type category. CMS then calculated each provider-type-specific adjustment factor as the following ratio:

$$\frac{(\sum Pre\text{-}revocation\ payments\ to\ all\ providers\ -\sum Post\text{-}revocation\ payments\ to\ all\ providers)}{\sum Pre\text{-}revocation\ payments\ to\ a\ revoked\ provider}$$

3.2 Deactivations

Savings:	The projected amount Medicare FFS did not pay fully deactivated providers during a 12-month period, based on a weighted moving average of each provider's historically paid claims and adjusted to exclude 1) estimated amounts from providers that may reactivate their enrollment within 12 months and 2) estimated amounts from expected billing by active providers for like services as previously billed by deactivated providers for the same beneficiaries.
Data Source:	1) PECOS, 2) Previous 12 months of CWF claims data for each deactivated provider, 3) Reactivation correction factor, and 4) Cost avoidance adjustment factor

[176] CMS's calculation of cost avoidance adjustment factors is based on methodology certified by HHS-OIG.

CMS has three regulatory reasons upon which to deactivate, or stop, a provider's billing privileges. These reasons are no submission of Medicare claims for 12 consecutive calendar months, failure to report a change in information (e.g., practice location, billing services, or ownership), and failure to respond to a CMS notice to submit or certify enrollment information.[177] Unlike revocations, deactivations have no re-enrollment bars. In most cases, a provider can reactivate its enrollment in Medicare at any time by submitting a new enrollment application or recertifying the information on file.

CMS calculates costs avoided for fully deactivated providers at the professional identifier and provider type level.[178] As the professional identifier, CMS uses the NPI for individual providers and the EIN for provider organizations. CMS defines a full deactivation as an NPI or EIN by provider type that has no approved enrollments and for which the latest action was a program-integrity-related deactivation within the fiscal year.[179] To calculate savings, CMS captures PECOS enrollment data and CWF claims data as of 90 days after end of the fiscal year to allow time for claims submission, adjudication, and appeals/resubmission.

CMS estimates the amount that Medicare did not pay fully deactivated providers in three steps: 1) projecting costs avoided, 2) accounting for reactivations within 12 months, and 3) accounting for billing picked up by active providers.

1. Projecting Costs Avoided

CMS projects what Medicare would have paid a fully deactivated provider based on the 12 months of claims history preceding the provider's full deactivation date. Using the paid claims in this period and placing higher weights on previous months of billing, CMS calculates the weighted moving average for each month in a future 12-month period to project the Medicare payments that provider would have received. The sum of the payment projections for each month represents the costs avoided for the deactivated provider during a 12-month period.

2. Accounting for Reactivations within 12 Months

Because deactivated providers can reactivate their enrollments at any time, CMS uses reactivation correction factors to more conservatively estimate savings. CMS calculates a reactivation correction factor specific to each deactivation reason, and each reactivation correction factor represents the proportion of the previous fiscal year's total deactivation savings attributed to providers who remained deactivated for 12 months or more. For a given fully deactivated provider, CMS multiplies the projected costs avoided for that provider by the appropriate reason-specific reactivation correction factor.

3. Accounting for Billing Picked Up by Active Providers

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[177] In addition to the three regulatory reasons, CMS may also deactivate providers for other reasons, e.g., due to death or voluntary withdrawal from Medicare. In determining savings, CMS excludes deactivation reasons that do not represent active intervention to promote program integrity.

[178] CMS uses the following provider types: Medicare Part B organization, Medicare Part B individual practitioner, DME supplier, home health agency, hospice, skilled nursing facility, and other Medicare Part A provider.

[179] In FY 2019, CMS implemented this updated definition of a fully deactivated provider to better characterize deactivation actions within fiscal year reporting periods.

CMS uses provider-type-specific adjustment factors to account for beneficiaries receiving care from other providers after their original provider is deactivated. Each adjustment factor estimates the percentage of a deactivated provider's previous billing not expected to be shifted to other active providers. Thus, an adjustment factor represents the proportion of projected costs avoided (after applying the reactivation correction factor) that CMS expects Medicare to realize as savings due to a deactivation. To estimate savings due to fully deactivating a provider, CMS multiplies the projected costs avoided (after applying the reactivation correction factor) for that provider by the appropriate provider-type-specific adjustment factor.

CMS developed the provider-type-specific adjustment factors by analyzing the change in service utilization by the beneficiaries of a historical sample of fully-deactivated providers.[180] For each fully-deactivated provider in the sample, CMS identified the beneficiaries and which services they received from that provider in the 180 days before the deactivation became effective. CMS then calculated the following amounts:

- *Pre-deactivation payments to the deactivated provider*: Payments to the deactivated provider for services rendered to the identified beneficiaries during the 180 days preceding the provider's deactivation
- *Pre-deactivation payments to all providers*: Payments to any provider, including the deactivated provider, for the same types of services furnished to the beneficiaries identified above (i.e., those who appeared in the deactivated provider's billing) during the 180 days preceding the deactivated provider's deactivation
- *Post-deactivation payments to all providers*: Payments to any provider for the same types of services furnished to the same beneficiaries identified above during the 180 days following the deactivated provider's deactivation

For each provider type, CMS summed each of the amounts—i.e., the pre-deactivation payments to a deactivated provider, the pre-deactivation payments to all providers, and the post-deactivation payments to all providers—that it calculated for each fully-deactivated provider in that provider type category. CMS then calculated each provider-type-specific adjustment factor as the following ratio:

$$\frac{(\sum Pre\text{-}deactivation\ payments\ to\ all\ providers - \sum Post\text{-}deactivation\ payments\ to\ all\ providers)}{\sum Pre\text{-}deactivation\ payments\ to\ a\ deactivated\ provider}$$

4 Other Actions

4.1 Payment Suspensions

Savings:	The projected amount Medicare FFS did not pay providers during payment suspension, based on a weighted moving average of each

[180] CMS's calculation of cost avoidance adjustment factors is based on methodology certified by HHS-OIG.

	provider's historically paid claims and adjusted to exclude the amount of billing adjudicated as payable during the projection period.
Data Source:	1) Unified Case Management (UCM) system, 2) PECOS, and 3) IDR claims data during the period of and 12 months prior to payment suspension for each provider

CMS has authority to suspend payment to a provider when there is reliable information that an overpayment exists, when payments to be made may not be correct, or when there is a credible allegation of fraud existing against a provider. When CMS approves a payment suspension, program integrity contractors (e.g., UPICs) coordinate with the MACs to implement a payment suspension edit to withhold, i.e., suspend, payment for allowable claims submitted during the period of payment suspension. CMS implements payment suspensions for six months and can approve extensions to the payment suspension period in six-month increments. Upon termination of the payment suspension, withheld funds are applied to any Medicare overpayment assessed on the provider.

CMS estimates costs avoided from payment suspensions at the level of the NPI and provider billing identifier, which is the CMS Certification Number (CCN) for Part A providers, the Provider Transaction Access Number (PTAN) for individual and organizational Part B providers, and the National Supplier Clearinghouse (NSC) number for DMEPOS suppliers.

CMS estimates the amount that Medicare did not pay providers on payment suspension in three steps: 1) projecting costs avoided, 2) accounting for billing adjudicated as payable during the projection period, and 3) accounting for revoked or deactivated providers. CMS includes a given provider in the savings calculation for the fiscal year in which CMS first implemented the provider's payment suspension. CMS captures claims data 90 days after the end of the fiscal year to allow time for claims submission and adjudication.

1. Projecting costs avoided

CMS projects what Medicare would have paid a provider on payment suspension based on the 12 months of claims history preceding the payment suspension effectuated date. Using the paid claims in this period, CMS calculates the weighted moving average for each month in a future six-month period to project the Medicare payments that provider would have received. The sum of the payment projections for each month represents the costs avoided for the provider during their six-month payment suspension period.

In the case that a provider's payment suspension is shorter than six months (e.g., the payment suspension has a termination date less than 180 days from effectuated date, or the provider is revoked or deactivated during the payment suspension), CMS adjusts the cost avoidance projection to reflect the length of payment suspension.

2. Accounting for billing adjudicated as payable during the projection period

To estimate savings, CMS subtracts the amount for claims processed during the payment suspension and adjudicated as payable from the cost avoidance projection, as this amount is either paid to the provider or used to settle any unpaid overpayment upon payment suspension termination. For providers whose payment suspension projection period is contained within the

fiscal year, CMS subtracts suspended payments from the cost avoidance projection. For providers placed on payment suspension late in the fiscal year and therefore for whom CMS does not have complete claims information, CMS projects the payable amount that would be suspended based on known claims adjudicated as payable during the payment suspension. CMS then subtracts this amount from the cost avoidance projection.

3. Accounting for revoked and deactivated providers

To avoid overlap with other metrics' projected savings, CMS excludes from payment suspension savings those providers revoked within three years or deactivated for a program integrity reason within one year prior to the payment suspension effectuated date.

If a provider was revoked or deactivated after CMS implemented a payment suspension, but prior to payment suspension termination (for those providers with a termination date within the fiscal year), CMS uses the date of revocation or deactivation as the termination date for the payment suspension, therefore only projecting costs avoided up to the point the provider was no longer approved to bill Medicare FFS.

4.2 Medicare Part D Reconciliation Data Reviews

CMS contracts with private health insurance companies and organizations to offer prescription drug benefits for Medicare beneficiaries who choose to enroll in Part D. Beneficiaries may join a stand-alone prescription drug plan (PDP) or a Medicare Advantage (MA) plan with prescription drug coverage. All Part D plans are required to provide a minimum set of prescription drug benefits, and Medicare subsidizes these basic benefits using four legislated payment mechanisms: direct subsidy, low-income subsidies, reinsurance subsidy, and risk corridors.

A plan receives monthly prospective payments from CMS for the direct subsidy, the low-income cost-sharing subsidy, and the reinsurance subsidy. During benefit-year-end reconciliation, CMS compares its prospective payments to a plan with the plan's actual cost data, submitted through prescription drug event (PDE) records[181] and direct and indirect remuneration (DIR)[182] reporting, to settle any residual payments required between CMS and the plan sponsor. CMS also determines any risk corridor payment.

CMS validates both PDE and DIR data in advance of reconciliation and quantifies savings for each initiative, described in the following sections. In the FY 2019 Report to Congress on the Medicare and Medicaid Integrity Programs, *Table 3: Medicare Savings* provides the sum of savings from both the PDE data quality review and DIR data review initiatives.

Prescription Drug Event Data Quality Review

[181] Every time a beneficiary fills a prescription under a Part D plan, the plan sponsor must submit a PDE summary record to CMS. A PDE record contains information about the beneficiary, prescriber, pharmacy, dispensed drug, drug cost, and payment.

[182] DIR is any price concession or arrangement that serves to decrease the costs incurred by a Part D sponsor for a drug. Examples of DIR include discounts, rebates, coupons, and free goods contingent on a purchase agreement offered to some or all purchasers, such as manufacturers, pharmacies, and enrollees. Some DIR, namely POS price concession, is already reflected in the drug price reported on the PDE. Plans must report other types of DIR annually to CMS.

Savings:	The sum of the differences in gross covered drug costs between the initial and corrected versions of PDEs flagged during pre-reconciliation data quality review and subsequently adjusted or deleted by Part D plan sponsors.
Data Source:	PDE records from the IDR, which are flagged and tracked by the data analysis contractor

During the benefit year, CMS conducts data analysis and validation of PDE records to flag data quality issues for Part D sponsors' review and action. This pre-reconciliation data quality review initiative promotes accuracy in the plan-reported financial data used in the Part D year-end payment reconciliation process. CMS's Part D data analysis contractor receives a weekly data stream from the Drug Data Processing System (DDPS)[183] and analyzes PDE records for outliers or potential errors in the following categories:

- Total gross drug cost
- Per-unit drug price
- Quantity/daily dosage
- Duplicate PDEs[184]
- MSP issues
- Covered plan-paid and low income cost-sharing amounts in the catastrophic coverage phase of the benefit

The Part D data analysis contractor posts reports of flagged PDEs to a PDE analysis website shared with Part D plan sponsors. Sponsors have specified time frames to review, investigate, and act on the reports by a) providing a written response explaining the validity of a PDE or b) adjusting or deleting a PDE accordingly if the PDE is invalid.[185] The Part D data analysis contractor stops reviewing and flagging PDEs for a given benefit year when CMS finalizes payment reconciliation, typically in September following the benefit year.

Among the PDEs flagged during pre-reconciliation data quality review, CMS quantifies savings by summing the differences in gross covered drug costs between the initial and corrected versions of PDEs adjusted or deleted by plan sponsors. This metric represents the reduction in drug costs included in the payment reconciliation process.[186] The calculation of data quality review savings

[183] Before CMS conducts data quality reviews, PDE records are subject to edits in both the Prescription Drug Front-End System and the DDPS.

[184] CMS's data analysis contractor looks for potential duplicate PDEs for the same beneficiary, DOS, and drug, where the PDEs have different values in one or more of other key claim identifiers and thus were not rejected by edits immediately upon submission.

[185] A PDE adjustment is made to the original PDE record, and the record is marked with an "adjustment" indicator. When a PDE record is deleted, the record is marked with a "deletion" indicator. Deleted PDEs are retained as records in the data system but are excluded from the reconciliation process.

[186] The impact of pre-reconciliation data quality review is not currently assessed through a comparative reconciliation simulation; thus, this metric represents aggregate savings potentially realized by Medicare, plans, and beneficiaries, depending on the circumstances.

typically uses benefit-year data captured in September following the benefit year.[187] For a given benefit year, CMS reports savings in the fiscal year during which it conducts that benefit year's reconciliation payment adjustments with plan sponsors.

Direct and Indirect Remuneration Data Review

Savings:	The sum of the differences in Medicare's reinsurance and risk corridor shares, comparing a reconciliation simulation using the initially-submitted DIR with the actual reconciliation using the reviewed and finalized DIR for each plan.
Data Source:	1) DIR data reported by Part D plan sponsors in the Health Plan Management System (HPMS) and 2) Part D Payment Reconciliation System

Part D plan sponsors submit benefit-year DIR reports through CMS's HPMS. The summary DIR report contains data at the plan benefit package level. If a sponsor received DIR at the sponsor or contract level, it must apply one of CMS's reasonable allocation methodologies to allocate DIR to the plan benefit package level.[188] Sponsors must also include good faith estimates for DIR that is expected for the applicable contract year but has not yet been received.

As part of the year-end reconciliation process, CMS reviews the submitted DIR data for potential errors and discrepancies. If CMS identifies a possible issue, it prepares a review results package for the plan sponsor to access in HPMS. The sponsor is responsible for investigating the issue and making any necessary changes to its DIR report. The sponsor must provide an explanation with any resubmission of its DIR data.

CMS uses the reviewed and finalized DIR data in the year-end Part D payment reconciliation process for each plan, specifically to determine the reconciliation amounts for Medicare's reinsurance subsidy and risk corridor payment/recoupment. Holding all other data constant, CMS also runs a reconciliation simulation for each plan using the initially submitted DIR data to calculate what the reinsurance and risk corridor amounts would have been. For each type of payment, CMS subtracts the actual amount from the simulated amount.[189] CMS calculates savings from DIR review as the sum of these reinsurance and risk corridor differences across all plans.[190] For a given benefit year, CMS reports savings in the fiscal year during which it conducts that benefit year's reconciliation payment adjustments with plan sponsors.

[187] For PDE adjustments/deletions that occur between plan sponsors' data submission deadline for payment reconciliation (typically the end of June) and September, associated savings are realized in CMS's global reconciliation re-opening, which usually occurs four years after a given payment year.

[188] Part D plan sponsors must also report DIR at the 11-digit National Drug Code level, so that CMS can provide annual sales of branded prescription drugs to the Secretary of the Treasury to determine the fee amount to be paid by each manufacturer.

[189] For the reinsurance subsidy, CMS compares Medicare's simulated and actual amounts owed, i.e., 80 percent of the allowable reinsurance costs; thus, the comparison does not involve CMS's monthly prospective reinsurance payments.

[190] Program of All-Inclusive Care for the Elderly (PACE) plans are excluded from this analysis, because PACE plans typically do not receive rebates.

Recovered Savings

CMS calculates recovered savings attributable to program integrity activities in Medicare FFS, Medicare Advantage (i.e., Part C), and Medicare Part D. Recovered savings represent amounts that CMS took back or retained from providers, plan sponsors, or other insurers/entities due to Medicare payment policy and requirements. The following table lists CMS's recovery activities.

Recovery Activities	Medicare Program
Overpayment Recoveries	
MSP Operations	FFS
MSP Commercial Repayment Center (CRC)	FFS
MAC Post-Payment Medical Reviews	FFS
Medicare FFS Recovery Audit Contractor (RAC) Reviews	FFS
Supplemental Medical Review Contractor (SMRC) Reviews	FFS
UPIC Post-Payment Reviews	FFS
Overpayments from Retroactive Revocations	FFS
Overpayments Related to Risk Adjustment Data	Part C and Part D
Medicare Part D Plan Sponsor Audits	Part D
Medicare Part D RAC Reviews	Part D
Cost Report Payment Accuracy	
Provider Cost Report Reviews and Audits	FFS
Cost-Based Plan Audits	Cost-Based Plans
Plan Penalties	
Medicare Part C and Part D Program Audits	Part C and Part D
Medical Loss Ratio (MLR) Requirement	Part C and Part D
Other Actions	
Party Status Appeals	FFS
Law Enforcement Referrals	
UPIC Law Enforcement Referrals	FFS
I-MEDIC Part C and Part D Law Enforcement Referrals	Part C and Part D

5 Overpayment Recoveries

Given the volume of claims submitted to Medicare, CMS cannot review every claim prior to payment. Thus, CMS conducts a wide range of post-payment activities to identify improper payments and recover overpayments. An overpayment is any amount a provider or plan receives in excess of amounts properly payable under Medicare statutes and regulations. Overpayments are

considered debts owed to the federal government, and CMS has the authority to recover these amounts. CMS reports savings from the following overpayment[191] recovery activities:

- *Medicare FFS*
  - MSP Operations
  - MSP Commercial Repayment Center (CRC)
  - MAC Post-Payment Medical Reviews
  - Medicare FFS Recovery Audit Contractor (RAC) Reviews
  - Supplemental Medical Review Contractor (SMRC) Reviews
  - UPIC Post-Payment Reviews
  - Overpayments from Retroactive Revocations

- *Medicare Part C and Part D*
  - Overpayments Related to Risk Adjustment Data
  - Medicare Part D Plan Sponsor Audits
  - Medicare Part D RAC Reviews

5.1 Medicare Secondary Payer Operations

Savings:	The amount of conditional and mistaken payments Medicare FFS recovered from 1) providers, 2) beneficiaries who received settlements from other insurers/WC carriers, and 3) global settlements with liability insurers.
Data Source:	1) CROWD system and 2) CMS records of global settlements with liability insurers

CMS's MSP operations include the recovery of mistaken and conditional payments made by Medicare, when another payer has primary payment responsibility (see Appendix B-1 Section 2.1 for MSP background information). CMS reports recovered Medicare payments in the fiscal year during which they are collected.[192] Mistaken payments may occur if information about other coverage is unavailable or inaccurate at the time a claim is received. Medicare makes conditional payments for covered services on behalf of beneficiaries, when the primary payer is not expected to pay promptly for a claim. For example, Medicare may make a conditional payment in a contested compensation case, when there is a delay between the beneficiary's injury and the primary payer's determination or settlement. The purpose of conditional payments is to ensure continuity of care for Medicare beneficiaries and to avoid financial hardship on providers while awaiting decisions in disputed cases. CMS initiates recovery actions once information about primary coverage becomes available, either through new reporting or settlement of a case.

[191] For the purpose of this document, the overpayment recoveries category includes CMS's recovery of mistaken and conditional Medicare payments, when Medicare should not be the primary payer. This occurs through MSP operations and the MSP Commercial Repayment Center.

[192] For full details of the savings methodology, please see CMS Publication 100-05: Medicare Secondary Payer Manual, Chapter 5 - Contractor Prepayment Processing Requirements.

The Benefits Coordination & Recovery Center (BCRC) recovers Medicare payments from beneficiaries who have received a settlement, judgment, award, or other payment related to a liability, no-fault, or WC case. The BCRC sends the beneficiary and authorized representative (if applicable) a notice of the claims conditionally paid by Medicare. The beneficiary has the opportunity to provide proof disputing any of the claims and documentation of his/her reasonable procurement costs (e.g., attorney fees and expenses), which the BCRC takes into account when determining the repayment amount. The BCRC then issues a demand letter with the amount owed to Medicare. A beneficiary may appeal a demand letter and may also request a partial or full waiver of recovery. Otherwise, the beneficiary must reimburse CMS for the conditional payments. Outstanding debts are referred to the Department of the Treasury for further collection action.

The MACs conduct MSP-related recovery from providers.[193] Activities include identifying claims to be recovered, requesting and receiving repayment, and referring unresolved debts to the Department of the Treasury. Most of the MACs' recovery efforts occur through claims processing. The MACs conduct post-payment adjustments for claims that another insurer/entity should have paid in part or full. In cases of duplicate primary payment by Medicare and another insurer/entity—i.e., the provider received a primary payment from both Medicare and another insurer/entity for a given episode of care—the MACs recover Medicare's portion from the provider.

CMS also pursues global settlement of liability cases involving many Medicare beneficiaries. Examples of such cases include mass tort and class action lawsuits. The full amount of a global settlement is reported in the fiscal year during which it is awarded.

5.2 Medicare Secondary Payer Commercial Repayment Center

Savings:	The amount of mistaken and conditional payments Medicare FFS recovered in cases when GHPs had primary payment responsibility as well as in liability, no-fault, and WC cases when the insurer/WC carrier has ongoing responsibility for medicals (ORM).
Data Source:	CROWD system

The CRC is CMS's RAC responsible for MSP cases when an entity such as an insurer, employer, or WC carrier is the identified debtor (see Appendix B-1 sections 2.1 and 5.1 for additional information about MSP operations). The CRC recovers Medicare's mistaken primary payments from GHPs (typically from the employer, insurer, claims processing third-party administrator, or other plan sponsor) as well as conditional payments from applicable plans (liability insurers, no-fault insurers, or WC carriers) when the insurer/WC carrier has accepted ORM. CMS pays the CRC on a contingency fee basis, i.e., a percentage of the amount the identified debtor returned to Medicare.

For recovery of conditional payments from applicable plans, the CRC first issues the insurer/entity a notice of the claims conditionally paid by Medicare. The insurer/entity has the opportunity to

[193] The MACs' MSP-related recovery efforts are not currently included in the MSP program obligations in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs.

dispute the claims with supporting documentation. After making a determination about any disputes, the CRC issues a demand letter with the amount owed to Medicare. Applicable plans have the right to appeal all or a portion of the demand amount. For the recovery of mistaken payments from GHPs, the recovery process begins with the demand letter. The identified debtor must reimburse CMS for the identified claims listed in the demand letter. GHPs do not have formal appeal rights but may use the defense process to dispute the amount of the debt. Outstanding debts are referred to the Department of the Treasury for further collection action.

CMS reports recovered Medicare payments in the fiscal year during which they are collected.[194] CMS calculates the CRC savings as the sum of direct payments from debtors and delinquent debt collections from the Department of the Treasury, minus excess collections that were refunded.[195, 196]

5.3 Medicare Administrative Contractor Post-Payment Medical Reviews

Savings:	The amount of MAC-identified overpayments that Medicare FFS recovered, minus the amount that had been collected on MAC-identified overpayments overturned on appeal in the fiscal year.
Data Source:	1) Healthcare Integrated General Ledger Accounting System (HIGLAS) and 2) VMS

While the MACs primarily focus on preventing improper payments (see Appendix B-1 sections 1.5 and 2.2), they may also conduct some post-payment review of claims when there is the likelihood of a sustained or high level of payment error. When conducting a post-payment review, a MAC may request additional documentation from a provider. The provider must submit documentation within a specified time frame, though the MAC has the discretion to grant extensions. If a provider does not submit the requested documentation in a timely manner, the MAC denies the claims.

The MAC applies Medicare coverage and coding requirements to determine if the provider received improper payments and sends the provider a review results letter. The MAC then adjusts the associated claims in the appropriate shared claims processing systems in order to recoup overpayments or reimburse underpayments. In the case of an overpayment, the MAC creates an accounts receivable and issues the provider a demand letter requesting repayment of the specific amount. Providers have multiple payment options, such as directly sending CMS a payment-in-full, setting up an extended repayment schedule, or having the MAC offset future payments from CMS. Delinquent debts may be referred to the Department of the Treasury for further collection action.

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[194] For full details of the savings methodology, please see CMS Publication 100-05: Medicare Secondary Payer Manual, Chapter 5 - Contractor Prepayment Processing Requirements.

[195] Excess collections may occur if the Department of the Treasury offsets against a payment due to the debtor by another federal program at the same time that a debtor makes a direct payment to the CRC.

[196] CMS does not include interest collected as savings; however, interest may be included in net MSP CRC collections amounts provided in other reports (e.g., the Medicare Secondary Payer Commercial Repayment Center Report to Congress).

Providers have the right to appeal improper payment determinations through the Medicare FFS appeals process.

Overpayment recoveries are tracked in HIGLAS for Part A and Part B receivables and in VMS for DME receivables. CMS calculates savings as the sum of collections received for Part A, Part B, and DME receivables in the fiscal year during which the collection occurred.[197] Offsets or recoupments made on overpayments that are fully or partially overturned on appeal are removed from savings in the fiscal year during which the appeal is processed.

There may be instances when the MAC cannot collect on an identified overpayment. In those instances, the receivable is closed in HIGLAS or VMS, and CMS does not include the amounts in the savings metric.

5.4 Medicare Fee-for-Service Recovery Audit Contractor Reviews

Savings:	The amount of Medicare FFS RAC-identified overpayments that Medicare recovered, minus 1) the amount of Medicare FFS RAC-identified underpayments reimbursed to providers and 2) the amount that had been collected on Medicare FFS RAC-identified overpayments overturned on appeal in the fiscal year.
Data Source:	RAC Data Warehouse (RACDW)

CMS has multiple RACs that review post-payment Medicare FFS claims in defined geographic regions.[198] The Medicare FFS RACs' reviews focus on service-specific issues related to national and local Medicare policy. CMS approves all new issues for potential audits before the Medicare FFS RACs begin reviews. The Medicare FFS RACs may submit proposed review issues to CMS on a rolling basis. At times, CMS will also send the Medicare FFS RACs issues of potential improper payments identified by the MACs, UPICs, or external entities (e.g., HHS-OIG and GAO). Each Medicare FFS RAC has the option to accept or decline these issues for review. CMS can also require the RACs to conduct specific reviews.

The Medicare FFS RACs identify overpayments and underpayments through claims data analysis and review of medical records, which they can request through ADR letters. If a provider does not submit the requested documentation in a timely manner, the Medicare FFS RAC denies the claims. CMS imposes limits on the number of ADRs Medicare FFS RACs may send within in a specified time frame as well as for each provider based on each provider's improper payment rate for past claims. CMS also sets an initial limit on the number of reviews the Medicare FFS RACs may conduct under each approved issue. Once a Medicare FFS RAC has reached this limit, CMS reassesses the approved issue before allowing the Medicare FFS RAC to conduct additional reviews

[197] In FY 2019, CMS updated the MAC post-payment review savings methodology to use overpayment transaction data from HIGLAS and VMS, instead of using reports submitted by the MACs. Due to data limitations, CMS reports collections on MAC-identified overpayments demanded on or after October 1, 2018. It is possible that the MACs tag some non-MAC-medical-review overpayments with the medical review tag, which would inflate savings.

[198] One Medicare FFS RAC reviews national DME, home health, and hospice claims, and four Medicare FFS RACs review other types of claims in four geographic regions.

on the issue. In addition, the Medicare FFS RACs must assess each approved issue every six months to check for and report any necessary updates to CMS. Medicare FFS RACs are not allowed to identify improper payments more than three years after a claim was paid.

After conducting a review, the Medicare FFS RAC sends the provider a review results letter. The provider has a specified time frame to request a discussion with the Medicare FFS RAC regarding any identified improper payments. The discussion period offers the provider the opportunity to submit additional documentation to substantiate the claims and allows the Medicare FFS RAC to review the additional information without the provider having to file an appeal. If warranted, the Medicare FFS RAC can reverse an improper payment finding during the discussion period and not proceed with administrative action.

After the discussion period, the Medicare FFS RAC refers an identified improper payment to the MAC in the appropriate claims processing jurisdiction. The MAC then adjusts the associated claim(s) in order to recoup overpayments or reimburse underpayments. In the case of an overpayment, the MAC creates an accounts receivable and issues the provider a demand letter requesting repayment of the specific amount. Providers have multiple payment options, such as directly sending CMS a payment-in-full, setting up an extended repayment schedule, or having the MAC offset future payments from CMS. Providers who disagree with a Medicare FFS RAC's improper payment determination have the right to use the Medicare FFS appeals process.[199]

Both the Medicare FFS RACs and the MACs record information in the RACDW, as related to the claims review and transactional status of RAC-identified improper payments. The Medicare FFS RACs provide CMS with monthly reports of all amounts identified and demanded. The MACs provide CMS with data on all RAC-identified overpayments collected, and all underpayments reimbursed. There may be overpayments that a Medicare FFS RAC identified in a prior fiscal year for which collections occur in the current fiscal year. The MACs also record appeal outcome information in the RACDW. If an overpayment is fully or partially overturned on appeal, any offsets or recoupments that had been made are removed from savings in the fiscal year of the appeal decision. Thus, CMS calculates savings attributed to Medicare FFS RACs as the sum of Medicare FFS RAC-identified overpayment collections received from providers, minus 1) the sum of Medicare FFS RAC-identified underpayments reimbursed to providers and 2) the sum of collections that had been made on Medicare FFS RAC-identified overpayments overturned on appeal during the fiscal year.

5.5 Supplemental Medical Review Contractor Reviews

Savings:	The amount of SMRC-identified overpayments that Medicare FFS collected.
Data Source:	SMRC reports

[199] As required by Section 1893(h) of the Social Security Act, CMS pays Medicare FFS RACs on a contingency fee basis. A Medicare FFS RAC must return its contingency fee if an improper payment determination is overturned on appeal. CMS subtracts the amount of returned contingency fees from its program integrity obligations in the fiscal year during which a RAC returns the funds.

CMS contracts with the SMRC to perform nationwide provider compliance specialty medical reviews of post-payment Medicare FFS claims in order to identify improperly paid claims. CMS assigns medical review projects to the SMRC on an as-needed basis. The projects focus on issues identified by various sources, including but not limited to the following:

- Other federal agencies, such as HHS-OIG and GAO
- CERT program
- UPICs
- Professional organizations
- CMS internal data analysis

The SMRC identifies overpayments by evaluating claims data and the associated medical records for compliance with Medicare's coverage, coding, and billing requirements, as related to the assigned project. The SMRC requests the necessary documentation through letters sent to providers. The SMRC does not perform a review for any claim previously reviewed by another review contractor.

The SMRC communicates its medical review findings to a provider in a final review results letter. Providers have the option to request a discussion and education (D&E) period with the SMRC. The D&E period provides an opportunity for a provider to review nonpayment findings with the SMRC and for the SMRC to educate the provider in improving future billing practices. During this period, a provider may also submit additional information and/or documentation to support payment of the claim(s) initially identified for denial. The provider receives an updated findings letter detailing the outcome of the D&E session.

After the D&E period, the SMRC refers any identified overpayments to the MACs for collection purposes. Providers who disagree with the SMRC's improper payment determinations have the right to use the Medicare FFS appeals process. Providers have multiple payment options, such as directly sending CMS a payment-in-full, setting up an extended repayment schedule, or having the MAC offset future payments from CMS.

The SMRC provides CMS with quarterly data reports on project-specific amounts of collected overpayments. The MACs generate these reports for the SMRC based on data from HIGLAS, VMS, or the MACs' internal reporting systems. CMS reports savings from SMRC reviews in the fiscal year during which overpayment amounts are collected. Therefore, there may be overpayments identified by the SMRC in a prior fiscal year for which collections occur in a later fiscal year. CMS does not currently report adjustments for collected overpayment amounts that may be later overturned on appeal.

5.6 Unified Program Integrity Contractor Post-Payment Reviews

Savings:	The amount of UPIC-identified overpayments that Medicare FFS recovered, minus the amount that had been collected on UPIC-identified overpayments overturned on appeal in the fiscal year.
Data Source:	1) HIGLAS and 2) VMS

During the course of an investigation, a UPIC may conduct post-payment reviews of suspect claims to identify instances of fraud. When conducting a post-payment review, a UPIC requests additional documentation from a provider. The provider must submit documentation within a specified time frame, though a UPIC has the discretion to grant extensions.[200] If a provider does not submit the requested documentation in a timely manner, the UPIC denies the claims.

The UPIC's clinical team reviews the provider's submitted documentation to determine if the claims billed to Medicare were appropriate. If claims are denied or adjusted during the post-payment review, the UPIC calculates an overpayment in accordance with the Program Integrity Manual.

Once a post-payment review is complete, the UPIC provides the results of the medical review to the provider[201] and refers the overpayment to the MAC in its jurisdiction for recovery. The MAC then adjusts the Part A, Part B, or DME claims associated with the overpayment in the respective shared claims processing system, and the provider is issued a demand letter requesting repayment of the overpayment. Providers have multiple payment options, such as directly sending CMS a payment-in-full, setting up an extended repayment schedule, or having the MAC offset future payments from CMS. The MAC may also recover overpayments from an escrow account when CMS terminates a payment suspension. Delinquent debts may be referred to the Department of the Treasury for further collection action. Providers have the right to appeal improper payment determinations through the Medicare FFS appeals process.

Overpayment recoveries are tracked in HIGLAS for Part A and Part B receivables and in VMS for DME receivables. CMS calculates savings as the sum of collections received for Part A, Part B, and DME receivables in the fiscal year during which the collection occurred. Therefore, there may be overpayments identified by a UPIC (or a previous Medicare FFS program integrity contractor) in a prior fiscal year for which collections accrued in the current fiscal year. Offsets or recoupments made on overpayments that are fully or partially overturned on appeal are removed from savings in the fiscal year during which the appeal is processed.

There may be instances when the MAC cannot collect on a UPIC-identified overpayment. In those instances, the receivable is closed in HIGLAS or VMS, and CMS does not include the amounts in the savings metric. To ensure unique attribution of savings, this metric also excludes UPIC-identified overpayments that are not referred to the MAC for recovery, per the request of law enforcement (see Appendix B-1 Section 9.1).

5.7 Overpayments from Retroactive Revocations

Savings:	The amount of overpayments identified due to full, retroactive revocations, multiplied by a historical proportion that Medicare FFS expects to recover.

[200] CMS Publication 100-08: Medicare Program Integrity Manual, Chapter 3 – Verifying Potential Errors and Taking Corrective Actions, § 3.2.3.2 – Time Frames for Submission.

[201] Depending on the status of investigations, UPICs have discretion regarding whether to send a provider a review results letter.

Data Source:	1) PECOS, 2) CMS revocations log, and 3) CWF claims data

When a provider is revoked from Medicare, the effective date is 30 days from the mailing of the letter notifying the provider of the revocation, except for those revocation reasons applied retroactively as specified in regulation. For example, if an investigator determines that a provider's license is suspended, CMS sets the effective date of that provider's revocation as the date the license was suspended. CMS has the authority to recover payments made to an ineligible provider. As part of their standard operating procedures, the MACs attempt to recover overpayments when a provider is retroactively revoked.

Providers are afforded the same CAP and appeal opportunities (see Appendix B-1 Section 3.1), whether the revocation effective date is retroactive or not.

The MACs do not currently track overpayment recoveries specifically related to retroactive revocations; thus, CMS estimates savings as follows:

1. *Identify overpayments associated with full, retroactive revocations*: CMS sums the amounts paid to fully,[202] retroactively revoked providers for dates of service between the effective date and implementation date of the revocation. For a given full, retroactive revocation, CMS attributes estimated savings to the fiscal year in which the revocation was implemented.[203]
2. *Adjust for historical recovery experience*: To estimate actual recoveries, CMS multiplies the amount of identified overpayments by a proxy, provider-type-specific adjustment factor based on the MACs' historical recovery rate of overpayments identified by previous Medicare FFS program integrity contractors. Based on a historical sample, each provider-type-specific adjustment factor is the ratio of the total amount of overpayments recovered by the MAC to the total amount of overpayments referred by previous Medicare FFS program integrity contractors.[204]

5.8 Overpayments Related to Risk Adjustment Data

Savings:	The amount of overpayments that Medicare recovered from plan sponsors, due to the retrospective elimination of invalid diagnosis codes in risk-adjusted payments.
Data Source:	Medicare Advantage and Prescription Drug System

As required by the Social Security Act, MA organizations and Part D sponsors are required to report and return identified overpayments. CMS risk adjusts per capita payments to MA organizations, Part D plan sponsors, Program of All-Inclusive Care for the Elderly (PACE) organizations, and

[202] CMS defines a full, retroactive revocation at the professional identifier level where there is at least one revoked enrollment, no other approved enrollments, and no active billing privileges.

[203] This metric excludes retroactive revocations submitted by UPICs to prevent possible overlap with the UPIC post-payment reviews metric, which quantifies recoveries of UPIC-identified overpayments.

[204] In FY 2019, CMS calculated an updated set of provider-type-specific adjustment factors.

some demonstration plans. HHS believes that overpayment statute contributed to increased attention to data accuracy and more accurate payment information submissions. In FY 2019, plan sponsors self-reported and returned approximately $46.1 million in overpayments.

5.9 Medicare Part D Plan Sponsor Audits

Medicare Part D Plan Sponsor Audits include the following activities:

- National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC) Part D Data Analysis Projects
- Medicare Part D Plan Sponsor Self-Audits

In the FY 2019 Report to Congress on the Medicare and Medicaid Integrity Programs, *Table 3: Medicare Savings* provides the sum of savings from both initiatives.

National Benefit Integrity Medicare Drug Integrity Contractor Part D Data Analysis Projects

Savings:	The amount of overpayments that Medicare recovered from Part D plan sponsors, as related to NBI MEDIC data analysis projects.
Data Source:	NBI MEDIC data analysis report for each project

CMS contracts with the NBI MEDIC, a program integrity contractor that assists with detecting and preventing fraud, waste, and abuse in the Medicare Part D program. The NBI MEDIC conducts data analysis projects related to specific Part D vulnerabilities in order to identify inappropriate payments. Data sources used to conduct data analysis include PDEs, Medicare FFS claims, plan formularies, and drug prior authorization information.

The NBI MEDIC submits its findings of improper payments to CMS and, once approved, sends letters to the associated Part D plan sponsors. Each letter contains a summary of the analysis methodology and the PDE records identified as inappropriately paid. Part D plan sponsors are required to delete the inappropriately-paid PDE records, and the NBI MEDIC validates the deletion.

CMS reports data analysis project savings in the fiscal year during which plan sponsors delete the inappropriate PDE records.

Medicare Part D Plan Sponsor Self-Audits

Savings:	The amount of overpayments that Medicare recovered from Part D plan sponsors due to self-audits.
Data Source:	Self-audit attestations and close-out letters

CMS uses Medicare Part D plan sponsor self-audits to evaluate the appropriateness of questionable payments for Part D covered drugs identified through data analysis. CMS contracts with the NBI MEDIC to conduct data analysis that identifies high-risk areas for inappropriate Medicare Part D

payments and plan sponsors with potential overpayments for recovery. CMS provides notification to Part D plan sponsors to conduct a self-audit. Upon completion of the plan sponsor self-audit review, CMS and the NBI MEDIC validate whether plan sponsors have deleted the identified inappropriate PDE records. CMS reports self-audit savings in the fiscal year during which the PDE records are deleted.

5.10 Medicare Part D Recovery Audit Contractor Reviews

Savings:	The amount of Medicare Part D RAC-identified overpayments that Medicare recovered from Part D plan sponsors.
Data Source:	Plan payment adjustment forms

The Medicare Part D RAC[205] reviewed post-reconciliation PDE records to identify improper payments made under the Medicare Part D benefit.[206] CMS authorized the RAC to conduct audits of specific topics during particular plan years of interest. The Medicare Part D RAC could also propose new audit issues, which were subject to CMS's review and approval. Example audit topics included improper payments made to excluded providers[207] or unauthorized prescribers[208] and inappropriate refills of certain drugs regulated by the Drug Enforcement Administration under the Controlled Substances Act. The Medicare Part D RAC could only identify improper payments on PDE records within the four years prior to a plan sponsor's current plan year.

The Medicare Part D RAC conducted automated, algorithm-based reviews as well as complex reviews using additional documentation requested from the plan sponsor. In addition to PDE records, the Medicare Part D RAC could also use other data sources, such as CMS's Medicare Exclusion Database, HHS-OIG's List of Excluded Individuals and Entities, or the General Services Administration's System of Award Management. The Medicare Part D RAC referred cases of suspected fraud directly to the NBI MEDIC.

The Medicare Part D RAC's improper payment findings underwent an independent quality check by CMS's Data Validation Contractor and then had to receive approval from CMS. If the Medicare Part D RAC's findings were approved, the plan sponsor received a Notification of Improper Payment, which was determined by an improper payment calculation. Medicare Part D plan sponsors were given the opportunity to appeal improper payment determinations.

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[205] The Medicare Part D RAC contract ended on December 31, 2015. However, an administrative and appeals option period was exercised through December 2017 to allow the Medicare Part D RAC to complete outstanding audit issues that were initiated prior to the end of the contract period and receive payment.

[206] During FY 2019, Medicare Part D RAC activities included the appeals and recoupment process. The audits, validations, and Notification of Improper Payments issuance were all completed during FY 2016.

[207] Excluded providers are not allowed to receive payment from Medicare or other federal health care programs. HHS-OIG has multiple authorities under which to exclude providers, such as a convictions related to patient abuse, health care fraud, or the misuse of controlled substances.

[208] An unauthorized prescriber is a provider who orders drugs for Medicare beneficiaries despite not being allowed to do so. The provider types with prescribing authority may vary by state, but some provider types do not have the authority to prescribe in any state.

Inappropriately-paid PDE records had to be deleted by the Part D plan sponsor after the final appeal decision or within a specified time period if no appeal was filed. CMS recoups overpayments through offsets to Medicare's monthly prospective payments to plan sponsors and reports these amounts as savings in the fiscal year during which the offsets occur.

6 Cost Report Payment Accuracy

Institutional providers and cost-based plans must submit cost reports, which CMS reviews or audits to ensure accurate payments in accordance with Medicare regulations. CMS reports savings from the following cost report activities:

- Provider Cost Report Reviews and Audits
- Cost-Based Plan Audits

6.1 Provider Cost Report Reviews and Audits

Savings:	The difference between as-submitted or revised reimbursable cost requests submitted by providers and the settlement amounts, as determined through audits or desk reviews, for each cost item submitted in Medicare FFS provider cost reports.
Data Source:	System for Tracking for Audit and Reimbursement Reports 104 and 106, as entered by the MACs

CMS determines final payment to the majority of institutional providers through a cost report reconciliation process performed by the MACs. CMS quantifies savings from the settlement of the following Medicare costs:

- Pass-through costs for hospitals paid under a PPS[209]
- All costs for critical access hospitals reimbursed on a cost-basis
- All costs for cancer hospitals reimbursed under the Tax Equity and Fiscal Responsibility Act
- Bad debts[210] claimed by all provider types

A provider must file its annual cost report with its respective MAC either five months after the end of the provider's fiscal year or 30 days after the Provider Statistical and Reimbursement (PS&R)[211]

[209] Pass-through costs refer to amounts paid outside of the PPS. Examples of Medicare's pass-through payments to hospitals include amounts for DSH qualification, graduate medical education, indirect medical education, nursing and allied health, bad debt, and organ acquisition.

[210] Bad debt refers to Medicare deductibles and coinsurance amounts that are uncollectible from beneficiaries. In calculating reimbursement, CMS considers a provider's bad debt if it meets specific criteria.

[211] CMS's PS&R system accumulates statistical and reimbursement data for processed and finalized Medicare Part A paid claims. The system generates various summary reports used by providers to prepare Medicare cost reports and by the MACs during the audit and settlement process.

reports are available, whichever date is later.[212] The annual cost report contains provider information such as facility characteristics, utilization data, costs, charges by cost center (in total and for Medicare), accumulation of Medicare claims data (e.g., days, discharges, charges, deductible and coinsurance amounts, etc.), and financial statement data.

Each MAC conducts desk reviews of the cost reports submitted by providers in its jurisdiction to assess the data for completeness, accuracy, and reasonableness. The scope of a desk review depends on the provider type and whether the submitted cost report exceeds any thresholds set by CMS for specific review topics. If needed, the MAC may request additional documentation from a provider to resolve issues.

The MAC determines whether the cost report can be settled based on the desk review or whether an audit is necessary. A cost report audit involves examining the provider's financial transactions, accounts, and reports to assess compliance with Medicare laws and regulations. The audit may be conducted at the MAC's location (in-house audit) or at the provider's site (field audit). The MAC may limit the scope of an audit to selected parts of a provider's cost report and related financial records.

During the desk review or audit process, the MAC proposes adjustments made to the provider's submitted costs, so that the cost report complies with Medicare's regulations. The MAC notifies the provider of any adjustments, and the provider has a specified time frame to respond with any concerns.

Final settlement of a cost report involves the MAC issuing a Notice of Program Reimbursement (NPR) to the provider and submitting settled cost report data to CMS. The NPR explains any underpayments owed to the provider or overpayments owed to Medicare. In the case of an overpayment, the provider is required to send a check payable to Medicare, or the MAC recoups amounts by offsetting future payments to the provider. In the case of an underpayment, CMS issues a check to the provider or reduces any outstanding overpayment.

A provider may appeal disputed adjustments if the Medicare reimbursement amount in controversy is at least $1,000. An appeal request must be filed within 180 days of receiving the NPR. Appeals disputing amounts of at least $1,000 but less than $10,000 are filed with the MAC and the CMS Appeals Support Contractor. Appeals disputing amounts of $10,000 or more are filed with the Provider Reimbursement Review Board.

In addition, a final settled cost report may be reopened to correct errors, comply with updated policies, or reflect the settlement of a contested liability. A provider may submit a request for reopening, or the MAC may reopen a cost report based on its own motion or at the request of CMS. A reopening is allowed within three years of an original NPR or a revised NPR concerning the same issue for reopening.[213]

CMS determines savings from the settlement of provider cost reports by calculating the difference between reimbursable costs per the providers' initial or revised cost reports and the settlement

[212] Provider Reimbursement Manual, Part II (PRM-II), § 104. Exceptions to this due date for "no Medicare utilization" cost reports are addressed in PRM-II, § 110.A.

[213] In the case of fraud, the MAC can reopen a cost report at any time.

amounts resulting from audits or desk reviews. CMS reports savings in the fiscal year during which an NPR is issued. If a successful appeal results in a revised NPR, CMS reports adjustments to savings in the fiscal year the revised NPR is issued.

6.2 Cost-Based Plan Audits

Savings:	The difference between Medicare reimbursable costs claimed by cost-based plans on originally-filed cost reports and CMS-determined reimbursable amounts, accounting for settlement refunds determined through audit and amounts overturned on appeal.
Data Source:	CMS tracking of audit reports and originally-filed cost reports

CMS reimburses Medicare cost-based plans based on the reasonable costs incurred for delivering Medicare-covered services to enrollees.[214] Medicare cost-based plans include Health Maintenance Organizations (HMO) and Competitive Medical Plans operated under Section 1876 of the Act and Health Care Prepayment Plans (HCPPs) established under Section 1833 of the Act.

CMS pays cost-based plans in advance each month based on an interim per capita rate for each Medicare enrollee. At the end of the cost-reporting period, each plan must submit a final cost report, claiming certain Medicare reimbursement for that plan. Upon receipt of the cost report, CMS may conduct an independent audit to determine if the costs are reasonable and reimbursable in accordance with CMS regulations, guidelines, and Medicare managed care manual provisions. CMS documents adjustments made to the plan's submitted costs, so that the cost report complies with Medicare's principles of payment and determines Medicare reimbursable amounts.

Based on the reconciliation of the CMS-determined Medicare reimbursable amounts and interim payments to the plan, CMS issues the plan an NPR indicating a balance due to the plan or to CMS. If the plan owes money to CMS, the plan has 30 days to provide payment, otherwise, interest is due. If CMS owes money to the plan, reimbursement is provided in a subsequent monthly payment to the plan.

Plans may appeal cost report adjustments that are greater than $1,000. Plans have 180 days to submit a formal written appeal.

CMS determines savings from cost-based plan audits by calculating the difference between Medicare reimbursable amounts determined through cost report audits and reimbursable amounts claimed by cost-based plans.[215] CMS attributes savings to the fiscal year in which NPRs are processed. If a plan receives a settlement refund or favorable appeal decision, CMS subtracts the

[214] Some Medicare cost plans provide Part A and Part B coverage, while others provide only Part B coverage. Some cost plans also provide Part D coverage. An HCPP operates like a Medicare cost plan but exclusively enrolls Part B only beneficiaries and provides only Part B coverage.

[215] The cost-based plan audits metric quantifies savings as the truing-up of plan payments. Year-over-year savings may fluctuate depending on the number of audited plans, membership size, and contract years of plans subject to audit, plan adherence to payment regulations, settlement decisions, and other factors.

refund or amount overturned on appeal from savings in the fiscal year during which the settlement refund or appeal is processed.

7 Plan Penalties

CMS has the authority to take enforcement actions when MA organizations or Part D sponsors fail to comply with program requirements. CMS reports financial penalties collected from plan sponsors, due to the following:

- Medicare Part C and Part D Program Audits
- Medical Loss Ratio (MLR) Requirement

7.1 Medicare Part C and Part D Program Audits

Savings:	The sum of civil money penalty (CMP) amounts collected from MA organizations and Part D plan sponsors, due to compliance violations determined during program audits.
Data Source:	CMS enforcement action records

CMS conducts program audits of MA organizations, Part D plan sponsors, and organizations offering Medicare-Medicaid plans (MMPs), hereafter, collectively referred to as plan sponsors. Program audits evaluate plan sponsors' compliance with core program requirements and ability to provide enrollees with access to health care services and prescription drugs. A routine program audit covers all of a plan sponsor's MA, MA-Prescription Drug (MA-PD), PDP, and MMP contracts with CMS. CMS annually determines the plan sponsors to be audited. CMS relies on a number of factors when selecting plan sponsors for audit, including performance data collected by or reported to CMS, complaints, and other factors that could increase a sponsor's risk of non-compliance (e.g., significant increases in enrollment, a large number of changes to a sponsor's drug formulary for a new plan year, or switching to a new pharmacy benefit manager close to the beginning of a new plan year). Other factors that affect plan sponsor selection include audit referrals from CMS central and/or regional offices and time since last audit. CMS initiates audits of plan sponsors throughout the year.

A program audit evaluates plan sponsor compliance in the following program areas, as applicable to the plan sponsor's operations:

- Compliance Program Effectiveness
- Part D Formulary and Benefit Administration
- Part D Coverage Determinations, Appeals, and Grievances
- Part C Organization Determinations, Appeals, and Grievances
- Special Needs Plans Model of Care
- MMP Service Authorization Requests, Appeals, and Grievances
- MMP Care Coordination and Quality Improvement Program Effectiveness

If audits or other monitoring activities determine compliance violations that adversely affected or have the substantial likelihood of adversely affecting enrollees,[216] CMS has the authority to impose CMPs against plan sponsors. Other enforcement actions include intermediate sanctions (e.g., suspension of marketing, enrollment, or payment) and terminations. The number of violations and history of noncompliance are factored into the enforcement action taken. All enforcement actions may be appealed. CMP appeal requests must be filed no later than 60 days after receiving a CMP notice.

CMS calculates a CMP using standard penalty amounts multiplied by either the number of affected enrollees (per-enrollee basis) or the number of affected contracts (per-determination basis). After CMS calculates the standard penalty amount, it adds any aggravating factor penalty amounts, which are also calculated on a per-enrollee or per-determination basis. An example of an aggravating factor is a history of prior offense. CMPs are limited to maximum amounts per violation based on the enrollment size of the organization.

Plan sponsors have the option to pay CMPs by sending a check payable to CMS, wiring funds to the Department of the Treasury, or deducting from CMS's regular monthly payments to the plan sponsor. CMS reports program audits savings in the fiscal year during which CMP amounts are collected from plan sponsors. Thus, there may be CMPs issued in a previous fiscal year for which collections occur in the current fiscal year.

7.2 Medical Loss Ratio Requirement

Savings:	The sum of remittances recovered from MA organizations and Part D sponsors, where each remittance equals the revenue of the MA organization or Part D sponsor contract for the contract year (subject to certain deductions for taxes/fees) multiplied by the difference between 0.85 and the credibility-adjusted (if applicable) MLR for the contract year.
Data Source:	MA organizations' and Part D sponsors' annual reports provided to CMS

A MLR represents the percentage of revenue a health insurance issuer uses for patient care or activities that improve health care quality, rather than for overhead expenses. MA organizations and Part D sponsors must report the MLR for each contract they have with CMS. A contract must have a minimum MLR of at least 85 percent to avoid financial and other penalties. Contracts beginning

[216] Examples of compliance violations that result in enforcement actions include the following: 1) inappropriate delay or denial of beneficiary access to health services or medications, 2) incorrect premiums charged to or unnecessary costs incurred by beneficiaries, and 3) inaccurate or untimely information provided to beneficiaries about health and drug benefits.

in 2014 or later are subject to this statutory requirement.[217] The minimum MLR requirement is intended to create incentives for MA organizations and Part D sponsors to reduce overhead expenses, such as marketing, profits, salaries, administrative expenses, and agent commissions, in order to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans.

A MLR is calculated as the percentage of Medicare contract revenue spent on the following:

- Incurred claims for clinical services*
- Incurred claims for prescription drugs
- Quality improving activities
- Direct benefits to beneficiaries in the form of reduced Part B premiums*

**Not applicable to Part D stand-alone contracts.*

Revenue includes enrollee premiums and CMS payments to the MA organization or Part D sponsor for enrollees. Certain taxes, fees, and community benefit expenditures may be deducted from the revenue portion of the MLR calculation.

If a MA organization or Part D sponsor has a MLR for a contract year that is less than 85 percent, the MA organization or Part D sponsor owes a remittance to CMS. CMS deducts the remittance from the regular monthly plan payments to the MA organization or Part D sponsor. Further MLR-related sanctions on MA organizations and Part D sponsors include a prohibition on enrolling new members after three consecutive years and contract termination after five consecutive years of failing to meet the minimum MLR requirement.

In general, MA organizations and Part D sponsors are required to report a contract's MLR in December following the contract year, and any payment adjustments are implemented the following July. The reporting deadline is earlier in the year for contracts that fail to meet the MLR threshold for two or more consecutive years, so that CMS has time to implement, prior to the open enrollment period, an enrollment sanction for any contract that fails to meet the MLR threshold for three or more consecutive years and contract termination for any contract that fails to meet the MLR threshold for five consecutive years. Once reported and attested by an insurer and reviewed by CMS, a MLR is considered final and may not be appealed. Savings are reported in the fiscal year during which remittances are recovered.[218]

CMS applies credibility adjustments to the MLRs of contracts with relatively low enrollment. A credibility adjustment is a method to address the impact of claims variability on the experience of smaller contracts by adjusting the MLR upward. CMS defines the enrollment levels for credibility

[217] MLR requirements apply to all MA organizations and Part D sponsors offering Part C and/or D coverage, including the following: 1) MA organizations with contract(s) including MA-PD plans (all MA contracts must include at least one MA-PD plan; some contracts may also include MA-only plans); 2) Part D stand-alone contracts; 3) Employer Group Waiver Plans with contracts offering MA and/or Part D; 4) Part D portion of the benefits offered by Cost HMOs/Competitive Medical Plans and employers/unions offering HCPPs; and 5) Dual Eligible Special Needs Plans. MA organizations report one MLR for each contract with MA-PD plans, instead of one MLR for nondrug benefits and another for prescription drug benefits. As discussed in the May 23, 2013 Medicare MLR final rule (78 FR 31284, 31285), CMS has waived the MLR requirement for PACE organizations.

[218] MLR remittances are transferred to the General Fund of the Treasury.

adjustments separately for MA and Part D stand-alone contracts. A contract with enrollment at or between specified levels (i.e., a partially credible contract) may add a scaled credibility adjustment (between 1.0 percent and 8.4 percent) to its MLR. This adjusted MLR is used both to determine whether the 85 percent requirement has been met and to calculate the amount of any remittance owed to CMS. Contracts with enrollment levels above the full-credibility threshold do not receive a credibility adjustment. For contracts with enrollment below a specified level (i.e., non-credible contracts), MLR sanctions do not apply.

8 Other Actions

8.1 Party Status Appeals

Savings:	The sum of the estimated amounts in controversy related to Medicare FFS appeals, where a Qualified Independent Contractor (QIC) participated as a party in the Level 3 appeal, ALJ hearing, and the ALJ ruled to uphold the Level 2 decision or dismissed the case.
Data Source:	QIC party status reports supported by Medicare Appeals System (MAS) data

The Medicare FFS appeals process includes five levels:[219]

- *Level 1:* Redetermination by a MAC is a review of the claim and supporting documentation by an employee who did not take part in the initial claim determination.
- *Level 2:* Reconsideration by a QIC[220] is an independent review of the initial determination, including the MAC's redetermination. For decisions made as to whether an item or service is reasonable and necessary, a panel of physicians or other health care professionals conducts the review.
- *Level 3:* Hearing before an ALJ or a review of the administrative record by an attorney adjudicator within the HHS Office of Medicare Hearings and Appeals (OMHA).[221] The amount remaining in controversy must meet the threshold requirement for this appeal level.
- *Level 4:* Review by the Medicare Appeals Council within the HHS DAB.[222] There are no requirements regarding the amount remaining in controversy for this appeal level.
- *Level 5:* Judicial review in U.S. District Court. The amount remaining in controversy must meet the threshold requirement for this appeal level.

If an appellant disagrees with the decision made at one level of the process, they can file an appeal to the next level. Each level of appeal has statutory time frames for filing an appeal and issuing a decision. The entities adjudicating the respective appeal conduct a new, independent review of the

[219] Pursuant to statutory requirements, CMS begins recouping overpayment amounts after Level 2. If the appellant receives a favorable decision in a subsequent level of appeal, CMS reimburses the amount collected with interest.

[220] CMS currently contracts with two Part A QICs, two Part B QICs, and one DME QIC.

[221] OMHA is independent of CMS.

[222] The Medicare Appeals Council within the DAB is independent of CMS.

case at each level, and are not bound by the prior levels' findings and decision. The same appeal rights apply for claims denied on either a prepayment or post-payment basis.

In support of Medicare program integrity efforts, CMS funds QICs' participation as a party in ALJ hearings in accordance with party status appeals regulatory provisions in 42 CFR § 405.1012.[223] In addition to QICs' performance of Level 2 appeals, a QIC may elect to participate in Level 3 appeals, either as a non-party participant in the proceedings on a request for an ALJ hearing, a witness, or as a party to an ALJ hearing. As a non-party participant, a QIC may file position papers and/or submit written testimony to clarify factual or policy issues in a case.[224] As a witness, the QIC's activities are limited to supporting a party in responding to policy or factual issues related to a particular case. As a party to an ALJ hearing, a QIC can better defend the Level 2 decision by filing position papers, submitting evidence, providing testimony to clarify factual or policy issues, calling witnesses, or cross-examining the witnesses of other parties. The additional rights afforded to parties are extremely beneficial to the ALJ hearing and the QIC's ability to successfully defend a claim denial.

Each fiscal year, CMS determines the funding for and number of hearings in which the QICs are able to participate as a party. The QICs receive the ALJ Notices of Hearing and identify hearings in which they elect to participate as a party. Within ten days of a QIC receiving a hearing notice, a QIC must notify the ALJ, the appellant, and all other parties that it intends to participate as a party.[225] Generally, the QICs elect party status when there are significant amounts in controversy, national policy implications, or particular areas of interest for CMS.

When CMS uses program integrity funding for a QIC to participate as a party and the ALJ either fully upholds the prior decision or dismisses the case,[226] CMS considers the estimated amount in controversy for upheld and dismissed cases as savings.[227] Savings are based on the "item original amount" field from the MAS. For both prepayment denials and overpayment determinations, this field represents the billed amount submitted by the provider for claims or claim lines under appeal. CMS reports savings in the fiscal year during which the QIC receives notice of the ALJ or attorney adjudicator's ruling to uphold the prior decision or dismiss the case. CMS does not currently adjust reported savings if the appellant pursues further appeal rights and receives a favorable decision at Level 4 or Level 5.

[223] CMS or one of its contractors (e.g., a MAC, QIC, RAC, UPIC, etc.) may elect to participate as a party in ALJ appeals, except when an unrepresented beneficiary files the hearing request.

[224] The QICs may elect non-party participation in accordance with 42 CFR § 405.1010. Non-party participation is incorporated into the QICs' operational activities and is not part of this savings metric.

[225] If multiple entities, i.e., CMS and/or contractors, file an election to be a party to a hearing, the first entity to file its election is made a party to the hearing (42 CFR § 405.1010).

[226] A case is dismissed when the ALJ or attorney adjudicator determines that the appellant or appeal did not meet certain procedural requirements. Appellant withdrawals are also counted under case dismissals.

[227] Due to data system limitations, there may be overlap across fiscal years with other Medicare FFS savings metrics that quantify savings from prepayment denials and overpayment recoveries.

9 Law Enforcement Referrals

UPICs (see Appendix B-1 sections 1.6, 2.3, and 5.6) and the Investigations MEDIC (I-MEDIC)[228] identify and investigate cases of suspected fraud related to Medicare FFS and Medicare Part C and Part D, respectively. UPIC and I-MEDIC investigations may involve providers, beneficiaries, and/or other entities. Once a UPIC or the I-MEDIC has gathered evidence to substantiate allegations of suspected fraud, CMS requires the contractor to refer such cases to law enforcement (e.g., HHS-OIG DOJ) for consideration of civil or criminal prosecution.

In certain types of cases, UPICs and the I-MEDIC must make an immediate advisement to HHS-OIG without first conducting an investigation. For example, a UPIC or the I-MEDIC must immediately advise HHS-OIG upon receiving allegations of kickbacks or bribes. As another example, the I-MEDIC must immediately advise HHS-OIG of fraud allegations made by current or former employees of provider organizations, MA organizations, or Part D plan sponsors.

When a UPIC or the I-MEDIC refers a case to law enforcement for criminal or civil investigation, it reports the estimated value of the case to CMS, typically based on total paid amounts for the alleged fraudulent activities.[229] If law enforcement accepts the referral, the UPIC or the I-MEDIC remains available to assist and provide information at the request of law enforcement. When cases result in restitution, judgments, fines, and/or settlements, the DOJ routes Medicare recoveries to CMS or the plan sponsor. The following sections describe how CMS reports savings attributable to UPICs' and the I-MEDIC's law enforcement referrals.

9.1 Unified Program Integrity Contractor Law Enforcement Referrals

Savings:	The estimated amount Medicare expects to recover from UPIC-referred cases accepted by law enforcement, adjusted for historical recovery experience.
Data Source:	1) UCM system and 2) Law enforcement adjustment factor

CMS reports on the value of UPICs' referrals accepted by law enforcement during the fiscal year, regardless of when the case concludes. Because the timeline of case resolution varies, CMS estimates the amount Medicare expects to recover by multiplying the value of the referrals by a law enforcement adjustment factor. This factor reflects the historical ratio of court-ordered restitutions, judgments, fines, and settlements to amounts previously referred by Medicare FFS program integrity contractors.

[228] In January 2019, CMS split the work of the NBI MEDIC into two contracts. Under this new set of contracts, the I-MEDIC performs Medicare Part C and Part D investigations of prescribers, pharmacies, and beneficiaries, while the NBI MEDIC continues to conduct specific Part D data analysis projects to support plan sponsor oversight. FY 2019 estimated savings include law enforcement referrals made by the NBI MEDIC and the I-MEDIC.

[229] Effective July 30, 2019, CMS requires contractors to estimate the value of the case based on a three-year lookback paid amount for claims associated with the alleged fraudulent activities.

9.2 Investigations Medicare Drug Integrity Contractor Part C and Part D Law Enforcement Referrals

Savings:	The estimated amount Medicare expects to recover from I-MEDIC-referred Part C and Part D cases accepted by law enforcement, adjusted for historical recovery experience.
Data Source:	1) UCM system and 2) Part C/D law enforcement adjustment factors

CMS reports on the value of the I-MEDIC's Part C and Part D referrals accepted by law enforcement during the fiscal year, regardless of when the case concludes. Because the timeline of case resolution varies, CMS estimates the amount Medicare[230] expects to recover by multiplying the value of the referrals by a Part-C-specific, Part-D-specific, or combined Part C and Part D law enforcement adjustment factor depending on the nature of each case. Each factor reflects the historical ratio of court-ordered restitutions, judgments, fines, and settlements to the amounts referred by the previous NBI MEDIC.

[230] The court may order funds be returned to Medicare and/or plan sponsor(s).

Appendix B-2 – Medicaid and Children's Health Insurance Program Savings Methodology

Introduction

Medicaid and Children's Health Insurance Program (CHIP) costs are shared between states and the federal government. To receive federal Medicaid and CHIP funds, states provide an estimated budget of their prospective costs, and the federal government contributes a specific percentage of these costs as a grant to the state. CMS determines the federal contribution amount using the Federal Medical Assistance Percentage (FMAP).[231] States then submit actual expenditure reports,[232] which CMS uses to reconcile grant amounts. States are required to report their expenditures to CMS within 30 days of the end of each quarter and may adjust their past reporting for up to two years after an expenditure was made.[233]

States and CMS share accountability for Medicaid and CHIP program integrity and ensuring proper use of both federal and state dollars. As such, CMS and the states collaborate to combat improper payments through multiple strategies. In *Table 4: Medicaid and CHIP Savings* of the FY 2019 Report to Congress on the Medicare and Medicaid Integrity Programs, CMS quantifies the federal share of Medicaid and CHIP program integrity savings stemming from Medicaid and CHIP financial management and state-reported Medicaid overpayment recoveries due to collaborative federal-state programs and state-level initiatives. The following sections describe the methodologies used to determine these savings.

1 Medicaid and CHIP Financial Oversight

CMS financial management staff[234] engages in financial oversight to ensure that state expenditures claimed for federal matching under Medicaid and CHIP are programmatically reasonable, allowable, and allocable in accordance with federal laws, regulations, and policy guidance. Federal funds paid to the state are referred to as the Federal Financial Participation (FFP). States are required to submit Medicaid and CHIP budget and expenditure data through the Medicaid Budget and Expenditure System/CHIP Budget and Expenditure System (MBES/CBES), which applies the appropriate FMAP to each expenditure to determine the FFP. CMS reports Medicaid and CHIP financial management savings as improper FFP that was either 1) averted due to financial management staff intervention or 2) recovered following financial management staff review or assistance in response to and resolution of financial issues.

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[231] Congressional Research Service Report R43847, *Medicaid's Federal Medical Assistance Percentage (FMAP)*, by Alison Mitchell

[232] States submit quarterly expenditure reports on forms CMS-64 and CMS-21 for Medicaid and CHIP, respectively. The CMS-64 and CMS-21 are records of actual costs of running Medicaid and CHIP. States are responsible for maintaining supporting documentation for all reported expenditures.

[233] 42 CFR § 430.30

[234] CMS stations financial management staff, including accountants and financial analysts, at CMS regional offices, in states, and in the CMS central office.

1.1 Averted Medicaid and CHIP Federal Financial Participation

Savings:	The total amount of FFP for which states agree to voluntarily 1) enter a credit adjustment on their expenditure report, 2) retract from their expenditure report, or 3) make a prior period credit adjustment on the current or a future expenditure report.
Data Source:	CMS's Medicaid regional office averted FFP at-risk form

The CMS financial management staff works to ensure that states submit Medicaid and CHIP claims only for allowable expenditures. CMS uses the following activities to identify potentially improper, i.e., "at-risk," FFP:

- Review of quarterly expenditure reports
- Technical assistance to states on financial management issues

If at-risk FFP is identified prior to finalizing the quarterly expenditure report, the state may make a credit adjustment on their expenditure report for the amount in question or retract the claim associated with the at-risk FFP. If identified after finalizing the expenditure report, the state agrees in writing and makes a prior period credit adjustment,[235] which retroactively adjusts the claim in question and offsets the at-risk FFP for which the state already received reimbursement. Averted Medicaid and CHIP FFP represents the total dollar amount of at-risk FFP that was prevented or offset due to CMS financial management staff intervention and oversight during the fiscal year.

The CMS financial management staff submits the averted FFP at-risk form to their division management for validation. CMS only reports approved amounts in the total averted Medicaid and CHIP FFP.

1.2 Recovered Medicaid and CHIP Federal Financial Participation

Savings:	The total amount of at-risk FFP that the states returned to CMS as a result of CMS financial oversight activities.
Data Source:	CMS's financial performance spreadsheet

The CMS financial management staff identifies potential improperly paid FFP through:

- Quarterly expenditure report reviews
- Annual financial management reviews
- Department of Health and Human Services Office of Inspector General (HHS-OIG) audits

[235] States may adjust claims from prior quarters by either increasing or decreasing the amount of the claim, and therefore increasing or decreasing the FFP. These adjustments often reflect resolved disputes between CMS and the state or reclassifications of expenditures.

If CMS and the state cannot resolve the issue and the state does not agree to return the improperly paid FFP, CMS initiates a disallowance action requiring the state to return the FFP.[236]

States have the right to request administrative reconsideration and/or DAB review to appeal a disallowance action within 60 days of receiving a disallowance letter. CMS may recover the disallowance amount if, following the DAB appeal, a decision has been rendered in CMS's favor or if the state did not appeal the disallowance and the 60-day filing period for an appeal has lapsed. CMS counts a disallowance as recovered once the state returns the associated FFP to CMS.

The total recovered Medicaid and CHIP FFP includes all at-risk FFP that has been recouped or returned to CMS within the fiscal year; thus, some amounts may be associated with financial issues identified in prior fiscal years. The total recovered Medicaid and CHIP FFP does not include any amounts actively under appeal.[237]

2 State-Reported Medicaid Overpayment Recoveries

States report Medicaid overpayment recoveries made through collaborative federal-state programs and state-level initiatives, including 1) UPICs, 2) state Medicaid RACs, 3) HHS-OIG-compliant false claims acts, and 4) other state program integrity activities.

As states and the federal government share in the cost of Medicaid, so too do the states and federal government share in overpayment recoveries. States have one year to return the federal share of an identified overpayment;[238] thus, some of the recovered amounts reported in the current fiscal year may be related to amounts identified in the previous fiscal year.

2.1 Unified Program Integrity Contractor Recoveries

Savings: The total recovered federal share of Medicaid overpayments identified by UPICs.

Data Source: State Medicaid program integrity quarterly reports, specifically:

- Form CMS 64.9C1, Line 5
- Form CMS 64.9OFWA, Line 5

In collaboration with states, CMS's UPICs conduct post-payment investigations and audits of Medicaid providers throughout the country and report identified overpayments to the states for recovery. CMS and the states collaborate to select issues and providers for audits. Any Medicaid provider, including FFS providers, managed care entities, and managed care network providers,

[236] 42 CFR § 430.42

[237] If FFP is appealed beyond the HHS DAB, CMS does not include these amounts in the total recovered Medicaid and CHIP FFP, even when the ultimate ruling is in CMS's favor.

[238] States have one year from the date of discovery to return the full federal share of an identified overpayment, regardless of the amount the state succeeds in collecting from the associated provider(s) (42 CFR § 433.300-316). If a state is unable to collect an overpayment because the provider is bankrupt or out of business, the state is not required to refund the federal share (42 CFR § 433.318).

may be subject to audit. After the associated states and providers have the opportunity to comment on any identified overpayments, CMS sends the states the final audit reports/final findings reports documenting total overpayments for recovery. States are responsible for sending demand letters to the appropriate providers, collecting overpayments, and remitting the federal share to CMS. Providers may appeal the findings of a final audit report through their state's administrative process.

CMS reports the recovered federal share of Medicaid overpayments identified by UPICs in the fiscal year during which the recovery occurred. The recovered federal share includes 1) amounts collected by states within the one-year time limit and 2) amounts refunded by states in cases when a state was not able to fully collect an identified overpayment within the one-year time limit.

2.2 State Medicaid Recovery Audit Contractor Recoveries

Savings:	The total recovered federal share of Medicaid overpayments identified by state Medicaid RACs, after subtracting contingency fees.
Data Source:	State Medicaid program integrity quarterly reports, specifically Form CMS 64 Summary, Lines 9E and 10E

Unless CMS grants an exception, states must contract with one or more Medicaid RACs to identify and recover overpayments as well as identify underpayments made to Medicaid providers. States determine the operations and focus areas for Medicaid RAC audits. CMS requires states to have an appeals process for providers seeking review of Medicaid RAC findings.

CMS reports the recovered federal share of Medicaid overpayments identified by Medicaid RACs in the fiscal year during which the recovery occurred. The calculation of the recovered federal share includes 1) the federal share of amounts collected by states within the one-year time limit, plus 2) the federal share of amounts refunded by states in cases when a state was not able to fully collect an identified overpayment within the one-year time limit, less 3) the federal share of Medicaid RAC fees.[239] The recovered federal share includes any necessary adjustments to previously-reported federal share amounts. For example, credit may be due back to the state for overpayment amounts previously refunded to CMS due to the expiration of the one-year time limit, but where the provider was subsequently determined as bankrupt or out of business.

2.3 Office of Inspector General Compliant False Claims Act Recoveries

Savings:	The net federal share of Medicaid false or fraudulent payments recovered as a result of state action under an HHS-OIG-compliant false claims act, after subtracting the state financial incentive.
Data Source:	State Medicaid program integrity quarterly reports, specifically Form CMS 64 Summary, Line 9C2

[239] CMS contributes the federal share of Medicaid RAC fees in the same proportion as the FMAP, up to the highest contingency fee rate of Medicare RACs.

Many states have false claims acts that establish civil liability to the state for individuals and entities that knowingly submit false or fraudulent claims under the state Medicaid program. If a state obtains a recovery related to false or fraudulent Medicaid claims, the federal government is entitled to a share of the recovery, in the same proportion as the FMAP. To encourage states to pursue civil Medicaid fraud, Section 1909 of the Act includes a financial incentive for states if their false claims acts meet certain requirements.[240] HHS-OIG, in consultation with the U.S. Attorney General, determines if a state's false claims act qualifies for the incentive, which is a 10-percentage-point increase in a state's share of recovered amounts.

CMS reports the net federal share of Medicaid false or fraudulent payments recovered under states' HHS-OIG-compliant false claims acts in the fiscal year during which the recoveries occurred. A state's compliance is subject to review before CMS awards a state the financial incentive; thus, the financial incentive does not appear in Form CMS 64 Summary, Line 9C2. Instead, CMS gives states the financial incentive on a finalization grant award. To report savings, CMS conservatively estimates the net federal share of recovered Medicaid false or fraudulent payments by subtracting out the state financial incentive for all states that report in Form CMS 64 Summary, Line 9C2.

2.4 Other State Program Integrity Recoveries

Savings:	The total recovered federal share of Medicaid overpayments identified through other state-level program integrity activities.
Data Source:	State Medicaid program integrity quarterly reports, specifically: • Form CMS 64.9C1, Lines 1A, 1B, 1C, 2, 3, 4, 6, and 8 • Form CMS 64.9OFWA, Lines 1A, 1B, 1C, 2, 3, 4, 6, 8, and 9

The states undertake a variety of program integrity activities to identify and recover improper payments, including the following:

- Provider audits
- Medicaid Fraud Control Unit (MFCU) investigations[241]
- Data mining activities conducted by state Medicaid agencies as well as MFCUs
- Settlements and judgments
- Civil monetary penalties

CMS reports the recovered federal share of Medicaid overpayments identified through state-level program integrity activities in the fiscal year during which the recovery occurred. The recovered federal share includes 1) amounts collected by states within the one-year time limit and 2) amounts refunded by states in cases when a state was not able to fully collect an identified overpayment

[240] Refer to https://oig.hhs.gov/fraud/state-false-claims-act-reviews for more information on HHS-OIG's requirements for states to receive the financial incentive.

[241] Refer to https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu for more information on MFCUs.

within the one-year time limit. The recovered federal share includes any necessary adjustments to previously-reported federal share amounts.[242] For example, credit may be due back to the state for overpayment amounts previously refunded to CMS due to the expiration of the one-year time limit, but where the provider was subsequently determined as bankrupt or out of business.

[242] States report total adjustments, which could be related to UPIC and/or other state program integrity activities.

Appendix C – Acronyms and Abbreviations

Acronym	Description
ACO	Accountable Care Organization
ADR	Additional Documentation Request
AFR	[HHS] Agency Financial Report
ALJ	Administrative Law Judge
ANOC	Annual Notice of Change
APS	Advanced Provider Screening [system]
AREMAC	Analytic and Reporting Environment for Medicaid & CHIP
BCRC	Benefits Coordination & Recovery Center
CAP	Corrective Action Plan
CD	Compact Disc
CERT	Comprehensive Error Rate Testing
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CMP	Civil Money Penalty
CMS	Centers for Medicare & Medicaid Services
COB&R	Coordination of Benefits & Recovery
CPI	[CMS] Center for Program Integrity
CPT	Common Procedural Terminology
CRC	Commercial Repayment Center [Recovery Auditor]
CROWD	Contractor Reporting of Operational and Workload Data
CWF	Common Working File
DAB	Departmental Appeals Board
DDPS	Drug Data Processing System
DIR	Direct and Indirect Remuneration
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics and Supplies
DOJ	Department of Justice
DOS	Date of Service
DRA	Deficit Reduction Act of 2005
DSH	Disproportionate Share Hospital
EIN	Employee Identification Number

Acronym	Description
EOC	Evidence of Coverage
FCBC	Fingerprint-based Criminal Background Check
FFP	Federal Financial Participation
FFS	Fee-for-Service
FISS	Fiscal Intermediary Shared System
FMAP	Federal Medical Assistance Percentage
FPS	Fraud Prevention System
FY	Fiscal Year
GAO	Government Accountability Office
GHP	Group Health Plan
GPO	Group Purchasing Organization
HCFAC	Health Care Fraud and Abuse Control Program
HCPCS	Healthcare Common Procedural Coding System
HCPP	Health Care Prepayment Plan
HEAT	Healthcare Enforcement and Action Team
HFPP	Healthcare Fraud Prevention Partnership
HHA	Home Health Agency
HHS	Department of Health & Human Services
HIGLAS	Healthcare Integrated General Ledger Accounting System
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization
HPMS	Health Plan Management System
IDR	Integrated Data Repository
I-MEDIC	Investigations MEDIC
IPERA	Improper Payments Elimination and Recovery Act of 2010
IPERIA	Improper Payments Elimination and Recovery Improvement Act of 2012
IPIA	Improper Payments Information Act of 2002
MAC	Medicare Administrative Contractor
MACBIS	Medicaid and CHIP Business Information Solutions
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug

Acronym	Description
MAS	Medicare Appeals System
MCS	Multi-Carrier System
MDP	Medicaid Drug Program
MEDIC	Medicare Drug Integrity Contractor
Medi-Medi	Medicare-Medicaid Data Match
MFCU	Medicaid Fraud Control Unit
MII	Medicaid Integrity Institute
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MLN	Medicare Learning Network®
MLR	Medical Loss Ratio
MMIS	Medicaid Management Information System
MMSEA	Medicare, Medicaid and SCHIP Extension Act of 2007
MPEC	Medicaid Provider Enrollment Compendium
MSIS	Medicaid Statistical Information System
MSP	Medicare Secondary Payer
MUE	Medically Unlikely Edit
NBI	National Benefit Integrity
NCCI	National Correct Coding Initiative
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
NPR	Notice of Program Reimbursement
OEOCR	Office of Equal Employment Opportunity & Civil Rights
OIG	Office of Inspector General
OMHA	Office of Medicare Hearings and Appeals
One PI	One Program Integrity
OPPS	Outpatient Prospective Payment System
ORM	Ongoing Responsibility for Medicals
O&R	Ordering and Referring [Edit]
PACE	Program of All-Inclusive Care for the Elderly
Part C	Medicare Advantage Part C Program
Part D	Medicare Prescription Drug Program

Acronym	Description
PDE	Prescription Drug Event
PDP	Prescription Drug Plan
PECOS	Provider Enrollment, Chain and Ownership System
PERM	Payment Error Rate Measurement
PMD	Power Mobility Device
PPS	Prospective Payment System
PS&R	Provider Statistical and Reimbursement [System or Report]
PTP	Procedure-to-Procedure [Edit]
QIC	Qualified Independent Contractor
RAC	Recovery Audit Contractor
RADV	Risk Adjustment Data Validation
RAPS	Risk Adjustment Processing System
ROI	Return on Investment
SBJA	Small Business Jobs Act of 2010
SMA	State Medicaid Agency
SMART	Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012
SMRC	Supplemental Medical Review Contractor
SOW	Statement of Work
TDD	Telecommunication Device for the Deaf
T-MSIS	Transformed-Medicaid Statistical Information System
TTY	Text Telephone
UCM	Unified Case Management [system]
UOS	Unit of Service
UPIC	Unified Program Integrity Contractor
UPL	Upper Payment Limit
USC	United States Code
VMS	Viable Information Processing Systems (VIPS) Medicare System
WC	Workers' Compensation
WCMSA	Workers' Compensation Medicare Set-Aside Agreement

Appendix D - Statutes Referenced in this Report

Public	Title	Short Title
74-271	The Social Security Act	The Act
90-248	Social Security Amendments of 1967	
104-191	Health Insurance Portability and Accountability Act of 1996	HIPAA
107-300	Improper Payments Information Act of 2002	IPIA
108-173	Medicare Prescription Drug, Improvement, and Modernization Act of	MMA
109-171	Deficit Reduction Act of 2005	DRA
110-173	Medicare, Medicaid and SCHIP Extension Act of 2007	MMSEA
110-275	Medicare Improvements for Patients and Providers Act of 2008	MIPPA
111-148	Patient Protection and Affordable Care Act	
111-204	Improper Payments Elimination and Recovery Act of 2010	IPERA
111-240	Small Business Jobs Act of 2010	SBJA
111-3	Children's Health Insurance Program Reauthorization Act of 2009	CHIPRA
112-242	Medicare IVIG Access and Strengthening Medicare and Repaying	SMART Act
112-248	Improper Payments Elimination and Recovery Improvement Act of 2012	IPERIA
114-10	Medicare Access and CHIP Reauthorization Act of 2015	MACRA

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FACT SHEET

January 30, 2023

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Medicare Advantage Risk Adjustment Data Validation Final Rule
(CMS-4185-F2)
Fact Sheet

In a final rule released today, the Centers for Medicare & Medicaid Services (CMS) finalized technical details regarding the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) program that CMS uses to recover improper risk adjustment payments made to Medicare Advantage (MA) plans. The RADV final rule will help CMS to protect the MA program (also known as "Medicare Part C") by addressing instances where Medicare paid Medicare Advantage Organizations (MAOs) more than they otherwise should have received because the medical diagnoses submitted for risk adjustment payment were not supported in the beneficiary's medical record. Specifically, this final rule codifies in regulation that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018.

MA Payment and the Role of RADV Audits

CMS contracts with private companies, called Medicare Advantage Organizations (MAOs), to offer various health plan options for Medicare beneficiaries. These MAOs provide all Medicare Part A and Part B benefits (also known as "Traditional Medicare" or "Medicare Fee-For-Service" (FFS)), and most offer additional benefits, such as Medicare drug coverage, beyond those covered under the Medicare FFS program. Nearly 30 million individuals receive their Medicare benefits through MA. CMS has a statutory obligation and fiduciary duty to ensure payments in the Medicare program are accurate, including conducting oversight of payments made to MAOs. This approach is well-established among other CMS programs and ensures consistency in CMS' oversight of the Medicare FFS and MA programs.

Section 1853(a)(1)(C) of the Social Security Act (the Act) requires CMS to risk-adjust payments made to MAOs. CMS pays each MAO a monthly amount for each beneficiary enrolled in an MA plan, which is adjusted to account for differences in health status amongst enrolled beneficiaries. This adjustment is referred to as "risk adjustment." Risk-adjusted payments are based on medical diagnoses submitted by the MAOs that, by long-standing regulations, must be supported in the Medicare enrollees' medical records to ensure accurate payment. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MAOs based on the health status and demographic characteristics of their enrolled beneficiaries, and that MAOs are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to

incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs).

Making accurate payments to MAOs is part of CMS' responsibility to ensure accurate payments across the Medicare program and ensures continued access to benefits and services for people with Medicare while safeguarding federal taxpayer dollars. Studies and audits done separately by CMS and the HHS Office of Inspector General (OIG) have shown that medical records do not always support the diagnoses reported by MAOs, which leads to billions of dollars in overpayments and increased costs to the Medicare program. RADV audits are the main corrective action for those improper payments. Through RADV audits, a sample of beneficiary medical records are provided by MAOs, and CMS reviews those records to verify that diagnoses reported for risk adjusted payments are accurate and supported in the medical record. Risk adjustment discrepancies can be aggregated to determine an overall level of payment error, which can then be extrapolated. The HHS-OIG also undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions. CMS can collect the improper payments identified during those HHS-OIG audits, including the extrapolated amounts calculated by the HHS-OIG.

Final Rule Policies

Extrapolation

Rather than applying extrapolation beginning for payment year (PY) 2011 audits as we proposed, we are finalizing a policy not to extrapolate RADV audit findings for PYs 2011-2017 and beginning extrapolation with the PY 2018 RADV audit. As a result, CMS will only collect the non-extrapolated overpayments identified in the CMS RADV audits and OIG audits between PY 2011 and PY 2017. CMS is not adopting any specific sampling or extrapolation audit methodology but will rely on any statistically-valid method for sampling and extrapolation that is determined to be well-suited to a particular audit. However, any extrapolation methodology adopted by CMS for RADV audits will be focused on MAO contracts that, through statistical modeling and/or data analytics, are identified as being at the highest risk for improper payments. While not required, CMS will continue to disclose our extrapolation methodology to MAOs, providing MAOs with the information sufficient to understand the means by which CMS extrapolated the RADV payment error.

Extrapolation has historically been a normal part of auditing practice at CMS, including in FFS Medicare, and CMS interprets our existing authority as authorizing the use of sampling and extrapolation in RADV audits. It is also expected that the use of extrapolation will incentivize MAOs to take meaningful steps to reduce improper risk adjusted payments in the future.

FFS Adjuster

The rule also finalizes a policy, as proposed, that CMS will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits. As described in the final rule, and consistent with a recent D.C. Circuit Court decision in *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. August 13, 2021, reissued November 1, 2021), *cert. denied*, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140), the requirement for actuarial equivalence in MA payments applies to how CMS risk adjusts the payments it makes to MAOs and not to the obligation to return overpayments for unsupported diagnosis codes, including overpayments identified during a RADV audit. In addition, we do not believe that it is reasonable to read the Act as requiring a

reduction in payments to MAOs by a statutorily set minimum adjustment in the coding pattern adjustment, while at the same time prohibiting CMS from paying at those reduced rates by mandating a FFS Adjuster for RADV audits.

The RADV final rule can be accessed at the Federal Register at https://www.federalregister.gov/public-inspection/current

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Report to the Congress, Medicare payment policy.

Washington, D.C. : Medicare Payment Advisory Commission, [1998]-

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Report to the Congress: Medicare Payment Policy

Volume I: Recommendations

March 1998



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Acknowledgements

When the Medicare Payment Advisory Commission held its first meeting in October 1997, it seemed inconceivable that its first report could be ready in just four months. Drawing on the work of its predecessors, together with the energy and enthusiasm about this new venture, the March report is now a reality.

This feat would not have been possible without the support and contributions of many individuals, both in Washington and around the country. Staff of the Congress, the Health Care Financing Administration (particularly the Enterprise Databases Group) and other agencies of the Department of Health and Human Services, the Congressional Budget Office, the Congressional Research Service, and the General Accounting Office provided invaluable information and advice.

The Commission has been fortunate to work with people who have consistently understood and responded to its needs in key areas. Social and Scientific Systems— especially Arlene Turner, Valerie Aschenbach, Jeff McCartney, Rosanne Russillo, Daksha Damera, Paul Menick, Charles Thomson, and Deborah Johnson— have superbly met the challenges posed by the Commission's diverse programming needs. Lynn Lewis has helped the staff convey complex and technical concepts in an effective manner. Franek Design Associates, Inc. contributed by giving the Commission's report its own distinctive design and shepherding the report through the production process.

The Commission's work on vulnerable populations was greatly advanced by the expert panel convened by Mathematica Policy Research. Marsha Gold, Robert Hurley, and Jessica Mittler were instrumental in arranging the panel. Thanks go to Susan Aldrich, Allan Bergman, Irene Fraser, Sandra Harmon-Weiss, Carter Marshall, Robert Master, Glen Rosselli, Paul Saucier, Mervin Shalowitz, Steven Somers, Craig Thornton, Carol Tobias, James Verdier, and Edward Wagner for their participation on the panel.

Others who have put their mark on this report include David Colby, who served as deputy director until December 1997, and Don Young, who served as co-executive director through October 1997. Another former staff member, Karen Fisher, also made important contributions. A number of other people played an important role in Commission activities during the past year. For their efforts, special thanks go to Anil Bamezai, Robert Bergmann, Tom Bradley, Al D'Alberto, Anthony Dreyfus, Cindy Dudzinski, Frank Eppig, Donna Farley, Beth Fuchs, David Gibson, Sheridan Gladhill, David Glass, Liz Mauser Goldstein, Leonard Gruenberg, Mel Ingber, Ann Iversen, Terry Kay, Richard Kronick, Ken Leong, Susan Levy, Joyce Mann, Joseph Martin, Clare McFarland, Sharon McIlrath, Steve Miller, James O'Keiff, Madeleine Smith, Don Thompson, Cynthia Tudor, Christine van Reenen, and Janet Wellham.

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Foreword

This is the first major report of the Medicare Payment Advisory Commission. The Commission began its work in October 1997. In conducting analyses and developing recommendations, we have drawn upon the experiences and work of our predecessors, the Physician Payment Review Commission and the Prospective Payment Assessment Commission, while shaping the agenda for this new body.

This report focuses on Medicare payment policy. Chapters consider all of the major payment issues facing the program, including those related to the Medicare+Choice program, fee-for-service policies affecting a variety of providers, service to special populations, and financing of graduate medical education. The Commission's June report will take on other policy issues concerning Medicare and its relationship to the broader health care system.

The Commission presents its work in two volumes. Volume I contains all of the Commission's recommendations as well as the rationales behind them. Volume II includes analytic papers that generally relate to the recommendations in Volume I. In some cases, these provide more detail on methods. In others, they provide supporting background information. We are hopeful that this approach will be satisfying and useful to the Congress and to others in the policy community and practice environment who rely on the Commission's work.

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Chapter 1

Context for Recommendations

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Chapter 1

Context for Recommendations

The Balanced Budget Act of 1997 (BBA) (P.L. 105-33) legislated changes affecting almost every aspect of the Medicare program. These changes were designed to produce significant savings, expand beneficiaries' choices to a wider selection of health plan options, and strengthen the traditional Medicare program. Implementing and monitoring the effects of the BBA will present major challenges to policy makers over the next decade.

The BBA provides the context for most of the Medicare Payment Advisory Commission's recommendations this year. The Commission's deliberations in its first five months have focused on ways to strengthen the legislation and clarify its intent. It has also addressed key issues in the implementation of the BBA to be undertaken by the Health Care Financing Administration (HCFA). As the Commission has examined these immediate issues, it has weighed the consequences over the longer term of the potential effects on service delivery and access to care.

A benefit of merging the Prospective Payment Assessment Commission (ProPAC) and the Physician Payment Review Commission (PPRC) into a new commission is that it allows a single body to look across the entire Medicare program. In this role, the Commission weighs the implications of policy change across the many components of the Medicare program, working toward greater consistency in the policies it recommends. In addition, the Commission has considered the interrelationships of policies and their effects across health care providers. It is particularly concerned about how to develop payment methods that encourage delivering care in an efficient yet clinically appropriate setting. The adoption of a new payment policy for hospital outpatient services, for example, undoubtedly will affect care delivered in ambulatory surgical settings and physicians' offices. At issue, too, is how payment policies for Medicare+Choice may affect the traditional Medicare program.

This chapter summarizes the policy changes enacted by the BBA. First, it elaborates on the Medicare+Choice program and the changes made to capitation payment policy. It then describes the challenging schedule for developing and implementing new prospective payment policies across a broad range of providers. Finally, the chapter highlights the Commission's approach to payment policy in Medicare fee for service, Medicare+Choice, and for special populations, and describes the potential interactions across payment policies.

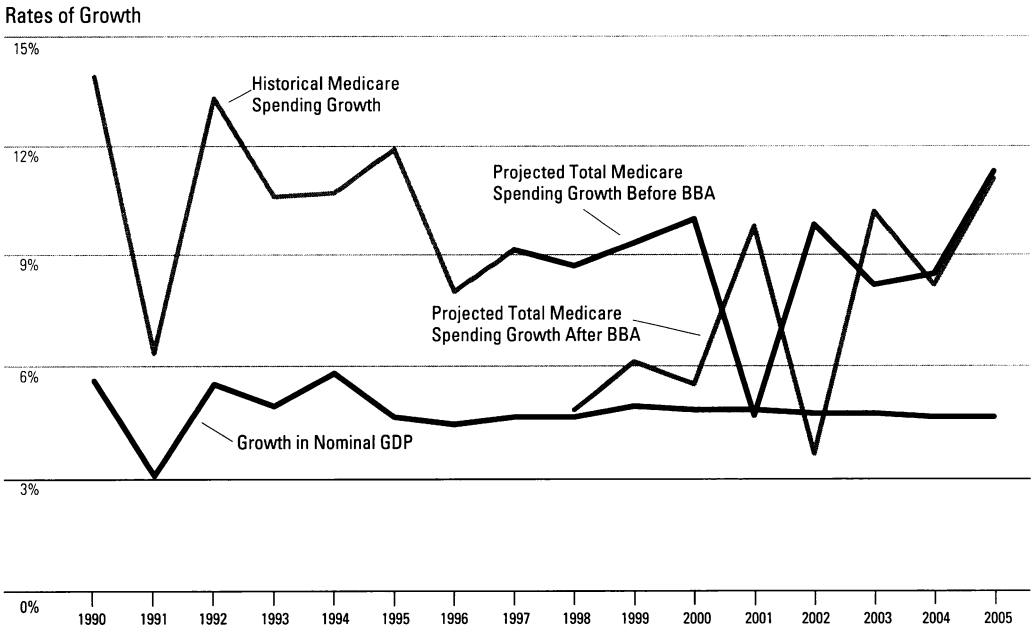
The Balanced Budget Act of 1997

Medicare's growing share of federal spending, about 11 percent of total outlays in 1995, made it a primary focus for reaching a balanced budget (CBO 1996). The BBA is expected to reduce Medicare spending by $115 billion relative to baseline projections over the five-year period from 1998 through 2002. Before the BBA, Medicare spending was projected to grow annually between 8 percent and 9 percent. With the passage of that legislation, spending growth is now expected to be more moderate, about 6 percent until 2002, or roughly 1 percentage point higher than nominal growth in the gross domestic product (GDP) (see Figure I-1-1). The BBA set specific policies to constrain growth through 2003, so projected spending thereafter reflects a return to previous rates of growth.

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Figure I-1-1

Historical Medicare Spending Growth and Projected Medicare Spending Growth Before and After the Balanced Budget Act of 1997 Compared to Growth in Nominal GDP, 1990-2005



SOURCE: Medicare Payment Advisory Commission analyses of data from the Congressional Budget Office, January 1997 and 1998 baselines.

The most fundamental change of the new legislation is the introduction of the Medicare+Choice program, which expands the range of health care options and significantly changes how Medicare pays health plans. The BBA also ensures choice by strengthening the traditional Medicare fee-for-service program through the design and implementation of prospective payment systems for ambulatory and post-acute care providers. In addition, the BBA addresses some longstanding issues, correcting many previous payment policies. One improves volume controls for physicians' services and reduces payments to teaching hospitals for indirect medical education costs. Other changes include direct payment to nurse practitioners and clinical nurse specialists, and various fraud and abuse provisions. In addition, the BBA mandates new preventive services for Medicare beneficiaries, like prostate and colorectal cancer screening, along with outpatient self-management training for diabetic patients.

The Medicare+Choice Program

The BBA broadens the health plan choices for Medicare beneficiaries, reflecting changes under way in the private insurance marketplace and within the Medicare program itself. As managed-care arrangements have expanded within the private sector, so too has enrollment in Medicare managed care (see Figure I-1-2). Since 1990, enrollment in Medicare risk-contracting plans has grown from 3 percent to 14 percent of all Medicare beneficiaries. The BBA also creates the Medicare+Choice program. Under its umbrella are plans now participating in the risk-contracting program, as well as preferred provider organizations, provider-sponsored organizations, private fee-for-service plans, and a demonstration of medical savings account plans.

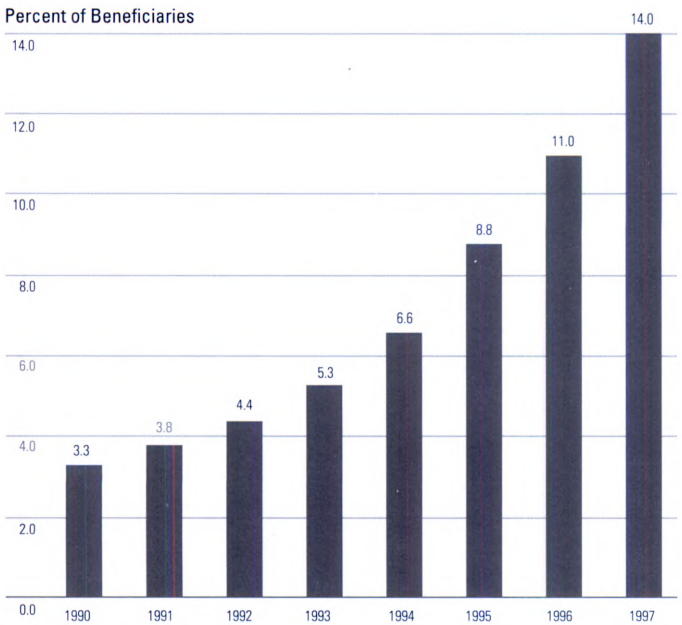
The BBA not only extends the range of health plan options, but will facilitate choice by expanding the availability of consumer information. Each year, Medicare beneficiaries will receive information that compares Medicare+Choice with traditional Medicare fee for service and explains the benefits and costs of health plans in their market area. They will also get information on the grievance and appeals process in the Medicare+Choice program. By 2003, those who enroll in health plans will be able to switch or disenroll only during an annual open season (with a three-month grace period to change their decision).

The new legislation improves capitation payment policy to encourage more health plans to participate. Under the previous policy, capitation payments were subject to high year-to-year volatility, especially in less populated counties. The potential for annual fluctuations in payment discouraged plans from participating in Medicare because they could not anticipate future payment rates. In addition, substantial variation in payment rates across geographic areas may have discouraged plan participation

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Figure I-1-2

Enrollment Growth in Medicare Risk-Contracting Plans



SOURCE: Medicare Payment Advisory Commission analysis of Medicare Managed Care Contract Reports.

NOTE: All data are for December.

where payment rates were low. To mitigate these two problems, the BBA establishes a new capitation payment method for Medicare+Choice plans. The payment rate for each county is calculated as the highest of a blend of the local and national rate, a minimum payment amount (or floor), or a minimum increase from the previous year's county rate.

The BBA also seeks to make payments across Medicare+Choice plans more equitable by requiring that risk adjusters based on health status be in place by January 2000. The new risk adjusters would ensure that plans with sicker beneficiaries would receive higher capitation payments than plans with healthier ones. The Secretary of Health and Human Services must develop and report on the new risk-adjustment methodology by March 1, 1999.

In order to implement the new risk adjusters, plans must submit data for hospital admissions beginning July 1997 and data from other sites beginning July 1998. Data reporting capabilities differ substantially across plans, particularly for ambulatory care, bringing into question the short-term feasibility of including health status in risk adjusters. Without comparable data from health plans, risk-adjusted capitation payments would reflect the information systems of health plans, not the health status of their enrollees. Proper risk adjustment will also require comparable data from the traditional Medicare program. While data reporting by health plans is expected to improve over time, data collected from the traditional Medicare program is not. As a result, establishing appropriate payment rates in the Medicare+Choice program relative to the fee-for-service program may be problematic.

Finally, the BBA introduces provisions for special populations by converting the Program of All-Inclusive Care for the Elderly (PACE) from a demonstration to a permanent Medicare program and an option under Medicaid. It also begins a new demonstration of for-profit providers in PACE. As payment policies evolve for the Medicare+Choice program, such as risk adjusters based on health status, the Commission will weigh the benefits of maintaining separate payment policies for PACE. Alternatively, the Commission may recommend payment policies that can apply more broadly across Medicare+Choice and special populations.

Prospective Payment Systems for Medicare Fee for Service

The BBA seeks to strengthen the traditional Medicare program by making major revisions to fee-for-service payment policies, thereby ensuring the ongoing availability of that program as a choice for Medicare beneficiaries. The legislated changes are expected to prolong the life of the Medicare Part A Trust Fund by a decade. Over the next few years, new prospective payment systems will be developed or implemented for skilled nursing facilities, hospital outpatient services, home health agencies, long-term care hospitals, and rehabilitation facilities. Many of these changes are long overdue.

Historically, Medicare reimbursed facilities on the basis of their costs, and physicians on the basis of their charges. This approach provided no incentives for the efficient provision of care and led to substantial growth in Medicare outlays. When the prospective payment system (PPS) for hospital inpatient services was adopted, these services represented 70 percent of Medicare spending, which was growing annually at 19 percent (HHS 1982). Medicare's implementation of prospective payment for hospitals was intended to give them incentives to deliver care more efficiently, make program budgeting more predictable, and reduce hospitals' administrative burden. By 1996, PPS hospital inpatient services consumed only 49 percent of Medicare dollars, while the annual growth rate in spending had dropped, on average, to 6.8 percent (Committee on Ways and Means 1996).

Success with this approach led policy makers to look to prospective payment systems to reduce costs and simplify payment methods for other health care providers. Developing a prospective payment system, however, requires setting the unit and level of payment, applying volume controls where appropriate, and making special adjustments to reflect differences in patient mix across providers. Additional adjustments may also be needed for broader goals, such as support for hospitals serving a disproportionate share of poor patients.

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Table I-1-1

Balanced Budget Act of 1997 Schedule for Developing or Implementing Prospective Payment Systems

Date	Provider Type
July 1998	Skilled nursing facilities
January 1999	Hospital outpatient departments
October 1999	Long-term care hospitals, home health agencies
October 2000	Rehabilitation facilities

SOURCE: Balanced Budget Act of 1997.

The BBA set a demanding schedule for implementing prospective payment systems for skilled nursing facilities, hospital outpatient departments, home health agencies, and rehabilitation facilities (see Table I-1-1). For these providers, the Secretary must adopt the new system by a specific date. For some providers, the BBA specifies key elements of that system. For long-term care hospitals, the Secretary must develop and report on a new prospective payment system.

Whether prospective payment will curb Medicare outlays will depend largely on its incentives to deliver health care efficiently. For example, moving to an average payment for a diagnosis-related group (DRG) per discharge under the PPS for inpatient care significantly shortened average length of stay. These efficiency gains were shared with the Medicare program as average costs per discharge fell over time (Ellis and McGuire 1988).

Furthermore, the ability of prospective payment systems to constrain program spending also depends on whether the approach discourages growth in volume and intensity growth related to unbundling or coding "creep." For example, to alleviate concerns that a prospective payment system for hospital outpatient services might lead to more visits, the BBA requires development of a volume control mechanism. Further savings are possible when the initial payment levels are set. Thus, for instance, the BBA limits outlays for home health services to 85 percent of what would have been paid if the new payment policy were not in place.

Simplifying and rationalizing payment policy is another important aspect of prospective payment. In the case of hospital outpatient services, the new system is expected to generate only modest savings, but to simplify the payment method substantially. Successful prospective payment systems also will rationalize payment by rewarding efficient providers, thus significantly redistributing payments. To make sure that payments are redistributed as intended, it will be crucial to monitor the new systems.

Issues for Developing Medicare Payment Policy

As the Commission has focused on the immediate issues the BBA raises, it has also considered the new law's effects over the long term. Improvements in payment policy for one provider may have unintended consequences for others. The new prospective payment systems required for Medicare fee for service will redistribute payments both within and across health care delivery sectors. And new payment policies for Medicare+Choice most likely will affect fee-for-service providers, while changes to traditional Medicare will affect private health plans. Decisions about risk adjustment, data reporting, expanded benefits, and cost containment inevitably will affect the entire Medicare program. In fulfilling its mandate, the Commission will consider how these policies interrelate and their potential effects for all providers.

Policies for Fee-for-Service Providers

Medicare currently makes fee-for-service payments to a variety of providers, among them physicians, acute care hospitals for both inpatient and outpatient care, home health agencies, skilled nursing facilities, hospices, ambulatory surgical centers, psychiatric and rehabilitation facilities, dialysis facilities, and clinical labs and durable medical equipment suppliers (see Table I-1-2). The share of total Medicare spending for each provider type varies substantially across sectors, 49 percent for hospital inpatient services, 21 percent for physicians' services and 9 percent for home health agencies (see Table I-1-3). Clearly, these sectors reflect different aspects of health care delivery by producing different types of services, and serving different types of beneficiaries. They are, nonetheless, interrelated, so that policy changes affecting one type of provider may have important implications for another.

Payment policies can be described by several common features:

- unit of payment,
- payment formula,
- method for setting annual updates, and
- beneficiary cost-sharing responsibilities.

Despite these commonalities, payment policies differ substantially by provider type (see Table I-1-2). For example, physicians' payments are made at the service level, while PPS hospital inpatient payments are made for all of the services provided in connection with a single discharge. Paying for a bundle of services, such as those for a particular inpatient admission, is thought to reduce incentives to provide too many services. In lieu of bundling, the payment policy for physicians uses a separate volume control mechanism that links payment rates to spending growth.[1]

[1] In some instances, physicians' services have also been bundled, such as the global surgical payment that covers the surgery and the care provided by the surgeon before and afterwards.

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Table I-1-2

Common Features of Payment Systems, by Provider Type

Provider Type	Unit of Payment	Basis of Payment	Payment Update Method	Payment Adjustments			Other Feature	Beneficiary Liability*
				Geographic	Access	Other		
Physician	Service	Resource-based relative value scale times the conversion factor.	Annual update set by sustainable growth rate system.	Geographic practice cost indexes applied to 89 payment areas.	20% bonus payments in Health Professional Shortage Areas.	Reduction in payment for some services when provided in non-office settings.	Spending control links updates in payment to volume growth.	20% of fee schedule amount plus balance billing (up to 9.25% of fee schedule amount).
Acute care hospitals	Discharge/ transfer	DRG relative weight times the standardized amount.	Annual update	Area wage adjustment for each MSA or statewide rural area.	Disproportionate share adjustment; provisions for sole community, Medicare-dependent and rural referral.	Indirect medical education.	Additional payment for graduate medical education. Special provisions for capital.	Deductible per spell of illness and copayment for 61-150 days.
Psychiatric facilities, long-term care hospitals, rehabilitation facilities	Discharge	Lower of actual costs or limit based on updated facility-specific historical costs (target amount). Costs minus 15% for capital.	Facility-specific annual increase to target amount, varies depending on relationship of costs to target amount.	Not applicable	None	Bonus or relief if costs are below or above target amount.	Exceptions payments for demonstrated costs substantially above target amounts.	Deductible per spell of illness and copayment for 61-150 days.
Skilled nursing facilities	Day for routine care, costs for ancillary and capital	Lower of actual per diem costs or limit for routine care. Costs for ancillary services and capital.	Annual update to routine cost limit (currently frozen).	Wage index adjustment to routine limits, based on MSA or statewide rural area.	None	None	Exceptions to routine cost limits; new facility exemption from limits.	After first 20 days, daily copayment.
Home health agencies	Visit	Lower of actual costs, or per visit limits that are applied to aggregate facility costs, or per beneficiary limit.	Annual update to per visit limits	Wage index adjustment to limits, based on MSA or statewide rural areas where service is provided.	None	Exceptions to limits.	None	None
Hospital outpatient department	Service	Lower of charges, costs, or blended rate subject to 5.8% reduction for operating and 10% reduction for capital.	Not applicable	Wage index adjustment to fee schedule portion of blend, based on MSA or statewide rural areas.	None	None	Extra payments for interns and residents.	20% of charges
Clinical lab & durable medical equipment	Service or item	Fee schedule	Periodic updates	Lab-regional fee schedules of fee schedule.	None	None	None	Lab=None DME=20%
Ambulatory surgical centers	Eight service cost categories	Fee schedule	Periodic updates	Wage index adjustment based on MSA or state-wide rural area.	None	None	None	20% of ASC rate
Hospice	Per diem	Daily rate subject to beneficiary cap.	Annual updates	Wage index adjustment based on MSA or state-wide rural area.	None	None	None	$5 for drugs; 5% of inpatient respite care rate limited to inpatient deductible amount.
Dialysis facilities	Per dialysis treatment (outpatient)	Composite rate bundles routine dialysis services.	None	Wage index adjustment based on MSA or state-wide rural area.	None	None	None	20% of rate

SOURCE: Medicare Payment Advisory Commission summary of law and regulation.

NOTE: This table illustrates basic features of payment policies for these provider types. Special exceptions or policies were not included.

*This reflects Medicare policy, but not actual out-of-pocket costs for the beneficiary. In particular, Medigap coverage is not reflected.

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Table I-1-3

Medicare Payments, Providers, and Beneficiary Use, by Fee-for-Service Sector

Provider/Service Type	Total 1996 Outlays (in Billions)	Percent of Total 1984 Outlays	Percent of Total 1996 Outlays	Number of Providers	Number of Beneficiaries That Used Services (in Thousands)	Percent of All Beneficiaries	Average Medicare Payment per User in 1996	Beneficiary Cost Sharing, as Percent of Total Payment
Hospital inpatient	$98.6	65%	49%	5,075	6,964	19%	$11,336	9%
Skilled nursing facility	11.7	1	6	15,553	1,233	3	6,325	n.a.
Home health agency	18.3	3	9	9,886	3,468	9	9,240	0
Hospice	2.0	–	1	2,135	309	1	6,058	n.a.
Physician	41.7	24	21	787,513	29,539	79	1,409	20[2]
Outpatient[1]	16.6	6	8	n.a.	19,709	53	778	40
Other	11.6	4	6	n.a.	n.a.	n.a.	n.a.	n.a.

SOURCE: Medicare Payment Advisory Commission compilation of data from the Health Care Financing Administration.

n.a. indicates that estimates are not currently available.

[1] Includes payments for outpatient services provided by hospitals, free-standing dialysis facilities, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, rural health clinics, and other providers of covered services.
[2] Excludes balance bills, which are limited to 15 percent of Medicare's approved payment.

Payment policies often have similar aims, but use different strategies to achieve them. For instance, both physician and hospital payments are adjusted for geographic variation in input prices, but the payment policies use different geographic areas and input price indexes. It seems clear that new prospective rates for rehabilitation facilities, home health agencies, and the others called for in the BBA should be geographically adjusted. How areas should be defined for this purpose is less clear, however.

Cost-sharing policies also differ across sectors, with possible consequences for where beneficiaries' seek care. For example, a beneficiary may face dramatically higher out-of-pocket costs if a service is performed in a hospital outpatient department than in a physician's office. The absence of copayments for home health care may also affect choices about care delivery. Some argue that the differences in policies are basically irrelevant, since only about 10 percent of Medicare beneficiaries cover their own cost sharing. Those without supplemental insurance, however, are predominantly the near-poor and African Americans, who are the most apt to be affected by these policies.

It is also unclear what additional adjustments should be incorporated into payments and to what sectors these should apply. For example, until now only PPS hospital inpatient payments have been adjusted for the costs of training physicians. The Commission is reviewing Medicare's role in supporting this activity. If it concludes that that support should continue, the Commission will also study whether payment to other types of providers should be adjusted to reflect the shift in training from inpatient to ambulatory settings.

Improving the performance of Medicare's fee-for-service program will require, at least in part, a better understanding of how the sectors relate to one another, both financially and in providing services. For instance, the implementation of prospective payment for hospital outpatient services is likely to change the volume of services provided not only in these sites, but also in physicians' offices and ambulatory surgical centers, since they are often close substitutes. Careful design of the outpatient prospective payment system should ensure care delivery in the most appropriate setting and minimize any disruption to beneficiaries.

Some inconsistencies across payment policies may be appropriate if they reflect different patient mixes or treatment protocols. Payment policies should be reexamined, however, if they produce payment differentials that simply reflect how the policies have evolved. Although Medicare beneficiaries can receive rehabilitation services either in skilled nursing facilities or in rehabilitation facilities, for instance, the payment mechanisms for both provider types differ. Currently, Medicare pays skilled nursing facilities a limit based on a facility-specific per diem for routine services, subject to a national average. Rehabilitation facilities are paid under the rules set by the Tax Equity and Fiscal Responsibility Act of 1982 for inpatient providers excluded from PPS. Resolving these discrepancies in payment approaches is complicated, however, by the differences in treatment approaches used by these providers.

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As a practical matter, it is difficult to determine whether the types of patients served or the services provided differ when comparing payments across sectors. Efforts to analyze payments across sectors are limited by the lack of reliable schemes to classify patients and the care they receive in different settings. Designing and implementing better policies will require more information, and should be revisited as new data become available.

Medicare+Choice and Fee-for-Service Payment Policies

Until 1998, Medicare's payments to private health plans were based on the average payments made on behalf of beneficiaries in the fee-for-service program. Under the Balanced Budget Act of 1997, Medicare+Choice payment rates are no longer directly linked to local fee-for-service spending. Instead, they blend average spending locally and nationally. In addition, payment floors guarantee some minimum level of base payment rate in all counties. Moreover, each year, local and national fee-for-service averages are updated to reflect overall growth in Medicare spending per capita; the BBA guarantees a minimum increase of 2 percent to base rates. Also, beneficiary liability under Medicare+Choice is not to exceed that in the fee-for-service program for the basic Medicare benefit package.

Substantial variation in payment rates across geographic areas may discourage health plans from participating in Medicare where payment rates are too low. As a result, the BBA sought to encourage plan participation by no longer setting payment rates entirely based on fee-for-service outlays at the county level. It reduces some of the variation in payments to health plans by blending local rates with the national average. While that may reduce variation in general, it does so across the board. The variation in fee-for-service spending results from differences in prices, patient health status, and in practice style. Because health plans can influence this last factor, it may be reasonable to remove this source of variation from their payments. Therefore, new payment approaches should be considered when policy makers are better able to disentangle these sources of variation across areas. Moreover, once better risk-adjustment methods are implemented and established within Medicare+Choice, it may be appropriate to reconsider the use of an input-price-adjusted national rate as the base rate for all health plans.

As a result of the BBA's new approach for setting capitation payments, payments to health plans are no longer comparable to average fee-for-service spending in communities nationwide. By setting a minimum payment rate, capitation payments in some counties are now over 50 percent higher than average fee-for-service spending. At the other extreme, payments to health plans are falling below fee-for-service spending in those counties with above-average spending. The implications of these differences in average spending for Medicare+Choice enrollees and for those in the traditional program are difficult to predict. Changes in enrollment, plan availability, benefit offerings, and beneficiary financial liability over the next few years should be carefully monitored so that problems of access and quality for beneficiaries in either Medicare+Choice or fee for service are detected promptly.

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Chapter 2

Medicare's Capitation Payments to Private Health Plans

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Chapter 2

Medicare's Capitation Payments to Private Health Plans

Two major components of the Medicare reforms that became law in the Balanced Budget Act of 1997 (BBA) (P.L. 105-33) were the expansion of options for private health plan participation in Medicare and a restructuring of the method for paying these plans. Options will be expanded through creation of a new Medicare+Choice program that will replace the current Medicare risk program starting in late 1998. The new method for setting capitation payments to private health plans was implemented by the Health Care Financing Administration (HCFA) with new rates that went into effect in January 1998, and further changes will be phased in through 2003.

This chapter describes how private health plans participating in Medicare are paid. It thus covers both the Medicare risk program and the new Medicare+Choice program that will replace it. The chapter first describes the new methodology established in the BBA for setting payment rates for plans. Second, it provides data on the pattern of payments under the new rules. Third, it explains the recommendations made by the Medicare Payment Advisory Commission (MedPAC). These recommendations address several technical flaws in the system created by the BBA. A companion chapter (Volume II, Chapter 1) provides additional information on how the new method works and on the models used by the Commission to simulate payments over the next five years.

Background on Medicare's Capitation Payments to Health Plans

Under the Balanced Budget Act of 1997, private health plans that contract with Medicare receive a monthly capitation payment for each enrollee. The methodology for calculating the capitation rate replaces the adjusted average per capita cost (AAPCC) methodology used through 1997. Actual payments to plans are adjusted for the characteristics of enrollees, including age, sex, and institutional status. The BBA requires a new system of risk adjusters based on health status to be implemented in 2000 (see Volume I, Chapter 3). Based on the capitation rate, plans must submit an adjusted community rate (ACR) proposal, which is used to determine the amount of Medicare noncovered benefits they are required to provide to enrollees and the premiums they may charge for additional benefits (see Volume I, Chapter 4).

Under the old system, Medicare paid plans 95 percent of an actuarial projection, at the county level, of what the program would have paid if the beneficiary had remained in traditional Medicare. Under the new system, a county's 1997 rate is the starting point for calculating its rates for 1998 and beyond (described below).

The old system was criticized for limiting the growth of Medicare managed care in some markets by paying too little and promoting it in others by paying more than necessary to compensate plans fairly.[1] The system also tended to hamper Medicare's ability to benefit from any efficiencies that managed care may achieve. The new system addresses these criticisms to some degree by lessening the variation and volatility in payment rates, as described below.

[1] For background information on the availability of plans and enrollment around the country, see the Commission's chart book, *Medicare Risk-Plan Participation and Enrollment: A Chart Book* (MedPAC 1997).

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Table I-2-1

Parameters in the Balanced Budget Act for Calculating Medicare's Payment Rates to Health Plans, 1998-2003

Year	Blended-Rate Proportions		Floor Rate	Percentage of Graduate Medical Education Payments Removed	National Growth Percentage
	Local	National			
1998	90%	10%	$367	20%	2.6%
1999	82	18	381*	40	3.9*
2000	74	26	398*	60	4.5*
2001	66	34	420*	80	5.4*
2002	58	42	445*	100	5.9*
2003	50	50	477*	100	7.2*

SOURCE: Medicare Payment Advisory Commission analysis of payment rate methodology under the Balanced Budget Act of 1997.

*Based on Congressional Budget Office projections, January 1997 baseline, with changes resulting from the Balanced Budget Act of 1997.

Calculating County Capitation Rates

Under the BBA, rates are set at the highest of three amounts calculated for each county:

- a rate calculated as a blend of an area-specific (local) rate and a national rate,
- a minimum or floor rate, and
- a rate reflecting a minimum increase from the previous year's rate.

Each year, the two components of the blended rate and the floor rate are updated by a national growth percentage. Each part of the system is described in more detail below.

Blended Rates

The blended rate is designed to shift payment gradually away from local county rates, which reflect wide variations in fee-for-service costs and utilization of services, toward a national average rate. Blending is designed to reduce rates in counties where payments historically have been higher than the national average rate, and to increase rates in counties where payments have been lower.

The local component of the blended rate is based on the 1997 county AAPCC with two adjustments. First, it is reduced over a five-year period to remove an amount corresponding to each county's Medicare spending due to payments for graduate medical education (GME). Second, it is updated each year by the annual national growth percentage (see Table I-2-1).

The national component of the blended rate is based on a weighted average of all county local rates. Before blended rates are calculated for each county, the national component is adjusted by an index designed to measure local input prices (for example, hospital wages). The blend of these two components starts at 90 percent local and 10 percent national in 1998 and shifts gradually to a 50:50 blend by 2003 (see Table I-2-1). As described below, blended rates may be raised or lowered to achieve budget neutrality.

Minimum (Floor) Rates

Each county is also subject to a floor rate, designed to raise payment in certain counties more quickly than would occur through the blended rate alone. The 1998 floor is established in law at $367 and will be raised each year by the national growth percentage. Based on growth rates estimated by the Congressional Budget Office (CBO), the floor will be $477 in 2003 (see Table I-2-1).

Minimum Increase

The minimum-increase rule protects counties that would otherwise receive only a small annual increase or an actual decrease. Each county's payment rate must be at least 102 percent of the previous year's rate.

Budget Neutrality

Once rates are calculated for each county, an additional adjustment may be made to meet the requirement that total payments under the new rules are no higher than they would have been if based on local payments only. This budget-neutrality adjustment is applied to the blended rates to raise or lower the county payment as necessary to meet this requirement. No adjustments, however, are made to rates based on the floor or minimum increase. Because no county rate may be reduced below its floor or minimum increase, it may not be possible to achieve budget neutrality in some years. This situation occurred with the calculation of 1998 rates.

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Table I-2-2

Calculation of Medicare's Monthly Payment to a Health Plan on Behalf of Selected Beneficiaries, Los Angeles County, California, 1998

Type of Beneficiary	(Part A Rate x Part A Risk Adjuster) + (Part B Rate x Part B Risk Adjuster) = Total Payment								
Male, Age 68, Non-Medicaid, Noninstitutionalized, Nonworking	($364.81	x	0.65)	+	($270.19	x	0.80)	=	$453.28
Female, Age 87, Non-Medicaid, Institutionalized, Nonworking	($364.81	x	2.10)	+	($270.19	x	1.65)	=	$1,211.91

SOURCE: Medicare Payment Advisory Commission analysis of payment rates.

NOTE: The basic monthly payment rate for Los Angeles County is $635.00. This amount would be paid for a hypothetical beneficiary for whom all risk adjusters had a value of 1.00.

National Growth Percentage

The national growth percentage is applied each year to the local and national components of the blended rate and to the floor rate. It is based on the projected per capita rate of growth in Medicare spending minus a specific reduction set in law. For 1998, the reduction is 0.8 percentage points below Medicare growth; from 1999 through 2002, it is 0.5 percentage points. There is no reduction after 2002. (Starting with the 1999 rates, adjustments will also be made for errors in previous years' projections.) The annual growth percentage for 1998, after the reduction, is 2.6 percent. Annual amounts for succeeding years have been estimated by CBO (see Table I-2-1).[2]

Rates for Disabled and ESRD Beneficiaries

Historically, payment rates for beneficiaries who are eligible for Medicare based on having a qualifying disability or end-stage renal disease (ESRD) have been set using similar methods as for aged beneficiaries, except that ESRD rates are calculated on a statewide basis. Each county thus has separate rates for aged and disabled beneficiaries and uses a state rate for ESRD beneficiaries. The BBA left in place the practice of separate rates for each county. As a result, the same reforms—including the same floor rate—apply to the calculations for both groups of beneficiaries, even though payments for disabled beneficiaries average about 14 percent lower than for aged beneficiaries. The Commission has recommended a change to this policy (described below).

Enrollee-Level Payments to Plans

Actual payments to plans depend on the characteristics of the beneficiaries who enroll. The rate for an enrollee's county of residence (or state in the case of ESRD enrollees) is adjusted by national risk adjusters to reflect each enrollee's demographic characteristics (see Table I-2-2). The risk adjusters currently used by Medicare are age, sex, disability status, institutional status, Medicaid enrollment, and whether the beneficiary works and has employment-based insurance coverage (referred to as working aged status). The BBA calls for implementation in 2000 of new risk adjusters to reflect health status (see Volume I, Chapter 3).

The actual payments to a plan on behalf of a particular beneficiary, even under the current risk-adjustment rules, can vary widely from the base county rates. An aged beneficiary in the most expensive category, for example, has a risk adjuster about six times that for the least expensive person. The values of risk adjusters will likely vary even more under the new system. One result is that actual payments can fall well below the floor rate.

County Payment Rates, 1997 and 1998

HCFA set the national growth percentage for 1998, based on its projection of overall Medicare growth, at 2.6 percent for aged beneficiaries. This amount results from an estimated 3.4 percent Medicare spending growth, less the statutory reduction of 0.8 percentage points. The reduction for GME spending for an average county is about 0.8 percent, so the effective average increase in county payment rates, before floors and minimum increases are applied, would be 1.8 percent.

[2] These amounts are taken from the January 1997 CBO baseline, as adjusted by CBO for changes enacted in the BBA. HCFA's preliminary estimate of 1999 rates, announced January 15, 1998, suggests that the national growth percentage for 1999 will be 2.0 percent, below that estimated by CBO. CBO's January 1998 baseline, released as this report was going to press, would substitute values of 4.3, 5.9, 5.9, and 6.9 for the values in Table I-2-1 for 2000 to 2003.

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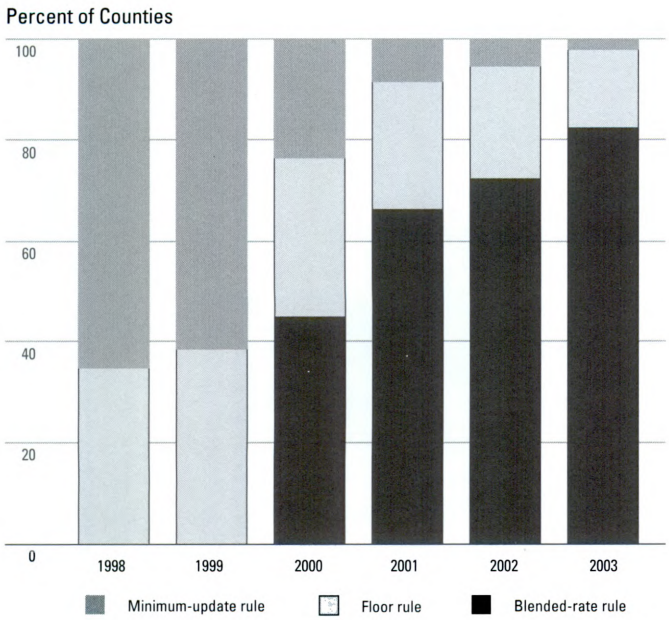
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Figure I-2-1

Rule Used to Determine Medicare's County Payment Rates, by Year, 1998-2003



SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

After applying the floors and minimum increases, the average county payment rate (weighted by beneficiaries) is $484, a 2.9 percent increase over 1997. The difference between this increase and the 1.8 percent increase expected from the formula results from the legislative requirement to apply floor rates and minimum increases. It also reflects an inability to meet the budget-neutrality requirement for the 1998 rates. Achieving budget neutrality would have required setting county rates at levels that would have fallen below either the minimum 2 percent increase or the floor rate.

As noted above, each county rate is set at the highest of the amounts calculated under three rules—its blended rate, minimum increase, and floor. Because of the low national growth percentage and the corresponding inability to achieve budget neutrality, no county rate for 1998 is set by the blended-rate rule. About one-third of all counties have rates set at the floor, with the rest receiving the minimum 2 percent increase (see Figure I-2-1).[3] Although many counties receive the floor rate, only 14 percent of beneficiaries and fewer than 2 percent of plan enrollees live in those counties.

Correcting Projection Errors

The average increase from 1997 to 1998 would have been even lower under the policy replaced by the BBA. As noted above, the national rate of increase each year is based on HCFA's projection of the rise in per capita Medicare spending from the current year to the year for which rates are being set. Both the old and new systems use projected spending, and both generally require later corrections if the actual spending trend differs from the projection. The exception is that the BBA did not allow a correction for errors in projecting 1997 growth.

Medicare spending for 1997 rose more slowly than had been projected. The revised estimate of 1997 spending, made in September 1997 as 1998 rates were being calculated, was about $10 per month (about 2.3 percent) lower than the projection made a year earlier. (Because other Medicare growth estimates have been revised downward since September 1997, it is likely that the March 1998 estimates of 1997 spending will show an even larger projection error.)

If a correction for this projection error had been applied, the 1997 base rates used as the starting point for the calculation of 1998 monthly county rates would have been lower. As a result, the effective national growth percentage would have been about 0.3 percent instead of 2.6 percent, after the statutory reduction. The effective growth percentage would have been negative after removing amounts attributable to GME spending. The absence of a correction led to excess payments to plans of over $600 million in 1998, based on the September 1997 revised estimate. Because the 1997 rates are the base for determining rates for future years as well, this overpayment will occur (and be compounded) each year.

The Congress could authorize HCFA to correct for the error in projecting 1997 spending when rates for future years are set. The usual approach would set the correct rates for future years, but would not recoup overpayments (or compensate for underpayments) for past years.[4]

Alternatively, the Congress may forgo any further correction and leave this overpayment in the system as a cushion for plans as they face other changes, such as the implementation of new risk adjusters in 2000—the first year in which the 1997 projection error could now be corrected. Higher payments might be an added incentive for new plans to participate in Medicare and could also deter plans from assessing new premiums or cutting back the extra benefits they offer enrollees.

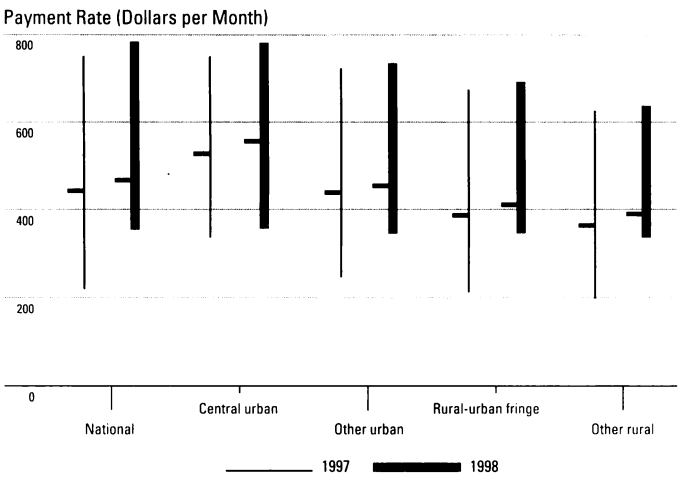
[3] The reduction of rates to the minimum increase has a relatively small effect at the county level. See Volume II, Chapter 1, for sample calculations of rates, including the dollar effect of the budget-neutrality adjustment.

[4] If the Congress chose to make this change, it would also need to determine whether it would apply the minimum 2 percent increase to the revised base rate, rather than the actual payment rate. If it chose to do so, counties might experience actual decreases from one year to the next when the correction was applied. If it chose not to do so, it would substantially delay the correction.

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Figure I-2-2

Average, Minimum, and Maximum Medicare County Payment Rates, by Location, 1997-1998



SOURCE: Medicare Payment Advisory Commission analysis of payment rates under the Balanced Budget Act of 1997.

NOTE: The tick mark on each bar indicates the mean county payment rate (weighted by the number of beneficiaries in each county).

Central urban counties are defined as the central counties in metropolitan areas of 1 million population or more; other urban refers to other counties in those metropolitan areas and any county in smaller metropolitan areas. Rural-urban fringe counties are defined as those nonmetropolitan counties that are adjacent to a metropolitan area, and other rural refers to nonmetropolitan counties not adjacent to a metropolitan area.

Geographic Variation in Payment Rates

Large variation in county payment rates was one of the motivating forces behind some of the changes enacted in the BBA (PPRC 1996; 1997). The imposition of a floor rate has removed some of the greatest variation. The combination of the low national growth percentage and the budget-neutrality rule, however, has delayed the application of the blended-rate rule. Only when county rates are more heavily based on the national component of the blended rate will more of the county variation be reduced.

Across the counties, there is a substantial range above and below the average payment rate (see Figure I-2-2). For 1997, the lowest rates in the country were $221 in two rural Nebraska counties (Arthur and Banner). The highest rates in 1997 were $767 and $748, respectively, in Richmond County, New York (Staten Island), and Dade County, Florida (Miami). In 1998 imposition of a floor brought the national minimum rate (excluding territories) up to $367, while the highest rate (Richmond County) rose to $783.[5] Despite these extreme values, about half of all beneficiaries live in counties with 1998 rates between about $400 and $540.

Regionally, payment varies considerably, with higher payments generally in central urban counties (see Figure I-2-2).[6] The 1998 floor mostly affects rural counties, but it raises rates for some urban counties as well. Since all counties not affected by the floor get the same increase for 1998 (2 percent), payment rates continue to be higher in urban areas and lowest in the most rural areas. The average payment in central urban counties is more than $100 above that for other urban counties and nearly $160 above that for rural counties. The range within each of the four urban-rural categories used for this analysis also remains substantial.

Payment rates range widely across markets. For example, plans serving southern Florida are paid an average of $675 per month in 1998, compared with $409 in Minneapolis-St. Paul. Moreover, within many markets that encompass more than one county, the range of monthly payment rates across counties is $200 or greater. Plans competing in the same market may receive substantially different payments for beneficiaries who live on opposite sides of a county boundary. These differing payment levels affect the benefits plans offer and the premiums they charge, and they appear to affect plan participation and enrollment as well (PPRC 1997; ProPAC 1997). The BBA will eventually reduce variation further, but generally not until increases are high enough to support blended rates. Among the largest markets, the only significant compression of variation for 1998 occurred in Minneapolis-St. Paul, where most of the suburban counties had rates raised to the $367 floor.

Projecting Rates for 1999 Through 2003

This section uses the results of simulations conducted by the Commission to assess the impact of the new payment rules established by the BBA. All simulations are based on a series of assumptions about spending and enrollment growth and are limited by the uncertainty of those assumptions. These simulations incorporate the published 1998 rates and simulated rates from 1999 to 2003, using CBO's assumptions about spending growth to set the annual national growth percentage.[7] The simulations also assume that enrollment will respond to changes in payment rates leading to a

[5] The BBA sets the floor rate for territories at the lower of $367 or 150 percent of the 1997 rate.

[6] For purposes of this analysis, four urban-rural categories are used. Central urban counties are defined as the central counties in metropolitan areas of 1 million population or more; other urban refers to other counties in those metropolitan areas and any county in smaller metropolitan areas. Rural-urban fringe counties are defined as those nonmetropolitan counties that are adjacent to a metropolitan area, and other rural refers to nonmetropolitan counties not adjacent to a metropolitan area.

[7] CBO estimates of spending growth are taken from the January 1997 baseline, as adjusted by CBO for changes enacted in the BBA. CBO's January 1998 baseline, released as this report was going to press, makes modest changes—some up and some down—in projected national growth percentages. Results of simulations using the January 1998 baseline include lower rates in all years and changes in the pattern of which rule determines the rate in a particular year.

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different distribution of plan enrollment across the United States (regardless of how much the level of enrollment changes).[8] In addition, any effect on county base rates of the new risk-adjustment system, to be implemented in 2000, has not been incorporated in this analysis.

Source of Payment Rate Determination

One way to understand the effect of the payment rate methodology is to consider what proportion of counties have their rates set by each of the three rules established in the BBA (blended rate, floor, and minimum update). This approach is helpful in identifying when the blended-rate rule's effect is canceled out by budget-neutrality adjustments or how quickly the effect of the floor disappears. But this approach can be misleading to the extent that large swings in the proportion of counties where payment is set by a particular rule may result from small shifts in actual payment rates.[9]

Based on the Commission's most recent projections, it is likely that no counties will have rates set by the blended-rate rule in 1999, the same result as in 1998. This result assumes that the projected national growth percentage for 1999 will be too low to achieve budget neutrality and that at least some enrollment shifts to counties affected by the floor rate or the minimum increase. Preliminary estimates of 1999 growth rates, published by HCFA on January 15, 1998, as part of the required 45-day notice of changes in payment rate methodology, also lead to the same conclusion. HCFA projects a national growth percentage of 2.0 percent, based on projected Medicare per capita growth for 1999 of 3.4 percent, less the reduction in law of 0.5 percentage points and a further reduction of 0.9 percent for an overprojection of 1998 rates (but without accounting for the removal of GME payments). This amount falls far below the 3.9 percent previously projected by CBO and used as the basis for simulations reported here and makes the absence of budget neutrality appear certain.

Starting in 2000, the national growth percentage is projected to be high enough to pay for greater enrollment in counties where rates have been raised to the floor or the minimum increase, while still supporting more generous blended rates for some counties. By 2003, when all transitions are complete, 82 percent of all counties are projected to be at their blended rate, with 2 percent raised to the minimum increase and 16 percent raised to the floor rate (see Figure I-2-1).[10]

After the various phased-in changes (the shift to a 50:50 local-national blended rate and complete removal of GME payments) are complete in 2003, the Commission projects that some counties will remain at floor rates unless a further change is made in the payment methodology. This result occurs because floor rates and blended rates will grow each year by the same amount. The small number of counties that are still affected by the minimum increase in 2003 should receive blended rates within another two to three years, given no further shift in the blend proportions. As long as the national growth percentage is greater than 2 percent, blended rates for these counties will eventually rise above the minimum increase.

Reducing Volatility in Payments

The BBA effectively eliminates the year-to-year volatility inherent in county payment rates under the old rules (PPRC 1996; 1997). In 1998, the $367 floor rate caused volatility in the sense that rates for many counties rose dramatically to achieve that floor. But, from 1999 to 2003, as various changes are phased in, county rates generally will grow by a minimum of 2 percent each year and a maximum of about 2 percentage points above the national growth percentage that year. Different increases among counties will reflect the relative magnitudes of such factors as the amount of GME payments being excluded and the level of input-price adjustments (for example, hospital wages). After 2003, all county rates will rise uniformly by the national growth percentage (except for those few counties still affected by the minimum-increase rule).

Reducing Variation in Payments

The rate system in the BBA will reduce the amount of variation occurring under current law—but only modestly by the time the 50:50 blended rates are fully phased in (see Figure I-2-3). Although central urban counties generally remain well above the national average and all other types of counties remain below, the range is projected to shrink over the first five years of new rates. In the first year, the only source for reducing variation is the use of the floor rate, since all other county rates rise by a uniform 2 percent. Floor rates apply to about half of the most rural counties and to decreasing proportions of counties in the more urban categories. After 2003, there will be almost no additional reduction in variation (beyond phasing out the counties that will still be receiving only the minimum update).

[8] See Volume II, Chapter 1, for further description of the simulation methods used in this analysis.

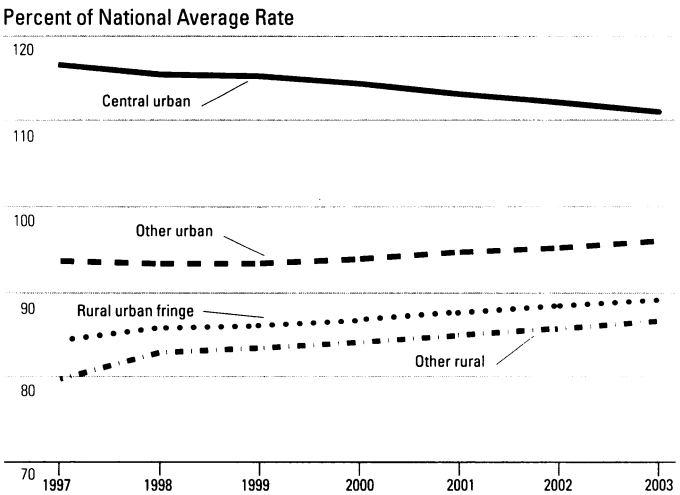
[9] For example, the simulations of 1998 payment rates that were made during congressional deliberations showed nearly half of all counties receiving blended rates. The revised national growth percentage used by HCFA lowered monthly rates an average of $2 per month, but eliminated all blended rates. See Volume II, Chapter 1, for further examples of the patterns of payment for counties with rates primarily determined by different rules.

[10] Results of simulations using HCFA's projection for 1999 and CBO's January 1998 baseline include an increased likelihood that blended rates will be effective first in 2001, rather than in 2000, due to the lower national growth percentages. Because rates would be lower in all years, more counties would have rates set at the floor or the minimum update in each year. These results, however, are preliminary.

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Figure I-2-3

Effect of New Rates on Regional Variation, Using Dynamic Enrollment-Growth Assumptions, 1997-2003



SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

Central urban counties are defined as the central counties in metropolitan areas of 1 million population or more; other urban refers to other counties in those metropolitan areas and any county in smaller metropolitan areas. Rural-urban fringe counties are defined as those nonmetropolitan counties that are adjacent to a metropolitan area, other rural refers to nonmetropolitan counties not adjacent to a metropolitan area.

At the individual county level, changes can be more dramatic (see Volume II, Chapter 1). Rural counties paid at very low rates get a big increase the first year, then stay at just under 80 percent of the national average. Counties with historically high rates will get only a 2 percent increase each year and thus fall from nearly two-thirds above the national rate to only 50 percent above it. Other counties converge toward rates driven by local input-price variations.

The degree to which variation is reduced is affected by at least two factors. First, the low national growth percentages projected for Medicare+Choice, combined with the guaranteed 2 percent increase, limit the influence of the blended rates. Second, stopping the blended rates at a 50:50 blend, together with the appropriate application of input-price adjustments, limits the potential for convergence toward a national rate.

The Commission's Recommendations

The new system in place for calculating county capitation rates addressed some but not all of the concerns about the old system. Because many of the changes are being phased in over several years, it may be too soon to evaluate their effects. At some point, policy makers may want to consider whether rates based on a 50:50 blend of local and national rates constitute the optimal solution or whether something quite different (for example, fully national rates or competitively bid rates) would be preferable. Based on the early experience in implementing the BBA system, however, several technical issues have arisen. In addition, it is important to consider a plan for systematic evaluation of the impact of the changes.

Action on the technical issues discussed below would preferably have occurred before rates for 1999 were established. Such action would have provided more immediate savings for the program and would have eliminated certain inequities. The BBA requires, however, that 1999 rates be announced by HCFA by March 1, 1998 (and that changes in methodology be announced 45 days earlier). Nevertheless, legislative changes can be made before the 2000 rates are determined.

Monitoring the Effects of Changes in County Rates

As noted above, a major goal of reforming the payment system was to reduce the variation in county payment rates that existed under the old system. The changes made by the BBA to accomplish this goal are generally consistent with the recommendations made by the Physician Payment Review Commission (PPRC) and Prospective Payment Assessment Commission (ProPAC), predecessors to this Commission. The impact of the changes, however, is complex. Health plans have already begun to make adjustments in premiums and benefits offered based on the 1998 rates. In addition, many organizations are evaluating whether to contract with Medicare—although final decisions for many will undoubtedly await the issuance of rules for Medicare+Choice in June 1998.

Recommendation

The net effect of changes in payment methodology on such factors as plan and beneficiary participation in Medicare+Choice, risk selection, plan premiums, supplemental benefits, beneficiary cost sharing, and access to care should be monitored. Attention should be given to the interaction between changes in payment rates and changes in risk adjustment; the role of the floor and minimum-increase rules; the effects of payment rates on new types of plans (for example, private fee-for-service plans); and the use of 50:50 blended rates as the end point of the new system.

As shown in this chapter (and Volume II, Chapter 1), simulations can estimate the reduction in rate variation expected from changes made by the BBA. Once a method is established for creating new risk adjusters, further simulations can project the combined impact of changes in both methodologies, subject to spending and enrollment growth assumptions. But simulations cannot so easily project the response of plans and beneficiaries to these changes.

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Monitoring these trends will have critical importance. Not only will such an evaluation be the basis for judging the success or failure of the changes made in the BBA, but it will also allow policy makers to consider additional changes as necessary to address adverse effects on beneficiaries.

The Commission plans to analyze the impact of BBA changes on levels of plan and beneficiary participation in Medicare+Choice, with particular emphasis on patterns that may result from different levels of payment or changes in payment in different counties. Other analysis will focus on changes in the premiums and cost sharing charged by plans, the benefits offered, the degree of risk selection that occurs, and the implications for beneficiary access to care or beneficiaries' decisions to disenroll. In addition to the Commission's role, it is essential that the Health Care Financing Administration, among others, be active in monitoring these trends. Sufficient resources should be available to HCFA to meet this need.

Setting a Floor Rate for Payments on Behalf of Disabled Beneficiaries

About 12 percent of all beneficiaries are eligible for Medicare because they are disabled. For the most part, they qualify as recipients of Social Security Disability Insurance (SSDI), a program for individuals who are unable to work due to a medical condition and who meet certain other conditions. They qualify for Medicare after receiving SSDI for 24 months and are classified as disabled by Medicare until they turn 65, after which they are not distinguished from aged beneficiaries.[11]

Disabled beneficiaries are only half as likely as aged beneficiaries to participate in Medicare risk plans. In June 1997, 5.8 percent of disabled beneficiaries were enrolled in risk plans, compared with 13.4 percent of aged beneficiaries. Enrollment growth, however, is about as rapid among disabled beneficiaries as among aged ones. The difference between the two groups' enrollment rates varies in different markets around the country.

For 1997, the U.S. per capita cost, the basis for setting county-level rates, was $400.98 for disabled beneficiaries and $466.95 for aged beneficiaries. Thus, spending on behalf of disabled beneficiaries was about 86 percent of that for aged beneficiaries. In spite of this lower average spending, the legislation did not set a separate floor rate for disabled beneficiaries. Had it done so, the equivalent floor rate would have been about $316 instead of the $367 floor set for aged beneficiaries.

Recommendation

Adjustments to payment rates on behalf of disabled beneficiaries should be made through a national risk adjuster when the new risk-adjustment system is implemented in 2000.

If this change is not made, the floor rate for payment on behalf of disabled beneficiaries should be set separately from the floor for payment on behalf of aged beneficiaries. It should be based on the difference between average fee-for-service spending for the two groups of beneficiaries.

The result of the high floor is that rates for disabled beneficiaries are set at the floor for about 78 percent of all counties in 1998, with the remaining counties getting the minimum increase. About 48 percent of all disabled beneficiaries, but only about 18 percent of the disabled beneficiaries who are enrolled in risk plans, live in these floor counties. For these counties, the high floor means that plans will be overpaid by as much as $60 per month for any disabled beneficiaries they enroll. The cost of this higher floor in 1998, without assuming any enrollment increases, is about $20 million to $30 million.[12]

This issue would best be addressed if the new system for risk adjustment, to be implemented in 2000, eliminates the separate county rates for disabled beneficiaries that are used today. By treating disability status as a risk-adjustment category, there would be a uniform payment differential, regardless of county of residence, for disabled versus aged beneficiaries—with further adjustments based on the health status indicators used in the new system. If new risk adjusters are implemented on schedule and treat disability in this way, the issue of a floor rate for disabled beneficiaries would become moot.

Alternatively, this error could be corrected by setting the floor for disabled beneficiaries at a level 14 percent below the floor for aged beneficiaries. This approach locks in the empirical difference in fee-for-service spending as of a particular year in setting floor rates. County differences based on 1997 spending would remain for counties above the floor. When implemented, rates for many counties would be reduced from the previous year's rates. To accomplish this change, the minimum increase (2 percent) must be waived for these counties.

[11] See *Medicare and the American Health System: Report to the Congress* (ProPAC 1997) for additional analysis of managed care and disabled beneficiaries.

[12] If this calculation were based on the total number of disabled managed-care enrollees who live in floor counties, the estimated savings would be about $36 million. Because the 1997 rate for some of these counties was higher than the $316 floor that is implied by the Commission's recommendation, the total cost of the higher floor is somewhat less, as noted.

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Alternate Budget Neutrality Mechanism

Under the rules set forth in the BBA, budget neutrality cannot always be achieved, depending on factors such as actual growth rates in Medicare spending. For example, the national growth percentage used in setting 1998 rates was too low to pay for the floors and minimum updates. The projected rate for 1999 would cause budget neutrality to fail again. The law includes no alternative mechanism to deal with this situation, leaving total payments higher than if based on local rates only. The additional cost to the Medicare trust fund of not achieving budget neutrality is estimated at about $100 million. The law appears not to allow HCFA the option of waiving the floor rate or minimum increase.

Recommendation

If budget neutrality cannot be achieved with the mechanism established in law, then an alternate mechanism should be provided for achieving budget neutrality.

It is possible that the Congress intended to waive budget neutrality when it could not be achieved through the mechanism in the law. But, assuming this is not the case, an appropriate solution is to write an alternate mechanism into the law for any year when all blended-rate counties are reduced to either their floor or minimum-increase rates without achieving budget neutrality.

Any alternate mechanism requires reducing payments below the floor or minimum-increase amounts, but it unclear whether the two rules should be treated differently. The policy rationale for the floor was that it represents a minimum payment amount appropriate to encourage plans where participation was low, while the minimum increase was designed to protect plans from the full effects of policy changes in any given year.

One mechanism would waive the rule that sets the minimum increase at 2 percent, while leaving the floor rate intact. In 1998, using this option would have resulted in lowering the minimum increase from 2 percent to about 1.6 percent. Another option would first lower the increase for floor counties to 2 percent, and then lower the increase for all counties by any additional amount necessary to achieve budget neutrality. A third option would reduce the increase for both types of counties by the same number of percentage points.

A legislative change to the budget neutrality rule cannot be made before the 1999 rates are determined, and current projections suggest that budget neutrality might be achieved for 2000 through 2003. Nevertheless, creating an alternate mechanism would be important if future national growth percentages fall below current projections.

Adjustments to County Base Rates

The county payment rates established under the BBA use the 1997 rates calculated under the old system as a starting point. As described above, the only change made to the 1997 rates, before blending local and national rates and applying floors and minimum updates, is the exclusion of fee-for-service payments made for graduate medical education.

There are three outstanding issues with respect to county base rates. One is the exclusion of Medicare payments to disproportionate-share hospitals (DSH) from the base rates. The second is the inclusion of estimated spending in Department of Veterans Affairs (VA) and Department of Defense (DOD) facilities. For both of these special payment categories, adjustments would allow plan capitation rates to reflect more accurately the underlying fee-for-service spending for which plan payments are being substituted. The third is the future rebasing of all county rates.

Recommendation

Additional modifications should be adopted to make base rates used for the local components of blended rates more reliable as estimates of expected patient care costs. These modifications, which should be implemented simultaneously, include:

- exclusion of special payments to hospitals serving a disproportionate share of low-income patients; and
- inclusion of the cost of care currently provided by other institutions (Departments of Veterans Affairs and Defense), to the extent that such care is likely to be furnished by Medicare+Choice plans.

To implement the latter, data on use of VA/DOD facilities—by Medicare beneficiaries in general and plan enrollees in particular—must be available at the county level.

When all transitions called for by the Balanced Budget Act (for example, shifting to a 50:50 blended rate) have occurred in 2003, consideration should be given to revising the county rates used for the local component of blended rates. In doing so, attention should be given to use of more current data, use of multiple years of data, and the consequences of using fee-for-service data in markets where Medicare+Choice penetration has grown considerably.

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Plans are overpaid to the extent that they do not pass on DSH payments to the appropriate hospitals.[13] DSH payments represent about 3 percent of plan payments nationwide. At the state level, DSH shares range from under 1 percent in three states to over 5 percent in three states. Variation at the county level is even greater, with a few counties topping 10 percent. Excluding these payments from the base rates would reduce the county payment rates and thus the payments to health plans. If these payments are removed from plan payments, a means could be provided for compensating the facilities that normally receive DSH payments, as previously recommended by ProPAC. These facilities could receive payments for the Medicare+Choice enrollees they treat using a mechanism analogous to that adopted in the BBA for distributing GME payments that were removed from plan payments.

To the extent that some beneficiaries receive services in VA/DOD facilities, county payment rates are inaccurate because those services are not included in the calculation of fee-for-service base rates. Services delivered in VA/DOD facilities also average about 3 percent of total Medicare costs across all states. Use of these facilities ranges from just above 1 percent in two states to 5 percent or more in seven states. Estimates of services delivered in VA/DOD facilities are not available at the county level.

Including VA/DOD services in county base rates would raise those rates to account for all services beneficiaries receive from government programs. The resulting higher rate would be the correct rate for paying plans for enrollees who make no use of VA/DOD facilities, whether or not they had done so prior to enrolling. At the same time, this rate would be too high on behalf of enrollees who failed to discontinue their use of VA/DOD facilities after enrolling with the plan. There is no available evidence, however, on the extent to which plan enrollees use VA/DOD facilities. Such use could decrease if enrollees understand that all care should be delivered by network providers. But use could increase if enrollees perceive problems in getting services they want from network providers (especially after 2002, when they are locked into their choice of plans for a full year).

Although the amounts represented by the two types of payments (DSH and VA/DOD) are offsetting at the level of national averages, they are not correlated at the state level. In fact, the correlation is slightly negative. For example, the state with proportionately the most services in VA/DOD facilities (South Dakota) has one of the lowest shares attributable to DSH payments. Even so, making these two adjustments in the same year might help balance the impact on plans in some, but not all, counties.

Several technical considerations will affect any decision to make these adjustments to base rates. First, as payment rates deviate from those calculated under the old system, adjustments will become increasingly difficult to implement.[14] Second, as long as payment rates are calculated at the county level, it will be necessary to measure the use of VA/DOD facilities at the county level. The only available analysis measured these services at the state level, but this same analysis could be repeated at the county level.[15]

A more general issue is the future rebasing of rates. In the absence of further changes in law, the blended rate will be based on 50 percent local rates in 2003 and thereafter. Thus, 1997 fee-for-service county spending will remain in the system in the absence of further legislative change, creating several concerns. First, given the volatility of county rates, especially for smaller counties, spending for any one year may not accurately measure underlying spending. Second, over time, 1997 spending will less accurately represent current patterns. Third, as the number of beneficiaries remaining in traditional Medicare drops, fee-for-service spending will become less accurate as a measure of overall spending. Today, enrollment in risk plans has exceeded 50 percent in only a handful of counties. But, as overall enrollment grows, the fee-for-service sector in certain counties could become too small to be an accurate basis for setting the local component of rates.

One approach to rebasing would be to use spending from a later year or an average across several years. This simple solution would move the base forward from 1997 patterns, and the use of a multi-year average would reduce the impact of volatility. But this solution would be vulnerable to the shrinkage of the fee-for-service sector in certain areas.

[13] In addition, if the method for making DSH payments is changed, as MedPAC is recommending, the inclusion of payments made under an old DSH policy in the base rates for paying plans will increasingly become a distortion (see Volume I, Chapter 6).

[14] One basic approach would be to make the adjustments to the 1997 base rates before the blending and other calculations are made (similar to how the GME exclusion has been implemented). But because a new exclusion would likely start at least two years into implementation of the BBA rules, it could affect the role of the annual 2 percent minimum increase.

[15] See *State Variation in the Resource Costs of Treating Aged Medicare Beneficiaries* (ProPAC 1996). Staff have determined that the VA and DOD have appropriate county-level data to support repeating this analysis at the county level.

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A different approach would remove or reduce further the use of local rates in the calculation of payment rates. An example of this approach would be to shift from the 50:50 blend of local and national rates to rates based totally on input-price-adjusted national rates. Simulations of these rates show that county variation would be further reduced, but that considerable variation based on input prices would remain. For example, average rates for central urban counties would fall from 11 percent above the national average (for the 50:50 blended rate) to 7 percent above (for the fully national rates). Similarly, average rates for the most rural counties would rise from 14 percent below the national average to only 9 percent below. In determining whether this would be an appropriate basis for setting rates, consideration should be given to what variations are appropriate to consider. National rates, in the current design, incorporate differences in local input prices, but not variations in the local population's health status and other characteristics or discretionary factors such as provider practice styles. Ideally, policies would hold plans and providers harmless for nondiscretionary sources of utilization variation, while creating incentives to reduce discretionary sources of variation.[16]

Input-Price Index

The national component of the blended rate is adjusted for each county by an index that reflects the relative input prices for services in that county compared to the national average input price. The BBA establishes an interim default index built on the hospital wage index and the physician geographic practice cost index (used in traditional Medicare payment systems). It applies these indexes in proportion to the amount of hospital and physician spending in Medicare as a whole. Thus, for 70 percent of the proportion of the payment attributable to Part A and for 13.6 percent of the payment attributable to Part B, the hospital wage index is applied. The geographic adjustment factors used for the Medicare Fee Schedule are applied to 66 percent of the proportion of the payment attributable to Part B. No index is applied to the remaining 30 percent of the proportion of the payment attributable to Part A or 20.4 percent of Part B.

Recommendation

As soon as feasible, an index reflecting local input prices faced by all types of health plans in delivering health services should be substituted for the interim index provided in the Balanced Budget Act of 1997.

The BBA authorizes the Secretary of Health and Human Services to create a new index for making input-price adjustments. Rather than using indexes developed for fee-for-service payment systems, it would be more appropriate to develop an index that would reflect local input prices faced by all types of health plans in delivering health services. Research is needed to develop the specifications for such an index.

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[16] See Chapter 14 of PPRC's *Annual Report to Congress 1996* (PPRC 1996) for a discussion of geographic adjustments of Medicare payments.

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Chapter 3

Risk Adjustment

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Chapter 3

Risk Adjustment

The Balanced Budget Act of 1997 (BBA) requires the risk adjustment of Medicare capitation payments starting in the year 2000. The first part of this chapter explains what risk adjustment is, why it is needed in Medicare, and what options are immediately available. The second part offers recommendations for implementing risk-adjusted capitation rates for Medicare+Choice plans.

Risk selection occurs when some health care plans attract predominantly healthy beneficiaries while others attract those in poorer health. Risk selection can be the result of beneficiaries' preferences; for example, some may be less willing to switch to a new health care plan once they become ill. Risk selection may also be affected by plans' decisions about the benefits, premiums, and networks they will offer.

Studies have repeatedly found significant risk selection in the Medicare risk-contracting program. New enrollees in Medicare managed-care plans appear quite healthy, with costs that are about 35 percent below the Medicare fee-for-service average in the six months before enrollment.[1] By contrast, beneficiaries disenrolling from managed-care plans had costs 60 percent higher than the Medicare fee-for-service average in the six months following disenrollment (PPRC 1996). The good health of new managed-care enrollees declines only slowly after enrollment, taking perhaps eight years to approach the level of the average Medicare fee-for-service beneficiary (PPRC Update 21). Data from the 1994 Medicare Current Beneficiary Survey indicate that the typical Medicare managed-care enrollee was much healthier than the average Medicare fee-for-service beneficiary (Riley et al. 1996).

Risk selection might be expected to vary significantly across Medicare+Choice plans. Plans will have differing benefit packages, provider networks, restrictions on out-of-network use, ownership, and information systems. Medical savings account (MSA) plans have already been identified as likely to attract healthier enrollees.[2] Other new Medicare+Choice plan types have not been as thoroughly analyzed. Some may be likely to experience favorable selection (enroll healthy beneficiaries) while others may encounter adverse selection (attract the less healthy).

Risk adjustment is the process of setting capitation rates that reflect health status, paying plans more to care for ill beneficiaries and less to care for healthy ones.[3] The payment rates might be based on the average cost of caring for patients with specific diagnoses, for example, $10,000 for a beneficiary with congestive heart failure but only $2,500 for one reporting no medical conditions. Plans disproportionately attracting healthy beneficiaries would see payments fall, while plans attracting the less healthy would see payments rise (see Table I-3-1).

[1] This was true even for markets with high Medicare managed-care enrollment (PPRC 1996).

[2] The Congressional Budget Office scored the MSA option for significant budgetary cost, because payment to the MSA would likely exceed the payment Medicare would otherwise have made on behalf of these healthy beneficiaries (PPRC 1996).

[3] Risk assessment, by contrast, means measuring risk selection but not necessarily changing payments (Dunn et al. 1995).

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Table I-3-1

Illustrating Risk Adjustment

Plan and Mix of Enrollees		Fraction of Population	Annual Payment Rate: No Risk Adjustment	Annual Payment Rate: With Risk Adjustment
Plan A:	Average Risk Profile			
	Congestive heart failure	33%	$5,000	$10,000
	All others	67	5,000	2,500
	All (average payment)	100	5,000	5,000
Plan B:	Favorable Selection			
	Congestive heart failure	22%	$5,000	$10,000
	All others	78	5,000	2,500
	All (average payment)	100	5,000	4,175
Plan C:	Adverse Selection			
	Congestive heart failure (CHF)	44%	$5,000	$10,000
	All others	56	5,000	2,500
	All (average payment)	100	5,000	5,825

SOURCE: Medicare Payment Advisory Commission.

NOTE: Data are for purposes of illustration only and do not reflect actual Medicare costs or payments.

Medicare's current payment methods are widely acknowledged to do a poor job of risk adjustment. The Medicare program adjusts payments using demographic and other information routinely recorded for all Medicare beneficiaries. For example, Medicare pays higher capitation rates for older beneficiaries. Demographics such as age and gender, however, provide little information about beneficiaries' health or health care needs. Demographics explain only 1 percent of the variation in individual beneficiaries' health care costs, and demographic differences do not account for managed-care enrollees' low costs prior to enrollment or for their significantly better health status (PPRC 1996; Riley et al. 1996).

This lack of adequate risk adjustment in the Medicare program causes a wide variety of problems. These problems can be viewed from three perspectives: the Medicare program, managed-care plans, or beneficiaries themselves.

From the Medicare program's standpoint, the lack of adequate risk adjustment increases spending. Medicare's capitation payments remain keyed to the cost of the average beneficiary, but plans attract healthier-than-average beneficiaries.[4] If Medicare had matched payments to the costs of this healthier group, program outlays would have fallen by perhaps $2 billion annually (PPRC 1997).

For managed-care plans, inadequate risk adjustment affects both profits and competition. Ideally, plans that can efficiently deliver high-value care would gain market share at the expense of others. But risk selection causes gains and losses unrelated to a plan's efficiency or value. A plan burdened with costly beneficiaries may not be able to compete, whereas a plan that attracts healthy ones may increase market share.

Finally, from the beneficiary's standpoint, the lack of adequate risk adjustment may affect access to and quality of care, particularly for those with high-cost conditions. Plans may be reluctant to develop programs tailored to these vulnerable populations because of the potential for financial losses if the plan attracts a significant number of such individuals. This could result in underinvestment in innovative approaches to care for the chronically ill.

Current Options for Medicare Risk Adjustment

This section reviews the recent progress with Medicare risk adjustment, starting from the recommendations made last year by the two predecessors of the Medicare Payment Advisory Commission (MedPAC). The risk adjustment provisions of the BBA are then summarized, and the section ends with a brief description of options for risk-adjustment in the year 2000.

[4] Prior to the BBA, capitation payments were set at 95 percent of projected Medicare fee-for-service cost per beneficiary. The BBA modified that, removing medical education costs, redistributing payment across counties, and reducing payment updates.

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1997 Recommendations

In 1997 both the Physician Payment Review Commission and the Prospective Payment Assessment Commission endorsed risk adjustment of Medicare capitation payments. Both commissions recommended that Medicare adopt risk-adjusted capitation rates based on health status, and that plans be required to report new data to allow Medicare to calculate those rates. The commissions emphasized the need for phasing in the new payment rates to avoid disrupting current Medicare risk-contracting relationships.

The commissions also described various approaches to restructuring payments. Risk adjustment could be based on beneficiaries' diagnoses as reported by plans, or on some other source of health status information. Additionally, it might be combined with partial capitation or outlier payments to create a closer fit between payments and individual beneficiaries' costs.

Available risk adjustment-methods capture a significant portion of the variation in costs and are an improvement over the current payment system. But the commissions acknowledged the drawbacks of these methods and the need to improve and supplement risk adjustment over the longer term. In particular, if the key concern is the financial incentive to serve those with very high need for care, then adjustment for health status alone may not be adequate.

Risk-Adjustment Provisions of the Balanced Budget Act of 1997

The Balanced Budget Act of 1997 provides a clear mandate and a tight timetable for improving risk adjustment in the Medicare program. Additional provisions of the BBA may affect the degree of risk selection, including broadening beneficiaries' choices and restructuring Medicare's enrollment process.

Many of Medicare's rules are designed to protect beneficiaries and to prevent overt discrimination against those in poor health. Plans cannot explicitly screen beneficiaries for health risks before they enroll, must charge everyone the same premium, and must have all marketing materials reviewed by the Health Care Financing Administration (HCFA).[5] In addition, once beneficiaries enroll, plans must have formal grievance procedures subject to external review for those who believe they have been unfairly denied services or reimbursement for care. Many of these provisions are maintained or strengthened under the BBA.

Several aspects of the Medicare risk-contracting program will change significantly, however. First, the Medicare+Choice provisions of the BBA broaden the types of plans available. Besides traditional managed-care plans, Medicare beneficiaries can choose from preferred provider organizations, unrestricted fee-for-service plans, provider-sponsored organizations, and high-deductible medical savings account plans. This wider range of choices may make risk selection more likely. Second, the process for enrollment and disenrollment from plans will change under the BBA. Currently, beneficiaries can enroll in or disenroll from managed-care plans on a monthly basis. Under the BBA, after a transition period, enrollment changes will occur primarily during an annual open enrollment period. During this annual open enrollment period beneficiaries will receive standardized information comparing plans.

The BBA provides a specific mandate for improving risk adjustment in the Medicare program. It calls for HCFA to implement a payment adjustment based on beneficiaries' health status. The same risk-adjustment method must be used for all Medicare+Choice plans. With some exceptions, payments to plans must be fully prospective capitation rates, that is, HCFA must specify the plans' payments at the start of the year.

The BBA gives HCFA the authority to collect encounter (claims-like) data from plans. These data will be HCFA's source of information on beneficiaries' diagnoses. As of January 1998, HCFA requires plans to report encounter data for all hospital discharges (and can ask for data from discharges that occurred after mid-1997). By mid-1998, HCFA can require plans to report encounter data from all sites of care, though this provision is not likely to be enforced immediately. In the spring of 1999, HCFA must report on the methods it will adopt for risk adjustment. Beginning in January 2000, HCFA is to pay plans on a risk-adjusted basis.

Risk-Adjustment Options Available to HCFA

HCFA has funded the development of several risk-adjustment models using diagnoses from claims or encounter data. Fundamentally, all the models using diagnosis data work the same way. They try to find diagnoses that identify substantial groups of beneficiaries with above-average costs. For example, since diabetes affects a large proportion of the elderly and tends to drive up medical care costs, all of these risk-adjustment models will set a higher capitation rate if diabetes is diagnosed. The payment weights are determined empirically from Medicare fee-for-service data, so that the higher payment for diabetics reflects their higher average costs under traditional Medicare.

[5] Some premium variation is allowed, such as variation across counties within a market area (see Volume I, Chapter 4). The premium (if any) charged to a beneficiary cannot, however, reflect the age, gender, health or other characteristics of the individual.

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Details of the particular risk-adjustment models vary significantly, however. Diagnostic cost groups (DCGs) take a relatively narrow approach to risk adjustment. DCGs use only inpatient diagnosis information, and place a beneficiary in at most one diagnosis category (Ellis et al. 1996). Hierarchical coexisting conditions (HCCs) take a much broader approach. HCCs use diagnosis information from inpatient and ambulatory care records, and allow beneficiaries to trigger a large number of diagnosis categories simultaneously (Ellis et al. 1996). Because payment in the HCC model reflects the sum of the payments for the individual categories, each diagnosis identified by the HCC model literally adds to payment. Yet another method, ambulatory care groups, takes information from all sites of care but places beneficiaries in at most one diagnostic group (Johns Hopkins 1995).

In the short run, the choice is narrowed further by the lack of ambulatory care diagnosis data. HCFA is working to collect inpatient information now, but for a variety of reasons it will be much more difficult to gather ambulatory care data. That limits immediate attention to the DCG model, which was designed to use inpatient-only data.[6] Over the longer run, other options will become available as data improve. These include HCCs and other models using diagnosis data from all sites, and payment methods that would pay plans in part based on services delivered (partial capitation).

Issues and Recommendations for Implementation of Risk Adjustment

Within this broad framework of risk adjustment using diagnoses reported in encounter data, HCFA must address a number of practical issues to ensure a smooth and fair transition to risk-adjusted payment rates. This section describes those issues and offers recommendations.

Phase-In of Rates

The introduction of risk-adjusted rates in Medicare involves more uncertainty than any other major payment revision that Medicare has made. This is due to the lack of data and to the unsettled state of risk-adjustment methodology. The potential for substantial changes in payment raises the possibility of disruption for plans and beneficiaries.

Recommendation

The Health Care Financing Administration should establish an orderly phase-in for all components of the risk-adjustment system, including data reporting, further development of risk-adjustment models, and implementation of adjusted payment rates. During the phase-in of risk adjustment, changes in plan payment rates should be limited to protect plans and the beneficiaries they serve from sharp swings in payment.

As soon as feasible, HCFA should announce operational details of its risk-adjustment system, to allow plans the necessary time to modify their contracts, accounts, and systems.

A significant factor creating uncertainty for the risk-adjustment process is the lack of data. Medicare is only now establishing the data reporting process for plans. Because plans do not currently provide these data, HCFA cannot simulate what any plan's risk-adjusted payment will be. That stands in contrast to Medicare's hospital prospective payment system or the Medicare physician fee schedule, where existing data were used to project how policy changes would affect providers. Finally, without data, there is no way to assess reporting differences among plans or to compare plans' reporting practices with data reporting in the Medicare fee-for-service payment baseline.

A second factor is the unsettled state of risk-adjustment methodology. Many options are available that may markedly affect payment rates, with little public discussion of their relative merits.

Third, significant changes are occurring in many other aspects of Medicare risk contracting. These include expansion of choices, introduction of an annual enrollment period, removal of teaching-related payments from the Medicare capitation rate, and geographic redistribution of Medicare payments. All of these factors make the Medicare+Choice market more volatile, and argue in favor of moderating payment changes caused by risk adjustment.

Plans' practical problems accommodating risk adjustment must also be considered. To arrange for data reporting, some plans may need to rewrite contracts with providers, while others may need to develop entirely new information systems. Plans' accounting systems may need to be modified to conform to Medicare's new payment method.[7] Some plans must consider whether or how to pass through any risk adjustment to their contracting providers.

[6] In theory, HCFA could run any model using any diagnosis data source. In practice, however, the DCG model was developed and optimized to run on inpatient data (Ellis et al. 1996).

[7] For example, lags in the processing of diagnosis data or in payment might require plans to accrue assets and liabilities in anticipation of future payments.

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Plans may want to accrue additional reserves (or perhaps reduce reserves) in anticipation of the implementation of risk adjustment. All this must take place against a backdrop where many other Medicare requirements for these plans are also changing.

HCFA can ease plans' administrative burden somewhat by announcing the full practical details of risk adjustment as early as possible. That would require rapid decisions on both the broad outline and the operational detail of the risk-adjustment system. Risk adjustment may require simultaneous changes in plans' core operating systems, such as accounting, billing, medical records, and contracts. A longer lead time to implement these changes will help smooth the transition to risk-adjusted rates.

Although all the above discussion argues for a relatively slow phase-in of payment changes, other factors argue for more rapid implementation. Primarily, to the extent that the existing payment structure reflects significant overpayment and underpayment due to risk selection, delaying the introduction of risk-adjusted rates perpetuates all the problems of the existing system. In addition, risk adjustment may move payment only partway toward an ideal risk-adjusted rate, because even the best methods do not fully capture risk selection and tend to underadjust for true differences in costs (Ellis et al. 1996). Finally, the proposed path for implementation (unadjusted rates to DCGs to HCCs) already includes some element of a phase-in because the DCG model should affect plans' average payments less than HCCs would. To some degree, then, the risk-adjusted rates probably make conservative adjustments to payment.

The most reasonable course is to proceed with risk adjustment but to moderate any changes in plans' payments through a reasonable phase-in period. This should be long enough to allow plans to adjust to the payment changes and to allow HCFA to refine its payment models without unduly delaying the intended beneficial effects of risk adjustment.

A phase-in could be accomplished in a variety of ways. First, the risk-adjusted rate could be blended with the existing payment rates. That would dampen all the financial incentives of the risk-adjustment system because payments would stay closer to their current levels. These less extreme payment weights would provide time to observe and improve the risk-adjustment system before subjecting plans to the full financial incentives that the risk-adjustment models will create.

A different approach would be to set some limit on the maximum payment change applicable to a plan in one year. This strategy would very directly provide plans with some security that they would not be subject to violent payment swings. Under this approach, plans with stable enrollment could be guaranteed a relatively stable payment rate.

Beneficiaries as well as plans would benefit from moderating any changes in payment. The benefits offered and premiums charged by plans depend critically on the level of Medicare's payment. Sharp swings in payment may, in part, result in large annual changes in those benefits and premiums. Phase-in limits on payment changes would allow plans and the beneficiaries they serve to adjust to the new rates in an orderly fashion.

Inpatient Data Versus Data from All Sites of Care

The key practical consideration for risk adjustment is data. In order to pay more for sick beneficiaries and less for healthy ones, Medicare has to have some systematic way to identify those beneficiaries. Information on beneficiaries' diagnoses would allow Medicare to set risk-adjusted rates, but plans do not currently report this type of information to Medicare.

Recommendation

As quickly as feasible, the Medicare program should develop the capability to use diagnosis data from all sites of care for risk adjustment.

HCFA should explore interim alternatives to full encounter data for ambulatory care settings, such as allowing plans to identify a subset of beneficiaries with costly diagnoses but no inpatient treatment.

In the short run, Medicare risk adjustment will probably be based on diagnosis data reported on inpatient hospitalizations only. Inpatient data are the most feasible to collect. Nearly all hospitals can report such information in a standard format, and the volume of data is small because there are relatively few hospitalizations per beneficiary per year. Inpatient diagnosis data are also more reliable, reflecting a reasoned professional judgment on the cause for hospitalization.

Although inpatient data are easier to collect, relying solely on such data has some significant drawbacks. First, it distorts incentives regarding hospitalization. Risk adjustment based on inpatient diagnoses results in higher payments only for hospitalized beneficiaries. Plans that are good at substituting ambulatory care for hospitalizations may suffer financially. The resulting incentives may affect hospitalization decisions, with plans encouraging their physicians to use inpatient over outpatient modes of treatment.

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At the extreme, reliance on inpatient-only data might encourage plans to hospitalize less severely ill beneficiaries. For example, patients who now receive same-day surgeries or outpatient observation stays might instead be treated on an inpatient basis.[8] To the extent that plans admit patients with lower levels of medical necessity, this would increase payments to the plan. Countering this tendency would require HCFA to monitor the medical necessity of admissions, disregard very short stays, or implement some other means to monitor the propensity to hospitalize patients.

Second, the use of inpatient-only diagnosis data would result in very large payments made on behalf of a relatively small proportion of the population. For the Medicare fee-for-service population, only about 20 percent of beneficiaries are hospitalized in any given year. Assuming plans' hospitalization rates are roughly similar, the DCG risk-adjustment model would set a high rate for these beneficiaries and a low rate for the remaining 80 percent of beneficiaries not hospitalized.

Ambulatory care encounter data, by contrast, give a broader picture of beneficiaries' diagnoses but raise significant practical problems for Medicare risk-contracting plans. Some plans do not generate this information in any standardized format. Relative to inpatient data, ambulatory care encounters involve much greater amounts of data (more encounters per beneficiary) and a vastly larger and more diverse array of providers (physicians, labs, clinics, therapists, hospital outpatient departments, and others). Costs for data collection would be significantly higher than those for inpatient data.

A second series of problems for ambulatory care data arises from the accuracy of coding. Diagnosis coding on outpatient claims commands far less attention than it does on inpatient claims. Many private payers, for example, do not even require that diagnoses be coded on ambulatory care claims (Dunn et al. 1995).

The lack of complete diagnosis coding in Medicare fee-for-service claims data raises another problem for the use of ambulatory care diagnosis data. Diagnosis coding in fee-for-service claims may show little persistence from year to year. For example, only half of beneficiaries coded as quadriplegics in one year receive that diagnosis the following year (see Volume II, Chapter 2). This causes a problem because Medicare's fee-for-service population is used as the baseline for setting payments. A plan's payment will rise if it reports above-average prevalence of disease for its enrollees. The benchmark for average prevalence, however, is the average reported in Medicare fee-for-service claims. If diagnosis data are underreported in those claims, plans can appear above average either due to truly higher incidence of disease or due merely to better reporting of data. Thus, if diagnoses are underreported in the baseline but correctly reported by a plan, this will increase Medicare outlays to the plan.[9]

Plans should be encouraged to identify enrollees with chronic illness and to report diagnosis information correctly and completely. Medicare payments, however, should reflect the true prevalence of disease and should not vary with plans' data reporting practices. The use of ambulatory care diagnosis data may require HCFA to develop an adjustment for variation in data reporting among plans. Over the longer term, use of such data may also necessitate recalculating the payment weights to reflect the typical treatment and data reporting practices of Medicare+Choice plans.

Finding some reasonable middle ground between inpatient data and full encounter data may prove difficult. The basic idea is simple: Plans would report information for beneficiaries with a particular diagnosis, hospitalized or not. Beyond that, HCFA must be able to apply the definition to the Medicare fee-for-service baseline (to calibrate the payment amount) and the definition must lead to data that may be audited. One approach would be to allow plans to report information on beneficiaries receiving a costly ambulatory service strongly related to a diagnosis. For example, plans might report cancer patients receiving outpatient chemotherapy.

The proper role of interim data reporting standards will depend in part on how soon plans can report complete encounter data. If most can do so quickly, it may not be worthwhile to invest in developing interim standards. If not, then the case for developing such standards is much stronger. The costs for creating and implementing interim standards for the partial reporting of ambulatory care data would have to be weighed against the clear drawbacks of staying with inpatient-only risk adjustment.

[8] In fee-for-service Medicare, some hospital stays of less than 48 hours duration are classified as outpatient observation stays and are paid as outpatient services rather than inpatient hospital admissions.

[9] The lack of persistence of coding and the problems this causes for risk adjustment appear to have been noticed only recently, in the course of setting capitation rates for Colorado Medicaid (Richard Kronick, University of California San Diego, personal communication, October 1997). In the first year of operation, however, managed-care plans actually underreported diagnosis data slightly relative to the Colorado Medicaid fee-for-service baseline (Tollen and Rothman 1998).

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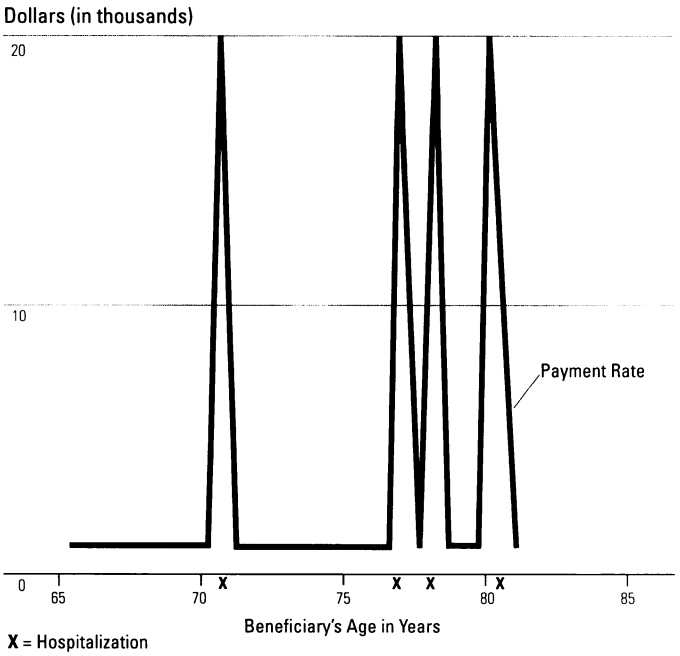
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Figure I-3-1

Illustrating the Volatility of Payments Over a Lifetime for Single-Year Risk-Adjustment Models



SOURCE: Medicare Payment Advisory Commission.

NOTE: Table illustrates payment for a risk-adjustment model using inpatient diagnoses, for a beneficiary hospitalized four times after the age of 65.

The Need for a Multiyear Framework for Risk-Adjustment Models

All the risk-adjustment models now being considered use a single year of diagnosis data and a single year of cost data. Accordingly, payment for an individual may swing significantly from year to year. Even within that simple one-year-at-a-time framework, HCFA must resolve some fundamental (and financially important) issues regarding the timing of diagnosis data and payment, and whether the risk adjuster should focus on acute care costs or the chronic risk related to a disease.

Recommendation

HCFA should adopt a risk-adjustment system that recognizes the future costs that beneficiaries are likely to incur, based on their diagnoses.

As soon as feasible, HCFA should refine its risk-adjustment methodologies to use more than a single year of data for diagnoses and costs.

HCFA needs to consider at least three major issues in the timing of diagnosis data and payments. First and most obviously, no method based on a single year's data will result in much stability of payments for individual beneficiaries. The risk-adjustment models being considered by HCFA yield a one-year payment hike based on the presence of a diagnosis, with payment returning to the baseline level in the subsequent year unless the diagnosis is reported again in that year. For risk adjustment based on inpatient data, the rate paid for a beneficiary will fluctuate widely over time (Figure I-3-1).[10] This is at odds with the underlying medical model of risk adjustment, namely, that permanent conditions should result in a permanently higher risk of need for care.

This instability of payment may prevent risk adjustment from creating a strong financial incentive to innovate. Ideally, the risk-adjustment process should allow plans to profit by caring well for the chronically ill. It should encourage plans to develop specialized programs that would better serve beneficiaries with chronic conditions. Instability of payment may hamper this goal. Because payments for individual beneficiaries would fluctuate widely from year to year, any such programs would have to have many enrollees to ensure a stable stream of revenues.

HCFA could consider creating a more stable payment basis by including more than a single year of diagnosis data in its risk-adjustment models. That not only would provide a more complete picture of a beneficiary's diagnoses, but would permit carrying over diagnoses for permanent conditions for several years. Using multiple years of diagnosis data would not be easy, however. It would require new research to set payment rates based on diagnosis data that spanned years. It would also add complexity by requiring HCFA to track beneficiaries' diagnoses over several years. Another way to stabilize payment rates would be to include more years of cost data in the risk-adjustment model. For example, using two years of data would let HCFA set rates that were (largely) stable for two years at a time.

The calibration of the payment rates raises a second important issue relating to the timing of the diagnosis data. Medicare will set a payment rate for each diagnosis that reflects average Medicare fee-for-service costs (at least initially). But the payment could reflect either the typical costs incurred in the year of the diagnosis or in the year afterwards.

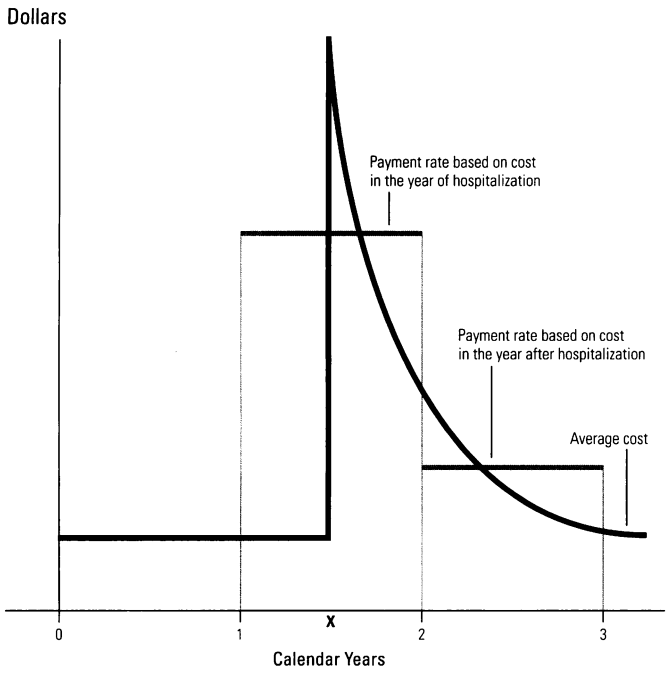
This issue can be discussed most clearly for the DCG model. DCGs set a high risk-adjusted rate only for hospitalized beneficiaries. For DCGs, therefore, the timing issue for payment calibration amounts to this question: Should the payment rate reflect the typical costs incurred in the year that the beneficiary was hospitalized, or should it reflect the typical costs in the following year?

[10] This also will be true for models using inpatient and ambulatory data if plans' diagnosis coding practices match those in Medicare fee-for-service claims data (see Volume II, Chapter 2).

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Figure I-3-2

Two Approaches to Setting Payment Amounts



X = Hospitalization

SOURCE: Medicare Payment Advisory Commission.

These two approaches would result in quite different payment rates for the DCG model (see Figure I-3-2).[11] Costs would be very high in the year of hospitalization due largely to the expenses of the hospital episode itself. Calibrating payment to match these average costs would result in very high payment for hospitalized beneficiaries and very low payment for all others. Costs incurred in the following year would be much lower, reflecting regression toward the mean in health care costs (Dunn et al. 1995).[12] Calibrating the model this way results in rates that vary much less between beneficiaries who are hospitalized and those who are not.

A third and related issue is the lag between reporting a diagnosis and counting that diagnosis for payment. HCFA has two strategies available. First, HCFA could set a plan's payments for a year based on diagnoses reported during the year. That approach simplifies the tracking of diagnosis data (no need to track data across years), but complicates payment. A retrospective adjustment would be necessary for diagnoses occurring during the year but reported after year-end. Second, HCFA could set payment using diagnoses from the prior year. That increases administrative complexity, requiring HCFA to track each beneficiary's diagnoses over time, but would simplify payment. The payment for each beneficiary could be specified in advance, and no retrospective settlement would be necessary.

These two separate timing issues, calibrating the payment rate and determining the payment lag, have quite different effects on plans' payments. The issue of payment calibration affects all plans: Calibrating the model to current-year costs will amplify the payment changes that any plan will see. The issue of payment timing, by contrast, is important only to plans whose mix and rate of diagnoses vary widely from year to year. These might be, for example, small plans, plans with high enrollee turnover, or plans with dramatic shifts in practice or data reporting patterns. Plans with a stable rate and mix of diagnoses will, by definition, receive roughly the same total payments whether current-year or prior-year diagnosis information is used.

Supplementing Risk Adjustment with Risk Sharing

Diagnosis-based risk-adjustment systems set payments that match the average cost of treating a particular disease. This will result in underpayment for patients with particularly severe disease or who undergo a catastrophic health care event. Risk adjustment may reduce incentives for risk selection, but will not by itself create neutral financial incentives for plans to provide specific services.

Recommendation

Medicare should undertake a large-scale demonstration of partial capitation or other methods that would pay plans partly on the basis of a capitated rate and partly on the basis of payment for services used.

Risk sharing—basing payments at least in part on actual services used—provides an alternative payment approach that can supplement the basic risk-adjustment system. The BBA specifically allows certain types of risk-sharing arrangements, such as reinsurance for catastrophic cases or reinsurance for large aggregate financial losses. Those methods result in sharing of the plan's financial risks for some cases or in some years.

[11] This is illustrated in more detail in Volume II, Chapter 2.

[12] Either way (current year or following year), all costs are accounted for. Spending is captured either in the DCG categories or in a residual category for all other beneficiaries. Higher payments in the DCG categories necessarily mean lower payments for the residual category.

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Partial capitation is a different approach to risk sharing. In its simplest form, plans would submit claims for all services.[13] Plans would receive both a reduced Medicare fee-for-service payment and a low capitation rate in some actuarially fair combination. This approach has the promise to offer incentives that apply toward all beneficiaries and that may be more economically neutral than either fee-for-service payment or capitation alone (Newhouse et al. 1997).

Partial capitation may have some secondary advantages as a method for paying Medicare+Choice plans. It would reduce the plan's overall financial risks, and so might be particularly useful for small plans, new plans, rural plans and perhaps provider-sponsored organizations. It also would provide a strong incentive for complete reporting of claims (encounter) data. Information of this type may eventually be needed to recalibrate Medicare's payments to some basis other than Medicare fee-for- service use and costs.

The partial capitation approach is not without significant drawbacks, however. Mainly, managed-care plans may object to the modified fee-for-service incentives that this approach is intended to create. In addition, the simplest forms of partial capitation would entail all the complexity of claims processing. Plans would have to submit claims from all sites of care. Each service would be priced and paid for by HCFA, a potentially difficult task given the variety of payment rules in effect for ambulatory care services (see Volume I, Chapter 1).

Monitoring and Continued Development of Medicare Risk Adjustment

Given how little is actually known about the practical details of risk adjustment, HCFA must plan for close monitoring of plans' responses to the rates. Significant changes in the data-reporting and risk-adjustment regulations should be expected as HCFA gains more experience with these methods.

Recommendation

HCFA should closely monitor plans' data reporting and the impact of payment changes and be prepared to undertake frequent, regular refinements of risk-adjustment policy. HCFA should explore the reliability and stability of its risk adjustment method for small plans and consider limits on payment changes for such plans.

In January 2000, Medicare's system for reporting encounter data and calculating risk-adjusted payment rates will have had little practical trial. Currently, HCFA is implementing risk-adjusted rates for a small number of plans in the ongoing Medicare Choices Demonstration.[14] That risk adjustment work is only now getting under way.

Given the untested nature of the system, it is reasonable to expect significant problems as well as significant opportunities for improvement over time. This calls for a systematic strategy for monitoring and refining the risk-adjustment system. Major changes should be expected as Medicare and plans gain experience with risk adjustment.

For a variety of reasons, small plans may be particularly vulnerable to problems with the risk-adjustment system, and these plans may require special attention. Such plans already have more unstable costs due to their small enrollment. In theory, risk adjustment should help stabilize such plans' finances and help offset fluctuations in costs.[15] In practice, small plans may still raise concerns. These plans may have fewer resources to report data completely, lower financial reserves, and reduced ability to smooth over variations in cash flow. Financially vulnerable plans—small plans, plans in rural areas, and new plans—might require additional protection from wide swings in payments.

For all plans, information from a variety of sources will give HCFA a firmer foundation for judging the accuracy and reliability of risk-adjustment methods. HCFA should correlate all the information it gathers about plans—enrollment and disenrollment rates, beneficiary mortality, costs per person, and data from existing and planned surveys—to cross-check its risk-adjustment formula. A close correlation among measures would strengthen the case for the risk-adjustment method used. A lack of correlation, by contrast, might point to areas needing further refinement of methods. Discrepancies among sources of data for an individual plan (for example, a plan with high mortality rates but low measured risk) might be used to target audits. Tracking of data for new enrollees and disenrollees might be used to demonstrate or identify variations in plans' data reporting practices (Tollen and Rothman 1998).

[13] Risk-sharing methods using only inpatient claims have also been extensively examined for use by Medicare (Wrightson et al. 1996).

[14] The Medicare Choices Demonstration is a HCFA initiative to offer a wider variety of plans to beneficiaries.

[15] For example, an unexpected increase in hospitalizations would increase a plan's costs but would also increase its risk-adjusted payment rate.

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Commission Members

Gail R. Wilensky, Ph.D., is chair of the Commission. She is the John M. Olin senior fellow at Project HOPE, where she analyzes and develops policies relating to health care reform and ongoing changes in the medical marketplace. She also frequently advises members of Congress and others on the policies and politics of health care reform. Former chair of the Physician Payment Review Commission, Dr. Wilensky has held several posts in the executive branch, most recently as deputy assistant to the President for policy development during the Bush Administration and, before that, as administrator of the Health Care Financing Administration. Recipient of numerous professional awards, she is a member of the Institute of Medicine, a trustee of the Combined Benefits Fund of the United Mine Workers of America, and a governor for the Research Triangle Institute. In addition to serving on many other professional committees and corporate boards, Dr. Wilensky is a well-known speaker who has published widely on health policy, economics, and financing. She received a B.A. in psychology and a Ph.D. in economics from the University of Michigan.

Joseph P. Newhouse, Ph.D., is vice chair of the Commission. He is the John D. MacArthur Professor of Health Policy and Management at Harvard University and director of Harvard's Division of Health Policy Research and Education. He has been at Harvard since 1988. Previously, Dr. Newhouse was a senior corporate fellow and deputy program manager for health sciences research and head of the economics department at RAND. He has conducted research in health care financing, economics, and policy and was principal investigator for the RAND Health Insurance Study. Dr. Newhouse has served on many technical panels for health-related organizations, including the National Academy of Social Insurance, the Agency for Health Care Policy and Research, the Health Care Financing Administration, the Workers' Compensation Research Institute, and the Association of American Medical Colleges. He is a member of the Institute of Medicine, as well as a former chair of the Prospective Payment Assessment Commission and a member of the Physician Payment Review Commission. He is also a past president of the Association for Health Services Research. Dr. Newhouse is editor of the *Journal of Health Economics* and associate editor of the *Journal of Economic Perspectives.* He received a B.A. from Harvard College and a Ph.D. in economics from Harvard University.

P. William Curreri, M.D., is president of Strategem of Alabama, Inc., an international health care marketing and consulting firm. Dr. Curreri has served as professor, chairman, and chief of surgery at the University of South Alabama. He was also on the faculties of the University of Washington School of Medicine and Cornell Medical Center. He previously served on the Physician Payment Review Commission. Dr. Curreri is a former president of the American Burn Association, the Society of University Surgeons, the Halstead Society, and the American Association for the Surgery of Trauma. Author of numerous articles on surgery, Dr. Curreri is a member of the editorial boards of several major surgical and burn care journals and a past editor-in-chief of *The American Surgeon.* A frequent adviser to the National Institutes of Health, Dr. Curreri was a member and former chair of its Surgery, Anesthesia, and Trauma Study Section. He is also a member of the American Board of Surgery and a former member of the executive committee of the board of governors of the American College of Surgeons, where he was secretary from 1987 to 1989. Dr. Curreri received a medical degree from the University of Pennsylvania and completed a surgical residency at the Hospital of the University of Pennsylvania.

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Anne B. Jackson is a member of the National Legislative Council of the American Association of Retired Persons and served as chairperson of the Health and Future Generations Committee. She also previously served on the Physician Payment Review Commission. A registered nurse for 45 years, she retired in 1989. Mrs. Jackson was a professor in the Department of Nursing at City University of New York and was medical supervisor, head nurse, and staff nurse for the Veterans Administration (now the Department of Veterans Affairs). She is a member of the Institute of Medicine's Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Mrs. Jackson received a bachelor's degree in education from Hunter College and a master's in nursing administration from Columbia University Teacher's College.

Spencer Johnson has been president of the Michigan Health and Hospitals Association since 1985. Previously, he was executive vice president of the Hospital Association of New York State. Mr. Johnson's prior experience includes staff positions on the U.S. Senate Committee on Human Resources and in the U.S. House of Representatives. He was associate director of the Domestic Council for Health, Social Security, and Income Assistance from 1976 to 1977, where he was responsible for policy planning and development for President Gerald Ford. He served on the Prospective Payment Assessment Commission as well as various boards, including those of the Albany Medical College, the Washington Hospital Center, the Alpha Center, and the Genesee Regional Health Planning Council. He is currently a board member of Blue Cross Blue Shield of Michigan and the MHA Insurance Company. Mr. Johnson received a B.A. in journalism from St. Bonaventure University and an M.P.A. in health policy and planning from Cornell University.

Peter Kemper, Ph.D., is vice president of the Center for Studying Health System Change. He directs the center's Community Tracking Study, a major national study of change in the health care system and its effect on health care delivery, access, cost, and quality. Before that, he was director of the Division of Long-Term Care Studies at the Agency for Health Care Policy and Research, where he headed studies of nursing home and home health care. Dr. Kemper has published widely on long-term care of the elderly, including home care for those with chronic care needs, nursing home use, and financing of care. Earlier in his career, he was a director of Mathematica Policy Research and an assistant professor at Swarthmore College. Dr. Kemper received a B.A. from Oberlin College and a Ph.D. in economics from Yale University.

Judith R. Lave, Ph.D., is professor of health economics at the Graduate School of Public Health and co-director of the Center for Research on Health Care at the University of Pittsburgh. She holds secondary appointments in the Katz Graduate School of Business and in the departments of economics and psychiatry. Previously, she served on the Prospective Payment Assessment Commission. At the U.S. Department of Health and Human Services, she was the director of the Division of Economic and Quantitative Analysis in the Office of the Deputy Assistant Secretary and director of the Office of Research in the Health Care Financing Administration. Dr. Lave is also a member of the Institute of Medicine and the National Academy of Social Insurance. She is past president of the Association for Health Services Research and the Foundation for Health Services Research. In addition, Dr. Lave chaired the technical panel on health and was a member of the expert panel on income and health care for the Advisory Council on Social Security. She served on the editorial boards of the *Journal of Health Politics, Policy, and Law* and the Health Administration Press. She received a B.A. from Queen's University in Canada, from which she also received an honorary LL.D., and a Ph.D. in economics from Harvard University.

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D. Ted Lewers, M.D., a practicing nephrologist and internist, is also on the staff at the Memorial Hospital in Easton, Maryland. A member of the board of trustees and secretary-treasurer of the American Medical Association, Dr. Lewers is medical director of the Easton and Chestertown Renal Treatment Center, chair of the board and chief executive officer at the Medical Mutual Liability Insurance Company of Maryland, and chair of the board of the Health Enhancement Center, Inc. Previously, he served on the Physician Payment Review Commission. Long active in organized medicine, Dr. Lewers served as president of the Medical and Chirurgical Faculty of Maryland from 1985 to 1986 and as vice chair of the American Medical Association's Relative Value Scale Update Committee. Dr. Lewers received a B.A. from the University of Maryland and a medical degree from the University of Maryland School of Medicine. He completed an internship at the University of Maryland (Baltimore), a residency at Maryland General Hospital, and a fellowship in nephrology at Georgetown University Hospital.

Hugh W. Long, Ph.D., is professor of health systems management at the Tulane University School of Public Health and Tropical Medicine in New Orleans. He also holds appointments at Tulane's School of Law and the Freeman School of Business, where he is a member of the graduate faculty. Dr. Long is the founder and faculty director of Tulane's master's of medical management degree program for physicians. Previously, he served on the Prospective Payment Assessment Commission. He has also taught at Yale, Stanford, San Jose State, and Ohio State universities. Dr. Long has served as an ad hoc adviser on health care financing to the Committee on Ways and Means of the U.S. House of Representatives and to the Committee on Finance of the U.S. Senate. He has also testified before these committees on matters of health financing policy. He currently serves as the chairman of the Medicare Geographic Classification Review Board. He is the author of numerous articles on health care financing and management and is a member of the faculty of the American College of Physician Executives. Dr. Long received a B.A. from Ohio State University, an M.B.A. and a Ph.D. in business administration and finance from Stanford University, and a J.D. from Tulane University.

William A. MacBain is senior vice president, Health Plan Operations—New York, for the Penn State Geisinger Health System and executive director of Penn State Geisinger Health Plan, Inc. He is a board member of the American Association of Health Plans and a past commissioner of the Prospective Payment Assessment Commission. His broad background in managed care encompasses general management operations, marketing, planning, finance, product and network development, rate setting, and government affairs. Mr. MacBain joined Penn State Geisinger in 1988. He began his career with Prepaid Health Plan where he advanced to director of plan administration. In 1982, Mr. MacBain was named vice president of finance for the Nassau (New York) Plan for Healthcare. After that, he was director of operations for HMO of Oklahoma in Tulsa. He has a B.A. and a master's degree in hospital and health service administration from Cornell University.

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Woodrow A. Myers, M.D., is director of health care management for the Ford Motor Company. He is responsible for health benefits for active and retired employees and their dependents, for occupational health and safety services, and for disability and workers' compensation programs. Previously, he was senior vice president and corporate medical director of The Associated Group (now Anthem Blue Cross Blue Shield). He was also New York City Health Commissioner and served as Indiana State Health Commissioner and secretary to the Indiana State Board of Health. Prior to that, Dr. Myers was associate director of the medical-surgical intensive care unit and chairman of the quality assurance program at the San Francisco General Hospital, as well as an assistant professor of medicine at the University of California, San Francisco. A past president of the Association of State and Territorial Health Officials and former adviser to the Committee on Labor and Human Resources, U.S. Senate, Dr. Myers has taught at Cornell University, University of California, San Francisco, and Indiana University. He is on the boards of Harvard University, UCSF/Stanford University Health Systems, and the Charles Drew Medical School in Los Angeles. He is also a fellow of the American College of Physicians and of the American College of Physician Executives and is a former Robert Wood Johnson Foundation clinical scholar. Dr. Myers received a B.S. from Stanford University, a medical degree from Harvard Medical School, and an M.B.A. from Stanford University Graduate School of Business.

Janet G. Newport is corporate vice president of regulatory affairs at PacifiCare Health Systems, Inc., the nation's largest coordinated care Medicare contractor. Her responsibilities include monitoring and supporting internal operational compliance, policy development, and regulatory interpretation. She also acts as the liaison with key regulatory agencies. Ms. Newport serves on several technical and advisory committees for the American Association of Health Plans and is an industry representative on the Health Care Financing Administration's (HCFA) Medicare Council. In addition, Ms. Newport has served as an industry representative on HCFA technical committees and is a former chair of the American Managed Care and Review Association's Medicare Task Force. She has more than 20 years of public affairs experience, including over 10 years running the Washington, D.C., office of another Medicare risk contractor. Ms. Newport received a B.A. from American University.

Alice F. Rosenblatt is senior vice president and chief actuary of WellPoint Health Networks, where she is responsible for the corporate actuarial and strategic planning functions. Before joining WellPoint in 1996, she was a principal at Coopers & Lybrand L.L.P, where she consulted with insurers, health plans, providers, and employers. She is a former senior vice president and chief actuary of Blue Cross Blue Shield of Massachusetts and Blue Cross of California. Other positions include work for The New England and William M. Mercer, Inc. Ms. Rosenblatt was on the board of governors of the Society of Actuaries and currently serves on the board of the American Academy of Actuaries. She previously chaired the academy's federal health committee and work group on risk adjustment. Ms. Rosenblatt has testified on risk adjustment before subcommittees of the Committees on Ways and Means and Energy and Commerce of the U.S. House of Representatives. She has a B.S. and an M.A. in mathematics from City College of New York and the City University of New York, respectively.

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John W. Rowe, M.D., is president of the Mount Sinai School of Medicine and the Mount Sinai Hospital in New York City, one of the nation's largest academic health science centers. He is also a professor of medicine and geriatrics. Before becoming president of Mount Sinai in 1988, Dr. Rowe was a professor of medicine and the founding director of the Division on Aging at Harvard Medical School and chief of gerontology at Boston's Beth Israel Hospital. He has written more than 200 scientific pieces, mostly on the physiology of the aging process, and a leading textbook of geriatric medicine. Dr. Rowe is director of the MacArthur Foundation Research Network on Successful Aging. He served on the board of governors of the American Board of Internal Medicine and as president of the Gerontological Society of America and is a member of the Institute of Medicine. He received a B.S. from Canisius College and a medical degree from the University of Rochester.

Gerald M. Shea is assistant to the president for government affairs at the American Federation of Labor-Congress of Industrial Organizations. Previously, he served as executive assistant to the union's president, executive assistant to its secretary-treasurer, director of its employee benefits department, and head of its health care reform campaign. He also served on the Prospective Payment Assessment Commission. Mr. Shea's prior experience includes 12 years with the national office of the Service Employees International Union, where he held various positions, including assistant to the president for government affairs and health care division director. Before that, he was executive director and business manager of two local unions. Mr. Shea is a member of the Joint Commission on the Accreditation of Health Care Organizations, the Foundation for Accountability, and the advisory board of the Social Security Administration. He received a B.A. from Boston College.

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Commission Staff

Lauren B. LeRoy, Ph.D., was executive director of the Medicare Payment Advisory Commission (MedPAC) until January 1998, and is now president and chief executive officer of Grantmakers in Health. From 1995 to 1997 she served as executive director of the Physician Payment Review Commission, where she had been deputy director since 1986. Before that, Dr. LeRoy was associate director of the Commonwealth Fund Commission on Elderly People Living Alone. She spent more than a decade at the Institute for Health Policy Studies, University of California, San Francisco, where she was assistant director and director of the Institute's Washington office. Before that, she was an analyst at the Department of Health, Education, and Welfare. Dr. LeRoy's research interests and published work have focused on Medicare reform, physician training and practice, the nurse labor market, and health care for the elderly. She is a member of the National Academy of Social Insurance and a fellow of the Association for Health Services Research. She received a Ph.D. in social policy planning from the University of California, Berkeley.

Laura A. Dummit was a deputy director through February 1998, and is now associate director, Health Financing and Systems Issues, in the U.S. General Accounting Office. At MedPAC, Ms. Dummit directed the implementation of the Commission's work on Medicare payment policies for all post-acute care providers, hospital outpatient departments, and facilities that provide dialysis, as well as issues related to Medicare and private sector capitation and managed-care policies. Before joining the Commission, Ms. Dummit was with the Alpha Center and the Office of the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services (HHS). Ms. Dummit received a master's of science in public health from the University of North Carolina at Chapel Hill.

Stuart Guterman is a deputy director. He oversees the Commission's work on a broad range of issues related to developing and evaluating Medicare payment rates, including fee-for-service hospital payment and Medicare+Choice payments. Mr. Guterman is also responsible for analyses of hospital payments and costs from all payers, as well as many access and quality issues. Before coming to the Commission, Mr. Guterman was chief of institutional studies in the Health Care Financing Administration's (HCFA) Office of Research. He received an M.A. in economics from Brown University and completed his course work toward a Ph.D. in economics at the State University of New York at Stony Brook.

Jack Ashby is a principal policy analyst. He is responsible for the Commission's work on the measurement of productivity and hospital product change, hospital financial analyses, the disproportionate share adjustment, and Medicare per capita cost analysis. Before joining the Commission, Mr. Ashby was vice president for finance at the District of Columbia Hospital Association. Previously, he held positions in hospital administration (at the University of Pittsburgh Medical Center) and hospital management engineering (at Blue Cross of Western Pennsylvania), and also worked for a Washington area health research firm. Mr. Ashby received a master's of hospital administration from the University of Michigan.

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Louisa A. Buatti is an analyst. Her responsibilities include work in the areas of scientific and technological advances affecting hospital payment updates, payment policies for home health care, end-stage renal disease payment policy, and rural health care providers. Prior to coming to the Commission, Ms. Buatti was special assistant to the associate administrator for policy at HCFA. She previously worked in HCFA's Bureau of Policy Development and in the Health Standards and Quality Bureau. Ms. Buatti received a master's of health sciences degree in health policy from the Johns Hopkins University and a B.A. from the University of Michigan.

Claire D. Burnett is a junior analyst. Her work at the Commission focuses on beneficiaries who are dually eligible for Medicare and Medicaid, federal policies supporting graduate medical education, and care for the dying. She received a master's degree in public health from the University of Rochester.

Wylene Carlyle is a member of the support staff. She has been with the Commission since January 1990. Before that, Ms. Carlyle was an administrative assistant at OSS Associates/Franklin School in Washington, D.C. She is certified in word processing, Lotus 1-2-3, and has extensive experience with personal computers.

Andrew L. Cosgrove is an analyst. His work focuses on hospital payments and costs by payer, Tax Equity and Fiscal Responsibility Act target rate update, post-acute care services in managed care, consumer information for managed care, and hospice issues. Prior to joining the Commission, Mr. Cosgrove was an analyst with the District of Columbia Commission on Health Care Finance, where he reviewed Medicaid reimbursement policy, especially long-term care financing. Before that, he was an analyst in the Information Technology Division of the University of Michigan. Mr. Cosgrove received a master's degree in public policy from the University of Michigan and a B.A. from the University of Rochester.

Delores J. Curtis is responsible for research contract management, the Commission's world wide web site, report production, and a variety of tasks involving office management and technical computer support. Ms. Curtis joined the Commission staff in April 1990 from the Office of the Assistant Secretary for Planning and Evaluation at HHS.

Diane Ellison is the office manager. Before joining the Commission, she spent 18 years working for U.S. Senator Bill Bradley. She served as the assistant to the senator's chief of staff and later as the senator's office manager. At the Commission, she is responsible for personnel, Commission meeting and annual retreat planning, and office operations.

Helaine I. Fingold is an analyst and general counsel. She is responsible for legislative and regulatory monitoring, consumer protection issues, Medicare+Choice plan standards, and Medicaid managed care issues. Ms. Fingold previously practiced health law with the law firm of Epstein Becker and Green. Before that, she was a legal/policy analyst with the Office of Research and Demonstrations at HCFA, and a staff attorney with the Office of the General Counsel, Health Care Financing Division, HHS. She received a J.D. from Northeastern University School of Law in Boston and a B.A. from the University of Massachusetts at Amherst.

Timothy F. Greene is a senior analyst. Since joining the Commission in July 1992, Mr. Greene has studied Medicare capital payment policy, outpatient payment reform, and diagnosis-related group refinement. Previously, he was with HCFA's Office of Research, where he worked on hospital payment policy, case-mix measurement, and hospital malpractice. While at HCFA, Mr. Greene was specially assigned to the Commission on the Future Structure of Veterans Health Care at the Department of Veterans Affairs. He received a master's of business administration from the Wharton School, University of Pennsylvania, and a master's in economics from the State University of New York at Stony Brook.

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Kevin J. Hayes, Ph.D., is a senior analyst. His work at the Commission focuses on analysis of claims and survey data to monitor Medicare beneficiaries' access to care, implementation of resource-based practice expense relative values, and the impact of the Medicare Fee Schedule on physician payment. Previously, he held various local and federal health care planning positions. He received a doctorate in health policy and administration from the University of North Carolina at Chapel Hill.

Annette Hennessey is management coordinator. Before joining the Commission, she worked for U.S. Senator Bill Bradley, where she was primarily responsible for administration of the legislative staff. At the Commission, she is involved in a range of administrative operations, including developing Commission policies and styles, managing staff administrative needs, and coordinating the design and relocation of the Commission's new offices. She received a bachelor's degree in political science from Mississippi State University in Starkville.

John F. Hoadley, Ph.D., was a principal policy analyst. In April, he is joining the Department of Health and Human Services as a division director in the Office of the Assistant Secretary for Planning and Evaluation. Before joining the Commission, he taught political science at Duke University, was a congressional fellow and legislative assistant for U.S. Representative Barbara B. Kennelly, and developed educational sessions for policy makers at George Washington University's National Health Policy Forum. Dr. Hoadley's most recent work at the Commission centered around Medicare+Choice (both payment and nonpayment issues), the changing health care market, and Medicaid managed care. Previously, he has worked on other issues, including health system reform, provider-sponsored organizations, risk adjustment, global budgets, and beneficiary perspectives on Medicare reform. He received a doctorate in political science from the University of North Carolina at Chapel Hill.

Christopher Hogan, Ph.D., is a principal policy analyst. His recent work at the Commission has focused on risk adjustment, the adjusted community rate, and improving the performance of traditional fee-for-service Medicare. In prior years, he conducted analyses of private insurers' fees, areas of poor access to care, and medical savings accounts. He has also worked on such issues as the Medicare volume performance standard system and Medicare beneficiaries' access to care. He holds a doctorate in economics from Northwestern University.

Ann Johnson is the executive assistant. She has been with the Commission since 1987. Over time her responsibilities have included assisting with financial management, report production, and supporting the executive staff. Previously, she was a secretary at the Food and Drug Administration.

Dana K. Kelley is a senior analyst. She joined the Commission in 1994. Her primary responsibilities relate to Medicare's coverage of and payment for skilled nursing facility services and services provided to beneficiaries with end-stage renal disease. She also works on issues related to hospital outpatient services and Medicare's disproportionate share payment adjustment. Before joining MedPAC, Ms. Kelley was an analyst with Lewin-VHI, a health care consulting firm. She received an M.P.A. from the University of Pittsburgh's Graduate School of Public and International Affairs and a B.A. from the College of William and Mary.

Deborah F. Kramer is the systems administrator. Before joining the Commission, she was a confidential assistant in the Executive Office of the President in the Office of Management and Budget and a legislative aide in the office of U.S. Senator Bill Bradley. At the Commission, she is responsible for computer network operations, telecommunication systems, and the production of publications. She received a bachelor's degree in public administration and is currently pursuing a master's degree in computer information systems.

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Craig K. Lisk is a senior analyst. He has been with the Commission since 1987, working on a variety of hospital-related issues, including the hospital payment update, graduate medical education payment policy, transfer payment, and hospital labor markets. He has also worked on issues related to post-acute care, managed care, and quality of care under Medicare. Previously, Mr. Lisk worked at the Congressional Budget Office in the Human Resources and Community Development Division, where he focused on selected Medicare hospital payment issues. He received an M.S. in public policy analysis and a B.A. in political science and statistics from the University of Rochester.

James E. Mathews, Ph.D., is an analyst. He is responsible for the Commission's work on payment policies for hospital outpatient departments and ambulatory surgical centers, payment and cost analyses for skilled nursing facilities and home health care, and issues related to the Medicare+Choice program, including competitive bidding, and enrollment and disenrollment. Before joining the Commission, Dr. Mathews held positions in the Executive Office of the President in the Office of Management and Budget, and in the Bureau of Policy Development at HCFA. He holds a doctorate in anthropology from the University of Chicago, as well as bachelor's and master's degrees from that university.

Stephanie Maxwell is an analyst. She is responsible for payment policy for PPS-excluded hospitals, including work related to rehabilitation and long-term care facility prospective payment. Before joining the Commission, Ms. Maxwell was a research associate at the Johns Hopkins School of Hygiene and Public Health, where she worked on several research contracts related to Medicare and hospital payment. Prior to that, she was a policy analyst for the Advisory Council on Social Security and a research assistant in the Office of the Assistant Secretary, U.S. Public Health Service. Ms. Maxwell received a B.A. in history magna cum laude from Oberlin College and this year receives a Ph.D. in health policy/health services research from Johns Hopkins University.

Katie Merrell served as a senior analyst. She is now a senior analyst at the Center for Health Administration Studies, University of Chicago. Before joining the Commission staff, she worked for Abt Associates in the areas of health economics research, income support, and education. She was also a research assistant for the board of governors of the Federal Reserve System, and a high school mathematics and computer science teacher. Her recent work at the Commission focused on the implementation of resource-based practice expense relative values, Medicare+Choice payment methods and market dynamics, and the recalibration of Medicare Fee Schedule components. Her past work at the Commission has focused on Medicare risk-plan payment policies, practice expense, geographic adjustment of the Medicare Fee Schedule, and simulating the effect of policy changes on fee schedule payments.

Michael J. O'Grady, Ph.D., is a senior analyst. Before joining the Commission, he worked for the Office for Civil Rights in both the Department of Health, Education and Welfare and the Department of Education. He was also a specialist in social legislation in the Education and Public Welfare Division of the Congressional Research Service. At the Commission, Mr. O'Grady focuses on federal premium contribution, competitive bidding under Medicare+Choice, and new options for traditional Medicare. He holds a doctorate in political science from the University of Rochester.

Julian H. Pettengill is a principal policy analyst. Since joining the Commission in 1988, he has focused primarily on policy issues related to Medicare's hospital prospective payment system. Recent work examined factors affecting health maintenance organizations' willingness to participate in the Medicare risk program. Before joining the Commission, he worked for the Congressional Research Service and for HCFA's Office of Research and Demonstrations, where he carried out most of the research leading to the development of the hospital case-mix index and other key features of the prospective payment system. He holds a master's degree in economics from Indiana University and completed his course work toward a Ph.D. in medical care organization at the University of Michigan.

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Molly Ryan is responsible for the Commission's budget and financial management. Ms. Ryan came to the Commission from HHS's Office of the Assistant Secretary for Planning and Evaluation, where she worked in the immediate and administrative offices. Before that, she worked in the Office of Education's Regulations Office at the former Department of Health, Education and Welfare.

Anne L. Schwartz, Ph.D., served as special assistant to the executive director until January 1998. At the Commission, her analytical work addressed a range of Medicare and Medicaid issues, including physician payment and access under Medicaid, and financial protection for Medicare beneficiaries. Most recently, she focused on graduate medical education financing and physician work force issues. Previously, she held various positions as a staff member in the U.S. House of Representatives. She received a doctorate in health policy from the Johns Hopkins University.

David W. Shapiro, M.D., J.D., is a senior analyst. After completing a residency in primary care internal medicine, he was a Veterans Administration/Robert Wood Johnson clinical scholar. At the Commission, he has worked on a variety of topics, including Medicare coverage decisions and the appeals process, medical liability reform, the Medicare Fee Schedule, and data capabilities of health plans. His current work focuses on quality of care. He received a medical degree from the University of California, Los Angeles, and a law degree from Yale University.

Sarah S. Thomas is a senior analyst. She works primarily on issues related to Medicare managed care, including trends and developments in Medicare+Choice, hospital payment, post-acute care, the Program of All-Inclusive Care for the Elderly, and urban critical access hospitals. Prior to joining Commission, Ms. Thomas held positions with the Group Health Association of America, the American Hospital Association, the Budget Division of the Commonwealth of Virginia's Department of Medical Assistance Services, and the Health Care Advisory Board. Ms. Thomas received an M.S. in health policy and management from the Harvard School of Public Health and a B.A. in history from Williams College.

Sally Trude, Ph.D., was a senior analyst. In March, she is joining Health Economics Research, Inc., as a senior policy analyst. Before joining the Commission staff, Dr. Trude was an associate policy analyst at RAND working on physician payment issues. This year, her work at the Commission included vulnerable populations under Medicare+Choice, managed-care data, sustainable growth rate system, and expenditure targets. Previously, she has studied the impact of the Medicare Fee Schedule on physicians and beneficiaries, and the Medicare volume performance standard system. She received a doctorate in public policy analysis from the RAND Graduate School.

Cynthia Wilson is the receptionist. Before joining the Commission staff, she was an accounting representative for United Service Life Insurance Company. She is certified as a clerk-typist.

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Commmission Responsibilities Mandated by Congress

The Medicare Payment Advisory Commission (MedPAC) was established by the Congress in the Balanced Budget Act of 1997 (BBA, P.L. 105-33). Under that legislation, MedPAC is directed to provide the Congress with advice and recommendations on policies affecting the Medicare program.

Within the scope of this general mandate, the BBA directs the Commission to review certain specific topics relating to Medicare. MedPAC is charged with considering issues of payment, risk adjustment, risk selection, quality of care, access to care, and other major issues relating to the implementation and further development of Medicare+Choice. Its responsibility with respect to the Medicare fee-for-service program includes considering methodologies for determining and updating payments, factors affecting expenditures for services in different sectors, and the impact of fee-for-service payment policies on access and quality of care for Medicare beneficiaries. The Commission is also required to review how Medicare payment policies affect health care delivery beyond the program itself and to assess the implications of broader health care system changes on Medicare.

MedPAC is to submit its findings on these topics to the Congress through two yearly reports. The first report, containing recommendations on Medicare payment policy, is to be submitted by March 1. The second report, exploring issues affecting the Medicare program and its relationship to the broader health care system, is to be submitted by June 1. MedPAC is also required to comment on reports submitted to the Congress by the Secretary of the Department of Health and Human Services.

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Glossary

Acronyms

AAHP	American Association of Health Plans
AAMC	Association of American Medical Colleges
AAPCC	Adjusted Average Per Capita Cost
AARP	American Association of Retired Persons
ACG	Ambulatory Care Group
ACR	Adjusted Community Rate
ADHC	Adult Day Health Center
ADL	Activities of Daily Living
AHA	American Hospital Association
AHCPR	Agency for Health Care Policy and Research, HHS
AMA	American Medical Association
APC	Ambulatory Patient Classifications
ASC	Ambulatory Surgical Center
BBA	Balanced Budget Act of 1997
BLS	Bureau of Labor Statistics
BSF	Benefits Stabilization Fund
CBO	Congressional Budget Office
CC	Complication and/or Comorbidity
CMI	Case-Mix Index
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1985
CORF	Comprehensive Outpatient Rehabilitation Facility
CPEP	Clinical Practice Expert Panel
CPI	Consumer Price Index
CPI-U	Consumer Price Index for Urban Consumers
CPT	Current Procedural Terminology
CRS	Congressional Research Service
DCG	Diagnostic Cost Group
DRG	Diagnosis-Related Group
DOD	Department of Defense
DSH	Disproportionate Share Hospital
ECI	Employment Cost Index
EM	Evaluation and Management
ESRD	End-Stage Renal Disease
FIM-FRG	Functional Independence Measure–Function Related Group
FTE	Full-Time Equivalent
FY	Fiscal Year
GAO	General Accounting Office
GDP	Gross Domestic Product
GME	Graduate Medical Education
GPCI	Geographic Practice Cost Index
HCC	Hierarchical Coexisting Conditions
HCFA	Health Care Financing Administration, HHS
HCPCS	HCFA Common Procedure Coding System
HHS	Department of Health and Human Services
HI	Hospital Insurance
HMO	Health Maintenance Organization
HPSA	Health Professional Shortage Area
HUD	Department of Housing and Urban Development
IADL	Instrumental Activities of Daily Living
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
IME	Indirect Medical Education
IMG	International Medical Graduate
LOS	Length of Stay
MCBS	Medicare Current Beneficiary Survey
MedPAC	Medicare Payment Advisory Commission

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MEI	Medicare Economic Index
MPCC	Medicare Per Capita Cost
NHSC	National Health Service Corps
NRAA	National Renal Administrators Administration
OBRA	Omnibus Budget Reconciliation Act
OPD	Outpatient Department
PACE	Program of All-Inclusive Care for the Elderly
PIP	Principal Inpatient Diagnosis
POS	Point of Service
PPO	Preferred Provider Organization
PPRC	Physician Payment Review Commission
PPS	Prospective Payment System
PRO	Peer Review Organization
ProPAC	Prospective Payment Assessment Commission
RBRVS	Resource-Based Relative Value Scale
RUC	RVS Update Committee
RVS	Relative Value Scale
RVU	Relative Value Unit
SAF	Standard Analytical Files (Medicare)
SMI	Supplementary Medical Insurance
SNF	Skilled Nursing Facility
SSDI	Social Security Disability Insurance
SSI	Supplemental Security Income
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982
VA	Department of Veterans Affairs
VPS	Volume Performance Standard

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Legislation (Listed Chronologically)

HMO Act	Health Maintenance Organization Act of 1973, P.L. 93-222, enacted December 29, 1973.
ERISA	Employee Retirement Income Security Act of 1974, P.L. 93-406, enacted September 2, 1974.
OBRA80	Omnibus Budget Reconciliation Act of 1980, P.L. 96-499, enacted December 5, 1980.
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982, P.L. 97-248, enacted September 3, 1982.
DEFRA	Deficit Reduction Act of 1984, P.L. 98-369, enacted July 18, 1984.
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. 99-272, enacted April 7, 1986.
OBRA86	Omnibus Budget Reconciliation Act of 1986, P.L. 99-509, enacted October 21, 1986.
OBRA87	Omnibus Budget Reconciliation Act of 1987, P.L. 100-203, enacted December 21, 1987.
MCCA	Medicare Catastrophic Coverage Act of 1988, P.L. 100-360, enacted July 1, 1988; repealed December 13, 1989.
OBRA89	Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, enacted December 19, 1989.
OBRA90	Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, enacted November 3, 1990.
OBRA93	Omnibus Budget Reconciliation Act of 1993, P.L. 103-66, enacted August 10, 1993.
	Social Security Act Amendments of 1994, P.L. 103-432, enacted October 31, 1994.
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, enacted August 21, 1996.
BBA	Balanced Budget Act of 1997, P.L. 105-33, enacted August 5, 1997

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Terms

Access: The ability to obtain needed health care services.

Activities of Daily Living (ADL): An index or scale that measures an individual's degree of independence in bathing, dressing, using the toilet, eating, and moving across a small room.

Adjusted Admissions: A measure of all patient care activity in a hospital, including both inpatient and outpatient care. Adjusted admissions are the sum of inpatient admissions and an estimate of the volume of outpatient services, expressed as the number of inpatient admissions that could have been produced with the same amount of resources. This estimate is calculated by multiplying outpatient visits by the ratio of outpatient charges per visit to inpatient charges per admission.

Adjusted Average Per Capita Cost (AAPCC): A county-level estimate of the average cost incurred by Medicare for each beneficiary in fee for service. Adjustments are made so that the AAPCC represents the level of spending that would occur if each county contained the same mix of beneficiaries. Before passage of the Balanced Budget Act of 1997, Medicare paid health plans 95 percent of the AAPCC, adjusted for the characteristics of the enrollees in each plan.

Adjusted Community Rate (ACR) Proposal: A process by which a health plan contracting with Medicare estimates the cost of providing services to its Medicare enrollees based on costs and revenues from its commercial business. Health plans estimate their ACRs annually and adjust the subsequent year's supplemental benefits or premiums offered so that they do not receive a higher rate of return on Medicare enrollees than they do on their commercial business.

Adverse Selection: Adverse selection occurs when a larger proportion of persons with poorer health status enroll in specific plans or insurance options, while a larger proportion of persons with better health status enroll in other plans or insurance options. Plans with a subpopulation with above-average costs are adversely selected. Plans with a subpopulation with below-average costs are favorably selected.

Aggregate Margin: A margin that compares revenues with expenses for a group of hospitals, rather than a single hospital. It is computed by subtracting the sum of expenses for all hospitals in the group from the sum of revenues and dividing by the sum of revenues. See PPS Inpatient Margin, PPS Operating Margin, Total Margin.

Allowed Charge: The amount Medicare approves for payment to a physician. Typically, Medicare pays 80 percent of the allowed charge and the beneficiary pays the remaining 20 percent. The allowed charge for a nonparticipating physician is 95 percent that of a participating physician. Nonparticipating physicians may bill beneficiaries for an additional amount above the allowed charge. See Balance Billing, Participating Physician and Supplier Program.

Ambulatory Patient Classifications (APC): A system for classifying outpatient services and procedures for purposes of payment. The APC system classifies some 7,000 services and procedures into about 300 procedure groups.

Ambulatory Surgical Center (ASC): A free-standing facility certified by Medicare that performs certain types of procedures on an outpatient basis.

Assignment (Medicare): A process under which Medicare pays its share of the allowed charge directly to the physician or supplier. Medicare will do this only if the physician accepts Medicare's allowed charge as payment in full (guarantees not to balance bill). Medicare provides other incentives to physicians who accept assignment for all patients under the Participating Physician and Supplier Program. See Balance Billing, Nonparticipating Physicians, Participating Physician, Participating Physician and Supplier Program.

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Balance Billing: In Medicare and private fee-for-service health insurance, the practice of billing patients in excess of the amount approved by the health plan. Under Medicare fee for service, a balance bill cannot exceed 15 percent of the allowed charge for nonparticipating physicians. See Allowed Charge, Limiting Charge, Participating Physician.

Basic DRG Payment Rate: The payment rate a hospital will receive for a Medicare patient in a particular diagnosis-related group. The payment rate is calculated by adjusting the standardized amount to reflect wage rates in the hospital's geographic area (and cost of living differences unrelated to wages) and the costliness of the DRG. See Standardized Amount, Diagnosis-Related Groups.

Behavioral Offset: See Volume Offset.

Beneficiary: Someone who is eligible for or receiving benefits under an insurance policy or plan. The term is commonly applied to people covered by the Medicare or Medicaid programs.

Beneficiary Liability: The amount beneficiaries must pay providers for Medicare-covered services. Liabilities include copayments and coinsurance amounts, deductibles, and balance billing amounts.

Benefit Package: Services covered by a health insurance plan and the financial terms of such coverage, including cost sharing and limitations on amounts of services. See Cost Sharing.

Budget Neutrality: For the Medicare program, adjustment of payment rates when policies change so that total spending under the new rules is expected to be the same as it would have been under the previous payment rules.

Bundling: The use of a single payment for a group of related services.

Capital Costs: Depreciation, interest, leases and rentals, taxes, and insurance on tangible assets like physical plant and equipment.

Capitation: A health insurance payment mechanism that pays a fixed amount per person per time period to cover services. Capitation may be used by purchasers to pay health plans or by plans to pay providers. See Medicare Risk Contract, Medicare+Choice.

Carrier: A private contractor that administers claims processing and payment for Medicare Part B services. See Supplementary Medical Insurance.

Case Mix: The mix of patients treated within a particular institutional setting, such as the hospital. Patient classification systems like DRGs can be used to measure hospital case mix. See DRGs and Case-Mix Index.

Case-Mix Index (CMI): The average DRG weight for all cases paid under PPS. The CMI is a measure of the relative costliness of the patients treated in each hospital or group of hospitals. See DRG.

Charges: The posted prices of provider services.

Coinsurance: A type of cost sharing where the insured party and insurer share payment of the approved charge for covered services in a specified ratio after payment of the deductible by the insured. For example, for Medicare physicians' services, the beneficiary pays coinsurance of 20 percent of allowed charges. See Allowed Charge, Copayment, Cost Sharing, Deductible.

Competitive Bidding: A pricing method that elicits information on costs through a bidding process to establish payment rates that reflect the costs of an efficient health plan or health care provider.

Composite Rate: Payment by Medicare that covers the bundle of services, tests, drugs, and supplies routinely required for dialysis treatment.

Conversion Factor: The multiplicative factor used to translate relative value units into dollar amounts for physician payments under a fee schedule.

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Conversion Factor Update: Annual percentage change to the conversion factor. For Medicare, the update is set by a formula to reflect medical inflation, changes in enrollment, growth in the economy, and changes in spending due to other changes in law. See Conversion Factor, Sustainable Growth Rate, Sustainable Growth Rate System, Volume Performance Standard System.

Copayment: A fixed dollar amount paid for a covered service by a health insurance enrollee. See Coinsurance and Deductible.

Cost Sharing: A general term referring to payments made by health insurance enrollees for covered services. Examples of cost sharing include deductibles, coinsurance, and copayments. See Balance Billing, Coinsurance, Copayment, Deductible.

Cost Shifting: Increasing revenues from some payers to offset losses and lower net payments from other payers.

Current Procedural Terminology (CPT): The coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association; basis of the HCFA Common Procedure Coding System.

Customary, Prevailing, and Reasonable (CPR): The method of paying physicians under Medicare from 1965 until implementation of the Medicare Fee Schedule in January 1992. Payment for a service was limited to the lowest of (1) the physician's billed charge for the service, (2) the physician's customary charge for the service, or (3) the prevailing charge for that service in the community. Similar to the usual, customary, and reasonable system used by private insurers. See Medicare Fee Schedule; Usual, Customary, and Reasonable.

Deductible: A type of cost sharing where the insured party pays a specified amount of approved charges for covered medical services before the insurer will assume liability for all or part of the remaining covered services. See Coinsurance, Copayment, Cost Sharing.

Diagnosis-Related Groups (DRGs): A system for determining case mix, used for payment under Medicare's PPS and by some other payers. The DRG system classifies patients into groups based on the principal diagnosis, type of surgical procedure, presence or absence of significant comorbidities or complications, and other relevant criteria. DRGs are intended to categorize patients into groups that are clinically meaningful and homogeneous with respect to resource use. Medicare's PPS currently uses almost 500 mutually exclusive DRGs, each of which is assigned a relative weight that compares its costliness to the average for all DRGs. See Case Mix.

Disproportionate Share (DSH) Adjustment: A payment adjustment under Medicare's PPS or under Medicaid for hospitals that serve a relatively large volume of low-income patients.

Dually Eligible: A Medicare beneficiary who also receives the full range of Medicaid benefits offered in his or her state.

Encounter Data: Description of the diagnoses made and services provided when a patient visits a health care provider under a managed-care plan. Encounter data provide much of the same information available on the bills submitted by fee-for-service providers.

Evaluation and Management (EM) Service: A nonprocedural service, such as a visit or consultation, provided by physicians to diagnose and treat diseases and counsel patients.

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Excluded Hospitals and Distinct-Part Units: Specialty hospitals (rehabilitation, psychiatric, long-term care, children's, and cancer) and distinct-part units in general hospitals (rehabilitation and psychiatric) that are excluded from Medicare's hospital inpatient PPS. Hospitals located in U.S. territories, federal hospitals, and Christian Science Sanatoria are also excluded from PPS. Excluded facilities are paid under cost-based reimbursement, subject to rate of increase limits. Rehabilitation facilities are slated to move to a prospective payment system in October 2000. Congress has also directed HCFA to develop a legislative proposal for a prospective payment system for long-term care facilities.

Favorable Selection: The result of enrolling in a health plan a disproportionate share of healthy individuals compared with the population from which the share is drawn. See Adverse Selection, Risk Adjustment, Risk Selection.

Federally Qualified Health Center (FQHC): A health center in a medically underserved area that is eligible to receive cost-based Medicare and Medicaid reimbursement.

Federally Qualified HMO: An HMO that has satisfied certain federal qualifications pertaining to organizational structure, provider contracts, health service delivery information, utilization review and quality assurance, grievance procedures, financial status, and marketing information, as specified in Title XIII of the Public Health Service Act. See Health Maintenance Organization.

Fee for Service: A method of paying health care providers for individual medical services rendered, as opposed to paying them salaries or capitated payments. See Capitation.

Fee Schedule: A list of predetermined payment rates for medical services. See Medicare Fee Schedule.

Fee Schedule Payment Area: A geographic area within which payment for a given service under the Medicare Fee Schedule does not vary. See Geographic Adjustment Factor.

Fiscal Intermediary: An entity, usually an insurance company, that has a contract with HCFA to determine and make Medicare payments for Part A and certain Part B benefits to hospitals and other providers of services and to perform related functions.

Fiscal Year: A 12-month period for which an organization plans the use of its funds, such as the federal government's fiscal year (October 1 to September 30). Fiscal years are referred to by the calendar year in which they end; for example, the federal fiscal year 1998 began October 1, 1997. Hospitals can designate their own fiscal years, and this is reflected in differences in the time periods covered by the Medicare Cost Reports. See PPS Year.

Five-Year Review: A review of the accuracy of Medicare's relative value scale that the Health Care Financing Administration is required to conduct every five years.

Functional Independence Measure - Function Related Group: A patient classification system developed for medical rehabilitation patients.

Geographic Practice Cost Index (GPCI): An index summarizing the prices of resources required to provide physicians' services in each payment area relative to national average prices. There is a GPCI for each component of the Medicare Fee Schedule: physician work, practice expense, and mal-practice expense. The indexes are used to adjust relative value units to determine the correct payment in each fee schedule payment area. See Fee Schedule Payment Area, Medicare Fee Schedule.

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Graduate Medical Education (GME): The period of medical training that follows graduation from medical school; commonly referred to as internship, residency, and fellowship training.

Gross Domestic Product (GDP): The total current market value of all goods and services produced domestically during a given period; differs from the gross national product by excluding net income that residents earn abroad.

Group-Model HMO: An HMO that pays a medical group a negotiated, per capita rate, which the group distributes among its physicians, often under a salaried arrangement. See Health Maintenance Organization, Independent Practice Association, Network-Model HMO, Staff-Model HMO.

HCFA Common Procedure Coding System (HCPCS): A coding system based on the American Medical Association's Current Procedural Terminology (CPT) coding system, expanded to accommodate additional services covered by Medicare.

Health Care Prepayment Plan (HCPP): A health plan with a Medicare cost contract to provide only Medicare Part B benefits. Some administrative requirements for these plans are less stringent than those of risk contracts or other cost contracts. See Medicare Cost Contract, Medicare Risk Contract.

Health Maintenance Organization (HMO): A type of managed-care plan that acts as both insurer and provider of a comprehensive set of health care services to an enrolled population. Benefits are typically financed through capitation with limited copayments, and services are furnished through a system of affiliated providers. See Group-Model HMO, Independent Practice Association, Managed Care, Network-Model HMO, Staff-Model HMO.

Health Plan: An organization that acts as insurer for an enrolled population. See Fee for Service, Managed Care.

Health Plan Employer Data and Information Set (HEDIS): A set of standardized measures of health plan performance. HEDIS allows comparisons between plans on quality, access, and patient satisfaction; membership and utilization; financial information; and health plan management. HEDIS was developed by employers, HMOs, and the National Committee for Quality Assurance.

Health Professional Shortage Area (HPSA): An urban or rural geographic area, a population group, or a public or nonprofit private medical facility that the Secretary of Health and Human Services determines is being served by too few health professionals. Physicians who provide services in HPSAs qualify for a Medicare bonus payment.

Hierarchical Coexisting Conditions Model (HCC): A risk-adjustment model that groups beneficiaries based on their diagnoses.

Hospital Inpatient Prospective Payment System (PPS): Medicare's method of paying acute care hospitals for inpatient care. Prospective per case payment rates are set at a level intended to cover operating costs for treating a typical inpatient in a given DRG. Payments for each hospital are adjusted for differences in area wages, teaching activity, care to the poor, and other factors. Hospitals may also receive additional payments to cover extra costs associated with atypical patients (outliers) in each DRG. Capital costs, originally excluded from PPS, are being phased into the system. By 2001, capital payments will be made on a fully prospective, per case basis. Prospective payment systems are also being developed for Medicare payments for home health services, outpatient hospital services, skilled nursing facilities, and rehabilitation facilities. See Capital Costs, Diagnosis-Related Groups, Outliers, Prospective Payment.

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Hospital Insurance (HI): The part of the Medicare program that covers the cost of hospital and related post-hospital services. Eligibility is normally based on prior payment of payroll taxes. Beneficiaries are responsible for an initial deductible per spell of illness and copayments for some services. Also called Part A coverage or benefits.

Indirect Medical Education (IME) Adjustment: A payment adjustment applied to DRG and outlier payments under PPS for hospitals that operate an approved graduate medical education program. For operating costs, the adjustment is based on the hospital's ratio of interns and residents to the number of beds. For capital costs, it is based on the hospital's ratio of interns and residents to average daily occupancy.

Instrumental Activities of Daily Living (IADL): An index or scale that measures a patient's degree of independence in aspects of cognitive and social functioning, including shopping, cooking, doing housework, managing money, and using the telephone.

Integrated Delivery System (IDS): An entity that usually includes a hospital, a large medical group, and an insurance vehicle such as an HMO or PPO. Typically, all provider revenues flow through the organization.

Intensity of Services: The number and complexity of resources used in producing a patient care service, such as a hospital admission or home health visit. Intensity of services reflects, for example, the amount of nursing care, diagnostic procedures, and supplies furnished.

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM): A diagnosis and procedure classification system designed to facilitate the collection of uniform and comparable health information. This system is used to group patients into DRGs.

Limiting Charge: The maximum amount that a nonparticipating physician is permitted to charge a Medicare beneficiary for a service; in effect, a limit on balance billing. Starting in 1993 the limiting charge has been set at 115 percent of the Medicare-allowed charge. See Allowed Charge, Balance Billing, Nonparticipating Physician.

Locality (Medicare): See Fee Schedule Payment Area.

Major Teaching Hospitals: Hospitals with an approved graduate medical education program and a ratio of interns and residents to beds of 0.25 or greater. See Other Teaching Hospitals, Indirect Medical Education Adjustment.

Malpractice Expense: The cost of professional liability insurance incurred by physicians. A component of the Medicare relative value scale. See Relative Value Scale.

Managed Care: Any system of health service payment or delivery arrangements where the health plan attempts to control or coordinate use of health services by its enrolled members in order to contain health expenditures, improve quality, or both. Arrangements often involve a defined delivery system of providers with some form of contractual arrangement with the plan. See Health Maintenance Organization, Independent Practice Association, Preferred Provider Organization.

Market Basket Index: An index of the annual change in the prices of goods and services providers use for producing health services. There are separate market baskets for PPS hospital operating and capital inputs; PPS-excluded facility operating inputs; and SNF, home health agency, and renal dialysis facility operating and capital inputs.

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Medicare: A health insurance program for people over 65, those eligible for Social Security disability payments, and those who need kidney dialysis or transplants. See Hospital Insurance, Supplementary Medical Insurance.

Medicare+Choice: A program created by the Balanced Budget Act of 1997 to replace the existing system of Medicare risk and cost contracts. Beneficiaries will have the choice during an open season each year to enroll in a Medicare+Choice plan or to remain in traditional Medicare. Medicare+Choice plans may include coordinated care plans (HMOs, PPOs, or plans offered by provider-sponsored organizations); private fee-for-service plans; or plans with medical savings accounts.

Medicare Choices Demonstration: A demonstration project designed to offer flexibility in contracting requirements and payment methods for Medicare's managed-care program. Participating plans include PSOs and PPOs. Plans are required to submit encounter data to HCFA, and most will test new risk-adjustment methods.

Medicare Cost Contract: A contract between Medicare and a health plan under which the plan is paid on the basis of reasonable costs to provide some or all Medicare-covered services for enrollees. See Health Care Prepayment Plan, Medicare Risk Contract.

Medicare Cost Report: An annual report required of institutions participating in the Medicare program. Records each institution's total costs and charges associated with providing services to all patients, the portion of those costs and charges allocated to Medicare patients, and the Medicare payments received.

Medicare Current Beneficiary Survey (MCBS): A longitudinal survey administered by HCFA that provides information on specific aspects of beneficiary access, utilization of services, expenditures, health insurance coverage, satisfaction with care, health status and physical functioning, and demographic information.

Medicare Economic Index (MEI): An index that tracks changes over time in physician practice costs. From 1975 through 1991, increases in prevailing charge screens were limited to increases in the MEI.

Medicare Fee Schedule: The resource-based fee schedule Medicare uses to pay for physicians' services. See Resource-Based Relative Value Scale, Conversion Factor, Geographic Practice Cost Index.

Medicare Risk Contract: A contract between Medicare and a health plan under which the plan receives monthly capitated payments to provide Medicare-covered services for enrollees, and thereby assumes insurance risk for those enrollees. A plan is eligible for a risk contract if it is a federally qualified HMO or a competitive medical plan. See Adjusted Average Per Capita Cost, Adjusted Community Rate, Medicare Cost Contract.

Medigap Insurance: Privately purchased individual or group health insurance policies designed to supplement Medicare coverage. Benefits may include payment of Medicare deductibles, coinsurance, and balance bills, as well as payment for services not covered by Medicare. Medigap insurance must conform to one of 10 federally standardized benefit packages.

National Claims History System: A HCFA data reporting system that combines both Part A and Part B claims in a common file. The National Claims History system became fully operational in 1991.

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Network-Model HMO: An HMO that contracts with several different medical groups, often at a capitated rate. Groups may use different methods to pay their physicians. See Group-Model HMO, Health Maintenance Organization, Independent Practice Association, Staff-Model HMO.

Nominal Value: Measurement of an economic amount in terms of current prices. See Real Value.

Nonparticipating Physician: A physician who does not sign a participation agreement and, therefore, is not obligated to accept assignment on all Medicare claims. See Assignment, Participating Physician, Participating Physician and Supplier Program.

Nursing Facility: An institution that provides skilled nursing care and rehabilitation services to injured, functionally disabled, or sick persons. Formerly, distinctions were made between intermediate care facilities and skilled nursing facilities. The Omnibus Budget Reconciliation Act of 1987 eliminated this distinction effective October 1, 1990, by requiring all nursing facilities to meet SNF certification requirements. See Skilled Nursing Facility.

Other Teaching Hospitals: Hospitals with approved graduate medical education program and a ratio of interns and residents to beds of less than 0.25. See Indirect Medical Education Adjustment, Major Teaching Hospitals.

Out-of-Pocket Expenditures: Health-related expenditures for which beneficiaries are financially liable. For Medicare beneficiaries, the total amount includes cost sharing for Medicare-covered services (for example, deductibles, copayments, and balance bills); the cost of Medicare Part B and private health insurance premiums; and the cost of noncovered services. See Cost Sharing, Balance Billing, Coinsurance, Copayment, Deductible.

Outliers: Cases that are substantially different from the rest of the population. With regard to hospital payment, these are classified as cases with extremely long lengths of stay (day outliers) or extraordinarily high costs (cost outliers) compared with others in the same DRG. Hospitals receive additional PPS payments for these cases.

Paid Amount: The portion of a submitted charge that is actually paid by both third-party payers and the insured, including copayments and balance bills. For Medicare this amount may be less than the allowed charge if the submitted charge is less, or it may be more because of balance billing. See Allowed Charge, Balance Billing, Payment Rate, Submitted Charge.

Participating Physician: A physician who signs a participation agreement, agreeing to accept assignment on all Medicare claims for one year. See Assignment.

Participating Physician and Supplier Program (PAR): A program that provides financial and administrative incentives for physicians and suppliers to agree in advance to accept assignment on all Medicare claims for a one-year period. See Assignment.

Payment Rate: The total amount paid for each unit of service rendered by a health care provider, including both the amount covered by the insurer and the insured person's cost sharing; sometimes referred to as payment level. Also used to refer to capitation payments to health plans. See Allowed Charge.

Per Diem Payment: Fixed daily payments that do not vary with the level of services used by the patient.

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Physician Work: A measure of the physician's time, physical effort and skill, mental effort and judgment, and stress associated with providing a medical service. A component of the resource-based relative value scale. See Relative Value Scale.

Point-of-Service (POS) Plan: A managed-care plan that combines features of both prepaid and fee-for-service insurance. Health plan enrollees decide whether to use network or nonnetwork providers at the time care is needed and usually are charged sizable copayments for selecting the latter. See Health Plan, Health Maintenance Organization, Preferred Provider Organization.

PPS Inpatient Margin: A measure that compares PPS operating and capital payments with Medicare-allowable inpatient operating and capital costs. Calculated by subtracting total Medicare-allowable inpatient operating and capital costs from total PPS operating and capital payments and dividing by total PPS operating and capital payments. See PPS Operating Margin.

PPS Operating Margin: A measure that compares PPS inpatient operating payments with Medicare-allowable inpatient operating costs. This measure excludes Medicare costs and payments for capital, direct medical education, organ acquisition, and other categories not included among Medicare-allowable inpatient operating costs. Calculated by subtracting total Medicare-allowable inpatient operating costs from total PPS inpatient operating payments and dividing by total PPS inpatient operating payments. See PPS Inpatient Margin.

PPS Year: A designation referring to hospital cost reporting periods that begin during a given federal fiscal year, reflecting the number of years since the initial implementation of PPS. For example, PPS 1 refers to hospital fiscal years beginning in federal fiscal year 1984. For a hospital with a fiscal year beginning July 1, PPS 1 covers the period from July 1, 1984 through June 30, 1985.

Practice Expense: The cost of nonphysician resources incurred by the physician to provide services. Examples are salaries and fringe benefits received by the physician's employees, and the expenses associated with the purchase and use of medical equipment and supplies in the physician's office. A component of the Medicare relative value scale. See Relative Value Scale.

Practice Expense Relative Value: A value that reflects the average amount of practice expenses incurred in performing a particular service. All values are expressed relative to the practice expenses for a reference service whose value equals one practice expense unit. See Relative Value Scale.

Preferred Provider Organization (PPO): A managed-care plan that contracts with networks or panels of providers to furnish services and be paid on a negotiated fee schedule. Enrollees are offered a financial incentive to use providers on the preferred list, but may use nonnetwork providers as well. See Managed Care.

Premium: An amount paid periodically to purchase health insurance benefits.

Productivity: The ratio of outputs (goods and services produced) to inputs (resources used in production). Increased productivity implies that an organization is producing more output with the same resources or the same output with fewer resources.

Professional Liability Insurance (PLI): The insurance physicians purchase to help protect themselves from the financial risks associated with medical liability claims.

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Program of All-Inclusive Care for the Elderly (PACE): First established as a HCFA demonstration program that uses managed care to serve frail elderly persons who have been assessed as eligible for nursing home placement and are, for the most part, dually eligible for Medicare and Medicaid. The program provides adult day health care and case management in addition to Medicare and Medicaid benefits to help the program participant maintain independent living in the community. The BBA made PACE a permanent program and began a new demonstration for for-profit sponsors of PACE sites.

Prospective Payment: A method of paying health care providers in which rates are established in advance. Providers are paid these rates regardless of the costs they actually incur.

Real Value: Measurement of an economic amount corrected for change in price over time (inflation), thus expressing a value in terms of constant prices. See Nominal Value.

Relative Value: A value that reflects a comparison with a standard. See Relative Value Scale.

Relative Value Scale (RVS): An index that assigns weights to each medical service; the weights represent the relative amount to be paid for each service. The RVS used in the Medicare Fee Schedule consists of three components: physician work, practice expense, and malpractice expense. See Malpractice Expense, Medicare Fee Schedule, Physician Work, Practice Expense, Resource-Based Relative Value Scale.

Relative Value Unit (RVU): The unit of measure for a relative value scale. RVUs must be multiplied by a dollar conversion factor to establish payment amounts. See Conversion Factor, Relative Value, Relative Value Scale.

Resource-Based Relative Value Scale (RBRVS): A relative value scale based on the resources involved in providing a service. See Relative Value Scale.

Revenue Share: The proportion of total revenue devoted to a particular type of expense. For example, the practice expense revenue share is that proportion of revenue used to pay for practice expense.

Risk Adjuster: A measure used to adjust payments in order to compensate for spending that is expected to be lower or higher than average, based on the health status or demographic characteristics of enrollees.

Risk Adjustment: The process used to adjust payments to plans to compensate for differences in health status of enrollees across plans.

Risk Contract: See Medicare Risk Contract.

Risk Selection: Any situation in which health plans differ in the health risk associated with their enrollees because of enrollment choices made by the plans or enrollees. As a result, one health plan's expected costs differ from another's due to underlying differences in their enrolled populations. See Adverse Selection, Favorable Selection.

Risk Sharing: A method, such as outlier payments, that places a health plan at less than full risk by covering the cost of selected services, providing additional payment amounts for high cost patients or to offset plan losses.

Rural Referral Center: Generally large rural hospitals that Medicare designates as serving patients referred by other hospitals or by physicians who are not members of the hospital's medical staff.

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Secondary Insurance: Any insurance that supplements Medicare coverage. The three main sources for secondary insurance are employers, privately purchased Medigap policies, and Medicaid.

Site-of-Service Differential: The difference in the amount paid to the physician when the same service is performed in different practice settings, for example, a colonoscopy in a physician's office or a hospital clinic.

Skilled Nursing Facility (SNF): An institution that has a transfer agreement with one or more hospitals, provides primarily inpatient skilled nursing care and rehabilitative services, and meets other specific certification requirements. See Nursing Facility.

Standardized Amount: An amount used as the basis for payment under PPS. It is intended to represent the national average operating cost of inpatient treatment for a typical Medicare patient in a reasonably efficient hospital in a large urban or other area. Standardized amounts are based on Medicare costs reported by hospitals for cost reporting periods ending in 1982, adjusted for geographic location and certain hospital characteristics, such as teaching activity. The adjusted amounts are updated to the year of payment by an annual update factor.

Submitted Charge: The charge submitted by a provider to the patient or a payer. See Paid Amounts.

Supplementary Medical Insurance (SMI): The part of the Medicare program that covers the costs of physicians' services, outpatient laboratory and X-ray tests, durable medical equipment, outpatient hospital care, and certain other services. This voluntary program requires payment of a monthly premium, which covers 25 percent of program costs, with the rest covered by general revenues. Beneficiaries are responsible for a deductible and coinsurance payments for most covered services. Also called Part B coverage or benefits.

Supplier: A provider of health care services, other than a practitioner, that is permitted to bill under Medicare Part B. Suppliers include independent laboratories, durable medical equipment providers, ambulance services, orthotists, prosthetists, and portable X-ray providers.

Sustainable Growth Rate: The target rate of expenditure growth set by the sustainable growth rate system. Similar to the performance standard under the previous volume performance standard system, except that the target depends on growth of gross domestic product instead of historical trends. See Sustainable Growth Rate System, Volume Performance Standard System.

Sustainable Growth Rate System: A revision to the volume performance standard system, enacted as part of the Balanced Budget Act of 1997. This system is the mechanism for setting fee updates for the Medicare Fee Schedule. It uses a single conversion factor, bases target rates of growth on growth of gross domestic product, and changes the previous method for calculating the conversion factor update to eliminate the two- year delay. See Volume Performance Standard System, Conversion Factor Update.

Swing-Bed Hospital: A hospital participating in the Medicare swing-bed program. This program allows rural hospitals with fewer than 100 beds to provide post-acute care services in acute care beds.

Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA): Legislation that, among other things, established limits on reimbursements for hospital inpatient operating costs per Medicare discharge. A facility's limit is derived from its costs in a base year updated to the current year by an annual update factor. Medicare payments for operating costs generally may not exceed the facility's limit. These provisions apply generally to hospitals and units excluded from PPS. See Excluded Hospitals and Distinct-Part Units.

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Total Margin: A measure that compares total hospital revenues with expenses for inpatient, outpatient, and nonpatient care activities. The total margin is calculated by subtracting total expenses from total revenues and dividing by total revenues.

Uncompensated Care: Care rendered by hospitals or other providers without payment from the patient or a government-sponsored or private insurance program. It includes both charity care, which is furnished without the expectation of payment, and bad debts, for which the provider has made an unsuccessful effort to collect payment due from the patient.

Update Factor: The year-to-year increase in base payment amounts for PPS hospitals and dialysis facilities, and in the target amounts for PPS-excluded hospitals and units. MedPAC's annual update recommendations are intended to reflect changes in the prices of inputs used to provide patient care services as well as changes in productivity, technological advances, quality of care, and long-term cost effectiveness of services. See Market Basket Index.

Usual, Customary, and Reasonable: A method used by private insurers for paying physicians based on charges commonly used by physicians in a local community. Sometimes called customary, prevailing, and reasonable charges. See Customary, Prevailing, and Reasonable.

Volume and Intensity of Services: The quantity of health care services per enrollee, taking into account both the number and the complexity (or mix) of the services provided.

Volume Offset: The change in the number and mix of services that is projected to occur in response to a change in fees. A 50 percent behavioral offset means that half the savings from fee reductions will be offset by increased volume and intensity of services. Used to estimate budget effects for Medicare payment changes. Also referred to as behavioral offset.

Volume Performance Standard (VPS) System: Recently replaced mechanism to adjust fee updates for the Medicare Fee Schedule based on how annual increases in actual expenditures compare with previously determined performance standard rates of increase. See Sustainable Growth Rate System.

Work Relative Value: A value that reflects the average amount of physician work incurred in performing a particular service, relative to that of other services. See Relative Value Scale.

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Report to the Congress, Medicare payment policy.

Washington, D.C. : Medicare Payment Advisory Commission, [1998]-

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Volume II: Analytical Papers

March 1998

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Acknowledgements

When the Medicare Payment Advisory Commission held its first meeting in October 1997, it seemed inconceivable that its first report could be ready in just four months. Drawing on the work of its predecessors, together with the energy and enthusiasm about this new venture, the March report is now a reality.

This feat would not have been possible without the support and contributions of many individuals, both in Washington and around the country. Staff of the Congress, the Health Care Financing Administration (particularly the Enterprise Databases Group) and other agencies of the Department of Health and Human Services, the Congressional Budget Office, the Congressional Research Service, and the General Accounting Office provided invaluable information and advice.

The Commission has been fortunate to work with people who have consistently understood and responded to its needs in key areas. Social and Scientific Systems— especially Arlene Turner, Valerie Aschenbach, Jeff McCartney, Rosanne Russillo, Daksha Damera, Paul Menick, Charles Thomson, and Deborah Johnson— have superbly met the challenges posed by the Commission's diverse programming needs. Lynn Lewis has helped the staff convey complex and technical concepts in an effective manner. Franek Design Associates, Inc. contributed by giving the Commission's report its own distinctive design and shepherding the report through the production process.

The Commission's work on vulnerable populations was greatly advanced by the expert panel convened by Mathematica Policy Research. Marsha Gold, Robert Hurley, and Jessica Mittler were instrumental in arranging the panel. Thanks go to Susan Aldrich, Allan Bergman, Irene Fraser, Sandra Harmon-Weiss, Carter Marshall, Robert Master, Glen Rosselli, Paul Saucier, Mervin Shalowitz, Steven Somers, Craig Thornton, Carol Tobias, James Verdier, and Edward Wagner for their participation on the panel.

Others who have put their mark on this report include David Colby, who served as deputy director until December 1997, and Don Young, who served as co-executive director through October 1997. Another former staff member, Karen Fisher, also made important contributions. A number of other people played an important role in Commission activities during the past year. For their efforts, special thanks go to Anil Bamezai, Robert Bergmann, Tom Bradley, Al D'Alberto, Anthony Dreyfus, Cindy Dudzinski, Frank Eppig, Donna Farley, Beth Fuchs, David Gibson, Sheridan Gladhill, David Glass, Liz Mauser Goldstein, Leonard Gruenberg, Mel Ingber, Ann Iversen, Terry Kay, Richard Kronick, Ken Leong, Susan Levy, Joyce Mann, Joseph Martin, Clare McFarland, Sharon McIlrath, Steve Miller, James O'Keiff, Madeleine Smith, Don Thompson, Cynthia Tudor, Christine van Reenen, and Janet Wellham.

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° Lauren LeRoy left the Commission at the end of January 1998 to become president and CEO of Grantmakers in Health. Murray Ross assumed the position of executive director in late February 1998.

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Foreword

This is the first major report of the Medicare Payment Advisory Commission. The Commission began its work in October 1997. In conducting analyses and developing recommendations, we have drawn upon the experiences and work of our predecessors, the Physician Payment Review Commission and the Prospective Payment Assessment Commission, while shaping the agenda for this new body.

This report focuses on Medicare payment policy. Chapters consider all of the major payment issues facing the program, including those related to the Medicare+Choice program, fee-for-service policies affecting a variety of providers, service to special populations, and financing of graduate medical education. The Commission's June report will take on other policy issues concerning Medicare and its relationship to the broader health care system.

The Commission presents its work in two volumes. Volume I contains all of the Commission's recommendations as well as the rationales behind them. Volume II includes analytic papers that generally relate to the recommendations in Volume I. In some cases, these provide more detail on methods. In others, they provide supporting background information. We are hopeful that this approach will be satisfying and useful to the Congress and to others in the policy community and practice environment who rely on the Commission's work.

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Chapter 1

Medicare's Capitation Payments to Private Health Plans: Sample Calculations and Simulation Methods

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Chapter 1

Medicare's Capitation Payments to Private Health Plans: Sample Calculations and Simulation Methods

The Balanced Budget Act of 1997 (BBA) (P.L. 105-33) completely restructured the method for calculating Medicare's capitation rates for paying health plans. It applies immediately to plans in the Medicare risk program and will apply to plans in the newly created Medicare+Choice program as it replaces the risk program in late 1998 and 1999. The new system includes changes designed to reduce the volatility in county payment rates from year to year and the variation in rates across the country. Reduced volatility and variation are in turn intended to encourage more participation by health plans and beneficiaries.

In Volume I, Chapter 2, the Medicare Payment Advisory Commission describes the method for determining the capitation rates at which health plans are paid and makes several recommendations for technical corrections to the payment method established in the BBA. That chapter also included analysis of the impact of the changes made by the BBA.

This chapter includes three types of supporting material. It is designed to help the reader understand better how the new payment rates are calculated and how different parts of the system interact—but not to offer additional impact analysis. First, the chapter provides examples of how rates are calculated. Second, it uses examples to illustrate interactions among the policies underlying the three different rules established as part of the new legislation. Finally, it documents in some detail the simulation model used by the Commission to estimate payment rates under the new rules.

Calculating County Payment Rates

The new method of setting county payment rates is being implemented, starting in 1998, to pay private health plans that contract with Medicare. The methodology is built on three basic rules. First, the method blends the 1997 local county rates calculated under the old system with an adjusted national rate in proportions that shift over six years to a 50:50 local-national blended rate (see Table II-1-1 for specific parameters on these and other rules). Second, counties are guaranteed a minimum increase of 2 percent over their previous year's rate. Third, rates must meet a minimum or floor rate that is set by law in 1998 and goes up each year. Each county's monthly payment rate is set as the highest of the three rates calculated from these three rules. The law also requires that payment rates be adjusted for budget neutrality to ensure that total payments under the new system equal those that would have made based on local payments only. This section describes and illustrates, using several sample counties, how county payment rates are calculated.[1]

[1] The term county, as used here and elsewhere, includes independent cities such as St. Louis, Baltimore, and numerous Virginia cities.

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Table II-1-1

Parameters in the Balanced Budget Act for Calculating Medicare's Payment Rates to Health Plans, 1998-2003

Year	Blended-Rate Proportions		Floor Rate	Percentage of Graduate Medical Education Payments Removed	National Growth Percentage
	Local	National			
1998	90%	10%	$367	20%	2.6%
1999	82	18	381 *	40	3.9 *
2000	74	26	398 *	60	4.5 *
2001	66	34	420 *	80	5.4 *
2002	58	42	445 *	100	5.9 *
2003	50	50	477 *	100	7.2 *

SOURCE: Medicare Payment Advisory Commission analysis of payment rate methodology under the Balanced Budget Act of 1997.

*Based on Congressional Budget Office projections, January 1997 baseline, with changes resulting from the Balanced Budget Act of 1997.

Table II-1-2

Illustrative Calculation of Medicare's Monthly Payment Rates for Sample Counties, 1998

County	Preliminary Calculation of Payment Rate Under Separate Rule				Final Calculation of Payment Rate	
	1997 Actual Rate	Minimum Update	Floor	Blended Rate (90:10)	Before Budget-Neutrality Adjustment	Actual Rate (After Budget-Neutrality Adjustment)
Dade, FL	$748.23	$763.19	$367.00	$737.10	$763.19	$763.19
Los Angeles, CA	622.55	635.00	367.00	625.92	635.00	635.00
San Francisco, CA	525.90	536.42	367.00	536.83	536.83	536.42
Hennepin, MN	405.63	413.74	367.00	419.34	419.34	413.74
Waupaca, WI	286.17	291.89	367.00	307.67	367.00	367.00
Arthur, NE	220.92	225.34	367.00	244.89	367.00	367.00

SOURCE: Medicare Payment Advisory Commission analysis of payment rates under the Balanced Budget Act of 1997.

NOTE: The first step is the calculation of three rates for each county, corresponding to the three rules in the Balanced Budget Act of 1997. Initially, each county's rate is the highest of the three rates. The budget-neutrality adjustment is then applied to rates set by the blended-rate rule. In 1998, the budget-neutrality adjustment lowered all blended rates so that they were no higher than the minimum update or floor rates. As a result, rates for Hennepin and San Francisco Counties were set by the minimum-update rule instead of the blend rule.

The first step in determining payment rates is to calculate three separate rates for each county: minimum-increase rate, floor rate, and blended rate (see Table II-1-2). Two of these calculations are simple. The *minimum increase* for all counties is 102 percent of the previous year's payment rate. The 1998 *floor rate* for all counties (other than territories) is $367.[2]

Calculation of the *blended rate* is more complex. The blended rate for 1998 is the sum of 90 percent of the local rate and 10 percent of the input-price-adjusted national rate. For each county, the *local rate* for 1998 is based on the county's 1997 rate, reduced by 20 percent of the county-specific proportion of Medicare spending that is attributable to graduate medical education (GME) and then increased by the 1998 national growth percentage (2.6 percent).[3] The *national rate* is calculated as an average, weighted by the number of beneficiaries in each county, of the local rates for all counties. Before blending, the national rate is adjusted by a county-specific input-price adjuster that is derived (according to a formula in the law) from the price adjusters used for Medicare's physician and hospital payments.

[2] The BBA sets the floor rate for territories at the lower of $367 or 150 percent of the 1997 rate.

[3] The value of 2.6 percent was based on projected Medicare growth per capita of 3.4 percent, minus a reduction in law of 0.8 percentage points.

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Initially, each county's rate is the highest of the three rates: the minimum increase, the floor, and the blended rate. For the sample counties in Table II-1-2, there are two counties whose rates are determined by each rule. The *budget-neutrality adjustment* is then applied to those counties with rates set by the blended-rate rule (Hennepin and San Francisco Counties in Table II-1-2). The law requires that rates never fall below those set by the other two rules. This adjustment is calculated to ensure that total payments under the new payment method equal total payments based on the rates that would have resulted if all counties used their local rates (that is, 1997 rates, excluding payments for GME and increased by the national growth percentage).

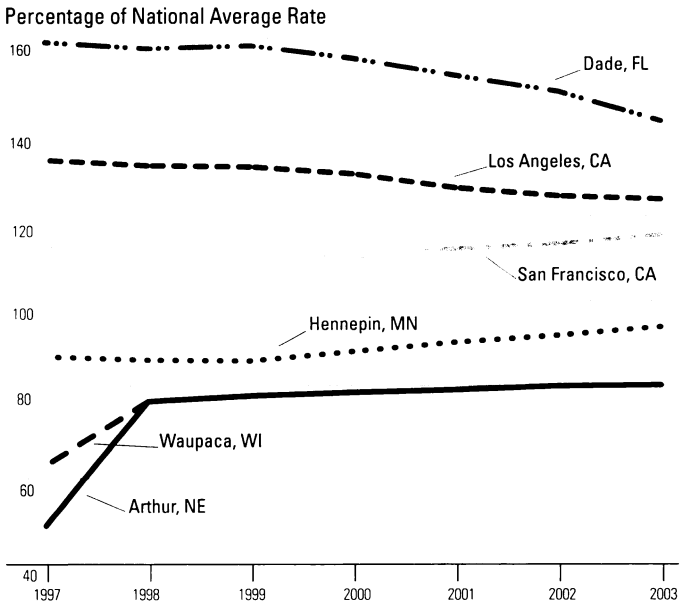
For 1998, the budget-neutrality adjustment caused blended rates for all counties to be lowered the maximum amount possible, to either the county's minimum-increase or its floor amount. The adjustments that would have been necessary to achieve budget neutrality would have reduced rates below the minimum-increase or floor amounts for these counties. The Commission has recommended changing the law to ensure that budget neutrality can always be achieved (see Volume I, Chapter 2).

For the sample counties in Table II-1-2, the budget-neutrality adjustment caused monthly rates for Hennepin and San Francisco to be reduced by no more than 1.5 percent of their payment rates. Had the adjustment been smaller, rates for these counties would have been set between the blended-rate and minimum-increase amounts.

In 1999, the minimum-increase amount will be calculated from the 1998 rates, but the local and national components of the blended rate will be calculated from the 1997 rates—with two years of increases for national growth and further phasing in of the blend percentages and the GME exclusion. The 1999 floor rate will be set at the 1998 floor, increased by the national growth percentage. Using estimates of future levels of the national growth percentage, rates can be calculated from the same methodology through 2003, as the various changes are phased in (see Figure II-1-1).

Figure II-1-1

Calculation of Medicare's Monthly Payment Rates for Sample Counties, 1997-2003



SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

The Effects of the Three BBA Rules on County Rates

The three rules established by the BBA each affect the distribution of payments across counties. The blended-rate rule can be characterized as the core of the system, working to shift from rates based only on local fee-for-service spending patterns to rates based in part on national average spending. The floor-rate and minimum-update rules were designed to modify the effect of this core policy, either speeding up the increases or tempering the reductions. The rules in combination were designed to reduce volatility and variation in payments.

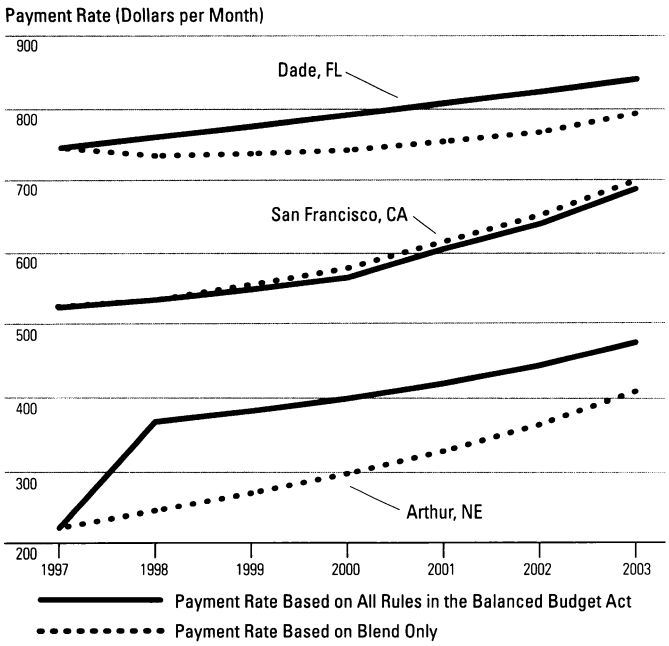
The interaction of the three rules is complex, particularly because of the county variation in input-price adjusters and the magnitude of GME payments. As a result, it can be misleading to characterize their effects in simple terms. For example, many minimum-update counties are large urban counties where payments have historically been high. As a result, some have assumed that the minimum-update rule serves to protect only these counties. Although this may be the most common pattern, the minimum update also protects some rural or urban counties with modest payment rates but a high proportion of GME expenses included in their base rates.

In addition to the system's complexity, there are trade-offs inherent in applying the three rules simultaneously. The higher county rates dictated by applying the floor and minimum-update rules are financed by lower rates elsewhere, creating a set of winners and losers relative to a system based only on blended rates. In considering future changes to the rate structure, it is important to understand these interactions.

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Figure II-1-2

Comparison of Simulated Medicare Payment Rates with Blended Rates, Selected Counties, 1997-2003



SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

This section illustrates how these rules interact. It first looks at three of the sample counties described in the previous section to compare how the floor rate and minimum increase, as well as the budget-neutrality requirement, change the rates from what they would have been if based on the blended-rate rule alone. The following three subsections focus successively on each of the three rules, using sample counties with rates based primarily on that particular rule. (Because the actual rule that determines the rate for a particular county often varies from year to year, these examples are counties where one rule predominates.) This analysis is based on simulations that use 1998 actual rates and rates estimated for 1999-2003 based on Congressional Budget Office (CBO) projections.[4] The results are sensitive to assumptions about spending and enrollment growth, as discussed below.

Overall Comparison

One way to illustrate how the new payment method works is to compare rates based on blended rates only with those resulting from applying the full system established by the BBA, which includes floors and minimum updates. In general, this analysis demonstrates how much higher some county rates are set because of the floor and minimum-update rules and how much the rates for blended-rate counties are reduced to maintain budget neutrality as closely as possible. The sample counties used here and in the following sections were selected to illustrate a variety of effects and to include different county characteristics.

The first illustration uses three of the sample counties described in the previous section (see Figure II-1-2). In Dade County, the 2 percent minimum update raises the payment above its blended rate. In the absence of the minimum update, rates would remain at or below 1997 levels for two or three years. This reflects the combined effect of three factors: high local rates blended with the lower national average rate, the exclusion of relatively large GME payments, and relatively low national growth percentages. By contrast, Arthur County, Nebraska, which had the lowest 1997 rate in the country, received the greatest increase due to the floor rate. The third example, San Francisco County, illustrates the reduction that occurs for a blended-rate county in order to achieve budget neutrality. These reductions are relatively modest, in part because the 2 percent minimum increase prevents the full reductions that would be necessary to achieve budget neutrality (see Volume I, Chapter 2).

Minimum-Update Counties

Counties where rates are based primarily on the minimum-update rule differ on several characteristics, as illustrated by the sample counties (see Figure II-1-3). Monthly payment rates in the three sample counties vary by about $200. In addition, two are central urban counties and one is rural. Not surprisingly, St. Louis City, which had a lower 1997 rate than the other two counties, receives a smaller gain above its blended rate from the guaranteed 2 percent increase. In fact, in 2003, the blended rate for St. Louis exceeds the minimum update.

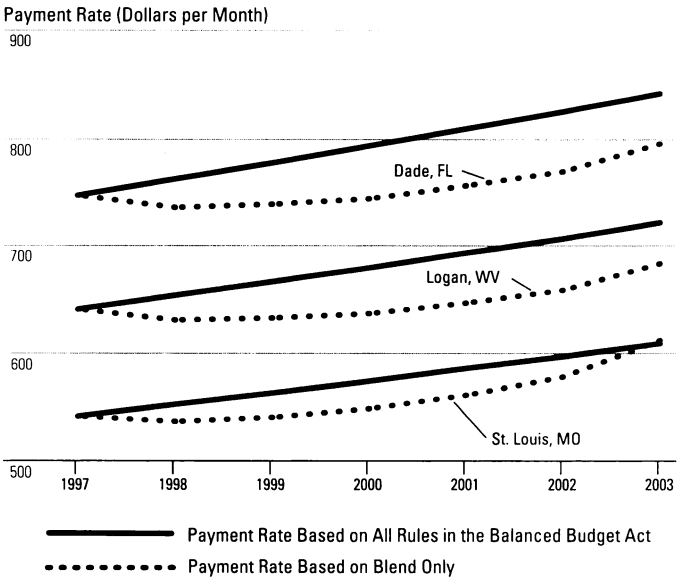
Beyond the application of the three rules, two other differences among counties affect the rates, as illustrated by the sample counties. First, the proportion of spending attributable to GME varies. Based on data from the Health Care Financing Administration (HCFA), GME represents 8.7 percent of spending in St. Louis, compared with 3.5 percent in Logan County and 1.9 percent in Dade County. Had the proportion in Dade been higher, for example, the gap between the actual rate and the blended rate would have been greater. Second, levels of input-price adjusters also vary by county. The value for Dade is 1.03, compared with 0.94 in St.

[4] CBO estimates of spending growth are taken from the January 1997 baseline, as adjusted by CBO for changes enacted in the BBA. HCFA's preliminary estimate of the 1999 national growth percentage, announced January 15, 1998, is 2.0 percent, well below the 3.9 percent estimated using this CBO baseline. CBO's January 1998 baseline, released as this report was going to press, makes modest changes—some up and some down—in projected national growth percentages. Results of simulations using these revisions include lower rates in all years and an increased likelihood that blended rates will be effective first in 2001, rather than in 2000. These results, however, are preliminary.

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Figure II-1-3

Comparison of Simulated Medicare Payment Rates with Blended Rates, Selected Counties with Rates Based Mostly on the Minimum Update, 1997-2003

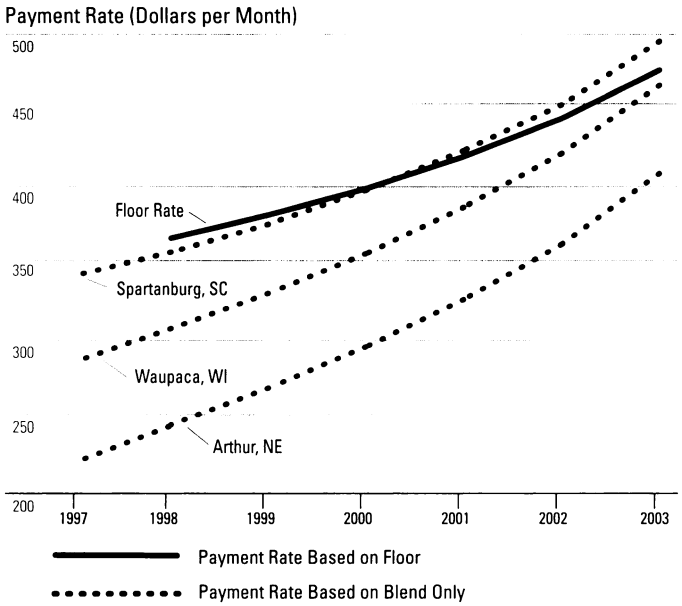


SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

Figure II-1-4

Comparison of Simulated Medicare Payment Rates with Blended Rates, Selected Counties with Rates Based Mostly on the Floor, 1997-2003



SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

Louis and 0.91 in Logan. The lower-than-average input-price adjuster and high GME spending for St. Louis combine to keep the blended rate low.

A comparison of the two counties with the highest rates in the country (one of which is not shown in Figure II-1-3) illustrates this point further. Richmond County, New York (Staten Island), had a 1997 payment rate similar to that in Dade. But it has a much higher level of GME spending (13.4 percent) and a much higher input-price factor (1.26). Excluding GME payments lowers the payment in Richmond, but the input-price factor raises it. Thus, under the rules in the BBA, these two factors offset each other, so that Dade and Richmond would have similar blended rates in 2003. By contrast, should the blend proportions be shifted further toward national rates in the future (after the GME exclusion is complete), Dade's rate would fall far below Richmond's because of its lower input-price factor.

If the annual national growth percentage stays above 2 percent, the blended rates for counties in this category will eventually surpass the minimum-update amounts, as occurs in St. Louis in 2003. With an annual national growth percentage in the range of 5 percent to 6 percent, the effect of the minimum update would be gone in 2005.

Floor-Rate Counties

The second set of examples includes counties where the 1998 blended rate is below the floor rate (see Figure II-1-4). The three counties in this example start at different levels. But rates for all three were raised to $367 in 1998. Because all these counties are below the national average, the phasing in of the blend proportions gradually moves their blended-rate amounts upward.[5] For Spartanburg County, South Carolina, the blended rate is projected to surpass the floor as of 2001, after which payment is set at the blended rate. For Waupaca County, Wisconsin, it is projected to stop just short of doing so in 2003.

Both the blended rate and the floor rate are updated annually by the same national growth percentage. As a result, rates for Waupaca and Arthur Counties are projected to remain at a floor rate—above their blended rates—beyond 2003, unless the Congress makes a further change in the payment rate methodology.

[5] Most of the counties in this category also have input-price factors below 1.0, so they would remain below the national average even if the blend shifted all the way to 100 percent national rates.

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Blended-Rate Counties

The third set of examples includes counties where rates are based mostly on the blend (see Figure II-1-5). In these cases, the final rates are reduced to meet budget neutrality. With the higher national growth percentages currently projected for 2002 and 2003, the reduction attributable to budget neutrality is only about $5 per month in 2003, after being about triple that amount when the gap is widest. The reduction for budget neutrality also gets smaller over time because there are fewer counties where the floor rate or minimum update is applicable.

For two of the sample counties (Westchester and San Francisco), the blended-rate rule raises rates even though these counties are already above the national average rate. This result occurs because these counties have input-price adjustment factors that are well above average (1.25 and 1.26, respectively).

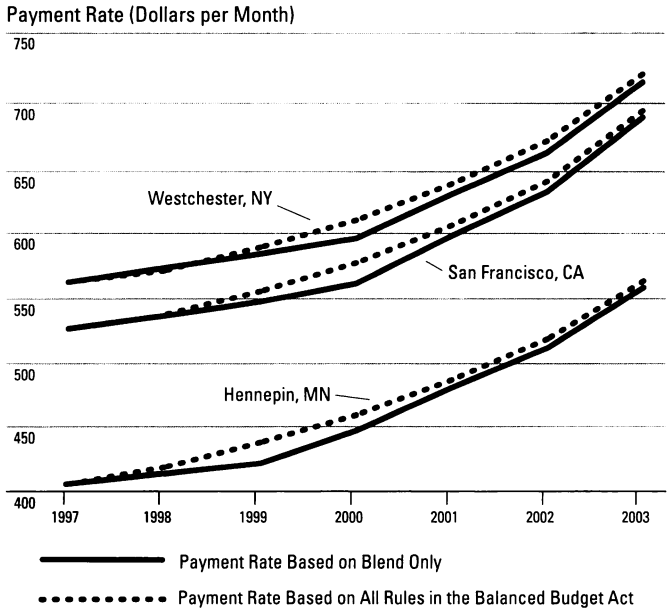
Methodology for Simulating County Payment Rates

Simulations were used during congressional deliberations to help evaluate the impact of new rules for setting payments to health plans. The staff of the Physician Payment Review Commission (PPRC) worked closely with the Congressional Research Service (CRS) and the Congressional Budget Office to provide this analytic support to the Congress.[6] CRS provided timely, county-level estimates of payment rates under alternative proposals based on a model in which the number of beneficiaries enrolled in each county remains as it was in 1996. CBO scored proposals, however, under the assumption that the program will continue to grow at different rates across the nation. PPRC developed a new model that shifts the number of beneficiaries enrolled in each county over time. Referred to as the dynamic model, it generally assumes higher enrollment for any county with an above-average payment rate increase or an existing trend of rapidly growing enrollment. These enrollment assumptions are detailed below. The dynamic model was designed primarily to help the Congress anticipate whether specific legislative proposals could be implemented in a budget-neutral manner if growth occurs as anticipated by CBO.

This section discusses the use of simulations in the analysis of different approaches for calculating county-level payments to health plans. It serves to document PPRC's dynamic simulation model, which was used to analyze payment rates for both congressional deliberations and this report.

Figure II-1-5

Comparison of Simulated Medicare Payment Rates with Blended Rates, Selected Counties with Rates Based Mostly on the Blend, 1997-2003



SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

Payment Simulation Models

Simulation models are a tool for providing estimates suggestive of the payment rates that will prevail under alternative legislative proposals. These estimates are important for determining the cost implications of each approach, including distributional consequences at the county level. Simulations also provided a test of whether budget neutrality—a requirement of most proposals—could be achieved and the effect on county rates of doing so.

Historically, estimates of alternative policies have been based on static models that take as fixed the distribution of plan enrollees across counties. During consideration of Medicare reforms in 1995, analyses of alternative models conducted by both congressional advisers and the Administration were based on static models. Static-model estimates are imprecise because they do not reflect changes in enrollment that are likely to occur. Recent growth in the Medicare risk program in some areas is quite high. The assumption in static models that the geographic distribution of enrollment will remain unchanged is therefore both unrealistic and

[6] This section is based on model building and analysis done by the Physician Payment Review Commission for the Congress during its deliberations on the Balanced Budget Act. PPRC provided assistance to the Congress on these matters in both 1995 and 1997. The dynamic simulation model was developed in 1997 to make simulation results more accurate by having the model reflect a behavioral response to payment changes.

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inconsistent with CBO's framework for establishing the costs of alternative proposals. In addition, changes in payment policy are likely to affect plan offerings and, in turn, beneficiary enrollment decisions.

Even if enrollment were not growing as rapidly as it is currently, a change in payment policy is likely to change enrollment rates in different areas. To make estimates that are more suggestive of how a particular policy is likely to work over time, it was necessary to make some assumptions about changes in enrollment.

The main value of a dynamic model is to determine whether a particular proposal for changing risk-plan payments could be budget-neutral, given the likely changes in enrollment over the budget period. For example, a policy of payment floors would be scored by CBO as not adding costs if it applies primarily in counties that currently have no enrollment. Under a dynamic model, raising payment to a floor rate may trigger subsequent enrollment that adds costs relative to current rates. The specific assumptions about enrollment growth affect both projected spending under alternative proposals and county-level rates.

Assumptions Underlying the Dynamic Model

The key assumption for the dynamic model involves how enrollment will change in response to different policies. The research literature provides little consensus about how plans and beneficiaries are likely to respond to changes in payment rates and benefit offerings (PPRC 1997). As a result, CBO and PPRC developed general rules to describe likely aggregate effects of enrollment growth and policy changes. These rules were designed mostly to provide a rigorous test of whether budget neutrality could be achieved. As such, they make relatively simple, but extreme enrollment-growth assumptions. More modest assumptions about enrollment growth could be used to see how sensitive the results are to these assumptions.

First, counties with extraordinary payment increases (such as some floor counties) are assumed to have rapid enrollment growth regardless of current enrollment levels, most of which are now close to zero. After a one-year lag for plans to sign contracts and start enrolling beneficiaries, these counties were assumed to achieve moderately high enrollment over a two-year period.[7]

Second, other counties with above-average payment increases are assumed to have enrollment growth that exceeds their recent trend growth. In these counties, future growth is set at the product of recent growth rates and the rate of increase in payments. This assumes up to a 1 percent enrollment increase for every 1 percent increase in payment, above and beyond trend enrollment growth.[8]

Furthermore, remaining counties with payment increases are assumed to continue their recent enrollment-growth trend. Counties with no payment increases are assumed to have zero enrollment growth. In no case is a county's enrollment allowed to surpass an upper-bound enrollment level.

How Dynamic Models Affect County-Level Payment Rate Estimates

The results of static and dynamic models differ only because of the budget-neutrality requirement, which is the only component of the calculation to involve the number of plan enrollees. The estimates differ for several reasons, a result that can be critical when comparing different proposals for payment rate changes. First, the distribution of enrollees across counties with different payment rates affects the size of the baseline budget, that is, the total expenditures for which the budget-neutrality comparison is made. Each year, the baseline budget is set as the product of the number of enrollees and the local payment rate (before blending or other calculations), summed across counties.

Since the distribution of beneficiaries changes under the dynamic model, the baseline budget changes. For example, if there is a net shift of enrollment toward counties with lower local rates, the budget becomes smaller. Projected spending as a result of payment changes is also affected by the distribution of enrollees. Thus, if payment rates rise in those same counties, the projected spending will rise. As a result of the effect both on the budget and on projected spending, proposals that can be implemented in a budget-neutral manner under a static model may be unaffordable under a dynamic model, where the budget may shrink and projected spending may grow based on the redistribution of enrollees.

Even if a particular payment rate proposal is affordable (that is, can achieve budget neutrality) under both models, the resulting county-level payment rates will differ because the proposal will require smaller or larger adjustments to rates to achieve budget neutrality. The effect of the enrollment pattern on payment rate estimates differs across proposals, due primarily to differences in the degree of enrollment shifts and the amount of money that is reallocated from the baseline budget. For example, as floors increase, they generate a stronger enrollment response which in

[7] The simulation model only requires assumptions about how enrollees are distributed across counties, not about how national enrollment grows. Total enrollment levels do not affect the calculation of payment rates, although they of course affect total payments. As a result, assumptions are stated in terms of the direction of change, not the magnitude of change. Thus the definition of parameters such as "moderately high enrollment" cannot be stated as precise numbers in the absence of an assumed national average enrollment growth.

[8] Just as numerical enrollment levels cannot be specified, this parameter is stated as "up to a 1 percent increase." The exact relationship depends on national average enrollment growth.

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turn leads to dynamic county estimates that diverge more from static estimates. Since the enrollment changes are due in part to payment policy changes, the redistribution of enrollees differs across proposals.

Comparing Estimates from Dynamic and Static Models

As noted above, use of the dynamic enrollment-growth assumptions tends to reduce both the national average payment and many individual county payments. By 2003, the average national payment (weighted by the number of beneficiaries per county) would be $596 under the dynamic model instead of $611 under the static model (see Figure II-1-6). This amounts to about a 2.5 percent reduction. At the county level, the changes are bimodal since some counties (for example, those already at the floor) are constrained from being reduced.

Comparing Simulated Rates to Actual Rates

The simulated 1998 rates provided to the Congress during its deliberations in 1997 did not precisely match the actual county rates published by HCFA. PPRC simulations during the congressional deliberations predicted that about one-half of all counties would receive blended rates in 1998. Because budget neutrality could not be achieved, there were no blended-rate counties in the final rates. Nevertheless, the difference at the individual county level is much smaller than this result might imply. Most blended rates were only a small amount above either a floor or minimum-increase level. On average, the actual 1998 monthly per enrollee payment rate (weighted by beneficiaries) was about $2 below PPRC's simulated rate. Among those counties for which actual rates were lower than simulated rates, the average monthly difference was about $5. Differences exceeded $10 in only 3 percent of all counties and exceeded $20 only in four Alaska counties (where no plans are offered).

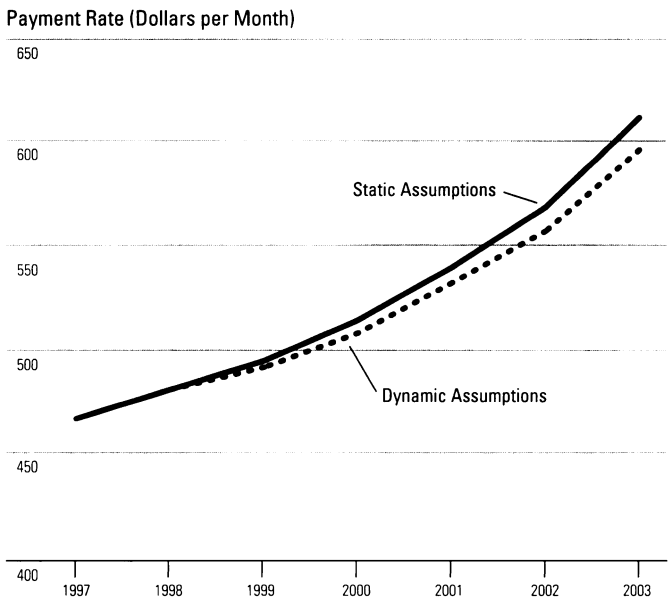
There are several reasons for differences between the results of the simulation and the actual rates. Some reasons are unique to decisions made for these simulations. Others may apply to any projected rates.

Estimates of the National Growth Percentage

HCFA's estimate of the national growth percentage (incorporating the statutory reduction of 0.8 percentage points for 1998) was 2.6 percent, substantially below the 3.4 forecast by CBO and used in simulations prepared for the Congress. This difference both lowered rates overall and, together with the effects of excluding GME payments and raising counties to the $367 floor, prevented budget neutrality from being achieved.

Figure II-1-6

Changes in Average Payment Rates, Using Both Static and Dynamic Enrollment-Growth Assumptions, 1997-2003



SOURCE: Medicare Payment Advisory Commission simulations of payment rates under the Balanced Budget Act of 1997.

NOTE: Analysis based on actual rates for 1998 and simulated rates for 1999 through 2003.

Calculations Based on Total Medicare Versus Parts A and B Separately

At the request of congressional committee staff, the CRS and PPRC models were designed to replicate HCFA's original simulation of the President's budget proposal. This replication did not, however, match the details in the final legislative language. For example, the exclusion of GME payments in the simulations was based on county-level proportions of Part A spending only, and separate annual national growth rates were applied to Part A and Part B spending. The legislative language called instead for combined Part A/Part B numbers (that is, GME as a percentage of all spending and one national growth rate percentage for Medicare as a whole). This technical difference matters for two reasons. First, there are large differences in the separate national growth percentages for 1998 (–8.7 percent for Part A and +26.0 percent for Part B, before the reduction provided in the BBA), in part due to the transfer of home health services to Part B. Second, the division of Medicare spending between Parts A and B varies fairly widely by county.

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New Data

For calculating 1998 rates, HCFA used newly updated numbers for fee-for-service and health plan enrollment, shares of spending attributed to GME, demographic characteristics, wage indexes, and geographic adjustment factors. Although these substitutions did not have a large effect on the results on average, they shifted results for some counties.

Conclusions

Several conclusions can be drawn about the differences between simulation results and actual published rates. First, the differences are quite small, only 1 percent for those counties where there were differences and less than half that for all counties. Second, small differences can matter considerably from the perspective of achieving budget neutrality in a system where the minimum increase is nearly as large as the average increase.

Third and perhaps most important, the actual rates for any year are calculated from the most recent projections of spending and enrollment growth. PPRC developed its dynamic enrollment-growth model to incorporate its best estimates of the distribution of enrollment growth. But, as PPRC and CRS regularly emphasized in reporting their projections, the accuracy of projected rates for future years depends on early estimates of those factors. Over time, revisions are made to these projections in order to reflect more recent information.

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Physician Payment Review Commission, *Annual Report to Congress 1997* (Washington, DC: 1997).

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Chapter 2

Risk Adjustment

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Chapter 2

Risk Adjustment

The Balanced Budget Act of 1997 (BBA) requires risk-adjusted payments to Medicare+Choice plans starting in the year 2000. This chapter looks at two major decisions the Health Care Financing Administration (HCFA) must make for the design of the risk-adjustment system.

Volume I, Chapter 3 gives much of the background for the analysis presented here. The BBA requires plans to begin reporting encounter data in 1998. These data provide information on each beneficiary's use of care and diagnoses. HCFA will use these diagnosis data for risk adjustment, paying more for beneficiaries with costly conditions and less for others. HCFA must propose a method for risk adjustment in March 1999, with risk-adjusted payment to begin the following year. Collection of hospital inpatient encounter data already has begun.

Numerous practical decisions must be made to implement risk-adjusted rates. HCFA must choose a source of data (inpatient or all sites of care) and corresponding risk-adjustment model. HCFA must compute the payment weights for each diagnosis and then integrate these with all the other determinants of plans' payments. HCFA and plans must establish the flow of encounter data from plans to HCFA and the risk-adjusted payment in return.

This chapter looks at two major issues for the design of Medicare risk adjustment. The first is whether to use inpatient data or data from all sites of care. Inpatient data are more reliable and easier for plans to report, but result in increased capitation rates only for hospitalized beneficiaries. The second major issue involves the timing of the risk-adjustment process. Payment amounts could reflect high acute-care costs incurred at time of diagnosis, or lower costs incurred in the subsequent year. A separate set of payment timing questions—when does a diagnosis count for payment, and when is payment made—have significant implications for plan operations and for the administrative complexity of the risk-adjustment system.

The final section of the chapter addresses the phase-in of payment rates. Risk adjustment involves significant uncertainty and major realignment of payments. Phase-in rules allow HCFA to moderate the financial incentives and payment changes that risk adjustment will create. Ultimately, discussion should not focus on whether or not to risk-adjust payments, but on how rapidly and to what extent payment changes should be made.

Encounter Data: Inpatient Versus All Sites of Care

Medicare's risk-adjusted payment rates could be based on diagnoses from inpatient hospitalizations only or on diagnoses reported from all sites of care. This choice will fundamentally affect the payment system, from the process for reporting data to the rates paid. This section looks at five factors relevant to this choice: the feasibility of collecting data, the reliability of the diagnosis information, the persistence of reported diagnoses across years, the impact on incentives to hospitalize a beneficiary, and the effect on the structure of payments. The section concludes with a brief sketch of alternatives for reporting limited ambulatory care diagnosis data.

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Feasibility

At least for the immediate future, it is far easier for all plans to report inpatient encounter data than to report both inpatient and ambulatory care data. First, a well-established standard for inpatient data (the 1992 uniform bill or UB92 standard) is already in use by nearly all hospitals. Standards for ambulatory care data are less well-accepted, and not all ambulatory care providers routinely generate such information. Second, there are relatively few inpatient forms to be submitted. In fee-for-service Medicare, for example, the average beneficiary generates roughly 0.4 hospital discharges per year, versus 23 bills from all ambulatory care sites. (Analysis by the Medicare Payment Advisory Commission [MedPAC] is not shown.) Finally, ambulatory care providers are far more numerous and diverse than hospitals, complicating plan efforts to specify reporting standards by contract.

Historically, HCFA has had little success collecting data for Medicare managed-care enrollees directly from hospitals. Existing regulations require hospitals to submit bills (so-called no pay bills) for Medicare managed-care enrollees. No payment depends on these bills, and perhaps unsurprisingly, only a small portion of such bills are submitted (GAO 1989).

The BBA may change this somewhat. Teaching hospitals must begin to submit no-pay bills for Medicare managed-care enrollees to receive related graduate medical education payments. These hospitals, however, account for less than half of Medicare fee-for-service discharges in total (ProPAC 1997).

HCFA recently has developed the standards for submission of inpatient data. Plans (not hospitals) will submit this information directly to HCFA's fiscal intermediaries. Plans must obtain the data from hospitals, then forward the information to HCFA.

Some plans may need to modify contracts with hospitals to ensure availability of these data. Plans that capitate hospitals or physician-hospital organizations may not receive inpatient information now. These plans will need to develop the contractual arrangements and systems to manage the flow of such data. In the longer term, these plans may want to pass through some of HCFA's risk-adjustment incentives to their capitated providers. Such an alignment of incentives would encourage hospitals and other providers to report the desired data in full.

Reliability

Hospital inpatient diagnoses appear much more reliable and more consistently reported than diagnoses in ambulatory care settings. Numerous studies since the inception of Medicare's hospital prospective payment system have found that coding of principal diagnosis is quite good, while coding of comorbid conditions is less so.

Diagnosis data from ambulatory care settings is generally less reliable. There is often significant lack of overlap between diagnosis profiles based on review of medical records, claims, and interviews with beneficiaries. There is very high variation in private-sector reporting of ambulatory care diagnosis data (Dunn et al. 1995).

The lower reliability of ambulatory care data might be due either to financial incentives or to structural problems. Few private-sector providers have requirements or incentives to report ambulatory care diagnosis data. Coding might improve once it begins to affect payment. Alternatively, there may be more structural problems—lack of systems software, inability to develop standards for a diffuse and heterogeneous provider population, or other factors—that may not be amenable to rapid change. Over time, as medical records become more computerized, these structural issues should play a smaller role.

Persistence

A third distinction between inpatient data and data from all sites of care is the persistence of reporting over time. If a diagnosis is reported for a beneficiary in one year, how likely is it that the diagnosis will be reported again in the subsequent year? A lack of persistence means that risk-adjusted payment for an individual may fluctuate widely from year to year.

It is unsurprising that hospital inpatient diagnoses show little persistence. Hospitalization tends to be sporadic, with few beneficiaries hospitalized in successive years. Of Medicare beneficiaries hospitalized in 1994 and surviving into 1995, for example, only about one-third were hospitalized again in 1995 (MedPAC analysis not shown).

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Table II-2-1

Lack of Persistence of Diagnosis Coding in Fee-for-Service Medicare

Diagnosis Category	Beneficiaries in Category in 1994	Of Those Identified in 1994, Percent in This Category in 1995
Hypertension	58,000	59%
Coronary artery disease	37,000	53
Chronic obstructive pulmonary disease	36,000	62
Congestive heart failure	28,000	61
Stroke	25,000	51
Dementia	11,000	59
Rheumatoid arthritis	8,000	55
High cost diabetes	6,000	58
Renal failure	5,000	56
Quadriplegia/paraplegia	600	52
Dialysis	500	59

SOURCE: Medicare Payment Advisory Commission analysis of 1994 and 1995 Medicare 5 percent Standard Analytic File (SAF) data.

NOTE: Diagnosis categories were taken from the hierarchical coexisting conditions model (Ellis et al. 1996). Analysis uses diagnoses from all sites of care.

A more surprising finding is that diagnoses often do not persist even when tracked across all sites of care. Even for serious and permanent medical conditions, the persistence of diagnosis coding in Medicare fee-for-service data is low (see Table II-2-1). Typically, beneficiaries with conditions coded in one year have a slightly greater than 50/50 chance of having those conditions recorded in the subsequent year.[1]

Neither approach (inpatient or all-sites data) will likely result in stable payment rates for individual beneficiaries. For inpatient data, lack of stability reflects the sporadic nature of hospitalization episodes. For ambulatory care data, it reflects coding practices. If plans' data reporting practices match those in Medicare fee-for-service claims, diagnoses will not be reported persistently.[2]

The lack of persistence of diagnoses and the resulting instability of payment may affect plans' operations. Annual revenues for small groups of beneficiaries are likely to fluctuate. That may create problems for new plans and small plans. If plans pass payments through to capitated providers, it may affect smaller providers as well. Finally, it may discourage the development of innovative programs for subsets of the chronically ill population, because the revenues to support such programs may vary significantly from year to year.

A further implication of the lack of persistence is that payments from risk adjustment do not match the underlying medical model of disease. Most conditions triggering increased payment are permanent, while the increased payment itself is transitory. Hospitalization for stroke, for example, might be a marker for a lifetime of elevated health care costs, but payments might increase for just one year.

A final implication is that the prevalence of disease is significantly underreported in a single year of Medicare fee-for-service data. Many beneficiaries with serious conditions reported in the prior year do not have those conditions reported in the subsequent year.

This underreporting significantly complicates the use of ambulatory diagnosis data for payment. Payments will reflect plans' reported prevalence of disease. More complete reporting will raise plans' payments. The finding of significant underreporting in existing data suggests that the potential increases in payment are large. HCFA may need to adjust for plans' data reporting practices.[3]

[1] The lack of persistence could not be attributed to factors other than reporting of diagnoses. For example, beneficiaries dying prior to 1995 (and thus having no 1995 claims) were excluded from the analysis. Repeating the comparison with the (presumed) more accurate inpatient-only diagnosis data for 1994 did not materially change results. In addition, the lack of persistence was relatively uniform across geographic areas (MedPAC analysis not shown).

[2] Diagnosis reporting from plans may improve once payment depends on diagnosis. For the fee-for-service baseline, by contrast, there is no strong financial incentive and HCFA can only instruct providers to code diagnoses more fully.

[3] A data reporting adjustment was done for the implementation of risk-adjusted rates for Colorado Medicaid (Tollen and Rothman 1998).

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HCFA must also weigh the potential for increases in Medicare payments before using ambulatory care diagnoses for payment. The BBA applies risk adjustments after plans' guaranteed annual update in county rates, so risk adjustment may affect plans' payments in aggregate. Total payments to plans will depend on whether the average Medicare+Choice enrollee has costlier diagnoses than the average Medicare fee-for-service enrollee. Severe underreporting of diagnoses in the baseline raises the potential for total payments to increase if plans report diagnoses more completely.

Incentive to Hospitalize

Using inpatient diagnoses for risk adjustment means that plans receive higher rates only for hospitalized beneficiaries and lower rates for all others. This clearly alters plans' financial incentives, because hospitalization would result in higher revenues but other modes of treatment would not.

First, this creates an incentive to shift the mix of services provided. Use of inpatient diagnosis data creates a disincentive to treat diseases in ambulatory rather than inpatient settings. It creates a financial bias against plans that have effectively substituted ambulatory care for hospitalizations. It may discourage plans from using such methods of treatment in the future, and may stifle development of innovative methods to manage chronic diseases on an ambulatory care basis.

Second, it alters the incentives for the overall rate of hospitalization. Currently, plans must weigh the cost of hospitalization against its medical benefits. With inpatient-only risk adjustment, the cost of hospitalization would be weighed against the resulting increased payment and medical benefits.

Some shift in the financial incentives for hospitalization might be considered desirable. Newhouse and others (1997), for example, argued strongly in favor of creating more nearly neutral financial incentives. They suggest using partial capitation, paying plans both a reduced capitation and reduced fee-for-service amounts.

Risk adjustment, however, is not designed to shift incentives for individual services. Risk-adjusted payment triggered by a hospitalization episode reflects average annual costs for such individuals, not the cost of the hospitalization. Where partial capitation results in payment in proportion to use of care costs, risk adjustment using inpatient diagnoses results in payments that may bear no particular relation to the typical cost of the relevant hospitalization episodes. Inpatient-only risk adjustment shifts incentives for hospitalization as a side effect of the process for obtaining data.

One possible outcome is that plans might hospitalize beneficiaries at lower levels of severity of illness. This might be addressed, for example, by screening out some hospitalizations or excluding very short hospital stays (Ellis and Ash 1995). Alternatively, HCFA could review hospitalizations for medical necessity, excluding hospitalizations that did not meet standard screens of medical necessity.[4]

Finally, the presence of these incentives does not guarantee that plans will in fact alter hospitalization practices. Hospitalization involves many factors, and hospitalized beneficiaries tend to be quite ill. Financial issues may play a minor role relative to medical concerns.

Choice of Model and Structure of Payments

HCFA has funded the development of risk-adjustment models using either inpatient or all-sites diagnosis data. Two models now appear to be primary candidates for risk adjustment. Diagnostic cost groups (DCGs) use inpatient diagnosis data, and assign each beneficiary to at most one diagnosis category. Hierarchical coexisting conditions (HCCs), by contrast, use all diagnosis data, both inpatient and ambulatory care.[5] HCCs allow beneficiaries to trigger multiple diagnosis categories simultaneously (Ellis et al. 1996).[6]

These two models result in a different structure of payments. Risk adjustment using inpatient data (DCGs) results in high payment for a small fraction of the population. Based on Medicare fee-for-service data, higher payment would be made on behalf of the 20 percent of beneficiaries hospitalized during the year (see Table II-2-2).[7] Diagnosis data from all sites, by contrast, would result in payments being spread more broadly, with perhaps 60 percent of beneficiaries triggering some higher payment (see Table II-2-2).

[4] For Medicare+Choice fee-for-service plans, however, HCFA is barred from reviewing medical necessity of services.

[5] In theory, either model could be run on any source of diagnosis data. In practice, the models were developed and fine-tuned for their respective data sources (Ellis et al. 1996).

[6] In practice, only 15 percent of beneficiaries have three or more categories assigned simultaneously (MedPAC analysis not shown).

[7] Early versions of DCGs excluded a significant number of hospitalizations based on physicians' presumed discretion regarding hospitalization (Ellis and Ash 1995). That would have resulted in a further narrowing of the population receiving high payment. The more recent version of DCGs used here, by contrast, does not screen out those hospitalizations (Ellis et al. 1996).

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Table II-2-2

Source of Diagnosis Data and the Structure of Payment

Data Source	Category	Annual Payment	Proportion of Population in Category
Inpatient only	No diagnosis	$3,700	80%
	Some diagnosis	10,800	20
All sites of care	No diagnosis	2,100	40
	Some diagnosis	7,200	60

SOURCE: Medicare Payment Advisory Commission analysis of Medicare 1994 and 1995 5 percent Standard Analytic File (SAF) data.

NOTE: For inpatient-only data, categories reflect the DCG model. For all-sites data, categories reflect the HCC model. Payments match average fee-for-service Medicare costs in the year following diagnosis. Dollar figures are based on an average of $5,000 per beneficiary.

Alternatives to Full Ambulatory Care Encounter Data

Given the costs and uncertainties for the collection and use of ambulatory care data, HCFA might consider alternatives. These are methods that would collect some ambulatory diagnosis information without requiring full ambulatory encounter data.

Sampling followed by review of medical records has been proposed as one alternative. Under this approach, the plan would review medical records for a random sample of beneficiaries. Plan staff or contractors would abstract diagnoses from these medical records and report this information to HCFA.

This approach would be useful to plans that do not now collect claims or encounter data from ambulatory care providers. Relatively modest sample sizes (a few thousand beneficiaries) would probably be sufficient to generate a reasonably stable overall payment rate for the plan.[8] Moreover, data produced by medical records abstracting personnel are likely to be more uniform and reliable than data reported by a wide variety of medical and billing staff.

A strategy of sampling medical records would raise three problems for HCFA. First, the method would not match the method HCFA would use to set payment amounts. For example, while payment amounts would be based on diagnoses reported during a year, this method would report all diagnoses in the medical record. At the minimum, HCFA would have to apply the medical records approach to a large sample of fee-for-service beneficiaries in order to calculate payment amounts.

A second issue relates purely to the use of a sample, not the method used to generate the diagnoses. Plans adopting a sampling approach would generate no diagnosis information for those not sampled. If those beneficiaries switched to a plan not using the sampling approach, HCFA would have to determine some default payment value for them.[9]

The final issue relates to the eventual recalibration of Medicare's payment amounts. At some point, HCFA may want to recalculate payment weights that reflect managed-care practices rather than the Medicare fee-for-service baseline. This requires detailed information on use of services—information that would not be present in diagnoses summarized from medical records. If most plans adopted this strategy, HCFA would not have adequate information for recalibration of weights.

An alternative approach would allow plans to report diagnoses for a specified subset of beneficiaries. For example, plans could report all beneficiaries with a diagnosis of cancer, whether hospitalized or not.

[8] A sample of this size would not allow the prevalence of any single disease to be estimated with great accuracy, but would be adequate for overall averages.

[9] If payments are based on prior-year diagnoses, HCFA must set such a default for beneficiaries just turning 65 with no Medicare diagnosis history. Use of sampling would mean that the default rate would apply to more beneficiaries.

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The subset approach would raise many of the same issues as sampling. Setting appropriate payment would require applying the subset method to the Medicare fee-for-service data. This probably requires that reporting be linked to a specific major service, for example, that plans report cancer patients receiving chemotherapy, surgery, palliative care, or hospice rather than all cancer patients. Linking reporting to specific high-cost services would also enhance HCFA's ability to audit the diagnosis data. Finally, like the sampling approach, identifying subsets would not provide detailed utilization data needed for any eventual recalibration of payment weights.

Despite these difficulties, these approaches deserve some attention. Complete ambulatory encounter data will be expensive for plans to produce and difficult for HCFA to use as well. The benefits and drawbacks of all options should be considered, including full encounter data, sampling for review of medical records, and reporting of diagnoses for selected subsets of beneficiaries.

Timing and Risk Adjustment: Prospective Versus Concurrent Models

A second major element for the design of Medicare's risk adjustment is timing between diagnosis, costs, and payments. HCFA's choices in this area will affect not only the flow of payments, but the payment weights (amounts) for different diagnoses as well.

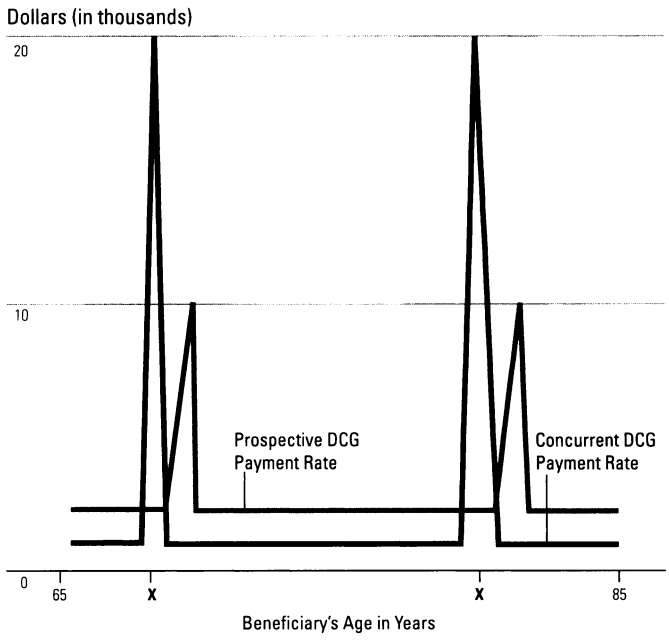
First, HCFA must determine when (what year) a diagnosis counts for payment and when payment is to be made. These choices affect the administrative complexity of risk adjustment, because beneficiaries and dollars must be tracked between the time of diagnosis and the time of payment.

Second, HCFA must determine what costs in the Medicare fee-for-service baseline will be used to determine the weight (payment) for each diagnosis. Payment could match typical costs in the year of diagnosis or those in the subsequent year. For the DCG model, for example, this would mean basing payment on the high acute-care costs in the year of hospitalization, or the lower costs of chronic and acute care the following year.

Throughout this section, the terms *concurrent* and *prospective* will be used to describe different approaches to timing. A concurrent method is one where there is no time lag between diagnoses and dollars. Concurrent payment means that a plan's payment for a year reflects diagnoses recorded that year. Concurrent weights mean that the level of payment reflects the high acute care costs in the year of diagnosis. A prospective method, by contrast, is one where diagnoses precede dollars. Prospective payment means that a plan's rates are based on diagnoses reported in the prior year. Prospective weights mean that the level of payment reflects the lower chronic-care costs in the year after diagnosis.

Figure II-2-1

Illustrating Concurrent and Prospective Risk Adjustment Over a Beneficiary's Lifetime



X = DCG Hospitalization

SOURCE: Medicare Payment Advisory Commission.

Payments in the DCG model provide an easy way to illustrate the two concepts of payment timing and payment amount (see Figure II-2-1). Concurrent and prospective payment weights result in "spikes" of different heights in Figure II-2-2. Concurrent and prospective payment timing, by contrast, determines the location of the payment spike, placing it in the year of hospitalization or the subsequent year.

Choices for payment weights (amounts) and payment timing affect two different sets of plans. Payment weights may affect all plans. Changing from concurrent to prospective weights could result in a large one-time change in any plan's payment. Payment timing, by contrast, has little impact on a plan with a stable enrolled population. If the rate and mix of enrollees' diagnoses do not change much over time, the plan's payments will be similar from year to year.

The first part of this section looks at questions for the timing of payment. Who will track beneficiaries switching plans between diagnosis and payment? How must plans' accounting systems and reserves accommodate the timing of payments? Does payment require a retrospective (end-of-year) settlement, and does the BBA allow such?

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The second part looks prospective and concurrent payment weights. The concurrent method results in much closer match between payments and costs, and much larger redistributions of payment. The causes and consequences of these large payment changes should be fully understood before judging which approach is superior.

Issues for the Timing of Payments

The choice between prospective and concurrent methods for setting plans' payments raises a significant number of practical issues for plans and for the Medicare program. These include the tracking of beneficiaries and payments over time, and the need for retrospective (end-of-year) settlement of payments.

Tracking Beneficiaries Over Time

One of the main practical advantages of concurrent payment is avoiding the need to track beneficiaries over time. With concurrent payment, the rates ultimately paid to a plan would reflect the plan's enrollees for the current year. There would be no need to maintain information on beneficiaries' diagnoses for the previous year.

Prospective payment timing, by contrast, requires that rates paid to the plan reflect diagnoses recorded for beneficiaries in the previous year. This would involve significantly more bookkeeping detail by HCFA to track diagnosis information for each beneficiary. In particular, HCFA would have to track beneficiaries who switched plans.[10] Truly new beneficiaries—those just turning 65—would have no such diagnosis history and would have to be paid for at some default rate.

Accounting and Reserves Issues

The two modes of payment timing have different implications for plans' administrative systems. Prospective payment timing would allow the plan to know its average Medicare payment per beneficiary at the start of the year. The plan would be at risk, however, for new enrollees and disenrollees. With concurrent payment timing, by contrast, the average payment per enrollee would not be known until all diagnoses for the year were reported. Final payment for the year would require a settlement after the end of the year. This has at least two impacts on plan operations. With concurrent payment, plans' accounting systems may need to accrue assets and liabilities against expected year-end settlements. Second and perhaps more substantively, plans may need to adjust their reserves or asset mix to account for the (potentially large) lump-sum adjustments that might be made at year-end with concurrent payment.[11]

Statutory Issues

Concurrent mode of payment requires that HCFA make some retrospective (after year-end) payments, because it takes some time to process the year's diagnosis information. That may or may not raise an issue relative to current law, depending on the intent and interpretation of the BBA. The BBA specifies that Medicare+Choice plans accept full financial risk on a prospective basis for all Medicare enrollees, with certain exceptions: outlier payments above a HCFA-determined threshold, reinsurance for emergency (and out-of-plan) care, reinsurance for aggregate losses in excess of 15 percent, and pass-through of risk to capitated providers. Concurrent payment—with the resulting retrospective adjustment of payments—may or may not require explicit legislative authority depending upon the legal interpretation of this language.

Prospective Versus Concurrent Payment Weights

This section begins with an empirical analysis of concurrent and prospective payment weights. Concurrent weights for diagnoses reflect typical Medicare fee-for-service costs in the year of diagnosis, while prospective weights reflect typical costs in the subsequent year. Concurrent weights result in greater redistributions of payment in three ways relevant to Medicare: across individuals, for new managed-care enrollees on average, and across geographic areas.

The second part explores why concurrent and prospective weights are so different, and what this may mean for risk adjustment. The concurrent approach provides a vastly closer match between payments and use of care. This leads to discussion of whether and to what extent risk adjustment should reflect use of care.

[10] This assumes that HCFA would use prior year diagnoses wherever those occurred. Payment for a plan's new enrollees, therefore, might be based on diagnoses recorded in Medicare fee-for-service or in another plan. If this is not the case, then a prospective approach would require that new enrollees in each plan be handled as special cases within the risk adjustment system.

[11] It is not immediately clear whether plans would want to increase reserves (due to uncertainty in HCFA's total payment) or reduce reserves (because HCFA's total payment would more nearly reflect variations in costs during the year).

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Table II-2-3

Prospective and Concurrent Risk Adjustment

Model	R-squared	Category	Annual Payment	Proportion of Population in Category
Prospective				
PIP-DCG	6%	No DCG	$3,700	80%
		Some DCG	10,800	20
HCC	8	No HCC	2,100	40
		Some HCC	7,200	60
Concurrent				
PIP-DCG	43	No DCG	1,100	80
		Some DCG	21,700	20
HCC	42	No HCC	200	40
		Some HCC	10,000	60

SOURCE: Medicare Payment Advisory Commission analysis of Medicare 1994 and 1995 5 percent Standard Analytic File (SAF) data. R-squared statistics taken from Ellis et al. (1996).

NOTE: PIP-DCG is the principal inpatient diagnostic cost group model. HCC is the hierarchical coexisting conditions model.

Three Empirical Analyses

The DCG and HCC risk-adjustment models (described above) were applied to Medicare fee-for-service claims in concurrent and prospective modes. For either approach, the concurrent method provides a much closer fit between payments and costs. These models capture over 40 percent of the variation in individuals' costs when applied concurrently, but only 6 percent to 8 percent in prospective mode (see Table II-2-3).[12]

The concurrent approach results in much higher payment weights for those with relevant diagnoses and correspondingly lower rates for others (see Table II-2-3). (For convenience, payment rates are expressed relative to a $5,000 per beneficiary per year average.) Concurrent DCGs using the principal inpatient diagnosis (PIP-DCGs), for example, would pay an average of almost $22,000 per year for hospitalized beneficiaries, but only $1,100 for the 80 percent of beneficiaries not hospitalized.[13] Similarly, concurrent HCCs would pay just $200 per beneficiary per year for 40 percent of the population without a payment-relevant diagnosis.[14]

The low costs of Medicare managed-care enrollees in the year prior to enrollment provide another relevant way to contrast prospective and concurrent models. This shows how the two approaches would affect payments for a group, in this case, beneficiaries who eventually joined managed-care plans. Because average health status of a large group changes slowly, this analysis of the preenrollment fee-for-service experience provides some gauge of the likely impact on rates paid for new enrollees.

Concurrent risk adjustment would almost fully account for the low average preenrollment costs of new managed-care enrollees (see Table II-2-4). This would result in risk-adjusted payments for this group that matched their low average Medicare fee-for-service costs. Prospective risk adjustment, by contrast, would not set payment quite so low for this cohort.

This analysis should be interpreted with caution. It demonstrates only relative (not absolute) performance of prospective and concurrent methods. The new enrollees studied are only a fraction of all managed-care enrollees, appear much healthier than average, and are likely to see health status changes over time. This analysis does not show what average risk-adjusted payments would be.

[12] This analysis uses Medicare fee-for-service claims from 1994 and 1995 as the source of the diagnosis and cost data.

[13] Both models set many different payment rates for diagnoses. Those rates were averaged together in this table to simplify presentation and discussion.

[14] The greater spread of the concurrent payment weights from highest-paid to lowest-paid categories has been noted in a variety of studies (Ellis et al. 1996; Dunn et al. 1995).

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Table II-2-4

Examining Managed-Care Enrollees' Low Costs in the Year Prior to Enrollment

Measure of Cost or Payment	Ratio of New Enrollees to Medicare FFS Comparison Group
Actual costs	0.72
Risk-adjusted payment	
Prospective DCG	0.88
Prospective HCC	0.89
Concurrent DCG	0.77
Concurrent HCC	0.74

SOURCE: Medicare Payment Advisory Commission analysis of Medicare 5 percent Standard Analytic File (SAF) and Enrollee Data Base (EDB) files, 1994 -1996.

NOTE: Sample consists of all Medicare beneficiaries with 24 months of Part A and Part B Medicare fee-for-service enrollment in 1994 through 1995. New HMO enrollees are those beneficiaries who subsequently enrolled in an HMO at any time in 1996. Analysis is based on costs and diagnoses reported in fee-for-service Medicare in the year prior to enrollment. PIP-DCG is the principal inpatient diagnostic cost group model. HCC is the hierarchical coexisting conditions model.

A third relevant test involves geographic variation in risk for the Medicare fee-for-service population. At first glance, it is not clear why risk variations across the fee-for-service population are relevant to managed-care payment. The connection is in the details of the actuarial calculation of rates. So long as payments are based on fee-for-service costs, each plan's rate will reflect its risk mix relative to the Medicare fee-for-service population (see Figure II-2-1).

Prior to the BBA, this connection was clear because all payments were based on local (county-level) fee-for-service costs. If a plan attracted the average beneficiary in its service area, it was to be paid a rate that matched local fee-for-service costs.[15] Omitting fee-for-service risk from the calculation would result in double-counting of risks because fee-for-service costs already reflect that risk. For example, if costs in a county are low because beneficiaries there are healthy, a plan that merely enrolled the average healthy beneficiary in that county would see payments fall if the baseline adjustment were not made.

Figure II-2-2

Risk Adjustment Relative to the Medicare Fee-for-Service Baseline

$$\text{Payment} = \text{FFS Spending} * \frac{\text{HMO Risk}}{\text{FFS Risk}}$$

SOURCE: Medicare Payment Advisory Commission.

The situation becomes more complex under the BBA payment formula, which involves a blend of local costs and national costs, with minimum (floor) rates. Risk adjustment relative to the fee-for-service baseline would apply to the portion of payment that remains based on local fee-for-service costs.[16]

Concurrent risk adjustment would result in larger adjustments to the 1997 Medicare fee-for-service county baseline (see Table II-2-5). In this table, the fee-for-service populations of Miami and Los Angeles both demonstrate high measured risk, while the Minneapolis–St. Paul fee-for-service population appears relatively healthy. Variation in measured risk is higher when models are run in concurrent mode.[17]

Risk adjustment need not result in geographic redistribution of payments. If managed-care enrollees in each area have the same average risk as their fee-for-service counterparts, the adjustment of the baseline merely keeps payment level. (In Figure II-2-2, the risk terms cancel.) The analysis suggests, however, that if geographic redistributions occur they will be larger under concurrent risk adjustment.

[15] In fact, plans were paid 95 percent of these costs, and the rate used was a projection of costs for the coming year.

[16] A complete treatment of this issue would separately specify what to do with these three components of the payment rates: national costs, local 1997 baseline costs, and payments in floor counties.

[17] Because this adjustment would apply only to part of plans' payments, the impact on total payment would be smaller than shown in Table II-2-5.

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Table II-2-5

Examining Variations in Risk Across Geographic Areas

City	1997 Capitation Rate	Risk Index for Area (U.S. = 1.0)			
		PIP-DCG		HCC	
		Prospective	Concurrent	Prospective	Concurrent
Miami	$748	1.15	1.19	1.38	1.51
Los Angeles	622	1.08	1.08	1.15	1.25
Minneapolis-St. Paul	393	0.97	0.90	0.89	0.81

SOURCE: Medicare Payment Advisory Commission analysis of Medicare 5 percent Standard Analytic File (SAF) data and AAPCC files.

NOTE: Analysis excludes age-ins and deaths during the 1994-1995 period, and so should be taken merely as indicative of the magnitude of the payment changes that would occur. PIP-DCG is the principal inpatient diagnostic cost group model. HCC is the hierarchical coexisting conditions model.

In summary, the analyses of this section gave a consistent picture of concurrent and prospective risk adjustment. The concurrent approach results in larger changes in payment, in three relevant dimensions: among beneficiaries, on average for the new enrollee cohort, and across geographic areas.

Explaining the Difference Between Prospective and Concurrent Risk Adjustment

While the previous section established that prospective and concurrent models are quite different, this section explores why they are different. Concurrent models show much higher correlation between payments and costs than prospective models do. The first step in assessing the merits of these models is to ask what causes the high correlation.

A concrete way to understand concurrent and prospective weights is to trace hospital spending in the DCG model. This simplifies discussion, because payment weights almost entirely reflect how the models categorize hospitalized beneficiaries.[18]

For either prospective or concurrent weights, all beneficiaries (and all costs) are accounted for somewhere, either in a category defined by a diagnosis or in the default (no diagnosis) category. The approaches differ strongly, however, in allocating hospitalized beneficiaries to these two categories, diagnoses or default.

The concurrent DCG model puts all hospitalized beneficiaries into some diagnosis group. It assigns no hospitalized beneficiaries to the default (no diagnosis) group.[19] All hospital costs, therefore, are assigned to the weights for the diagnosis groups.[20]

No hospital costs are assigned to the weight for the default (no diagnosis) group.[21] This complete partition of hospital costs occurs because the diagnoses used for assignment to categories and the hospital costs come from the same year of claims data.

The prospective DCG model, by contrast, allocates only part of hospital costs to the DCG diagnosis categories. These are the costs of beneficiaries hospitalized both the prior year (determining the diagnosis) and the current year (incurring the cost). About one-third of beneficiaries have a hospitalization in each of two successive years. Very roughly speaking, prospective DCGs allocate one-third of hospital costs to a specific diagnosis, leaving the other two-thirds in the default (no diagnosis) category. This occurs because the diagnoses used for assignment to categories and the hospital costs come from different years of claims data.

[18] In practice, the weights will reflect all costs for these beneficiaries, not just their hospital costs.

[19] As noted above, the DCG version used for this analysis includes no screens on hospitalizations. Beneficiaries whose hospitalizations were excluded by such screens would fall into the default (no diagnosis) category.

[20] Hospital costs are used for purposes of discussion. The model actually allocates all costs of hospitalized beneficiaries to the diagnosis group, and none of the costs of hospitalized beneficiaries to the default (no diagnosis) group.

[21] This separation of hospitalized beneficiaries largely accounts for the high R-squared statistics of the concurrent DCG model. Merely separating the hospitalized beneficiaries (but ignoring diagnoses) produces an R-squared statistic of 0.35, versus the 0.43 of the concurrent DCG model (MedPAC analysis not shown).

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This difference between prospective and concurrent payment weights can be described two ways. The literal description is that the prospective model divides hospital costs into "subsequent" hospitalizations and "others," where a subsequent hospitalization means a hospitalization following one in the previous year. The weight for a diagnosis only reflects the cost of subsequent hospitalizations, with the costs of all other hospitalizations averaged into the default (no diagnosis) category.[22]

A less literal but more useful description is that the payment weights of the concurrent model capture acute, unpredictable episodes of care (Dunn et al. 1995; Ellis et al. 1996). For the prospective model, by contrast, the cost of such episodes is averaged into the default (no diagnosis) category when calculating the payment weights.

Describing the difference in methods in terms of unpredictable acute care gives one way to characterize the choice of methods. Should payment rates reflect the costs of unpredictable acute episodes or not? Doing so results in a closer match of payments and costs, but allows a much greater share of payment to depend on services actually performed by the plan.

One view of this issue is that financing acute unpredictable episodes is the function of insurance. From this perspective, concurrent risk adjustment may begin to encroach on plans' traditional role as insurers because so much of payment will depend on the actual use of services during the year. In the concurrent DCG model, 78 percent of total payment is triggered by use of services (hospitalization).[23] In the prospective DCG model, by contrast, 26 percent of total payment is triggered by hospitalization.

An alternative view is that a high dependence of payment on service use may be a reflection of good performance of the risk adjuster. If variations in use of care are due mainly to variations in health status, then a high correlation of use and payment would be a desirable outcome of the risk-adjustment process. For individual beneficiaries, for example, those who are hospitalized tend to be in poorer health than those who are not. When viewed at the level of the plan, however, variations in hospitalization rates may reflect practice patterns, structure of benefits, or other significant factors in addition to health status.

Summary and Conclusion: The Importance of Phase–In

The potential for phasing-in the risk-adjusted rates offers a simple way to adjust the intensity of the incentives created by risk adjustment. With a phase-in clearly defined, any feasible model can be implemented to some degree, simply by averaging risk-adjusted payment with existing payment rates. A viable and easy phase-in mechanism changes the debate from whether or not to risk adjust to how much to risk adjust.

The simplest phase-in of rates would be to average the rates paid for each beneficiary under the old system with risk-adjusted rates. Payment could initially be based heavily on current rates but move later to a greater emphasis on the risk-adjusted rate.

An alternative approach would be to place an explicit limit on the amount by which risk adjustment can change any plans' rates in any one year. This would directly address plans' aversion to sharp swings in payment, and would also moderate any instability of payment for small or new plans.

Deciding the speed of the phase-in requires balancing the problems of the existing system against the flaws of any proposed risk- adjustment approach. A slow phase-in perpetuates all the problems of the existing payment method. Currently, Medicare makes no payment distinctions based on the health status of managed-care enrollees, causing many problems for the Medicare risk-contracting program (see Volume I, Chapter 2). With this as the baseline, a system that begins by making some modest adjustment based on hospitalized beneficiaries is apt to move payments in the right direction, because hospitalized beneficiaries are on average a very ill portion of the Medicare population.

In the longer run, Medicare will have more options for risk adjustment and more experience with the current system. The likely initial approach to risk adjustment, DCGs, will distort the incentive to hospitalize, but plans' practices may or may not respond to this incentive. Over the longer run, HCFA may have the option of moving to complete encounter data for risk adjustment as well as fine-tuning methods. The phase-in of rates allows HCFA to begin moving in this direction while the development of risk adjustment.

[22] Use of the term subsequent hospitalization does not imply any medical linkage between the two hospitalizations. Initial and subsequent hospitalizations may be medically unrelated, but just happened to occur in successive years.

[23] That is, a plan with no hospitalizations would be paid roughly 78 percent less than the $5,000 per beneficiary per year average in Table II-2-3.

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Appendix A

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D. Ted Lewers, M.D., a practicing nephrologist and internist, is also on the staff at the Memorial Hospital in Easton, Maryland. A member of the board of trustees and secretary-treasurer of the American Medical Association, Dr. Lewers is medical director of the Easton and Chestertown Renal Treatment Center, chair of the board and chief executive officer at the Medical Mutual Liability Insurance Company of Maryland, and chair of the board of the Health Enhancement Center, Inc. Previously, he served on the Physician Payment Review Commission. Long active in organized medicine, Dr. Lewers served as president of the Medical and Chirurgical Faculty of Maryland from 1985 to 1986 and as vice chair of the American Medical Association's Relative Value Scale Update Committee. Dr. Lewers received a B.A. from the University of Maryland and a medical degree from the University of Maryland School of Medicine. He completed an internship at the University of Maryland (Baltimore), a residency at Maryland General Hospital, and a fellowship in nephrology at Georgetown University Hospital.

Hugh W. Long, Ph.D., is professor of health systems management at the Tulane University School of Public Health and Tropical Medicine in New Orleans. He also holds appointments at Tulane's School of Law and the Freeman School of Business, where he is a member of the graduate faculty. Dr. Long is the founder and faculty director of Tulane's master's of medical management degree program for physicians. Previously, he served on the Prospective Payment Assessment Commission. He has also taught at Yale, Stanford, San Jose State, and Ohio State universities. Dr. Long has served as an ad hoc adviser on health care financing to the Committee on Ways and Means of the U.S. House of Representatives and to the Committee on Finance of the U.S. Senate. He has also testified before these committees on matters of health financing policy. He currently serves as the chairman of the Medicare Geographic Classification Review Board. He is the author of numerous articles on health care financing and management and is a member of the faculty of the American College of Physician Executives. Dr. Long received a B.A. from Ohio State University, an M.B.A. and a Ph.D. in business administration and finance from Stanford University, and a J.D. from Tulane University.

William A. MacBain is senior vice president, Health Plan Operations—New York, for the Penn State Geisinger Health System and executive director of Penn State Geisinger Health Plan, Inc. He is a board member of the American Association of Health Plans and a past commissioner of the Prospective Payment Assessment Commission. His broad background in managed care encompasses general management operations, marketing, planning, finance, product and network development, rate setting, and government affairs. Mr. MacBain joined Penn State Geisinger in 1988. He began his career with Prepaid Health Plan where he advanced to director of plan administration. In 1982, Mr. MacBain was named vice president of finance for the Nassau (New York) Plan for Healthcare. After that, he was director of operations for HMO of Oklahoma in Tulsa. He has a B.A. and a master's degree in hospital and health service administration from Cornell University.

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Woodrow A. Myers, M.D., is director of health care management for the Ford Motor Company. He is responsible for health benefits for active and retired employees and their dependents, for occupational health and safety services, and for disability and workers' compensation programs. Previously, he was senior vice president and corporate medical director of The Associated Group (now Anthem Blue Cross Blue Shield). He was also New York City Health Commissioner and served as Indiana State Health Commissioner and secretary to the Indiana State Board of Health. Prior to that, Dr. Myers was associate director of the medical-surgical intensive care unit and chairman of the quality assurance program at the San Francisco General Hospital, as well as an assistant professor of medicine at the University of California, San Francisco. A past president of the Association of State and Territorial Health Officials and former adviser to the Committee on Labor and Human Resources, U.S. Senate, Dr. Myers has taught at Cornell University, University of California, San Francisco, and Indiana University. He is on the boards of Harvard University, UCSF/Stanford University Health Systems, and the Charles Drew Medical School in Los Angeles. He is also a fellow of the American College of Physicians and of the American College of Physician Executives and is a former Robert Wood Johnson Foundation clinical scholar. Dr. Myers received a B.S. from Stanford University, a medical degree from Harvard Medical School, and an M.B.A. from Stanford University Graduate School of Business.

Janet G. Newport is corporate vice president of regulatory affairs at PacifiCare Health Systems, Inc., the nation's largest coordinated care Medicare contractor. Her responsibilities include monitoring and supporting internal operational compliance, policy development, and regulatory interpretation. She also acts as the liaison with key regulatory agencies. Ms. Newport serves on several technical and advisory committees for the American Association of Health Plans and is an industry representative on the Health Care Financing Administration's (HCFA) Medicare Council. In addition, Ms. Newport has served as an industry representative on HCFA technical committees and is a former chair of the American Managed Care and Review Association's Medicare Task Force. She has more than 20 years of public affairs experience, including over 10 years running the Washington, D.C., office of another Medicare risk contractor. Ms. Newport received a B.A. from American University.

Alice F. Rosenblatt is senior vice president and chief actuary of WellPoint Health Networks, where she is responsible for the corporate actuarial and strategic planning functions. Before joining WellPoint in 1996, she was a principal at Coopers & Lybrand L.L.P, where she consulted with insurers, health plans, providers, and employers. She is a former senior vice president and chief actuary of Blue Cross Blue Shield of Massachusetts and Blue Cross of California. Other positions include work for The New England and William M. Mercer, Inc. Ms. Rosenblatt was on the board of governors of the Society of Actuaries and currently serves on the board of the American Academy of Actuaries. She previously chaired the academy's federal health committee and work group on risk adjustment. Ms. Rosenblatt has testified on risk adjustment before subcommittees of the Committees on Ways and Means and Energy and Commerce of the U.S. House of Representatives. She has a B.S. and an M.A. in mathematics from City College of New York and the City University of New York, respectively.

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John W. Rowe, M.D., is president of the Mount Sinai School of Medicine and the Mount Sinai Hospital in New York City, one of the nation's largest academic health science centers. He is also a professor of medicine and geriatrics. Before becoming president of Mount Sinai in 1988, Dr. Rowe was a professor of medicine and the founding director of the Division on Aging at Harvard Medical School and chief of gerontology at Boston's Beth Israel Hospital. He has written more than 200 scientific pieces, mostly on the physiology of the aging process, and a leading textbook of geriatric medicine. Dr. Rowe is director of the MacArthur Foundation Research Network on Successful Aging. He served on the board of governors of the American Board of Internal Medicine and as president of the Gerontological Society of America and is a member of the Institute of Medicine. He received a B.S. from Canisius College and a medical degree from the University of Rochester.

Gerald M. Shea is assistant to the president for government affairs at the American Federation of Labor-Congress of Industrial Organizations. Previously, he served as executive assistant to the union's president, executive assistant to its secretary-treasurer, director of its employee benefits department, and head of its health care reform campaign. He also served on the Prospective Payment Assessment Commission. Mr. Shea's prior experience includes 12 years with the national office of the Service Employees International Union, where he held various positions, including assistant to the president for government affairs and health care division director. Before that, he was executive director and business manager of two local unions. Mr. Shea is a member of the Joint Commission on the Accreditation of Health Care Organizations, the Foundation for Accountability, and the advisory board of the Social Security Administration. He received a B.A. from Boston College.

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Staff Biographies

Lauren B. LeRoy, Ph.D., was executive director of the Medicare Payment Advisory Commission (MedPAC) until January 1998, and is now president and chief executive officer of Grantmakers in Health. From 1995 to 1997 she served as executive director of the Physician Payment Review Commission, where she had been deputy director since 1986. Before that, Dr. LeRoy was associate director of the Commonwealth Fund Commission on Elderly People Living Alone. She spent more than a decade at the Institute for Health Policy Studies, University of California, San Francisco, where she was assistant director and director of the Institute's Washington office. Before that, she was an analyst at the Department of Health, Education, and Welfare. Dr. LeRoy's research interests and published work have focused on Medicare reform, physician training and practice, the nurse labor market, and health care for the elderly. She is a member of the National Academy of Social Insurance and a fellow of the Association for Health Services Research. She received a Ph.D. in social policy planning from the University of California, Berkeley.

Laura A. Dummit was a deputy director through February 1998, and is now associate director, Health Financing and Systems Issues, in the U.S. General Accounting Office. At MedPAC, Ms. Dummit directed the implementation of the Commission's work on Medicare payment policies for all post-acute care providers, hospital outpatient departments, and facilities that provide dialysis, as well as issues related to Medicare and private sector capitation and managed-care policies. Before joining the Commission, Ms. Dummit was with the Alpha Center and the Office of the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services (HHS). Ms. Dummit received a master's of science in public health from the University of North Carolina at Chapel Hill.

Stuart Guterman is a deputy director. He oversees the Commission's work on a broad range of issues related to developing and evaluating Medicare payment rates, including fee-for-service hospital payment and Medicare+Choice payments. Mr. Guterman is also responsible for analyses of hospital payments and costs from all payers, as well as many access and quality issues. Before coming to the Commission, Mr. Guterman was chief of institutional studies in the Health Care Financing Administration's (HCFA) Office of Research. He received an M.A. in economics from Brown University and completed his course work toward a Ph.D. in economics at the State University of New York at Stony Brook.

Jack Ashby is a principal policy analyst. He is responsible for the Commission's work on the measurement of productivity and hospital product change, hospital financial analyses, the disproportionate share adjustment, and Medicare per capita cost analysis. Before joining the Commission, Mr. Ashby was vice president for finance at the District of Columbia Hospital Association. Previously, he held positions in hospital administration (at the University of Pittsburgh Medical Center) and hospital management engineering (at Blue Cross of Western Pennsylvania), and also worked for a Washington area health research firm. Mr. Ashby received a master's of hospital administration from the University of Michigan.

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Louisa A. Buatti is an analyst. Her responsibilities include work in the areas of scientific and technological advances affecting hospital payment updates, payment policies for home health care, end-stage renal disease payment policy, and rural health care providers. Prior to coming to the Commission, Ms. Buatti was special assistant to the associate administrator for policy at HCFA. She previously worked in HCFA's Bureau of Policy Development and in the Health Standards and Quality Bureau. Ms. Buatti received a master's of health sciences degree in health policy from the Johns Hopkins University and a B.A. from the University of Michigan.

Claire D. Burnett is a junior analyst. Her work at the Commission focuses on beneficiaries who are dually eligible for Medicare and Medicaid, federal policies supporting graduate medical education, and care for the dying. She received a master's degree in public health from the University of Rochester.

Wylene Carlyle is a member of the support staff. She has been with the Commission since January 1990. Before that, Ms. Carlyle was an administrative assistant at OSS Associates/Franklin School in Washington, D.C. She is certified in word processing, Lotus 1-2-3, and has extensive experience with personal computers.

Andrew L. Cosgrove is an analyst. His work focuses on hospital payments and costs by payer, Tax Equity and Fiscal Responsibility Act target rate update, post-acute care services in managed care, consumer information for managed care, and hospice issues. Prior to joining the Commission, Mr. Cosgrove was an analyst with the District of Columbia Commission on Health Care Finance, where he reviewed Medicaid reimbursement policy, especially long-term care financing. Before that, he was an analyst in the Information Technology Division of the University of Michigan. Mr. Cosgrove received a master's degree in public policy from the University of Michigan and a B.A. from the University of Rochester.

Delores J. Curtis is responsible for research contract management, the Commission's world wide web site, report production, and a variety of tasks involving office management and technical computer support. Ms. Curtis joined the Commission staff in April 1990 from the Office of the Assistant Secretary for Planning and Evaluation at HHS.

Diane Ellison is the office manager. Before joining the Commission, she spent 18 years working for U.S. Senator Bill Bradley. She served as the assistant to the senator's chief of staff and later as the senator's office manager. At the Commission, she is responsible for personnel, Commission meeting and annual retreat planning, and office operations.

Helaine I. Fingold is an analyst and general counsel. She is responsible for legislative and regulatory monitoring, consumer protection issues, Medicare+Choice plan standards, and Medicaid managed care issues. Ms. Fingold previously practiced health law with the law firm of Epstein Becker and Green. Before that, she was a legal/policy analyst with the Office of Research and Demonstrations at HCFA, and a staff attorney with the Office of the General Counsel, Health Care Financing Division, HHS. She received a J.D. from Northeastern University School of Law in Boston and a B.A. from the University of Massachusetts at Amherst.

Timothy F. Greene is a senior analyst. Since joining the Commission in July 1992, Mr. Greene has studied Medicare capital payment policy, outpatient payment reform, and diagnosis-related group refinement. Previously, he was with HCFA's Office of Research, where he worked on hospital payment policy, case-mix measurement, and hospital malpractice. While at HCFA, Mr. Greene was specially assigned to the Commission on the Future Structure of Veterans Health Care at the Department of Veterans Affairs. He received a master's of business administration from the Wharton School, University of Pennsylvania, and a master's in economics from the State University of New York at Stony Brook.

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Kevin J. Hayes, Ph.D., is a senior analyst. His work at the Commission focuses on analysis of claims and survey data to monitor Medicare beneficiaries' access to care, implementation of resource-based practice expense relative values, and the impact of the Medicare Fee Schedule on physician payment. Previously, he held various local and federal health care planning positions. He received a doctorate in health policy and administration from the University of North Carolina at Chapel Hill.

Annette Hennessey is management coordinator. Before joining the Commission, she worked for U.S. Senator Bill Bradley, where she was primarily responsible for administration of the legislative staff. At the Commission, she is involved in a range of administrative operations, including developing Commission policies and styles, managing staff administrative needs, and coordinating the design and relocation of the Commission's new offices. She received a bachelor's degree in political science from Mississippi State University in Starkville.

John F. Hoadley, Ph.D., was a principal policy analyst. In April, he is joining the Department of Health and Human Services as a division director in the Office of the Assistant Secretary for Planning and Evaluation. Before joining the Commission, he taught political science at Duke University, was a congressional fellow and legislative assistant for U.S. Representative Barbara B. Kennelly, and developed educational sessions for policy makers at George Washington University's National Health Policy Forum. Dr. Hoadley's most recent work at the Commission centered around Medicare+Choice (both payment and nonpayment issues), the changing health care market, and Medicaid managed care. Previously, he has worked on other issues, including health system reform, provider-sponsored organizations, risk adjustment, global budgets, and beneficiary perspectives on Medicare reform. He received a doctorate in political science from the University of North Carolina at Chapel Hill.

Christopher Hogan, Ph.D., is a principal policy analyst. His recent work at the Commission has focused on risk adjustment, the adjusted community rate, and improving the performance of traditional fee-for-service Medicare. In prior years, he conducted analyses of private insurers' fees, areas of poor access to care, and medical savings accounts. He has also worked on such issues as the Medicare volume performance standard system and Medicare beneficiaries' access to care. He holds a doctorate in economics from Northwestern University.

Ann Johnson is the executive assistant. She has been with the Commission since 1987. Over time her responsibilities have included assisting with financial management, report production, and supporting the executive staff. Previously, she was a secretary at the Food and Drug Administration.

Dana K. Kelley is a senior analyst. She joined the Commission in 1994. Her primary responsibilities relate to Medicare's coverage of and payment for skilled nursing facility services and services provided to beneficiaries with end-stage renal disease. She also works on issues related to hospital outpatient services and Medicare's disproportionate share payment adjustment. Before joining MedPAC, Ms. Kelley was an analyst with Lewin-VHI, a health care consulting firm. She received an M.P.A. from the University of Pittsburgh's Graduate School of Public and International Affairs and a B.A. from the College of William and Mary.

Deborah F. Kramer is the systems administrator. Before joining the Commission, she was a confidential assistant in the Executive Office of the President in the Office of Management and Budget and a legislative aide in the office of U.S. Senator Bill Bradley. At the Commission, she is responsible for computer network operations, telecommunication systems, and the production of publications. She received a bachelor's degree in public administration and is currently pursuing a master's degree in computer information systems.

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Craig K. Lisk is a senior analyst. He has been with the Commission since 1987, working on a variety of hospital-related issues, including the hospital payment update, graduate medical education payment policy, transfer payment, and hospital labor markets. He has also worked on issues related to post-acute care, managed care, and quality of care under Medicare. Previously, Mr. Lisk worked at the Congressional Budget Office in the Human Resources and Community Development Division, where he focused on selected Medicare hospital payment issues. He received an M.S. in public policy analysis and a B.A. in political science and statistics from the University of Rochester.

James E. Mathews, Ph.D., is an analyst. He is responsible for the Commission's work on payment policies for hospital outpatient departments and ambulatory surgical centers, payment and cost analyses for skilled nursing facilities and home health care, and issues related to the Medicare+Choice program, including competitive bidding, and enrollment and disenrollment. Before joining the Commission, Dr. Mathews held positions in the Executive Office of the President in the Office of Management and Budget, and in the Bureau of Policy Development at HCFA. He holds a doctorate in anthropology from the University of Chicago, as well as bachelor's and master's degrees from that university.

Stephanie Maxwell is an analyst. She is responsible for payment policy for PPS-excluded hospitals, including work related to rehabilitation and long-term care facility prospective payment. Before joining the Commission, Ms. Maxwell was a research associate at the Johns Hopkins School of Hygiene and Public Health, where she worked on several research contracts related to Medicare and hospital payment. Prior to that, she was a policy analyst for the Advisory Council on Social Security and a research assistant in the Office of the Assistant Secretary, U.S. Public Health Service. Ms. Maxwell received a B.A. in history magna cum laude from Oberlin College and this year receives a Ph.D. in health policy/health services research from Johns Hopkins University.

Katie Merrell served as a senior analyst. She is now a senior analyst at the Center for Health Administration Studies, University of Chicago. Before joining the Commission staff, she worked for Abt Associates in the areas of health economics research, income support, and education. She was also a research assistant for the board of governors of the Federal Reserve System, and a high school mathematics and computer science teacher. Her recent work at the Commission focused on the implementation of resource-based practice expense relative values, Medicare+Choice payment methods and market dynamics, and the recalibration of Medicare Fee Schedule components. Her past work at the Commission has focused on Medicare risk-plan payment policies, practice expense, geographic adjustment of the Medicare Fee Schedule, and simulating the effect of policy changes on fee schedule payments.

Michael J. O'Grady, Ph.D., is a senior analyst. Before joining the Commission, he worked for the Office for Civil Rights in both the Department of Health, Education and Welfare and the Department of Education. He was also a specialist in social legislation in the Education and Public Welfare Division of the Congressional Research Service. At the Commission, Mr. O'Grady focuses on federal premium contribution, competitive bidding under Medicare+Choice, and new options for traditional Medicare. He holds a doctorate in political science from the University of Rochester.

Julian H. Pettengill is a principal policy analyst. Since joining the Commission in 1988, he has focused primarily on policy issues related to Medicare's hospital prospective payment system. Recent work examined factors affecting health maintenance organizations' willingness to participate in the Medicare risk program. Before joining the Commission, he worked for the Congressional Research Service and for HCFA's Office of Research and Demonstrations, where he carried out most of the research leading to the development of the hospital case-mix index and other key features of the prospective payment system. He holds a master's degree in economics from Indiana University and completed his course work toward a Ph.D. in medical care organization at the University of Michigan.

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Molly Ryan is responsible for the Commission's budget and financial management. Ms. Ryan came to the Commission from HHS's Office of the Assistant Secretary for Planning and Evaluation, where she worked in the immediate and administrative offices. Before that, she worked in the Office of Education's Regulations Office at the former Department of Health, Education and Welfare.

Anne L. Schwartz, Ph.D., served as special assistant to the executive director until January 1998. At the Commission, her analytical work addressed a range of Medicare and Medicaid issues, including physician payment and access under Medicaid, and financial protection for Medicare beneficiaries. Most recently, she focused on graduate medical education financing and physician work force issues. Previously, she held various positions as a staff member in the U.S. House of Representatives. She received a doctorate in health policy from the Johns Hopkins University.

David W. Shapiro, M.D., J.D., is a senior analyst. After completing a residency in primary care internal medicine, he was a Veterans Administration/Robert Wood Johnson clinical scholar. At the Commission, he has worked on a variety of topics, including Medicare coverage decisions and the appeals process, medical liability reform, the Medicare Fee Schedule, and data capabilities of health plans. His current work focuses on quality of care. He received a medical degree from the University of California, Los Angeles, and a law degree from Yale University.

Sarah S. Thomas is a senior analyst. She works primarily on issues related to Medicare managed care, including trends and developments in Medicare+Choice, hospital payment, post-acute care, the Program of All-Inclusive Care for the Elderly, and urban critical access hospitals. Prior to joining Commission, Ms. Thomas held positions with the Group Health Association of America, the American Hospital Association, the Budget Division of the Commonwealth of Virginia's Department of Medical Assistance Services, and the Health Care Advisory Board. Ms. Thomas received an M.S. in health policy and management from the Harvard School of Public Health and a B.A. in history from Williams College.

Sally Trude, Ph.D., was a senior analyst. In March, she is joining Health Economics Research, Inc., as a senior policy analyst. Before joining the Commission staff, Dr. Trude was an associate policy analyst at RAND working on physician payment issues. This year, her work at the Commission included vulnerable populations under Medicare+Choice, managed-care data, sustainable growth rate system, and expenditure targets. Previously, she has studied the impact of the Medicare Fee Schedule on physicians and beneficiaries, and the Medicare volume performance standard system. She received a doctorate in public policy analysis from the RAND Graduate School.

Cynthia Wilson is the receptionist. Before joining the Commission staff, she was an accounting representative for United Service Life Insurance Company. She is certified as a clerk-typist.

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Appendix B

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Commission Responsibilities Mandated by Congress

The Medicare Payment Advisory Commission (MedPAC) was established by the Congress in the Balanced Budget Act of 1997 (BBA, P.L. 105-33). Under that legislation, MedPAC is directed to provide the Congress with advice and recommendations on policies affecting the Medicare program.

Within the scope of this general mandate, the BBA directs the Commission to review certain specific topics relating to Medicare. MedPAC is charged with considering issues of payment, risk adjustment, risk selection, quality of care, access to care, and other major issues relating to the implementation and further development of Medicare+Choice. Its responsibility with respect to the Medicare fee-for-service program includes considering methodologies for determining and updating payments, factors affecting expenditures for services in different sectors, and the impact of fee-for-service payment policies on access and quality of care for Medicare beneficiaries. The Commission is also required to review how Medicare payment policies affect health care delivery beyond the program itself and to assess the implications of broader health care system changes on Medicare.

MedPAC is to submit its findings on these topics to the Congress through two yearly reports. The first report, containing recommendations on Medicare payment policy, is to be submitted by March 1. The second report, exploring issues affecting the Medicare program and its relationship to the broader health care system, is to be submitted by June 1. MedPAC is also required to comment on reports submitted to the Congress by the Secretary of the Department of Health and Human Services.

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Glossary

Acronyms

AAHP	American Association of Health Plans
AAMC	Association of American Medical Colleges
AAPCC	Adjusted Average Per Capita Cost
AARP	American Association of Retired Persons
ACG	Ambulatory Care Group
ACR	Adjusted Community Rate
ADHC	Adult Day Health Center
ADL	Activities of Daily Living
AHA	American Hospital Association
AHCPR	Agency for Health Care Policy and Research, HHS
AMA	American Medical Association
APC	Ambulatory Patient Classifications
ASC	Ambulatory Surgical Center
BBA	Balanced Budget Act of 1997
BLS	Bureau of Labor Statistics
BSF	Benefits Stabilization Fund
CBO	Congressional Budget Office
CC	Complication and/or Comorbidity
CMI	Case-Mix Index
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1985
CORF	Comprehensive Outpatient Rehabilitation Facility
CPEP	Clinical Practice Expert Panel
CPI	Consumer Price Index
CPI-U	Consumer Price Index for Urban Consumers
CPT	Current Procedural Terminology
CRS	Congressional Research Service
DCG	Diagnostic Cost Group
DRG	Diagnosis-Related Group
DOD	Department of Defense
DSH	Disproportionate Share Hospital
ECI	Employment Cost Index
EM	Evaluation and Management
ESRD	End-Stage Renal Disease
FIM-FRG	Functional Independence Measure–Function Related Group
FTE	Full-Time Equivalent
FY	Fiscal Year
GAO	General Accounting Office
GDP	Gross Domestic Product
GME	Graduate Medical Education
GPCI	Geographic Practice Cost Index
HCC	Hierarchical Coexisting Conditions
HCFA	Health Care Financing Administration, HHS
HCPCS	HCFA Common Procedure Coding System
HHS	Department of Health and Human Services
HI	Hospital Insurance
HMO	Health Maintenance Organization
HPSA	Health Professional Shortage Area
HUD	Department of Housing and Urban Development
IADL	Instrumental Activities of Daily Living
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
IME	Indirect Medical Education
IMG	International Medical Graduate
LOS	Length of Stay
MCBS	Medicare Current Beneficiary Survey
MedPAC	Medicare Payment Advisory Commission

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MEI	Medicare Economic Index
MPCC	Medicare Per Capita Cost
NHSC	National Health Service Corps
NRAA	National Renal Administrators Administration
OBRA	Omnibus Budget Reconciliation Act
OPD	Outpatient Department
PACE	Program of All-Inclusive Care for the Elderly
PIP	Principal Inpatient Diagnosis
POS	Point of Service
PPO	Preferred Provider Organization
PPRC	Physician Payment Review Commission
PPS	Prospective Payment System
PRO	Peer Review Organization
ProPAC	Prospective Payment Assessment Commission
RBRVS	Resource-Based Relative Value Scale
RUC	RVS Update Committee
RVS	Relative Value Scale
RVU	Relative Value Unit
SAF	Standard Analytical Files (Medicare)
SMI	Supplementary Medical Insurance
SNF	Skilled Nursing Facility
SSDI	Social Security Disability Insurance
SSI	Supplemental Security Income
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982
VA	Department of Veterans Affairs
VPS	Volume Performance Standard

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Legislation (Listed Chronologically)

HMO Act	Health Maintenance Organization Act of 1973, P.L. 93-222, enacted December 29, 1973.
ERISA	Employee Retirement Income Security Act of 1974, P.L. 93-406, enacted September 2, 1974.
OBRA80	Omnibus Budget Reconciliation Act of 1980, P.L. 96-499, enacted December 5, 1980.
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982, P.L. 97-248, enacted September 3, 1982.
DEFRA	Deficit Reduction Act of 1984, P.L. 98-369, enacted July 18, 1984.
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. 99-272, enacted April 7, 1986.
OBRA86	Omnibus Budget Reconciliation Act of 1986, P.L. 99-509, enacted October 21, 1986.
OBRA87	Omnibus Budget Reconciliation Act of 1987, P.L. 100-203, enacted December 21, 1987.
MCCA	Medicare Catastrophic Coverage Act of 1988, P.L. 100-360, enacted July 1, 1988; repealed December 13, 1989.
OBRA89	Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, enacted December 19, 1989.
OBRA90	Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, enacted November 3, 1990.
OBRA93	Omnibus Budget Reconciliation Act of 1993, P.L. 103-66, enacted August 10, 1993.
	Social Security Act Amendments of 1994, P.L. 103-432, enacted October 31, 1994.
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, enacted August 21, 1996.
BBA	Balanced Budget Act of 1997, P.L. 105-33, enacted August 5, 1997

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Terms

Access: The ability to obtain needed health care services.

Activities of Daily Living (ADL): An index or scale that measures an individual's degree of independence in bathing, dressing, using the toilet, eating, and moving across a small room.

Adjusted Admissions: A measure of all patient care activity in a hospital, including both inpatient and outpatient care. Adjusted admissions are the sum of inpatient admissions and an estimate of the volume of outpatient services, expressed as the number of inpatient admissions that could have been produced with the same amount of resources. This estimate is calculated by multiplying outpatient visits by the ratio of outpatient charges per visit to inpatient charges per admission.

Adjusted Average Per Capita Cost (AAPCC): A county-level estimate of the average cost incurred by Medicare for each beneficiary in fee for service. Adjustments are made so that the AAPCC represents the level of spending that would occur if each county contained the same mix of beneficiaries. Before passage of the Balanced Budget Act of 1997, Medicare paid health plans 95 percent of the AAPCC, adjusted for the characteristics of the enrollees in each plan.

Adjusted Community Rate (ACR) Proposal: A process by which a health plan contracting with Medicare estimates the cost of providing services to its Medicare enrollees based on costs and revenues from its commercial business. Health plans estimate their ACRs annually and adjust the subsequent year's supplemental benefits or premiums offered so that they do not receive a higher rate of return on Medicare enrollees than they do on their commercial business.

Adverse Selection: Adverse selection occurs when a larger proportion of persons with poorer health status enroll in specific plans or insurance options, while a larger proportion of persons with better health status enroll in other plans or insurance options. Plans with a subpopulation with above-average costs are adversely selected. Plans with a subpopulation with below-average costs are favorably selected.

Aggregate Margin: A margin that compares revenues with expenses for a group of hospitals, rather than a single hospital. It is computed by subtracting the sum of expenses for all hospitals in the group from the sum of revenues and dividing by the sum of revenues. See PPS Inpatient Margin, PPS Operating Margin, Total Margin.

Allowed Charge: The amount Medicare approves for payment to a physician. Typically, Medicare pays 80 percent of the allowed charge and the beneficiary pays the remaining 20 percent. The allowed charge for a nonparticipating physician is 95 percent that of a participating physician. Nonparticipating physicians may bill beneficiaries for an additional amount above the allowed charge. See Balance Billing, Participating Physician and Supplier Program.

Ambulatory Patient Classifications (APC): A system for classifying outpatient services and procedures for purposes of payment. The APC system classifies some 7,000 services and procedures into about 300 procedure groups.

Ambulatory Surgical Center (ASC): A free-standing facility certified by Medicare that performs certain types of procedures on an outpatient basis.

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Assignment (Medicare): A process under which Medicare pays its share of the allowed charge directly to the physician or supplier. Medicare will do this only if the physician accepts Medicare's allowed charge as payment in full (guarantees not to balance bill). Medicare provides other incentives to physicians who accept assignment for all patients under the Participating Physician and Supplier Program. See Balance Billing, Nonparticipating Physicians, Participating Physician, Participating Physician and Supplier Program.

Balance Billing: In Medicare and private fee-for-service health insurance, the practice of billing patients in excess of the amount approved by the health plan. Under Medicare fee for service, a balance bill cannot exceed 15 percent of the allowed charge for nonparticipating physicians. See Allowed Charge, Limiting Charge, Participating Physician.

Basic DRG Payment Rate: The payment rate a hospital will receive for a Medicare patient in a particular diagnosis-related group. The payment rate is calculated by adjusting the standardized amount to reflect wage rates in the hospital's geographic area (and cost of living differences unrelated to wages) and the costliness of the DRG. See Standardized Amount, Diagnosis-Related Groups.

Behavioral Offset: See Volume Offset.

Beneficiary: Someone who is eligible for or receiving benefits under an insurance policy or plan. The term is commonly applied to people covered by the Medicare or Medicaid programs.

Beneficiary Liability: The amount beneficiaries must pay providers for Medicare-covered services. Liabilities include copayments and coinsurance amounts, deductibles, and balance billing amounts.

Benefit Package: Services covered by a health insurance plan and the financial terms of such coverage, including cost sharing and limitations on amounts of services. See Cost Sharing.

Budget Neutrality: For the Medicare program, adjustment of payment rates when policies change so that total spending under the new rules is expected to be the same as it would have been under the previous payment rules.

Bundling: The use of a single payment for a group of related services.

Capital Costs: Depreciation, interest, leases and rentals, taxes, and insurance on tangible assets like physical plant and equipment.

Capitation: A health insurance payment mechanism that pays a fixed amount per person per time period to cover services. Capitation may be used by purchasers to pay health plans or by plans to pay providers. See Medicare Risk Contract, Medicare+Choice.

Carrier: A private contractor that administers claims processing and payment for Medicare Part B services. See Supplementary Medical Insurance.

Case Mix: The mix of patients treated within a particular institutional setting, such as the hospital. Patient classification systems like DRGs can be used to measure hospital case mix. See DRGs and Case-Mix Index.

Case-Mix Index (CMI): The average DRG weight for all cases paid under PPS. The CMI is a measure of the relative costliness of the patients treated in each hospital or group of hospitals. See DRG.

Charges: The posted prices of provider services.

Coinsurance: A type of cost sharing where the insured party and insurer share payment of the approved charge for covered services in a specified ratio after payment of the deductible by the insured. For example, for Medicare physicians' services, the beneficiary pays coinsurance of 20 percent of allowed charges. See Allowed Charge, Copayment, Cost Sharing, Deductible.

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Competitive Bidding: A pricing method that elicits information on costs through a bidding process to establish payment rates that reflect the costs of an efficient health plan or health care provider.

Composite Rate: Payment by Medicare that covers the bundle of services, tests, drugs, and supplies routinely required for dialysis treatment.

Conversion Factor: The multiplicative factor used to translate relative value units into dollar amounts for physician payments under a fee schedule.

Conversion Factor Update: Annual percentage change to the conversion factor. For Medicare, the update is set by a formula to reflect medical inflation, changes in enrollment, growth in the economy, and changes in spending due to other changes in law. See Conversion Factor, Sustainable Growth Rate, Sustainable Growth Rate System, Volume Performance Standard System.

Copayment: A fixed dollar amount paid for a covered service by a health insurance enrollee. See Coinsurance and Deductible.

Cost Sharing: A general term referring to payments made by health insurance enrollees for covered services. Examples of cost sharing include deductibles, coinsurance, and copayments. See Balance Billing, Coinsurance, Copayment, Deductible.

Cost Shifting: Increasing revenues from some payers to offset losses and lower net payments from other payers.

Current Procedural Terminology (CPT): The coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association; basis of the HCFA Common Procedure Coding System.

Customary, Prevailing, and Reasonable (CPR): The method of paying physicians under Medicare from 1965 until implementation of the Medicare Fee Schedule in January 1992. Payment for a service was limited to the lowest of (1) the physician's billed charge for the service, (2) the physician's customary charge for the service, or (3) the prevailing charge for that service in the community. Similar to the usual, customary, and reasonable system used by private insurers. See Medicare Fee Schedule; Usual, Customary, and Reasonable.

Deductible: A type of cost sharing where the insured party pays a specified amount of approved charges for covered medical services before the insurer will assume liability for all or part of the remaining covered services. See Coinsurance, Copayment, Cost Sharing.

Diagnosis-Related Groups (DRGs): A system for determining case mix, used for payment under Medicare's PPS and by some other payers. The DRG system classifies patients into groups based on the principal diagnosis, type of surgical procedure, presence or absence of significant comorbidities or complications, and other relevant criteria. DRGs are intended to categorize patients into groups that are clinically meaningful and homogeneous with respect to resource use. Medicare's PPS currently uses almost 500 mutually exclusive DRGs, each of which is assigned a relative weight that compares its costliness to the average for all DRGs. See Case Mix.

Disproportionate Share (DSH) Adjustment: A payment adjustment under Medicare's PPS or under Medicaid for hospitals that serve a relatively large volume of low-income patients.

Dually Eligible: A Medicare beneficiary who also receives the full range of Medicaid benefits offered in his or her state.

Encounter Data: Description of the diagnoses made and services provided when a patient visits a health care provider under a managed-care plan. Encounter data provide much of the same information available on the bills submitted by fee-for-service providers.

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Evaluation and Management (EM) Service: A nonprocedural service, such as a visit or consultation, provided by physicians to diagnose and treat diseases and counsel patients.

Excluded Hospitals and Distinct-Part Units: Specialty hospitals (rehabilitation, psychiatric, long-term care, children's, and cancer) and distinct-part units in general hospitals (rehabilitation and psychiatric) that are excluded from Medicare's hospital Inpatient PPS. Hospitals located in U.S. territories, federal hospitals, and Christian Science Sanatoria are also excluded from PPS. Excluded facilities are paid under cost-based reimbursement, subject to rate of increase limits. Rehabilitation facilities are slated to move to a prospective payment system in October 2000. Congress has also directed HCFA to develop a legislative proposal for a prospective payment system for long-term care facilities.

Favorable Selection: The result of enrolling in a health plan a disproportionate share of healthy individuals compared with the population from which the share is drawn. See Adverse Selection, Risk Adjustment, Risk Selection.

Federally Qualified Health Center (FQHC): A health center in a medically underserved area that is eligible to receive cost-based Medicare and Medicaid reimbursement.

Federally Qualified HMO: An HMO that has satisfied certain federal qualifications pertaining to organizational structure, provider contracts, health service delivery information, utilization review and quality assurance, grievance procedures, financial status, and marketing information, as specified in Title XIII of the Public Health Service Act. See Health Maintenance Organization.

Fee for Service: A method of paying health care providers for individual medical services rendered, as opposed to paying them salaries or capitated payments. See Capitation.

Fee Schedule: A list of predetermined payment rates for medical services. See Medicare Fee Schedule.

Fee Schedule Payment Area: A geographic area within which payment for a given service under the Medicare Fee Schedule does not vary. See Geographic Adjustment Factor.

Fiscal Intermediary: An entity, usually an insurance company, that has a contract with HCFA to determine and make Medicare payments for Part A and certain Part B benefits to hospitals and other providers of services and to perform related functions.

Fiscal Year: A 12-month period for which an organization plans the use of its funds, such as the federal government's fiscal year (October 1 to September 30). Fiscal years are referred to by the calendar year in which they end; for example, the federal fiscal year 1998 began October 1, 1997. Hospitals can designate their own fiscal years, and this is reflected in differences in the time periods covered by the Medicare Cost Reports. See PPS Year.

Five-Year Review: A review of the accuracy of Medicare's relative value scale that the Health Care Financing Administration is required to conduct every five years.

Functional Independence Measure - Function Related Group: A patient classification system developed for medical rehabilitation patients.

Geographic Practice Cost Index (GPCI): An index summarizing the prices of resources required to provide physicians' services in each payment area relative to national average prices. There is a GPCI for each component of the Medicare Fee Schedule: physician work, practice expense, and malpractice expense. The indexes are used to adjust relative value units to determine the correct payment in each fee schedule payment area. See Fee Schedule Payment Area, Medicare Fee Schedule.

Graduate Medical Education (GME): The period of medical training that follows graduation from medical school; commonly referred to as internship, residency, and fellowship training.

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Gross Domestic Product (GDP): The total current market value of all goods and services produced domestically during a given period; differs from the gross national product by excluding net income that residents earn abroad.

Group-Model HMO: An HMO that pays a medical group a negotiated, per capita rate, which the group distributes among its physicians, often under a salaried arrangement. See Health Maintenance Organization, Independent Practice Association, Network-Model HMO, Staff-Model HMO.

HCFA Common Procedure Coding System (HCPCS): A coding system based on the American Medical Association's Current Procedural Terminology (CPT) coding system, expanded to accommodate additional services covered by Medicare.

Health Care Prepayment Plan (HCPP): A health plan with a Medicare cost contract to provide only Medicare Part B benefits. Some administrative requirements for these plans are less stringent than those of risk contracts or other cost contracts. See Medicare Cost Contract, Medicare Risk Contract.

Health Maintenance Organization (HMO): A type of managed-care plan that acts as both insurer and provider of a comprehensive set of health care services to an enrolled population. Benefits are typically financed through capitation with limited copayments, and services are furnished through a system of affiliated providers. See Group-Model HMO, Independent Practice Association, Managed Care, Network-Model HMO, Staff-Model HMO.

Health Plan: An organization that acts as insurer for an enrolled population. See Fee for Service, Managed Care.

Health Plan Employer Data and Information Set (HEDIS): A set of standardized measures of health plan performance. HEDIS allows comparisons between plans on quality, access, and patient satisfaction; membership and utilization; financial information; and health plan management. HEDIS was developed by employers, HMOs, and the National Committee for Quality Assurance.

Health Professional Shortage Area (HPSA): An urban or rural geographic area, a population group, or a public or nonprofit private medical facility that the Secretary of Health and Human Services determines is being served by too few health professionals. Physicians who provide services in HPSAs qualify for a Medicare bonus payment.

Hierarchical Coexisting Conditions Model (HCC): A risk-adjustment model that groups beneficiaries based on their diagnoses.

Hospital Inpatient Prospective Payment System (PPS): Medicare's method of paying acute care hospitals for inpatient care. Prospective per case payment rates are set at a level intended to cover operating costs for treating a typical inpatient in a given DRG. Payments for each hospital are adjusted for differences in area wages, teaching activity, care to the poor, and other factors. Hospitals may also receive additional payments to cover extra costs associated with atypical patients (outliers) in each DRG. Capital costs, originally excluded from PPS, are being phased into the system. By 2001, capital payments will be made on a fully prospective, per case basis. Prospective payment systems are also being developed for Medicare payments for home health services, outpatient hospital services, skilled nursing facilities, and rehabilitation facilities. See Capital Costs, Diagnosis-Related Groups, Outliers, Prospective Payment.

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Hospital Insurance (HI): The part of the Medicare program that covers the cost of hospital and related post-hospital services. Eligibility is normally based on prior payment of payroll taxes. Beneficiaries are responsible for an initial deductible per spell of illness and copayments for some services. Also called Part A coverage or benefits.

Indirect Medical Education (IME) Adjustment: A payment adjustment applied to DRG and outlier payments under PPS for hospitals that operate an approved graduate medical education program. For operating costs, the adjustment is based on the hospital's ratio of interns and residents to the number of beds. For capital costs, it is based on the hospital's ratio of interns and residents to average daily occupancy.

Instrumental Activities of Daily Living (IADL): An index or scale that measures a patient's degree of independence in aspects of cognitive and social functioning, including shopping, cooking, doing housework, managing money, and using the telephone.

Integrated Delivery System (IDS): An entity that usually includes a hospital, a large medical group, and an insurance vehicle such as an HMO or PPO. Typically, all provider revenues flow through the organization.

Intensity of Services: The number and complexity of resources used in producing a patient care service, such as a hospital admission or home health visit. Intensity of services reflects, for example, the amount of nursing care, diagnostic procedures, and supplies furnished.

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM): A diagnosis and procedure classification system designed to facilitate the collection of uniform and comparable health information. This system is used to group patients into DRGs.

Limiting Charge: The maximum amount that a nonparticipating physician is permitted to charge a Medicare beneficiary for a service; in effect, a limit on balance billing. Starting in 1993 the limiting charge has been set at 115 percent of the Medicare-allowed charge. See Allowed Charge, Balance Billing, Nonparticipating Physician.

Locality (Medicare): See Fee Schedule Payment Area.

Major Teaching Hospitals: Hospitals with an approved graduate medical education program and a ratio of interns and residents to beds of 0.25 or greater. See Other Teaching Hospitals, Indirect Medical Education Adjustment.

Malpractice Expense: The cost of professional liability insurance incurred by physicians. A component of the Medicare relative value scale. See Relative Value Scale.

Managed Care: Any system of health service payment or delivery arrangements where the health plan attempts to control or coordinate use of health services by its enrolled members in order to contain health expenditures, improve quality, or both. Arrangements often involve a defined delivery system of providers with some form of contractual arrangement with the plan. See Health Maintenance Organization, Independent Practice Association, Preferred Provider Organization.

Market Basket Index: An index of the annual change in the prices of goods and services providers use for producing health services. There are separate market baskets for PPS hospital operating and capital inputs; PPS-excluded facility operating inputs; and SNF, home health agency, and renal dialysis facility operating and capital inputs.

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Medicare: A health insurance program for people over 65, those eligible for Social Security disability payments, and those who need kidney dialysis or transplants. See Hospital Insurance, Supplementary Medical Insurance.

Medicare+Choice: A program created by the Balanced Budget Act of 1997 to replace the existing system of Medicare risk and cost contracts. Beneficiaries will have the choice during an open season each year to enroll in a Medicare+Choice plan or to remain in traditional Medicare. Medicare+Choice plans may include coordinated care plans (HMOs, PPOs, or plans offered by provider-sponsored organizations); private fee-for-service plans; or plans with medical savings accounts.

Medicare Choices Demonstration: A demonstration project designed to offer flexibility in contracting requirements and payment methods for Medicare's managed-care program. Participating plans include PSOs and PPOs. Plans are required to submit encounter data to HCFA, and most will test new risk-adjustment methods.

Medicare Cost Contract: A contract between Medicare and a health plan under which the plan is paid on the basis of reasonable costs to provide some or all Medicare-covered services for enrollees. See Health Care Prepayment Plan, Medicare Risk Contract.

Medicare Cost Report: An annual report required of institutions participating in the Medicare program. Records each institution's total costs and charges associated with providing services to all patients, the portion of those costs and charges allocated to Medicare patients, and the Medicare payments received.

Medicare Current Beneficiary Survey (MCBS): A longitudinal survey administered by HCFA that provides information on specific aspects of beneficiary access, utilization of services, expenditures, health insurance coverage, satisfaction with care, health status and physical functioning, and demographic information.

Medicare Economic Index (MEI): An index that tracks changes over time in physician practice costs. From 1975 through 1991, increases in prevailing charge screens were limited to increases in the MEI.

Medicare Fee Schedule: The resource-based fee schedule Medicare uses to pay for physicians' services. See Resource-Based Relative Value Scale, Conversion Factor, Geographic Practice Cost Index.

Medicare Risk Contract: A contract between Medicare and a health plan under which the plan receives monthly capitated payments to provide Medicare-covered services for enrollees, and thereby assumes insurance risk for those enrollees. A plan is eligible for a risk contract if it is a federally qualified HMO or a competitive medical plan. See Adjusted Average Per Capita Cost, Adjusted Community Rate, Medicare Cost Contract.

Medigap Insurance: Privately purchased individual or group health insurance policies designed to supplement Medicare coverage. Benefits may include payment of Medicare deductibles, coinsurance, and balance bills, as well as payment for services not covered by Medicare. Medigap insurance must conform to one of 10 federally standardized benefit packages.

National Claims History System: A HCFA data reporting system that combines both Part A and Part B claims in a common file. The National Claims History system became fully operational in 1991.

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Network-Model HMO: An HMO that contracts with several different medical groups, often at a capitated rate. Groups may use different methods to pay their physicians. See Group-Model HMO, Health Maintenance Organization, Independent Practice Association, Staff-Model HMO.

Nominal Value: Measurement of an economic amount in terms of current prices. See Real Value.

Nonparticipating Physician: A physician who does not sign a participation agreement and, therefore, is not obligated to accept assignment on all Medicare claims. See Assignment, Participating Physician, Participating Physician and Supplier Program.

Nursing Facility: An institution that provides skilled nursing care and rehabilitation services to injured, functionally disabled, or sick persons. Formerly, distinctions were made between intermediate care facilities and skilled nursing facilities. The Omnibus Budget Reconciliation Act of 1987 eliminated this distinction effective October 1, 1990, by requiring all nursing facilities to meet SNF certification requirements. See Skilled Nursing Facility.

Other Teaching Hospitals: Hospitals with approved graduate medical education program and a ratio of interns and residents to beds of less than 0.25. See Indirect Medical Education Adjustment, Major Teaching Hospitals.

Out-of-Pocket Expenditures: Health-related expenditures for which beneficiaries are financially liable. For Medicare beneficiaries, the total amount includes cost sharing for Medicare-covered services (for example, deductibles, copayments, and balance bills); the cost of Medicare Part B and private health insurance premiums; and the cost of noncovered services. See Cost Sharing, Balance Billing, Coinsurance, Copayment, Deductible.

Outliers: Cases that are substantially different from the rest of the population. With regard to hospital payment, these are classified as cases with extremely long lengths of stay (day outliers) or extraordinarily high costs (cost outliers) compared with others in the same DRG. Hospitals receive additional PPS payments for these cases.

Paid Amount: The portion of a submitted charge that is actually paid by both third-party payers and the insured, including copayments and balance bills. For Medicare this amount may be less than the allowed charge if the submitted charge is less, or it may be more because of balance billing. See Allowed Charge, Balance Billing, Payment Rate, Submitted Charge.

Participating Physician: A physician who signs a participation agreement, agreeing to accept assignment on all Medicare claims for one year. See Assignment.

Participating Physician and Supplier Program (PAR): A program that provides financial and administrative incentives for physicians and suppliers to agree in advance to accept assignment on all Medicare claims for a one-year period. See Assignment.

Payment Rate: The total amount paid for each unit of service rendered by a health care provider, including both the amount covered by the insurer and the insured person's cost sharing; sometimes referred to as payment level. Also used to refer to capitation payments to health plans. See Allowed Charge.

Per Diem Payment: Fixed daily payments that do not vary with the level of services used by the patient.

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Physician Work: A measure of the physician's time, physical effort and skill, mental effort and judgment, and stress associated with providing a medical service. A component of the resource-based relative value scale. See Relative Value Scale.

Point-of-Service (POS) Plan: A managed-care plan that combines features of both prepaid and fee-for-service insurance. Health plan enrollees decide whether to use network or nonnetwork providers at the time care is needed and usually are charged sizable copayments for selecting the latter. See Health Plan, Health Maintenance Organization, Preferred Provider Organization.

PPS Inpatient Margin: A measure that compares PPS operating and capital payments with Medicare-allowable inpatient operating and capital costs. Calculated by subtracting total Medicare-allowable inpatient operating and capital costs from total PPS operating and capital payments and dividing by total PPS operating and capital payments. See PPS Operating Margin.

PPS Operating Margin: A measure that compares PPS inpatient operating payments with Medicare-allowable inpatient operating costs. This measure excludes Medicare costs and payments for capital, direct medical education, organ acquisition, and other categories not included among Medicare-allowable inpatient operating costs. Calculated by subtracting total Medicare-allowable inpatient operating costs from total PPS inpatient operating payments and dividing by total PPS inpatient operating payments. See PPS Inpatient Margin.

PPS Year: A designation referring to hospital cost reporting periods that begin during a given federal fiscal year, reflecting the number of years since the initial implementation of PPS. For example, PPS 1 refers to hospital fiscal years beginning in federal fiscal year 1984. For a hospital with a fiscal year beginning July 1, PPS 1 covers the period from July 1, 1984 through June 30, 1985.

Practice Expense: The cost of nonphysician resources incurred by the physician to provide services. Examples are salaries and fringe benefits received by the physician's employees, and the expenses associated with the purchase and use of medical equipment and supplies in the physician's office. A component of the Medicare relative value scale. See Relative Value Scale.

Practice Expense Relative Value: A value that reflects the average amount of practice expenses incurred in performing a particular service. All values are expressed relative to the practice expenses for a reference service whose value equals one practice expense unit. See Relative Value Scale.

Preferred Provider Organization (PPO): A managed-care plan that contracts with networks or panels of providers to furnish services and be paid on a negotiated fee schedule. Enrollees are offered a financial incentive to use providers on the preferred list, but may use nonnetwork providers as well. See Managed Care.

Premium: An amount paid periodically to purchase health insurance benefits.

Productivity: The ratio of outputs (goods and services produced) to inputs (resources used in production). Increased productivity implies that an organization is producing more output with the same resources or the same output with fewer resources.

Professional Liability Insurance (PLI): The insurance physicians purchase to help protect themselves from the financial risks associated with medical liability claims.

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Program of All-Inclusive Care for the Elderly (PACE): First established as a HCFA demonstration program that uses managed care to serve frail elderly persons who have been assessed as eligible for nursing home placement and are, for the most part, dually eligible for Medicare and Medicaid. The program provides adult day health care and case management in addition to Medicare and Medicaid benefits to help the program participant maintain independent living in the community. The BBA made PACE a permanent program and began a new demonstration for for-profit sponsors of PACE sites.

Prospective Payment: A method of paying health care providers in which rates are established in advance. Providers are paid these rates regardless of the costs they actually incur.

Real Value: Measurement of an economic amount corrected for change in price over time (inflation), thus expressing a value in terms of constant prices. See Nominal Value.

Relative Value: A value that reflects a comparison with a standard. See Relative Value Scale.

Relative Value Scale (RVS): An index that assigns weights to each medical service; the weights represent the relative amount to be paid for each service. The RVS used in the Medicare Fee Schedule consists of three components: physician work, practice expense, and malpractice expense. See Malpractice Expense, Medicare Fee Schedule, Physician Work, Practice Expense, Resource-Based Relative Value Scale.

Relative Value Unit (RVU): The unit of measure for a relative value scale. RVUs must be multiplied by a dollar conversion factor to establish payment amounts. See Conversion Factor, Relative Value, Relative Value Scale.

Resource-Based Relative Value Scale (RBRVS): A relative value scale based on the resources involved in providing a service. See Relative Value Scale.

Revenue Share: The proportion of total revenue devoted to a particular type of expense. For example, the practice expense revenue share is that proportion of revenue used to pay for practice expense.

Risk Adjuster: A measure used to adjust payments in order to compensate for spending that is expected to be lower or higher than average, based on the health status or demographic characteristics of enrollees.

Risk Adjustment: The process used to adjust payments to plans to compensate for differences in health status of enrollees across plans.

Risk Contract: See Medicare Risk Contract.

Risk Selection: Any situation in which health plans differ in the health risk associated with their enrollees because of enrollment choices made by the plans or enrollees. As a result, one health plan's expected costs differ from another's due to underlying differences in their enrolled populations. See Adverse Selection, Favorable Selection.

Risk Sharing: A method, such as outlier payments, that places a health plan at less than full risk by covering the cost of selected services, providing additional payment amounts for high cost patients or to offset plan losses.

Rural Referral Center: Generally large rural hospitals that Medicare designates as serving patients referred by other hospitals or by physicians who are not members of the hospital's medical staff.

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Secondary Insurance: Any insurance that supplements Medicare coverage. The three main sources for secondary insurance are employers, privately purchased Medigap policies, and Medicaid.

Site-of-Service Differential: The difference in the amount paid to the physician when the same service is performed in different practice settings, for example, a colonoscopy in a physician's office or a hospital clinic.

Skilled Nursing Facility (SNF): An institution that has a transfer agreement with one or more hospitals, provides primarily inpatient skilled nursing care and rehabilitative services, and meets other specific certification requirements. See Nursing Facility.

Standardized Amount: An amount used as the basis for payment under PPS. It is intended to represent the national average operating cost of inpatient treatment for a typical Medicare patient in a reasonably efficient hospital in a large urban or other area. Standardized amounts are based on Medicare costs reported by hospitals for cost reporting periods ending in 1982, adjusted for geographic location and certain hospital characteristics, such as teaching activity. The adjusted amounts are updated to the year of payment by an annual update factor.

Submitted Charge: The charge submitted by a provider to the patient or a payer. See Paid Amounts.

Supplementary Medical Insurance (SMI): The part of the Medicare program that covers the costs of physicians' services, outpatient laboratory and X-ray tests, durable medical equipment, outpatient hospital care, and certain other services. This voluntary program requires payment of a monthly premium, which covers 25 percent of program costs, with the rest covered by general revenues. Beneficiaries are responsible for a deductible and coinsurance payments for most covered services. Also called Part B coverage or benefits.

Supplier: A provider of health care services, other than a practitioner, that is permitted to bill under Medicare Part B. Suppliers include independent laboratories, durable medical equipment providers, ambulance services, orthotists, prosthetists, and portable X-ray providers.

Sustainable Growth Rate: The target rate of expenditure growth set by the sustainable growth rate system. Similar to the performance standard under the previous volume performance standard system, except that the target depends on growth of gross domestic product instead of historical trends. See Sustainable Growth Rate System, Volume Performance Standard System.

Sustainable Growth Rate System: A revision to the volume performance standard system, enacted as part of the Balanced Budget Act of 1997. This system is the mechanism for setting fee updates for the Medicare Fee Schedule. It uses a single conversion factor, bases target rates of growth on growth of gross domestic product, and changes the previous method for calculating the conversion factor update to eliminate the two- year delay. See Volume Performance Standard System, Conversion Factor Update.

Swing-Bed Hospital: A hospital participating in the Medicare swing-bed program. This program allows rural hospitals with fewer than 100 beds to provide post-acute care services in acute care beds.

Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA): Legislation that, among other things, established limits on reimbursements for hospital inpatient operating costs per Medicare discharge. A facility's limit is derived from its costs in a base year updated to the current year by an annual update factor. Medicare payments for operating costs generally may not exceed the facility's limit. These provisions apply generally to hospitals and units excluded from PPS. See Excluded Hospitals and Distinct-Part Units.

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Total Margin: A measure that compares total hospital revenues with expenses for inpatient, outpatient, and nonpatient care activities. The total margin is calculated by subtracting total expenses from total revenues and dividing by total revenues.

Uncompensated Care: Care rendered by hospitals or other providers without payment from the patient or a government-sponsored or private insurance program. It includes both charity care, which is furnished without the expectation of payment, and bad debts, for which the provider has made an unsuccessful effort to collect payment due from the patient.

Update Factor: The year-to-year increase in base payment amounts for PPS hospitals and dialysis facilities, and in the target amounts for PPS-excluded hospitals and units. MedPAC's annual update recommendations are intended to reflect changes in the prices of inputs used to provide patient care services as well as changes in productivity, technological advances, quality of care, and long-term cost effectiveness of services. See Market Basket Index.

Usual, Customary, and Reasonable: A method used by private insurers for paying physicians based on charges commonly used by physicians in a local community. Sometimes called customary, prevailing, and reasonable charges. See Customary, Prevailing, and Reasonable.

Volume and Intensity of Services: The quantity of health care services per enrollee, taking into account both the number and the complexity (or mix) of the services provided.

Volume Offset: The change in the number and mix of services that is projected to occur in response to a change in fees. A 50 percent behavioral offset means that half the savings from fee reductions will be offset by increased volume and intensity of services. Used to estimate budget effects for Medicare payment changes. Also referred to as behavioral offset.

Volume Performance Standard (VPS) System: Recently replaced mechanism to adjust fee updates for the Medicare Fee Schedule based on how annual increases in actual expenditures compare with previously determined performance standard rates of increase. See Sustainable Growth Rate System.

Work Relative Value: A value that reflects the average amount of physician work incurred in performing a particular service, relative to that of other services. See Relative Value Scale.

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Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model

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This article describes the CMS hierarchical condition categories (HCC) model implemented in 2004 to adjust Medicare capitation payments to private health care plans for the health expenditure risk of their enrollees. We explain the model's principles, elements, organization, calibration, and performance. Modifications to reduce plan data reporting burden and adaptations for disabled, institutionalized, newly enrolled, and secondary-payer subpopulations are discussed.

INTRODUCTION

Medicare is one of the world's largest health insurance programs, with annual expenditures exceeding $200 billion. It provides health insurance to nearly 40 million beneficiaries entitled by elderly age, disability, or ESRD. Approximately 11 percent of Medicare beneficiaries are enrolled in private managed care health care plans, with the rest in the traditional FFS program. The 1997 BBA modified the Medicare managed care (MMC) and other capitated programs, collectively called M+C.[1] Medicare pays private plans participating in M+C a monthly capitation rate to provide health care services to enrolled beneficiaries.

Historically, capitation payments to MMC plans were linked to FFS expenditures by geographic area, with payments set at 95 percent of an enrollee's county's adjusted average per capita cost (AAPCC). The AAPCC actuarial rate cells were defined by: age, sex, Medicaid enrollment (indicating poverty), institutional status (for nursing home residents), and working aged status (for beneficiaries with employer-based insurance where Medicare is a secondary payer). Separate county factors were calculated for the aged and non-aged disabled (under 65 years), and at the State-level only (due to small numbers), for ESRD-entitled beneficiaries.

The AAPCC payment methodology explains only about 1-percent of the variation in expenditures for Medicare beneficiaries, and does not pay more for sicker people. Thus, research showed that the managed care program was increasing total Medicare Program expenditures, because its enrollees were healthier than FFS enrollees, and the AAPCC did not account for this favorable selection (Brown et al., 1993; Riley et al., 1996; Mello et al.,

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[1] The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) renames the M+C program Medicare Advantage. However, since this renaming does not officially take place until 2006, we continue to use M+C.

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2003). Also, more money was not directed to plans enrolling sicker beneficiaries, or to plans specializing in treating high-cost populations, such as beneficiaries with particular chronic diseases or high levels of functional impairment.

The M+C program fundamentally changed the MMC payment method, including a mandate for health-based Medicare capitation payments by 2000. To support this mandate, the BBA required managed care organizations (MCOs) to report inpatient encounter data (i.e., records for each inpatient admission of a plan's enrollees noting, among other things, the beneficiaries' diagnoses) beginning in 1998. In 2000 CMS, which administers the Medicare Program, implemented the PIP-DCG model as a health-based payment adjuster (Pope et al., 2000a). This model estimates beneficiary health status (expected cost next year) from AAPCC-like demographics and the worst principal inpatient diagnosis (principal reason for inpatient stay) associated with any hospital admission. PIP-DCG-based payments were introduced gradually, with only 10 percent of total Medicare capitation payments adjusted by PIP-DCG factors in 2000. The other 90 percent of payments were still adjusted using a purely demographic (AAPCC-like) model.

The PIP-DCG model was intended as a transition, a feasible way to implement risk adjustment based on the readily available, already audited inpatient diagnostic data. Relying on inpatient diagnoses is the PIP-DCG model's major shortcoming, since only illnesses that result in hospital admissions are counted; MCOs that reduce admis-sions (e.g., through good ambulatory care) can end up with apparently healthier patients and lower payments. Congress's BIPA (2000) addressed the PIP-DCG limitations by requiring the use of ambulatory diagnoses in Medicare risk-adjustment, to be phased in from 2004 to 2007 at 30, 50, 75, and 100 percent of total payments. CMS began collecting encounter data from MCOs for the physician office and hospital outpatient settings (i.e., records of each enrollee visit to these providers with dates, procedures performed, diagnoses, etc.) in October 2000 and April 2001, respectively. However, following complaints from MCOs about the burden of reporting encounter data, CMS suspended data collection in May 2001, ultimately adopting a drastically streamlined data reporting strategy (discussed later).

CMS evaluated several risk-adjustment models that use both ambulatory and inpatient diagnoses, including ACGs (Weiner et al., 1996), the chronic disease and disability payment system (CDPS) (Kronick et al., 2000), clinical risk groups (CRGs) (Hughes et al., 2004), the clinically detailed risk information system for cost (CD-RISC) (Kapur et al., 2003), and DCG/HCCs (Pope et al, 2000b). CMS chose the DCG/HCC model for Medicare risk-adjustment, largely on the basis of transparency, ease of modification, and good clinical coherence. The DCG/HCC model, part of the same DCG family of models as the PIP-DCG, was developed with CMS funding by researchers at RTI International[2] and Boston University, with clinical input from physicians at Harvard Medical School.[3]

Prior to implementing Medicare risk-adjustment in 2004, the DCG/HCC model developers and CMS staff adapted the original model for consistency with CMS' simplified data collection, and for customized fit for Medicare subpopulations. The resulting CMS-HCC model reflects these

2 The early development of the DCG/HCC model was done by Health Economics Research, Inc. while under contract to CMS. However, RTI International acquired Health Economics Research, Inc. in 2002.

3 The original version of the DCG/HCC model is described in Ellis et al. (1996). The DCG/HCC model has been refined as described in Pope et al., 1998 and 2000b.

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Medicare-specific adaptations of the DCG/HCC model and provides a comprehensive framework for Medicare risk-adjustment.

This article describes the DCG/HCC and CMS-HCC models. The next section describes the DCG/HCC model, including the principles and elements of its diagnostic classification system and how its performance compares to earlier models. We then describe the modifications to accommodate the simplified data that lead to the CMS-HCC model. The final section describes the CMS-HCC model adaptations for subpopulations.

DCG/HCC MODEL PRINCIPLES

Diagnostic Classification System

The following ten principles guided the creation of the diagnostic classification system.

Principle 1—Diagnostic categories should be clinically meaningful. Each diagnostic category is a set of ICD-9-CM codes (Centers for Disease Control and Prevention, 2004). These codes should all relate to a reasonably well-specified disease or medical condition that defines the category. Conditions must be sufficiently clinically specific to minimize opportunities for gaming or discretionary coding. Clinical meaningfulness improves the face validity of the classification system to clinicians, its interpretability, and its utility for disease management and quality monitoring.

Principle 2—Diagnostic categories should predict medical expenditures. Diagnoses in the same HCC should be reasonably homogeneous with respect to their effect on both current (this year's) and future (next year's) costs. (In this article we present prospective models predicting future costs.)

Principle 3—Diagnostic categories that will affect payments should have adequate sample sizes to permit accurate and stable estimates of expenditures. Diagnostic categories used in establishing payments should have adequate sample sizes in available data sets. Given the extreme skewness of medical expenditure data, the data cannot reliably determine the expected cost of extremely rare diagnostic categories.

Principle 4—In creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each disease process, while the effects of unrelated disease processes accumulate. Because each new medical problem adds to an individual's total disease burden, unrelated disease processes should increase predicted costs of care. However, the most severe manifestation of a given disease process principally defines its impact on costs. Therefore, related conditions should be treated hierarchically, with more severe manifestations of a condition dominating (and zeroing out the effect of) less serious ones.

Principle 5—The diagnostic classification should encourage specific coding. Vague diagnostic codes should be grouped with less severe and lower-paying diagnostic categories to provide incentives for more specific diagnostic coding.

Principle 6—The diagnostic classification should not reward coding proliferation. The classification should not measure greater disease burden simply because more ICD-9-CM codes are present. Hence, neither the number of times that a particular code appears, nor the presence of additional, closely related codes that indicate the same condition should increase predicted costs.

Principle 7—Providers should not be penalized for recording additional diagnoses (monotonicity). This principle has

two consequences for modeling: (1) no condition category should carry a negative payment weight, and (2) a condition that is higher-ranked in a disease hierarchy (causing lower-rank diagnoses to be ignored) should have at least as large a payment weight as lower-ranked conditions in the same hierarchy.

Principle 8—The classification system should be internally consistent (transitive). If diagnostic category A is higher-ranked than category B in a disease hierarchy, and category B is higher-ranked than category C, then category A should be higher-ranked than category C. Transitivity improves the internal consistency of the classification system, and ensures that the assignment of diagnostic categories is independent of the order in which hierarchical exclusion rules are applied.

Principle 9—The diagnostic classification should assign all ICD-9-CM codes (exhaustive classification). Since each diagnostic code potentially contains relevant clinical information, the classification should categorize all ICD-9-CM codes.

Principle 10—Discretionary diagnostic categories should be excluded from payment models. Diagnoses that are particularly subject to intentional or unintentional discretionary coding variation or inappropriate coding by health plans/providers, or that are not clinically or empirically credible as cost predictors, should not increase cost predictions. Excluding these diagnoses reduces the sensitivity of the model to coding variation, coding proliferation, gaming, and upcoding.

In designing the diagnostic classification, principles 7 (monotonicity), 8 (transitivity), and 9 (exhaustive classification) were followed absolutely. For example, if the expenditure weights for our models did not originally satisfy monotonicity, we imposed constraints to create models that did. Judgment was used to make tradeoffs among other principles. For example, clinical meaningfulness (principle 1) is often best served by creating a very large number of detailed clinical groupings. But a large number of groupings conflicts with adequate sample sizes for each category (principle 3). Another tradeoff is encouraging specific coding (principle 5) versus predictive power (principle 2). In current coding practice, non-specific codes are common. If these codes are excluded from the classification system, substantial predictive power is sacrificed. Similarly, excluding discretionary codes (principle 10) can also lower predictive power (principle 2). We approached the inherent tradeoffs involved in designing a classification system using empirical evidence on frequencies and predictive power, clinical judgment on relatedness, specificity, and severity of diagnoses, and the judgment of the authors on incentives and likely provider responses to the classification system. The DCG/HCC models balance these competing goals to achieve a feasible health-based payment system.

Elements and Organization

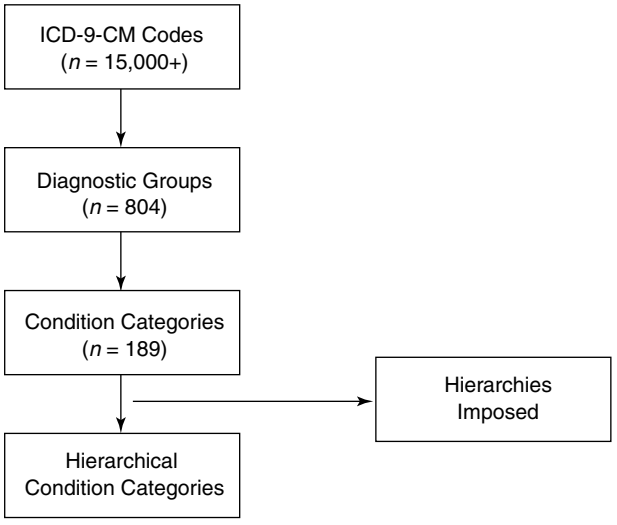
As shown in Figure 1, the HCC diagnostic classification system first classifies each of over 15,000 ICD-9-CM codes into 804 diagnostic groups, or DxGroups. Each ICD-9-CM code maps to exactly one DxGroup, which represents a well-specified medical condition, such as DxGroup 28.01 Acute Liver Disease. DxGroups are further aggregated into 189 Condition Categories, or CCs.[4] CCs describe a broader set of similar diseases, generally organized into body systems, somewhat like ICD-9-CM major diagnostic categories.

[4] Most CCs are assigned entirely with ICD-9-CM codes. But CCs 185-189 are assigned by beneficiary utilization of selected types of DME, such as wheelchairs. CC 173, Major Organ Transplant, is defined by procedure codes only. CC 129, ESRD is defined by Medicare entitlement status. None of these CCs are included in the CMS-HCC model.

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Figure 1

Hierarchical Condition Categories Aggregations of ICD-9-CM Codes



NOTE: ICD-9-CM is *International Classification of Diseases, Ninth Revision, Clinical Modification.*
SOURCE: (Pope et al., 2000b.)

Although they are not as homogeneous as DxGroups, CCs are both clinically- and cost-similar. An example is CC 28 Acute Liver Failure/Disease that includes DxGroups 28.01 and 28.02 Viral Hepatitis, Acute or Unspecified, with Hepatic Coma.

Hierarchies are imposed among related CCs, so that a person is only coded for the most severe manifestation among related diseases. For example (Figure 2), ICD-9-CM Ischemic Heart Disease codes are organized in the Coronary Artery Disease hierarchy, consisting of 4 CCs arranged in descending order of clinical severity and cost, from CC 81 Acute Myocardial Infarction to CC 84 Coronary Athlerosclerosis/Other Chronic Ischemic Heart Disease. A person with an ICD-9-CM code in CC 81 is excluded from being coded in CCs 82, 83, or 84 even if codes that group into those categories were also present. Similarly, a person with ICD-9-CM codes that group into both CC 82 Unstable Angina and Other Acute Ischemic Heart Disease, and CC 83 Angina Pectoris/Old Myocardial Infarction is coded for CC 82, but not CC 83. After imposing hierarchies, CCs become Hierarchical Condition Categories, or HCCs.[5]

Although HCCs reflect hierarchies among related disease categories, for unrelated diseases, HCCs accumulate. For example, a male with heart disease, stroke, and cancer has (at least) three separate HCCs coded, and his predicted cost will reflect increments for all three problems. The HCC model is more than simply additive because some disease combinations interact. For example, the presence of both Diabetes and Congestive Heart Failure (CHF) could increase predicted cost by more (or less) than the sum of the separate increments for people who have diabetes or CHF alone.

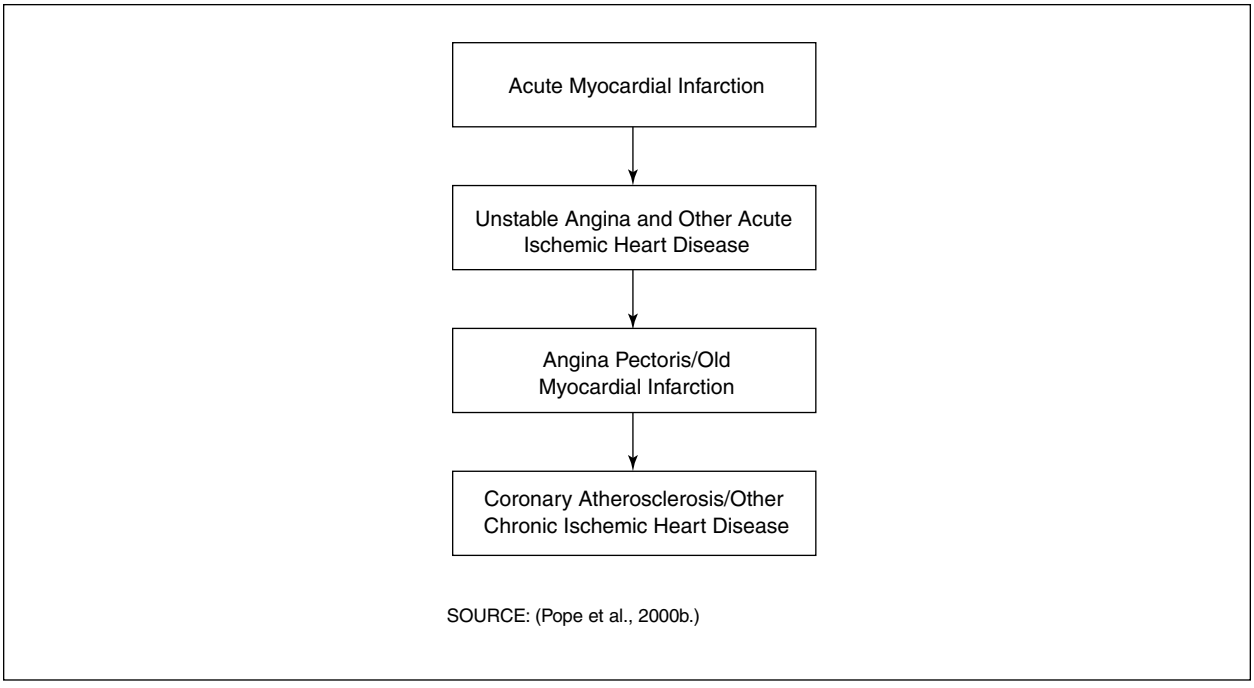
We tested 35 two- and three-way interactions among six common and high-cost chronic diseases defined by HCCs or

[5] The full list of hierarchies used in the CMS-HCC model is available on request from the authors.

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Figure 2

Hierarchical Condition Categories Coronary Artery Disease Hierarchy



groups of HCCs: diabetes, cerebrovascular disease, vascular disease, or chronic obstructive pulmonary disease (COPD), CHF, and coronary artery disease (Pope et al., 2000b), as well as three interactions of several of these conditions with renal failure.[6] Simple additivity yields most of the explanatory power, in the sense that adding all 38 interactions barely increased the base DCG/HCC model's R^2 (from 11.10 to 11.13 percent). However, six interactions were substantial in magnitude, statistically significant, and clinically plausible. Hence, to improve clinical face validity and predictive accuracy for important subgroups of beneficiaries, we include them in the DCG/HCC model. For example, the simultaneous presence of CHF and COPD leads to higher expected costs than would be calculated by adding the separate increments for CHF and COPD alone.

Because a single beneficiary may be coded for none, one, or more than one DxGroup or HCC, the DCG/HCC model can individually price tens of thousands of distinct clinical profiles using fewer than 200 parameters. The model's structure thus provides, and predicts from, a detailed comprehensive clinical profile for each individual.

HCCs are assigned using hospital and physician diagnoses from any of five sources: (1) principal hospital inpatient; (2) secondary hospital inpatient; (3) hospital outpatient; (4) physician; and (5) clinically-trained non-physician (e.g., psychologist, podiatrist). The DCG/HCC model does not distinguish among sources; in particular, it places no premium on diagnoses from inpatient care. Using Medicare 5-percent sample FFS data, we investigated adding diagnoses from other sources (Pope et al., 2000b). Adding diagnoses from home health providers raised the explanatory power of the base model from

[6] In later work unpublished work, we also examined all two-way interactions of cancer with the other six diagnoses, but did not find any significant effects.

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11.15 to 11.65 percent. Further adding diagnoses from DME suppliers raised the explanatory power from 11.65 to 11.85 percent. All other sources of diagnoses either add no predictive power (SNF, ASC, or hospice) or detract from predictive power (clinical laboratory and radiology/imaging clinics). Diagnoses assigned by home health and DME providers are likely to be less reliable than those assigned by physicians or other providers with greater clinical training. Diagnoses from laboratory and imaging tests are also problematic given the significant proportion of rule-out diagnoses. In implementing the CMS-HCC model, potential gains in predictive power from using additional sources were balanced against the costs of collecting and auditing these data; the decision was to only ask MCOs to collect diagnoses from the five baseline sources previously listed.

Consistent with principle 10, we excluded discretionary diagnostic categories (HCCs) from the preliminary prospective payment model. We excluded diagnoses that were vague/non-specific (e.g., symptoms), discretionary in medical treatment or coding (e.g., osteoarthritis), not medically significant (e.g., muscle strain), or transitory or definitively treated (e.g., appendicitis). We also excluded HCCs that did not (empirically) add to costs, and finally, the five HCCs that were defined by the presence of procedures or use of DME, because, as much as possible, we wanted payments to follow what medical problems were present as opposed to what services were offered.[7] Altogether, we excluded 88 of the 189 HCCs, leaving 101 HCCs in the preliminary prospective payment model. As discussed further, additional HCCs were excluded from the final, 70-category CMS-HCC model.

The DCG/HCC model also relies on demographics. Demographic adjusters included in the model are 24 mutually exclusive age/sex cells (e.g., female, age 65-69), an indicator for at least 1-month of Medicaid enrollment in the base year (a poverty indicator), and an indicator of originally disabled status. The age cells distinguish beneficiaries currently entitled to Medicare by age (65 or over) versus disability (under 65); a separate, explicit aged versus disabled entitlement status indicator would be redundant. The originally disabled indicator distinguishes beneficiaries who are currently age 65 or over, but were first entitled to Medicare before age 65 by disability. The age/sex, Medicaid, and originally disabled categories add to each other and to the HCC diagnostic categories.[8] The demographic variables are the same as have been used in the PIP-DCG model, and are discussed at greater length elsewhere (Pope et al., 2000a).

Figure 3 displays a hypothetical clinical vignette of a female age 79, eligible for Medicaid and diagnosed with acute myocardial infarction (AMI), angina pectoris, COPD, renal failure, chest pain, and an ankle sprain. Note that although this female receives CCs for both AMI and angina, she receives no HCC for angina because AMI is a more severe manifestation of coronary artery disease. Also note that while payment includes additive increments for females age 75-79 (demographic categories not shown in Figure 3), Medicaid, AMI, COPD, and renal failure, the HCCs for major symptoms and other injuries are excluded from the payment calculation. Chest pain is a symptom associated with a variety of medical conditions ranging from minor to serious, and sprains are transitory, with minimal implications for next year's cost.

[7] The DME HCCs were developed to predict costs associated with functional impairment not captured by diagnoses. Although they did improve prediction for the functionally impaired, substantial under-prediction remained (Pope et al., 2000b; Kautter and Pope, 2001).

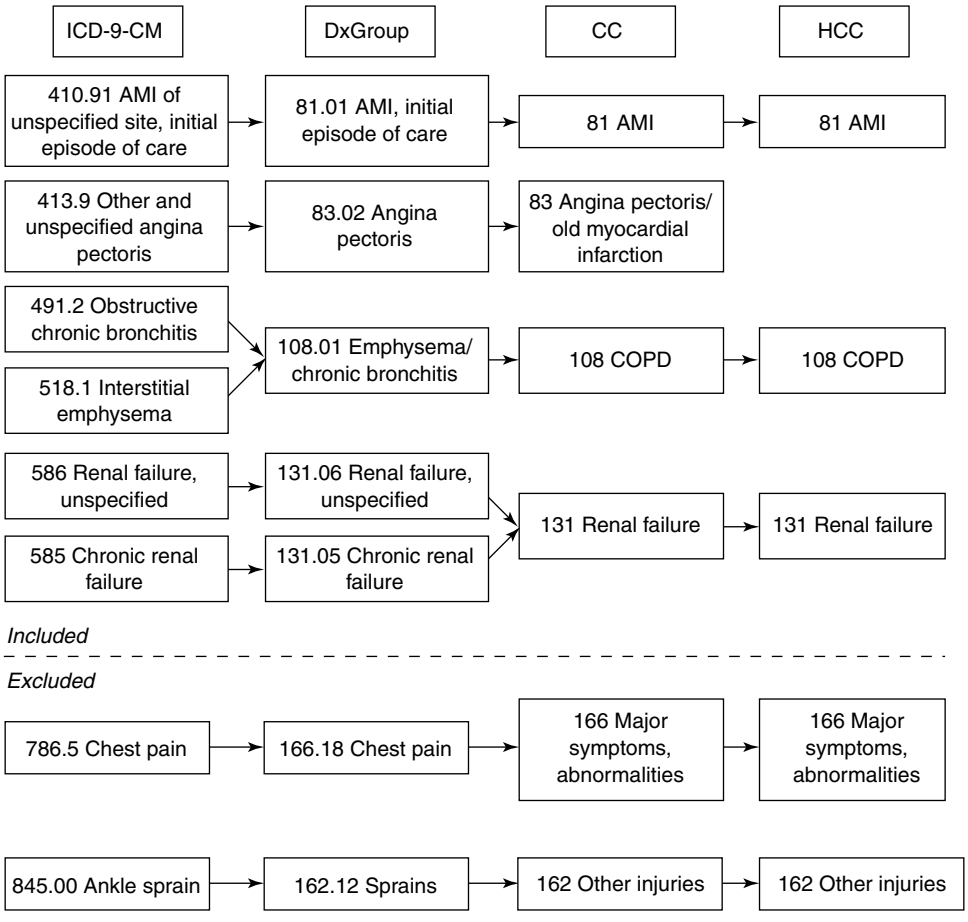
[8] We did not systematically investigate interactions of age and sex with HCCs (diagnoses). This is a subject for future research.

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Figure 3

Clinical Vignette for Hierarchical Condition Categories Classification 79 Year Old Female with AMI, Angina Pectoris, COPD, and Renal Failure



NOTES: AMI is acute myocardial infarction. COPD is chronic obstructive pulmonary disease.

SOURCE: (Pope et al., 2000b.)

PERFORMANCE OF DCG/HCC AND PIP-DCG MODELS

The predictive accuracy of risk-adjustment models is typically judged by the R^2 statistic (percentage of variation explained) to measure predictive accuracy for individuals and predictive ratios (ratios of mean predicted to mean actual expenditures for subgroups of beneficiaries) to measure predictive accuracy for groups. The R^2 of age/sex, PIP-DCG, and DCG/HCC models as measured on 1996-1997 Medicare's 5-percent sample FFS data are: age/sex, 1.0 percent; PIP-DCG, 6.2 percent; and DCG/HCC, 11.2 percent.

Adding PIP-DCG to demographic predictors (age/sex) increases predictive power sixfold. Adding secondary inpatient and ambulatory diagnoses (hospital outpatient and physician), and arraying them in a multi-condition cumulative model (DCG/HCC) nearly doubles the power again. Besides the R^2, another interesting summary statistic is the percentage of payments based on demographic variables: 100

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Table 1

Predictive Ratios[1] for Alternative Risk-Adjustment Models

Category	Model		
Quintiles of Expenditures	Age/Sex	PIP-DCG	DCG/HCC
First (Lowest)	2.66	2.09	1.23
Second	1.93	1.54	1.23
Third	1.37	1.10	1.14
Fourth	0.95	0.84	1.02
Fifth (Highest)	0.44	0.75	0.86
Top 5 Percent	0.28	0.61	0.77
Top 1 Percent	0.17	0.47	0.69
Hospitalizations			
None	1.33	1.07	1.03
1	0.63	1.02	1.02
2	0.44	0.91	0.98
3 or More	0.26	0.69	0.82
Diagnoses[2]			
Heart Failure	0.47	0.74	0.97
Heart Attack	0.45	0.78	0.98
COPD	0.59	0.79	0.99
Hip Fracture	0.56	0.83	0.99
Depression	0.54	0.77	0.92
Colorectal Cancer	0.60	0.78	0.98
Cerebral Hemorrhage	0.44	0.73	1.04

[1] Mean predicted cost divided by mean actual cost.

[2] From either inpatient or ambulatory setting.

NOTES: Expenditures, hospitalizations, and diagnoses are measured in the base year. COPD is chronic obstructive pulmonary disease.

SOURCE: (Pope et al., 2000b.)

percent in a demographic model, 81 percent in the PIP-DCG model, but only 43 percent in the DCG/HCC model (Pope et al., 2001). With over one-half of payments determined by diagnoses, the DCG/HCC model moves decisively away from the AAPCC demographic-based payment system.

Table 1 shows predictive ratios for selected groups of Medicare beneficiaries. Ratios close to 1.0 indicate accurate prediction of costs; less than 1.0, under prediction; and, more than 1.0, over prediction. The PIP-DCG model improves substantially on age/sex, and in almost all cases, the DCG/HCC model improves significantly on the PIP-DCG model. This is true even for hospitalizations, where the PIP-DCG model distinguishes between those hospitalized or not, while the DCG/HCC model makes no distinction by source of diagnosis.[9] Despite the DCG/HCC model's impressive gains over the age/sex and PIP-DCG models, it still under-predicts for the most expensive and most often hospitalized beneficiaries.

CMS-HCC MODEL

This section describes how the DCG/HCC model was modified before implementation as the M+C risk adjuster for capitation payments in 2004. We will refer to the modified model as CMS-HCC.

DCG/HCC Model Modification to Simplify Data Collection

When several MCOs withdrew from the M+C program around the year 2000, CMS sought to improve plan retention. Since some MCOs had complained of the burden of collecting encounter data for risk-adjustment, CMS sought to develop risk adjustment models that predict well and rely on ambulatory data, but with reduced data col-

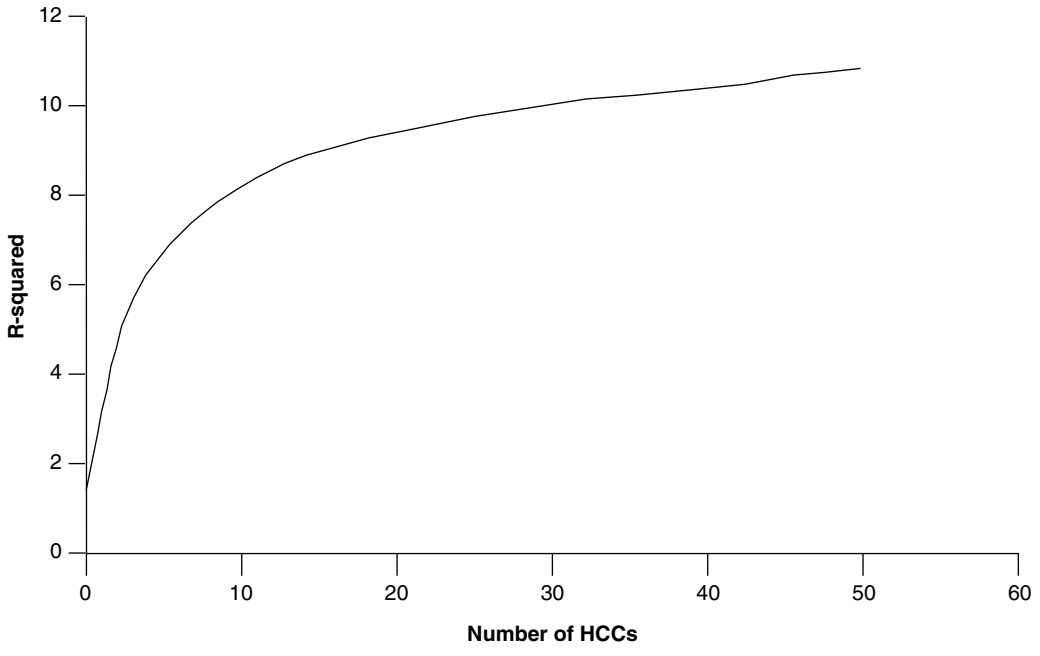
[9] The DCG/HCC model captures multiple conditions that might be diagnosed in multiple inpatient stays, whereas the PIP-DCG model captures only the single principal inpatient diagnosis most predictive of future costs if multiple inpatient stays occur.

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Figure 4

Model Explanatory Power as a Function of Number of Hierarchical Condition Categories (HCC)



NOTES: All models, including the one with zero HCCs, include 24 age/sex cells, and Medicaid and originally disabled status. Results based on stepwise regression analysis.

SOURCE: (Pope et al., 2001.)

lection requirements. One measure of the data collection burden imposed by a model is its number of diagnostic categories.[10]

We investigated the relationship between number of diagnostic categories used in the DCG/HCC model and its predictive power (Pope et al., 2001). Figure 4 plots the relationship between number of diagnostic categories and model explanatory power measured by R^2. Diagnostic categories (HCCs) were entered into the model in descending order of their incremental explanatory power using stepwise regression. The base model (with zero HCCs) includes 26 demographic variables, the 24 age/sex cells, and Medicaid and originally disabled status. Its R^2 is 1.69 percent.

The incremental contribution to predictive power declines rapidly with the number of diagnostic categories added to the model. The first diagnostic category entered by the stepwise regression is CHF, which more than doubles the demographic model R^2 to 4.11 percent. The second condition category entered is COPD, raising the R^2 to 4.94 percent. This is an incremental gain of 0.83 percentage points, substantial, but much less then the increment of 2.42 percentage points due to CHF. With 5 HCCs included, 61 percent of the maximum explanatory power of the full (101 HCC) model is attained; with 10 HCCs, 74 percent of the maximum is achieved; with 20, 85 percent, and with 30, 90 percent. The incremental R^2 from adding a diagnostic category is 0.48 percentage points at 5 HCCs; 0.26 percentage points at 10 HCCs; 0.08 percentage points at 20 HCCs; and 0.05 percentage points at 30 HCCs.

[10] The relationship between number of diagnostic categories and data collection burden is controversial. Some MCOs seemed to feel that it would be less burdensome to report all diagnoses, which CMS allows.

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This analysis shows that a parsimonious risk-adjustment model with a substantially reduced number of diagnostic categories is almost as predictive as a full model. But parsimony has a cost. In limiting the number of conditions that affect payment, many serious, high-cost diagnoses—especially rare ones—will be ignored. MCOs enrolling beneficiaries with excluded diagnoses will be disadvantaged, and beneficiaries with such conditions may not be well served by MCOs.

CMS considered these results, and consulted with clinicians, on the tradeoff between number of diagnostic categories and predictive power, and also other criteria for diagnostic categories to include in risk adjustment, such as well-defined diagnostic criteria and clinical coherence and homogeneity. It was important that the HCC hierarchies not be disrupted by deletion of higher-ranked HCCs while lower-ranked HCCs were retained. After this process, CMS selected 70 HCCs to include in the CMS-HCC model. The choices reflect a balance among the competing considerations of reducing data collection burden, maximizing predictive power, including rare, high-cost conditions, and selecting only well-defined and clinically coherent conditions. Generally, the higher-cost, more severe conditions at the top of the HCC disease hierarchies were retained, while some lower-cost, more frequent and more discretionary conditions at the bottom of the hierarchies were pruned. For example, in the coronary artery disease hierarchy, AMI (heart attack), other acute IHD (e.g., unstable angina), and angina pectoris/old myocardial infarction were retained, but chronic IHD (e.g., coronary atherosclerosis) was excluded.

After the CMS-HCC model was finalized, a list of approximately 3,000 of the more than 15,000 ICD-9-CM diagnosis codes was identified that are sufficient to define the model's 70 HCCs. In addition, because the CMS-HCC model does not give extra credit for multiple reports of the same diagnosis, MCOs need only report a single encounter during the relevant year of data collection that establishes the diagnosis. The information required for the single encounter is: (1) beneficiary identification number, (2) date (to establish that the diagnosis was made during the relevant reporting period), (3) setting (to establish that the diagnosis was made in one of the allowed hospital or physician settings), and (4) ICD-9-CM diagnosis code. In short, MCOs are required to report only the minimum.

Concern about the quality of diagnostic reporting is the greatest in physician offices, where diagnoses have not heretofore affected payment, and recording of diagnoses is less rigorously practiced than in hospitals. The auditing standard that CMS has promulgated for reporting of physician office diagnoses is that a physician has established the diagnosis in the medical record, and that medical coders have recorded it in accordance with ICD-9-CM rules. CMS will conduct coding audits, but not clinical audits. That is, CMS will require MCOs to demonstrate that a diagnosis is present in the medical record on the specified date and has been coded according to ICD-9-CM. CMS will not require clinical verification of these diagnoses, such as diagnostic test results.

CMS-HCC Model Calibration

We calibrated the CMS-HCC model to 1999-2000 Medicare 5-percent sample FFS data for beneficiaries entitled by age or disability (beneficiaries entitled by ESRD were excluded). The model is prospective, meaning that diagnoses collected in a base year (1999) are used to predict expenditures in the following year (2000). An

important operational change from the PIP-DCG model is that the data lag will be eliminated, making the application of the model consistent with its calibration. With the PIP-DCG model, the data collection period for a payment year ended 6 months before the start of the year, i.e., on June 30 of the previous year, so that final capitation rates could be published by January 1 of the payment year. With the CMS-HCC model, provisional rates will be established by January 1 based on 6-month lagged data, and final rates will be available by June 30 of the payment year based on the previous calendar year's diagnoses. A reconciliation process will adjust the first 6 months of payments to the final rates, if necessary.

A standard set of sample restrictions was employed to ensure a population of beneficiaries with complete 12-month base year diagnostic profiles and complete payment year Medicare expenditures from the FFS claims for aged and disabled beneficiaries (Pope et al., 2000b). Decedents are included in the payment year for their eligible period. Complete FFS claims are not available for months of M+C enrollment or when Medicare is a secondary payer, and M+C plans are not responsible for hospice care, so these months were excluded from our sample. The final sample size is 1,337,887 beneficiaries.

We summed all Medicare payments for a beneficiary for months in 2000 satisfying our sample restrictions, excluding (1) deductibles and copayments paid by the beneficiary; (2) hospice payments; and (3) indirect medical education payments. Hospice and indirect medical education payments are excluded because they were not included in M+C capitation rates, but were paid directly to hospices and teaching hospitals utilized by M+C enrollees. Payments were annualized by dividing them by the fraction of months in 2000 that satisfy our sample restrictions; all analyses are weighted by this eligibility fraction. In general, annualization and weighting ensures that monthly payments are correctly estimated for all beneficiaries, including those who died (Ellis et al., 1996).[11]

The model was calibrated using weighted least squares multiple regression. The CMS-HCC regression model estimated for the combined aged and disabled Medicare population is shown in Table 2.

The elements of the model are:

- Age/sex cells (24).
- Medicaid interacted with sex and age/disabled entitlement status.
- Originally disabled status interacted with sex.
- HCC diagnostic categories (70).
- Interactions of diagnostic categories with entitlement by disability (5).
- Disease interactions (6).

The R^2 for this model is 9.8 percent. Several coefficients are constrained because the unconstrained coefficients violate the principle that higher-ranked conditions in a hierarchy should have higher predicted costs, or for other reasons.[12]

As an example of expenditure prediction, consider our hypothetical scenario in Figure 3 of a female age 79 eligible for Medicaid diagnosed with AMI, angina pectoris, COPD, renal failure, chest pain, and an ankle sprain. The female receives the following incremental cost predictions: female, 75 to 79, $2,562; aged, female, Medicaid, $616; AMI (HCC 81), $1,885; angina pectoris, $0; COPD (HCC 108), $1,936; renal failure (HCC 131), $2,908;

[11] In our calibration, we did not make any geographic adjustments to Medicare payments. In past work, we have found that deflating payments by a geographic input price index had little effect on estimated risk-adjustment model parameters.

[12] Clinical consultants to CMS suggested that metastatic cancer is not consistently correctly coded, so HCCs 7 and 8 were constrained to have equal coefficients. HCCs 81 and 82 were constrained to have equal coefficients because the ICD-9-CM diagnostic detail CMS collects from health plans is not sufficient to distinguish them.

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Table 2

Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC) Combined, Community, and Institutional Models

	Models		
	Combined	Community	Institutional
Number of Observations	1,337,887	1,291,308	65,593
R^2	0.0977	0.0976	0.0596
Adjusted R^2	0.0977	0.0976	0.0589
Dependent Variable Mean	5,352	5,213	8,937
Root Mean Square Error	13,407	13,337	15,954
Model Parameters	105	105	50

Variable		Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio	
Female								
0-34 Years		678	3.81	598	3.36	5,457	11.72	
35-44 Years		1,110	8.82	1,012	8.03	5,457	11.72	
45-54 Years		1,177	11.20	1,096	10.40	5,457	11.72	
55-59 Years		1,463	11.87	1,360	11.00	5,457	11.72	
60-64 Years		1,996	17.26	1,924	16.56	5,457	11.72	
65-69 Years		1,648	42.11	1,572	40.15	5,970	11.73	
70-74 Years		2,061	60.25	1,970	57.42	6,049	17.09	
75-79 Years		2,562	71.59	2,475	68.56	5,089	19.63	
80-84 Years		2,998	71.39	2,936	68.34	4,813	22.51	
85-89 Years		3,360	63.45	3,408	61.01	4,515	23.28	
90-94 Years		3,683	46.81	4,077	46.25	4,048	19.08	
95 Years or Over		3,128	23.27	4,130	25.32	2,980	10.34	
Male								
0-34 Years		405	2.72	346	2.32	5,664	13.77	
35-44 Years		701	6.63	617	5.81	5,664	13.77	
45-54 Years		1,059	12.15	973	11.14	5,664	13.77	
55-59 Years		1,460	13.42	1,386	12.68	5,664	13.77	
60-64 Years		1,824	17.90	1,755	17.13	5,664	13.77	
65-69 Years		1,827	41.47	1,774	40.28	7,435	13.24	
70-74 Years		2,380	59.66	2,323	58.17	6,350	14.34	
75-79 Years		3,031	69.04	2,960	67.13	6,210	16.45	
80-84 Years		3,454	62.03	3,372	59.83	6,201	17.67	
85-89 Years		4,129	52.24	4,050	49.80	6,366	17.40	
90-94 Years		4,505	32.20	4,620	31.08	5,378	11.29	
95 Years or Over		4,753	15.83	5,307	15.89	4,287	5.34	
Medicaid and Originally Disabled Interactions with Age and Sex								
Medicaid-Female-Disabled		1,141	11.31	1,133	11.18	—	—	
Medicaid-Female-Aged		616	12.91	940	18.18	—	—	
Medicaid-Male-Disabled		632	6.80	592	6.31	—	—	
Medicaid-Male-Aged		788	10.33	944	11.62	—	—	
Originally Disabled-Female		1,231	17.34	1,213	16.44	—	—	
Originally Disabled-Male		809	11.66	757	10.73	—	—	
Disease Coefficients	**Label**							
HCC1	HIV/AIDS	3,587	13.16	3,514	12.88	6,893	5.42	C1
HCC2	Septicemia/Shock	4,365	34.74	4,563	32.92	4,854	13.89	
HCC5	Opportunistic Infections	3,643	10.43	3,346	9.29	6,893	5.42	C1
HCC7	Metastatic Cancer and Acute Leukemia	7,438	81.16	7,510	81.00	2,771	4.54	
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	7,438	81.16	7,510	81.00	2,771	4.54	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	3,540	35.91	3,539	35.51	2,319	3.50	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	1,209	26.35	1,194	25.79	1,330	4.01	

Refer to NOTES at end of table.

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Table 2—Continued

Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC) Combined, Community, and Institutional Models

Variable		Models						
		Combined		Community		Institutional		
		Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio	
Disease Coefficients	**Label**							
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	3,827	37.71	3,921	36.90	3,137	10.49	
HCC16	Diabetes with Neurologic or Other Specified Manifestation	2,931	30.09	2,833	28.43	3,137	10.49	
HCC17	Diabetes with Acute Complications	2,056	7.84	2,008	7.41	3,137	10.49	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	1,839	18.35	1,760	17.32	3,137	10.49	
HCC19	Diabetes without Complication	1,055	26.10	1,024	25.02	1,308	5.32	
HCC21	Protein-Calorie Malnutrition	3,818	27.52	4,727	29.77	2,193	6.49	
HCC25	End-Stage Liver Disease	4,496	14.91	4,616	14.92	1,375	5.09	
HCC26	Cirrhosis of Liver	2,727	11.93	2,645	11.37	1,375	5.09	
HCC27	Chronic Hepatitis	1,839	6.73	1,841	6.71	1,375	5.09	
HCC31	Intestinal Obstruction/ Perforation	1,997	21.69	2,094	21.62	1,375	5.09	
HCC32	Pancreatic Disease	2,336	17.30	2,281	16.61	1,375	5.09	
HCC33	Inflammatory Bowel Disease	1,574	10.25	1,575	10.16	1,375	5.09	
HCC37	Bone/Joint/Muscle Infections/ Necrosis	2,629	19.68	2,546	18.41	2,539	4.42	
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	1,683	27.72	1,653	26.93	1,463	3.61	
HCC44	Severe Hematological Disorders	5,055	30.80	5,188	30.69	2,299	4.08	
HCC45	Disorders of Immunity	4,224	26.77	4,260	26.64	2,299	4.08	
HCC51	Drug/Alcohol Psychosis	1,571	6.57	1,810	6.99	1,131	6.06	
HCC52	Drug/Alcohol Dependence	1,477	6.15	1,361	5.44	1,131	6.06	
HCC54	Schizophrenia	2,592	26.75	2,786	27.04	1,131	6.06	
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	2,024	30.00	2,209	30.85	1,131	6.06	
HCC67	Quadriplegia, Other Extensive Paralysis	5,665	27.45	6,059	27.20	504	3.94	
HCC68	Paraplegia	5,665	27.45	6,059	27.20	504	3.94	
HCC69	Spinal Cord Disorders/ Injuries	2,484	17.77	2,526	17.45	504	3.94	
HCC70	Muscular Dystrophy	2,239	3.82	1,981	3.27	504	3.94	
HCC71	Polyneuropathy	1,480	19.74	1,377	18.06	504	3.94	
HCC72	Multiple Sclerosis	2,329	11.44	2,654	12.19	504	3.94	
HCC73	Parkinson's and Huntington's Diseases	1,954	19.69	2,436	22.04	504	3.94	
HCC74	Seizure Disorders and Convulsions	1,334	17.25	1,381	16.68	504	3.94	
HCC75	Coma, Brain Compression/ Anoxic Damage	2,396	7.88	C1 2,912	8.62	C1 504	3.94	C2
HCC77	Respirator Dependence/ Tracheostomy Status	10,417	29.54	10,783	28.46	7,259	8.19	
HCC78	Respiratory Arrest	7,543	20.23	7,327	18.79	7,259	8.19	
HCC79	Cardio-Respiratory Failure and Shock	3,451	42.70	3,550	42.39	1,481	4.31	
HCC80	Congestive Heart Failure	2,055	38.48	2,141	38.54	903	4.16	
HCC81	Acute Myocardial Infarction	1,885	31.23	1,785	29.13	1,476	5.75	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	1,885	31.23	1,785	29.13	1,476	5.75	
HCC83	Angina Pectoris/Old Myocardial Infarction	1,246	22.82	1,205	21.76	1,476	5.75	

Refer to NOTES at end of table.

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Table 2—Continued

Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC) Combined, Community, and Institutional Models

Variable		Models						
		Combined		Community		Institutional		
		Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio	
Disease Coefficients	**Label**							
HCC92	Specified Heart Arrhythmias	1,362	31.73	1,363	30.95	961	4.62	
HCC95	Cerebral Hemorrhage	1,901	10.05	2,011	9.88	774	4.01	
HCC96	Ischemic or Unspecified Stroke	1,498	20.90	1,569	20.34	774	4.01	
HCC100	Hemiplegia/Hemiparesis	1,678	13.96	2,241	16.61	504	3.94	
HCC101	Cerebral Palsy and Other Paralytic Syndromes	767	3.34	840	3.42	504	3.94	C2
HCC104	Vascular Disease with Complications	3,432	36.22	3,473	35.49	2,612	6.30	
HCC105	Vascular Disease	1,662	39.94	1,832	41.72	583	3.72	
HCC107	Cystic Fibrosis	1,936	45.73	1,929	44.87	1,180	4.69	
HCC108	Chronic Obstructive Pulmonary Disease	1,936	45.73	1,929	44.87	1,180	4.69	
HCC111	Aspiration and Specified Bacterial Pneumonias	3,010	20.47	3,556	21.53	2,377	6.82	
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess	1,151	6.55	1,034	5.68	2,377	6.82	
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	1,975	13.36	1,791	11.96	5,102	5.46	
HCC130	Dialysis Status	15,926	26.97	15,778	25.96	15,959	5.82	
HCC131	Renal Failure	2,908	23.20	2,954	22.73	2,152	6.26	
HCC132	Nephritis	1,541	6.95	1,401	6.23	2,152	6.26	
HCC148	Decubitus Ulcer of Skin	3,888	32.32	5,285	37.28	1,628	5.98	
HCC149	Chronic Ulcer of Skin, Except Decubitus	2,381	26.76	2,485	26.65	1,346	3.98	
HCC150	Extensive Third-Degree Burns	4,427	2.36	4,935	2.54	1,274	3.37	
HCC154	Severe Head Injury	2,396	7.88	C1 2,912	8.62	C1 1,274	3.37	
HCC155	Major Head Injury	1,211	8.43	1,239	8.08	1,274	3.37	C3
HCC157	Vertebral Fractures w/o Spinal Cord Injury	2,462	20.64	2,514	20.23	504	3.94	C2
HCC158	Hip Fracture/Dislocation	1,301	13.37	2,010	18.51	0	—	
HCC161	Traumatic Amputation	3,965	17.86	C2 4,322	17.92	C2 1,274	3.37	C3
HCC164	Major Complications of Medical Care and Trauma	1,438	18.25	1,346	16.60	1,347	3.66	
HCC174	Major Organ Transplant Status	3,790	8.55	3,702	8.37	4,523	11.13	
HCC176	Artificial Openings for Feeding or Elimination	3,810	23.84	4,054	22.39	4,523	11.13	
HCC177	Amputation Status, Lower Limb/Amputation Complications	3,965	17.86	C2 4,322	17.92	C2 1,274	3.37	C3
Disabled/Disease Interactions								
D-HCC5	Disabled Opportunistic Infections	3,965	5.49	4,047	5.52	—	—	
D-HCC44	Disabled Severe Hematological Disorders	4,649	9.98	4,580	9.72	—	—	
D-HCC51	Disabled Drug/Alcohol Psychosis	2,830	7.12	2,608	6.32	—	—	
D-HCC52	Disabled Drug/Alcohol Dependence	2,160	6.90	2,122	6.61	—	—	
D-HCC107	Disabled Cystic Fibrosis	9,691	6.70	9,547	6.63	—	—	

Refer to NOTES at end of table.

Table 2—Continued

Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC) Combined, Community, and Institutional Models

Variable		Models					
		Combined		Community		Institutional	
		Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio	Parameter Estimate	*t*-ratio
Disease Interactions							
INT1	DM-CHF1	1,265	14.62	1,296	14.46	1,064	2.91
INT2	DM-CVD	490	4.05	639	4.89	—	—
INT3	CHF-COPD	1,261	14.82	1,238	14.06	1,906	4.95
INT4	COPD-CVD-CAD	316	1.49	406	1.82	—	—
INT5	RF-CHF1	857	3.94	1,202	5.24	—	—
INT6	RF-CHF-DM1	4,185	18.48	4,433	18.71	—	—

NOTES: Beneficiaries with the three-way interaction RF-CHF-DM are excluded from the two-way interactions DM-CHF and RF-CHF. DM is diabetes mellitus (HCCs 15-19). CHF is congestive heart failure (HCC 80). COPD is chronic obstructive pulmonary disease (HCC 108). CVD is cerebrovascular disease (HCCs 95-96, 100-101). CAD is coronary artery disease (HCCs 81-83). RF is renal failure (HCC 131). "|" means coefficients of HCCs are constrained to be equal. C1, C2, and C3 denote non-contiguous constraints.

SOURCE: Pope, G.C. and Kautter, J., RTI International, Ellis, R.P. and Ash, A.S., Boston University, Ayanian, J.Z., Harvard Medical School and Brigham and Women's Hospital, Iezzoni, L.I., Harvard Medical School and Beth Israel Deaconess Medical Center, Ingber, M.J., Levy, J.M., and Robst, J., Centers for Medicare & Medicaid Services, Analysis of 1999-2000 Medicare 5% Standard Analytic File (SAF).

chest pain, $0; and ankle sprain, $0[13] (Table 2). Her total cost prediction is the sum of these increments, or $9,907.

Calibration of DCG/HCC models on several years of data reveals increasingly thorough diagnostic coding. For example, if 1999 diagnoses are used to predict expenditures with a model calibrated on 1996/1997 data, mean expenditures will be over predicted. If more complete coding over time is not accounted for, MCOs will be overpaid by the use of current diagnoses with a model calibrated on historical data. CMS makes a slight downward adjustment in HCC-predicted expenditures to account for this.

CMS-HCC Models for Subpopulations

Medicare beneficiaries differ along characteristics that are important for risk adjustment. First, they may be entitled to Medicare in one of three ways: age, disability, or ESRD. Second, some beneficiaries reside in institutions rather than in the community. Third, some enrollees are new to Medicare and do not have complete diagnostic data. Fourth, Medicare is a secondary payer for some beneficiaries. To account for the different cost and diagnostic patterns of these disparate subgroups of beneficiaries, the CMS-HCC model was adapted for Medicare subpopulations. This section describes models for subpopulations.[14]

Beneficiaries Entitled by Disability

Approximately 12 percent of Medicare beneficiaries are entitled to Medicare because they are under age 65 and have a medical condition that prevents them from working (the disabled). Models calibrated on the full Medicare population (excluding ESRD eligibles), mostly reflect cost patterns among the elderly, the other 88 percent of the population. The implications of some diagnoses might differ between the elderly and disabled. For example, a diagnosis that is disabling may be more severe, and the cost of treating a disease may vary by age. We considered allowing differences in incremental expenditure weights for some diagnoses (HCCs) for the disabled (Pope et al., 1998; 2000b).

[13] The female receives no incremental cost prediction for angina pectoris because AMI is higher-ranked in the coronary artery disease hierarchy and excludes angina. No incremental prediction is made for chest pain and ankle sprain because these diagnoses are not included in the CMS-HCC model.

[14] Risk-adjustment models for ESRD-entitled and functionally-limited beneficiaries are not described in this article.

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Using Medicare's 5-percent sample FFS data (1996-1997), we estimated the DCG/HCC model separately on aged and disabled subsamples. We evaluated differences in age versus disabled parameter estimates according to their statistical significance, magnitude, clinical plausibility, and frequency of occurrence in the disabled population (Pope et al., 2000b). Based on these considerations, we chose nine diagnostic categories to receive incremental payments when they occur among disabled beneficiaries. Five of these categories remained significantly different for the disabled when the CMS-HCC model was re-estimated on 1999-2000 data: opportunistic infections, severe hematological disorders (e.g., hemophilia, sickle cell anemia), drug/alcohol psychosis, drug/alcohol dependence, and cystic fibrosis. Incremental annual payments for these conditions among the disabled (in addition to base payments for the elderly) are substantial, ranging from $2,160 to $9,691.

Other than for these five conditions, disease risk-adjustment weights are the same for the aged and disabled populations. The CMS-HCC model is estimated on a combined sample of aged and disabled beneficiaries, with disabled interactions for these five diagnostic categories. The combined aged/disabled model is shown in Table 2.

Community and Institutional Residents

Using the newly available Medicare MDS, we identified long–term nursing home residents in the current (i.e., payment) year. Long-term nursing home residence was defined as continuously residing in a nursing home for at least 90 days, as indicated by a 90-day clinical assessment reported by the nursing facility through the MDS. In our prospective risk-adjustment modeling sample of 1,337,887 beneficiaries, 65,593 beneficiaries, or 5 percent, had at least 1 month of long-term nursing facility residence in 2000.[15]

Table 3 compares sample sizes and mean expenditures by demographic categories for community and institutional residents, and shows predictive ratios from the CMS-HCC model calibrated on the combined community/institutional sample (Table 2). Nearly one-half (49 percent) of long-term nursing facility residents are age 85 or over. Facility residents are only 2 percent of the combined community plus institutional population for females age 70 to 74, but fully 37 percent of the combined population for females age 95 or over.

Overall, institutional residents are 71 percent more expensive than community residents, $8,937 in mean annualized expenditures compared to $5,213. The age profiles of expenditures are quite different. Among community residents, mean expenditures rise steadily with age in the under 65 disabled population and then again in the elderly population, except for a slight decline for the oldest females. In contrast, among the institutionalized, mean expenditures are fairly constant across all ages until they decline significantly among the oldest old. For all age/sex cells except the oldest old, mean expenditures for the institutionalized are substantially higher than for community-dwelling beneficiaries.

However, although not shown in Table 3, among beneficiaries diagnosed with particular HCCs, mean expenditures for the institutionalized are often similar to those of community residents. For example, among all beneficiaries with CHF (HCC 80), expenditures for the institutionalized are $11,719, which is $255 less than for community residents. More generally, when classifying people by the presence of

[15] Beneficiaries with both community and long-term institutional months in the same year are included in both samples, weighted by the fraction of their total months alive in the year in each status.

Table 3

Descriptive Statistics for Community and Institutionalized Residents

	Community			Institutional		
Variable	Observations	Mean Annualized Expenditures	Predictive Ratio[1]	Observations	Mean Annualized Expenditures	Predictive Ratio[1]
Overall	1,291,308	5,213	0.99	65,593	8,937	1.12
Demographics						
Female						
0-34 Years	7,007	3,623	1.00	49	9,251	0.99
35-44 Years	15,566	4,332	1.00	199	9,395	0.94
45-54 Years	22,077	4,692	1.00	473	8,869	1.07
55-59 Years	14,023	5,254	1.00	343	10,168	0.91
60-64 Years	15,793	5,993	1.00	501	9,906	1.04
65-69 Years	129,970	3,714	1.00	1,380	10,961	0.99
70-74 Years	171,775	4,372	1.00	3,098	10,901	0.97
75-79 Years	157,586	5,260	1.00	6,260	9,458	1.08
80-84 Years	111,303	6,101	0.99	9,801	8,797	1.13
85-89 Years	66,301	6,882	0.97	12,294	8,054	1.19
90-94 Years	26,852	7,606	0.92	9,535	7,146	1.29
95 Years or Over	8,074	7,338	0.83	4,729	5,734	1.42
Male						
0-34 Years	10,272	2,868	1.00	106	10,622	0.95
35-44 Years	22,913	3,666	1.00	384	9,596	0.92
45-54 Years	29,377	3,968	1.00	606	10,186	0.91
55-59 Years	16,391	4,651	1.00	438	10,340	0.96
60-64 Years	18,581	5,214	1.00	588	10,486	1.00
65-69 Years	105,856	4,018	1.00	1,132	12,432	0.88
70-74 Years	128,874	5,014	1.00	1,921	11,501	0.99
75-79 Years	106,402	6,207	1.00	2,842	11,411	1.04
80-84 Years	64,263	7,083	1.00	3,404	11,049	1.06
85-89 Years	30,765	8,144	0.99	3,116	10,754	1.08
90-94 Years	9,343	8,731	0.97	1,783	9,489	1.20
95 Years or Over	1,944	9,062	0.92	611	8,096	1.37
Medicaid	196,604	6,523	0.97	33,074	8,895	1.17
Originally-Disabled	81,894	7,614	0.99	7,415	10,606	1.11

[1] Ratio of mean expenditures predicted by the Centers for Medicare & Medicaid Services - Hierarchical Condition Categories (CMS-HCC) model for combined community/institutional samples to mean actual expenditures.

SOURCE: Pope, G.C. and Kautter, J., RTI International, Ellis, R.P. and Ash, A.S., Boston University, Ayanian, J.Z., Harvard Medical School and Brigham and Women's Hospital, Iezzoni, L.I., Harvard Medical School and Beth Israel Deaconess Medical Center, Ingber, M.J., Levy, J.M., and Robst, J., Centers for Medicare & Medicaid Services, Analysis of 1999-2000 Medicare 5% Standard Analytic File (SAF).

a single diagnosis, expenditures for the institutionalized may be higher, lower, or about the same.

Thus, the main reason that people in facilities cost more is that they have more medical problems, a distinction that is fully accounted for by the HCCs. In fact, the predictive ratios from the combined CMS-HCC model for community and institutional beneficiaries are, respectively, 0.99 and 1.12 (Table 3). This means that the combined model, on average, under predicts expenditures for community residents by 1 percent, and over predicts expenditures for long–term nursing home residents by 12 percent. Lower expenditures among facility residents adjusting for disease burden could result from substituting non-Medicare for Medicare-reimbursed services; since most nursing home service are not reimbursed by Medicare. Also, greater monitoring of nursing home than community residents may identify and prevent problems leading to hospitalization. The under-prediction for community residents and over-prediction for facility residents is most severe for the oldest age groups, most likely due to decisions to limit

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aggressive care for very old residents in nursing homes. The over-prediction of the costs of the institutionalized, together with their different cost patterns by age and diagnosis, led us to consider differentiating the CMS-HCC model for community and institutional populations.

Within a multiple regression model estimation framework, we investigated alternative approaches to allowing differences in the model between community and institutional residents, ultimately choosing to estimate separate models. This properly calibrates the prediction of each group's costs, while allowing all demographic and disease coefficients to differ between community and institutional populations.

In addition to the combined model, Table 2 shows the CMS–HCC community and institutional models. Not surprisingly, the community model R^2 and most of the demographic and disease coefficients are very similar to the combined model, because community residents comprise 95 percent of the combined sample. A few coefficients show greater differences. The community coefficients for the oldest age cells are significantly larger than the combined model coefficients because the lower-cost very old institutionalized have been removed from these cells. The community coefficients for the aged enrolled in Medicaid are also significantly higher, as are several HCC coefficients.

The institutional model R^2 is considerably lower than the community model. But some of the community model's predictive power comes from distinguishing beneficiaries who are healthy (no diagnoses) versus sick (with diagnoses), while the institutional model is explaining cost variations among a population comprised entirely of impaired individuals. Diagnoses help explain why someone might be institutionalized (i.e., distinguish healthy from sick), but are not as powerful in explaining expenditure differences among the institutionalized. Disease (HCC) coefficients tend to be smaller in the institutional model than in the community model (Table 2). Diagnoses are less predictive of incremental costs among the more uniformly expensive institutional population than they are among the community population.

We constrained certain groups of demographic and diagnostic coefficients in the institutional model to be equal (Table 2), because the small available sample of institutionalized beneficiaries resulted in their low prevalence in some diagnostic categories (HCCs) and made it difficult to obtain stable estimates of each separate parameter. For the same reason, we included no disabled interaction terms, and only two of the disease interaction terms in the institutional model. Also, HCC 158 Hip Fracture/Dislocation was excluded because its coefficient was negative.

The age/sex coefficients for the institutionalized are much higher than for community residents except for the oldest ages. This implies that institutionalized beneficiaries are predicted to be expensive regardless of their diagnostic profile (e.g., even lacking any of the diagnoses included in the CMS-HCC model), whereas community residents are predicted to be expensive only if diagnosed with at least one of the serious diseases included in the CMS-HCC model. This makes sense since institutionalization itself is a marker of poor health, aside from diagnostic profile, but the institutionalized age/sex coefficients decline for the oldest ages, and fall below the community coefficients. Medical treatment may be less aggressive for old, frail beneficiaries who are institutionalized.

Among the institutional population, the coefficient for Medicaid was negative and the coefficients for originally disabled was statistically insignificant. These variables

were excluded from the institutional model. Beneficiaries often qualify for Medicaid after spending down their personal assets to pay for a lengthy nursing home stay. Thus, Medicaid may be a proxy for beneficiaries in the later portion of their stays, when they are less expensive than in the earlier, post-acute phase of their nursing home tenure.

New Medicare Enrollees

The CMS–HCC model requires a complete 12-month base year diagnostic profile to predict the next year's expenditures. Beneficiaries without 12 months base year Medicare enrollment, but at least 1 month of prediction year enrollment, are defined as new enrollees. About two–thirds of new enrollees are age 65.[16] New enrollees may be under age 65 if they become eligible for Medicare by disability; they may be over age 65 if they delay Medicare enrollment or are not originally enrolled in both Parts A and B.[17] We developed a demographic model to predict expenditures for new enrollees who lack the data needed to apply the CMS-HCC model.

Table 4 presents frequencies and mean annualized expenditures from the 5-percent FFS sample data for new enrollees and continuing enrollees. Continuing enrollees are defined as beneficiaries having 12 months of Parts A and B Medicare enrollment in the base year and at least 1 month in the prediction year. For female and male new enrollees age 65, mean annualized expenditures are $2,729 and $2,900, respectively, less than one-half of costs of continuing enrollees ($6,952 for female and $6,055 for male). For almost all new enrollees age 65, the original reason for Medicare entitlement is age.[18] In contrast, continuing enrollees age 65 were originally entitled to Medicare by disability, and hence are much more expensive. For other ages, mean expenditures of new and continuing enrollees are much more similar. To achieve sufficient sample sizes in all age ranges to calibrate the new enrollees model, we merged the new and continuing enrollees samples, which resulted in a sample size of 1,495,225 with mean expenditures of $5,184. For age 65, actual new enrollees dominate the combined sample, and the cost weight reflects their (low) relative costs. Continuing enrollees age 65 are included in the sample to calibrate the originally disabled coefficient for age 65. For other than age 65, the sample is dominated by continuing enrollees, but their costs appear to proxy actual new enrollee costs reasonably well for younger or older ages.

Beneficiaries for Whom Medicare is a Secondary Payer

Working aged beneficiaries are Medicare beneficiaries, age 65 or over, with private group health insurance coverage from their or their spouse's employer. By law, Medicare is a secondary payer for these beneficiaries. The primary private health plan must pay for medical expenses to the extent of its defined benefits. Only if Medicare covers services not covered by the private plan, or has more generous coverage (e.g., lower deductibles or copayments) for Medicare-covered services, is Medicare responsible for payment, and then only to the extent of the difference in

[16] To simplify the new enrollees model, we recoded new enrollees age 64 on February 1 with an original reason for Medicare entitlement of aged to age 65. Thus, the age 65 cell in the new enrollees model combines new enrollees ages 64 and 65 on February 1 of the prediction year whose original reason for entitlement is aged.

[17] For example, a beneficiary might be entitled to Part A (hospital insurance) by age at age 65 or over, but might not pay Part B (physician insurance) premium until an older age.

[18] Some age 65 new enrollees might have originally been entitled to Medicare by disability when under age 65, but then have rejoined the work force and lost their Medicare eligibility, only to re-enroll at age 65.

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Table 4

Descriptive Statistics for New and Continuing Medicare Enrollees[1]

Age/Sex Category	New Enrollees[2] Observations	New Enrollees[2] Mean Annualized Expenditures	Continuing Enrollees[3] Observations	Continuing Enrollees[3] Mean Annualized Expenditures
Female				
0-34 Years	2,540	3,532	7,037	3,653
35-44 Years	3,685	4,341	15,717	4,385
45-54 Years	5,891	4,814	22,431	4,767
55-59 Years	4,029	4,903	14,277	5,354
60-64 Years	3,310	5,705	16,159	6,094
65 Years	58,946	2,729	3,336	6,952
66 Years	1,448	3,319	29,534	3,401
67 Years	845	3,349	31,560	3,684
68 Years	531	3,116	32,578	3,740
69 Years	504	3,608	33,893	3,905
70-74 Years	1,311	4,672	173,829	4,461
75-79 Years	471	5,063	161,843	5,387
80-84 Years	200	6,043	118,144	6,276
85-89 Years	95	8,111	75,186	7,035
90-94 Years	46	5,931	34,135	7,500
95 Years or Over	15	6,457	11,886	6,795
Male				
0-34 Years	3,434	3,089	10,342	2,934
35-44 Years	4,281	3,690	23,172	3,746
45-54 Years	5,820	4,099	29,814	4,074
55-59 Years	4,120	4,603	16,677	4,772
60-64 Years	4,196	4,775	18,986	5,346
65 Years	46,262	2,900	3,940	6,055
66 Years	1,546	3,205	24,472	3,644
67 Years	872	2,976	25,279	3,933
68 Years	570	3,501	25,915	4,145
69 Years	490	3,638	27,009	4,295
70-74 Years	1,223	5,700	130,148	5,087
75-79 Years	429	6,476	108,214	6,307
80-84 Years	144	5,916	66,505	7,231
85-89 Years	63	8,028	32,848	8,326
90-94 Years	19	13,027	10,601	8,827
95 Years or Over	2	3,221	2,420	8,867

[1] Aged and disabled beneficiaries. Excludes working aged and ESRD beneficiaries.

[2] Enrollees with less than 12 months of base year eligibility.

[3] Enrollees with 12 months of base year eligibility.

SOURCE: Pope, G.C. and Kautter, J., RTI International, Ellis, R.P. and Ash, A.S., Boston University, Ayanian, J.Z., Harvard Medical School and Brigham and Women's Hospital, Iezzoni, L.I., Harvard Medical School and Beth Israel Deaconess Medical Center, Ingber, M.J., Levy, J.M., and Robst, J., Centers for Medicare & Medicaid Services, Analysis of 1999-2000 Medicare 5% Standard Analytic File (SAF).

coverage. Medicare expenditures for working aged beneficiaries are lower for this reason, as well as because working may be a proxy for better health.[19] Estimation of a separate model for the working aged is not feasible with the sample sizes available from the Medicare's 5-percent FFS sample. A simple adjustment to CMS–HCC model predictions is a multiplier that scales cost predictions to be lower for these beneficiaries.

We defined the working aged as beneficiaries otherwise satisfying the requirements of our 1999-2000 aged/disabled prospective modeling sample who had at least 1 month of working aged status in the prediction year (2000). There are 19,057 beneficiaries in our working aged sample, or about 1.4 percent as many individuals as in our aged/disabled sample. The mean annualized expenditures of the working aged are $966, less than one-fifth as much as for the aged/disabled community sample ($5,213). The CMS–HCC community

[19] Throughout this section, we use the terms working and working aged to include both those who are actually working, and the spouses of those who are working.

model over-predicts mean working aged expenditures by a factor of 3.66. Essentially, we define the working aged multiplier as the ratio of mean actual to mean predicted expenditures for the working aged sample, where expenditures are predicted by the CMS-HCC community model. With an adjustment for beneficiaries who have a mixture of working aged and non-working-aged months in the payment year, the working aged multiplier is 0.215.

CONCLUSIONS

CMS' adaptation of the DCG/HCC model makes substantially more accurate predictions of medical costs for M+C enrollees than has previously been possible. Its use is intended to redirect money away from MCOs that cherry-pick the healthy, while providing the MCOs that care for the sickest patients the resources to do so. The ultimate purpose of the CMS-HCC payment model is to promote fair payments to MCOs that reward efficiency and encourage excellent care for the chronically ill. The CMS-HCC model will continue to evolve. Additional diagnoses may be needed to predict drug expenditures incurred under the drug benefit enacted by MMA (2003). The model may need to be recalibrated to reflect new treatment patterns and disease prevalence. Diagnosis-based risk adjustment may need to be coordinated with disease management programs and incentives for quality of care.

The model has evolved over two decades of research,[20] with careful attention to clinical credibility, real-world incentives and feasibility tradeoffs. Continuous feedback between government technical staff and policymakers at CMS on the one hand, and research organization and academic researchers on the other, has shaped the CMS-HCC model. Much of the recent research reported in this article has related to adapting the model for Medicare subpopulations. The use of a single modeling framework—the CMS-HCC model—provides unity and organization to the subgroup models with the unique features specific to certain types of beneficiaries. Comprehensive risk adjustment, based on ambulatory as well as inpatient diagnoses, is just beginning to be implemented. Thus, it is too early to tell whether it will achieve its goals. As risk adjustment continues to be incorporated in Medicare payments to MCOs, it will be important to evaluate its impact on these organizations and the beneficiaries they serve, especially organizations that care for the chronically ill and their enrollees. This will tell us a great deal about the feasibility and consequences of matching health care resources to needs.

[20] The DCG line of risk-adjustment research dates back to the report by Ash et al. (1989), based on research begun in 1984.

ACKNOWLEDGMENT

The authors would like to thank Helen Margulis for her exceptional computer programming assistance.

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Incorporating New Research Into Medicare Risk Adjustment

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Background: The Medicare Advantage payment system underpays health plans that enroll beneficiaries with multiple and complex chronic conditions.

Objectives: This article addresses 3 major problems in the current payment system: (1) underreporting of chronic disease prevalence in fee-for-service (FFS) Medicare claims data, (2) overpayment of healthier and underpayment of sicker beneficiaries in the current payment system, and (3) underpayment for new beneficiaries in Medicare Advantage plans that require the beneficiaries to have at least one chronic disease to enroll.

Research Design: We incorporate 2 years of data and a count of chronic diseases in the current Medicare payment model. We develop a separate payment adjustment for new enrollees.

Subjects: A nationally representative sample of FFS beneficiaries in the 2004–2006 Medicare 5% claims data.

Measures: We use predictive ratios to evaluate whether our enhanced model improves the predictive accuracy over the current model overall and for subsets of beneficiaries.

Results: The underreporting of chronic disease prevalence in Medicare FFS by 20% leads to systematic bias in the disease coefficients and demographic adjusters. The enhanced model reduces the level of payment for healthy beneficiaries and increases the payment for beneficiaries with multiple and complex chronic conditions. It improves payment for plans that enroll new enrollees with specific chronic conditions.

Conclusions: Our enhanced model reduces financial incentives for health plans to engage in risk selection against beneficiaries with multiple chronic conditions.

Key Words: Medicare advantage, risk adjustment, chronic disease, aged, rate setting

(*Med Care* 2011;49: 295–300)

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Supported by XLHealth.

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Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.lww-medicalcare.com).

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ISSN: 0025-7079/11/4903-0295

Spending in Medicare is highly concentrated; for example, two-thirds of Medicare spending is by beneficiaries with 5 or more chronic diseases.[1] Beneficiaries with complex and comorbid conditions can benefit from high-quality, integrated and coordinated medical care. This can be difficult to obtain in the fee-for-service (FFS) sector and thus beneficiaries with multiple chronic conditions often receive lower quality of care.[2] Consequently, the Centers for Medicare and Medicaid Services (CMS) has encouraged beneficiaries to enroll in Medicare Advantage (MA) programs, which covered about a quarter of Medicare beneficiaries in 2010. Special Needs Plans, a subset of MA plans, focus on providing coordinated care for beneficiaries with chronic conditions.

MA plans need to be paid appropriately to avoid risk selection. Payment rates for MA plans are based on diagnosed conditions and demographics measured within the FFS system. The literature recognizes that the current system overpays for healthier than average beneficiaries and underpays MA plans caring for beneficiaries with complex and comorbid conditions.[3–8] The current model relies on an additive model to predict spending for Medicare beneficiaries and largely ignores higher cost of treating patients with multiple chronic diseases, especially those with 4, 5, or more chronic conditions.[9–12] The current risk adjustment model has not been substantially updated since January 2004 and was based on research conducted primarily in the late 1990s.

We propose a revised payment model that includes the latest research on persistency of chronic diseases and recognizes the higher costs of treating beneficiaries with multiple chronic diseases to encourage MA plans to enroll and care for beneficiaries with complex and comorbid diseases. We also propose an adjustment for the health status of new enrollees into MA plans that requires the enrollee to have a chronic disease upon entry.

CURRENT RISK ADJUSTMENT MODEL

The current CMS model adjusts for the beneficiaries' most severe conditions, demographics (age and gender), dual eligibility, disability status, original reason for entitlement, and interactions between a few medical conditions. The risk adjustment model is based on the work originally done by Pope et al[13,14] and then modified by CMS. The current model uses hierarchical condition categories (HCCs) that map all ICD-9-CM diagnosis codes into 189 distinct condition categories. Diagnoses representing similar diseases are first organized into body systems and within that body system, ICD-9-CM codes with similar expected annual expenditures are

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combined together. Ultimately, CMS decided to use only 70 of the 189 condition categories, arguing that the more parsimonious model predicted almost as well as the full model.[14] Hence, some chronic conditions were excluded from the final model. The 70 HCCs are ranked hierarchically such that the most severe manifestation of a set of related conditions is coded. The payment does not depend on where the diagnosis is made, for example, inpatient versus outpatient. The HCC payment levels are continually updated with new data, but the underlying HCC groupings are not.

The current model takes into account 4 two-way and 2 three-way interactions among 6 common and high cost chronic diseases. Among the nonaged and disabled Medicare population, 5 additional conditions associated with high frequencies of disability are interacted with disability status. In April 2009, CMS instituted a 1.041 normalization factor for the age-disabled payment model to MA plans, which would reduce payments across all MA plans. This adjustment does not affect the relative level of payment between sick and healthy beneficiaries.

Community, institutional, and new enrollee populations are calibrated separately with parameter estimates updated every 2 years with a 4- to 5-year time lag (eg, 2005/2006 data are used to set 2010 rates). Beneficiaries with end-stage renal disease (ESRD) have separate parameter estimates that take into account whether the person is on dialysis, the person had a kidney transplant (with and without pancreas transplant), and their level of functioning grafts. We focus only on the community-dwelling population, but our concepts apply to other populations as well.

New beneficiaries are not assigned HCCs in their first year of enrollment because CMS does not have diagnosis data from the prior year. Instead, all new enrollees are assumed to have the health status of the average Medicare beneficiary, and are reimbursed accordingly. This can be problematic for Special Needs Plans if the beneficiary needs to have at least one chronic disease to enroll in the plan.

METHODS

Data Sets

We use the Medicare 5% sample (2004–2006), a commonly used, nationally representative sample of all Medicare beneficiaries. From the initial sample of 2,525,005, we created a community FFS sample by excluding beneficiaries enrolled in MA plans, institutionalized beneficiaries (90 or more days in a special needs facility), and beneficiaries who have ESRD or are disabled. Institutionalized, disabled, and ESRD beneficiaries are treated slightly differently in the Medicare calculations, and MA beneficiaries are not used in the calculation used to set their rates. Because they are missing essential clinical data, we dropped beneficiaries without both Part A and B coverage or were not a US resident between 2004 and 2006.

We divided the sample into 2 separate groups: (1) new enrollees and (2) aged beneficiaries meeting the conditions described earlier. New enrollees are defined as beneficiaries who completed the age of 65 in 2006 and were not previously disabled (N = 32,013). The second group of beneficiaries are age 65 years or older as of January 1, 2004, enrolled for a full 24 months of 2004 and 2005 and at least one day in 2006 (N = 1,115,936).

Variable Selection

The dependent variable is the 2006 annualized total Medicare expenditures adjusted for the number of months that the beneficiary was alive in 2006. For example, a beneficiary alive for 6 months in 2006 is given a weight of 0.5. The dependent variable is the amount the Medicare program paid and does not reflect any out-of-pocket spending by Medicare beneficiaries or payments by Medicare supplemental (Medigap) plans.

We examined 2 validated comorbidity measures to estimate the incremental costs of treating beneficiaries with multiple chronic diseases.[15,16] Both measures were independently entered into the model as index and as dummy variables (present/absent) for each comorbid condition. We created a third measure that counts the number of chronic diseases based on definitions developed by the Clinical Classification Software (CCS) at Agency for Healthcare Research and Quality.[17] The CCS software groups all ICD-9-CM codes into 285 mutually exclusive diagnoses groups, which are updated annually. We only used the CCS groups corresponding to chronic diseases. The CCS measure is a count of the number of chronic conditions.

The CCS methodology was designed to be a comprehensive measure used in any clinical setting that uses ICD-9-CM; a primary advantage over the Elixhauser and Deyo/Charlson measures, which were designed for inpatient settings only. In addition, the Elixhauser and Deyo/Charlson measures are based on a restricted list of conditions, whereas a count of CCS includes all chronic conditions. Finally, the CCS categories are updated annually.

We also investigated using 2 years of FFS data as an alternative to using only 1 year. The clinical rationale is clear—when a beneficiary acquires a chronic disease such as diabetes or chronic obstructive pulmonary disease (COPD), the beneficiary will likely have the disease for life. However, the current FFS payment system does not provide financial incentives for FFS providers to record all chronic diseases on each claim form. As a result, the number of chronic diseases could be significantly undercounted. This could bias the calculation of HCC scores and demographic factors because some of the chronic conditions are not recorded annually.

Estimation and Predictive Ratios

We use a multivariate linear regression and predictive ratios (PRs) to calculate and then compare the current and proposed models. A split sample methodology is used. Parameter estimates based on 50% of a randomly chosen sample (557,973 observations) are used to predict expenditures in 2006. The other half is used to test the predictive power of the model. PRs are a standard approach in the risk-adjustment literature to compare alternative models.[14,18,19] PRs are the predicted level of total payments divided by the actual expenses for the same group of beneficiaries in the same year. The objective is to create a model with PRs as close to 1.0 as possible to avoid risk selection. A ratio <1.0 means the predicted pay-

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ment is lower than the actual spending, and MA plans will have a financial incentive to avoid these individuals. If the ratio is >1.0, then the predicted spending is above actual spending; MA plans will be encouraged to enroll these beneficiaries.

PRs allow comparisons of subgroups of the population to detect areas where risk selection can occur versus R-squared, which only provides information about variability explained. One hundred random (with replacement) samples, with 1000 beneficiaries in each sample were drawn. We used the same process for subgroups (eg, males) to determine the possibility of risk selection in certain subgroups of the population. We chose 1000 beneficiaries as an approximation of the size of the MA plans. We repeat this process 100 times to calculate 95% confidence intervals (using the 2.5th and 97.5th percentile PR values).

RESULTS

Table 1 shows the characteristics of the sample. Particularly important to note are that 30% of Medicare beneficiaries have 5 or more recorded chronic diseases and about 10% of the sample has at least 1 mental illness.

Persistency

Table 2 shows that chronic diseases are not consistently or persistently reported over time in Medicare FFS. For example, based on only 1 year of data, 13.7% of beneficiaries were identified as having COPD; but using 2 years of data, 18.9% were identified as having COPD. Assuming a beneficiary had COPD both years, 38% of beneficiaries with COPD are underreported using only 1 year of data. The level of underreporting for 5 common chronic diseases varied from 13.5% for diabetes to 38.0% for COPD. Overall, approximately 20% more chronic diseases are recorded using 2 years of data. This is a significant undercount and could bias the regression coefficients.

By using 2 years of data, the current model lowered nearly all the parameter estimates (data not shown). This can be explained statistically—beneficiaries with unreported chronic conditions are likely to have higher costs than beneficiaries with no chronic conditions. However, the regression coefficients estimated using 1 year of data compensates for this undercount by inflating the coefficients on the demographic and HCC variables.

It is inappropriate to use 1 year of data to calculate the coefficients to set the payment rates and then use 2 years of data to calculate the expected payment, but this approximates what happens. Although the Medicare program calculates the rates based on 1-year data in the FFS sector, MA plans record the prevalence of chronic disease more accurately, which resembles the 2-year data. This could lead to overpayments by as much as 20% if MA plans recorded all the chronic conditions.

Current Model

We calculated the payment rates using the first half of the split sample. The first model attempts to replicate the current payment method. The base payment of $2771 reflects the cost of a woman age 65 to 69 with no diseases that warrant an HCC score and no other characteristics (dual eligible, etc) that are included in the model (Appendix Table A1, Supplemental Digital Content, online only, available at: http://links.lww.com/MLR/A167). Expenditures increase with age, for example, women 70 to 74 years of age are $414 more expensive than women 65 to 69. Among the HCC groups, metastatic cancer and acute leukemia (HCC, 7) has the highest value of $14,732.

Most coefficients are statistically significant at $P \leq 0.01$, which is not surprising given the large sample size. There are some HCCs with relatively few observations and this could result in potentially unstable and confusing results. The number of beneficiaries with a specific HCC varies considerably from 10 beneficiaries with extensive third-degree burns to 89,226 with diabetes without complication. A few parameter estimates are surprisingly small given the seriousness of the illness. For example, the value for breast, prostate, colorectal, and other cancers and tumors (HCC, 10) is only $1835. There are some statistically insignificant coefficients that also tended to be negative (eg, coma/brain

TABLE 1. Characteristics of Aged Medicare Beneficiary Sample

Characteristics	Medicare Sample (N = 1,115,936)
Female	58.9%
65–69 yr	13.4%
70–74 yr	23.9%
75–79 yr	22.9%
80–84	19.4%
≥85	20.4%
Male	40.9%
65–69 yr	16.9%
70–74 yr	28.6%
75–79 yr	24.2%
80–84	17.4%
≥85	13.0%
Originally disabled	7.2%
Dual eligible in 2006	12.2%
No. chronic diseases (count of CCS categories) in 2005	
None	13.2%
1	11.6%
2	14.9%
3	16.1%
4	13.9%
≥5	30.3%
Prevalence of specific chronic diseases in 2005	
Chronic kidney failure	2.5%
Congestive heart failure	9.2%
COPD	13.7%
Diabetes	20.8%
Cardiovascular disease	68.9%
Mental illnesses	11.1%

Diabetes is defined as ICD-9-CM 250.x (all); chronic obstructive pulmonary disease is 490.x to 496.x (all); cardiovascular disease is 390.x to 459.x; congestive heart failure is 428.x (all); chronic kidney failure is 585.x (all); mental illness is 290.x to 318.x (all), 331.x (all), 357.5, 425.5, 535.3, 571.1, 648.3 to 648.4, 655.5, 760.7, 779.5, 790.3, 797, 965.0, E95xx, V11xx, V15xx, V663, V7xxx.

COPD indicates chronic obstructive pulmonary disease; CCS, Clinical Classification Software.

Source: 2004–2006 Medicare 5% sample.

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TABLE 2. Consequence of Inconsistent Reporting of Chronic Disease: Using 1 Versus 2 Years of Data

	1-Year Data (2005) Recorded Prevalence (%)	2-Year Data (2004 and/or 2005) Recorded Prevalence (%)	Increase in Prevalence (%)
Chronic kidney failure	2.5	3.2	28.0
Congestive heart failure	9.2	12.5	35.9
Chronic obstructive pulmonary disorder	13.7	18.9	38.0
Diabetes mellitus	20.8	23.6	13.5
Cardiovascular disease	68.9	78.4	13.8

Diabetes is defined as ICD-9-CM 250.x (all); chronic obstructive pulmonary disease is 490.x to 496.x (all); cardiovascular disease is 390.x to 459.x; congestive heart failure is 428.x (all); chronic kidney failure is 585.x (all), mental illness is 290.x to 318.x (all), 331.x (all), 357.5, 425.5, 535.3, 571.1, 648.3 to 648.4, 655.5, 760.7, 779.5, 790.3, 797, 965.0, E95xx, V11xx, V15xx, V663, V7xxx.
Source: 2004–2006 Medicare 5% sample.

compression/anoxic damage; HCC, 75). The interaction between chronic kidney failure and congestive heart failure had a statistically significant negative parameter. A beneficiary with these 2 diseases has their total cost of care reduced by $614, yet the lower cost of care is unlikely and is contrary to the literature that suggests having multiple chronic diseases require more complex care. The usual procedure for CMS is to exclude HCCs with negative parameters. We chose not to remove these parameters to stay consistent with the theoretical model developed by Pope et al that suggest these diseases are important predictors. This highlights the potential need to revisit the HCC groupings because medical practice may have changed since the HCC groupings were created in the late 1990s. Another possibility is relatively small sample sizes used to create some of the parameter estimates.

The overall PRs for the current model using 1 year of data were close to 1.0 suggesting that the model works reasonably well for a cross-section of Medicare beneficiaries (Table 3). However, we also observed that the PRs are above 1.0 for healthier and less expensive beneficiaries whereas less than 1.0 for sicker and more expensive beneficiaries, which is consistent with the literature on risk selection by MA plans.

Enhanced Model

We then explored various refinements to the current model. Specifically, we investigated various combinations of the inclusion of 2 years of data and 1 of 3 comorbidity measures – (1) the Elixhauser, (2) the Deyo/Charlson, or (3) the CCS count measures—to improve the PRs of the current model. Comparing the various comorbidity measures, we see that the comorbid conditions identified by Elixhauser explained slightly more variation than the set of conditions identified by Charlson-Deyo, and both improved the PRs when using both 1 and 2 years of data (data not shown). The inclusion of the CCS count measure had the greatest effect on the PRs over the other 2 comorbid measures and was therefore included in the enhanced model. The final, or "enhanced," model includes 2 years of data.

TABLE 3. Average Predictive Ratios (With 95% Confidence Intervals) on Medicare 5-Percent Sample (N = 1,115,936)

	Current	Enhanced
Female, all ages	0.99 (0.89, 1.13)	0.99 (0.89, 1.12)
Female, age 65–69	0.97 (0.85, 1.12)	0.97 (0.85, 1.12)
Female, age 70–74	0.99 (0.85, 1.13)	0.99 (0.85, 1.11)
Female, age 75–79	0.99 (0.85, 1.13)	0.99 (0.85, 1.12)
Female, age 80–84	0.98 (0.88, 1.12)	0.98 (0.87, 1.11)
Female, ≥85	0.99 (0.90, 1.09)	0.98 (0.88, 1.09)
Male, all ages	0.98 (0.85, 1.14)	0.97 (0.84, 1.14)
Male, age 65–69	0.99 (0.86, 1.14)	0.98 (0.85, 1.10)
Male, age 70–74	0.98 (0.85, 1.14)	0.98 (0.84, 1.11)
Male, age 75–79	0.98 (0.85, 1.14)	0.98 (0.88, 1.09)
Male, age 80–84	0.98 (0.87, 1.08)	0.98 (0.87, 1.08)
Male, age ≥85	1.00 (0.88, 1.12)	1.00 (0.88, 1.12)
Previous year expenditures		
0–20th percentile	1.50 (1.20, 1.80)	1.24 (0.99, 1.55)
20th–40th percentile	1.22 (1.05, 1.46)	1.22 (1.06, 1.47)
40th–60th percentile	1.05 (0.93, 1.18)	1.11 (0.99, 1.26)
60th–80th percentile	0.89 (0.80, 0.99)	0.97 (0.87, 1.08)
80th–95th percentile	0.85 (0.79, 0.93)	0.86 (0.80, 0.94)
95th–100th percentile	0.84 (0.78, 0.93)	0.78 (0.72, 0.85)
No. chronic diseases		
None	1.46 (1.21, 1.83)	1.01 (0.80, 1.31)
1	1.14 (0.98, 1.29)	0.96 (0.83, 1.15)
2	1.07 (0.95, 1.22)	0.99 (0.87, 1.13)
3	1.00 (0.87, 1.14)	0.97 (0.85, 1.12)
4	0.97 (0.82, 1.12)	0.99 (0.88, 1.11)
≥5	0.90 (0.82, 0.98)	0.99 (0.88, 1.11)
Specific chronic diseases		
Diabetes	0.97 (0.86, 1.10)	0.98 (0.89, 1.10)
Congestive heart failure	0.98 (0.90, 1.05)	0.96 (0.89, 1.04)
Chronic kidney failure	0.93 (0.86, 1.01)	0.94 (0.87, 1.01)
Cardiovascular disease	0.95 (086, 1.06)	0.98 (0.89, 1.08)
COPD	0.95 (0.86, 1.06)	0.97 (0.88, 1.09)
Mental illness		
None	1.00 (0.89, 1.11)	0.98 (0.84, 1.13)
One or more	0.92 (0.84, 1.03)	0.98 (0.88, 1.10)
Schizophrenia	0.96 (0.89, 1.07)	1.00 (0.93, 1.11)

Enhanced model for the Medicare 5-percent data is the current HCC model plus counts of CCS categories (1, 2, 3, 4, 5 or more) with 2 years of data. The previous year expenditure cut-offs are 0 to 20th percentile $0 to $400, 20th to 40th percentile $400 to $1232, 40th to 60th percentile $1232 to $3017, 60th to 80th percentile $3017 to $10319, 80th to 95th percentile $10319 to $44575, 95th to 100th percentile $44575 and above. Diabetes is defined as ICD-9-CM 250.x (all); chronic obstructive pulmonary disease is 490.x to 496.x (all); cardiovascular disease is 390.x to 459.x; congestive heart failure is 428.x (all); chronic kidney failure is 585.x (all), mental illness is 290.x to 318.x (all), 331.x (all), 357.5, 425.5, 535.3, 571.1, 648.3 to 648.4, 655.5, 760.7, 779.5, 790.3, 797, 965.0, E95xx, V11xx, V15xx, V663, V7xxx.
COPD indicates chronic obstructive pulmonary disease.
Source: 2004–2006 Medicare 5% sample.

Our final parameters for the enhanced model are in Appendix Table A1 (Supplemental Digital Content, online only, available at: http://links.lww.com/MLR/A167). The addition of 2 years of data and CCS count measure improve the variability explained slightly from $R^2 = 0.101$ in the current model to $R^2 = 0.104$ in the enhanced model. The most important improvement occurs in the PRs for subgroups of

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the population. As expected, no major differences in the PRs exist between the current and the enhanced models for random groups of beneficiaries or for basic demographic characteristics (Table 3).

The main objective is for the PRs to overlap with 1.0 for all subgroups of the population to reduce incentives for risk selection. The enhanced model achieves this in 4 crucial subgroups. Overpayment is corrected for Medicare beneficiaries in the 0 to 20th percentile of expenditures in the previous year and for beneficiaries with zero chronic diseases. Underpayment is corrected for Medicare beneficiaries in the 60th to 80th percentile and for beneficiaries with 5 or more chronic diseases.

We tried some other alternatives. We tested the CCS categories with 1 and 2 years of data; the combination of 2 years of data and the count of the CCS categories most improved the predictive accuracy of the model (Appendix Table B1, Supplemental Digital Content, online only, available at: http://links.lww.com/MLR/A168). Two years of data significantly improves the predictive accuracy of the model because it recognizes the persistency and the underreporting of chronic disease in the Medicare FFS population.

To address the possibility that the CCS count variable is identifying missing variables, we tested variations on our enhanced model by including all 189 HCCs instead of the 70 HCCs that CMS uses (Appendix Table B1, Supplemental Digital Content, online only, available at: http://links.lww.com/MLR/A168). Our results are similar to the results of Pope et al that suggest the additional 119 HCCs do very little to improve the predictive accuracy of the model.

New Enrollees

We compared the cost of beneficiaries who completed 65 years of age and newly enrolled in Medicare with different levels of chronic disease (Table 4). Beneficiaries with any of the listed chronic diseases were substantially more expensive than the average Medicare beneficiary. For example, in 2006, the Medicare program spent an average of $4393 on a new enrollee in 2006. However, the expected cost for new enrollees with diabetes mellitus was $7764 and $33,304 for beneficiaries with chronic kidney failure. MA plans that enroll one of these individuals and get paid only $4393 are likely to lose a considerable amount of money. Most MA plans have between 5% and 8% new enrollees each year but it varies from plan to plan.

TABLE 4. Average Medicare Expenditures of New Enrollees (N = 32,013) in 2006

All Medicare beneficiaries	$4393
Diabetes mellitus	$7764
Chronic obstructive pulmonary disorder	$16,675
Congestive heart failure	$26,794
Cardiovascular disease	$31,364
Chronic kidney failure	$33,304

Expenditures scaled to 12 months. Diabetes is defined as ICD-9-CM 250.x (all); chronic obstructive pulmonary disease is 490.x to 496.x (all); cardiovascular disease is 390.x to 459.x; congestive heart failure is 428.x (all); chronic kidney failure is 585.x (all), mental illness is 290.x to 318.x (all), 331.x (all), 357.5, 425.5, 535.3, 571.1, 648.3 to 648.4, 655.5, 760.7, 779.5, 790.3, 797, 965.0, E95xx, V11xx, V15xx, V663, V7xxx.
Source: 2004–2006 Medicare 5% sample.

DISCUSSION

The current model includes a parsimonious number of common combinations of chronic diseases. Our analysis suggests that their inclusion does little to improve the PRs in the enhanced model (Appendix Table B1, Supplemental Digital Content, online only, available at: http://links.lww.com/MLR/A168). The literature suggests that interactions between chronic conditions may be important, but to identify and test every combination of chronic conditions would be virtually impossible. The CCS count measure represents general combinations of chronic diseases by adding an extra parameter value depending on the number of chronic diseases that a person has (1, 2, 3, 4, 5 or more). Conceptually, it reflects that the cost of treating someone with both disease A and disease B is greater than the cost of treating one person with disease A and a different person with disease B. The interaction of diseases A and B adds to the cost. Our empirical estimates (Appendix Table A1, Supplemental Digital Content, online only, available at: http://links.lww.com/MLR/A167) suggest that the cost increases dramatically after the beneficiary has 5 or more chronic conditions.

The number of CCS categories used as an adjustment variable has limitations. First, all chronic conditions are considered as equal although some are more serious than others. Fortunately, the HCCs already differentiate complex versus simple chronic conditions. The intention of the CCS variable is to differentiate persons with 0, 1, 2, 3, 4, 5 or more chronic conditions since, according to the literature, the number of chronic conditions in addition to the type of chronic condition increases costs and results in poorer outcomes. The CCS count measure is not intended to be a measure of comorbidity severity. We counted a beneficiary as having a CCS category if the person had an inpatient diagnosis with the condition or 2 distinct outpatient diagnoses with that condition. This approach eliminates "rule out" conditions.

As another concern, the CCS categories include conditions that were explicitly excluded from the HCCs. However, our empirical results show that the count of the number of chronic conditions is associated with higher costs in Medicare beneficiaries and, unless these costs are recognized, health plans will engage in risk selection. The disadvantage of the simple CCS count is gaming by upcoding the number of chronic diseases. However, this is on the FFS side; CMS is already concerned that MA plans have this incentive because the plans are already paid on the basis of the number of chronic conditions (HCC categories).

Administrative feasibility is of concern with any risk adjustment model. The CCS categories are in the public domain and do not require collection of new data. Also, no additional administrative efforts are anticipated if Medicare used 2 years of FFS data instead of 1 year.[18] In fact, incorporating 2 years of data could reduce the level of gaming by MA plans; HCC scores are reduced and the probability increases that a beneficiary is correctly identified as having a chronic disease. Thus MA plans would have reduced incentives to up-code.

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CONCLUSION

Although the current model substantially overpays beneficiaries with zero chronic diseases and systematically underpays beneficiaries with multiple chronic diseases, the enhanced model reduces the incentives for health plans to engage in risk selection. In the enhanced model, the PRs are similar for beneficiaries with zero through 5 or more chronic diseases. Using 2 years of FFS data increases the number of chronic disease recorded by approximately 20% and reduces the coefficients of the demographic and HCC scores by approximately 20%. The result of this bias in the current model is overpayment to MA plans by approximately 20%.

The current model disadvantages MA plans that enroll beneficiaries new to the Medicare program by failing to take into account their existing chronic diseases. To improve accuracy of Medicare payments, one method would be to substitute in the higher costs of new enrollees (Table 4). Another alternative is to calculate the average cost of the MA plan that the newly eligible beneficiary is enrolling into, compare it to the average cost of the average MA plan, and then assume that new enrollees are similar in health status to the current enrollees.

The current Medicare risk adjustment model does not perform well for beneficiaries with the greatest need for coordinated care—beneficiaries with persistent chronic disease and especially beneficiaries with 5 or more chronic diseases. They are also responsible for most of the Medicare spending and generally have the worst outcomes. The enhanced model significantly improves the PRs for beneficiaries with multiple chronic diseases, but do not completely eliminate the financial disincentives. Two possible areas of improvements could be to better assess frailty and/or to include drug data.

ACKNOWLEDGMENTS

The authors thank Robert Herbert for the data analysis; Jonathan Weiner for his advice and comments.

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ORIGINAL CONTRIBUTION

Geographic Variation in Diagnosis Frequency and Risk of Death Among Medicare Beneficiaries

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Context Because diagnosis is typically thought of as purely a patient attribute, it is considered a critical factor in risk-adjustment policies designed to reward efficient and high-quality care.

Objective To determine the association between frequency of diagnoses for chronic conditions in geographic areas and case-fatality rate among Medicare beneficiaries.

Design, Setting, and Participants Cross-sectional analysis of the mean number of 9 serious chronic conditions (cancer, chronic obstructive pulmonary disease, coronary artery disease, congestive heart failure, peripheral artery disease, severe liver disease, diabetes with end-organ disease, chronic renal failure, and dementia) diagnosed in 306 hospital referral regions (HRRs) in the United States; HRRs were divided into quintiles of diagnosis frequency. Participants were 5 153 877 fee-for-service Medicare beneficiaries in 2007.

Main Outcome Measures Age/sex/race–adjusted case-fatality rates.

Results Diagnosis frequency ranged across HRRs from 0.58 chronic conditions in Grand Junction, Colorado, to 1.23 in Miami, Florida (mean, 0.90 [95% confidence interval {CI}, 0.89-0.91]; median, 0.87 [interquartile range, 0.80-0.96]). The number of conditions diagnosed was related to risk of death: among patients diagnosed with 0, 1, 2, and 3 conditions the case-fatality rate was 16, 45, 93, and 154 per 1000, respectively. As regional diagnosis frequency increased, however, the case fatality associated with a chronic condition became progressively less. Among patients diagnosed with 1 condition, the case-fatality rate decreased in a stepwise fashion across quintiles of diagnosis frequency, from 51 per 1000 in the lowest quintile to 38 per 1000 in the highest quintile (relative rate, 0.74 [95% CI, 0.72-0.76]). For patients diagnosed with 3 conditions, the corresponding case-fatality rates were 168 and 137 per 1000 (relative rate, 0.81 [95% CI, 0.79-0.84]).

Conclusion Among fee-for-service Medicare beneficiaries, there is an inverse relationship between the regional frequency of diagnoses and the case-fatality rate for chronic conditions.

JAMA. 2011;305(11):1113-1118 www.jama.com

Disease diagnoses are considered a fundamental input for adjusting health outcomes as well as expenditures to credit systems that care for patients who are sicker than average. Ideally, a diagnosis would be solely an attribute of the patient, unaffected by the process of observation.

A recent investigation demonstrated an association between regional diagnostic practice and the number of diagnoses made in the small proportion of Medicare beneficiaries who changed residence during a 3-year period (approximately 5%).[1] Although patients who moved had a similar number of diagnoses prior to moving, those who moved from low– to high–practice intensity regions accumulated more than twice as many diagnoses than those moving in the opposite direction.

The evidence that diagnoses can be associated with system factors led us to explore how frequency of diagnosis might relate to outcomes in the fee-for-service Medicare population as a whole. Specifically, we hypothesized that patients diagnosed with chronic conditions in regions with high diagnosis frequency would have lower all-cause case-fatality rates than those diagnosed in regions with low diagnosis frequency.

METHODS

Overview

To investigate the geographic variation in diagnosis frequency, we measured the frequency with which 9 serious chronic conditions were diag-

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nosed among the fee-for-service Medicare population in each of 306 hospital referral regions (HRRs) in the United States. We categorized the HRRs into quintiles of diagnosis frequency and measured physician encounters and diagnostic testing. We examined death rates across the quintiles, first for the population as a whole and then within strata of a specified number of chronic conditions (ie, 0, 1, 2, 3).

Data

We analyzed a 20% sample of Medicare beneficiaries in 2007. We restricted the analysis to those beneficiaries who were fully enrolled in Part A and Part B throughout 2007 and who were 65 through 99 years old on December 31, 2007, or who were fully enrolled beginning January 1, 2007, until their death that year and who were 65 through 99 years old at their time of death. Because their claims data are incomplete, beneficiaries enrolled in risk-contract health maintenance organizations were excluded. The final sample totaled 5 153 877 beneficiaries.

Diagnosis Frequency

We counted the number of chronic conditions documented in the claims for each beneficiary during 2007. We used the 9 major chronic conditions based on the work of Iezzoni et al,[2] as adapted for the 2008 Dartmouth Atlas of Health Care. The conditions were cancer with poor prognosis, chronic obstructive pulmonary disease, coronary artery disease, congestive heart failure, peripheral artery disease, severe liver disease, diabetes with end-organ disease, chronic renal failure, and dementia.

For a beneficiary to be counted as having a chronic condition, the diagnosis had to be either coded on at least 1 hospital discharge abstract following an inpatient stay or on at least 2 claims involving physician contact that were at least 7 days apart. The latter requirement was used to reduce the likelihood of erroneously including "rule out" diagnoses. A beneficiary was counted as either having or not having each of the 9 conditions, and the total number of conditions for each beneficiary was calculated (range, 0-9).

We calculated the mean number of chronic conditions per beneficiary within each of the 306 HRRs to examine the variation in diagnosis frequency across the Medicare population as a whole. The HRRs were sorted in terms of increasing diagnosis frequency and grouped into quintiles based on population counts (ie, approximately 1 million beneficiaries per quintile). Within each quintile, we examined the distribution of the number of chronic conditions diagnosed. To assess system factors that may be related to the likelihood of diagnosis, we examined 4 measures reflecting physician encounters and diagnostic testing: the number of physician visits, the number of different physicians seen, the number of imaging tests obtained, and the number of laboratory tests obtained.

Rate of Death

The primary outcome was rate of death in specific groups, measured as either mortality (the population-based rate of death in which the denominator is the entire population in the quintile) or case fatality (the case-based rate of death in which the denominator is the portion of the population in the quintile that has received the diagnosis in question).

The denominator for the population-based mortality rate was the fully entitled Medicare population in the quintile obtained from the Medicare denominator file. The denominator for case-fatality rate was the number of individuals who had the diagnosis in question within that population. For both measures, the numerator was the number of deaths from any cause in calendar year 2007 among those appearing in the denominator. The fact of death was obtained from the Medicare administrative files. To control for population differences across quintiles, all death rates were adjusted for age, sex, and race using the indirect method (which used 20 age/sex/race cells and obtained standardized rates from the group as a whole).

Analytic Approach

To consider the relationship of diagnosis frequency and rate of death, we compared age/sex/race–adjusted population-based mortality across the 5 diagnosis frequency quintiles. We repeated the comparison using age/sex/race–adjusted case-fatality in analyses restricted to individuals diagnosed with a specified number of chronic conditions (ie, 0, 1, 2 and 3).

To examine the relationship in specific diagnoses, we compared case fatality across quintiles for each of the 9 chronic conditions. We used logistic regression to adjust for age, sex, and race (using 20 indicator variables for each of the aforementioned age/sex/race cells) and the number of other conditions diagnosed (also using indicator variables to allow for a nonlinear relationship). We estimated 9 different models—one for each condition—with a different (but overlapping) sample for each target condition (eg, only patients with congestive heart failure are included in the congestive heart failure model). Each was evaluated for face validity. Death rates increased with age and the number of conditions and were higher in men and blacks than in women and nonblacks. Each model estimated the expected number of deaths among beneficiaries with a given condition. We constructed the observed to expected ratio (O:E) for each quintile. We used the ratio of O:E in the very high quintile to the O:E in the very low quintile to summarize the association between diagnosis frequency and case fatality.

Pearson correlation coefficients (r) were calculated to describe the relationship at the HRR level (n=306) between diagnosis frequency and the 4 measures reflecting physician encounters and diagnostic testing. Confidence intervals (95% CIs) around the Pearson r values were calculated using the Fisher r-to-z transformation; 95% CIs at the population level (eg, quintile, patients with 1 chronic condi-

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tion) were calculated empirically using the bootstrap method. Linear regression was performed to test for trends, using 2-sided *P* values and with a 5% significance level. All statistical analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, North Carolina) or STATA version 11 (StataCorp, College Station, Texas). The study was approved by the Dartmouth College institutional review board.

RESULTS

Variation in Diagnosis Frequency

In 2007, the mean number of chronic conditions diagnosed among Medicare beneficiaries across 306 HRRs was 0.90 (95% confidence interval [CI], 0.89-0.91; median, 0.87 [interquartile range, 0.80-0.96]). As shown in FIGURE 1, the frequency of diagnosis varied substantially with geography. The mean number of chronic conditions diagnosed per Medicare beneficiary ranged from 0.58 in Grand Junction, Colorado, and Idaho Falls, Idaho, to 1.23 in Miami, Florida, and McAllen, Texas.

The distribution of the number of chronic conditions varied accordingly. FIGURE 2 depicts this distribution for each of the 5 quintiles of diagnosis frequency. Beneficiaries in the highest quintile were almost twice as likely to have had a diagnosis of 3 or more chronic conditions than those in the lowest quintile (14.3% vs 7.7%; relative rate, 1.86 [95% confidence interval {CI}, 1.84-1.88]). Conversely, beneficiaries in the lowest quintile of diagnosis frequency were more likely to have no chronic condition diagnosis at all (57.3% vs 44.4%; relative rate, 1.29 [95% CI, 1.28-1.30]).

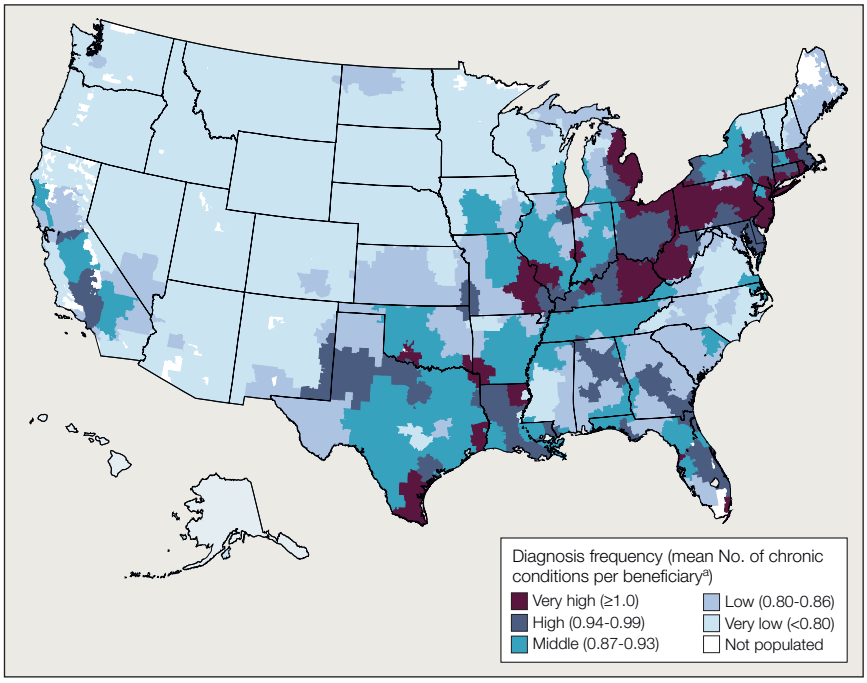
Diagnosis Frequency and Measures of Physician Encounters and Diagnostic Testing

The TABLE shows the relationship between diagnosis frequency and measures of physician encounters and diagnostic testing. Across the 306 HRRs, diagnosis frequency had a strong positive correlation with each of the 4 measures: the number of physician visits (r=0.72), number of different physicians seen (r=0.59), number of imaging tests (r=0.72), and number of laboratory tests (r=0.33). The Table also shows that the mean number of physician visits increased in a stepwise fashion in progressively higher quintiles of diagnosis frequency (P=.002 for trend). A similar pattern was evident for the 3 other measures of physician encounters and diagnostic testing.

Diagnosis Frequency and Risk of Death

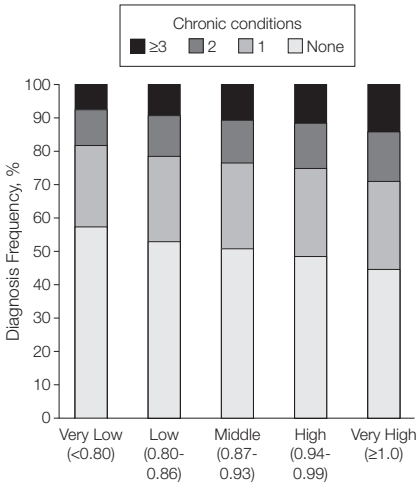
The relationship between diagnosis frequency and population-based mortality is illustrated in the left-hand portion of FIGURE 3. When considering the entire population within each quintile, there was little relationship between diagnosis frequency and age/sex/race–adjusted all-cause mortality: 49 per 1000 in lowest quintile of diagnostic frequency; 52, 55, and 52 per 1000 in the intervening quintiles; and 53 per 1000 in the highest quintile (P=.31 for trend).

Figure 1. Variation in Number of Chronic Conditions Diagnosed Among Medicare Beneficiaries in the United States, 2007



[a]Values in parentheses indicate range for each quintile.

Figure 2. Distribution of Chronic Conditions Among Medicare Beneficiaries Across Regions With Varying Diagnosis Frequency



See Table 1 for denominator data used to calculate diagnosis frequency.
[a]Values in parentheses indicate range for each quintile.

The relationship between diagnosis frequency and case-fatality is illustrated in the right-hand portion of

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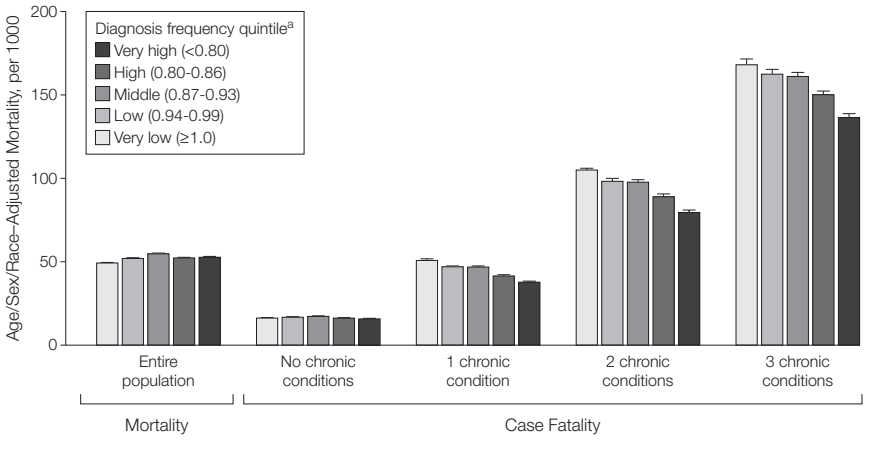
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Table. Relationship Between Diagnosis Frequency and Measures of Physician Encounters and Diagnostic Testing in the United States, 2007

	Measure of Physician Encounters and Diagnostic Testing, per Beneficiary			
	Physician Visits, No.	Different Physicians Seen, No.	Imaging Studies, No.	Laboratory Tests, No.
Correlation with diagnosis frequency, *r* (95% CI)[a]	0.72 (0.66-0.77)	0.59 (0.51-0.66)	0.72 (0.66-0.77)	0.33 (0.23-0.43)
Diagnosis frequency, quintile mean (95% CI)				
Very low (n = 1 019 557)	11.35 (11.32-11.38)	3.80 (3.79-3.81)	3.66 (3.65-3.68)	10.15 (10.11-10.18)
Low (n = 1 038 091)	12.94 (12.90-12.97)	4.26 (4.25-4.26)	4.16 (4.15-4.17)	11.90 (11.87-11.93)
Middle (n = 1 019 701)	13.20 (13.17-13.24)	4.21 (4.21-4.22)	4.36 (4.35-4.37)	11.96 (11.92-11.99)
High (n = 1 039 413)	14.90 (14.85-14.93)	4.68 (4.67-4.69)	4.53 (4.52-4.55)	12.45 (12.41-12.49)
Very high (n = 1 037 115)	16.19 (16.14-16.24)	4.95 (4.94-4.96)	4.69 (4.68-4.71)	13.93 (13.89-13.97)
P value for trend	.002	.008	.008	.01

Abbreviations: CI, confidence interval; HRR, hospital referral region.
[a]Across 306 hospital referral regions.

Figure 3. Population-Based Mortality and Case Fatality Across Regions With Varying Diagnosis Frequency



Error bars indicate 95% confidence intervals. Relative rates of death in regions with very high vs very low diagnosis frequency: relative rate, 1.07 (95% CI, 1.06-1.08 [*P*=.31 for trend]) for entire population; 0.97 (95% CI, 0.94-1.00 [*P*=.46 for trend]) for no chronic conditions; 0.74 (95% CI, 0.72-0.76 [*P*=.006 for trend]) for 1 chronic condition; 0.76 (95% CI, 0.74-0.78 [*P*=.007 for trend]) for 2 chronic conditions; 0.81 (95% CI, 0.79-0.84 [*P*=.01 for trend]) for 3 chronic conditions. Entire population, N=5 153 877; no chronic conditions, n=2 611 646; 1 chronic condition, n=1 318 809; 2 chronic conditions, n=665 093; 3 chronic conditions, n=331 999; not shown are 226 300 persons with 4 or more conditions.
[a]Quintiles indicate mean number of chronic conditions per beneficiary. Values in parentheses indicate range for each quintile.

Figure 3. In all regions, case-fatality increased as the number of chronic conditions diagnosed increased. Among Medicare beneficiaries diagnosed with 0, 1, 2, and 3 conditions in the United States as a whole, the case-fatality rate was 16, 45, 93, and 154 per 1000, respectively (data not shown).

When focusing on the subsets of Medicare beneficiaries with a fixed number of chronic conditions, increased diagnosis frequency was associated with declining case fatality. Among patients diagnosed with 1 condition, case fatality was 51 per 1000 for HRRs in the lowest quintile of diagnosis frequency; 47, 47, and 41 per 1000 in the intervening quintiles; and 38 per 1000 in the highest quintile (*P*=.006 for trend). Among these patients, the relative rate of death in the highest to lowest diagnosis frequency quintile was 0.74 (95% CI, 0.72-0.76).

A similar stepwise relationship was observed across the quintiles among the subsets diagnosed with 2 and 3 chronic conditions (*P*=.007 and *P*=.01 for trend, respectively). For both subsets the relative rate of death in the highest vs lowest diagnosis frequency quintile was significantly less than 1: among patients with 2 chronic conditions, the relative rate was 0.76 (95% CI, 0.74-0.78); among those with 3 chronic conditions, the relative rate was 0.81 (95% CI, 0.79-0.84).

FIGURE 4 shows the relative rate of death in the highest to lowest diagnosis frequency quintile among beneficiaries diagnosed with each of the 9 chronic conditions. For each condition, the relative rate was significantly less than 1. In 7 of 9 conditions, a significant stepwise relationship was observed across quintiles (*P*<.05 for trend for all).

COMMENT

As the number of diagnoses of chronic conditions increased in individual patients, there was an associated increased risk of death. However, as the number of diagnoses increased among geographically defined populations (ie, across quintiles of diagnosis frequency), there was little relationship with population-based mortality. These apparently paradoxical findings were explained by a third observation: among patient subgroups with a given number of chronic conditions, there was a consistent stepwise decrement in case fatality as diagnosis frequency increased.

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As with all observational data, causality cannot be directly tested. Our analysis could be limited by residual confounding—ie, from variables that could explain increased diagnosis frequency as well as declining case fatality. The conventional explanation for our findings would be that the geographic variation in diagnosis frequency reflects underlying differences in disease burden, ie, regions with high diagnosis frequencies must have sicker patients. However, this explanation fails to explain why population-based mortality is stable across quintiles of diagnosis frequency.

Another explanation would suggest that regions with high diagnosis frequencies are more effective in treating sick patients, thereby reducing mortality rates that otherwise would have been substantially increased. While the population of patients in the lowest quintile of diagnosis frequency may have fewer chronic conditions, those who do have fewer also may have poor access to health services (eg, fewer specialists, longer wait times), leading to increased case fatality. Conversely, the population in the highest quintile of diagnosis frequency may have more chronic conditions yet better access to services (and perhaps more experienced physicians), leading to decreased case fatality. However, to produce the observed pattern of reductions in case fatality in a stepwise relationship, another condition would have to be met: access and the ability to provide effective care must be directly related to diagnosis frequency. Given the required conditions, the conventional explanation is not particularly parsimonious.

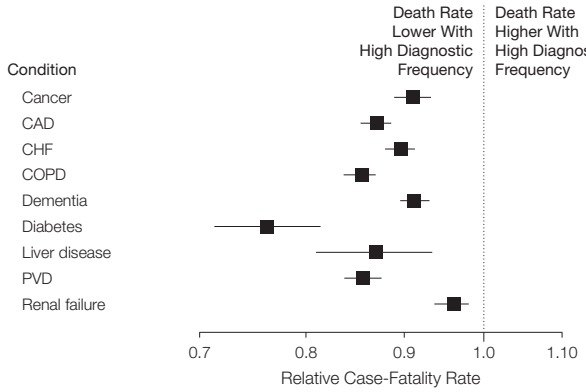
An alternative explanation may be that geographic variation in diagnosis frequency substantially reflects the intensity of observation. This is consistent with the associations we report between diagnosis frequency and measures of physician encounters and diagnostic testing. This explanation provides a more parsimonious explanation for our case-fatality findings; ie, if diagnosis frequency reflects intensity of observation, then the pattern of case fatality we observed here would be expected. More testing and more opportunities to make diagnoses may translate into the typical patient given a diagnosis being less sick. The finding of Song et al[1]—that the number of diagnoses accumulated by migrating Medicare beneficiaries is associated with the location to which they moved—provided evidence from a natural experiment that supports this hypothesis.

Our analysis has a number of limitations. First, although Medicare claims are the most complete population-based data available in the United States, they are not entirely complete. Specifically, beneficiaries enrolled in plans outside of fee-for-service (plans that receive capitated payments from Medicare, such as Medicare Advantage) are not included in claims data. Although the proportion of beneficiaries enrolled in these plans is not correlated with diagnosis frequency across HRRs (in fact, enrollment is most common in the very low and very high quintiles), the possibility of differential selection raises the question of whether the relationship we observed would be present in the entire Medicare population. This highlights the importance of developing mechanisms to capture data from capitated plans[3] to foster population-based analyses.

Second, the ability of the logistic regression models to adequately isolate the effect of each individual condition from others may be limited. To address this concern, we repeated the analysis on the subset of patients with no other confounding diagnoses: those diagnosed with only 1 chronic condition. This analysis also showed lower case fatality in the very high quintile of diagnostic frequency for each of the 9 chronic conditions.

Third, the accuracy of coding diagnostic data are open to question. If in-

Figure 4. Relative Rates of Death in Regions With Very High vs Very Low Diagnosis Frequency Among Beneficiaries Diagnosed With Each of 9 Chronic Conditions



Condition	Very High Diagnostic Frequency		Very Low Diagnostic Frequency	
	No. of Deaths	No. With Condition	No. of Deaths	No. With Condition
Cancer	11852	41797	9607	33290
CAD	25693	315531	14613	194759
CHF	26120	149906	18102	104296
COPD	21863	200023	14945	147933
Dementia	19585	103215	14029	77594
Diabetes	2064	43358	1360	29904
Liver disease	1199	5328	844	3896
PVD	18106	196100	8946	95773
Renal failure	13612	67258	9554	52727

Relative rates were calculated using logistic regression adjusted for age/sex/race and number of coexisting chronic conditions and are not calculable from raw counts of numbers of deaths and numbers with each condition. CAD indicates coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; PVD, peripheral vascular disease.

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accuracies are random and not associated with region, they would not affect our findings. Coding practices, however, could vary across regions. It is possible that coding is relatively incomplete in the lowest quintile and relatively complete in the highest quintile. Alternatively, these differences could be purposeful—that is, the result of "gaming" efforts to increase reimbursements (or improve apparent quality) in the highest quintile.[4,5] Although we have no evidence that this is the case, such practices could explain our results.

The frequency of diagnoses reported in claims data are routinely used in methods for risk adjustment in comparative effectiveness research,[6,7] the evaluation of readmissions following hospitalization,[8,9] and in paying insurance plans under the Medicare Advantage program.[10] If diagnosis is not solely an attribute of underlying disease burden, adjustments based on frequency of diagnosis may introduce bias into efforts to compare outcomes, pay for health care, and assess the extent of geographic variation in health care delivery. On the other hand, if more diagnoses (and more frequent encounters and diagnostic testing as well as greater spending) improve outcomes, then standard methods of risk adjustment may provide a more accurate comparison of effectiveness and efficiency. Future research must further evaluate the contribution of the process of observation to diagnosis frequency and explore mechanisms to better measure disease burden.

Author Contributions: Dr Welch had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Welch, Wennberg.
Acquisition of data: Gottlieb.
Analysis and interpretation of data: Welch, Sharp, Gottlieb, Skinner, Wennberg.
Drafting of the manuscript: Welch, Sharp, Wennberg.
Critical revision of the manuscript for important intellectual content: Gottlieb, Skinner, Wennberg.
Statistical analysis: Welch, Sharp, Gottlieb, Skinner, Wennberg.
Obtained funding: Skinner.
Administrative, technical, or material support: Wennberg.
Study supervision: Welch.
Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Wennberg reported serving as a paid consultant to the Foundation for Informed Medical Decision Making and Health Dialog and receiving royalties from Health Dialog. No other authors reported disclosures.
Funding/Support: This study was partially supported by grant PO1-AG19783 from the National Institute on Aging.
Role of the Sponsor: The National Institute on Aging had no role in the design and conduct of the study; the collection, analysis, and interpretation of the data; or the preparation, review, or approval of the manuscript.
Disclaimer: The views expressed herein do not necessarily represent the views of the Department of Veterans Affairs or the United States Government.

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MMRR
Medicare & Medicaid Research Review
2014: Volume 4, Number 2

A publication of the Centers for Medicare & Medicaid Services, Office of Information Products & Data Analytics

Measuring Coding Intensity in the Medicare Advantage Program

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Background: In 2004, Medicare implemented a system of paying Medicare Advantage (MA) plans that gave them greater incentive than fee-for-service (FFS) providers to report diagnoses.

Data: Risk scores for all Medicare beneficiaries 2004–2013 and Medicare Current Beneficiary Survey (MCBS) data, 2006–2011.

Measures: Change in average risk score for all enrollees and for stayers (beneficiaries who were in either FFS or MA for two consecutive years). Prevalence rates by Hierarchical Condition Category (HCC).

Results: Each year the average MA risk score increased faster than the average FFS score. Using the risk adjustment model in place in 2004, the average MA score as a ratio of the average FFS score would have increased from 90% in 2004 to 109% in 2013. Using the model partially implemented in 2014, the ratio would have increased from 88% to 102%. The increase in relative MA scores appears to largely reflect changes in diagnostic coding, not real increases in the morbidity of MA enrollees. In survey-based data for 2006–2011, the MA-FFS ratio of risk scores remained roughly constant at 96%. Intensity of coding varies widely by contract, with some contracts coding very similarly to FFS and others coding much more intensely than the MA average. Underpinning this relative growth in scores is particularly rapid relative growth in a subset of HCCs.

Discussion: Medicare has taken significant steps to mitigate the effects of coding intensity in MA, including implementing a 3.4% coding intensity adjustment in 2010 and revising the risk adjustment model in 2013 and 2014. Given the continuous relative increase in the average MA risk score, further policy changes will likely be necessary.

Keywords: Medicare, payment systems, FFS, Capitation, risk adjusted payments, Managed Care Organizations

ISSN: 2159-0354

doi: http://dx.doi.org/10.5600/mmrr.004.02.a06

Medicare & Medicaid Research Review
2014: Volume 4, Number 2

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Introduction

General

Enrollment in the Medicare Advantage Program has increased dramatically, growing from 9.3 million beneficiaries in March 2008 to 15.4 million in March 2014, an increase of 66% in just six years.

Concerns about overpayment as a result of favorable risk selection have confronted the Medicare program throughout the history of Medicare contracting with health maintenance organizations and other private plans. In the late 1980s, Medicare paid health plans using a system that adjusted for demographic factors such as age and gender, but plan enrollees were healthier than fee-for-service beneficiaries with the same demographic characteristics, and, as a result, health plans were estimated to be overpaid by approximately 11% (Brown, Bergeron, Clement, Hill, & Retchin, 1993).[1]

In order to reward health plans for attracting sicker-than-average enrollees, and to discourage plans from constructing business models designed to avoid risk, Medicare and other payers have increasingly turned to diagnosis-based risk-adjusted payment systems in which health plans are paid more for enrollees expected to need more care. While mitigating the incentive to enroll only healthy people, diagnosis-based risk adjustment creates another set of incentives: to find and report as many diagnoses as possible. Risk-adjusted payment using plan-reported diagnostic information creates a dilemma—there are strong policy reasons to pay plans more if they enroll sicker people,

[1] Systems in which payment is based, at least in part, on patient diagnoses create an incentive for providers or plans to report all appropriate diagnoses. Most notably, after the advent of the inpatient prospective payment system, which used diagnosis related groups (DRGs), hospital case-mix increased.

but measuring morbidity using plan-reported diagnostic data provides strong incentives for plans to increase the reported morbidity of enrollees (Government Accountability Office, 2012).

Medicare Risk Adjustment

The first Medicare risk program was established under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. From 1982 to 1999, this program paid health plans (known as TEFRA health maintenance organizations [HMOs]) a monthly amount per enrollee based on 95 percent of the estimated costs of treating an average beneficiary in the traditional fee-for-service (FFS) program. This amount was adjusted for demographic factors such as age and gender (Hellinger & Wong, 2000; Lichtenstein, Thomas, Adams-Watson, Lepkowski, & Simone, 1991).

The Balanced Budget Act of 1997 made significant changes under the Medicare+Choice (M+C) program, including requiring the development of a new risk adjustment system that incorporated morbidity information. Medicare began using diagnoses from inpatient hospitalizations in 2000 to adjust payments to health plans. The Benefits Improvement Protection Act of 2000 required the use of ambulatory diagnoses in Medicare risk-adjustment, and Medicare implemented the CMS-HCC (Centers for Medicare & Medicaid Services-Hierarchical Condition Categories) risk adjustment model in 2004 and fully phased it in by 2007. The CMS-HCC incorporated both inpatient and ambulatory diagnoses that were categorized into 70 HCCs that were determined to be predictive of costs (Pope, *et al.*, 2004). In 2003 the Medicare Modernization Act (MMA) renamed the program "Medicare Advantage (MA)."

The MA payment system uses diagnostic information to assign a risk score to each beneficiary, where the average beneficiary in fee-for-service has a risk score of 1.0. MA plans are paid the product of their bid multiplied by the enrollee's risk score—that is, if an MA plan bids $1,000/month for an enrollee with a risk score of 1.0, and then enrolls a beneficiary with a risk score of 1.2, the plan gets paid $1,200/month for that enrollee (1.2 * $1,000/month).

This payment system creates incentives for MA plans to find and report as many diagnoses as can be supported by the medical record. For office-based services, physicians billing FFS are paid based on the procedures performed—for example, one amount for an intermediate office visit, a different amount for a skin biopsy—but are not paid based on the number of diagnoses that are reported (provided there is at least one that supports the need for the service provided). If, for example, a FFS patient with quadriplegia and a urinary tract infection (UTI) has an office visit for treatment of the UTI, the payment to the physician will be no more if both the UTI and quadriplegia are reported on the claim than if only the UTI is reported. Coding guidelines specify that the quadriplegia can legitimately be coded if it contributes to the complexity of care, but unlike the situation for MA plans, in FFS there is no incentive to report more than one diagnosis. In contrast, MA plans have a strong incentive to do so. In addition to the incentives to report more completely, the method of collecting diagnostic information also provides MA plans additional opportunities to increase risk scores. FFS diagnoses are drawn only from health care claims submitted for payment. MA plans may also review medical records and can report all diagnoses that are supported in the record, including those that were not reported by physicians on any health care claim or encounter record. MA plans can also employ nurses to visit enrollees in their homes to conduct health assessments and report diagnoses that are found.

As noted, payment to MA plans is calibrated based on coding patterns in FFS. If, for example, Jane Doe would have a risk score of 1.0 if she were in FFS, the implicit assumption in the design of the MA payment system is that she would have the same risk score of 1.0 if she were enrolled in MA. Alternatively, if the same Jane Doe had a risk score of 1.1 if enrolled in MA, then her plan would be overpaid. As we use the phrase, 'coding intensity' is the difference between the scores that a group of beneficiaries would have if enrolled in MA and their scores in FFS.

If we find that MA plans code with high intensity, that does not provide information about whether MA plans are 'overcoding' or whether FFS providers are 'undercoding.' Similarly, one cannot infer whether MA coding is any more or less accurate than FFS. However, for the purposes of creating an equitable MA payment system, the relevant question is whether MA risk scores are systematically different than those risk scores would be in FFS, and not which set of scores is more accurate. Suppose, for example, that average expenditure per FFS beneficiary is $10,000/year, and that the average risk score for all FFS beneficiaries is 1.0. The goal of the payment system is to assure that—if all of those beneficiaries were to enroll in MA—the average payment to MA plans would be approximately $10,000 per beneficiary. If, however, FFS systematically underreports diagnoses and MA reports them more completely, then the average risk score in MA would be greater than 1.0, and MA plans would be paid more than $10,000 per beneficiary. The goal of the risk adjustment system is to assure that MA plans that enroll sicker-than-average beneficiaries are paid appropriately, but not to increase payment for an average beneficiary.

As a result of concern about the effects of incentives to increase coding intensity on MA plan payment levels, the Deficit Reduction Act of 2005 directed CMS to measure and adjust for coding intensity (Department of Health and Human Services, 2007), and in the 2010 payment year CMS adjusted risk scores by 3.41% to reflect anticipated differences between MA and FFS coding (Department of Health and Human Services, 2009). The Government Accountability Office (2012) estimated that in 2010 MA beneficiary risk scores were at least 4.8% and perhaps as much as 7.1% higher than they likely would have been if the same beneficiaries had been continuously enrolled in FFS. The Affordable Care Act directs CMS to increase the coding intensity adjustment to at least 4.71% in 2014, and further increase it to at least 5.71% by 2018 (PPACA & HCERA, 2010). The American Taxpayer's Relief Act of 2012 further increases the minimum coding intensity adjustment to 4.91% in 2014 and 5.91% in 2018.

The risk adjustment model implemented in 2004 was recalibrated in 2007, 2009, and 2013.[2] These changes slowed the growth in measured MA risk scores somewhat. Further, as described in more detail below, since 2014, CMS has adopted substantial changes to the model, particularly relating to several diagnoses that have been subject to coding intensity efforts by MA plans (Department of Health and Human Services, 2013). In 2014 the risk score is a blend, weighting the risk score calculated using the 2013 model by 25% and the risk score calculated using the 2014 model by 75%.

Concerns about coding intensity in MA plans would be minor if coding in FFS were relatively complete, because in that case there would be little opportunity for MA plans to legitimately increase risk scores through efforts at increasing diagnostic

[2] HCCs are constrained for a variety of reasons, including methodological and policy reasons. Starting in 2013, the coefficients for the four most severe diabetes HCCs were constrained to the same amount, eliminating the opportunity to increase revenue by increasing the reported severity of diabetes within these four HCCs.

reporting. However, FFS coding is known to be both incomplete and variable. Incomplete coding is evidenced by lack of persistence in coding of chronic conditions. For instance, among Medicare beneficiaries diagnosed with quadriplegia in one year, only 61% had a diagnosis of quadriplegia reported in the subsequent year (Medicare Payment Advisory Commission, 1998). Coding intensity also varies geographically; in the Hospital Referral Regions (HRRs) with the most intense practice patterns, the probability that a beneficiary is diagnosed with three or more chronic conditions is double the probability in low-intensity HRRs, with no evidence of differences in underlying prevalence (Welch, Sharp, Gottlieb, Skinner, & Wennberg, 2011).

Incomplete and variable coding provide ample opportunities for MA plans to increase risk scores of beneficiaries through coding intensity efforts, and a number of vendors actively market services that help plans to do so (Gorman Health Group, 2013; Leprechaun, 2013), often advertising high returns on investment (ROIs) for their services.

This paper uses recent data as well as improved methods to estimate the effects of coding intensity on MA risk scores, with particular attention to variation over time in coding intensity, variation in coding intensity across plans, and variation in the diagnoses most subject to coding intensity efforts. Before describing our methods, we'll review what is known about risk selection in the MA program.

Evidence on Risk Selection

Concerns about overpayment as a result of favorable risk selection have confronted the Medicare program throughout its history of contracting with HMOs and other private plans. For example, Brown *et al*. (1993) found that health plans were overpaid by approximately 11% under the Medicare risk program during the late 1980s because plans experienced favorable selection; on average, risk plan enrollees were healthier than fee-for-service beneficiaries with the same demographic characteristics, with lower prior reimbursements and fewer indicators of chronic health problems (Brown *et al*., 1993). Several studies confirmed that the favorable risk selection for early HMOs continued during the early 1990s (Mello, Stearns, Norton, & Ricketts, 2003; Call, Dowd, Feldman, & Maciejewski, 1999; Physician Payment Review Commission, 1996; Riley, Chiang, Ingber, & Tudor, 1996). For example, Mello *et al*. (2003) found that Medicare beneficiaries with a history of cancer or stroke were significantly less likely to be enrolled in HMOs.

Recent analyses suggest that the various policy changes that have been implemented over the past decade—such as the implementation of the CMS-HCC model, the addition of an open enrollment period, and additional refinements of the risk adjustment system—have reduced the degree of selection bias between Medicare Advantage (MA) and the traditional FFS program. For example, Newhouse, Price, Huang, McWilliams, & Hsu (2012) recently found that differences in risk scores for beneficiaries switching from the traditional FFS program to MA and beneficiaries remaining in the traditional program narrowed by a factor of 3 between 2004 and 2008 (with the difference between risk scores for beneficiaries switching into MA and those staying in the traditional FFS program changing from -0.113 to -0.037); and differences in adjusted mortality rates narrowed by a factor of 2 between 1988 and 2008 (with mortality among beneficiaries in MA as a percentage of mortality among beneficiaries in the traditional FFS program increasing from 85 percent to 93 percent) and were almost equal between persons enrolled in MA for five or more years and traditional FFS enrollees (Newhouse *et al*., 2012). Similarly, McWilliams,

Hsu, and Newhouse (2012) found reductions in differences between MA and FFS for self-reported health and health care use between 2001 and 2003 and between 2006 and 2007. However, there continues to be evidence of selection bias in disenrollment from MA plans (Riley, 2012; Medicare Payment Advisory Commission, 2012; Morrisey, Kilgore, Becker, Smith, & Delzell, 2012).

Methods

Ideally, we would measure coding intensity by running an experiment with a large group of beneficiaries, in which one-half of the group was randomly assigned to MA, the other half to FFS, and we observed the risk scores of each group. The difference between the average score in MA and FFS would be a good estimate of coding intensity. In the absence of performing this experiment, we use a variety of inferential approaches. As shown below, average MA risk scores increased much more rapidly than average FFS scores from 2004 to 2013. There are three potential explanations for the relative increase in MA scores. First, the composition of MA enrollment might have changed; for example, MA enrollees in 2013 might be older, relative to FFS, than MA enrollees in 2004, and, as a result have higher risk scores. Second, even if there were no change in the composition of MA enrollees, MA enrollees might have gotten sicker more quickly than FFS beneficiaries. Third, it is possible that coding intensity increased in MA. Below, we assess the plausibility of each of these three potential explanations concluding that greater coding intensity is by far the most likely explanation.

We evaluate whether changes in MA scores relative to FFS scores are due to coding intensity efforts or to changes in the composition of enrollees by analyzing the contribution of changes in risk scores for four types of beneficiaries: stayers, leavers, joiners, and switchers—where stayers are beneficiaries in either MA or FFS for two consecutive years; leavers are beneficiaries, primarily decedents, who were in one sector in the first year, but not Medicare eligible in the second year; joiners are beneficiaries, primarily those turning 65, who were not Medicare eligible in the first year; and switchers are beneficiaries who move from FFS to MA (or vice-versa) between two consecutive years. To the extent that the contribution of leavers, joiners, or switchers differed between MA and FFS, then we will have evidence that part of the differential growth in risk scores between MA and FFS is a result of differences arising from enrollment decisions or mortality of beneficiaries, or "caseload dynamics" for shorthand. However, if risk scores increase more rapidly for MA stayers than for similar FFS stayers, then we will have evidence that coding intensity accounts for part of the more rapid growth in MA scores.

Our analysis assumes that in the absence of coding intensity efforts, the risk score for a given MA beneficiary would increase, on average, at the same rate as the risk score for an otherwise similar FFS beneficiary from one year to the next. This appears to be a reasonable assumption, and would only be incorrect if MA beneficiaries were actually getting sicker more quickly than FFS beneficiaries. We analyze changes in the relative mortality rate of MA and FFS enrollees as an independent method of assessing the relative morbidity of beneficiaries in the two sectors. If MA enrollees are, in fact, getting sicker more quickly than FFS beneficiaries, we would expect to see MA mortality rates increase relative to FFS mortality.

Data

For each year from 2004 to 2013, we used three Medicare administrative files with beneficiary level data: the Enrollment Database (EDB); the

Common Medicare Environment, which contains the MA contract number; and the Risk Adjustment Processing System, which contains the risk score. For each year from 2004 to 2013, we computed the risk score using each HCC's coefficient (i.e., weight) that was used to pay plans in 2004–2006. Analyses of coding intensity based on risk scores have not appeared in the peer-reviewed literature.

We excluded beneficiaries not enrolled in both Parts A and B, because diagnostic information would be incomplete. Beneficiaries enrolled in cost contracts, hospice, or the ESRD program were also excluded, because of differences in payment methodology. Risk scores were computed prior to any normalization and MA-wide adjustment for differences in coding.

Decomposition of Risk Score Growth

To decompose the changes in risk scores, we analyze beneficiaries based on their enrollment as of July 1 of each of two consequent years (called a "cohort"). We analyze nine cohorts, from the first cohort under the new adjustment system in 2004–2005 through the most recent one in 2012–2013, estimating the contribution of each type of beneficiary—stayers, joiners, leavers, and switchers—to the overall change in risk score. The decomposition method is described in the Supplemental Appendix.

Contract-Level Analyses

To assess the extent to which coding intensity differs across contracts, we calculate the rate of increase in risk scores for stayers for contracts that continuously participated in Medicare from 2004 through 2011, had at least 10,000 enrollees in both 2004 and 2011, and whose ratio of 2011 enrollment to 2004 enrollment was between 25% and 300%. The subset of contracts account for approximately 85% of enrollment in 2004 and 42% in 2011. For each contract and cohort, we define the excess increase in risk score for stayers as the difference between the increase in risk scores for stayers in the contract and the increase in risk scores for FFS beneficiaries, controlling for age and decedent status (details are in the Supplemental Appendix).[3] The cumulative excess increase in risk score is the sum of this amount over the seven cohorts from 2004 to 2005 through 2010 to 2011. Contracts are divided into deciles (weighted by 2011 enrollment) based on the cumulative excess increase in scores for stayers.

The growth in relative prevalence of each HCC was calculated separately for the MA and FFS sector as well as by decile of coding intensity among the continuously participating contracts.

Analysis of Medicare Current Beneficiary Survey (MCBS) Data

We analyze the MCBS to provide an assessment of the relative risk of MA and FFS beneficiaries that is independent of the data reported by MA plans or FFS providers. As described more fully in the Supplemental Appendix, in the first stage of the analysis, we use MCBS data from 2004 to 2011 to estimate a regression model to predict the sum of Part A plus Part B expenditures. The regression is estimated on FFS enrollees. Independent variables are demographic characteristics (age, gender, Medicaid status, and institutional status), self-reported health status (excellent, very good, good, fair, or poor), and self-report of whether the respondent has ever been diagnosed with hypertension, heart attack, heart failure, stroke, cancer, or diabetes, and dummy variables for each year. In the second stage, we use the regression coefficients to predict expenditures for each FFS

[3] The contract-level analysis implicitly assumes that the increase in FFS risk scores for a beneficiary of a given age and decedent status is uniform geographically.

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and MA respondent in the sample, and compare the average predictions for MA and FFS.

Results

Mean risk scores in MA increased faster than in FFS from 2004 to 2013—by 0.305 in MA, compared to 0.106 in FFS (Exhibit 1). As measured using the risk model in effect in 2004, MA scores grew from 90.2% of FFS scores in 2004 to 109.1% in 2013, an increase of 18.9 percentage points.[4]

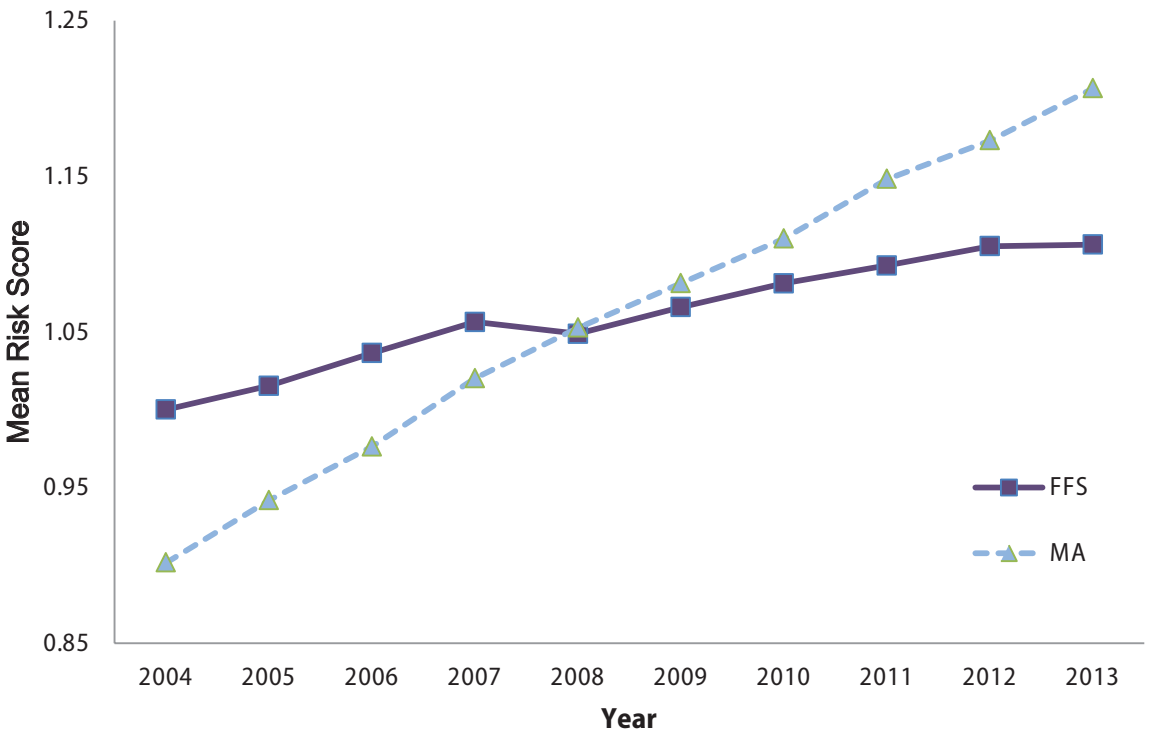
Decomposition of Risk Score Growth

Risk scores among MA stayers increased more quickly than risk scores among FFS stayers in every cohort (Exhibit 2). Across the two-year cohorts, the growth in risk scores for FFS stayers averaged 0.088. In contrast, in MA the growth in mean risk scores for stayers was 0.106 in 2004–2006, 0.119 in 2006–2010, and 0.132 in 2010–2013. The difference between the rate of growth in risk scores for MA and FFS stayers is substantial, with average MA scores increasing one-third more rapidly than FFS scores.

As was shown in Exhibit 1, the average MA risk score increased 0.025 more rapidly than the average FFS score from 2004 to 2005. Differential changes between MA and FFS in caseload dynamics account for approximately one-half of this 0.025 difference (Exhibit 3). As was shown in Exhibit 2, risk scores for FFS stayers increase by approximately 0.088 per year. However, as was shown in Exhibit 1, the

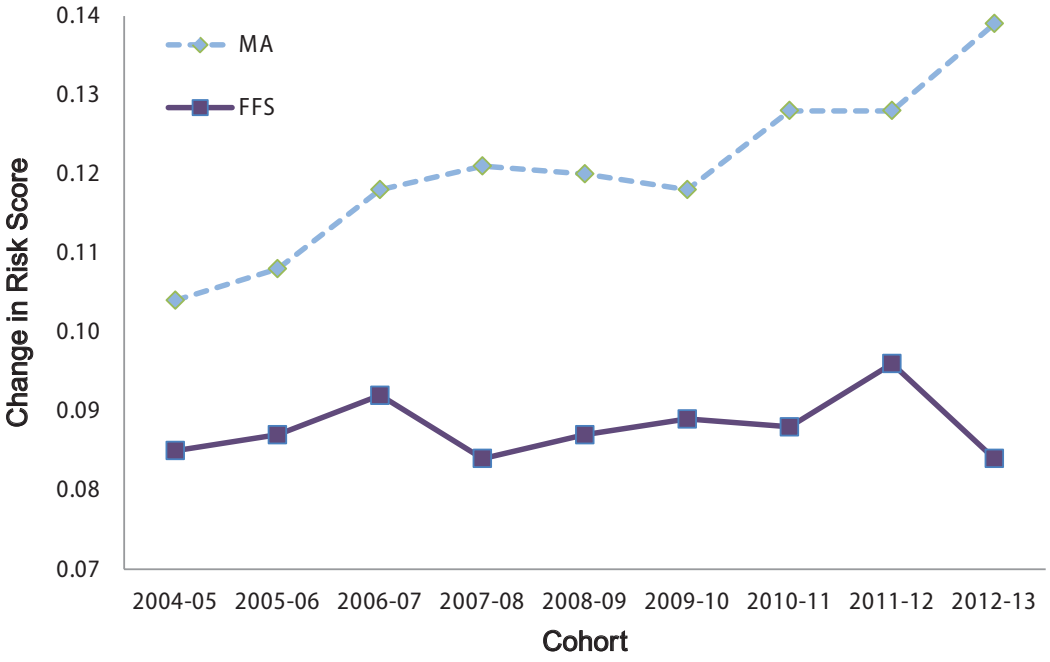
[4] As noted, the payment rules, however, did change in a variety of ways.

Exhibit 1. Mean Risk Scores, MA vs. FFS, 2004–2013 (2004 Model)



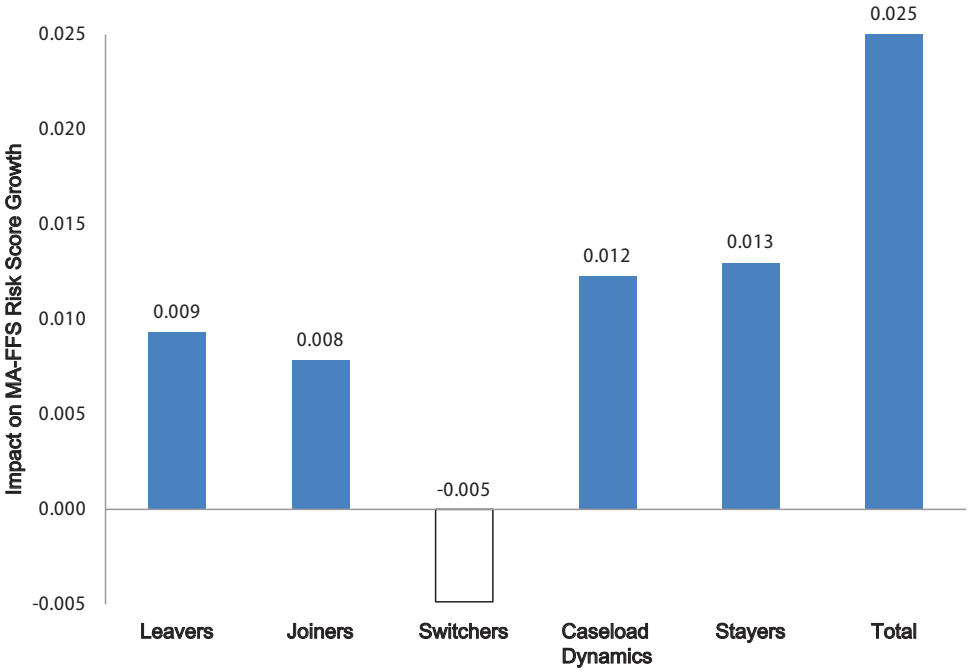
NOTE: 2004 HCC model, which here has been normalized to 1.00 for FFS in 2004. For payment purposes, this model was modified and recalibrated in 2007, 2009, 2013, and 2014. Risk scores were adjusted by -3.41%, starting in 2010. Diagnoses from FFS diagnostic radiology claims were excluded starting in 2008.
SOURCE: Authors' analysis of Medicare administrative data.

Exhibit 2. Growth in Risk Scores Among Stayers, MA vs. FFS, 2004–2013



NOTE: 2004 model. Stayers are beneficiaries who were enrolled in MA (or in FFS) on July 1 of two consecutive years.
SOURCE: Authors' analysis of Medicare administrative data.

Exhibit 3. Sources of Differential Growth in MA and FFS Risk Scores, 2004–2005



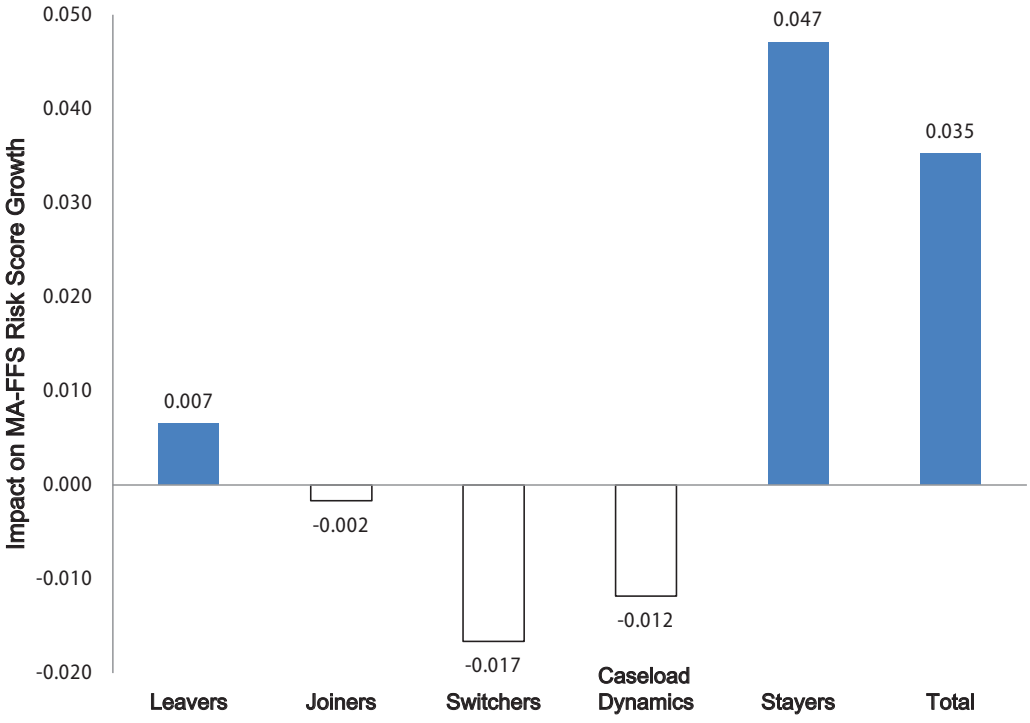
NOTE: 2004 model. Caseload dynamics is the sum of leavers (e.g., decedents), joiners (e.g., newly eligibles), and switchers. Total is the sum of caseload dynamics and stayers.
SOURCE: Authors' analysis of Medicare administrative data.

average FFS risk score increases by approximately 0.012 per year. Caseload dynamics account for the difference between the 0.088 growth for stayers and the 0.012 for all FFS beneficiaries—relatively high risk score decedents exit the caseload and are replaced by relatively low risk score 65 year olds.

From 2004 to 2005, caseload dynamics caused greater restraint in the growth of FFS risk scores than in MA (Exhibit 3). Decedents are a greater proportion of FFS beneficiaries than of MA enrollees and, similarly, 65 year olds are a greater proportion of FFS than of MA. Primarily as a result of the greater proportion of decedents in FFS, the average MA risk score in 2005 increased by 0.009 more than the average FFS score. Similarly, as a result of the greater proportion of 65 year olds in FFS, the average MA score increased by 0.008 more than the average FFS score. These effects were partially balanced by the effects of switchers—relatively low risk beneficiaries switching from FFS to MA, and relatively high risk beneficiaries switching from MA to FFS. Despite the partially counterbalancing effect of switchers, the net effect of caseload dynamics was to cause the average MA score to increase 0.012 more rapidly than the average FFS score from 2004 to 2005. The remaining 0.013 of the difference in growth rate between MA and FFS scores is accounted for by the fact that risk scores for stayers increased more rapidly in MA than in FFS.

Although caseload dynamics accounted for part of the more rapid growth in MA risk scores in 2004–2005, in 2012–2013 the effects of caseload dynamics reversed, causing the average MA risk score to grow more slowly than FFS (Exhibit 4). Decedents have a similar effect in 2012–2013 as in

Exhibit 4. Sources of Differential Growth in MA and FFS Risk Scores, 2012–2013



NOTE: 2004 model. Caseload dynamics is the sum of leavers (e.g., decedents), joiners (e.g., newly eligibles), and switchers. Total is the sum of caseload dynamics and stayers.
SOURCE: Authors' analysis of Medicare administrative data.

2004–2005, but the effects of joiners and switchers are different in the latter period than in the former. In contrast to the 2004–2005 results, in 2012–2013 the proportion of 65 year olds was similar in MA and FFS, and joiners do not have much effect on the difference between MA and FFS in risk score growth rates. Switchers had a small negative effect in 2004–2005, but a much larger negative effect in 2012–2013.[5] As was shown in Exhibit 2, the difference between MA and FFS in the rate of increase in risk scores for stayers widened in 2013, accounting for the larger effect of stayers in Exhibit 4 than in Exhibit 3.

On average over the 2004–2013 period, caseload dynamics had virtually no net effect on the difference between MA and FFS in the rate of growth of risk scores, and the greater increase in risk scores for MA stayers compared to FFS appears to account for most of the reason for the differential growth (Exhibit 5). Caseload dynamics led to more rapid increases in risk scores in MA in the early part of the period, but to slower increases in the latter part and, on balance, made very little contribution to the differential growth in scores.

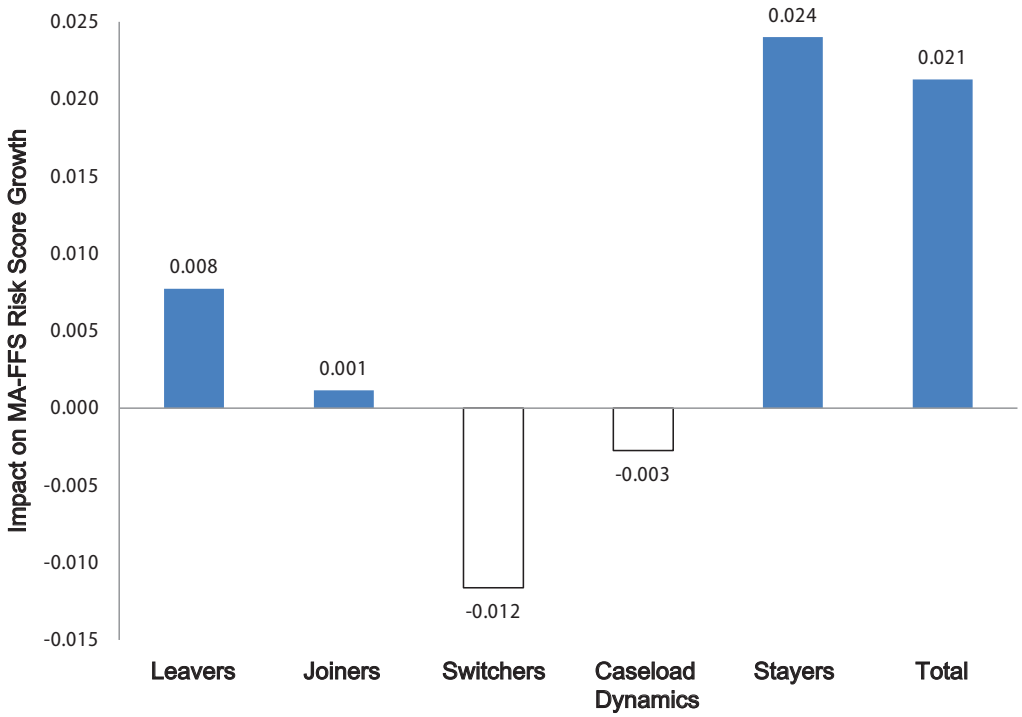
We have shown that more rapid increase in risk scores for MA stayers than for FFS stayers largely accounts for the more rapid growth in MA risk scores seen in Exhibit 1.

Relative Morbidity of MA Enrollees: Analyses of Mortality and MCBS Data

We analyze mortality rates in MA and FFS during the 2004–2012 period to test the hypothesis that

[5] The difference between 2004-05 and 2012-13 is primarily a result of the fact that disenrollees from MA to FFS had higher risk scores in the latter cohort than in the earlier one.

Exhibit 5. Sources of Differential Growth in MA and FFS Risk Scores, Average 2004–2013



NOTE: 2004 model. Caseload dynamics is the sum of leavers (e.g., decedents), joiners (e.g., newly eligibles), and switchers. Total is the sum of caseload dynamics and stayers.
SOURCE: Authors' analysis of Medicare administrative data.

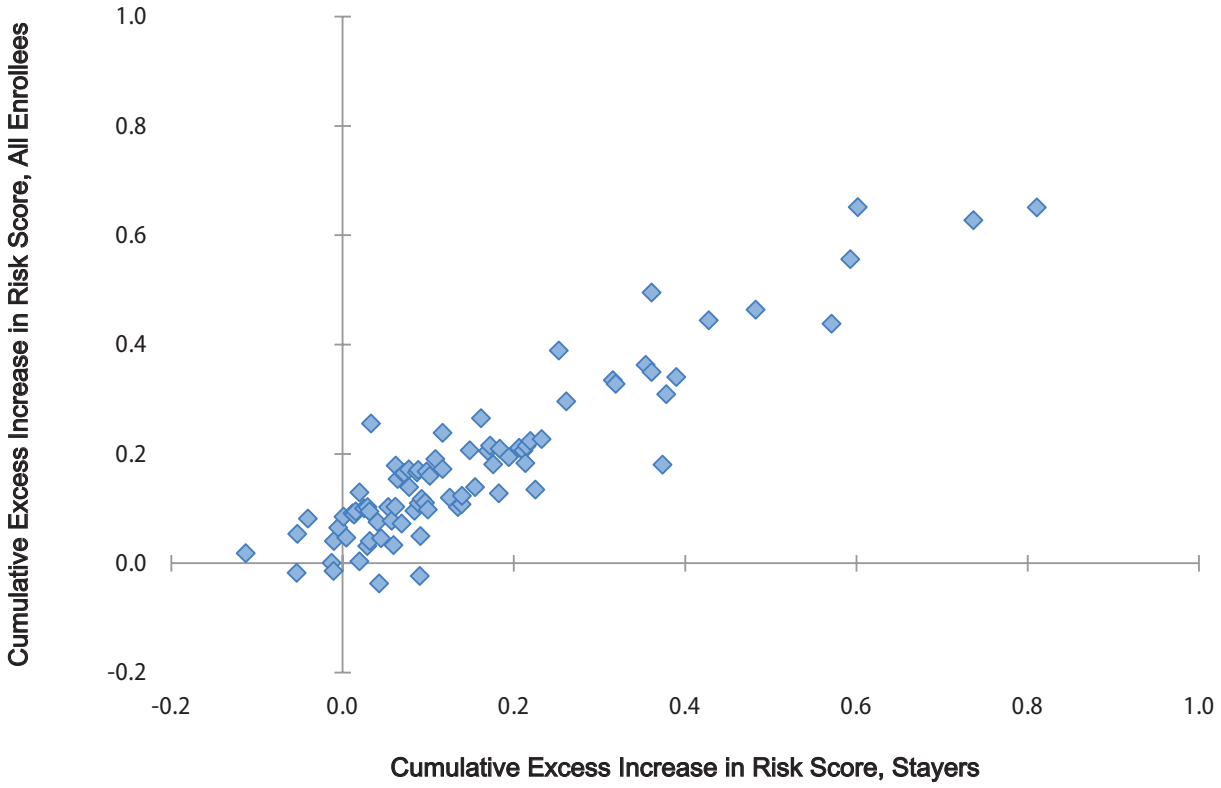
MA beneficiaries declined in health relative to FFS beneficiaries. Mortality rates declined somewhat more rapidly in MA than in FFS from 2004 to 2012, providing no support for the hypothesis that the underlying morbidity of MA beneficiaries increased relative to FFS (See Supplemental Appendix Exhibit A3 & A4). As noted earlier, mortality rates were lower in MA than in FFS.

We use MCBS data to provide an assessment of relative risk of MA and FFS beneficiaries that is independent of data reported by MA plans or FFS providers. As described in the Supplemental Appendix, we predict spending for each MA and FFS beneficiary using demographic information, self-reported health status, and the respondent's report of whether she has ever been diagnosed with hypertension, heart attack, heart failure, stroke, cancer, or diabetes. Predicted expenditures for MA enrollees average approximately 96% of predicted expenditures for FFS beneficiaries, and the ratio does not appear to have changed systematically over the 2006 to 2011 period. Results from this analysis are shown in the Supplemental Appendix Exhibit A8.

Contract-Level Analyses

There is a striking amount of heterogeneity across MA contracts in the extent to which risk scores for stayers increased from 2004 to 2011 (Exhibit 6). The fourteen contracts accounting for 10% of MA enrollment that coded least aggressively had cumulative increases in risk scores for stayers at or below the level in FFS (i.e., cumulative excess increase at or below zero). Conversely, the four contracts in the top decile, including one with over 200,000 members, had a cumulative excess increase

Exhibit 6. Cumulative Excess Increase in Risk Scores, All Enrollees vs. Stayers Only, by Contract, 2004–2011



NOTE: 2004 model. Continuously participating contracts (N=86).
SOURCE: Authors' analysis of Medicare administrative data.

of 0.59 or more (at least 0.08 per year). Contracts in which risk scores for stayers increased more rapidly than in FFS also had overall risk scores that increased more rapidly than FFS (r=.92).

Increases in diagnostic coding are especially large in a relatively small number of largely discretionary HCCs (Exhibit 7).[6] For example, in 2012, 1.2% of FFS beneficiaries were coded with drug or alcohol dependence, compared to 8.1% of beneficiaries in the 10% of MA contracts with the highest level of coding intensity (as measured by the cumulative excess increase in risk scores for stayers shown in Exhibit 6). Similarly, polyneuropathy is recorded three times as often in the top decile of MA plans as in FFS. In addition, MA plans, particularly those in the top decile of coding intensity, both increased the rate at which diabetes was reported, and shifted the distribution towards the highest paying diabetes HCC (HCC 15). Among the top decile of plans, the prevalence of this HCC increased from 2.5% in 2004 to 20.1% in 2012. In contrast, for diagnoses such as heart attack and hip fracture, where there is little discretion in diagnosis, prevalence in the top decile of plans is similar to, or below, FFS levels (see Supplemental Appendix Exhibit A5).

In 2014 Medicare started using a revised model, which we term the "2014 model." In part as a result of the analysis shown in Exhibit 7, the polyneuropathy HCC was restructured to remove diabetic neuropathy, and the renal failure HCC was restructured to exclude chronic kidney disease stages 1–3 and was split into acute and chronic kidney conditions, among other changes. These changes build on the changes made in 2013 that constrained the payment weights for each of the four most severe diabetes HCCs to be equal, removing the ability of MA plans to generate extra revenue by increasing the reported severity of diabetes within these four HCCs.

As a result of the changes to the model in 2013 and 2014, the impact of coding effort on risk scores is smaller using the new 2014 model than with the older 2004 model. As shown in Exhibit 8, if the 2014 model had been in place in 2013, the average MA risk score in 2013 would have been slightly higher than the average FFS score. Even using the new model, the average MA score increased substantially relative to the average FFS score from 2004 to 2013, but the rate of increase was somewhat slower than when measured with the 2004 model—an increase of 2.2% per year in relative MA score using the 2004 model (Exhibit 1)—compared to approximately 1.6% per year using the 2014 model. This result suggests that some coding intensity efforts—such as increasing the reported severity of diabetes or coding chronic kidney disease more aggressively—have been neutralized by the 2014 model, but others have not.

Discussion

In the 2004–2013 period, the mean MA risk score increased 2.2 percentage points per year more quickly than the mean FFS score using the 2004 model and 1.6 percentage points more quickly using the 2014 model. Comprehensive risk adjustment was first implemented in Medicare Advantage in 2004 and was not fully phased in until 2007 when 100% of Part C payments were risk adjusted. It is possible that during this phase-in period when plans were first reporting diagnosis codes from ambulatory settings, the level of coding by MA plans was not as comprehensive

[6] An HCC is considered "discretionary" if it is based on diagnoses that providers may or may not record for patients having the diagnosis. For example, there is relatively little discretion in whether a diagnosis of 'hip fracture' should be recorded for a patient presenting with an apparent hip fracture. In contrast, there is substantial discretion about whether a patient being assessed in an annual wellness visit should be recorded as exhibiting 'alcohol or drug abuse'. Discretion might also result from either a choice of ICD-9 codes (e.g., pneumonia vs. sepsis in an inpatient setting) or underlying ambiguity of the condition (e.g., depression vs. anxiety).

Exhibit 7. Top Ten HCCs of Relative Prevalence in the Top Decile of MA Contracts, 2004 vs. 2012.

			Prevalence							
			2004				2012			
Rank	HCC	Description	FFS Mean	MA Mean	MA Top Decile	Ratio, Top Decile:FFS	FFS Mean	MA Mean	MA Top Decile	Ratio, Top Decile:FFS
1	52	Drug/Alcohol Dependence	0.6%	0.4%	0.5%	0.75	1.2%	1.7%	8.1%	6.64
2	15	Diabetes with Renal or Peripheral Circ. Manifest.	2.5%	2.5%	2.5%	0.98	4.0%	7.1%	20.1%	5.07
3	131	Renal Failure	3.5%	2.7%	2.7%	0.79	9.9%	14.6%	38.2%	3.85
4	71	Polyneuropathy	3.8%	3.1%	3.3%	0.85	6.5%	10.1%	20.1%	3.09
5	83	Angina Pectoris/Old Myocardial Infarction	5.3%	4.6%	5.0%	0.96	4.9%	7.9%	15.0%	3.03
6	55	Major Depressive, Bipolar, & Paranoid Disorders	3.9%	2.4%	3.0%	0.76	5.7%	7.5%	14.1%	2.50
7	105	Vascular Disease	11.2%	7.8%	8.1%	0.73	13.6%	15.4%	33.3%	2.44
8	108	Chronic Obstructive Pulmonary Disease	13.4%	10.7%	12.5%	0.93	13.3%	14.5%	25.3%	1.90
9	100	Hemiplegia/Hemiparesis	1.1%	0.8%	0.6%	0.57	1.2%	1.3%	2.0%	1.77
10	157	Vertebral Fractures without Spinal Cord Injury	1.1%	0.8%	0.7%	0.62	1.1%	1.0%	1.7%	1.58

NOTE: 2004 model. Low-prevalence HCCs (<1% in 2012) were excluded.

Top decile defined using 2004–2011 data.

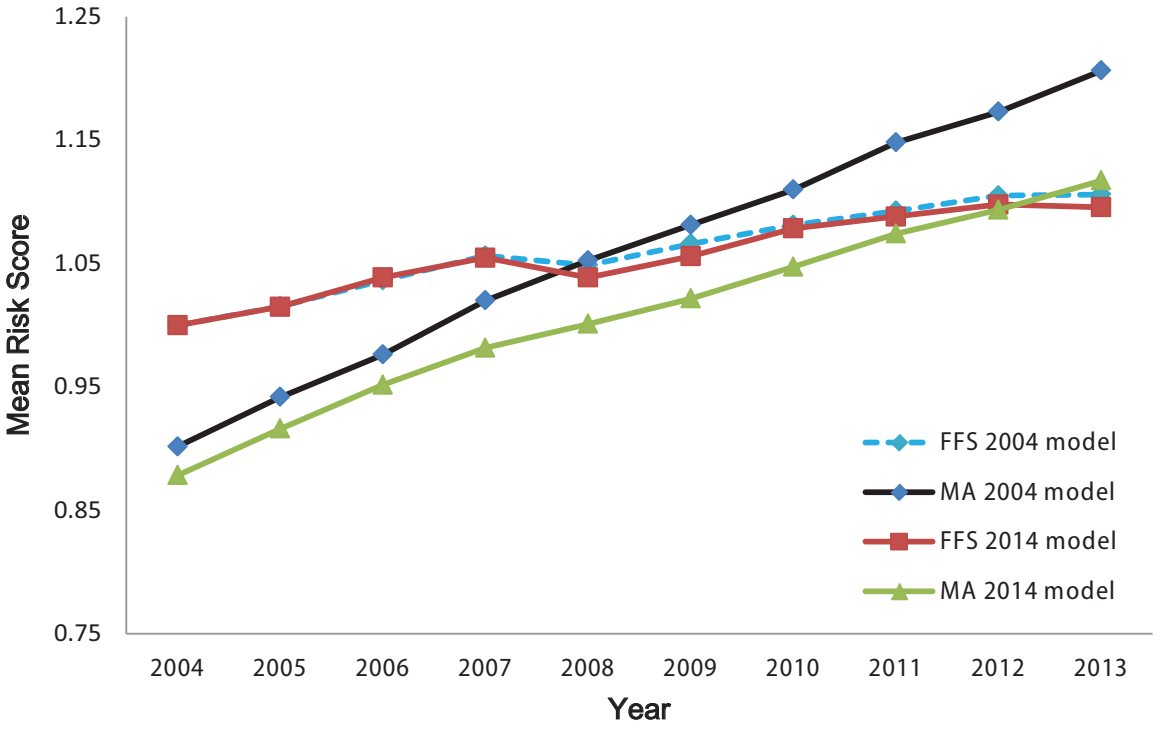
SOURCE: Authors' analysis of Medicare administrative data.

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Exhibit 8. Mean Risk Scores, MA vs. FFS, 2004–2013 (2004 & 2014 Models)



NOTE: CMS will use the "2014 model" for payment purposes for the first time in 2014, when it will receive a weight of 75%. This exhibit simulates past payment assuming full implementation. Here, both models have been normalized to 1.00 of the FFS mean in 2004.
SOURCE: Authors' analysis of Medicare administrative data.

as FFS. If that were the case, the relatively faster growth in risk scores during this period could be attributable to plans "catching up" to FFS, rather than coding more intensely than FFS. The true difference in average MA and FFS risk, which is beyond the scope of this paper, is a worthy topic for future research.

It appears that most of the reason that MA risk scores increased more quickly than FFS scores is due to increases in relative coding intensity—measured as increases in risk scores for stayers—with little of it accounted for by changes in enrollment mix. There is little sign of coding intensity slowing; in fact, Exhibit 2 shows that it may be increasing (using the 2004 model).

Our conclusion is supported by several findings. Our analysis of joiners, leavers, switchers, and stayers shows clearly that changes in the composition of the MA caseload do not account for the increase in relative MA risk scores. Risk scores for stayers increased more quickly for MA enrollees than for FFS beneficiaries—by an average of 0.088 for FFS stayers, compared to 0.120 for MA stayers (Exhibit 2), and it is this difference that accounts for the relative increase in MA risk scores (Exhibit 5).

In principle, risk scores for stayers could have increased more quickly in MA because of differences in characteristics at baseline; for example, risk scores typically increase more quickly for older beneficiaries than for younger beneficiaries. If MA enrollees were older than FFS beneficiaries, then MA scores (unadjusted for age) would have increased more quickly than FFS, even if there were no change in coding intensity. However, the age distribution of MA enrollees is

relatively similar to the age distribution of FFS beneficiaries, and slight differences between the sectors in the age distribution do not account for differences in the rate of growth of risk scores. As a second example, risk scores may increase more quickly for beneficiaries with lower initial risk scores than for those with higher initial scores, because of regression toward the mean. However, baseline risk scores are higher in MA than in FFS in the later part of the analysis period, precluding aregression-toward-the-mean explanation for MA's more rapid growth in scores.

In addition, if MA enrollees were actually sicker, relative to FFS beneficiaries, in 2013 than in 2004, then we would have expected to see some reflection of this in our analysis of mortality rates and of self-reported health status information. In contrast, mortality rates in MA declined more quickly than mortality rates in FFS, and there was no evidence of a trend in self-reported illness, suggesting that MA enrollees did not actually become relatively sicker over the time period.

In an observational study such as this one, it is never possible to conclusively rule out all alternative hypotheses. MA risk scores increased more rapidly than FFS scores. We have shown that this did not result from a change in the composition of MA enrollees. And we have shown that using two independent measures of health status—self-reported health from the MCBS and information on mortality—that there is no indication that MA enrollees actually were getting any sicker than FFS beneficiaries. While it is theoretically possible that some explanation other than greater coding intensity accounts for the relative increase in MA risk scores, we are unable to suggest any plausible alternative hypotheses.

We have also shown that there is substantial heterogeneity across plans in coding intensity, with some plans coding at approximately the same level as FFS, while several others created a cumulative increase in coding intensity from 2004 to 2011 of 60% or more.

Coding more carefully may have real health benefits. Better identification of problems and better documentation of problems that have been identified could improve the quality of treatment provided and may even lower costs—or they may lead to unnecessary treatment and higher costs. In either case, however, the purpose and design of the risk-adjusted payment system is not to improve the quality of coding. It is to ensure that plans are paid according to the health of the patients they enroll. It is unlikely that the increased payments achieved by plans through increased coding intensity are related to substantial health benefits that better coding might produce.

CMS and the Congress have responded to the increase in risk scores over time in several ways. First, starting in 2010, CMS lowered payment by 3.41% by applying an across-the-board coding adjustment. The coding intensity adjustment will increase to 4.91% in 2014 and to at least 5.91% in 2018. Second, starting in 2013, CMS set the four most severe diabetes HCCs (HCC15-HCC18) to have the same payment coefficient (Department of Health and Human Services, 2012). As a result, recording diagnoses that move enrollees from HCC18 (diabetes with ophthalmologic or unspecified manifestation) into HCC15 (diabetes with renal or peripheral circulatory manifestation) will no longer increase revenue for MA plans. Third, CMS made further changes to the model in 2014, removing some of the HCCs that were the subject of MA efforts at increasing coding intensity.[7]

[7] CMS is also recovering overpayments identified by risk adjustment data validation (RADV) audits of selected MA contracts.

Relative MA risk scores have been increasing at least 1% per year (Exhibit 8) and are likely to continue to do so, even though MCBS-based risk scores have been roughly constant.[8] The legislated increase in coding intensity adjustment is 0.25% per year from 2014 through 2018. The President's Budget for 2015 proposes increasing the minimum adjustment to 0.67% per year through 2020, plateauing at 8.51% in 2020 and thereafter, much closer to the expected increase in relative risk scores. The across-the-board adjustments do not address the substantial heterogeneity in plan-level results shown in Exhibit 6.

It is challenging to accurately measure the effects of coding intensity on MA risk scores and even more challenging to devise optimal policy responses. Uncertainty about the extent to which coding intensity would persist beyond the early years of using diagnostic information, uncertainty about whether some of the changes observed in MA risk scores might have been due to changes in underlying morbidity of MA enrollees, and heterogeneity across plans in coding intensity each create challenges in evaluating appropriate policy responses. In addition, it is unclear to what extent MA plans coded less completely than FFS in 2004, and how much of the increase in coding intensity reflects MA simply catching up to FFS levels, and how much represents going above and beyond. The Department of Health and Human Services is continuing its analysis of the relative risk of MA and FFS enrollees to improve the ability of the Medicare program to accurately pay for MA beneficiaries.

Disclaimer

The authors report no conflicts of interest related to this analysis. The content is solely the responsibility of the authors and does not necessarily reflect the views of the Department of Health and Human Services.

[8] Some would expect that MA plans will react to the 2013 and 2014 model changes by finding other HCCs on which to focus their efforts, and the success of coding intensity efforts may well increase in the future.

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Acknowledgment

Data were available through a data use agreement (#212990) between the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the Centers for Medicare & Medicaid Services (CMS). The authors appreciate the assistance of David Freund of Fu Associates and Andrew Bindman and the programming work of Acumen, LLC.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

HUMANA INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:23-cv-909-O
	)	
XAVIER BECERRA, et al.,	)	
	)	
Defendants.	)	
	)	

DECLARATION OF JENNIFER DUPEE

I, Jennifer Dupee, declare that the following statements are true and correct to the best of my knowledge and belief, that they are based on my personal knowledge, or they are based on information supplied to me in the ordinary course of my job duties:

1) I am employed by the Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS"), located at 7500 Security Boulevard, Baltimore, MD 21244.

2) I am the Director of the Division of Audits and Vulnerabilities Group (AVG), a component of CMS's Center for Program Integrity (CPI). I have held this position since September 2020. Before I was named Director in 2020, I served as Director of the Governance Management Group (GMG). I served in that capacity for nearly two years. I first joined CMS in 2011 and have nearly fourteen years of experience with Medicare reimbursement and program integrity issues.

3) As Director of AVG, I am familiar with and responsible for implementing the reimbursement rules and procedures for auditing Medicare Advantage Plans. *See* 42 U.S.C.. §§ 1395w-21 to 1395w-28; 42 C.F.R. §§ 422.310(e), 422.311. In particular, I am familiar with

and am a subject matter expert on Risk Adjustment Data Validation (RADV) audits performed by CMS. *See* 42 C.F.R. §§ 422.310(e), 422.311.

4) As Director of AVG, I have personal knowledge of the contract-specific RADV audits for Payment Years (PYs) 2011-15 and 2018.

5) Payment year ("PY") 2018 is the first payment year for which CMS will use extrapolation in contract-specific RADV audits. CMS did not conduct any contract-specific RADV audits for PYs 2016 and 2017. For PYs 2011-2015, CMS did conduct contract-specific RADV audits, but will not make extrapolated recoveries.

6) For the contract-specific RADV audits for PYs 2011 through 2013, CMS selected thirty Medicare Advantage contracts per year to audit. For each selected contract, CMS sorted RADV-eligible beneficiaries by their cumulative risk scores, placed them into three strata (high, medium, low), and selected 67 beneficiaries for audit in each stratum (a total of 201 beneficiaries were sampled per contract). CMS reviewed medical records for these sampled enrollees to determine overpayments, but it will not extrapolate any of its findings to other enrollees in the contract for which CMS did not review medical records. For the contract-specific RADV audits for PYs 2011 through 2013, CMS will only seek to recover the total net overpayment amount for the audited enrollees and will not seek any extrapolated overpayment recoveries.

7) For PYs 2014 and 2015, CMS selected MA enrollees and contracts for RADV audits by first using a multiple regression model to estimate a predicted overpayment for each enrollee in the MA program's RADV-eligible population. CMS ranked each RADV-eligible enrollee based on the amount of overpayment predicted by the model. CMS then used a multi-tiered approach to select enrollees and contracts. For Tier 1, CMS selected the top 300 ranked enrollees. For Tier 2, CMS applied a sub-cohort methodology that established a sampling frame

that focused on 190 contracts that had enrollees: (1) with certain diseases, and (2) ranked in the top decile of enrollees predicted to have the greatest overpayments. CMS selected a sample of thirty enrollees from each selected contract and reviewed medical records for those sampled enrollees, and it will only seek to recover the total net overpayment amount for the sampled enrollees. CMS will not seek any extrapolated overpayment recoveries for the contract-specific RADV audits for PYs 2014 and 2015.

8) The methodology for the PY 2018 RADV audits, which CMS is currently conducting, is described in a document titled "PY 2018 Audit Methods and Instructions" that CMS posted on its RADV webpage on November 15, 2024. *See* Medicare Advantage Risk Adjustment Data Validation Program, https://www.cms.gov/data-research/monitoring-programs/medicare-risk-adjustment-data-validation-program. This document includes details such as sampling methods, medical record submission requirements, and a payment error calculation methodology including extrapolation. A true and accurate copy of this document is attached hereto as Attachment A.

9) For PY 2018, in accordance with the methods described in the PY 2018 Audit Methods and Instructions document, CMS selected two tiers of MA contracts for RADV audits. Tier 1 includes forty-five contracts. CMS selected these forty-five contracts by first using improper payment prediction models (with indicators such as CMS Hierarchical Condition Categories (CMS-HCCs), demographics, disease persistency, past audit results, and national error rate sampling results) to identify the top 10% of all RADV-eligible enrollees in the MA program likely to have had improper payments made for them and thus likely to have the greatest reduction in risk scores in a RADV audit. CMS then sorted MA contracts into three categories: large, medium, and small. For each category, CMS first selected the twelve contracts with the

highest percentages of their enrollees likely to have improper payments. CMS then selected three contracts randomly from all the contracts in each category that had at least some enrollees in the top 10% of all enrollees likely to have improper payments. This resulted in CMS selecting fifteen contracts from each of the three categories, and forty-five total for Tier 1.

10) For each contract being audited in Tier 1, in accordance with the methods described in the PY 2018 Audit Methods and Instructions document, CMS selected a group of interest of RADV-eligible enrollees from the contract, and a sample of enrollees from within that group of interest. This group of interest is sometimes referred to as a "sampling frame" or "sub-cohort," and for Tier 1, includes all of the contract's RADV-eligible enrollees that were in the top 10% of all RADV-eligible enrollees in the program most likely to have improper payments.

11) In all Tier 1 audits where the group of interest contains more than thirty-five enrollees, CMS selected a sample of thirty-five enrollees from the group of interest. CMS will review medical records for these sampled enrollees, identify the average change in risk score for the sampled enrollees due to RADV, and, as long as thirty or more enrollees remain in the sample at the time payment error calculations are done at the end of the audit (some enrollees may be removed from the sample due to certain, rare hardship and other administrative exceptions), will extrapolate these findings to the entire group of interest to determine a total overpayment amount for the group of interest. However, CMS will not extrapolate any of its findings to other enrollees in the contract outside of the group of interest.

12) In Tier 1 audits where the group of interest contains thirty-five or fewer enrollees, CMS will only audit these enrollees and will not use extrapolation.

13) Tier 2 includes fifteen contracts. CMS selected these fifteen contracts by first sorting MA contracts into three categories: large, medium, and small. For each category, CMS

selected the four contracts with the highest proportion of RADV eligible enrollees that had all of their Encounter Data System (EDS) CMS-HCCs, based on diagnoses submitted by the audited contract to the EDS, derived only from linked or unlinked chart review records. CMS then selected one contract randomly from all the contracts in the group that had at least one RADV eligible enrollee that had all of their EDS CMS-HCCs, based on diagnoses submitted by the audited contract to the EDS, derived only from linked or unlinked chart review records. This resulted in CMS selecting five contracts from each of the three categories, and fifteen total for Tier 2.

14) For each contract under audit in Tier 2, in accordance with the methods described in the PY 2018 Audit Methods and Instructions document, CMS has selected a group of interest of RADV-eligible enrollees from the contract, and a sample of enrollees from within that group of interest. For Tier 2, the group of interest includes all of the contract's RADV-eligible enrollees that had all of their EDS CMS-HCCs, based on diagnoses submitted by the audited contract to the EDS, derived only from linked or unlinked chart review records.

15) In all Tier 2 audits where the group of interest contains more than thirty-five enrollees, CMS selected a sample of thirty-five enrollees from the group of interest. CMS will review medical records for these sampled enrollees, identify the average change risk score for the samples enrollees due to RADV, and as long thirty or more enrollees remain in the sample at the time payment error calculations are done at the end of the audit (some enrollees may be removed from the sample due to certain, rare hardship and other administrative exceptions), will extrapolate these findings to the other enrollees within the group of interest to determine a total overpayment amount for the group of interest. However, CMS will not extrapolate any of its findings to other enrollees in the contract outside of the group of interest.

16) In Tier 2 audits where the group of interest contains thirty-five or fewer enrollees, CMS will only audit these enrollees and will not use extrapolation.

17) Attached hereto as Attachment B is a true and accurate chart providing summary data and statistics for each Medicare Advantage contract selected for a Tier 1 contract-specific audit for PY 2018. Attached hereto as Attachment C is a true and accurate chart providing summary data and statistics for each Medicare Advantage contract selected for a Tier 2 contract-specific audit for PY 2018. The contract number, contract name, and contract type have been redacted from both charts. The nine Humana contracts selected for audit in PY 2018, all of them among the forty-five contracts selected for Tier 1 audits, have been shaded gray in Attachment B.

18) Each chart contains, for each contract, in columns from left to right: the number of RADV eligible enrollees ("RADV Eligible Population," Column D), the number of enrollees within the group of interest ("Tier 1 Group of Interest," Column E), the contract's total Medicare Advantage enrollee population (Column F), and the percentage of the contract's total Medicare Advantage enrollee population within the sampling frame ("Percentage of MA Population in Group of Interest)," Column G).

19) The charts for Tiers 1 and 2 show, at each Column E respectively, that there are six audited contracts with groups of interest smaller than thirty-five enrollees. CMS will not use sampling and extrapolation to calculate overpayments for these six contracts but will instead review the medical records of each enrollee in the group of interest and recoup any overpayments that it specifically identifies.

20) Among the audited contracts for which CMS will use extrapolation, the smallest group of interest is forty-three enrollees. *See* Attachment C, Row 2, Column E. In this audit, in

accordance with the methods described in the PY 2018 Audit Methods and Instructions document, CMS will review the medical records of thirty-five enrollees and extrapolate the lower bound of the 90 percent confidence interval of the average change in risk score, to each of the forty-three enrollees in the group of interest.

21) Among the audits that will include extrapolation, five will have groups of interest smaller than 100 enrollees, and more than one-quarter will have groups of interest smaller than 400 enrollees. *See* Column E in Attachments B and C. Three audits with extrapolation will extrapolate findings to groups of interest that are less than 2% of the contract's total enrollee population. *See* Column G in in Attachments B and C. Nine audits will extrapolate out to groups of interest less than 5% of the contract's total enrollee population. *See id.* And twenty-three will extrapolate out to less than 10% of the audited contract's total enrollee population. *See id.*

22) Further, thirty-nine out of the fifty-four extrapolated audits will extrapolate out to groups of interest less than 20% of the contract's total enrollee population, all but two will extrapolate out to groups of interest less than 30% of the contract's total enrollee population, and all of the audits will calculate extrapolated overpayments for less than 45% of the beneficiary population. *See id.*

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on:

Date: 12/5/24



Jennifer Dupee
Director, Division of Audits and Vulnerabilities Group
Center for Program Integrity
Centers for Medicare & Medicaid Services

Payment Year 2018
Medicare Advantage Contract-Specific
Risk Adjustment Data Validation (RADV)

Audit Methods and Instructions

(CMS Website Version)

November 14, 2024

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1 Purpose

This document communicates the Centers for Medicare & Medicaid Services' (CMS) audit methods and instructions to a Medicare Advantage Organization (MAO) selected for a payment year (PY) 2018 contract-specific RADV audit.[1] The MAO should closely review this document and referenced attachments to understand the full scope and requirements for the audit.

2 Background

Section 1853(a)(1)(C) of the Social Security Act requires that CMS risk-adjust payments made to MAOs. Risk adjustment strengthens the Medicare Advantage (MA) program by ensuring that appropriate payments are made to MAOs based on the health status and demographic characteristics of their enrolled beneficiaries. MAOs submit enrollees' diagnosis data[2] to CMS until the final risk adjustment data submission deadline to receive risk adjusted payments from CMS. CMS published information about how PY 2018 MA risk adjusted payments were calculated—including risk adjustment factors and hierarchical condition categories (CMS-HCCs)—in the Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information (April 3, 2017).[3]

CMS conducts RADV audits pursuant to 42 C.F.R. § 422.310(e), which requires MAOs to submit a sample of medical records (MRs) from face-to-face encounters to CMS for validation of risk adjustment data. Contract-specific RADV audits are CMS' main corrective action to identify overpayments made to MAOs when there is a lack of documentation in MRs to support the diagnoses reported by MAOs for risk adjusted payments.[4] For each MA contract-specific RADV audit for PYs 2018, CPI will define a sample unit and sampling frame, select a sample of enrollees from within the sampling frame, and extrapolate audit results to the sampling frame.

Each MA contract-specific RADV audit includes:

- Planning: CMS defines a sample unit, sampling frame, and sample selection method.
- Initiation: CMS sends an Audit Notice and provides audit methods and instructions.

[1] In the past, CMS referred to a MA contract-level RADV audit (now referred to as a contract-specific RADV audit) using the acronym CONXX, where XX referred to the two-digit payment year. This acronym may still be used in CMS systems for a limited time until CMS can make terminology updates.

[2] Risk adjusted payments to MAOs for a given PY are required to be substantiated by diagnoses documented in MRs from face-to-face encounters with dates of service in the year prior to the PY (i.e., data collection year).

[3] https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2018.pdf

[4] A CMS contract-specific RADV audit focuses on the health conditions (i.e. diagnoses) self-reported by an MAO for the purpose of receiving risk adjusted payments, not on confirming other data/factors from CMS' systems of records that impact payments.

- MR Submission: The MAO submits MRs to CMS during a MR submission window for enrollees selected in the audit sample.
- Analysis and Issuance of an Audit Report Package: CMS analyzes the output from MR reviews, calculates payment errors, and issues an Audit Report Package to the MAO.[5]

3 Important Dates to Remember

The following are important dates to remember for the PY 2018 MA contract-specific RADV audit:

- MR submission window opens: November 14, 2024
- Hardship Exception Request Deadline: March 3, 2025
- MR Submission Deadline (window closes): April 21, 2025

4 Statistical Sampling Methodology

This section describes the sampling frame, sample unit definition, sample design, and sample selection method for this audit.

4.1 Sampling Frame

Note: The points of contact for each MA contract selected for audit in PY 2018 will receive a version of this document that contains only one of two versions (A or B) of this Sampling Frame section based on the sampling frame used for their audit.

Version A

CMS defined the sampling frame for this MA contract-specific RADV audit by identifying enrollees that:

1. Were continuously enrolled in the audited MA contract from January of the data collection year (2017) through January of the payment year (2018)
2. Were enrolled in Medicare Part B coverage for all 12 months during the data collection year (2017)
3. Had at least one risk adjustment diagnosis in the International Classification of Diseases, Clinical Codes with a 2017 date of service that led to at least one CMS-HCC assignment for the payment year (2018)
4. Were not in an End Stage Renal Disease status from January of the data collection year (2017) through January of the payment year (2018)
5. Were not in a hospice status from January of the data collection year (2017) through January of the payment year (2018),

[5] MAOs have appeal rights pursuant to 42 C.F.R. § 422.311(c).

6. Were not part of any OIG audit or other pertinent settlement that included data from January of the data collection year (2017) through January of the payment year (2018), and
7. Were ranked in the top decile of PY 2018 RADV eligible enrollees in RADV eligible MA contracts by one or both of CPI's PY 2018 MA improper payment prediction models,[6] and therefore predicted to have the greatest reduction in their risk score as a result of a RADV audit.

Version B

CMS defined the sampling frame for this MA contract-specific RADV audit by identifying enrollees that:

1. Were continuously enrolled in the audited MA contract from January of the data collection year (2017) through January of the payment year (2018)
2. Were enrolled in Medicare Part B coverage for all 12 months during the data collection year (2017)
3. Had at least one risk adjustment diagnosis in the International Classification of Diseases, Clinical Codes with a 2017 date of service that led to at least one CMS-HCC assignment for the payment year (2018)
4. Were not in an End Stage Renal Disease status from January of the data collection year (2017) through January of the payment year (2018)
5. Were not in a hospice status from January of the data collection year (2017) through January of the payment year (2018),
6. Were not part of any OIG audit or other pertinent settlement that included data from January of the data collection year (2017) through January of the payment year (2018), and
7. Had all of their Encounter Data System (EDS) CMS-HCCs, based on diagnoses submitted by the audited MAO to the EDS, only derived from linked or unlinked chart review records.[7]

4.2 Sample Unit Definition

The sample unit is an MA contract enrollee that meets the sampling frame criteria.

4.3 Sample Selection Method

CMS selected a statistically valid random sample of 35 enrollees from the sampling frame by:

[6] Types of entities that could have been selected for contract-specific RADV audits included Coordinated Care Plans (CCPs), local Health Maintenance Organizations (HMOs), local preferred provider organizations (PPOs), Regional PPOs, Provider-Sponsored Organizations (PSOs), Special Needs Plans (SNPs) Demonstrations, Medical Savings Accounts (MSAs) Contracts, Private Fee for Service Contracts, and Employer/Union Only Direct Contract PFFS plans.

[7] A linked chart review is a chart review that is linked to a previously accepted encounter data record, allowing CMS and other oversight entities to identify the specific item or service that is associated with a risk-adjustment-eligible diagnosis. An unlinked chart review is a chart review that adds diagnoses to the encounter data without identifying the encounter data record associated with the diagnoses.

1. Establishing a seed number using a random number generator[8]
2. Sorting enrollees (i.e., sample units) included in the sampling frame by CMS' unique identifier for each enrollee, and
3. Using statistical software tool to perform simple random sampling (without replacement) method to randomly select 35 enrollees.[9]

5 Audit Initiation

CMS initiates an MA contract-specific audit by sending the MAO an Audit Notice. Upon receiving the letter, the MAO should begin taking steps to assign points of contact (POCs), review available audit sample data, and begin gathering MRs.

5.1 Audit Notice

CMS sends an Audit Notice to the Chief Executive Officer (CEO) and Medicare Compliance Officer (MCO) to initiate the MA contract-specific RADV audit. The letter provides important information about the audit, including the opportunity to establish and/or update the points of contact (POCs) for the audit and links to important documents.

5.2 Points of Contact

The CEO and/or MCO may establish POCs to help their organization comply with audit requirements throughout the audit lifecycle. A maximum of seven individuals, including the CEO and MCO, may be designated as POCs. POCs' contact information must be provided to CMS on the POC Form (see Attachment 1). Once the form is completed, only the CEO or MCO may submit the POC Form to RADVCONTechSupport@radvcdat.com. A separate POC Form must be submitted for each contract if multiple contracts for an MAO are selected for an audit.

Designated POCs will receive an email from RADVCONTechSupport@radvcdat.com. The email will instruct POCs to use the CMS secure RADV system, the Central Data Abstraction Tool (CDAT), to register and access sensitive RADV audit data. Information about the RADV audit is only provided to designated POCs. The sooner POC Forms are submitted, the sooner POCs will be able to register and access CDAT.

5.3 Enrollee Data List

CMS will make an enrollee data list (EDL) available in the audited MA contract's secure portal within CDAT to communicate the enrollees and hierarchical condition categories (CMS-HCCs) selected for audit. A POC for the MAO should access the EDL as soon as it is available to give the MAO the maximum amount of time available to gather and submit the necessary MRs for the audit.

[8] The seed number was generated using the SAS CALL routine random number generator.

[9] The software tool used was the SAS PROC SurveySelect function. Note that if the audited MA contract has fewer than 35 enrollees identified in the sampling frame, then all enrollees are included in the RADV audit sample.

The EDL is a Microsoft Excel file with three worksheets (or tabs):

1. Data Dictionary (DD) – Describes each column in the EDL.
2. Sampled Enrollee List – Includes the sampled enrollees, CMS-HCCs, and associated diagnosis codes that the MAO submitted to the Risk Adjustment Processing System (RAPS) and/or Encounter Data Processing System (EDPS) for which the MAO must submit MRs to CMS via CDAT.
3. Sampling Frame – Includes identifiers for all enrollees included in the sampling frame and a flag indicating which enrollees are selected in the sample, for reference only.

6 MR Requirements and Submission Instructions

The audited MAO must submit at least one valid MR and MR coversheet to CMS to substantiate each audited CMS-HCC included in the EDL. A valid MR for RADV purposes is a legibly signed and dated medical record that documents diagnoses and services provided during a face-to-face visit and conducted by an appropriately credentialed provider within the designated data collection period. The signature on the medical record must be the signature of the credentialed provider that conducted the face-to-face visit.

The MAO must submit MRs and MR coversheets within CDAT while the MR submission window is open. For instructions on how to submit an MR and MR coversheet within CDAT, review the *CDAT User Guide* in the Plan Library within CDAT. The MAO must request MRs from hospitals and physicians/practitioners that provided services to enrollees and documented diagnoses associated with enrollees' audited CMS-HCCs during the appropriate data collection period.[10] The data collection period for PY 2018 is January 1, 2017, through December 31, 2017.

For each sampled enrollee, the MAO can submit a maximum number of MRs equal to five times the number of audited CMS-HCCs. For example, if a sampled enrollee has two audited CMS-HCCs in the EDL, the maximum number of MRs an MAO can submit for that enrollee is 10 MRs (2 CMS-HCCs * 5). An MAO may submit these 10 MRs in any combination for the two audited HCCs.

The MR submission process includes two parts, MR intake and diagnosis code abstraction. Each MR submitted to CMS for RADV purposes will be reviewed during the MR intake process to ensure it is valid. Only valid MRs and acceptable MR coversheets will move forward to the diagnosis code abstraction step of the RADV audit. See Appendix A for a list of reasons (i.e., reason codes) why a MR (and its associated MR coversheet) can be deemed invalid.

6.1 Completing the MR Coversheet

This section includes guidance for completing the MR coversheet during the submission process in CDAT. For step-by-step instructions for accessing an electronic version of the MR coversheet template, please refer to the *CDAT User Guide* in the CDAT Plan Library. Hardcopy or "printable" coversheets are

[10] 42 C.F.R. §422.310(d)(3)

not provided. The MR coversheet allows CDAT users to submit documents (MR only or MR and attestation [MR+ATT]) or confirm no documents (No MR) for a specific sampled enrollee and audited CMS-HCC. The system will allow only the MR file to be uploaded as a PDF file to a coversheet.

The MR coversheet template displays submission information in five sections:

Section I: MA Contract Information. Displays the Contract Name, Current Contract ID, and Sample Year Contract ID for the selected enrollee.

Section II: Enrollee Information. Displays details about the selected enrollee, including the Enrollee ID, Medicare Beneficiary Identifier (MBI), Date of Birth (DOB), Last Name, and First Name. Note: When completing the submission process, the MAO must ensure the enrollee on the coversheet matches the enrollee on the MR. Submitting a MR for the wrong enrollee may lead to a Protected Health Information (PHI)/Personally Identifiable Information (PII) issue and will result in an invalid submission.

Section III: Document to be Attached. Indicates the type of MR uploaded. The uploaded file should contain one MR only. When completing the MR coversheet in CDAT, the MAO is required to select a document type for the submission. The document type determines which coding guidelines (Inpatient or Outpatient) should be applied.

- **One Physician Specialist/Hospital Outpatient Record:** This type of record is submitted for one date of service and can be a physician office visit; a standalone hospital outpatient visit (for example, an emergency room visit or outpatient procedure report); a standalone document from an inpatient stay (Consult, Progress Note, History & Physical, Emergency Room or Operative Report); a Health Risk Assessment (HRA); or a visit with a physical therapist, occupational therapist, or speech language pathologist (not occurring in an inpatient setting). For an outpatient record, enter the one date of service documented in the record. A credentialed provider's documentation, such as a progress note or a consult form, can be added to this record and submitted as an outpatient record as long as the date of service is within the data collection period and the MR has a valid signature and credentials.
- **One Hospital Inpatient Record:** This type of record can be a full inpatient hospital record or an inpatient rehabilitation record and must include both an admission date and a discharge date. Enter a date range using both admission date and discharge date documented in the record. The discharge data must be in the data collection year for the MR to be accepted as an inpatient record.

Section IV: Designated CMS-HCCs for this MR. This section displays which audited CMS-HCC(s) is designated for this MR. A MR with multiple CMS-HCCs will have each CMS-HCC on a separate row with the accompanying ICD codes for each. All the enrollee's audited CMS-HCCs are available for designation on each MR coversheet. Note: If the MR documents more than one of the audited CMS-HCCs for the enrollee, the MAO should select all applicable CMS-HCCs when completing the MR coversheet and submit the MR only once. The MAO should avoid submitting the same MR multiple times for the same or different CMS-HCC(s).

Section V: File Content/Coding Guidelines. This includes Provider Type (Inpatient or Outpatient), Admission and Discharge Dates for Inpatient Record, and Date of service for Outpatient Record.

CMS includes pre-populated MA contract information and enrollee identifiers. All other information is supplied by the MAO.

The MR coversheet should be completed according to the *CDAT User Guide* and reviewed for accuracy prior to submitting in CDAT. The following information should be verified prior to submitting each coversheet:

1. MR coversheet is correctly labeled "CY 2018 Contract-Level RADV" on all pages.
2. All data fields in Section I contain data.
3. All data fields in Section II contain enrollee data that matches the name on the MR submitted. The birth date may be used as a secondary identifier for common shortened names if it is present on the MR. MAOs can note on the coversheet reasons that explain any name variance.
4. Section III, IV, and V are populated as directed with at least one CMS-HCC indicated. If any unusual format or population issues are noted, the automated intake process may be routed to a manual process for confirmation.
5. Year of Review field must be "2017". For a hospital inpatient record, the Discharge Date Year of Review field is populated with "2017". For a physician/specialist/hospital outpatient/observation record, the Year of Review field is populated with "2017".
6. All fields in the MR Submission Information section (File Name, Submitted By, and Submission Date) must contain data.
7. On page 2, the MR coversheet displays the ICD-10-CM codes that correspond to the audited CMS-HCCs selected within Section IV of the MR coversheet.

6.2 Preparing the MR File

The MAO must submit MR documentation for each audited CMS-HCC. To do so, the MAO must create a MR file that contains one MR and, if applicable, one completed CMS-generated attestation. Please note that if the MAO intends for the MR documentation to substantiate more than one audited CMS-HCC for the enrollee, then it must indicate all applicable CMS-HCCs on the MR coversheet and submit the MR only once to validate multiple CMS-HCCs. The MAO should avoid submitting the same MR documentation multiple times. The MAO must attach each MR file to an electronic MR coversheet for submission into CDAT. An MR file submitted to CDAT cannot exceed 100MB.

Although CMS does not review MRs based on the naming convention, CMS encourages the MAO to name the MR file using the following:

1. Use the enrollee ID as provided in the sample list (e.g. 12345678)
2. Include the model number[11] for 2017 dates of service (e.g., V22), and

[11] CMS updates the MA payment system periodically to map diagnosis codes to categories of diagnoses. With each release of reclassification, a new version of the CMS-HCC model is finalized. One of the CMS-HCC model numbers used for the clinical services provided in payment year 2018 should be identified in the coversheet.

3. Include one CMS-HCC in your naming convention (e.g., HCC017)

In this example, the file name would be: 12345678_V22_HCC017. The MAO should avoid duplicate file names when submitting multiple MRs for the same CMS-HCC(s). Use unique file names for each MR. If multiple MRs are submitted for the same set of CMS-HCCs, add a Version number at the end (_v1, _v2).

MRs lacking the necessary provider signature and/or credentials require a signed attestation to be considered valid and eligible for RADV review. If a completed CMS-generated attestation is submitted, it must appear on the first page of the MR file. For additional information on the CMS-generated attestation, see Section 6.4. If applicable, the MAO should prepare each MR file containing one completed CMS-generated attestation and one MR in a PDF format.

6.3 Checking the MR File before Submission

After the MR file has been prepared according to these instructions, the MAO must complete the MR coversheet and upload the MR file in CDAT following instructions in the *CDAT User Guide*. When attaching the MR file to the MR coversheet in CDAT, the MAO must identify the type of record being submitted. If "One Physician Specialist/ Hospital Outpatient Record" or "One Observation Record" is selected, only outpatient coding guidelines will apply. If "One Hospital Inpatient Record" is selected, only inpatient coding guidelines will apply. Ensure the conditions in the inpatient MR are documented and authenticated by an acceptable risk adjustment physician specialty.

Check the MR file to ensure that:

- The MR contained in the file corresponds with the MR coversheet for which it is being submitted.
- It does not contain multiple MRs.
- All text and images are legible.
- It does not exceed 100MB

All MR coversheets and associated MR files must be submitted by the MR Submission Deadline (see Important Dates to Remember). The MAO will receive feedback on the validity of submitted MRs via the Intake Feedback Report in CDAT.

6.4 MR Attestation

MRs submitted for this audit that do not contain physician/practitioner signatures or credentials (i.e. Physician Assistant) will result in errors under the MR review process. If a MR lacks the necessary physician/practitioner signature and/or credentials, CMS allows the MAO to submit a CMS-generated attestation form (PDF file) with the MR. CMS-generated attestations are accepted only for physician and hospital outpatient MRs (i.e., not for inpatient hospital MRs).

A CMS-generated attestation must be signed by a physician/practitioner who attests responsibility for conducting and documenting the health services in the accompanying physician or outpatient MR that the MAO submits. By signing and documenting credentials on the attestation and identifying the date of service, physicians/practitioners are attesting to the MR entry being submitted for this audit.

CMS-generated attestations will be accepted only for MRs that the MAO indicates on the coversheet and should be coded accordingly. Attestations are only acceptable for physician/outpatient sites for dates of service between January 1 to December 31, 2017.

Elements of the CMS-generated attestation are pre-populated by CMS (e.g., name, date of birth, Medicare identifiers, contract name and ID) for data integrity purposes. Because it contains PHI/PII, this document will only be made available to the MAO's POCs via the plan portal within CDAT.

For point-and-click instructions on how to submit a CMS-generated attestation form in CDAT, the MAO should review the *CDAT User Guide*.

CMS reviews each submitted attestation form for validity. Attestations will be found valid if they meet the following criteria:

1. Attestation is a CMS-generated attestation form only.
2. The CMS-generated attestation is completed in its entirety, signed, and dated by the physician/practitioner who provided those services.
3. The completed fields include the printed physician/practitioner's name, the date of service of the MR to which they are attesting, the physicians/practitioner's specialty or credential (i.e. Physician Assistant), and the signature and date by the physician/practitioner that conducted the face-to-face visit.

Attestations will be deemed invalid if one (or more) of the following conditions is true:

1. The CMS-generated attestation Form is altered
2. The attestation is Incomplete
3. Date of service on the attestation form does not match the MR
4. Enrollee name does not match both coversheet and MR
5. Entire Inpatient Record (Attestations are accepted only for physician and hospital outpatient MRs. Inpatient records that indicate a specific date of service and progress note are considered outpatient records and can include an attestation)
6. The attestation form is not CMS-generated (only a CMS Generated Attestation Form is acceptable)
7. Unacceptable provider credentials
8. Unacceptable signature(s), including an attestation that is signed by someone other than the physician/practitioner with or without explanation (retired, expired, Power of Attorney, etc.)

Valid attestations move forward through the MR intake process to the diagnosis code abstraction process. Attestations that are deemed invalid will result in an error and the associated MR will be considered invalid.

7 MR Intake and Feedback Process

CMS reviews all submitted MR files and coversheets during the MR intake process to determine which ones are valid and invalid. Each submitted MR file and coversheet combination are assigned a unique Coversheet ID. While the MR submission window is open, if a MR file and coversheet combination is determined to be invalid, the MAO may submit another one to replace it. Accordingly, CMS encourages the MAO to get submissions in as early as possible. CMS continues the MR intake process until all submissions are reviewed.

CMS will provide daily feedback about each submitted MR file and coversheet throughout the MR intake process. An MAO's POC may access an Intake Feedback Report (IFR) within CDAT. The IFR provides the status of intake processing for each MR submitted during the MR submission window.[12] Once intake processing is complete for a given MR, the IFR is updated to indicate if the MR passed all intake validity checks. If it did not, then the IFR will list the reason(s) why it did not pass. Instructions for how to access the IFR are included in the Plan Library within CDAT. The IFR will be available to the MAO's POCs throughout the audit lifecycle.

Only MR files and coversheets that pass all MR intake checks and are determined to be valid will be forwarded to the diagnosis code abstraction process. Only valid MRs are eligible to be used as a basis for medical record review determination appeal, if applicable.

8 Hardship Exception Request Process

CMS recognizes there may be extraordinary circumstances preventing an audited MAO from providing MRs to CMS and complying with audit requirements. Examples of extraordinary circumstances include natural disasters and seizure of MRs by law enforcement. An MAO experiencing an extraordinary circumstance may request a hardship exception for: (1) the MA contract-specific RADV audit, (2) an audited enrollee(s), and/or (3) an audited CMS-HCC(s).

A hardship exception request for an MA contract must include the RADV Audit Number (RAN) for the contract, which was communicated in the Audit Notice, and a justification for the request.

A hardship exception request for an audited enrollee(s) or CMS-HCC(s) must include a completed *Hardship Exception Request Form* (see Attachment 2), which requires a justification for each audited enrollee and/or CMS-HCC for which the MAO is seeking a hardship exception. Note that the *Hardship Exception Request Form* is also available for download in the CDAT Plan Library.

The justification for a hardship exception request should include a detailed description of the incident/issue preventing the collection of a MR(s) to support an audited CMS-HCC(s). The supporting documentation should contain the relevant information for CMS to fully understand the incident/issue, such as any communications related to the incident and proof of the incident (e.g., copy of an insurance

[12] The IFR within CDAT does not provide the results of diagnosis coding abstraction activities. Instead, CMS will provide diagnosis coding abstraction results when it issues an Audit Findings Report at the end of an audit.

claim receipt by the provider, police report, or news article). Do not include any PHI within your hardship request. Any request that contains PHI will immediately be rejected by CMS.

All hardship exception requests and supporting documentation should be submitted to radv@cms.hhs.gov. Please include "PY18 Hardship Exception Request" in the subject line. The email may come from the approved Point of Contact (POC) but should carbon copy the Medicare Compliance Officer (MCO) or CEO.

CMS will review each hardship exception request on a case-by-case basis and a submission does not guarantee approval by CMS. If approved, the hardship exception request is valid only for a specific RADV audit.

We encourage an audited MAO to begin requesting and submitting MRs as soon as possible to not have delays in collecting MRs from health care providers prevent the timely submission of MRs to CMS. CMS does not consider the following scenarios to be justification for granting a hardship exception: record retention issues, health care providers not responding to a request, issues related to lost records, retired health care providers, and human resource issues.

All hardship requests must be submitted to CMS as soon as possible and no later than the Hardship Exception Request Submission Deadline (see Important Dates to Remember).

9 Diagnosis Code Abstraction

From all valid MRs that pass MR intake, CMS abstracts diagnosis codes in accordance with International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Guidelines for Coding and Reporting[13], and *Coding Clinic for ICD-10-CM and ICD-10-PCS*[14] quarterly newsletters published by the American Hospital Association's Central Office on ICD-10-CM and ICD-10-PCS. CMS' affirmation of the Coding Clinic as the official source of coding information is noted in the Federal Register, Vol. 74, No. 165, at pgs. 43,784, 43791-98, Thursday, August 27, 2009. An MAO submitting MRs to substantiate audited CMS-HCCs must also follow these guidelines and newsletters; instructions in this document; requirements set forth in Chapter 7 of the *CMS Medicare Managed Care Manual;* and all requirements set forth in Medicare regulations, Parts C and D contracts, and Electronic Data Interchange Agreements.

Each submitted valid MR may be subjected to up to three rounds of review by certified MR coders. An initial MR review to abstract ICD-10-CM codes is conducted on all submitted valid MRs. MRs that do not substantiate the one or more audited CMS-HCCs for which they were submitted will undergo a second review. A physician review is conducted on each MR where there is disagreement between the first and second medical review about whether, or to what degree, an audited CMS-HCC(s) is discrepant (see

[13] ICD-10-CM Coding Guidelines: https://www.cms.gov/medicare/coding-billing/icd-10-codes

[14] Coding Clinic Advisor: https://www.codingclinicadvisor.com/aha-central-office

below for information on what makes a coding review discrepant). Physician review is the last step in the MR diagnosis code abstraction process.

10 Payment Error Calculation Methodology

RADV audits confirm the presence of diagnoses that map to CMS-HCCs in MR documentation submitted by an MAO. A risk adjustment discrepancy is identified when an original CMS-HCC(s) used for payment for a sampled enrollee, based on diagnosis code data self-reported by an MAO, differs from the CMS-HCC(s) assigned after MR diagnosis code abstraction is completed by CMS through the RADV audit process. Risk adjustment discrepancies are aggregated for sampled enrollees to determine the average change in sampled enrollees' risk scores as a result of the RADV audit, which is then used to estimate an overpayment amount for collection for the sampling frame using a statistically valid extrapolation technique.

Detailed information about MA risk adjustment and enrollee risk score calculation is published each year by CMS.[15] Risk adjustment models and supporting data and documentation are available for PY 2006 through the present. All enrollee risk score calculations during a RADV audit use the published model for the relevant PY, including the relevant normalization, coding intensity adjustment, and frailty factors (if applicable). CMS will use the most recently available data from CMS systems of records and post-RADV results of audited CMS-HCCs to calculate payment errors for sampled enrollees and estimate the payment error for the sampling frame.[16]

10.1 Payment Error Calculation for Sampled Enrollees

CMS calculates the "RADV enrollee total payment error" for each enrollee selected in the RADV audit sample by completing the following steps:

1. Running the sampled enrollee's diagnosis codes that are abstracted by CMS from valid MRs submitted by the MAO for RADV[17], and other necessary data for the enrollee sourced from CMS systems of records, through the relevant PY's MA payment model to determine the "RADV enrollee risk score".[18]

[15] https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents. These documents comprise the Medicare Advantage (MA), and Medicare+Choice (M+C) advance notices of methodological changes; announcements issued with MA or M+C rates; and special reports.

[16] Data from CMS systems of records that contributes to MA payment error calculations may include items such as the following: Medicare Beneficiary Identifier (MBI), Health Insurance Claim Number (HICN), Date of Birth, Sex, Original Reason for Entitlement Code (OREC), and Medicaid Dual Status.

[17] No payment error will be calculated for any sampled enrollees and/or audited CMS-HCCs for which CMS has approved a Hardship Exception.

[18] If CMS abstracts a diagnosis code (that maps to a CMS-HCC) that was not previously submitted by the MAO for risk payment prior to the data submissions deadline(s), and such a diagnosis code was found in a valid MR that substantiates any manifestation of an audited CMS-HCC in the RADV audit sample (i.e., even if a MR only

2. Calculating "RADV monthly enrollee risk payment amounts" by multiplying the "RADV enrollee risk score" after normalization, adjustment, and blending (if applicable) by the appropriate county rate for months in which the sampled enrollee was covered by the plan and not in an End Stage Renal Disease (ESRD) or hospice status.
3. Summing the "RADV monthly enrollee risk payment amounts" and applying all other relevant payment components[19] and adjustments to determine the "RADV Enrollee Risk Payment Amount".
4. Calculating "RADV enrollee monthly payment error" by subtracting each month's "RADV monthly enrollee risk payment amount" from the "original monthly payment amount" that was previously received by the MAO.
5. Summing the "RADV enrollee monthly payment error" amounts for the PY to determine the "RADV enrollee total payment error".

Note that the "RADV enrollee monthly payment error" amount can be positive, $0, or negative.[20] When positive, an overpayment condition exists related to the sampled enrollee.

10.2 Use of Extrapolation to Estimate Overpayment Amount for the Sampling Frame

Extrapolation is expected to be the standard practice beginning with CMS RADV audits of MA contracts from PY 2018.[21] In rare circumstances, however, CMS may use its discretion to not utilize extrapolation, such as when the original number of enrollees identified in the sampling frame is less than 30[22] or when unforeseen circumstances (e.g., MRs for sampled enrollees are destroyed in a natural disaster and are

substantiates a lower manifestation of an audited CMS-HCC), then CMS will include the "additional CMS-HCC" when calculating a specific RADV sampled enrollee's "RADV enrollee risk score". Note, however, that the crediting of "additional CMS-HCCs" during a RADV audit can only offset overpayment amounts and can never result in additional risk adjustment payments to an MAO since this would circumvent the final risk adjustment data submission deadlines described at 42 C.F.R. § 422.310(g)(2)(ii). An MAO is not permitted to appeal determinations made by CMS during a RADV audit regarding whether to give credit for additional CMS-HCCs. *See* 79 Fed. Reg. 29932 (May 23, 2014).

[19] Other relevant payment components include rebates, premiums, and other factors.

[20] In rare instances when CMS decides not to extrapolate to estimate total payment error for the sampling frame, if a net underpayment condition exists when the "RADV enrollee monthly payment error" amounts for all sampled enrollees are summed, then the net underpayment amount will be capped at $0.

[21] 88 Fed. Reg. 6650 (Feb. 1, 2023)

[22] When the original number of enrollees in the sampling frame is less than 30 and CMS is auditing all CMS-HCCs (for those original enrollees) for which the MA contract received risk adjusted payments, CMS will audit the entire sampling frame without the use of extrapolation.

not otherwise available) disturb the statistical validity of the audit sample.[23] When extrapolation is utilized, CMS will extrapolate the estimated payment error only to enrollees within the sampling frame.

For this MA contract-specific RADV audit, CMS intends to use extrapolation to estimate an overpayment amount for collection. More specifically, this will be accomplished by:

1. Calculating the average change in risk score ($\overline{\Delta R}$) for the sampled enrollees, where n represents the number of sampled enrollees and ΔR_i represents the change in risk score for a sampled enrollee:

$$\overline{\Delta R} = \frac{1}{n}\sum_{i=1}^{n} \Delta R_i$$

2. Deriving the variance ($s^2_{\Delta R}$) of the change in risk score for each sampled enrollee:

$$s^2_{\Delta R} = \sum_{i=1}^{n} \frac{(\Delta R_i - \overline{\Delta R})^2}{n-1}$$

3. Calculating the estimate of the variance of the average change in risk score ($VAR(\overline{\Delta R})$) for the sampling frame, where N represents the number of enrollees in the sampling frame:

$$VAR(\overline{\Delta R}) = \left(\frac{N-n}{N}\right)\frac{s^2_{\Delta R}}{n}$$

4. Computing the lower bound of the 90 percent confidence interval (δ) of the change in risk score:

$$\delta = \overline{\Delta R} - 1.645\sqrt{VAR(\overline{\Delta R})}$$

5. Multiplying the calculated lower bound of the change in risk score by the sum of county rates in the sampling frame to obtain an estimated payment error for the sampling frame, where c_i represents the county rate for an enrollee in the sampling frame of the audited MA contract:

$$PE = \sum_{i=1}^{N} \delta c_i = \delta \sum_{i=1}^{N} c_i$$

[23] In instances where hardship exception requests are approved by CMS and the total number of enrollees remaining in the sample falls below 30, CMS will not use extrapolation.

11 Audit Report Package

When CMS completes the MA contract-specific RADV audit, it posts an Audit Report Package in the audited MA contract's secure portal within CDAT and notifies the MAO's POCs via email. An Audit Report Package includes a letter and Excel workbook with audit results that will provide detailed feedback about each sampled enrollee and audited CMS-HCC. CMS will also provide a help document(s) to assist an MAO in understanding the contents of the Audit Report Package.

12 RADV and the Requirement to Report and Return Plan-Identified Overpayments

In accordance with 42 CFR 422.326, an MAO is required to report and return any plan-identified overpayments within 60 days of being identified. However, as a contract selected for a CMS PY 2018 RADV audit and in accordance with 42 CFR 422.326(d), please suspend the reporting of overpayments to the Risk Adjustment Overpayment Reporting (RAOR) module in the Health Plan Management System (HPMS) and the submission of data corrections in RAPS and/or EDPS for PY 2018 for enrollees included in this audit's sampling frame (which includes the sampled enrollees) until further notice. For plan-identified overpayments related to enrollees in the subject MA contract that are not included in the sampling frame for this RADV audit, your organization is required to report any plan-identified overpayment to CMS in accordance with 42 CFR 422.326.

13 CMS Email Support Resources

The POCs associated with an audited MA contract may request technical support regarding use of the CDAT system by sending an email to the CDAT Technical Support Email Box at RADVCONTechsupport@radvcdat.com.

Individuals with general questions about CMS' MA contract-specific RADV audits may send an email to radv@cms.hhs.gov.

Appendix A: Invalid MR Reason Codes[24]

INV1 –Wrong Record/No name. The MR name and identifying information is completely different from the name on the MR coversheet (sampled beneficiary CMS- HCC). Validity Check Question: *Does the MR correctly identify the sampled beneficiary?*

INV2 – Missing signature. The MR submitted is not signed. Note that an attestation is not a consideration for this invalid reason code, the only consideration is if the MR has a signature. Validity Check Question: *Is the MR signed?*

INV3 – Name variation. The name on the MR is similar but does not match the MR coversheet. Validity Check Question: *Is the name on the MR an acceptable variance of the name of the sampled beneficiary?*

INV4 – Date missing. The date of service is missing entirely or partially complete (e.g. month/day only). Validity Check Question: *Is there a complete date of service on the MR?*

INV5 – Invalid medical record source. The medical record source is not on the acceptable sources of data list.[25] Data from hospital inpatient facilities, outpatient facilities, and physician office visits are the only valid data sources for RADV. Invalid sources include hospice, home health, lab only, super-bill, and non-face to face encounters. Validity Check Question: *Is the MR from a valid source?*

INV7 – Credentials missing. The MR is signed but there is no credential in the signature and no credential (MD, DO, NP) or specialty reference (Renal, Cardiology, PCP, Hospitalist, Attending, etc.) for the one specific physician/practitioner named on the document (heading, defined provider type in signature line).[26] Validity Check Question: *Are you able to confirm an acceptable credential or specialty (e.g., MD, PA, DPM, Cardiology, Internal Medicine)?*

INV14 – Date outside data collection period. The MR date of service is not within the data collection period.[27] Validity Check Question: *Is the date on the MR within the data collection period?*

INV17 – **Something other than a MR is attached.** The submission includes a coversheet, but the attached document is not a MR. Validity Check Question: *Is acceptable MR documentation included?*

[24] Some invalid reason codes used in CMS RADV audits in the past have been discontinued, which is why there may be gaps between enumerated reason codes.

[25] Acceptable Sources of Data for PY2018 are located in Chapter 7 of the CMS Medicare Managed Care Manual, Table 22: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c07.pdf.

[26] Acceptable Physician Specialty Types for PY2018 are located in Chapter 7 of the CMS Medicare Managed Care Manual, Table 19: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c07.pdf.

[27] Valid Inpatient MRs must have a discharge date within the data collection period.

INV20 – Miscellaneous INV. There is a MR issue that hasn't already been identified in any of the INV questions. Validity Check Question: *Is the record free from invalid issues not otherwise addressed through existing INV checks?*

Attachment 1: Points of Contact Form

This attachment is incorporated by reference. Please see the document, *Attachment 1 - Points of Contact Form*, that accompanied the Audit Notice in HPMS.

Attachment 2: Hardship Exception Request Form

This attachment is incorporated by reference. Please see the document, *Attachment 2 - Hardship Exception Request Form*, that accompanied the Audit Notice in HPMS.

Contract ID	Contract Name	Contract Type (HPMS Plan Type)	RADV Eligible Population	Tier 1 Group of Interest	MA Population	Percentage of MA Population in Group of Interest
REDACTED	REDACTED	REDACTED	3	1	2,574	0.04%
REDACTED	REDACTED	REDACTED	30,120	9,737	1,140,698	0.85%
REDACTED	REDACTED	REDACTED	20	6	468	1.28%
REDACTED	REDACTED	REDACTED	43	5	234	2.14%
REDACTED	REDACTED	REDACTED	5,584	466	10,262	4.54%
REDACTED	REDACTED	REDACTED	7,109	650	12,452	5.22%
REDACTED	REDACTED	REDACTED	19,204	2,250	38,754	5.81%
REDACTED	REDACTED	REDACTED	1,102	116	1,826	6.35%
REDACTED	REDACTED	REDACTED	4,668	561	8,310	6.75%
REDACTED	REDACTED	REDACTED	456,179	79,157	1,030,644	7.68%
REDACTED	REDACTED	REDACTED	8	3	38	7.89%
REDACTED	REDACTED	REDACTED	15,668	2,879	35,045	8.22%
REDACTED	REDACTED	REDACTED	1,452	267	2,944	9.07%
REDACTED	REDACTED	REDACTED	1,755	501	4,695	10.67%
REDACTED	REDACTED	REDACTED	12,171	3,015	21,855	13.80%
REDACTED	REDACTED	REDACTED	3,229	821	5,871	13.98%
REDACTED	REDACTED	REDACTED	26,404	6,849	48,368	14.16%
REDACTED	REDACTED	REDACTED	8,061	1,895	13,003	14.57%
REDACTED	REDACTED	REDACTED	3,383	1,418	9,394	15.09%
REDACTED	REDACTED	REDACTED	9,204	2,334	15,227	15.33%
REDACTED	REDACTED	REDACTED	12,975	5,348	32,018	16.70%
REDACTED	REDACTED	REDACTED	11,774	3,180	18,931	16.80%
REDACTED	REDACTED	REDACTED	26,037	7,256	41,376	17.54%
REDACTED	REDACTED	REDACTED	46,319	13,546	76,889	17.62%
REDACTED	REDACTED	REDACTED	569	202	1,144	17.66%
REDACTED	REDACTED	REDACTED	277	99	555	17.84%
REDACTED	REDACTED	REDACTED	96	30	166	18.07%
REDACTED	REDACTED	REDACTED	37,626	10,194	55,825	18.26%
REDACTED	REDACTED	REDACTED	138,774	37,325	202,568	18.43%
REDACTED	REDACTED	REDACTED	75,526	21,946	111,135	19.75%
REDACTED	REDACTED	REDACTED	11,994	3,889	18,666	20.83%
REDACTED	REDACTED	REDACTED	58,430	17,764	84,721	20.97%
REDACTED	REDACTED	REDACTED	6,482	2,367	10,903	21.71%
REDACTED	REDACTED	REDACTED	21,693	7,844	34,423	22.79%
REDACTED	REDACTED	REDACTED	7,609	2,529	11,056	22.87%
REDACTED	REDACTED	REDACTED	1,098	376	1,606	23.41%

Contract ID	Contract Name	Contract Type (HPMS Plan Type)	RADV Eligible Population	Tier 1 Group of Interest	MA Population	Percentage of MA Population in Group of Interest
REDACTED	REDACTED	REDACTED	25,963	12,189	51,672	23.59%
REDACTED	REDACTED	REDACTED	6,687	2,497	10,315	24.21%
REDACTED	REDACTED	REDACTED	240	76	294	25.85%
REDACTED	REDACTED	REDACTED	317,169	123,682	468,509	26.40%
REDACTED	REDACTED	REDACTED	341	140	499	28.06%
REDACTED	REDACTED	REDACTED	5,954	2,897	10,322	28.07%
REDACTED	REDACTED	REDACTED	112	51	175	29.14%
REDACTED	REDACTED	REDACTED	483	232	524	44.27%
REDACTED	REDACTED	REDACTED	28,097	17,965	40,322	44.55%

Contract ID	Contract Name	Contract Type (HPMS Plan Type)	RADV Eligible Population	Tier 2 Group of Interest	MA Population
REDACTED	REDACTED	REDACTED	9,628	43	16,271
REDACTED	REDACTED	REDACTED	22,529	426	38,171
REDACTED	REDACTED	REDACTED	392	9	792
REDACTED	REDACTED	REDACTED	12,224	906	29,803
REDACTED	REDACTED	REDACTED	6,479	583	13,054
REDACTED	REDACTED	REDACTED	3,102	260	5,809
REDACTED	REDACTED	REDACTED	11,495	1,106	22,694
REDACTED	REDACTED	REDACTED	817	73	1,473
REDACTED	REDACTED	REDACTED	3,223	358	6,402
REDACTED	REDACTED	REDACTED	9,999	786	14,029
REDACTED	REDACTED	REDACTED	32,202	2,730	47,881
REDACTED	REDACTED	REDACTED	20,058	1,677	29,143
REDACTED	REDACTED	REDACTED	60,010	5,505	91,883
REDACTED	REDACTED	REDACTED	1,173	148	2,118
REDACTED	REDACTED	REDACTED	24,062	3,182	41,446

Percentage of MA Population in Group of Interest
0.26%
1.12%
1.14%
3.04%
4.47%
4.48%
4.87%
4.96%
5.59%
5.60%
5.70%
5.75%
5.99%
6.99%
7.68%