

STONE MAGNANINI

COMPLEX LITIGATION

February 13, 2023

VIA ECF

Hon. Catherine O'Hagan Wolfe, Clerk of the Court
U.S. Court of Appeals for the Second Circuit
Thurgood Marshall United States Courthouse
40 Foley Sq., New York NY 10007

Re: *U.S. ex rel. SW Challenger v. eviCore Healthcare MSI, LLC*, No. 22-530

Dear Ms. Wolfe,

I respectfully submit this letter pursuant to Rule 28(j) of the Federal Rules of Appellate Procedure to advise the Court of the February 1, 2023, final rule by CMS on Medicare risk adjustment and audit procedures ("Final Rule") (copy attached), which is relevant to the issues raised in this appeal. The appeal is scheduled for argument this Wednesday, February 15, 2023 (before Sack, Carney, and Bianco, C.JJ.), and Plaintiffs may refer to the Final Rule at the argument.

Plaintiffs alleged below and argue on appeal that, because CMS relies on the risk data reported by MCOs to compute capitated payments (A-148 (¶ 69) (citing 42 C.F.R. 421.304)), it is imperative that MCOs and their subcontractors work diligently to ensure these data do not overstate risk. Br. 48 (rigging review process to "seek upward adjustments to capitation payments" violates FCA). eviCore argues "CMS regulations and guidance[] are ... designed to prevent MCOs from ... *denying* medically necessary services. This regulation does not reflect a CMS concern that MCOs or their prior authorization vendors would approve too many services that health care providers order for their patients." Opp. 11 (internal citations omitted). In the Final Rule, CMS states that "there is an incentive for [MCOs] to potentially over-code diagnoses to increase their payments, that is, to code diagnoses not properly substantiated by medical record documentation."

Respectfully submitted,

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Enclosure

Cc: All Counsel of Record (via ECF)

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88 FR 6643-01, 2023 WL 1366662(F.R.)
RULES and REGULATIONS
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

Wednesday, February 1, 2023

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

***6643 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, ***6644** 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 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.[FN1]

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) [FN2] 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.[FN3] 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 *6645 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.[FN4]) 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,[FN5] nor are they intended to identify all improper diagnosis submissions made by MAOs for risk adjustment payment.[FN6]

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.[FN7] 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,[FN8] 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.[FN9] 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.[FN10]

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\(g\)](#). [FN11] 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 *6646 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.[FN12] 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).[FN13] 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 *6647 documents, including the Medicare Managed Care Manual.[FN14] 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 [FN15] 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.[FN16] (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.[FN17]
- 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).[FN18]
- On April 25, 2019, we posted updates to existing documentation related to the study data, as well as additional data on the CMS website.[FN19]
- 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.[FN20]
- On June 28, 2019, we issued a notice in the Federal Register ([84 FR 30983](#)) [FN21] that we replicated the FFS Adjuster Study and published a summary of that replication as an addendum to the study on the CMS website.[FN22] 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 *6648 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.[FN23]

As part of this extension, we explained our determination that we were unable to meet the 3-year timeline for publication.[FN24] 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.[FN25] 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.

***6649** 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.[FN26] 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 [*6650](#) 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 *6651 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 ***6652** 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.” [FN27] 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.” [FN28]

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 CFR 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.[FN29] 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.[FN30] 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.”).[FN31]

***6653** 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,[FN32] 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 *6654 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 *6655 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; [FN33] 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).[FN34] 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.[FN35] 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, ***6656** 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).[FN36] 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 *6657 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.[FN37] 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.[FN38])

- 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,[FN39] 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 *6658 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.[FN40] (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 *6659 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.[FN41] 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.[FN42] 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, *6660 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 medical 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.[FN43] (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,[FN44] 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.[FN45] The Medicare program, including MA, has also been identified by the GAO as a high-risk *6661 program due to the risk of substantial improper payments.[FN46]

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 *6662 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 ***6663** 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.[FN47]

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 [FN48] 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 *6664 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,^[FN49] 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	Source or calculation
		(\$ in millions)—	
		non-extrapolated	
(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

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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
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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.

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 (02)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

42 CFR § 422.300

2. Section 422.300 is revised to read as follows:

42 CFR § 422.300

§ 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.

42 CFR § 422.310

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

42 CFR § 422.310

§ 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.

* * * * *42 CFR § 422.311

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

42 CFR § 422.311

§ 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

Footnotes

- 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>.
- 4 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf>.

- 5 For example, the Department of Justice is responsible for pursuing 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 2021 included 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 (Contract 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.
- 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>.
- 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>.
- 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>.
- 26 See 83 FR 55038.
- 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 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.
- 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>.
- 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.
- 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.
- 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>.
- 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.a.spx.
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.
- 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 (Contract 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>.
- 46 <https://www.gao.gov/highrisk/medicare-program-improper-payments>.
- 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.
- 49 Any changes to the CMS-HCC payment model are published in the annual payment notice.