No. 25-11293

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

HUMANA, INCORPORATED;
HUMANA BENEFIT PLAN OF TEXAS, INCORPORATED,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., Secretary,
U.S. Department of Health and Human Services, in his official capacity;
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Texas

BRIEF FOR APPELLANTS

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STATEMENT REGARDING ORAL ARGUMENT

The government believes that oral argument is warranted to address any questions the panel may have regarding the complex regulatory scheme at issue and the rationales supporting the challenged rule.

CERTIFICATE OF INTERESTED PERSONS

A certificate of interested persons is not required, as defendants-appellants are all governmental parties. 5th Cir. R. 28.2.1.

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INTRODUCTION

Medicare Advantage is an alternative to traditional Medicare in which the Centers for Medicare & Medicaid Services (CMS) pays predetermined amounts to private insurers, known as Medicare Advantage organizations (MAOs), to insure Medicare beneficiaries. These payments are based in part on medical diagnoses that MAOs report for their beneficiaries; MAOs receive larger payments when they report that their beneficiaries are sicker. CMS requires that submitted diagnoses be supported by the beneficiary's medical records, but MAOs sometimes submit diagnoses that lack such support. MAOs also use various methods to find additional diagnoses that increase the likelihood the MAO will submit unsupported diagnoses for payment. CMS is estimated to overpay MAOs by over $10 billion a year because MAOs report diagnoses that lack medical-record support.

This case concerns a CMS rule (the Final Rule) that announced how CMS would expand its audit program to recover more of these overpayments. Plaintiffs challenge CMS's decision not to incorporate a Fee-for-Service Adjuster (FFS Adjuster) in the rule. The adjuster would have allowed MAOs to keep some portion of the payments they receive for diagnoses that lack medical-record support. Plaintiffs argue that an FFS Adjuster is necessary to compensate MAOs because the payments CMS makes for submitted diagnoses are too low.

The district court vacated the Final Rule not for this reason or because of any flaw in the rule itself, but rather on a procedural ground: that the Final Rule was not a "logical outgrowth" of the notice of proposed rulemaking (Proposed Rule). That conclusion is wrong. As relevant here, the Proposed Rule and the Final Rule are substantively identical: CMS proposed not to implement an FFS Adjuster, and the Final Rule adopted that precise approach. The Final Rule was therefore plainly a logical outgrowth of the Proposed Rule.

The district court instead relied on perceived differences in the *reasons* CMS offered in the preambles of the Proposed and Final Rules. However, neither the Medicare statute nor the Administrative Procedure Act (APA) supports applying the "logical outgrowth" requirement in this manner. The Medicare statute's text applies that requirement only to a "provision" of a regulation, not to the agency's reasoning. In any event, CMS gave more than sufficient notice of its reasoning because the Proposed Rule and the Final Rule rested on the same rationale: that it is inappropriate to reduce recoveries in audits—which enforce CMS's medical-record documentation requirement—to address concerns about payment rates.

The district court's unprecedented demand for congruence in an agency's explanations in the preambles to the proposed and final rules would prevent agencies from improving regulations in response to public comments as Congress intended. The law does not support or permit the court's approach.

STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court pursuant to 28 U.S.C. § 1331. ROA.19. The district court granted summary judgment for plaintiffs, denied summary judgment for defendants, and entered final judgment on September 25, 2025. ROA.26926-28. Defendants timely filed a notice of appeal on November 21, 2025. ROA.26929. This Court has jurisdiction over the appeal under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether the district court erred in vacating and remanding the Final Rule, 88 Fed. Reg. 6643 (Feb. 1, 2023) (ROA.17069-91), on the ground that the Final Rule was not a "logical outgrowth" of the Proposed Rule.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. The Medicare Part C risk adjustment model

Medicare is a federal health insurance program for the elderly and disabled that is administered by CMS. *See* 42 U.S.C. § 1395 *et seq.* Part A of the Medicare statute covers inpatient hospital care and certain other kinds of institutional care. *See id.* § 1395d(a). Part B is an optional supplemental insurance program that covers many outpatient medical and other health services. *See id.* §§ 1395j, 1395k(a). Under Parts A and B, known as "'traditional'" or "fee-for-service" (FFS) Medicare, "CMS itself acts as the insurer, paying healthcare providers

directly for beneficiaries' medical services." *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 872 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (2022).

Part C, also known as Medicare Advantage (MA), gives beneficiaries the option to receive their Medicare benefits through a private insurance plan rather than directly from CMS. *See* 42 U.S.C. § 1395w-21(a). Such plans generally must provide at least the same benefits available under traditional Medicare. *See id.* § 1395w-22(a)(1). CMS pays MAOs "in advance a monthly lump sum . . . for every beneficiary that they enroll, without regard to the services that the beneficiaries will actually receive." *UnitedHealthcare*, 16 F.4th at 872; *see* 42 U.S.C. § 1395w-23(a)(1)(A). The plans in turn pay healthcare providers for care provided to their enrollees. *UnitedHealthcare*, 16 F.4th at 872.

CMS's monthly payments to an MAO for a particular beneficiary are intended to reflect the amount CMS would otherwise spend in traditional Medicare for a beneficiary with the same health status and demographic factors. Specifically, the statute directs the Secretary to "adjust the payment amount . . . for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, . . . so as to ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C). CMS accordingly adjusts payments up or down from a base amount "to reflect the health status" of each beneficiary, among other factors. *United States ex rel. Swoben v. United*

Healthcare Ins. Co., 848 F.3d 1161, 1167 (9th Cir. 2016). These adjustments are intended to ensure that Medicare Advantage plans "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)." 88 Fed. Reg. at 6644 (ROA.17070). Absent such risk adjustment, MAOs would have strong "incentives to enroll only the healthiest, and thus least expensive, beneficiaries while steering clear of the sickest and costliest." *UnitedHealthcare*, 16 F.4th at 873-74.

To determine the amount of these risk adjustments and ensure "actuarial equivalence," CMS uses its Hierarchical Condition Category (CMS-HCC) risk adjustment model, which is calibrated based on traditional Medicare data. 88 Fed. Reg. at 6644 (ROA.17070). The model uses regression analysis to produce coefficients, known as "risk factors" or "relative factors," that provide a measure of Medicare's expected marginal costs for each medical condition and demographic factor. *See* 88 Fed. Reg. at 6644-45 (ROA.17070-71); ROA.18883. For any specific beneficiary, adding up the risk factors for that individual's conditions and demographic factors creates a "risk score" that expresses the beneficiary's expected costs relative to the average Medicare beneficiary, who by definition has a risk score of 1.0. 88 Fed. Reg. at 6645 (ROA.17071); ROA.18884.

CMS uses these risk scores to adjust MAOs' payments for each beneficiary. 88 Fed. Reg. at 6645 (ROA.17071). For example, in 2023, an 80-year-old male who is neither institutionalized nor Medicaid-eligible (risk factor 0.556) and has diabetes without complication (0.105) and rheumatoid arthritis (0.421) would have had a risk score of 1.082. CMS, *Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 74-76 (Apr. 1, 2019), https://perma.cc/GEJ9-5VT4. CMS would therefore have paid the MAO 108.2% of the base payment amount to cover that beneficiary—that is, 8.2% more than for the average beneficiary.

Because CMS calculates risk scores based on beneficiary data and diagnosis codes submitted by MAOs, 42 C.F.R. § 422.310(b), (d), (e); 88 Fed. Reg. at 6645 (ROA.17071), proper payment depends on the accuracy of the reported diagnoses. For example, if an MAO wrongly reports that a non-diabetic beneficiary has diabetes (risk factor 0.105), that diagnosis code will erroneously increase the beneficiary's risk score and thus the insurer's payment by 10.5% of the base amount. It is therefore crucial that "an MAO may only report a diagnosis when that diagnosis is properly supported by the beneficiary's medical records." 88 Fed. Reg. at 6646 (ROA.17072); *see also UnitedHealthcare*, 16 F.4th at 877; *Swoben*, 848 F.3d at 1168. To enforce this requirement, Medicare regulations establish that

CMS may audit diagnosis codes against the medical record and that insurers will be required to return payments due to unsupported diagnoses. *See, e.g.*, 42 C.F.R. § 422.310(e).

2. Coding incentives and the coding-pattern adjustment

Because MAOs are paid based on the diagnoses they report, MAOs have an incentive to report more diagnoses to increase their payments. *See* ROA.26251-53; *UnitedHealthcare*, 16 F.4th at 876. Thus, for example, many MAOs conduct "chart reviews," which may entail using artificial intelligence or third-party vendors to scan patients' medical records to identify additional diagnoses to report for payment. ROA.19915. The Department of Health and Human Services' Office of Inspector General (OIG) found that in 2017, MAOs obtained $2.7 billion in payments for diagnoses that were reported solely because of chart reviews and were not linked to any treatment provided to that beneficiary, ROA.19929—for example, beneficiaries reported as having vascular disease but lacking any records indicating treatment for such disease, ROA.19925. *See also Swoben*, 848 F.3d at 1168 (False Claims Act litigation involving "one-way" chart reviews that only added but never deleted diagnoses); *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 672 (9th Cir. 2018) (same). Such payments "may be a payment integrity concern if diagnoses are inaccurate or unsupported—making the associated risk-adjusted payments inappropriate." ROA.19929. The Medicare

Payment Advisory Commission (MedPAC), an independent legislative-branch agency that advises Congress on Medicare issues, ROA.26144, found that "[i]n 2020, differences in diagnostic coding caused Medicare to pay MA plans $12 billion more than it would have spent if the same beneficiaries had been enrolled in FFS Medicare," ROA.26246.

Congress has long recognized that coding practices in Medicare Advantage reduce payment accuracy, or "actuarial equivalence," by making payments to MAOs too high. Noting the existence of "differences in [diagnosis] coding patterns between Medicare Advantage plans" and traditional Medicare providers, Congress directed the Secretary to study and "ensure that [risk] adjustment . . . reflects" those differences. *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5301(b)(2), 120 Stat. 4, 51 (2006). After conducting that study, CMS implemented a coding-pattern adjustment that reduced all Medicare Advantage risk scores by 3.41% for 2010, which CMS indicated was "conservative." ROA.18408. Congress subsequently codified and extended the coding-pattern adjustment by mandating that CMS reduce Medicare Advantage risk scores even further, setting a minimum reduction of 5.9% from 2019 onwards. 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III).

3. Unsupported diagnoses, RADV audits, and the FFS Adjuster

Payments to MAOs based on unsupported diagnoses—diagnosis codes that lack medical-record documentation—are a particular overpayment concern. CMS has estimated that MAOs obtain over $10 billion in such overpayments each year, and that 7% of all payments to MAOs are overpayments. ROA.21952. Both OIG and the Government Accountability Office have identified Medicare Advantage as a high-risk program due to the volume of overpayments to MAOs. 88 Fed. Reg. at 6645 (ROA.17071).

CMS's principal mechanism for enforcing the medical-record-documentation requirement is the Risk Adjustment Data Validation (RADV) program. 88 Fed. Reg. at 6645 (ROA.17071). RADV audits test, for a sample of a plan's enrollees, whether reported diagnoses are actually documented in the medical record. *Id.* Plaintiffs challenge CMS's explanations for the methodologies to be used in these audits, so some understanding of those methodologies is necessary to understand plaintiffs' claims.

For many years, recoveries for unsupported diagnoses CMS discovered during RADV audits "were limited to enrollee-level adjustments" for the specific "enrollees sampled in the audits." 88 Fed. Reg. at 6645-46 (ROA.17071-72). Thus, "for the few MA plans . . . audited, payment recovery amounts were small." *Id.*

After pausing RADV audits for several years to refine its audit methodology, CMS released an informal proposal in 2010 to use "statistical methods to calculate extrapolated improper payments" for an entire contract. 88 Fed. Reg. at 6646 (ROA.17072); *see* ROA.7929. Thus, rather than simply recovering overpayments for specific unsupported diagnoses discovered in the audit sample, CMS would extrapolate an error rate from that sample to the entire contract. 88 Fed. Reg. at 6646 (ROA.17072). By using sampling and extrapolation—which "have been used to calculate improper payments in" traditional Medicare "for decades," 88 Fed. Reg. at 6648 (ROA.17074)—CMS could effectively conduct a broader audit of the contract. *See Dominion Ambulance, LLC v. Azar*, 968 F.3d 429, 440 (5th Cir. 2020) (upholding use of sampling and extrapolation and noting that "courts have concluded that 'statistical sampling is the only feasible method available' for HHS to effectively audit waste and fraud in the Medicare and Medicaid programs"); *see also Chaves Cnty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 922 (D.C. Cir. 1991); *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005); *Ratanasen v. California Dep't of Health Servs.*, 11 F.3d 1467, 1469-71 (9th Cir. 1993).

Some MAOs objected to this methodology on the ground that a broader audit would cause them to be underpaid. Their theory is exceedingly complex, but at a high level, they contended that CMS's payment rates for diagnoses—the risk

factors discussed above—are too low. 88 Fed. Reg. at 6646 (ROA.17072). That is so, these MAOs contended, because CMS's risk adjustment model calculates payment rates based on diagnosis data from traditional Medicare, which the MAOs characterized as "unaudited." *Id.* As a result, they argued, medical conditions are overdiagnosed in traditional Medicare, which causes the risk adjustment model to underestimate the cost of treating particular conditions relative to their true cost. *Id.* And because the payment rates or risk factors for these conditions are too low, payments to MAOs will violate the Medicare statute's actuarial-equivalence requirement if MAOs are limited to collecting payment for diagnoses that actually have medical-record support. *Id.*

To counteract this underpayment, these MAOs argued, CMS should allow them to keep some payments that CMS would otherwise recover through RADV audits for lack of medical-record documentation. 88 Fed. Reg. at 6646 (ROA.17072). Allowing MAOs to keep payments for unsupported diagnoses—or in other words, lowering the "documentation standard"—would, in their view, compensate MAOs for underlying payment rates that were too low. *Id.*

To accommodate these MAOs' concerns, CMS released a new version of the audit methodology in 2012 that stated that CMS intended to adopt an "FFS Adjuster." ROA.8223. The adjuster would serve "as an offset to the preliminary recovery amount" identified in an RADV audit, ROA.8223, allowing MAOs to

retain some portion of the payments they collected for unsupported diagnoses. The methodology did not specify the amount of the FFS Adjuster but instead stated that "[t]he actual amount of the adjuster will be calculated by CMS based on a" future study. ROA.8224. That study (the FFS Adjuster Study) ultimately concluded that an FFS Adjuster was unwarranted because "errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations." ROA.7911-12. CMS has never applied the FFS Adjuster in an issued RADV audit. 88 Fed. Reg. at 6647 (ROA.17073).

B. The Challenged RADV Rule

In 2018, CMS issued a notice of proposed rulemaking (Proposed Rule) in which it proposed to codify a methodological approach for all non-finalized RADV audits. 88 Fed. Reg. at 6647 (ROA.17073). As in 2010 and 2012, CMS proposed to "recover overpayments based on extrapolated audit findings through the use of statistically valid random sampling techniques." 83 Fed. Reg. 54,982, 55,038 (Nov. 1, 2018) (ROA.10455).

CMS also proposed not to apply an FFS Adjuster. 83 Fed. Reg. at 55,040 (ROA.10457). CMS cited the results of the FFS Adjuster Study but also determined that, "even if we had found that diagnosis error in FFS claims data led to systematic payment error in the MA program, we no longer believe that a

RADV-specific payment adjustment would be appropriate." *Id.* at 55,041 (ROA.10458). CMS explained that it was "inappropriate" to use "an adjustment to RADV recoveries"—that is, allowing MAOs to keep some payments for unsupported diagnoses—"to remedy payment accuracy concerns" with CMS's risk adjustment model. *Id.* As the agency noted, "RADV audits do not address issues with the accuracy of payments based on" valid diagnoses, but are rather "used to recover payments based on diagnoses that are not supported by medical record documentation, which thus should not have been reported to CMS." *Id.* "If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation," the agency explained, "that entire payment is in error and should be recovered in full, because the payment standard has not been met, and the MA organization is not entitled to any payment for that diagnosis." *Id.* The agency further reasoned that addressing payment accuracy by altering audit recoveries "would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans." *Id.*

For several years, CMS did not issue a final rule but instead engaged in further dialogue with the public. 88 Fed. Reg. at 6647-48 (ROA.17073-74). CMS released various data and materials underlying the FFS Adjuster Study, as well as a replication of the study that provided additional data not preserved from the original study. *Id.* CMS also extended the comment period several times and

specifically sought additional comment regarding whether 42 U.S.C. § 1395w-23(a)(1)(C)—which contains the actuarial-equivalence requirement and the coding-pattern adjustment—"mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology." 84 Fed. Reg. 30,983, 30,983 (June 28, 2019) (ROA.10468).

CMS promulgated the final RADV Rule (Final Rule) in 2023. *See* 88 Fed. Reg. 6643 (ROA.17069-91). The Final Rule provided that CMS would use extrapolation in RADV audits, but only for audits from payment year 2018 onward. *Id.* at 6643-44 (ROA.17069-70). The rule also provided that CMS would not apply an FFS Adjuster in RADV audits for two reasons. *Id.*

First, the Final Rule explained that "[i]t would be inappropriate" to use RADV audits to address claims of systemic payment error in "the analyses performed to determine the risk adjustment coefficients used to calculate risk scores, and thus risk-adjusted payments." 88 Fed. at 6658 (ROA.17084). CMS likewise agreed with commenters like MedPAC who stated that, even if systemic error in payment rates existed, "applying an FFS Adjuster to RADV would not be the appropriate remedy to address that bias." *Id.* at 6656 (ROA.17082); *see also* ROA.3151-52 (MedPAC comments regarding FFS Adjuster).

CMS reasoned that the Medicare statute's payment-accuracy provision—the actuarial-equivalence requirement—does not apply "to the obligation of MAOs to return improper payments" discovered in RADV audits, but instead "applies only to how CMS risk adjusts the payments it makes to MAOs." 88 Fed. Reg. at 6644 (ROA.17070). CMS explained that RADV audits instead "enforce[] the longstanding medical record documentation regulatory requirement," *id.* at 6658 (ROA.17084), by "recover[ing] payments that were made improperly based on diagnoses not supported by medical record documentation," *id.* at 6656 (ROA.17082). Thus, "[i]f a payment is made to an MAO based on a diagnosis code not supported by 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." *Id.* at 6656-57 (ROA.17082-83). CMS further noted that, "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." *Id.* at 6657 (ROA.17083).

Second, the Final Rule explained that the theory that payment rates were too low was inconsistent with Congress's requirement that CMS reduce payment rates by ever-larger amounts through the coding-pattern adjustment. CMS reasoned that "it would not be reasonable to read the" statute "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." 88 Fed. Reg. at 6644 (ROA.17070).

The Final Rule did not rely on the empirical findings from the FFS Adjuster Study. 88 Fed. Reg. at 6659 (ROA.17085). CMS recognized that commenters had engaged in "lengthy analysis and critique" of the study and that some commenters had offered counter-studies. *Id.* CMS explained, however, that "[e]ven if systematic payment error exists, it does not impact the requirement that submitted diagnoses must be adequately supported by medical records" and that it was inappropriate to correct any systemic payment errors through the RADV program. *Id.* CMS also offered substantive reasons why it disagreed with "commenters who claim that our study or their counter-studies provide evidence that FFS errors systematically reduce payments to MAOs." *Id.*

Finally, CMS explained that its reasoning was consistent with the D.C. Circuit's decision in *UnitedHealthcare*, 16 F.4th 867. 88 Fed. Reg. at 6656 (ROA.17082). *UnitedHealthcare* did not address RADV audits but instead upheld CMS's decision not to incorporate a similar FFS Adjuster in another Medicare Advantage rule known as the Overpayment Rule, 42 C.F.R. § 422.326. *UnitedHealthcare*, 16 F.4th at 869. That rule "requires that, if an insurer learns a diagnosis it submitted to CMS for payment lacks support in the beneficiary's

medical record, the insurer must refund that payment within sixty days." *Id.* An MAO challenged the rule on a similar ground to the one raised here—that requiring MAOs to return payments for unsupported diagnoses without applying an FFS Adjuster would violate actuarial equivalence. *Id.* at 882.

The D.C. Circuit rejected that argument, concluding 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.'" *UnitedHealthcare*, 16 F.4th at 885 (alterations in original). Interpreting the Medicare statute, the court held that this "requirement does not apply to the separate statutory obligation on insurers to refund overpayments they erroneously elicit from CMS" or to the Overpayment Rule. *Id.* at 884. The court further noted that, even if the requirement did apply, "there is no evidence of any . . . systemic skew in traditional Medicare data, and, indeed, UnitedHealth never challenged the values CMS assigned to the relative factors." *Id.* at 885. The court concluded that "UnitedHealth cannot now use actuarial equivalence to litigate belated objections to the risk-adjustment model or the level of its monthly payments through the back door of the Overpayment Rule." *Id.* at 887. The court also found "implausible" UnitedHealth's "underlying premise . . . that traditional Medicare data includes a

significant rate of unsupported diagnosis codes that ultimately depresses the payments to Medicare Advantage insurers." *Id.* at 888.

In the final RADV Rule, CMS explained that its decision not to apply an FFS Adjuster was consistent with *UnitedHealthcare* because, although *UnitedHealthcare* did not address RADV, "[t]he RADV program, like the Overpayment Rule, applies after" risk-adjusted payments are made "to require MAOs to refund any payment to which they are not entitled, based on diagnoses that lack support in the medical record." 88 Fed. Reg. at 6656 (ROA.17082).

C. Prior Proceedings

Plaintiffs Humana Inc. and Humana Benefit Plan of Texas, Inc. filed suit under the APA, 5 U.S.C. § 701 *et seq.*, to challenge the Final Rule. Plaintiffs raised three claims: (1) that CMS's decision not to include an FFS Adjuster in the Final Rule was arbitrary, capricious, contrary to law, or in excess of statutory authority, ROA.52; (2) that CMS's decision to apply the rule to audits for payment year 2018 and later was in excess of statutory authority and an abuse of discretion, ROA.54; and (3) that CMS's decision not to include an FFS Adjuster failed to comply with notice-and-comment rulemaking requirements because the decision relied in part on *UnitedHealthcare*, 16 F.4th 867, which was decided after publication of the Proposed Rule, ROA.55.

The district court denied the government's motion to transfer venue and to dismiss for lack of standing and ripeness, ROA.394.

The district court subsequently entered summary judgment for plaintiffs and vacated and remanded the RADV Rule. ROA.26927. The court ruled solely on plaintiffs' third claim, "that the Final Rule is procedurally invalid as it was not a 'logical outgrowth' of the Proposed Rule," ROA.26918, reasoning that CMS "chang[ed] the justifications for the rule" from the Proposed Rule to the Final Rule, ROA.26919. The court reasoned that the Final Rule's rationale "that an FFS Adjuster is neither required nor appropriate in the context of RADV audits because the actuarial-equivalence requirement does not apply as a matter of law" did not "logically flow[] from one of the Proposed Rule's justifications." ROA.26920.[1] The court concluded that "Plaintiffs should not have reasonably anticipated that CMS's discussion regarding whether FFS Adjusters correct payment errors or simply create inequities would result in a finding that actuarial equivalence does not apply." ROA.26922.

The district court also rejected the government's reliance on CMS's additional request for comment regarding whether the provision containing the actuarial-equivalence requirement should inform its proposal not to adopt an FFS

[1] The court did not address the Final Rule's reasoning regarding the coding-pattern adjustment because the government did not contend that it was present in the Proposed Rule. ROA.26920.

Adjuster. The court reasoned that "[t]here is no specific indication here that would alert the reader to the fact that CMS was considering abandoning [its] justifications for a finding that actuarial equivalence does not apply." ROA.26923. Finally, the court rejected the government's arguments that CMS was not required to seek comment on a question of statutory interpretation, and that any error was harmless. ROA.26925-26.

SUMMARY OF ARGUMENT

The Medicare statute's notice-and-comment rulemaking provision, which is distinct from similar requirements in the APA, provides that a "provision" of a final rule can take effect only if it is a "logical outgrowth" of a proposed rule. Here, the Final Rule complied with that requirement because it followed exactly the same approach—declining to include an FFS Adjuster—as the Proposed Rule. The Final Rule was therefore plainly a logical outgrowth of the Proposed Rule.

The district court nonetheless concluded that the Proposed Rule provided inadequate notice because of perceived differences in the *reasons* stated in the preambles to the Proposed Rule and the Final Rule. But the Medicare statute's "logical outgrowth" requirement applies to a "provision" of a final rule, not the reasons given for that provision. Neither the district court nor the parties have cited any case finding that such differences in reasoning alone violate the APA or the Medicare statute, and the Supreme Court upheld a rule against a "logical

outgrowth" challenge when the reasoning in the final rule did not appear in the proposed rule at all. In any event, the Proposed Rule and the Final Rule both relied on the same rationale: RADV audits are intended to recover payments to which MAOs were never entitled because of a lack of medical-record documentation, not to ensure actuarial equivalence, so it is inappropriate to limit RADV audit recoveries based on payment-accuracy concerns even if the risk adjustment model produces payments that are too low.

The district court's contrary reasoning is fundamentally flawed. The court's belief that the agency changed its reasoning rests in large part on a failure to appreciate that the Proposed Rule's discussions of "systemic payment error" and "payment accuracy" referred to the same concept as the Final Rule's discussion of "actuarial equivalence." Accurate payments are those that are actuarially equivalent; systemic payment error occurs when payments are biased downwards or upwards and therefore not actuarially equivalent. Moreover, CMS specifically requested additional comment on how the statutory clause that contains the actuarial-equivalence requirement should inform its proposal not to incorporate an FFS Adjuster. Interested parties should therefore have foreseen that the agency might take the position that the actuarial-equivalence requirement does not require CMS to limit RADV audit recoveries to remedy payment-accuracy concerns. Nothing more was required.

STANDARD OF REVIEW

The Court "review[s] a grant of summary judgment de novo, applying the same standard as the district court." *Board of Miss. Levee Comm'rs v. U.S. EPA*, 674 F.3d 409, 417 (5th Cir. 2012).

ARGUMENT

THE RADV RULE COMPLIED WITH THE MEDICARE STATUTE'S NOTICE-AND-COMMENT REQUIREMENTS

CMS fully complied with all applicable notice-and-comment-rulemaking requirements in promulgating the RADV Rule. The Proposed Rule informed the public that CMS intended not to incorporate an FFS Adjuster in its audit methodology, and the Final Rule in fact adopted that approach. The Proposed Rule therefore more than adequately framed the subjects for discussion such that interested parties should have anticipated the agency's final approach.

A. The Medicare Statute Requires Only that the Final Rule Be a Logical Outgrowth of the Proposed Rule

The Medicare statute contains independent notice-and-comment rulemaking provisions distinct from those in the APA. *See Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019) (explaining that Medicare statute, rather than APA, defines notice-and-comment-rulemaking requirements in Medicare). In addition to requiring publication of proposed regulations and a 60-day comment period, 42 U.S.C. § 1395hh(b)(1), the statute specifies that "a provision" of a final rule "that

is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule . . . shall not take effect" without further opportunity for comment. *Id.* § 1395hh(a)(4). The statute's "logical outgrowth" language refers to case law developed under the APA and discussed below.

Under the APA, courts have held that an agency fails to give sufficient notice in two types of cases: first, when "the divergence between the proposed action and the final action was so great that parties affected by the final action had no way of knowing that the agency was considering one or more critical elements of the final action"; and second, when "the agency relied on data to support its final action that was not known to affected parties until the agency announced its final action." 1 Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 5.3, at 686 (7th ed. 2024); 32 *Wright & Miller's Federal Practice & Procedure* § 8183 (2d ed.), Westlaw (database updated Sep. 2025) (identifying same "two lines of judicial precedent").

In the first category, which is relevant only when "a final rule includes a requirement that differs . . . from the . . . proposed rule," 1 Hickman & Pierce, *supra*, § 5.3.1, at 686, notice is sufficient if the final rule "is a 'logical outgrowth' of the proposed rule," *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021) (quoting *National Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1115 (D.C. Cir. 2019)). In other words, "the notice must 'adequately frame the subjects for

discussion' such that 'the affected party "should have anticipated" the agency's final course in light of the initial notice.'" *Id.* (quoting *National Lifeline Ass'n*, 921 F.3d at 1115). "If a party 'should have anticipated' that course, it 'reasonably should have filed [its] comments on the subject during the notice-and-comment period.'" *Id.* (alteration in original) (quoting *Texas Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 381 (5th Cir. 2021)). The agency's proposed rule is not "required to 'specifically identify "every precise proposal which [the agency] m[ight] ultimately adopt,"'" and the agency can "implement[] changes in the final rule 'instigated by . . . comments' during the rulemaking." *Id.* at 448 (first, second, and fourth alterations in original) (quoting *Chemical Mfrs. Ass'n v. U.S. EPA*, 870 F.2d 177, 203 (5th Cir. 1989)). The Medicare statute's "logical outgrowth" language refers to this line of cases.

The rule in the second category "require[s] agencies to disclose, in time to allow for meaningful comment, technical data or studies on which they relied in formulating proposed rules." *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 246 (D.C. Cir. 2008) (Kavanaugh, J., concurring in part, concurring in the judgment in part, and dissenting in part). *But see id.* (explaining that this rule "cannot be squared with the text of § 553 of the APA" and "creates a serious jurisprudential problem because the Supreme Court later rejected this kind of freeform interpretation of the APA"). Thus, for example, this Court has vacated a

rule where the agency "conceded that it violated the APA when it failed to provide additional notice and the opportunity to comment on a study that was 'critical to the Rule's issuance.'" *Airlines for Am. v. U.S. Dep't of Transp.*, 166 F.4th 487, 488 (5th Cir. 2026) (en banc) (per curiam); *see also* 32 *Wright & Miller's Federal Practice & Procedure*, *supra*, § 8183 (explaining that this "line of precedent requires agencies to disclose scientific and technical information that they have relied upon in developing a rule in order to allow effective comments"). It is unclear whether the Medicare statute's "logical outgrowth" language encompasses this line of cases, and, in any event, plaintiffs here do not contend that CMS failed to disclose any technical data or studies that it relied on for the Final Rule.

This Court recently stated in *Texas Ass'n of Manufacturers* that "[t]he agency's rationale for the rule must be made clear and subjected to public comment," 989 F.3d at 382, but that statement must be understood in light of the fact that the case fell squarely within the second category discussed above. The Court ultimately held that the agency failed to provide adequate notice because the final rule relied on new data and a new data-analysis methodology that were not previously disclosed. *Id.* at 383-84. This Court has since cited that portion of *Texas Ass'n of Manufacturers* for the proposition that "[i]f an agency promulgates a rule based on 'completely new and different data' that 'supplant[s]' or 'replace[s] its original data,' the agency may need to 'afford interested parties an opportunity

to challenge the underlying factual data relied upon.'" *Airlines for Am. v. U.S. Dep't of Transp.*, 127 F.4th 563, 579 (5th Cir.) (second and third alterations in original), *vacated per curiam*, 154 F.4th 323 (5th Cir. 2025), *on reh'g en banc per curiam*, 166 F.4th 487 (5th Cir. 2026).

Neither the parties nor the district court have cited any decision of any court striking down a rule solely because of differences in how the preambles to the proposed and final rules explained the agency's reasoning, as opposed to a failure to disclose critical technical data or studies. Here, such an approach would be inconsistent with the Medicare statute's text, which applies the "logical outgrowth" requirement only to a "provision" of a regulation: "If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking . . . , such provision . . . shall not take effect" without "further opportunity for public comment." 42 U.S.C. § 1395hh(a)(4). A requirement in the text of a regulation is a "provision" of that regulation, but an agency's explanation for that requirement in the preamble is not. *See Provision*, Black's Law Dictionary (12th ed. 2024) (defining "[p]rovision" as "[a] clause in a statute, contract, or other legal instrument").

More generally, "the very premise of" notice-and-comment rulemaking is "that rules evolve from conception to completion." *Brennan v. Dickson*, 45 F.4th 48, 69 (D.C. Cir. 2022). Thus, even with respect to the actual substance of a

regulation's text, "the APA does not require that rules be subjected to multiple cycles of notice and comment until the version adopted as final is identical to the last notice of proposed rulemaking." *Id.* That principle applies with even greater force to an agency's *explanations* for a regulation's requirements. Thus, in *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007), the Supreme Court considered a logical-outgrowth challenge to a final rule that omitted an exception previously included in the proposed rule. The Court upheld the rule, reasoning that the agency's change in position was "reasonably foreseeable": "[s]ince the proposed rule was simply a proposal, its presence meant that the Department was *considering* the matter; after that consideration the Department might choose to adopt the proposal or to withdraw it." *Id.* The Court further found sufficient the agency's *explanation* for its reversal between the proposed rule and the final rule—that the final rule's approach "is 'more consistent' with [the] statutory language"—even though that explanation never appeared in the proposed rule. *Id.* *Compare* 39 Fed. Reg. 35,382, 35,382 (Oct. 1, 1974) (proposed rule), *with* 40 Fed. Reg. 7404, 7405 (Feb. 20, 1975) (final rule). The Supreme Court did not suggest that the proposed rule needed to provide notice of the explanation the agency gave in the final rule.

B. The Proposed Rule Gave Sufficient Notice for the Final Rule

1. CMS fully complied with the Medicare statute's notice requirement because the relevant "provision" of the Final Rule was plainly a "logical outgrowth" of the Proposed Rule. 42 U.S.C. § 1395hh(a)(4). In the Proposed Rule, the agency "propose[d] not to include an FFS Adjuster in any final RADV payment error methodology." 83 Fed. Reg. at 55,041 (ROA.10458); *see also id.* at 54,984, 55,048. In the Final Rule, the agency adopted that proposal. 88 Fed. Reg. at 6644 (ROA.17070). There is accordingly no difference in text or substance between the Proposed Rule and the Final Rule with respect to any FFS Adjuster. Nor did the Final Rule rely on undisclosed technical data or studies.

The district court's ruling rested not on a violation of these notice requirements but rather the court's decision to apply the "logical outgrowth" test to the explanations offered in the rule's preamble. The court found the rule unlawful because, in the court's view, the Final Rule's reasoning "that an FFS Adjuster is neither required nor appropriate in the context of RADV audits because the actuarial-equivalence requirement does not apply as a matter of law" did not "logically flow[] from one of the Proposed Rule's justifications." ROA.26920. As discussed above, however, this Court has never held that an agency violated notice-and-comment rulemaking requirements solely on that ground; nor have other courts recognized such a requirement. *See supra* pp. 23-27. Such a rule

would be inconsistent with the Medicare statute's limitation of the "logical outgrowth" requirement to "a provision" of "a final regulation," 42 U.S.C. § 1395hh(a)(4), and with precedent like *Long Island Care at Home*, 551 U.S. at 175, which found notice adequate even though the agency's explanation for its change of position in the final rule never appeared in the proposed rule. *See supra* pp. 26-27.

2. Even if this Court were to apply the "logical outgrowth" test to CMS's reasoning, the RADV Rule would more than pass muster. The preamble to the Proposed Rule "'adequately frame[d] the subjects for discussion' such that 'the affected party "should have anticipated" the agency's final course in light of the initial notice.'" *Huawei Techs.*, 2 F.4th at 447 (quoting *National Lifeline Ass'n*, 921 F.3d at 1115).

The argument some MAOs made for the FFS Adjuster was that errors in the data used to calibrate CMS's risk adjustment model cause the model to underestimate the cost of treating various conditions—that is, the "risk factors" for those diagnoses. Thus, if MAOs were limited to collecting payment for properly-supported diagnoses, their payments would be too low and not actuarially equivalent. These MAOs therefore argued that they should be allowed to retain some of the payments they collect for diagnoses that lack medical-record support. *See supra* pp. 10-11.

CMS decided not to include an FFS Adjuster in both the Proposed Rule and the Final Rule because, in CMS's view, this payment-accuracy concern does not bear on recoveries in RADV audits, which are instead intended to enforce the medical-record documentation requirement by recovering payments to MAOs for unsupported diagnoses. CMS accordingly concluded that it was improper to use RADV audits to correct any systematic underpayment of insurers even if the risk adjustment model produced payment rates that were not actuarially equivalent. Thus, the preamble to the Proposed Rule explained:

> RADV audits are used to recover payments based on diagnoses that are not supported by medical record documentation, which thus should not have been reported to CMS. If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met, and the MA organization is not entitled to any payment for that diagnosis. RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation. Consequently, an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate. For this reason, we believe that it would not be appropriate to correct any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts.

83 Fed. Reg. at 55,041 (ROA.10458).

The Final Rule relied on the same reasoning:

> 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.

88 Fed. Reg. at 6658 (ROA.17084). In places, the Final Rule also used the statutory term "actuarial equivalence," 42 U.S.C. § 1395w-23(a)(1)(C)(i):

> [W]e 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. . . . "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]." . . . 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 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.

88 Fed. Reg. at 6656-57 (ROA.17082-83) (third alteration in original) (citations omitted) (quoting *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 870 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (2022)).

As these passages demonstrate, the Proposed Rule's reasoning "adequately frame[d] the subjects for discussion" such that plaintiffs "should have anticipated the agency's final course in light of the initial notice." *Huawei Techs.*, 2 F.4th at 447 (quotation marks omitted). Indeed, the reasons CMS offered are identical: that even if the MAOs were right that payment rates were too low, payment-accuracy concerns do not bear on RADV audits, which are instead intended to

recover payments to which MAOs are not entitled because they were made based on diagnoses unsupported by medical records.

C. The District Court's Contrary Reasoning Is Flawed

1. The district court's contrary reasoning is deeply flawed. The court's primary rationale appears to be that "[p]laintiffs should not have reasonably anticipated that CMS's discussion" in the Proposed Rule "would result in a finding that actuarial equivalence does not apply" to RADV audits. ROA.26922. But the court failed to appreciate that, in this context, "actuarial equivalence," "systemic payment error in the MA program," and "payment accuracy" refer to the same concepts. Both actuarial equivalence and payment accuracy refer to the statutory objective that the risk adjustment model should produce appropriate payments to MAOs; systemic payment error refers to payments that are biased downwards or upwards such that they fail to achieve actuarial equivalence because they do not approximate what CMS would spend on the same beneficiaries in traditional Medicare. *See supra* pp. 4-7, 10-12. Thus, the Proposed Rule's statement that "it would not be appropriate to correct any systematic payment error in the MA program" by adjusting RADV audit recoveries, 83 Fed. Reg. at 55,041 (ROA.10458), gave direct notice of the Final Rule's reasoning that it was not appropriate to limit RADV audit recoveries to address actuarial-equivalence

concerns—and, necessarily, that actuarial equivalence does not *require* CMS to do so.

Any doubt as to whether CMS's reasoning in the Proposed Rule encompassed the statutory actuarial-equivalence requirement was resolved in CMS's 2019 request for additional comment. That request sought "comment on whether 42 U.S.C. 1395w-23—and in particular clause (a)(1)(C)," which contains the actuarial-equivalence requirement as well as the coding-pattern adjustment—"mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology." 84 Fed. Reg. at 30,983 (ROA.10468). CMS thus gave notice that it was specifically considering whether or not the clause containing the actuarial-equivalence requirement bears on RADV audit recoveries. An agency plainly provides sufficient notice "when it has 'expressly asked for comments on a particular issue.'" *Brennan*, 45 F.4th at 69. For the same reason, although the district court did not suggest it was necessary for the agency to do so, the request for additional comment also gave notice that the agency might rely on the coding-pattern adjustment in its final rule.

The district court objected that "[t]here is no specific indication here that would alert the reader to the fact that CMS was considering abandoning the just-mentioned justifications for a finding that actuarial equivalence does not apply"

and that CMS's citation to the statute "signals to the reader that CMS believes the" cited provisions "are applicable to RADV audits." ROA.26923. But the agency had already proposed not to include an FFS Adjuster on the ground that payment-accuracy concerns are not a proper ground for limiting RADV audit recoveries. The request for additional comment, in specifically asking the public for comment on whether or not the statutory clause containing the actuarial-equivalence requirement should "inform" that proposal, gave more than enough notice that "interested parties 'should have anticipated' that" CMS might conclude that actuarial equivalence does not limit or bear on RADV audit recoveries. *Texas Ass'n of Mfrs.*, 989 F.3d at 381 (quotation marks omitted). Any interested parties who believed that RADV audit recoveries *are* limited by actuarial equivalence therefore had notice to submit comments accordingly.

2. The district court also reasoned that the Proposed Rule "does not give the reader any indication that CMS is reconsidering an over thirteen-year-old precedent regarding the application of the actuarial-equivalence provision to RADV audits," ROA.26922, but it is not obvious what "precedent" the district court was referring to. The proposed audit methodology CMS released in 2010 (13 years before the Final Rule) did not mention an FFS Adjuster or actuarial equivalence. *See* ROA.7929-31. Perhaps the district court was referring to the audit methodology CMS released in 2012 (13 years before the district court's

decision), but that methodology stated only that CMS intended to use an FFS Adjuster—whose amount would be calculated in the future—to address MAOs' concerns about underpayment. *See* ROA.8223-24. The document does not discuss actuarial equivalence, whether actuarial equivalence constrains RADV audits, or whether actuarial equivalence requires an FFS Adjuster. In any event, the 2018 Proposed Rule plainly indicated that CMS intended to take the opposite approach to the 2012 methodology—that is, not to include an FFS Adjuster—on the ground that it was inappropriate to use RADV audits to address payment-accuracy concerns. The Proposed Rule therefore gave clear notice that the agency was proposing to reverse whatever positions the district court interpreted CMS as having taken in 2012.

The district court also criticized in a footnote CMS's reliance on the D.C. Circuit's decision in *UnitedHealthcare*, 16 F.4th 867, ROA.26924 n.31, but the Final Rule reasoned only that CMS's "position is consistent with the D.C. Circuit's decision in" that case, not that the decision was an independent reason to adopt the Final Rule, 88 Fed. Reg. at 6656 (ROA.17082). Nothing in the Medicare statute or the APA prohibits an agency from discussing intervening case law that supports—or undercuts—its position. Moreover, the Proposed Rule expressly cited the district court litigation from which the D.C. Circuit appeal arose and stated that "the government is reviewing that decision and considering its response," 83 Fed.

Reg. at 55,040 n.29 (ROA.10457 n.29), and commenters likewise cited the district court decision, 88 Fed. Reg. at 6656 (ROA.17082).

3. Finally, the district court asserted that the Final Rule "abandons the Proposed Rule's stated rationale that 'correct[ing] any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts . . . would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans.'" ROA.26921 (alterations in original) (quoting 83 Fed. Reg. at 55,041 (ROA.10458)). The court believed that the inequity rationale "does not appear in the Final Rule, and thus could not have been a contributing factor for the new justification." ROA.26922.

The district court's conclusion is factually wrong and contradicted by the Federal Register. The Final Rule did not abandon the inequity rationale; to the contrary, it expressly relied on it. The Final Rule specifically stated that, "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." 88 Fed. Reg. at 6657 (ROA.17083). Nor would CMS have violated any notice requirement if the Final Rule had omitted that rationale. No principle of law prevents an agency from omitting reasoning from the Final Rule that was included in the Proposed Rule.

If applied to other cases, the district court's demand for stringent correspondence between the reasons stated in a proposed rule and in a final rule would impose an unprecedented constraint on agencies' ability to improve rules through notice and comment. "If an agency were required to issue a second notice and provide an opportunity for a second set of comments every time it decided to make a change in response to the first round of comments, the rulemaking process would be endless." 1 Hickman & Pierce, *supra*, § 5.3.1, at 687. The court's position here would require agencies to engage in repeated notice-and-comment cycles not only until the final *rule* is identical to the proposed rule, but also until the agency's final *explanation* is identical to that in the proposed rule. Neither the Medicare statute nor the APA requires or permits that result.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8,463 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Times New Roman 14-point font, a proportionally spaced typeface.

s/ Weili J. Shaw
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ADDENDUM

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42 U.S.C. § 1395w-23

§ 1395w–23. Payments to Medicare+Choice organizations

(a) Payments to organizations

(1) Monthly payments

(A) In general

Under a contract under section 1395w–27 of this title and subject to subsections (e), (g), (i), and (l) and section 1395w–28(e)(4) of this title, the Secretary shall make monthly payments under this section in advance to each Medicare+Choice organization, with respect to coverage of an individual under this part in a Medicare+Choice payment area for a month, in an amount determined as follows:

. . . .

(C) Demographic adjustment, including adjustment for health status

(i) In general

Subject to subparagraph (I), the Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

(ii) Application of coding adjustment

For 2006 and each subsequent year:

(I) In applying the adjustment under clause (i) for health status to payment amounts, the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part[2] A and B to the extent that the Secretary has identified such differences.

(II) In order to ensure payment accuracy, the Secretary shall annually conduct an analysis of the differences described in subclause

[2] So in original. Probably should be ‘‘parts’’.

(I). The Secretary shall complete such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years. In conducting such analysis, the Secretary shall use data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(III) In calculating each year's adjustment, the adjustment factor shall be for 2014, not less than the adjustment factor applied for 2010, plus 1.5 percentage points; for each of years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage point; and for 2019 and each subsequent year, not less than 5.9 percent.

(IV) Such adjustment shall be applied to risk scores until the Secretary implements risk adjustment using Medicare Advantage diagnostic, cost, and use data.

. . . .

42 U.S.C. § 1395hh

§ 1395hh. Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term ‘‘regulations’’ means, unless the context otherwise requires, regulations prescribed by the Secretary.

. . . .

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the

proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

. . . .

No. 25-11293

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

HUMANA, INCORPORATED;
HUMANA BENEFIT PLAN OF TEXAS, INCORPORATED,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., Secretary,
U.S. Department of Health and Human Services, in his official capacity;
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Texas

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Tab 1

APPEAL,ATTN,CLOSED

U.S. District Court
Northern District of Texas (Fort Worth)
CIVIL DOCKET FOR CASE #: 4:23-cv-00909-O

Humana Inc. et al v. Becerra et al
Assigned to: Chief District Judge Reed O'Connor
Case in other court: United States Court of Appeals 5th Circuit, 25-11293
Cause: 05:702 Administrative Procedure Act

Date Filed: 09/01/2023
Date Terminated: 09/25/2025
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedure Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

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Date Filed	#	Docket Text
09/01/2023	1 (p.14)	COMPLAINT against Xavier Becerra, United States Department of Health and Human Services filed by Humana Inc., Humana Benefit Plan of Texas, Inc.. (Filing fee $402; Receipt number ATXNDC-14003234) Plaintiff will submit summons(es) for issuance. In each Notice of Electronic Filing, the judge assignment is indicated, and a link to the Judges Copy Requirements and Judge Specific Requirements is provided. The court reminds the filer that any required copy of this and future documents must be delivered to the judge, in the manner prescribed, within three business days of filing. Unless exempted, attorneys who are not admitted to practice in the Northern District of Texas must seek admission promptly. Forms, instructions, and exemption information may be found at www.txnd.uscourts.gov, or by clicking here: Attorney Information - Bar Membership. If admission requirements are not satisfied within 21 days, the clerk will notify the presiding judge. (Attachments: # 1 (p.14) Cover Sheet) (Durst, Timothy) (Entered: 09/01/2023)
09/01/2023	2 (p.61)	New Case Notes: A filing fee has been paid. File to: Judge O Connor. Pursuant to Misc. Order 6, Plaintiff is provided the Notice of Right to Consent to Proceed Before A U.S. Magistrate Judge. Clerk to provide copy to plaintiff if not received electronically. Attorneys are further reminded that, if necessary, they must comply with Local Rule 83.10(a) within 14 days or risk the possible dismissal of this case without prejudice or without further notice. (sre) (Entered: 09/01/2023)
09/01/2023	3 (p.63)	CERTIFICATE OF INTERESTED PERSONS/DISCLOSURE STATEMENT by Humana Benefit Plan of Texas, Inc., Humana Inc.. (Clerk QC note: Affiliate entry indicated). (Durst, Timothy) (Entered: 09/01/2023)
09/01/2023	4 (p.66)	Request for Clerk to issue Summons filed by Humana Benefit Plan of Texas, Inc., Humana Inc.. (Attachments: # 1 (p.14) Summons Request for Xavier Becerra - U.S. Attorney General, # 2 (p.61) Summons Request for Xavier Becerra - U.S. Attorney for N.D.Texas, # 3 (p.63) Summons Request for United States Department of Health and Human Services, # 4 (p.66) Summons Request for United States Department of Health and Human Services - U.S. Attorney General, # 5 (p.78) Summons Request for United States Department of Health and Human Services - U.S. Attorney for N.D.Texas) (Durst, Timothy) (Entered: 09/01/2023)
09/01/2023	5 (p.78)	Summons issued as to Xavier Becerra, United States Department of Health and Human Services, U.S. Attorney, and U.S. Attorney General. (saw) (Entered: 09/01/2023)

09/01/2023	6 (p.90)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14004713) filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Blalack, K Lee) (Entered: 09/01/2023)
09/01/2023	7 (p.98)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14004887) filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Bock, Elizabeth) (Entered: 09/01/2023)
09/01/2023	8 (p.104)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14005036) filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Deaton, David) (Entered: 09/01/2023)
09/01/2023	9 (p.112)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14005113) filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Schneller, Jonathan) (Entered: 09/01/2023)
09/01/2023	10 (p.120)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14005175) filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Sokoler, Jennifer) (Entered: 09/01/2023)
09/01/2023	11 (p.129)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14005229) filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Sullivan, Stephen) (Entered: 09/01/2023)
09/01/2023	12 (p.135)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14005266) filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Welles, Heather) (Entered: 09/01/2023)
09/21/2023	13 (p.141)	SUMMONS Returned Executed as to United States Department of Health and Human Services ; served on 9/11/2023. (Attachments: # 1 (p.14) Proof of Service re: U.S. Attorney General, # 2 (p.61) Proof of Service re: United States Department of Health and Human Services) (Durst, Timothy) (Entered: 09/21/2023)
09/21/2023	14 (p.150)	SUMMONS Returned Executed as to Xavier Becerra ; served on 9/11/2023. (Attachments: # 1 (p.14) Proof of Service re: U.S. Attorney General, # 2 (p.61) Proof of Service re: United States Department of Health and Human Services) (Durst, Timothy) (Entered: 09/21/2023)
10/12/2023	15 (p.159)	SUMMONS Returned Executed as to Xavier Becerra ; served on 10/4/2023. (Durst, Timothy) (Entered: 10/12/2023)
10/12/2023	16 (p.163)	SUMMONS Returned Executed as to United States Department of Health and Human Services ; served on 10/4/2023. (Durst, Timothy) (Entered: 10/12/2023)
10/17/2023	17 (p.167)	NOTICE of Attorney Appearance by James Bickford on behalf of Xavier Becerra, United States Department of Health and Human Services. (Filer confirms contact info in ECF is current.) (Bickford, James) (Entered: 10/17/2023)
10/17/2023	18 (p.168)	MOTION / Joint Motion Regarding Schedule for Responding to the Complaint and

		Briefing Potential Rule 12 Motions filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Durst, Timothy) (Entered: 10/17/2023)
10/18/2023	19 (p.174)	ORDER: Responsive Brief due by 2/6/2024. Responses due by 12/8/2023. Reply brief due by 3/22/2024. (Ordered by Judge Reed C. O'Connor on 10/18/2023) (sre) (Entered: 10/18/2023)
11/02/2023	20	ELECTRONIC ORDER granting 6 (p.90) Application for Admission Pro Hac Vice of Blalack, K Lee. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 11/2/2023) (chmb) (Entered: 11/02/2023)
11/02/2023	21	ELECTRONIC ORDER granting 7 (p.98) Application for Admission Pro Hac Vice of Bock, Elizabeth. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 11/2/2023) (chmb) (Entered: 11/02/2023)
11/02/2023	22	ELECTRONIC ORDER granting 8 (p.104) Application for Admission Pro Hac Vice of Deaton, David. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 11/2/2023) (chmb) (Entered: 11/02/2023)
11/02/2023	23	ELECTRONIC ORDER granting 9 (p.112) Application for Admission Pro Hac Vice of Schneller, Jonathan. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 11/2/2023) (chmb) (Entered: 11/02/2023)
11/02/2023	24	ELECTRONIC ORDER granting 10 (p.120) Application for Admission Pro Hac Vice of Sokoler, Jennifer. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 11/2/2023) (chmb) (Entered: 11/02/2023)
11/02/2023	25	ELECTRONIC ORDER granting 11 (p.129) Application for Admission Pro Hac Vice of Sullivan, Stephen. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 11/2/2023) (chmb) (Entered: 11/02/2023)
11/02/2023	26	ELECTRONIC ORDER granting 12 (p.135) Application for Admission Pro Hac Vice of Welles, Heather. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 11/2/2023) (chmb) (Entered: 11/02/2023)
12/01/2023	27 (p.175)	Unopposed Motion for Extension of Time to File Answer filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 12/01/2023)
12/04/2023	28 (p.178)	ORDER: Upon consideration of Defendants' Unopposed Motion for Extension of Time to Respond to the Complaint, it is hereby ORDERED that the motion is

		granted and the following briefing schedule adopted: 27 (p.175) Unopposed Motion for Extension of Time to File Answer filed by United States Department of Health and Human Services, Xavier Becerra. Responsive Brief due by 2/13/2024., Reply Brief due by 3/22/2024., Responses due by 12/15/2023. (Ordered by Judge Reed C. O'Connor on 12/4/2023) (sre) (Entered: 12/04/2023)
12/15/2023	29 (p.179)	MOTION to Transfer Case out of District/Division , MOTION to Dismiss for Lack of Jurisdiction () filed by Xavier Becerra, United States Department of Health and Human Services with Brief/Memorandum in Support. (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 12/15/2023)
02/13/2024	30 (p.209)	RESPONSE filed by Humana Benefit Plan of Texas, Inc., Humana Inc. re: 29 (p.179) MOTION to Transfer Case out of District/Division MOTION to Dismiss for Lack of Jurisdiction (Attachments: # 1 (p.14) Appendix in Support of Plaintiffs' Opposition to Defendants' Motion to Transfer Venue or Dismiss) (Durst, Timothy) (Entered: 02/13/2024)
03/08/2024	31 (p.364)	MOTION for Extension of Time to File Response/Reply to 30 (p.209) Response/Objection, filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 03/08/2024)
03/11/2024	32 (p.367)	ORDER granting 31 (p.364) Motion for Extension of Time to File Reply: Replies due by 3/29/2024. (Ordered by Judge Reed C. O'Connor on 3/11/2024) (bdb) (Entered: 03/11/2024)
03/28/2024	33 (p.368)	MOTION for Extension of Time to File Response/Reply to 30 (p.209) Response/Objection, filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 03/28/2024)
03/29/2024	34 (p.371)	ORDER granting 33 (p.368) Motion to Extend Time to File Reply. Replies due by 4/5/2024. (Ordered by Judge Reed C. O'Connor on 3/29/2024) (bdb) (Entered: 03/29/2024)
04/05/2024	35 (p.372)	REPLY filed by Xavier Becerra, United States Department of Health and Human Services re: 29 (p.179) MOTION to Transfer Case out of District/Division MOTION to Dismiss for Lack of Jurisdiction (Bickford, James) (Entered: 04/05/2024)
06/07/2024	36 (p.384)	ORDER: Before the Court are Defendants' Motion to Transfer Venue or Dismiss, filed December 15, 2023 (ECF No. 29 (p.179)); Plaintiffs' Response, filed February 13, 2024 (ECF No. 30 (p.209)); and Defendants' Reply, filed April 5, 2024 (ECF No. 35 (p.372)). For the reasons stated below, Defendants' Motion is DENIED. (Ordered by Judge Reed C. O'Connor on 6/7/2024) (sre) (Entered: 06/07/2024)
06/20/2024	37 (p.396)	MOTION / Joint Motion Regarding Schedule for Briefing Potential Rule 56 Motions filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Durst, Timothy) (Entered: 06/20/2024)
06/21/2024	38 (p.403)	ORDER GRANTING JOINT MOTION REGARDING SCHEDULE FOR BRIEFINGPOTENTIAL RULE 56 MOTIONS 37 (p.396) : Defendants lodge the administrative record by August 23, 2024, Defendants file an answer by September 6, 2024, Plaintiffs file a motion for summary judgment by October 7, 2024, Defendants file a cross-motion for summary summary judgment and response to

		plaintiff's motion for summary judgment by November 22, 2024, Plaintiffs file a reply in support of their motion for summary judgment and response to -motion for summary judgment January 27, 2025, Defendants file a reply in support of their cross-motion for summary judgment February 28, 2025. (Ordered by Judge Reed C. O'Connor on 6/21/2024) (sre) (Entered: 06/21/2024)
06/21/2024		Per 38 (p.403) , Answer due from Xavier Becerra on 9/6/2024; United States Department of Health and Human Services on 9/6/2024. (sre) (Entered: 06/21/2024)
08/23/2024	39 (p.406)	NOTICE of *Conventional Filing of Administrative Record* filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Index of Administrative Record, # 2 (p.61) Certification) (Bickford, James) (Entered: 08/23/2024)
08/26/2024	40 (p.425)	Notice of Manual Filing of USB by Xavier Becerra, United States Department of Health and Human Services (placed under separate cover in the clerk's office) (mmw) (Entered: 08/26/2024)
09/06/2024	41 (p.428)	ANSWER to 1 (p.14) Complaint,,,,, filed by Xavier Becerra, United States Department of Health and Human Services. Unless exempted, attorneys who are not admitted to practice in the Northern District of Texas must seek admission promptly. Forms and Instructions found at www.txnd.uscourts.gov, or by clicking here: Attorney Information - Bar Membership. If admission requirements are not satisfied within 21 days, the clerk will notify the presiding judge. Attorneys are further reminded that, if necessary, they must comply with Local Rule 83.10(a) within 14 days or risk the possible dismissal of this case without prejudice or without further notice. (Bickford, James) (Entered: 09/06/2024)
09/06/2024	42 (p.446)	CERTIFICATE OF INTERESTED PERSONS/DISCLOSURE STATEMENT by Xavier Becerra, United States Department of Health and Human Services. (Clerk QC note: No affiliate entered in ECF). (Bickford, James) (Entered: 09/06/2024)
10/07/2024	43 (p.448)	MOTION for Summary Judgment filed by Humana Benefit Plan of Texas, Inc., Humana Inc. (Attachments: # 1 (p.14) Proposed Order) (Durst, Timothy) (Entered: 10/07/2024)
10/07/2024	44 (p.453)	Brief/Memorandum in Support filed by Humana Benefit Plan of Texas, Inc., Humana Inc. re 43 (p.448) MOTION for Summary Judgment (Durst, Timothy) (Entered: 10/07/2024)
10/07/2024	45 (p.514)	Appendix in Support filed by Humana Benefit Plan of Texas, Inc., Humana Inc. re 43 (p.448) MOTION for Summary Judgment (Attachments: # 1 (p.14) Declaration(s) of Heather Welles, # 2 (p.61) Additional Page(s) App. 000009 - 000742, # 3 (p.63) Additional Page(s) App. 000743 001244, # 4 (p.66) Additional Page(s) App. 001245 001563, # 5 (p.78) Additional Page(s) App. 001564 002228, # 6 (p.90) Additional Page(s) App. 002229 003185, # 7 (p.98) Additional Page(s) App. 003186 004136, # 8 (p.104) Additional Page(s) App. 004137 005197, # 9 (p.112) Additional Page(s) App. 005198 006411, # 10 (p.120) Additional Page(s) App. 006412 - 007337, # 11 (p.129) Additional Page(s) App. 007338 008067, # 12 (p.135) Additional Page(s) App. 008068 - 008907) (Durst, Timothy) (Entered: 10/07/2024)
10/10/2024	46 (p.9428)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14984070) filed by America's Health Insurance Plans (Attachments: # 1 (p.14) Certificate of Good Standing, # 2 (p.61)

		Proposed Order). Party America's Health Insurance Plans added.Attorney David W. Ogden added to party America's Health Insurance Plans(pty:am) (Ogden, David) (Entered: 10/10/2024)
10/10/2024	47 (p.9434)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14984073) filed by America's Health Insurance Plans (Attachments: # 1 (p.14) Certificate of Good Standing, # 2 (p.61) Proposed Order)Attorney Kevin Matthew Lamb added to party America's Health Insurance Plans(pty:am) (Lamb, Kevin) (Entered: 10/10/2024)
10/10/2024	48 (p.9440)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14984079) filed by America's Health Insurance Plans (Attachments: # 1 (p.14) Certificate of Good Standing, # 2 (p.61) Proposed Order)Attorney Thomas K Bredar added to party America's Health Insurance Plans(pty:am) (Bredar, Thomas) (Entered: 10/10/2024)
10/10/2024	49 (p.9446)	Application for Admission Pro Hac Vice with Certificate of Good Standing (Filing fee $100; Receipt number ATXNDC-14984083) filed by America's Health Insurance Plans (Attachments: # 1 (p.14) Certificate of Good Standing, # 2 (p.61) Proposed Order)Attorney Julia May added to party America's Health Insurance Plans(pty:am) (May, Julia) (Entered: 10/10/2024)
10/10/2024	50 (p.9451)	MOTION for Leave to Proceed Without Local Counsel filed by America's Health Insurance Plans (Attachments: # 1 (p.14) Proposed Order) (Ogden, David) (Entered: 10/10/2024)
10/11/2024	51	ELECTRONIC ORDER granting 46 (p.9428) Application for Admission Pro Hac Vice of David W. Ogden. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 10/11/2024) (chmb) (RG) (Entered: 10/11/2024)
10/11/2024	52	ELECTRONIC ORDER granting 47 (p.9434) Application for Admission Pro Hac Vice of Kevin M. Lamb. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 10/11/2024) (chmb) (RG) (Entered: 10/11/2024)
10/11/2024	53 (p.9456)	ORDER: Having considered the 50 (p.9451) Motion, the Court finds that it is well taken, and should be and is GRANTED. It is therefore ORDERED that AHIP may proceed without local counsel. (Ordered by Judge Reed C. O'Connor on 10/11/2024) (bdb) (Entered: 10/11/2024)
10/11/2024	54	ELECTRONIC ORDER granting 48 (p.9440) Application for Admission Pro Hac Vice of Thomas K. Bredar. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 10/11/2024) (chmb) (RG) (Entered: 10/11/2024)
10/11/2024	55	ELECTRONIC ORDER granting 49 (p.9446) Application for Admission Pro Hac Vice of Julia M. May. Important Reminder: Unless excused for cause, an attorney who is not an ECF user must register within 14 days of the date the attorney appears in a case pursuant to LR 5.1(f) and LCrR 49.2(g). (Ordered by Judge Reed C. O'Connor on 10/11/2024) (chmb) (RG) (Entered: 10/11/2024)
10/14/2024		

	56 (p.9457)	MOTION to Participate as Amicus Curiae (Unopposed) re 43 (p.448) MOTION for Summary Judgment filed by America's Health Insurance Plans (Attachments: # 1 (p.14) Exhibit(s) A - Proposed Amicus Brief, # 2 (p.61) Proposed Order) (Ogden, David) (Entered: 10/14/2024)
10/16/2024	57 (p.9490)	ORDER: Before the Court is the Unopposed 56 (p.9457) Motion for America's Health Insurance Plans (AHIP) to Participate as Amicus Curiae. The Court exercises its discretion to GRANT leave to file the amicus curiae brief. (Ordered by Judge Reed C. O'Connor on 10/16/2024) (mmw) (Entered: 10/16/2024)
10/16/2024	58 (p.9491)	AMICUS CURIAE in Support filed by America's Health Insurance Plans re 43 (p.448) MOTION for Summary Judgment (mmw) (Entered: 10/16/2024)
11/14/2024	59 (p.9518)	Unopposed MOTION for Extension of Time to File Cross-Motion for Summary Judgment filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 11/14/2024)
11/15/2024	60 (p.9521)	ORDER: Before the Court is Defendants' Unopposed Motion for Extension of Time to File Cross-Motion for Summary Judgment (ECF No. 59 (p.9518)), filed November 14, 2024. The Court, having considered the Motion, finds that good cause is shown for the extension. Accordingly, the Motion is GRANTED. Defendants SHALL file their cross-motion for summary judgment on or before December 5, 2024. All other deadlines in the Court's June 21, 2024, Order (ECF No. 38 (p.403)) remain unchanged. (Ordered by Judge Reed C. O'Connor on 11/15/2024) (sre) (Entered: 11/15/2024)
12/05/2024	61 (p.9522)	Cross MOTION for Summary Judgment filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 12/05/2024)
12/05/2024	62 (p.9524)	Brief/Memorandum in Support filed by Xavier Becerra, United States Department of Health and Human Services re 61 (p.9522) Cross MOTION for Summary Judgment (Bickford, James) (Entered: 12/05/2024)
12/05/2024	63 (p.9585)	RESPONSE filed by Xavier Becerra, United States Department of Health and Human Services re: 43 (p.448) MOTION for Summary Judgment (Bickford, James) (Entered: 12/05/2024)
12/05/2024	64 (p.9646)	Appendix in Support filed by Xavier Becerra, United States Department of Health and Human Services re 63 (p.9585) Response/Objection, 62 (p.9524) Brief/Memorandum in Support of Motion (Attachments: # 1 (p.14) Additional Page(s) 290 to 649, # 2 (p.61) Additional Page(s) 650 to 682) (Bickford, James) (Entered: 12/05/2024)
01/21/2025	65 (p.10328)	MOTION for Extension of Time to File Response/Reply to 61 (p.9522) Cross MOTION for Summary Judgment , 43 (p.448) MOTION for Summary Judgment filed by Humana Inc., Humana Benefit Plan of Texas, Inc. (Attachments: # 1 (p.14) Proposed Order) (Durst, Timothy) (Entered: 01/21/2025)
01/23/2025	66 (p.10335)	ORDER: Before the Court is Plaintiffs' Unopposed Motion for Extension of Time to File Reply Brief in Support of Plaintiffs' Motion for Summary Judgment and Opposition to Defendants Cross-Motion for Summary Judgment (ECF No. 65 (p.10328)), filed January 21, 2025. The Court, having considered the Motion, finds that good cause is shown for the extensions requested therein. Accordingly, the Motion is GRANTED. Plaintiffs SHALL file their reply brief in support of their

		motion for summary judgment and opposition to Defendants' cross-motion for summary judgment on or before February 3, 2025. Defendants SHALL file their reply in support of their cross-motion for summary judgment on or before March 7, 2025. (Ordered by Judge Reed C. O'Connor on 1/23/2025) (sre) (Entered: 01/23/2025)
02/03/2025	67 (p.10336)	RESPONSE filed by Humana Benefit Plan of Texas, Inc., Humana Inc. re: 61 (p.9522) Cross MOTION for Summary Judgment (Durst, Timothy) (Entered: 02/03/2025)
02/03/2025	68 (p.10339)	Brief/Memorandum in Support filed by Humana Benefit Plan of Texas, Inc., Humana Inc. re 61 (p.9522) Cross MOTION for Summary Judgment , 43 (p.448) MOTION for Summary Judgment */ Plaintiffs' Consolidated Reply in Support of Motion for Summary Judgment and Opposition to Defendants' Cross-Motion for Summary Judgment* (Durst, Timothy) (Entered: 02/03/2025)
02/26/2025	69 (p.10389)	MOTION for Extension of Time to File Response/Reply to 61 (p.9522) Cross MOTION for Summary Judgment filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 02/26/2025)
02/27/2025	70 (p.10392)	ORDER: Before the Court is Defendants' Unopposed 69 (p.10389) Motion for Extension of Time to File Reply in Support of Defendants' Cross-Motion for Summary Judgment. The Motion is GRANTED. Defendants SHALL file their reply on or before March 21, 2025. (Ordered by Judge Reed C. O'Connor on 2/27/2025) (mmw) (Entered: 02/27/2025)
03/19/2025	71 (p.10393)	MOTION for Leave to File A 30-Page Reply filed by Xavier Becerra, United States Department of Health and Human Services (Attachments: # 1 (p.14) Proposed Order) (Bickford, James) (Entered: 03/19/2025)
03/19/2025	72 (p.10396)	Brief/Memorandum in Support filed by Xavier Becerra, United States Department of Health and Human Services re 71 (p.10393) MOTION for Leave to File A 30-Page Reply (Bickford, James) (Entered: 03/19/2025)
03/20/2025	73 (p.10398)	ORDER: Before the Court is Defendants' 71 (p.10393) Motion for Leave to File a 30-Page Reply. It is hereby ORDERED that the Motion is GRANTED. Defendants shall file a reply of no more than 30 pages on or before March 21, 2025. (Ordered by Judge Reed C. O'Connor on 3/20/2025) (mmw) (Entered: 03/20/2025)
03/21/2025	74 (p.10399)	REPLY filed by Xavier Becerra, United States Department of Health and Human Services re: 61 (p.9522) Cross MOTION for Summary Judgment (Bickford, James) (Entered: 03/21/2025)
03/27/2025	75 (p.10434)	Administrative Record consisting of Rulemaking Record filed by Xavier Becerra, United States Department of Health and Human Services. (Attachments: # 1 (p.14) Certification, # 2 (p.61) Index, # 3 (p.63) Part 1 of 76, # 4 (p.66) Part 2 of 76, # 5 (p.78) Part 3 of 76, # 6 (p.90) Part 4 of 76, # 7 (p.98) Part 5 of 76, # 8 (p.104) Part 6 of 76, # 9 (p.112) Part 7 of 76, # 10 (p.120) Part 8 of 76, # 11 (p.129) Part 9 of 76, # 12 (p.135) Part 10 of 76, # 13 (p.141) Part 11 of 76, # 14 (p.150) Part 12 of 76, # 15 (p.159) Part 13 of 76, # 16 (p.163) Part 14 of 76, # 17 (p.167) Part 15 of 76, # 18 (p.168) Part 16 of 76, # 19 (p.174) Part 17 of 76, # 20 Part 18 of 76, # 21 Part 19 of 76, # 22 Part 20 of 76, # 23 Part 21 of 76, # 24 Part 22 of 76, # 25 Part 23 of 76, # 26 Part 24 of 76, # 27 (p.175) Part 25 of 76, # 28 (p.178) Part 26 of 76, # 29 (p.179) Part 27 of 76, # 30 (p.209) Part 28 of 76, # 31 (p.364) Part 29 of 76, # 32 (p.367) Part 30 of 76, # 33 (p.368) Part 31 of 76, # 34 (p.371) Part 32 of 76, # 35

		(p.372) Part 33 of 76, # 36 (p.384) Part 34 of 76, # 37 (p.396) Part 35 of 76, # 38 (p.403) Part 36 of 76, # 39 (p.406) Part 37 of 76, # 40 (p.425) Part 38 of 76, # 41 (p.428) Part 39 of 76, # 42 (p.446) Part 40 of 76, # 43 (p.448) Part 41 of 76, # 44 (p.453) Part 42 of 76, # 45 (p.514) Part 43 of 76, # 46 (p.9428) Part 44 of 76, # 47 (p.9434) Part 45 of 76, # 48 (p.9440) Part 46 of 76, # 49 (p.9446) Part 47 of 76, # 50 (p.9451) Part 48 of 76, # 51 Part 49 of 76, # 52 Part 50 of 76, # 53 (p.9456) Part 51 of 76, # 54 Part 52 of 76, # 55 Part 53 of 76, # 56 (p.9457) Part 54 of 76, # 57 (p.9490) Part 55 of 76, # 58 (p.9491) Part 56 of 76, # 59 (p.9518) Part 57 of 76, # 60 (p.9521) Part 58 of 76, # 61 (p.9522) Part 59 of 76, # 62 (p.9524) Part 60 of 76, # 63 (p.9585) Part 61 of 76, # 64 (p.9646) Part 62 of 76, # 65 (p.10328) Part 63 of 76, # 66 (p.10335) Part 64 of 76, # 67 (p.10336) Part 65 of 76, # 68 (p.10339) Part 66 of 76, # 69 (p.10389) Part 67 of 76, # 70 (p.10392) Part 68 of 76, # 71 (p.10393) Part 69 of 76, # 72 (p.10396) Part 70 of 76, # 73 (p.10398) Part 71 of 76, # 74 (p.10399) Part 72 of 76, # 75 (p.10434) Part 73 of 76, # 76 (p.26912) Part 74 of 76, # 77 (p.26928) Part 75 of 76, # 78 (p.26929) Part 76 of 76) (Bickford, James) (Entered: 03/27/2025)
09/25/2025	76 (p.26912)	ORDER: For the foregoing reasons, the Court GRANTS Plaintiffs' 43 (p.448) Motion and DENIES Defendants' 61 (p.9522) Motion. Therefore, it is ORDERED that the Final Rule is hereby VACATED and REMANDED for further consideration consistent with this opinion. (Ordered by Chief District Judge Reed O'Connor on 9/25/2025) (hcc) (Entered: 09/25/2025)
09/25/2025	77 (p.26928)	FINAL JUDGMENT: It is ORDERED, ADJUDGED, and DECREED that: 1. Plaintiffs' Motion for Summary Judgment is GRANTED. 2. Defendants' Cross-Motion for Summary Judgment is DENIED. 3. The Centers for Medicare and Medicaid Services's February 1, 2023, Final Rule promulgated at 88 Fed. Reg. 6643 is VACATED and REMANDED to the agency. (Ordered by Chief District Judge Reed O'Connor on 9/25/2025) (hcc) (Entered: 09/25/2025)
11/21/2025	78 (p.26929)	NOTICE OF APPEAL as to 77 (p.26928) Judgment, to the Fifth Circuit by Xavier Becerra, United States Department of Health and Human Services. T.O. form to appellant electronically at Transcript Order Form or US Mail as appropriate. Copy of NOA to be sent US Mail to parties not electronically noticed. IMPORTANT ACTION REQUIRED: Provide an electronic copy of any exhibit you offered during a hearing or trial that was admitted into evidence to the clerk of the district court within 14 days of the date of this notice. Copies must be transmitted as PDF attachments through ECF by all ECF Users or delivered to the clerk on a CD by all non-ECF Users. See detailed instructions here. (Exception: This requirement does not apply to a pro se prisoner litigant.) Please note that if original exhibits are in your possession, you must maintain them through final disposition of the case. (Bickford, James) (Entered: 11/21/2025)
12/30/2025	79 (p.26930)	USCA Case Number 25-11293 in United States Court of Appeals 5th Circuit for 78 (p.26929) Notice of Appeal, filed by United States Department of Health and Human Services, Xavier Becerra. (tle) (Entered: 12/30/2025)

Tab 2

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

HUMANA INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:23-cv-909-O
	)	
ROBERT F. KENNEDY, JR., et al.,	)	
	)	
Defendants.	)	
	)	

NOTICE OF APPEAL

Please take notice that the Defendants hereby appeal to the United States Court of Appeals for the Fifth Circuit from the final judgment entered on September 25, 2025, ECF No. 77.

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General
Civil Division

MICHELLE BENNETT
Assistant Director
Federal Programs Branch

/s/ James Bickford
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Counsel for Defendants

Date: November 21, 2025

Tab 3

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

HUMANA INC. and HUMANA BENEFIT PLAN OF TEXAS, INC.,	§	
Plaintiffs,	§	
v.	§	**Civil Action No. 4:23-cv-00909-O**
XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	§	
Defendants.	§	

FINAL JUDGMENT

This Judgment is issued pursuant to Fed. R. Civ. P. 58(a).

This action came on for consideration by the Court, and the issues having been duly considered and a decision duly rendered.

It is **ORDERED**, **ADJUDGED**, and **DECREED** that:

1. Plaintiffs' Motion for Summary Judgment is **GRANTED**.
2. Defendants' Cross-Motion for Summary Judgment is **DENIED**.
3. The Centers for Medicare and Medicaid Services's February 1, 2023, Final Rule promulgated at 88 Fed. Reg. 6643 is **VACATED and REMANDED to the agency**.
4. The clerk shall transmit a true copy of this Final Judgment to the parties.

SO ORDERED on this **25th** day of **September, 2025.**

Reed O'Connor
CHIEF UNITED STATES DISTRICT JUDGE

Tab 4

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

HUMANA INC. and HUMANA BENEFIT PLAN OF TEXAS, INC.,	§	
Plaintiffs,	§	
v.	§	**Civil Action No. 4:23-cv-00909-O**
XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	§	
Defendants.	§	

ORDER

Before the Court are Plaintiffs' Motion for Summary Judgment (ECF No. 43); Defendants' Cross-Motion for Summary Judgment (ECF No. 61); Plaintiffs' Combined Response and Reply (ECF No. 67); and Defendants' Reply (ECF No. 74). For the reasons stated below, Plaintiffs' Motion is **GRANTED** and Defendants' Motion is **DENIED**.

I. BACKGROUND[1]

This case involves actuarial issues relating to how Medicare Advantage Organizations ("MAOs") are compensated for providing Medicare benefits. MAOs are private insurers who contract with the Medicare Advantage program to cover enrollees's Medicare benefits. The Centers for Medicare and Medicaid Services ("CMS") pays contracted MAOs a prospective fixed monthly amount based on risk-adjusted cost estimates for services provided to Medicare Advantage program enrollees.

[1] Unless otherwise cited, the Court's recitation of the facts is taken from Plaintiff's Complaint. *See* Pls.' Compl., ECF No. 1.

On February 1, 2023, CMS issued a final rule ("Final Rule") adopting a new policy for calculating payment recoveries in Medicare Advantage audits. The Final Rule allows CMS to recover suspected overpayments from audited Medicare Advantage contracts by sampling a small number of contract enrollees and statistically extrapolating these audit results across a contract's entire enrollee population. It then recovers contract-wide repayments based on those estimates.

Every June, MAOs, such as Humana Inc. and Humana Benefit Plan of Texas, Inc. (collectively, "Humana" or "Plaintiffs"), submit and negotiate bids with CMS for the following year's plans. Through this process, CMS and the MAOs determine each plan's benefits and pricing, which they later memorialize in Medicare Part C contracts. After this bidding and contracting process concludes, and during an enrollment period from October to December preceding the coverage year, Medicare beneficiaries can enroll in any Medicare Advantage plan covering the geographic area where they live.

Medicare Advantage programs use a different compensation structure from plans available under Medicare Parts A and B, which use a fee-for-service payment model. Unlike Medicare Parts A and B, which pay doctors directly, the Medicare Advantage program contracts with private insurers such as Humana to cover enrollees' Medicare benefits. MAOs commit to provide enrollees with benefits that match or exceed those available under Medicare Parts A and B. In exchange, CMS prospectively pays MAOs a fixed monthly amount based on the cost that the agency estimates it would incur to provide fee-for-service Medicare benefits to those same enrollees.

To harmonize these different compensation structures, the Medicare statute requires "actuarial equivalence" between payments to MAOs and the payments that CMS would expect to make for the same enrollees' healthcare expenses in the fee-for-service Medicare program.

42 U.S.C. § 1395w–23(a)(1)(C)(i). Ensuring actuarial equivalence requires CMS to apply an actuarially sound method of "risk adjustment." *Id.* § 1395w–23(a)(3)(A). Risk adjustment is a way of statistically estimating the healthcare costs of a particular pool of Medicare Advantage beneficiaries and then increasing or decreasing payment based on their unique risk factors. The Medicare statute requires CMS to adjust the base payment for each enrollee to account for certain "risk factors," including "age, disability status, gender, institutional status, and . . . health status . . . so as to ensure actuarial equivalence" with fee-for-service Medicare. *Id.* § 1395w–23(a)(1)(C)(i).

CMS bases its ultimate payment to insurers on (1) the base rate and (2) the risk source unique to each Medicare Advantage enrollee considering that enrollee's demographic and health characteristics. Each enrollee in a Medicare Advantage plan has the same "base rate"—an estimate of the expected cost to provide fee-for-service Medicare benefits to an enrollee with average health and demographic characteristics in the covered locale. CMS sets base rates through an annual bidding process. MAOs, including Humana, submit bids for each Medicare Advantage plan, stating the amount of revenue they estimate will be necessary to provide benefits to an enrollee of average risk in a given geographic area in the next calendar year. The MAOs must certify "based on generally accepted actuarial principles" that projected revenues will cover (1) an average enrollee's fee-for-service Medicare benefits, and (2) any supplemental benefits—services not covered by fee-for-service Medicare—that the MAOs commit to provide. 42 C.F.R. § 422.254(b)(5).

To determine how much to pay MAOs, CMS built its payment model on data from fee-for-service Medicare. The agency develops estimates of the expected marginal costs associated with particular types of diagnosis codes. These are based on how much CMS pays healthcare providers

who submitted claims for services rendered to fee-for-service Medicare beneficiaries where the providers' claims included those same codes.

To confirm the accuracy of those codes, the United States Department of Health and Human Services ("HHS"), CMS's parent agency, implemented the Risk Adjustment Data Validation ("RADV"). Under the RADV, CMS and the Inspector General for HHS ("HHS-OIG") audit a subset of Medicare Advantage contracts. The contract administrator is required to submit medical records for a sample of enrollees. CMS or HHS-OIG subsequently reviews those medical records to ensure the documented conditions correspond with the diagnosis codes submitted to CMS. CMS then recoups payments from MAOs for any diagnosis codes it deems undocumented in the medical record.

Historically, CMS recouped only payments corresponding to individual diagnosis codes from the enrollee sample. But in 2010, CMS announced that it would start using RADV audits to calculate payment error estimates for the entire enrollee population of the audited Medicare Advantage contract and recover extrapolated contract-wide repayments based on those estimates. Under that proposal, CMS would audit diagnosis codes for only a sample of a contract's enrollees but would use the results to recoup an extrapolated payment associated with the statistically estimated rate of undocumented diagnosis codes for the entire contract.

Commenters identified a critical flaw in this approach. Humana and others explained that the agency's proposal was actuarially unsound because it would simultaneously use two very different sets of data to measure diagnoses—non-validated fee-for-service Medicare Claims Data for the development of payment rates, and validated Medicare Advantage Claims Data documented in medical records on the back end of the RADV audit.[2] In other words, CMS's

[2] Pls.' App. Supp. Mot. Summ. J. (RADV Comment) App. 7493, ECF No. 45-11.

proposal would have estimated the agency's costs associated with a given diagnosis code based on claim forms submitted by fee-for-service Medicare providers but would pay audited MAOs based only on diagnosis codes documented in the enrollees' medical records. Humana and others contested that the proposal would systematically underpay audited MAOs and thus no longer compensate them for the risks they were accepting.

CMS agreed with the comments and, in February 2012, publicly adopted what it called a Fee-for-Service Adjuster ("FFS Adjuster") in a revised RADV audit methodology. The FFS Adjuster would account for the difference in the two data points by conducting a RADV-like review of records submitted to support fee-for-service Medicare claims data and applying the findings as an offset to any payments that it recovered in extrapolated RADV audits. From 2012 to 2018, the FFS Adjuster operated to ensure actuarial equivalence by offsetting the payments.

But, in 2018, CMS proposed a new rule which would get rid of the FFS Adjuster due to a study it had conducted[3] and a finding that it would be inequitable to correct the payments made to audited plans but not to non-audited plans. 83 Fed. Reg. 54982, 55037–41 (Nov. 1, 2018) ("Proposed Rule"). In 2023, CMS issued the Final Rule, which eliminated the FFS Adjuster on the grounds that RADV audits do not have to comply with the statute's actuarial-equivalence mandate and the Coding-Intensity Adjustment forecloses use of an FFS Adjuster. 88 Fed. Reg. 6643 (Feb. 1, 2023).

On September 1, 2023, Plaintiffs filed their complaint against Xavier Becerra in his official capacity as Secretary of U.S. Department of Health and Human Services, and United States Department of Health and Human Services ("Defendants") in the Northern District of Texas,

[3] When commenters asked to see the study, CMS informed them that it had been misplaced. Subsequently, CMS replicated the study to reach the same result. And after commenters poked many holes in the replicated study, CMS abandoned it entirely when promulgating the Final Rule.

where Humana Benefit Plan of Texas, Inc. resides. The Complaint brought three claims for relief under the Administrative Procedure Act ("APA"), alleging that (1) the Final Rule is arbitrary and capricious and contrary to law because it reverses CMS's FFS Adjuster policy without adequate explanation, (2) CMS abused its discretion in deciding to apply the new policy retroactively beginning in payment year 2018 because it relied solely on legal justifications that misinterpret the Medicare Statute, and (3) CMS promulgated the Final Rule without observance of procedure required by law.[4] The Parties filed cross-motions for summary judgment, which are now ripe for review.

II. LEGAL STANDARD

In a case challenging an agency action under the APA, summary judgment "serves as the mechanism for deciding" whether the action "is supported by the administrative record and otherwise consistent with the APA standard of review." *Gadhave v. Thompson*, No. 3:21-cv-2938-D, 2023 WL 6931334, at *1 (N.D. Tex. Oct. 19, 2023) (citation omitted). The agency resolves "factual issues to arrive at a decision supported by the administrative record." *Yogi Metals Grp. Inc. v. Garland*, 567 F.Supp.3d 793, 797–98 (S.D. Tex. 2021) (citation omitted), *aff'd*, 38 F.4th 455 (5th Cir. 2022). The district court then applies the APA standards of review to determine whether, as a matter of law, "the evidence in the administrative record permitted the agency to make the decision it did." *MRC Energy Co. v. U.S. Citizenship & Immigr. Servs.*, No. 3:19-cv-2003-K, 2021 WL 1209188, at *3 (N.D. Tex. Mar. 31, 2021) (citation omitted). The entire case is thus a question of law, with the district court sitting as an appellate tribunal. *See Id.* If a court determines the contested agency action falls short of the APA's substantive or procedural

[4] Pls.' Compl. 38–42, ECF No. 1.

requirements, the reviewing court "shall" set aside the unlawful agency action. 5 U.S.C. § 706(2)(A)–(D); *Data Mktg. P'ship v. U.S. Dep't of Lab.*, 45 F.4th 846, 859 (5th Cir. 2022).

III. ANALYSIS

Plaintiffs contend that they are entitled to summary judgment on all three of their claims: (1) the Final Rule is arbitrary and capricious and contrary to law because it reverses CMS's FFS Adjuster policy without an adequate explanation; (2) CMS abused its discretion in deciding to apply the new policy retroactively beginning in payment year 2018 because it relied solely on legal justifications that misinterpret the Medicare Statute; and (3) CMS promulgated the Final Rule without observance of procedure required by law.[5] In contrast, Defendants claim that they are entitled to summary judgment on all three of Plaintiffs' claims.[6] Because as discussed *infra*, the Court finds that the Final Rule is procedurally invalid as it was not a "logical outgrowth" of the Proposed Rule, the Court need not and will not address the other claims.

Plaintiffs claim that Defendants violated the APA's procedural requirements by abandoning their justifications for the Proposed Rule in favor of new justifications for the Final Rule.[7] "In the Fifth Circuit, the logical-outgrowth rule requires [CMS] to provide 'fair notice' of the eventual Final Rule." *Mock v. Garland*, 75 F.4th 563, 583 (5th Cir. 2023) (quoting *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 381 (5th Cir. 2021)). To be a logical outgrowth, the proposed rule must "adequately frame the subjects for discussion such that the affected party should have anticipated the agency's final course in light of the initial notice." *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021) (citation modified). "If interested parties 'should have anticipated' that the change was possible, and thus reasonably

[5] *See generally* Pls.' Br. Supp. Mot. Summ. J., ECF No. 44.
[6] *See generally* Defs.' Br. Supp. Mot. Summ. J., ECF No. 62.
[7] *See* Pls.' Br. Supp. Mot. Summ. J. 33, ECF No. 44.

should have filed their comments on the subject during the notice-and-comment period, then the rule is deemed to constitute a logical outgrowth of the proposed rule." *Id.* (quoting *Tex. Ass'n of Mfrs.*, 989 F.3d at 381). Here, as in *Texas Association of Manufacturers*, "[Plaintiffs] do not object to a substantive change in the text of the Proposed Rule and the Final Rule, but to the change in the justification for the Proposed Rule and the justification for the Final Rule." 989 F.3d at 382.

The notice of proposed rulemaking initially offered two rationales for its proposal not to include an FFS Adjuster in any sampling and extrapolation methodology: (1) an empirical analysis, and (2) the proposition that "correct[ing] any systematic payment error in the [Medicare Advantage] program through a payment adjustment that was only applied to audited contracts . . . would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans."[8] While the comment period was still open, CMS requested comment on "whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C) . . . mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform [its] proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology."[9]

Ultimately, CMS offered two different justifications for the Final Rule: (1) that an FFS Adjuster is neither required nor appropriate in the context of RADV audits because the actuarial-equivalence requirement does not apply as a matter of law; and (2) that the Coding-Intensity Adjustment forecloses use of an FFS Adjuster.[10]

Plaintiffs contend that the Defendants' violated the APA's logical-outgrowth rule by changing the justifications for the rule.[11] In response, Defendants' assert that the rational for the Final Rule was made clear by the first proposed justifications and the additional request for

[8] Pls.' App. Supp. Mot. Summ. J. (Nov. 2018 Proposed Rule), App. 731, ECF No. 45-2.
[9] Pls.' App. Supp. Mot. Summ. J. (June 2019 RADV Proposed Rule), App. 741, ECF No. 45-2.
[10] Pls.' Consol. Resp. and Reply 32, ECF No. 68.
[11] Pls.' Br. Supp. Mot. Summ. J. 40–42, ECF No. 44.

comment.[12] Additionally, Defendants assert that any error was harmless as there is no likelihood that the result would have been different as their interpretation of the statute is correct.[13] In rebuttal, Plaintiffs reassert their claim that the Final Rule's justifications did not logically flow from the Proposed Rule's justifications and argue that Defendants cannot save their procedural failures by "cherry-pick[ing]" generic and broad sentences from the Proposed Rule.[14] Plaintiffs further contend that the error was not harmless.[15] In their Reply, Defendants reassert their logical outgrowth and harmlessness arguments, and argue—for the first time—that they did not need to abide by the APA's notice-and-comment requirement for statutory interpretation.[16] The Court will address each of the preceding arguments.

The Court begins with the Parties' respective positions regarding the logical outgrowth rule. As discussed above, CMS's justifications for the Final Rule are (1) that an FFS Adjuster is neither required nor appropriate in the context of RADV audits because the actuarial-equivalence requirement does not apply as a matter of law, and (2) that the Coding-Intensity Adjustment forecloses use of an FFS Adjuster.[17] Defendants do not and cannot assert that their second justification (the Coding-Intensity Adjustment) logically flowed from the Proposed Rule's justifications.[18] Thus, as the Parties do, the Court's analysis focuses on the first justification (the actuarial-equivalence requirement).

Defendants claim that their legal justification for the Final Rule logically flowed from one of the Proposed Rule's justifications and the request for additional comment. Specifically,

[12] Defs.' Resp. 44–45, ECF No. 63.
[13] *Id.* at 45–46.
[14] Pls.' Consol. Resp. and Reply 32–33, ECF No. 68.
[15] *Id.* at 34.
[16] Defs.' Reply 26–28, ECF No. 74.
[17] Pls.' Consol. Resp. and Reply 32, ECF No. 68.
[18] *See* Defs.' Br. Supp. Mot. Summ. J. 44–45, ECF No. 62.

Defendants allege the following justification emanated from the Proposed Rule: "the proposition that 'a RADV-specific payment adjustment' would not be an 'appropriate' response to 'systematic payment error,' because 'RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation.'"[19] But this abandons the Proposed Rule's stated rationale that "correct[ing] any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts . . . would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans."[20] To support their assertion that the justifications for the Final Rule logically flowed from the Proposed Rule's first justification, Defendants selectively quote from the Proposed Rule.[21] Because context is important, the Court includes the entirety of the relevant section below and bolds the parts Defendants quoted:

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

[19] *Id.* at 45 (citing 83 Fed. Reg. at 55,041).
[20] *Id.* (citing Nov. 2018 Proposed Rule, App. 731, ECF No. 45-2).
[21] *Id.*

> only, we would not include an FFS Adjuster in any RADV extrapolated audit methodology. We welcome public comments on this study.[22]

This articulated reasoning, if true, may support a finding that it is "inequitable to correct any systematic errors in the payments made to audited plans only" or that RADV audits do not result in the systematic underpayment of MAOs. However, it does not give the reader any indication that CMS is reconsidering an over thirteen-year-old precedent regarding the application of the actuarial-equivalence provision to RADV audits.[23] Indeed, the Proposed Rule's justification (that FFS Adjusters introduce inequities) does not appear in the Final Rule, and thus could not have been a contributing factor for the new justification. CMS's discussion regarding whether FFS Adjusters correct payment errors or simply create inequities is not enough to connect the dots.

Defendants contend that any procedural defects were remedied when CMS requested comment on "whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C) . . . mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform [its] proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology."[24] But this is not enough. *Mock*, 75 F.4th at 584 ("merely informing the public, in a generic sense, of the broad subjects and issues the Final Rule would address is insufficient."). Accordingly, the Court finds that Plaintiffs should not have reasonably anticipated that CMS's discussion regarding whether FFS Adjusters correct payment errors or simply create inequities would result in a finding that actuarial equivalence does not apply.[25]

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[22] Nov. 2018 Proposed Rule, App. 731, ECF No. 45-2.

[23] *Id.* The Court further notes that other courts regularly reject the cherry picking of sentences to satisfy the notice requirements of the APA. *See, e.g.*, *Env't Integrity Project v. EPA*, 425 F.3d 992, 998 (D.C. Cir. 2005) (quoting *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005)) ("[A]n exercise in 'looking over a crowd and picking out your friends," . . . does not advise interested parties how to direct their comments and does not comprise adequate notice under APA § 533(c).").

[24] *Id.* (citing 84 Fed. Reg. at 30,983)

[25] This finding is bolstered by the fact that actuarial equivalence applies between Medicaid and MAOs, and CMS's discussion here involves equity between only MAOs. Therefore, it is not reasonably discernable

Defendants next claim that their request for additional comment should have made its intention to switch justifications "clear and subjected to public comment."[26] That request for additional comment provides, in its entirety:

> That proposal rested on two grounds. First, we conducted a study which indicated that diagnosis error in FFS claims data does not lead to systematic payment error in the Medicare Advantage (MA) program. Second, we suggested that it would be inequitable to correct any systematic errors made in the payments to audited plans only. We continue to welcome public comment on this proposal. We are also seeking comment on whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C), which requires risk adjustment in subclause (a)(1)(C)(i), mandates a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C)(iii)—mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology.[27]

There is no specific indication here that would alert the reader to the fact that CMS was considering abandoning the just-mentioned justifications for a finding that actuarial equivalence does not apply. Rather, CMS cites all three sub-sections in a manner which signals to the reader that CMS believes the sub-sections are applicable to RADV audits.[28]

In an attempt to save the Final Rule from the APA's procedural requirements, Defendants point to one non-party comment to show that it was easily discernable that CMS was considering reversing their long-standing finding that actuarial equivalence applies.[29] But, the Fifth Circuit has directly addressed this contention, holding that even if "a few members of the public happened to divine the Government's unspoken thoughts, comments such as these do not satisfy the

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that CMS's comments about inequities between MAOs would result in a finding that actuarial equivalence does not apply between Medicaid and MAOs for the purposes of these audits.

[26] Defs.' Br. Supp. Mot. Summ. J. 45, ECF No. 62.

[27] June 2019 RADV Proposed Rule, App. 741, ECF No. 45-2.

[28] *See id.* ("which **requires** risk adjustment in subclause (a)(1)(C)(i)" to ensure actuarial equivalence, "**mandates** a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C)(iii)") (emphasis added).

[29] Defs.' Br. Supp. Mot. Summ. J. 46, ECF No. 62.

Government's obligation to afford the general public an opportunity to respond to clearly stated proposals."[30] *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 975 (5th Cir. 2023) (citation modified) (citing *Tex. Ass'n of Mfrs.*, 989 F.3d at 383). Thus, even though a few commenters submitted opinions regarding actuarial equivalence, the Court finds that Defendants' broad and affirmative reference to sub-sections of a statute did not satisfy their burden to notify the public with any reasonable specificity that they were considering finding actuarial equivalence inapplicable.[31] *See Mock*, 75 F.4th at 584 ("But merely informing the public, in a generic sense, of the broad subjects and issues the Final Rule would address is insufficient. Instead, the Proposed and Final Rule must be alike in kind so that commentators could have reasonably anticipated the Final Rule.").[32]

[30] The Court notes that even though Defendants were able to identify at least one comment on whether actuarial equivalence is required for RADV audits, the entirety of the "comment and response" section of the Final Rule contains only one reference to "actuarial equivalence." *See* Pls.' App. Supp. Mot. Summ. J. (Final Rule), App. 7349–53, ECF No. 45-11. That reference is contained withing a series of other comments and states as follows: "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." *Id.* at 7350. This comment does not address whether actuarial equivalence applies across RADV audits, but rather whether extrapolating the audit of a few patients across the entirety of the contract violates actuarial equivalence. And as best the Court can tell, the "response" does not address the comment.

[31] This determination is strengthened by the fact that CMS seemingly based its reasoning on a D.C. Circuit opinion, dealing with a different statutory provision, which was issued well after the comment period closed. While Defendants assert that they did not rely on the case, by the Court's count, it was cited nineteen times to support CMS's new justification in the Final Rule. *See* Final Rule 7343–63, ECF No. 45-11 (citing *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. August 13, 2021, *reissued* November 1, 2021)). It cannot be said that the public had a fair opportunity to comment on a justification that is seemingly based on an opinion issued after the comment period closed. *See* June 2019 RADV Proposed Rule, App. 741, ECF No. 45-2 (providing that the comment period for the Proposed Rule "closes at 5 p.m. on August 28, 2019").

[32] The Court further notes that CMS seemingly failed to consider the relevant factors under the "surprise switcheroo" doctrine, given the sudden and absolute switch in interpretation. *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 189 n.6 (5th Cir. 2023) (citing *Azar*, 587 U.S. at 571; *Env't Integrity Project*, 425 F.3d at 996).

Moreover, Defendants—for the first time in their Reply—assert that they did not have "an obligation to seek comment on [their] statutory interpretations."[33] As a preliminary matter, this argument fails because courts do not consider arguments made for the first time in a reply. *Herrera v. United States*, No. 4:16-CR-107-A, 2019 WL 4806140, at *3 (N.D. Tex. Oct. 1, 2019) (citing *United States v. Cervantes*, 132 F.3d 1106, 1111 (5th Cir. 1998)).

But even if the Court did consider it, it plainly fails. Defendants' assertion is based on the premise that interpretive rules, unlike legislative rules, need not be subjected to notice and comment. *See, e.g.*, *Flight Training Int'l, Inc. v. Fed. Aviation Admin.*, 58 F.4th 234, 240–41 (5th Cir. 2023). However, the Fifth Circuit has held that when a rule "repudiates or is irreconcilable with a prior legislative rule, the second rule . . . must itself be legislative." *Id.* at 241. The "statutory interpretation" Defendants now rely upon is irreconcilable with the prior rule's longstanding principle that actuarial equivalence applies to RADV audits. Therefore, Defendants' argument that they had no obligation to participate in notice and comment also fails on the merits. *See Azar v. Allina Health Servs.*, 587 U.S. 566, 572–86 (2019) (rejecting a similar argument regarding the obligation to participate in notice and comment).

Finally, citing *Shinseki v. Sanders*, 556 U.S. 396, 411 (2009), Defendants assert that any error they committed was harmless as there is no likelihood that the result would have been different because their interpretation is the "the best reading of the statute" under *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024).[34] In essence, Defendants ask the Court to find that an agency need not comply with the APA's stringent requirements, as long as the agency's interpretation of a statute is the best reading. Defendants do not cite to a single case, and the Court

[33] Defs.' Reply 27, ECF No. 74.
[34] Defs.' Resp. 55, ECF No. 63; Defs.' Reply 32, ECF No. 74.

cannot find any in which a court considered this argument much less made such a holding. And this Court declines to be the first.

Moreover, holding that Defendants' failure to satisfy the APA's notice-and-comment requirement was harmless based on a finding that the interpretation was the best reading of the statute ostensibly violates the well-established principle that agencies must "consider . . . important aspect[s] of the problem," including, "of course, considering the costs and benefits associated with the regulation." *Chamber of Com. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023) (citing *Mexican Gulf Fishing*, 60 F.4th at 973). And as part of that cost-benefit analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id.*

Here, because there was no meaningful notice of Defendants' ultimate finding that actuarial equivalence does not apply to RADV audits, there was no meaningful dialogue regarding the costs and benefits of the surprise changes. The harm caused by the lack of discussion—which is an independent ground for vacatur and remand—is exacerbated by the Final Rule's application back to 2018. While the Parties dispute whether this is impermissibly retroactive, it is undisputed that companies like Plaintiffs relied upon and operated under the old rule's guidance from 2018–2023. Consequently, Plaintiffs, and others, will potentially bear enormous unforeseen costs as a result of their reliance on CMS's nearly thirteen-year-old position from 2018–2023. Thus, the Court concludes that Defendants' error was not harmless.

As a result of the foregoing, the Court finds that Defendants' failure to comply with the procedural requirements of the APA was not harmless. Consequently, the Court must **VACATE** and **REMAND** the Final Rule for further consideration.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Plaintiffs' Motion and **DENIES** Defendants' Motion**.** Therefore, it is **ORDERED** that the Final Rule is hereby **VACATED** and **REMANDED** for further consideration consistent with this opinion.

SO ORDERED on this **25th day** of **September, 2025**.

Reed O'Connor
CHIEF UNITED STATES DISTRICT JUDGE

Tab 5

February 24, 2012

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

Introduction

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

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

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

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

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

Background

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

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

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

A. Sampling

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

Sampling Frame

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

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

Sample Size and Strata

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

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

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

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

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

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

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

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

B. <u>Payment Error Calculation</u>

Enrollee-level Payment Error Calculation

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

Payment Error Extrapolation Calculation

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

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

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

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

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

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

Payment Recovery Amount and the Fee-For-Service Adjuster

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

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

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

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

Tab 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS–4185–P]

RIN 0938–AT59

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

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

ACTION: Proposed rule.

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

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

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

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT:

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

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

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

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

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

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

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

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

I. Executive Summary

A. Purpose

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

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

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

B. Summary of the Major Provisions

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

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

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

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

a. Background

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

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

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

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

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

b. Risk Adjustment Data Validation Initiatives

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

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

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

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

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

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

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

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

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

c. Discussion of Proposals

(1) Extrapolation

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

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

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

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

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

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

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

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

(2) Application to Payment Year 2011 and Subsequent Years

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

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

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

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

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

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

Continued

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

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

(3) Implementation

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

(4) Recoupment of Improper Payments in Part C

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

(5) FFS Adjuster

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

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

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

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

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

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

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

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

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

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

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

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

d. Proposed Changes

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

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

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

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

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

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

D. Implementing Other Changes

1. Clarification Regarding Accreditation for Quality Improvement Programs

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

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

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

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

III. Collection of Information Requirements

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

§ 422.254 Submission of bids.

* * * * *

(b) * * *

(1) * * *

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

* * * * *

(3) * * *

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

(ii) [Reserved]

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

* * * * *

(c) * * *

(3) * * *

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

* * * * *

(e) * * *

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

* * * * *

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

§ 422.264 Calculation of savings.

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

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

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

* * * * *

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

§ 422.300 Basis and scope.

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

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

§ 422.310 Risk adjustment data.

* * * * *

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

* * * * *

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

§ 422.311 RADV audit dispute and appeal processes.

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

* * * * *

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

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) * * *

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

* * * * *

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

§ 422.560 Basis and scope.

(a) * * *

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

(b) * * *

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

* * * * *

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

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means:

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

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

Tab 7

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS–4185–N4]

RIN 0938–AT59

Medicare and Medicaid Programs; Risk Adjustment Data Validation

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

ACTION: Proposed rule; request for additional comment; announcement of the release of additional data.

SUMMARY: This document summarizes actions taken to date, requests public comment on additional subjects, and announces that CMS is releasing additional material, including study data, related to the Risk Adjustment Data Validation (RADV) provisions of the proposed rule titled ''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'' that was published in the November 1, 2018 **Federal Register**, 83 FR 55037. The comment period for the RADV provisions of this proposed rule ends on August 28, 2019.

DATES: The comment period for CMS RADV provisions (that is, section II.C.2. of the November 1, 2018 proposed rule and proposed §§ 422.300, 422.310(e) and 422.311(a) of the regulation text) closes at 5 p.m. on August 28, 2019.

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

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Jonathan Smith (410) 786–4671 or Joanne Davis (410) 786–5127.

SUPPLEMENTARY INFORMATION:

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

I. Request for Public Comment

On November 1, 2018, we published a proposed rule containing provisions related to the Risk Adjustment Data Validation (RADV) audit program, 83 FR 55037 through 55041 and 55077, including the proposal not to apply a Fee-for-Service Adjuster (FFS Adjuster) in any RADV extrapolated audit methodology. That proposal rested on two grounds. First, we conducted a study which indicated that diagnosis error in FFS claims data does not lead to systematic payment error in the Medicare Advantage (MA) program. Second, we suggested that it would be inequitable to correct any systematic errors made in the payments to audited plans only. We continue to welcome public comment on this proposal. We are also seeking comment on whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C), which requires risk adjustment in subclause (a)(1)(C)(i), mandates a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C) (iii)—mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology.

II. Summary of Prior Notices

Since we published the FFS Adjuster Study on October 26, 2018,[1] we have published several related notices.

On December 27, 2018 (83 FR 66661), we announced an extension of the comment period for the RADV provisions until April 30, 2019 and a plan to release data underlying the October 26, 2018 FFS Adjuster Study.

On March 6, 2019 (84 FR 8069), we announced the release of data underlying the FFS Adjuster Study, both through the Office of Enterprise Data Analytics (OEDA) and on the Private Plans Team website. Data made available to the public through a data use agreement included all of the following:

- An input file originating from a dataset that Research Triangle Institute (RTI) supplied. It represents the calibration data that RTI used for the Centers for Medicare and Medicaid Services Hierarchical Condition Category (CMS–HCC) model version that CMS used to calculate 2009 MA payments.
- An input file containing medical record review findings from a RADV-like review that CMS undertook on a sample of calendar year 2008 medical records.
- FFS data containing 10 datasets that represent the entire 5 percent sample of all final 2004 and 2005 diagnosis codes used for MA model calibrations through 2011.
- An HCC file containing the mapping from International Classification of Disease, 9th Revision diagnosis code to Version 12 of the CMS–HCC model. Diagnosis codes have been modified to remove decimals.
- A file consolidating MA data for beneficiaries who meet eligibility criteria for Contract-Level Risk RADV audits from three sources: The adjusted Monthly Membership Report (MMR), the Model Output File (MOF), and the CMS Enrollment Database (EDB).
- A file consolidating MA data for beneficiaries who did not meet all eligibility criteria for the Contract-Level RADV audits from three sources—adjusted MMR, MOF, and CMS EDB.
- Additional documentation and data related to the RADV FFS Adjuster Study was posted on the Private Plans Team website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-*

[1] The Executive Summary and Technical Appendix of the study are both available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html.*

Adjustment-Data-Validation-Program/Resources.html. This data included a RADV Data Dictionary and Provisional Coefficients workbook.

On April 30, 2019 (84 FR 18215), we announced an additional extension of the comment period for the RADV provision until August 28, 2019. We also announced that we would be releasing additional data underlying the FFS Adjuster Study, including additional data containing Protected Health Information, to all parties who entered an applicable data use agreement and paid the required fee. This data has been available since June 14, 2019. The forms and instructions to request this data and previously released data remain available via the CMS website at *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/*. Updates to existing documentation related to the study data, as well as additional data without Protected Health Information, were posted on the CPI Private Plans Team website on April 25, 2019.

III. Release of Additional Study Material and Further Request for Public Comment

We have now replicated the FFS Adjuster Study and published a summary of that replication as an addendum to the study at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html*. The results of the replication are broadly consistent with the initial implementation of the study. The purpose of this replication was to allow us to both 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 have been preserved and published in the addendum or at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.htm*. In addition, the addendum contains further discussion of the study's assumptions and methodology. We are also releasing the programming language used to implement the replication of the study, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html,* along with a description of the technical requirements for use of that programming language. It is our intention that the release of this programming language, together with the earlier release of the data used as inputs, will allow for robust public comment on the FFS Adjuster Study.

We welcome public comment on that subject, and all subjects raised in this notice and the notices discussed previously, until 5 p.m. on August 28, 2019.

Dated: June 21, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–13891 Filed 6–27–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 207, 215, 216, and 234

[Docket DARS–2019–0026]

RIN 0750–AK38

Defense Federal Acquisition Regulation Supplement: Reliability and Maintainability in Weapon System Design (DFARS Case 2019–D003)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DOD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2018 that requires the use of reliability and maintainability sustainment factors in weapon system design.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before August 27, 2019, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2019–D003, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2019–D003'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2019–D003.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2019–D003'' on your attached document.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2019–D003 in the subject line of the message.
- *Fax:* 571–372–6094.
- *Mail:* Defense Acquisition Regulations System, Attn: Ms. Kimberly Bass, OUSD(A&S)DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to amend the DFARS to implement section 834 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91). Section 834 amends title 10, United States Code (U.S.C.), to add section 2443, sustainment factors in weapon system design, which requires program managers or comparable requiring activity officials exercising program management responsibilities to ensure that reliability and maintainability are included in the performance attributes of the key performance parameters on sustainment during the development of capabilities requirements for major weapon systems design and contracts for the—

- Engineering and manufacturing development of a weapon system, including embedded software; or
- Production of a weapon system, including embedded software.

As a matter of policy, the Under Secretary of Defense for Acquisition and Sustainment directed application of the requirements of 10 U.S.C. 2443 to the technical maturation and risk reduction phase.

II. Discussion and Analysis

The following changes to the DFARS are proposed to implement 10 U.S.C. 2443:

DFARS 207.106(S–70)(2)(ii)(A) implements 10 U.S.C. 2443 as an additional requirement for major systems, and provides guidance to the acquisition team during acquisition planning to ensure that reliability and maintainability are included in the performance attributes of the key performance parameters on sustainment during the development of capabilities requirements.

DFARS 207.106(S–72)(5) informs the contracting officer to ensure best

Tab 8

TABLE 1 TO PARAGRAPH (a)(1)—Continued

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

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

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[FR Doc. 2023–02109 Filed 1–31–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS–4185–F2]

RIN 0938–AT59

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

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

ACTION: Final rule.

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

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

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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

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

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

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

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

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

II. Background

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

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

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

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

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

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

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

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

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

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

B. Purpose and Description of Contract-Level RADV Audits

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

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

C. History of the Contract-Level RADV Program

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Informal Proposal Comments and the FFS Adjuster

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

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

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

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

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

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

3. The 2012 Methodology

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

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

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

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

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

4. The 2018 RADV Proposed Rule

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

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

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

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

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

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

[16] *Id.* at 4–5.

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

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

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

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

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

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

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

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

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

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

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

III. Provisions of the RADV Final Rule

A. Extrapolation of RADV Audit Findings

1. Use of Extrapolation in the Medicare Program

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

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

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

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

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

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

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

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

2. Summary of Proposed Rule

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

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

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

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

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

TABLE 1—DIABETES HCCS

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

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

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

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

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

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

[26] See 83 FR 55038.

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

3. Summary of Public Comments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[28] *Id.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Summary of Final Policies

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

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

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

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

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

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

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

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

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

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

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

B. Fee-For-Service Adjuster

1. Description of an FFS Adjuster

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

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

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

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

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

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

2. Summary of 2018 Proposed Rule

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

3. Summary of Public Comments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

and will, therefore, have inherent limitations.

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

4. Summary of Final Policies

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

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

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

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

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

IV. Collection of Information Requirements

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

V. Regulatory Impact Analysis

A. Statement of Need

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

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

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

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

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

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

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

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

B. Overall Impact

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

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

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

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

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

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

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

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

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

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

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

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

C. Regulatory Review Cost

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

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

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

D. Detailed Economic Analysis

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

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

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

1. Expected Impact of These Provisions

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

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

Using this data, we can conclude as follows:

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

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

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

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

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

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

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

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

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

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

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

2. Alternatives Considered

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

a. Alternatives Related to the Extrapolation of RADV Findings

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

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

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

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

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

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

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

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

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

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

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

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

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

[$ in millions]

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

E. Accounting Statement and Table

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

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

TABLE 4—ACCOUNTING STATEMENT—CLASSIFICATION OF ESTIMATED TRANSFERS

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

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

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

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

List of Subjects in 42 CFR Part 422

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

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

PART 422—MEDICARE ADVANTAGE PROGRAM

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

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

Subpart G—PAYMENTS TO MEDICARE ADVANTAGE ORGANIZATIONS

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

§ 422.300 Basis and scope.

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

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

§ 422.310 Risk adjustment data.

* * * * *

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

* * * * *

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

§ 422.311 RADV audit dispute and appeal processes.

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

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

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

* * * * *

Dated: January 26, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 230126–0026]

RIN 0648–BL75

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

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

ACTION: Final rule.

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

DATES: Effective February 1, 2023.