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

HUMANA INC.,

and

HUMANA BENEFIT PLAN OF TEXAS, INC.,

Plaintiffs,

v.

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.

No. _____

COMPLAINT FOR DECLARATORY & INJUNCTIVE RELIEF

INTRODUCTION

1. This lawsuit challenges the federal government's arbitrary and capricious reversal of a policy governing payment audits conducted by the Medicare Advantage program. At stake is the financial stability of this enormously popular government health-insurance program, which provides life-saving healthcare coverage for more than 30 million seniors.

2. On February 1, 2023, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule adopting a new policy for calculating payment recoveries in Medicare Advantage audits. The agency did not even try to offer an empirical or actuarial justification for its new audit methodology, relying instead on purely legal rationales—none of which withstand scrutiny. Because CMS's reliance on faulty legal rationales is arbitrary and capricious and contrary to law in violation of the Administrative Procedure Act ("APA"), Plaintiffs Humana Inc. and Humana Benefit Plan of Texas, Inc. ("Plaintiffs") respectfully request that this Court vacate the final rule and enjoin the agency from applying the new policy in any audit of Plaintiffs.

3. Humana Inc. is a leading health and well-being company committed to helping millions of members achieve their best health, including through its subsidiary Medicare Advantage organizations that offer the full spectrum of health-benefit plans for Medicare beneficiaries.[1] Nearly half of all Medicare beneficiaries receive their benefits through private Medicare Advantage plans like the ones administered by Humana.[2] Medicare Advantage enrollees report high levels of satisfaction with their coverage and often receive more benefits

[1] This Complaint refers to Humana Inc. and its subsidiary Medicare Advantage organizations collectively as "Humana."

[2] *See* Jeannie Fuglesten Biniek, Anthony Damico, Meredith Freed, Tricia Neuman & Nancy Ochieng, *Medicare Advantage in 2023: Enrollment Update and Key Trends*, Kaiser Family Foundation (Aug. 9, 2023), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/.

than are available under traditional Medicare, which is also known as "fee-for-service Medicare." When beneficiaries enroll in a Medicare Advantage plan each year, a Medicare Advantage organization commits to cover their full Medicare benefits—and often more—in exchange for a flat monthly payment from CMS. The Medicare statute also requires CMS to adjust the flat monthly payments, in part, to account for the health risks associated with different enrollees so that Medicare Advantage organizations are fully compensated for the risks they assume when they commit to cover those enrollees' Medicare benefits. When making these risk-adjusted payments to Medicare Advantage organizations, the Medicare statute requires CMS to maintain "actuarial equivalence" with fee-for-service Medicare, such that the agency pays Medicare Advantage organizations the same amount for each enrollee that it would expect to pay to cover that enrollee in traditional fee-for-service Medicare. To that end, the Medicare statute requires CMS and Medicare Advantage organizations to observe stringent actuarial requirements at every step of the bidding and payment process.

4. Earlier this year, CMS promulgated a regulation (the "Final Rule") that upends the Medicare Advantage program's compensation model, allowing the agency to claw back payments that CMS made to Medicare Advantage organizations years after the fact based on agency audits that violate these basic actuarial principles. The Final Rule permits CMS to recover funds from audited Medicare Advantage plans using a documentation standard inconsistent with the standard it used to develop the Medicare Advantage payment model in the first place. This inconsistent documentation standard violates published standards of actuarial practice. Internal documents produced by CMS show that, more than a decade ago, the agency recognized that the very double standard CMS now seeks to implement would be actuarially unsound. In fact, in 2012, CMS publicly promised to adjust any audit recoveries to account for

this double standard. And Medicare Advantage organizations like Humana relied on that assurance for years when structuring their Medicare Advantage bids to CMS and related business practices. Nonetheless, in 2018, CMS unexpectedly reversed course. The agency issued a Proposed Rule reneging on its prior commitment, proposing to upend the bargain at the foundation of the Medicare Advantage program—that CMS pays Medicare Advantage organizations the same amount it would cost the agency to provide Medicare benefits to the same enrollees under traditional fee-for-service Medicare. During the pendency of the Proposed Rule, the agency apparently searched in vain for years for a reasoned justification for reversing its position, offering ever-changing explanations that have fallen away time and again under scrutiny.

5. After giving itself multiple extensions, CMS released the Final Rule in February 2023. In that rule, CMS abandoned every explanation it has ever offered to justify its about-face. Instead, it asserted—for the very first time—that the Medicare statute allows the agency to recover billions of dollars from Medicare Advantage organizations through audits that *do not observe any actuarial standards at all*. That newly invented and self-serving reading of the Medicare statute (which expressly requires the agency to ensure "actuarial equivalence" between fee-for-service Medicare and Medicare Advantage payments) is textually wrong and actuarially unsound. Making matters worse, CMS seeks to apply the Final Rule retroactively to contracts that Humana entered into with CMS in reliance on the agency's promise that it would maintain consistent documentation standards between fee-for-service Medicare and Medicare Advantage when auditing payments to Medicare Advantage organizations like Humana.

6. CMS's shifting justifications and erroneous legal reasoning violate the APA's prohibition on arbitrary, capricious, and unlawful agency action. And CMS's decision to apply

its new policy retroactively exceeds the agency's statutory authority and abuses its discretion under the APA. The Final Rule will alter the Medicare Advantage program's actuarial foundations, with unpredictable consequences for Medicare Advantage organizations and the millions of seniors who rely on the Medicare Advantage program for their healthcare. The APA forbids CMS from taking such drastic action without a reasoned explanation reconciling the agency's policy with controlling statutory mandates. Accordingly, Plaintiffs respectfully ask the Court to vacate the Final Rule and enjoin the agency from applying the new policy in any audit of Plaintiffs.

THE PARTIES

7. Plaintiff Humana Inc. is a Delaware corporation whose principal place of business is Jefferson County, Kentucky. As of 2023, Humana Inc. and its subsidiaries contracted directly with more than 900,000 physicians and healthcare professionals and more than 3,660 hospitals nationwide to provide medical care to enrollees in their Medicare Advantage plans. Humana Inc. and its subsidiaries serve approximately 18 percent of all Medicare Advantage enrollees—more than 5.5 million seniors and other eligible enrollees.

8. Plaintiff Humana Benefit Plan of Texas, Inc., is a Texas corporation whose principal place of business is Dallas County, Texas. Humana Benefit Plan of Texas is an authorized insurance company licensed to offer health maintenance organization ("HMO") plans in the state of Texas. It administers Medicare Advantage plans as a subsidiary of Humana Inc., pursuant to a Medicare Part C contract with CMS that Humana Benefit Plan of Texas first executed on August 27, 2020. It offers coverage to Medicare Advantage enrollees in Texas.

9. Humana Inc. and its subsidiaries conduct significant business in the state of Texas, employing more than 5,100 people in the state and serving more than 1.8 million members statewide, including Medicare Advantage, Medicare Part D, Dual-Eligible Special

Needs Plans, and TRICARE members. Through its Medicare Advantage subsidiaries, Humana serves more than 425,000 Medicare Advantage beneficiaries who reside in Texas. The Medicare benefits of these Texas citizens will be threatened by the Final Rule at issue in this case.

10. Defendant Xavier Becerra ("the Secretary") is the Secretary of Defendant U.S. Department of Health and Human Services ("HHS"). Plaintiffs are suing the Secretary in his official capacity. The Secretary administers the Medicare Advantage program through CMS, which is a component agency of HHS.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this case under 28 U.S.C. § 1331. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, and the APA, 5 U.S.C. §§ 702, 703, and 706.

12. Venue is proper under 28 U.S.C. § 1391(e).

FACTUAL ALLEGATIONS

I. The Medicare Advantage Program Provides a Popular and Efficient Mechanism for Seniors to Access Medicare Benefits.

13. Since 1965, the Medicare program has provided health insurance to Americans aged 65 or older, individuals suffering from serious long-term disabilities, and patients with end-stage renal disease. CMS, an agency of HHS, administers the Medicare program under the Secretary's authority and supervision. The fee-for-service Medicare program consists of Medicare Part A, which covers inpatient hospital care, and Medicare Part B, which covers outpatient medical care. Medicare Parts A and B are known as traditional Medicare, or fee-for-service Medicare. This case concerns the payment system for Medicare Part C, also known as Medicare Advantage. Under Medicare Part C, private insurers called Medicare Advantage

organizations bid to provide Medicare-eligible enrollees with at least the same coverage available under Medicare Parts A and B. Humana is a Medicare Advantage organization.

14. Medicare Advantage organizations cover fee-for-service Medicare benefits and often more, such as benefits designed to address social determinants of health and specialized clinical needs. Every June, Medicare Advantage organizations like Humana submit and negotiate bids with CMS for the following year's plans. Through this process, CMS and the Medicare Advantage organizations determine each plan's benefits and pricing, which they later memorialize in Medicare Part C contracts. *See* 42 U.S.C. §§ 1395w-21 through 1395w-28. A single contract might apply to multiple Medicare Advantage plans, and Medicare Advantage organizations often have several contracts with CMS.

15. After this bidding and contracting process concludes, Medicare beneficiaries can enroll in any Medicare Advantage plan covering the geographic area where they live, generally during an enrollment period extending from October to December preceding the coverage year. *Id.* § 1395w-21(b)(1), (e)(3)(B). Local plans cover specific counties, while regional plans cover larger Medicare Advantage regions designated by CMS. *Id.* §§ 1395w-23(d)(1)-(2), 1395w-28(b)(4). Over the past decade, Medicare Advantage enrollment has more than doubled: In 2023, more than 30 million Americans, representing nearly half of the eligible Medicare population, are enrolled in a Medicare Advantage plan.[3]

16. To further the goals of the Medicare Advantage program, Congress requires CMS to use a payment model that fundamentally differs from the compensation model used in fee-for-service Medicare. In fee-for-service Medicare, CMS directly pays healthcare providers to treat

[3] *Medicare Advantage in 2023: Enrollment Update and Key Trends*, *supra* n.2. In 2023, 18 percent of Medicare Advantage enrollees are enrolled in a Humana plan. *Id.*

Medicare beneficiaries. This fee-for-service model reimburses providers retrospectively for each specific service they render to Medicare beneficiaries. Under Part A, CMS reimburses hospitals and other facilities for each inpatient stay. *See* 42 U.S.C. § 1395ww(d)(1)-(4). Under Part B, CMS pays providers a set amount for each medically necessary procedure they perform. *Id.* § 1395*l*(a)(1). The fee-for-service Medicare payment model incentivizes *more* care but not necessarily *better* care—the more procedures healthcare providers perform for fee-for-service Medicare beneficiaries, the more CMS pays them.

17. The Medicare Advantage program uses a different compensation structure—one designed to incentivize more efficient care and better benefits. Rather than pay doctors and hospitals for each service performed, the program contracts with private insurers like Humana to cover enrollees' Medicare benefits. Medicare Advantage organizations commit to provide enrollees with benefits that match *or exceed* those available under Medicare Parts A and B; in exchange, CMS pays Medicare Advantage organizations prospectively 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. Unlike in fee-for-service Medicare, Medicare Advantage payments are not tethered to the volume of medical care enrollees ultimately consume, removing the incentive to provide unnecessary services. The program's fixed-payment structure also shifts financial risk to Medicare Advantage organizations. They foot the bill when an enrollee consumes more medical services than anticipated but retain the savings when an enrollee consumes fewer services than expected.

18. By decoupling payment from service volume, Congress hoped to bring to Medicare "the health benefit design, delivery, and cost containment innovations that have

occurred in the private sector."[4] Congress expected those efficiencies would be passed on to Medicare beneficiaries as plans competed to attract enrollees through superior benefits and lower costs, which would be achieved through cost-sharing arrangements and efficient, high-quality provider networks.

19. Congress achieved these goals. Today, Medicare Advantage organizations offer plan benefits going far beyond fee-for-service Medicare, including dental care, hearing aids, and over-the-counter drugs.[5] And they continue to produce cost savings for enrollees. The average monthly premium for Medicare Advantage plans has steadily decreased, from $32.91 in 2015 to $19 in 2022.[6]

20. Medicare Advantage enrollees report 40 percent less out-of-pocket healthcare spending and are 29 percent less likely to be hospitalized for avoidable reasons than their counterparts in fee-for-service Medicare.[7] Humana, in particular, has been on the cutting edge of innovation. As of 2020, 67 percent of its enrollees sought care from network physicians in value-based care models that focus on patient outcomes rather than volume of medical services, leading to 165,000 fewer hospital admissions compared to fee-for-service Medicare and 90,000 fewer emergency-room visits.[8] Ninety-eight percent of Medicare Advantage enrollees report that

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[4] H.R. Rep. No. 105-217, at 585 (1997), https://www.congress.gov/105/crpt/hrpt217/CRPT-105hrpt217.pdf.

[5] *See CMS Releases 2022 Premiums and Cost-Sharing Information for Medicare Advantage and Prescription Drug Plans*, CMS (Sept. 30, 2021), https://www.cms.gov/newsroom/press-releases/cms-releases-2022-premiums-and-cost-sharing-information-medicare-advantage-and-prescription-drug.

[6] *Id.*; *see also Medicare Advantage Premiums Remain Stable; Enrollment at All-Time High*, CMS (Sept. 21, 2015), https://www.cms.gov/newsroom/press-releases/medicare-advantage-premiums-remain-stable-enrollment-all-time-high.

[7] *See 2021 State of Medicare Advantage* at 12, 18, Better Medicare Alliance (May 2021), https://bettermedicarealliance.org/publication/2021-state-of-medicare-advantage-report/.

[8] *See Value-based Care Report: Physician Progress and Patient Outcome* at 2, 9, Humana (2020), https://digital.humana.com/VBCReport/VBC_Report_2020_digital.pdf.

they are satisfied with their coverage.[9] The Congressional Budget Office projects that by 2030, the majority of Medicare beneficiaries will be enrolled in Medicare Advantage.[10] In short, Medicare Advantage plans offer lower costs, better clinical outcomes, and higher customer satisfaction than fee-for-service Medicare.

II. The Medicare Advantage Payment Model Adjusts Payments to Private Insurers Based on the Risks They Assume to Provide Medicare Benefits for Particular Enrollees.

21. The Medicare Advantage program rests on a foundational bargain: A private health-insurance organization commits to provide Medicare-eligible enrollees with at least the same benefits they would receive in fee-for-service Medicare. In exchange, CMS pays the health insurer the same amount that the fee-for-service Medicare program would expect to pay to cover traditional Medicare benefits for the same enrollees. The Medicare statute codifies this bargain with its command that payments to Medicare Advantage organizations must be "actuarial[ly] equivalen[t]" to the payments that CMS would expect to make for those enrollees' healthcare expenses in the fee-for-service Medicare program. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).

22. To "ensure actuarial equivalence," *id.*, Congress required that CMS develop and apply an actuarially sound method of "risk adjustment," *id.* § 1395w-23(a)(3). 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.[11] Among other things, risk adjustment "reduce[s] the incentive for [Medicare

[9] *2021 State of Medicare Advantage*, *supra* n.7, at 21.

[10] *Id*. at 5; *see also* Medicare-CBO's Baseline as of March 6, 2020, Congressional Budget Office (Mar. 19, 2020), https://www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf.

[11] CMS, Medicare Managed Care Manual, ch. 7, § 20 (2014), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf.

Advantage] plans to prefer enrolling healthier-than-average beneficiaries."[12] 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. 42 U.S.C. § 1395w-23(a)(1)(C)(i). In other words, the Medicare Advantage risk-adjustment system must ensure that CMS "pay[s] the same amount to Medicare Advantage insurers for their beneficiaries' care as CMS would spend on those same beneficiaries if they were instead enrolled in traditional Medicare."[13]

23. CMS's ultimate payments to Medicare Advantage organizations have two components: (1) a "base rate" that is the same for each enrollee in a given locale, which represents the agency's estimate of the expected cost to provide fee-for-service Medicare benefits to an enrollee with average health and demographic characteristics in that locale, and (2) a "risk score" unique to each Medicare Advantage enrollee that accounts for that enrollee's actual demographic and health characteristics.

A. CMS Payments to Medicare Advantage Organizations Begin with "Base Rates."

24. CMS sets base rates for Medicare Advantage compensation through an annual bidding process. Every June, Medicare Advantage organizations submit bids to CMS for the plans they intend to offer the following year. A Medicare Advantage organization must commit to a benefits package that equals or exceeds the benefits available under fee-for-service Medicare. Each bid must state the funds the Medicare Advantage organization estimates it

[12] CMS, Report to Congress: Risk Adjustment Medicare Advantage at 4 (2018), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.

[13] *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867, 883 (D.C. Cir. 2021).

would need to provide those benefits to an enrollee of average risk in the relevant geographic area. 42 C.F.R. § 422.254(a)(1). In developing these bids, Medicare Advantage organizations account for the specific characteristics of expected enrollees in the relevant geographic area and the payment rates and risk-adjustment methodology that CMS annually discloses. The Medicare Advantage organization's bid must be certified by a member of the American Academy of Actuaries, *see* 42 U.S.C. § 1395w-24(a)(6)(A)(iii); 42 C.F.R. § 422.254(b)(5), and CMS must confirm that the bid is based on sound actuarial estimates, *see* 42 U.S.C. § 1395w-24(a)(6)(B); 42 C.F.R. § 422.256(b).

25. CMS then compares the Medicare Advantage organization's bid for an average enrollee to a CMS-created benchmark that serves as a ceiling for base payments. CMS sets these benchmarks based on average fee-for-service Medicare spending per beneficiary in the geographic area at issue. If a Medicare Advantage organization's bid is lower than the CMS benchmark, the bid becomes the base rate for each enrollee in that plan. 42 U.S.C. § 1395w-23(a)(1)(B)(i). If the organization's bid is higher than the CMS benchmark, then the benchmark becomes the organization's base rate for each enrollee in that plan. *Id.* § 1395w-23(a)(1)(B)(ii).

B. CMS Adjusts Payments for Particular Enrollees Based on "Risk Scores" Reflecting Their Health Status and Other Risk Factors.

26. A Medicare Advantage organization's base rate is just the starting point for calculating the risk it assumes for a given beneficiary and the compensation it is due from CMS for assuming that risk. That base rate reflects the estimated monthly cost of benefits for a fee-for-service Medicare beneficiary with *average* health risks. But many Medicare Advantage enrollees are more or less healthy than this average enrollee.

27. CMS accounts for these differences—and complies with Congress's risk-adjustment mandate—through a payment-adjustment methodology called the "CMS-HCC

Model." This model adjusts the base-rate payment for a given enrollee based on a "risk score,"[14] paying Medicare Advantage organizations less for enrollees with lower risk scores and more for enrollees with higher risk scores. The agency calculates an enrollee's risk score based on demographic and health factors specific to the enrollee. To measure enrollees' health risks, CMS uses "diagnosis codes," which are numeric codes associated with different health conditions. Medicare Advantage organizations most often receive these diagnosis codes from claims forms that doctors and other healthcare providers submit for their enrollees, and then the Medicare Advantage organizations submit those codes to CMS as part of the risk-adjustment payment process. Humana alone receives claims forms containing diagnosis codes from more than 900,000 contracted providers in its network, as well as numerous other out-of-network providers.[15]

28. After CMS receives these diagnosis codes from Medicare Advantage organizations, the agency groups related diagnosis codes into "Hierarchical Condition Categories," or "HCCs," each of which represents a group of related health conditions.[16] To capture the expected future costs associated with diagnosis codes in each group of conditions, the agency assigns a "risk coefficient" to every HCC reflecting the average fee-for-service Medicare spending associated with the diagnosis codes in that HCC.[17]

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[14] Medicare Managed Care Manual, *supra* n.11, ch. 7, § 70.1.

[15] Healthcare providers follow the same basic process when they treat beneficiaries in fee-for-service Medicare, but in that case they submit claims forms, including diagnosis codes, directly to CMS.

[16] *See* CMS, Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies ("2023 Rate Notice") at 4 (Apr. 4, 2022), https://www.cms.gov/files/document/2023-announcement.pdf.

[17] Medicare Managed Care Manual, *supra* n.11, ch. 7, § 70.2.3. *See also id.* ch. 8, § 60.2, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c08.pdf.

29. To derive its risk coefficients, CMS performs a statistical regression analysis measuring the association between diagnosis codes in each HCC and fee-for-service Medicare payments.[18] The regression estimates the average incremental healthcare cost to CMS when a fee-for-service Medicare beneficiary's claims include at least one diagnosis code in a given HCC.

30. In measuring the association between healthcare expenses and diagnosis codes reported by providers, at no point does CMS confirm that fee-for-service Medicare beneficiaries' diagnosis codes are documented in their medical records. Instead, the calculation measures the expected cost associated with the provider's *reporting* of the diagnosis code in the claim form—regardless of whether the provider documented the condition in the beneficiary's medical record, provided any course of treatment, or took any other action with respect to the reported condition. CMS could measure the costs to fee-for-service Medicare associated with diagnoses or treatments that are *documented* in the beneficiaries' medical records, but the agency chose instead an estimation process that measures only costs associated with the diagnosis codes that providers *reported* in claims forms they submitted to fee-for-service Medicare.

31. After estimating the spending associated with different diagnosis codes in fee-for-service Medicare claims data, CMS performs a statistical "normalization" that translates its cost estimates into coefficients for different diagnosis codes, which can be added together to calculate risk scores representing the actuarial risks associated with an enrollee's reported diagnosis codes and demographic characteristics. Following this normalization process, an average Medicare beneficiary is expected to have a risk score of exactly 1.0. Each year, CMS publishes a rate notice describing, among other things, the diagnosis codes it will use to risk adjust payments to

[18] Medicare Managed Care Manual, *supra* n.11, ch. 7, § 70.1.

Medicare Advantage organizations and the coefficient for each diagnosis code. Medicare Advantage organizations rely on these annual rate notices to prepare and submit their Medicare Advantage bids to CMS. Actuaries for these organizations factor the coefficients from the rate notices—as well as the documentation standards used to develop them—into estimates of the revenue required to provide benefits to an enrollee of average risk in a given geographic area. *See* 42 U.S.C. § 1395w-24(a)(6)(A)(iii); 42 C.F.R. § 422.254(b)(5).

32. The annual rate notices are also key to determining a Medicare Advantage enrollee's risk score, which is the sum of all of their risk coefficients. This risk score includes not only health-risk coefficients for diagnosis codes but also demographic coefficients measuring the anticipated costs associated with age, sex, and other factors identified by CMS. A Medicare Advantage organization's payment for an enrollee is the plan's base rate multiplied by the enrollee's risk score:

33. In a simplified example using the risk coefficients that CMS set for payment year 2023, a 77-year-old woman whose providers submit diagnosis codes to the Medicare Advantage plan for acute myocardial infarction, chronic obstructive pulmonary disease, and pneumococcal pneumonia would have a risk score of 1.135—or, stated another way, 0.135 (13.5 percent) above average:

Risk Score	**Risk Coefficient**[19]
Female, age 75-79	0.420
Acute myocardial infarction (HCC 86)	0.219

[19] *See* 2023 Rate Notice, *supra* n.16, at 123-27.

Chronic obstructive pulmonary disease (HCC 111)	0.291
Pneumococcal pneumonia (HCC 115)	0.205
Total Risk Score	**1.135**

34. If the plan's base rate in this example is $1,000 per month, CMS would pay the Medicare Advantage organization that administers the plan a monthly premium of $1,135 for this enrollee—the $1,000 base rate multiplied by the enrollee's risk score of 1.135.

C. Congress Designed a "Coding-Intensity Adjustment" to Account for Different Incentives in Fee-for-Service Medicare and Medicare Advantage.

35. In designing this risk-adjustment system, Congress feared that the program's incentive structure could systematically increase risk scores for Medicare Advantage enrollees, undermining actuarial equivalence between Medicare Advantage and fee-for-service Medicare. Whereas fee-for-service Medicare providers are compensated based on services rendered, payments to Medicare Advantage organizations depend in part on the diagnosis codes reported to CMS. So while fee-for-service Medicare providers have "no incentive to report more than one" diagnosis code, Medicare Advantage organizations are incentivized to report all of an enrollee's diagnosis codes.[20] CMS refers to this dynamic as an incentive for Medicare Advantage organizations to "report more completely" than healthcare providers in fee-for-service Medicare. CMS has long recognized that the relatively greater "completeness" of diagnosis codes reported for Medicare Advantage enrollees as compared to fee-for-service Medicare beneficiaries is separate and distinct from the question of whether diagnosis codes reported for Medicare

[20] *See* Richard Kronick & W. Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, Medicare & Medicaid Research Review, CMS, Vol. 4, No. 2, E3 (2014), https://www.cms.gov/mmrr/downloads/mmrr2014_004_02_a06.pdf/.

Advantage enrollees are more or less likely to be documented in the underlying medical records than those reported for fee-for-service Medicare beneficiaries.[21]

36. To address the two programs' differing incentives, Congress instructed CMS to develop and apply a "coding adjustment." *See* 42 U.S.C. § 1395w-23(a)(1)(C)(ii). CMS must "annually conduct an analysis of" "differences in coding patterns between Medicare Advantage plans and providers under part[s] A and B" and "ensure that the results of such analysis are incorporated . . . into" each year's risk scores. *Id.* § 1395w-23(a)(1)(C)(ii)(I)-(II). The resulting downward adjustment to risk scores to account for the incentive to code more completely in Medicare Advantage is sometimes referred to as the "coding-pattern adjustment" or "coding-intensity adjustment."

37. Congress has set statutory minimums for the coding-intensity adjustment. *See id.* § 1395w-23(a)(1)(C)(ii)(III). Each year, before Medicare Advantage organizations submit their bids, CMS announces the size of the coding-intensity adjustment for the following payment year—the amount by which risk scores will be reduced to account for "differences in coding patterns" between fee-for-service Medicare and Medicare Advantage. *Id.* § 1395w-23(k)(2)(B)(iv)(III). Since 2019, CMS has applied the congressionally mandated minimum coding-intensity adjustment of 5.9 percent, reducing each enrollee's risk score by 5.9 percent before multiplying it by the base rate to compute the monthly payment for the enrollee. The 77-

[21] *Id.* at E3-E4; Advance Notice of Methodological Changes for Calendar Year (CY) 2009 for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies, at 12 (Feb. 22, 2008), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/advance2009.pdf.

year-old woman described above, for example, would have her risk score of 1.135 reduced by 5.9 percent, for a coding-intensity-adjusted risk score of 1.068.[22]

III. CMS's Final Rule Fails to Reconcile Medicare Advantage Payment Audits with the Agency's Statutory Mandates.

38. CMS periodically audits the diagnosis codes that Medicare Advantage organizations submit to the agency; CMS conducts so-called Risk Adjustment Data Validation ("RADV") audits to perform this validation function. *See* 42 C.F.R. § 422.311. The RADV audit program "validat[es]" the diagnosis codes that Medicare Advantage organizations submit as part of the statutorily mandated risk-adjustment process. *See* 42 C.F.R. § 422.310(e); 42 U.S.C. § 1395w-23(a)(3)(B). According to CMS, RADV audits "ensure[] the integrity and accuracy of risk adjustment payment data," 42 C.F.R. § 422.2, thereby "further[ing] actuarial equivalence."[23] Each year, CMS audits a subset of Medicare Advantage contracts and requires the Medicare Advantage organizations that administer those contracts to submit medical records for a sample of their enrollees. 42 C.F.R. § 422.310(e). CMS then evaluates whether the medical records document the diagnosis codes the Medicare Advantage organizations submitted to the agency.

39. For many years after launching the RADV audit program in 1999, CMS recouped the payments corresponding only to those specific diagnosis codes within the audited sample that were not documented in the medical records. For example, if a RADV audit found that the medical records of the 77-year-old woman described above did not document a diagnosis code

[22] In addition to the coding-intensity adjustment, CMS also adjusts the risk score by applying the "normalization factor" described above, *supra* ¶ 31, which accounts for the trend in the average risk score of fee-for-service Medicare beneficiaries between the year used to calibrate the model and the payment year.

[23] Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Benefit Programs, 75 Fed. Reg. 19,678, 19,747 (Apr. 15, 2010).

for her acute myocardial infarction (HCC 86), CMS would recoup from the Medicare Advantage organization the payment equal to $219 per month—the base rate of $1,000 multiplied by 0.219, the risk coefficient of the undocumented acute myocardial infarction.[24]

A. In 2010, CMS Announces Its Plan to "Extrapolate" RADV Audits, Ringing Actuarial Alarm Bells within the Industry.

40. In 2010, however, CMS announced that it would start using RADV audits to estimate how many diagnosis codes lack documentation in the medical records across an audited Medicare Advantage contract's entire enrollee population—and to recover extrapolated contract-wide repayments based on those estimates. Under this new proposal, CMS would still audit diagnosis codes for only a small sample of a contract's enrollees, but would use the results to statistically estimate and recoup an extrapolated payment associated with the projected rate of undocumented diagnosis codes for the entire audited contract.[25] Thus, rather than paying Medicare Advantage organizations based on *reported* diagnosis codes they obtain from healthcare providers, as CMS had always done, the agency proposed using RADV audits to pay audited organizations based only on a statistical estimate of the diagnosis codes documented in enrollees' medical records.

41. In a comment letter to CMS in January 2011, Humana 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"—

[24] For simplicity, this example does not account for the coding-intensity adjustment.

[25] CMS, Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits Request for Comment at 3 (Dec. 20, 2010).

documented in medical records—"on the back end of the [RADV] audit."[26] That documentation inconsistency, Humana explained, "would fundamentally undermine the risk adjustment payment model by significantly underpaying" Medicare Advantage organizations "for the risks they assume."[27] In other words, CMS calculates the cost estimates for its risk-adjustment payment model (and therefore payment rates for Medicare Advantage contracts) based on *claims data*—the expenses associated with the presence of a diagnosis code in a *claim* form that a provider submits for the treatment of a fee-for-service Medicare beneficiary. CMS uses *claims forms*, not *medical records*, to calculate the payment model's cost estimates. This is a critical distinction because fee-for-service Medicare beneficiaries' medical records often do not contain documentation of the diagnosis codes listed in their providers' claims for payment. The American Academy of Actuaries agreed with Humana's concerns, warning CMS that this "type of data inconsistency not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities."[28] The next year, the group adopted an authoritative Actuarial Standard of Practice ("ASOP") requiring that the "type of input data that is used in the application of [a] risk

[26] Letter from Heidi Margulis, Sr. Vice President, Humana, to Cheri Rice, Acting Director of CMS, Re: Comment on RADV Sampling and Error Calculation Methodology ("2011 Humana Comment Letter") at 2 (Jan. 21, 2011); *see also* Letter from Vanessa Olson, Senior Vice President, Humana, to Seema Verma, Administrator, CMS, Re: Comment on 2018 Proposed Rule, Technical Appendix, and Addendum ("2019 Humana Comment Letter") at 10 n.36 (Aug. 28, 2019), https://www.regulations.gov/comment/CMS-2018-0133-0257 (citing Humana's 2011 Comment Letter to CMS on RADV Sampling and Error Calculation Methodology).

[27] 2011 Humana Comment Letter, *supra* n.26, at 1.

[28] Letter from Thomas F. Wildsmith, Vice President, American Academy of Actuaries, to Cheri Rice, Acting Director, CMS, Re: Comment on RADV Sampling and Error Calculation Methodology ("AAA Comment Letter") at 2 (Jan. 21, 2011), https://www.actuary.org/content/comments-cms-radv.

adjustment [model] . . . be reasonably consistent with the type of data used to develop the model."[29]

42. The American Academy of Actuaries expected this data inconsistency to produce underpayments to Medicare Advantage organizations because the differing documentation standards would result in CMS using a larger pool of fee-for-service Medicare beneficiaries when calculating the average costs associated with a diagnosis code than if the agency relied on medical-record documentation to perform the same calculation.[30] As a matter of simple math, dividing the costs associated with a diagnosis code across a larger pool of beneficiaries will tend to yield lower averages. To give a simplified example, if CMS were to divide $1,000 of total spending associated with epilepsy among 100 beneficiaries whose doctors *report* an epilepsy diagnosis code in fee-for-service Medicare claims data, it would calculate an average incremental cost of $10 per beneficiary with a *reported* epilepsy code. But if the agency instead *audited* those claims forms against the underlying medical records for those beneficiaries and found that 50 of the diagnosis codes were not documented in the medical records, it would divide the $1,000 in spending associated with epilepsy across only the remaining 50 diagnosis codes, for an average expected incremental cost of $20 per beneficiary with a *documented* diagnosis code. Using unaudited data therefore leads to a larger denominator that decreases the agency's estimate of the average cost associated with epilepsy diagnosis codes. CMS's lower estimate, in turn, yields lower payments to Medicare Advantage organizations for each epilepsy diagnosis code they report for Medicare Advantage enrollees.

[29] Actuarial Standards Bd., The Use of Health Status Based Risk Adjustment Methodologies, § 3.2 (2012), http://www.actuarialstandardsboard.org/pdf/asop045_164.pdf.

[30] AAA Comment Letter, *supra* n.28, at 2.

43. This risk-adjustment methodology can adequately compensate Medicare Advantage organizations for the risks they assume in insuring their enrollee populations because CMS's risk-adjustment model is supposed to predict costs according to the existence of certain data markers: diagnosis codes reported in claims data. What matters in the agency's rate-setting calculations is whether those data markers are predictive of future costs; under the agency's rate-setting approach, it does not matter whether those data markers would be documented in the underlying medical records. If CMS opted to base its risk-adjustment model on a different data marker—for instance, diagnosis codes documented in medical records—the payment rates for Medicare Advantage organizations would differ significantly. Returning to the epilepsy example, the rate would be $20, rather than the $10 that CMS predicted using unaudited fee-for-service Medicare claims data.

44. These lower payment rates do not undercompensate Medicare Advantage organizations or disrupt actuarial equivalence *so long as* CMS maintains *consistency* in the documentation standards between fee-for-service Medicare and Medicare Advantage. CMS can compensate Medicare Advantage organizations in an actuarially sound manner using cost estimates based on either diagnosis codes reported in claims forms or diagnosis codes documented in medical records—as long as it uses the same documentation standard to calculate payments. To continue the above example, if the epilepsy diagnosis codes that physicians report to Medicare Advantage organizations are not documented in the medical records at the same 50 percent rate as in fee-for-service Medicare claims data, then a population of 100 enrollees with reported epilepsy codes will include 50 enrollees whose medical records actually document the codes and another 50 whose medical records do not. The lower $10 per-reported-code estimate will pay an additional $1,000 for those 100 enrollees—the incremental expense associated with

100 *reported* epilepsy diagnosis codes in fee-for-service Medicare claims data. If CMS instead chose to calculate rates and pay Medicare Advantage organizations using only diagnosis codes documented in the medical records, the higher $20 per-code estimate will pay an additional $1,000 for the 50 enrollees whose medical records document the codes—again, the same amount CMS would expect to pay that same population in fee-for-service Medicare. In either scenario, maintaining consistency between the documentation standard used to set Medicare Advantage payment rates and the documentation standard used to calculate those payments will ensure actuarial equivalence between the two programs and accurately compensate Medicare Advantage organizations for the health risks of their enrollees.

45. The actuarial defect with CMS's 2010 RADV proposal was that it threatened to introduce a double standard by: (1) using *reported* diagnosis codes when estimating fee-for-service Medicare costs, resulting in lower cost estimates and thus lower Medicare Advantage payment rates; *and* (2) using only diagnosis codes *documented* in the medical records to make actual payments to audited Medicare Advantage organizations, resulting in fewer Medicare Advantage payments. When extrapolated across entire Medicare Advantage contracts, this documentation mismatch would have first estimated lower payment rates and then applied the lower rates to fewer Medicare Advantage enrollees.

46. Commenters in 2010 also expressed concern to CMS about the effect of the proposal on Medicare Advantage organizations' past and future bids. Humana explained that if its prior bids had accounted for the revenue reduction threatened by the proposed RADV audit methodology, they "would have been substantially higher, resulting in higher member premiums and/or fewer supplemental benefits offered to members."[31] And the American Academy of

[31] 2011 Humana Comment Letter, *supra* n.26, at 8.

Actuaries noted that "the uncertainty related to a plan's ultimate post-audit risk score could make it difficult for actuaries to . . . certify the plan bid."[32]

47. CMS documents obtained under the Freedom of Information Act show that the agency reviewed independent market analyses voicing similar concerns. One report circulated within CMS concluded that "RADV audits completed so far have mostly uncovered that physicians keep poor records and not that [Medicare Advantage] plans have been systematically misstating medical records to inflate premiums." CMS's proposed audit methodology, the report predicted, would make Medicare Advantage plans "bid higher for Medicare contracts and charg[e] seniors higher premiums with lower benefits to price for ongoing audit fines." CMS moved quickly to address these concerns. The agency sent a February 2011 letter to Medicare Advantage organizations acknowledging that commenters had proposed an adjustment mechanism to account for the inconsistent documentation standards in the proposed RADV audit methodology. CMS stated that the agency was "thoroughly evaluating all comments and anticipate[d] making changes to [the] draft" methodology.

48. Other internal agency documents show that CMS *knew* the documentation inconsistency would result in systematic underpayments to Medicare Advantage organizations. CMS acknowledged that its use of unaudited fee-for-service Medicare claims data—which include diagnosis codes "for beneficiaries who don't actually have the disease, or for whom the medical record documentation is not clear"—to set risk coefficients for payments to Medicare Advantage organizations "***tends to reduce the estimated average costs of various conditions*** and therefore our [Medicare Advantage] risk adjustment factors." One internal CMS document provided an illustration, featuring four hypothetical fee-for-service Medicare beneficiaries whose

[32] AAA Comment Letter, *supra* n.28, at 2.

healthcare providers reported a diagnosis code for diabetes in claims forms submitted to the agency, but where only three of the beneficiaries' medical records actually documented such a diagnosis code. This illustration showed that by using diagnosis codes reported in claims forms to estimate how much fee-for-service Medicare would pay to cover these beneficiaries—the "Diabetes on Claim?" column—but medical records to make payments to Medicare Advantage organizations—the "Diabetes in medical record?" column—CMS would depress the average expected cost associated with a diabetes diagnosis code by 25 percent, from $4,000 to $3,000.

Internal CMS Document

Why does FFS Diagnosis Error Matter?

	Diabetes on Claim?	Diabetes in medical record?	FFS Cost
Beneficiary A	Yes	Yes	$4000
Beneficiary B	Yes	Yes	$4000
Beneficiary C	Yes	Yes	$4000
Beneficiary D	Yes	No	$0
		Total	$12,000
		Diabetes Value for MA payment	$3,000

In this example, fee-for-service Medicare paid $12,000 in benefits for this population of four beneficiaries. If CMS determined the beneficiaries' expected healthcare expenditures based only on *reported* diagnosis codes in claims forms, it would divide that $12,000 by the four diabetes diagnosis codes for an average cost of $3,000 (the "Diabetes Value for MA payment" in CMS's document). But if it instead determined the average expected healthcare expenditures based on diagnosis codes documented in the medical records, it would divide $12,000 among only the

three beneficiaries whose medical records document their diagnosis code, for an average cost of $4,000.

49. Either figure—$3,000 or $4,000—could compensate Medicare Advantage organizations in an actuarially equivalent manner *if* CMS used the same documentation standard to "develop" the payment rate (*i.e.,* calculate the risk coefficients) that it uses to "apply" the payment rate (*i.e.,* calculate risk-adjustment payments and recoupments). If CMS used *documented* diagnosis codes to calculate the risk coefficient for diabetes and also paid the Medicare Advantage organization only for enrollees with *documented* diagnosis codes in the medical records, it would calculate a $4,000 average cost per enrollee and pay the organization that amount for three enrollees—a total of $12,000. Similarly, if CMS used only diabetes diagnosis codes *reported* in fee-for-service Medicare claims data to calculate the risk coefficient and paid the organization for all enrollees *reported* to have diabetes diagnosis codes, it would calculate a $3,000 average cost and pay the organization that amount for four enrollees—also a total of $12,000.

50. But CMS's 2010 proposal—to use *reported* diagnosis codes to calculate risk coefficients while paying audited organizations only for *documented* diagnosis codes—would have calculated a $3,000 average cost for diabetes diagnosis codes and paid that amount for only three enrollees, for a total of just $9,000. This scenario would have resulted in CMS paying the Medicare Advantage organization $3,000 less than fee-for-service Medicare would pay for the same four beneficiaries' Medicare benefits. In its internal documents, CMS illustrated why this inconsistency in the documentation standard was problematic with the graphic below, showing that using inconsistent documentation standards would compensate a Medicare Advantage

organization $9,000 (shown in the final column) to provide care expected to cost fee-for-service Medicare $12,000 (shown in the "Plan Cost" column).

Internal CMS Document

Why does FFS Diagnosis Error Matter?

	Diabetes reported by MA plan?	Diabetes in medical record?	CMS Payment to Plan	Plan Cost	RADV	CMS Payment to Plan
Beneficiary A	Yes	Yes	$3000	$4000		$3000
Beneficiary B	Yes	Yes	$3000	$4000		$3000
Beneficiary C	Yes	Yes	$3000	$4000		$3000
Beneficiary D	Yes	No	$3000	$0	($3000)	$0
Beneficiary E	Yes	No	$3000	$0	($3000)	$0
		Total	$15,000	**$12,000**	($6,000)	**$9,000**

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51. CMS thus concluded internally that it could not use "one documentation standard for RADV, which is perfection," and "another documentation standard for risk adjustment, which reflects a certain level of [fee-for-service Medicare] codes that aren't documented in a medical record." Rather, CMS reasoned that "[f]or our payments to be as accurate as possible, we should be using the same standard for both." To remedy this actuarial defect, CMS considered a so-called Fee-for-Service Adjuster ("FFS Adjuster") that would "offset . . . recovery amounts under RADV" audits to account for diagnosis codes in fee-for-service Medicare claims data that were not documented in the beneficiaries' medical records. By "tak[ing] into account how CMS payments would change if [the] perfection standard that is applied under RADV was also used when calculating risk-adjustment model values," this FFS Adjuster would ensure "that RADV and [Medicare Advantage] payments are on the same documentation standard." Given the underpayments threatened by its inconsistent documentation standard, the agency concluded that the FFS Adjuster "makes sense and from a technical point of view is the right thing to do."

B. In 2012, CMS Publicly Acknowledges This Actuarial Problem by Committing to Apply a "Fee-for-Service Adjuster" to Extrapolated RADV Audits, and Humana Relies on This Commitment in Structuring Its Medicare Advantage Bids.

52. In February 2012, CMS issued a notice that publicly adopted the FFS Adjuster in a revised RADV audit methodology, which recognized "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)," and promised to "account[] for" that difference using the FFS Adjuster.[33] CMS stated that it would calculate the FFS Adjuster "based on a RADV-like review of records submitted to support [fee-for-service Medicare] claims data," and would apply it "as an offset" to any payments that it recovered in extrapolated RADV audits.[34]

53. In the years that followed the 2012 notice, Humana expressly premised its Medicare Advantage bids on the understanding that CMS would use an FFS Adjuster in RADV audits and structured its business practices in reliance on the agency's 2012 commitment. Humana's annual bid certifications explicitly relied on CMS's public commitment to account for the different documentation standards used to calculate Medicare Advantage payment rates and conduct RADV audits *before* recouping any payments associated with diagnosis codes that were not documented in enrollees' medical records.[35]

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[33] CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level at 1-2 (Feb. 24, 2012), 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.

[34] *Id.*

[35] 2019 Humana Comment Letter, *supra* n.26, at 17 (quoting Bid ID H0028-004 (Aug. 10, 2017)) ("[R]evenue and risk score projections in the bid(s) are based on the assumption that final risk scores will be calculated and payments and overpayments will be determined consistent with the fact that CMS has used diagnoses contained in administrative claims data (and not medical records) to calculate risk coefficients and risk scores for [Medicare] FFS beneficiaries.").

54. For more than six years, CMS said nothing else publicly or to Humana about how the FFS Adjuster would work. Though CMS approved Humana's Medicare Advantage bids each year, the agency did not respond to Humana's bid certifications. CMS did not even announce a methodology for *calculating* the FFS Adjuster, let alone apply an FFS Adjuster to "offset" and finalize pending RADV audits. Instead, the agency allowed its RADV audits to drag on for years, leaving Medicare Advantage organizations in limbo on the details of the FFS Adjuster.

C. In 2018, CMS Proposes Retracting the FFS Adjuster Based on a Deeply Flawed Study.

55. In late 2018, after years of silence, CMS unexpectedly abandoned its commitment to the FFS Adjuster. This reversal was closely tied to litigation over a different Medicare Advantage payment regulation ("the Overpayment Rule"), which required Medicare Advantage organizations to return any funds received for individual diagnosis codes that the Medicare Advantage organization knew were not documented in the medical record.[36] Judge Rosemary M. Collyer of the U.S. District Court for the District of Columbia vacated the Overpayment Rule on September 7, 2018. Judge Collyer pointed to the same inconsistent documentation standard at the heart of the RADV dispute to find that automatically requiring Medicare Advantage organizations to refund payments for diagnosis codes that were not documented in the medical record, without taking into account the presence of codes in fee-for-service Medicare claims data that also were not documented in the medical record, would "inevitabl[y]" undercompensate

[36] *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.D.C. 2018); *see also* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,843, 29,921 (May 23, 2014) ("For example, a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment.").

them.[37] Among other things, Judge Collyer held that this discrepancy departed from CMS's 2012 promise of an FFS Adjuster in the RADV audit context, which had recognized the need to account for the inconsistent documentation standards.[38]

56. On November 1, 2018, just two months after Judge Collyer's decision vacating the Overpayment Rule, CMS broke its six-year silence on the FFS Adjuster with a new Proposed Rule for RADV audits. The Proposed Rule reversed course on the FFS Adjuster, announcing that no FFS Adjuster would be applied to extrapolated RADV audit recoveries. The Proposed Rule relied heavily on a study purportedly showing that diagnosis codes in fee-for-service Medicare claims data that were not documented in the medical record did not "bias" payments to Medicare Advantage organizations. As an alternative rationale for eliminating the FFS Adjuster, CMS stated that even if unaudited fee-for-service Medicare claims data *did* systematically bias payments to Medicare Advantage organizations, a "RADV-specific payment adjustment" would be inappropriate because it "would introduce inequities between audited and unaudited" organizations "by only correcting the payments made to audited" organizations.[39] CMS did not initially release the study or its underlying data, nor did CMS's Chief Actuary certify the study, as required by agency guidelines.

57. Just four days after releasing the Proposed Rule and study, CMS rushed the study into court to seek reconsideration of Judge Collyer's holding that the Overpayment Rule violated the Medicare Act's requirement of actuarial equivalence. Judge Collyer denied the agency's

[37] *Azar*, 330 F. Supp. 3d at 184-87.
[38] *Id.* at 189-90.
[39] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54,982, 55,041 (Nov. 1, 2018).

motion, ruling that CMS should not have waited until the "11th hour" to produce the study and introduce it into the Overpayment Rule litigation.[40] The United States Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") later reversed Judge Collyer's ruling, holding that actuarial equivalence does not apply to the Overpayment Rule but also observing—importantly for this case—that RADV audits are "plainly distinguishable" from overpayment refunds.[41]

58. The late-released study was the centerpiece of CMS's proposal to abandon the FFS Adjuster. After commenters noted that CMS's Proposed Rule did not divulge enough information about the study to allow for meaningful review, the agency trickled out additional data over months before eventually admitting that it had *lost* key outputs from the study and would need to replicate its analysis. In June 2019, CMS released its second attempt at the study, which came to a similar conclusion as the original: that "diagnosis error in . . . FFS [claims] data does not" lead to systematic "payment bias" in the Medicare Advantage program.[42]

59. This do-over confirmed that the study was as ramshackle as the process that produced it. Commenters, including Humana, explained how a series of methodological errors by the agency *guaranteed* that its study would produce the exact result the agency needed in the Overpayment Rule litigation by finding no payment bias regardless of what the underlying data actually showed. Among other methodological flaws, Humana noted that CMS had drastically underestimated the rates of diagnosis codes in fee-for-service Medicare claims data that were not documented in the medical record and had introduced a statistically inexplicable "adjustment"

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[40] *UnitedHealthcare Ins. Co. v. Azar*, 2020 WL 417867, at *4 (D.D.C. Jan. 27, 2020).

[41] *Becerra*, 16 F.4th at 870, 893 n.1.

[42] CMS, Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits – Technical Appendix, at 16 (Oct. 26, 2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Technical-Appendix.pdf.

that was guaranteed to erase any payment bias the study would have otherwise detected. When external expert actuaries retained by Humana replicated the study eliminating these errors, they found that the presence of diagnosis codes in fee-for-service Medicare claims data not documented in the associated medical records deflated Medicare Advantage payment rates by at least 9.9 percent as compared to payment rates derived from audited data that included only diagnosis codes documented in the medical record.[43]

60. In short, when properly analyzed, even CMS's flawed and incomplete study actually *confirmed* that eliminating the FFS Adjuster would disrupt actuarial equivalence. CMS's own internal documents seemed to acknowledge this fact, describing an earlier version of the study that had estimated Medicare Advantage payments would be 8.1 percent higher if the agency's risk-adjustment "model had been built using perfect data."

61. In its comment on the Proposed Rule, Humana also explained that the Medicare statute's mandatory coding-intensity adjustment does not license CMS to conduct actuarially unsound RADV audits lacking an FFS Adjuster. As CMS has repeatedly acknowledged, the coding-intensity adjustment and RADV audits address two distinct actuarial problems: The coding-intensity adjustment accounts for Medicare Advantage organizations' greater incentive to code more completely than fee-for-service Medicare providers, whereas RADV audits "validat[e] that diagnosis codes submitted for risk adjustment are documented in the medical record" and do not address "coding pattern differences" between Medicare Advantage and fee-

[43] *See* Ross Winkelman, Actuarial Report on CMS' November 1, 2018 Proposed Rule at 8, 19 (Aug. 27, 2019), https://www.regulations.gov/comment/CMS-2018-0133-0257; *see also* Bo Martin, Comment Regarding CMS's Proposals Not to Implement a "Fee-for-Service Adjuster" For RADV Audits and To Implement a Sub-Cohort Audit Method, § 4.5.4 (Aug. 27, 2019), https://www.regulations.gov/comment/CMS-2018-0133-0257.

for-service Medicare.[44] Humana explained that the coding-intensity adjustment's slight reduction to Medicare Advantage payment rates in no way authorizes CMS to conduct contract-wide extrapolated audits using a different documentation standard than was used to develop the Medicare Advantage risk-adjustment payment model.

62. Finally, Humana's comment letter also explained that CMS lacked statutory authority to eliminate the FFS Adjuster *retroactively*.[45] Humana noted that applying the agency's proposal only prospectively would *not* "be contrary to the public interest," and that retroactive application therefore was not permissible under 42 U.S.C. § 1395hh(e)(1)(A)(ii).[46] In particular, Humana explained that its legitimate reliance on CMS's past promises—which had underpinned Humana's Medicare Advantage bid calculations for years—outweighed any conceivable public interest in upending Humana's bid assumptions years after the fact.[47]

IV. CMS's Final Rule Abandons Its Own Study and Instead Relies Solely on Erroneous Legal Rationales to Argue that RADV Audits Need Not Honor Actuarial Principles.

63. CMS published its Final Rule on February 1, 2023—more than four years after issuing its Proposed Rule, more than three years after receiving Humana's comments, and after twice extending its statutory deadline to finalize the Proposed Rule.[48] The Final Rule disavowed the study that had been the Proposed Rule's chief justification, emphasizing its "inherent

[44] CMS, Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information at 41 (Apr. 3, 2017), https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2018.pdf.

[45] 2019 Humana Comment Letter, *supra* n.26, at 19-22.

[46] *Id.* at 20.

[47] *Id.* at 17, 21-22.

[48] 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 ("Final Rule"), 88 Fed. Reg. 6643 (Feb. 1, 2023), https://www.govinfo.gov/content/pkg/FR-2023-02-01/pdf/2023-01942.pdf.

limitations."[49] CMS likewise declined to rely on the Proposed Rule's only other rationale for dispensing with the FFS Adjuster—the contention that using an FFS Adjuster would somehow "introduce inequities between audited and unaudited plans." Rather than defend the actuarial soundness of its new policy, the agency simply declared that "[e]ven if systematic payment error exists"—that is, even if diagnosis codes in fee-for-service Medicare claims data that are not documented in the medical record in fact depress Medicare Advantage payment rates, as the evidence has repeatedly shown—an FFS Adjuster was not required because that systematic under-compensation "does not impact the requirement that submitted [diagnosis codes] must be adequately supported by medical records."[50] To support its pursuit of actuarially unsound audit recoveries, the agency offered two new, purely legal rationales.

64. *First*, while the Final Rule recognized that the D.C. Circuit's decision in the Overpayment Rule litigation, *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), did not address RADV audits, CMS nevertheless asserted that *Becerra* is "consistent with" the proposition that the "actuarial equivalence provision of the [Medicare] statute applies only to how CMS risk adjusts the payments it makes to [Medicare Advantage organizations] and not to the obligation of [Medicare Advantage organizations] to return improper payments (for example, payments for unsupported diagnosis codes)."[51] But the agency—which never sought comment on *Becerra*'s significance to the Proposed Rule—said nothing about the key differences that *Becerra* itself highlighted, neglecting even to mention the D.C. Circuit's observation that the RADV audit context is "materially distinct" from payment recoveries under

[49] *Id.* at 6659.
[50] *Id.*
[51] *Id.* at 6644.

the Overpayment Rule.[52] Among other key differences, whereas the Overpayment Rule "requires only that an insurer report and return to CMS *known* errors in its beneficiaries' diagnoses," contract-level "RADV audits . . . would effectively eliminate—and require repayment for—*all* unsupported codes in a Medicare Advantage insurer's data."[53] The Final Rule does not explain beyond *ipse dixit* why *Becerra*'s reasoning nevertheless applies to RADV audits and exempts this agency policy from the Medicare statute's actuarial-equivalence requirement.

65. Before issuing the Final Rule, CMS had never even hinted at the view that RADV audits are exempt from this statutory requirement. On the contrary, CMS had recognized that RADV audits function specifically to "further actuarial equivalence."[54] CMS's proposal of an FFS Adjuster in 2012 and its attempt to study the actuarial justifications for such an adjustment in 2018 further confirmed the agency's understanding that RADV audits must satisfy actuarial equivalence. And rightly so: There is no conceivable reason why Congress would have allowed the agency to unravel the actuarial soundness of the Medicare Advantage program—and evade the Medicare statute's actuarial-equivalence requirement—through actuarially baseless contract-wide audit recoveries.

66. Nor did the agency explain why, even absent a statutory mandate, it would be reasonable for a critically important health-insurance program to ignore sound actuarial principles. CMS made no attempt to defend its new methodology as actuarially sound, or to

[52] *Becerra*, 16 F.4th at 892.
[53] *Id.* (emphasis added).
[54] 75 Fed. Reg. at 19,747, *supra* n.23; *see also* 42 U.S.C. § 1395w-23(a)(3)(B) (requiring CMS to collect data from Medicare Advantage organizations in order to develop risk-adjustment methodology); 42 C.F.R. § 422.308(c) (describing risk-adjustment process, including data collection); *id.* § 422.310(e) (mandating "[v]alidation of risk adjustment data").

explain why the agency could simply abandon an actuarially sound remedy for the inconsistent documentation standards that it chose to apply to RADV audits, a fix it had previously recognized as "the right thing to do" in the administration of a health-benefits program on which tens of millions of seniors rely for their healthcare.

67. *Second*, CMS stated that it is not required to apply an FFS Adjuster because "it would be unreasonable to interpret the [Social Security] 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 requirements (by requiring an offset to the recovery amount calculated for CMS audits)."[55] In other words, CMS asserted that Congress's mandate of a minimum downward adjustment of risk scores—the coding-intensity adjustment—means that the actuarial-equivalence requirement does not "requir[e] an offset" to RADV audit recoveries in the form of an FFS Adjuster.

68. That rationale's premise is false on its face: The FFS Adjuster does not "prohibit" CMS from enforcing "longstanding documentation requirements," but only requires that any such enforcement honor fundamental actuarial principles by taking into account the documentation standard used to calibrate CMS's risk-adjustment payment model. CMS is free to enforce documentation requirements so long as it does so in a manner that does not disrupt actuarial equivalence. Regardless, CMS's one-sentence rationale offered no logical justification for the agency's conclusion. As Humana explained in its comments on the Proposed Rule, the coding-intensity adjustment and FFS Adjuster both further actuarial equivalence but do so by targeting different issues: The coding-intensity adjustment furthers actuarial equivalence

[55] Final Rule, *supra* n.48, at 6656.

between fee-for-service Medicare and Medicare Advantage by addressing Medicare Advantage organizations' incentive to code more completely than fee-for-service Medicare providers; the FFS Adjuster furthers actuarial equivalence by addressing the inconsistent documentation standards used to calculate Medicare Advantage payment rates and RADV audit recoveries. For at least a decade before the Final Rule, CMS repeatedly pointed to the distinction between these two contexts to assure commenters that the coding-intensity adjustment was not "duplicative of any RADV audit-related adjustments" and that CMS was not "double counting the impact" of diagnosis codes submitted to CMS that were not documented in the medical record.[56]

69. The Final Rule does not even try to explain how the coding-intensity adjustment's limited reduction of payments to account for more complete diagnosis coding in Medicare Advantage—a reduction that Medicare Advantage organizations can specifically factor into their bids—would give CMS free rein to ***further*** reduce such payments after the bids are submitted without regard for basic actuarial principles. Given CMS's longstanding position that the coding-intensity adjustment and RADV audits address distinct issues, the Final Rule fails to explain why the coding-intensity adjustment would have any bearing on the actuarial principles that govern RADV audits. And to the extent CMS has now abandoned its longstanding position that the two issues are distinct, it failed to explain why the coding-intensity adjustment would not therefore be "duplicative of any RADV audit-related adjustments," as commenters had long questioned.[57]

[56] CMS, Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 18-19 (Apr. 5, 2010), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2011.pdf.

[57] *Id.* at 18.

70. In reality, the coding-intensity adjustment underscores that ensuring actuarial equivalence requires CMS to maintain consistency between the documentation standard used to calculate payments to Medicare Advantage organizations and the documentation standard used to calibrate Medicare Advantage payment rates. Just as greater coding intensity in Medicare Advantage required an adjustment to maintain consistency between the two programs, so too does the presence of diagnosis codes in fee-for-service Medicare claims data that are not documented in the medical record.

71. Finally, the Final Rule announced the agency's intent to apply the new policy retroactively, beginning with payment-year 2018 RADV audits. Although CMS abandoned its even more draconian plan to extrapolate audit results all the way back to payment year 2011, it did not address commenters' concerns that retroactively applying the Final Rule nonetheless exposes Medicare Advantage organizations to unanticipated and unaccounted-for liabilities at odds with CMS's past promises.

CAUSES OF ACTION

COUNT I:

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT — RATIONALE FOR FINAL RULE (5 U.S.C. § 706(2)(A), (C))

72. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs.

73. Under the APA, the Court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary [and] capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C).

74. Defendants' promulgation of the Final Rule is a final agency action within the meaning of Section 704 of the APA. First, the Final Rule consummates CMS's decision-making process on whether it will apply an FFS Adjuster in its extrapolated RADV audits of Medicare Advantage organizations. Second, several significant consequences flow from the Final Rule, including (1) the final RADV audit methodology that binds CMS and Medicare Advantage organizations, and (2) the revenue that Humana and other Medicare Advantage organizations can reasonably project when certifying bids for benefit plans offered to beneficiaries of the program.

75. Defendants offer no empirical or factual justification for their decision not to apply an FFS Adjuster. To the contrary, Defendants expressly disclaim any reliance on their prior study. Instead, Defendants' decision not to apply an FFS Adjuster in RADV audits is based exclusively on two legal arguments. Both arguments are incorrect.

76. In addition, Defendants' articulation of these legal rationales does not adequately explain the justification for their change in policy, particularly after acknowledging for many years that an FFS Adjuster would be required to correct the inconsistent documentation standard used in RADV audits. Defendants' failure to provide an adequate, reasoned explanation for their action in adopting the Final Rule violates the APA's requirements for reasoned agency decision-making.

77. Defendants' promulgation of the Final Rule is therefore arbitrary and capricious and not in accordance with law, in violation of 5 U.S.C. § 706(2)(A), and in excess of Defendants' statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

COUNT II:

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT — RETROACTIVITY (5 U.S.C. § 706(2)(A), (C))

78. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs.

79. Under the APA, the Court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary [and] capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C).

80. Section 1871(e) of the Medicare statute prohibits CMS from applying rules retroactively unless "retroactive application is necessary to comply with statutory requirements" or "failure to apply the change retroactively would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A).

81. CMS must publish an annual rate notice that includes the risk and other factors to be used in adjusting payment rates under the Medicare Advantage program for the relevant contract year. 42 U.S.C. § 1395w-24(b)(1), (2). CMS never disclosed the elimination of the FFS Adjuster in any of the annual rate notices on which Humana relied to construct its bids to CMS for the Medicare Advantage program.

82. Since at least 2012, Humana's Medicare Advantage bids have been predicated on its reasonable understanding that CMS would apply an FFS Adjuster before making any recoupments resulting from RADV audits.

83. Humana's actuaries certified that its prior-year bids were actuarially sound based on an estimate of the revenue required to pay for the benefits that they expected Humana to provide to its Medicare Advantage enrollees. As Humana explained in its bid submission to

CMS each year, that certification was based on the reasonable assumption that "final risk scores will be calculated and payments and overpayments will be determined consistent with the fact that CMS has used diagnoses contained in administrative claims data (and not medical records) to calculate risk coefficients and risk scores for [Medicare] FFS beneficiaries," and that CMS "will . . . apply[] a Fee-for-Service Adjuster . . . to account 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 ([Medicare] FFS claims)."[58]

84. CMS's application of the Final Rule to RADV audits for prior years undermines the basis on which Humana's Medicare Advantage bids were certified to the agency. Application of the Final Rule to any Medicare Advantage contract before Humana was able to account for the Final Rule in bids underlying that contract is retroactive.

85. CMS abused its discretion by concluding that retroactive application of the Final Rule is necessary to comply with statutory requirements.

86. CMS further abused its discretion by concluding that failure to apply the Final Rule retroactively is contrary to the public interest.

87. Defendants' promulgation of a Final Rule that applies to payment years before 2024 therefore exceeds their statutory authority and constitutes an abuse of discretion. 5 U.S.C. § 706(2)(A), (C).

[58] 2019 Humana Comment Letter, *supra* n.26, at 17-18 (quoting Bid ID H0028-004 (Aug. 10, 2017)).

COUNT III:

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT — INADEQUATE NOTICE
(5 U.S.C. § 706(2)(D))

88. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs.

89. Under the APA, the Court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

90. CMS's final decision to reverse its policy and exclude an FFS Adjuster from its new RADV audit methodology rests in large part on the D.C. Circuit's reasoning in *UnitedHealthcare v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), a decision that was not yet released when CMS issued the Proposed Rule on November 1, 2018. At no point after the decision was released did CMS request comment on whether or how this decision impacted the application of an FFS Adjuster to RADV audits. Plaintiffs and other commenters were thus deprived of a meaningful opportunity to comment on a central justification for the Final Rule.

91. Defendants' promulgation of the Final Rule therefore does not observe the notice-and-comment procedure required by the APA, in violation of 5 U.S.C. § 706(2)(D). This violation prejudiced Plaintiffs by preventing them from submitting a fully developed comment that would have offered additional specific and credible objections to CMS's reliance on *Becerra* and thus had an effect on CMS's decision to promulgate the Final Rule.

REQUEST FOR RELIEF

Plaintiffs respectfully request that this Court:

A. Declare that the Final Rule is arbitrary, capricious, an abuse of discretion, and

otherwise not in accordance with law, 5 U.S.C. § 706(2)(A), and in excess of Defendants' statutory jurisdiction, authority, or limitations, or short of statutory right, 5 U.S.C. § 706(2)(C), because CMS's decision not to apply an FFS Adjuster in RADV audits rests on incorrect legal arguments and is inadequately explained;

B. Declare that the Final Rule is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, 5 U.S.C. § 706(2)(A), and in excess of Defendants' statutory jurisdiction, authority, or limitations, or short of statutory right, 5 U.S.C. § 706(2)(C), because CMS abused its discretion by applying the Final Rule retroactively;

C. Declare that the Final Rule was promulgated without observance of procedure required by law, 5 U.S.C. § 706(2)(D), because it deprived Plaintiffs of a meaningful opportunity to comment on a central justification for the Final Rule;

D. Set aside the Final Rule as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, 5 U.S.C. § 706(2)(A), and in excess of CMS's statutory jurisdiction, authority, or limitations, or short of statutory right, 5 U.S.C. § 706(2)(C), and as promulgated without observance of procedure required by law, 5 U.S.C. § 706(2)(D);

E. Enjoin Defendants from enforcing against Humana any payment recoveries calculated using the new RADV audit methodology announced in the Final Rule; and

F. Provide such further relief as the Court may deem just and proper.

Dated: September 1, 2023

Respectfully submitted,

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* Pro hac vice application forthcoming