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. 4:23-cv-00909-O

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTEREST OF AMICUS CURIAE[1]

America's Health Insurance Plans ("AHIP") is the national trade association representing the health insurance plan community. AHIP advocates for public policies that expand affordable health coverage for all Americans, including through the Medicare Advantage program at issue in this case. AHIP's members provide health coverage and other financial health and wellness benefits through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare Advantage.

AHIP's members include private insurance plans known as Medicare Advantage organizations ("MAOs") that contract with the Centers for Medicare & Medicaid Services ("CMS") to provide health care coverage to enrollees through the Medicare Advantage program, a public-private partnership that offers an alternative to federally administered fee-for service ("FFS") Medicare. Fifty-seven AHIP members offer Medicare Advantage plans. AHIP is thus well situated to recognize and explain how the CMS rule in question ("the Final Rule") will severely damage the Medicare Advantage program to the detriment of the millions of Americans who depend on it for high-quality, low-cost health care.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Final Rule in this case gives rise to retroactive liability for MAOs based on CMS's decision to renege on its decade-long commitment to apply a "Fee-for-Service Adjuster" ("FFS Adjuster") when calculating any extrapolated recovery in a risk adjustment data validation ("RADV") audit. That about-face is unlawful for all the reasons explained in Humana's summary

[1] No counsel for a party authored this brief in whole or in part, and no entity or person other than amicus, its members, and its counsel made a monetary contribution intended to fund the brief's preparation or submission. Plaintiff Humana, Inc. is an AHIP member. All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a)(2), (4).

judgment motion. *See* ECF No. 44. AHIP writes separately to make three points on behalf of the broader health insurance plan community.

First, the Medicare Advantage program improves health outcomes for millions of Americans while promoting cost-saving practices. For those reasons, it is critical to the nation's health care system. Medicare Advantage plans deliver numerous benefits that are superior compared to FFS Medicare, including reduced cost sharing and supplemental benefits such as dental and vision care not covered by FFS Medicare. As a result, enrollment in Medicare Advantage has steadily increased since the program's inception in 1998. Today, a majority of eligible Medicare beneficiaries are enrolled in Medicare Advantage plans. Disruption to the program will harm those beneficiaries.

Second, if left to stand, the Final Rule will disrupt the Medicare Advantage program by overturning MAOs' settled expectations. In 2012, CMS publicly committed to MAOs that it would apply an FFS Adjuster when calculating extrapolated payment recoveries in RADV audits. That adjustment is necessary, CMS acknowledged, because the agency determines the level of payments it makes to MAOs for their members' health status based on diagnoses in *unaudited* FFS claims, but then in a RADV audit CMS imposes a different, more stringent documentation standard that requires every diagnosis to be *confirmed* against a patient's medical record. CMS recognized that standard actuarial practice requires an adjustment for that discrepancy. But the Final Rule now reverses that longstanding CMS policy and reneges on the commitment to comply with that actuarial imperative—a reversal that is unprincipled and materially reduces the compensation CMS will pay to MAOs. Worse, the Final Rule applies CMS's new "no adjustment" policy not only prospectively but retroactively to RADV audits of prior payment years going all the way back to payment year 2018. CMS has thus retroactively rewritten the rules of the road MAOs relied on

for years in submitting their bids and entering into contracts with CMS. Penalizing MAOs' justified reliance on CMS to keep its promises is both unfair and unlawful.

Third, the Final Rule's reliance on a separate adjustment called the "Coding-Intensity Adjustment" to eliminate the FFS Adjuster was neither reasonable nor reasonably explained. The Medicare statute requires CMS to apply a Coding-Intensity Adjustment to address differences in the completeness of Medicare Advantage and FFS diagnosis coding. That adjustment—which is to MAOs' detriment—does not address the impact of divergent documentation standards in RADV audits or justify dispensing with a needed correction that would benefit MAOs. To the contrary, the Medicare statute requires CMS to apply adjustments *wherever* necessary "to ensure actuarial equivalence" between payments to MAOs and expected costs under FFS Medicare for the same beneficiary populations. 42 U.S.C. § 1395w-23(a)(1)(C)(i). From 2012 to 2023, CMS endorsed commenters' conclusion that an FFS Adjuster is required to ensure actuarial equivalence, without any suggestion that the Coding-Intensity Adjustment in place during that period obviated the need for an FFS Adjuster. CMS's prior and longstanding policy is consistent with the best reading of the statute, and CMS has offered no persuasive reason for departing from it.

The Court should grant summary judgment to Humana and set aside the Final Rule.

ARGUMENT

I. THE MEDICARE ADVANTAGE PROGRAM IS A CRITICAL COMPONENT OF AMERICA'S HEALTH CARE SYSTEM

Whether through standard government contracts or other public-private partnerships, business relationships with private entities are essential to numerous government programs like Medicare Advantage that continue to grow in scale and importance. No entity would partner with the government, however, if it did not expect the government to adhere to its commitments. The ability to rely on the government's word is of paramount importance in Medicare, which depends

on partnerships with private insurers and providers to serve the consumers, patients, and beneficiaries who receive needed medical care.

In 1997, Congress created Medicare Advantage or Medicare Part C (originally called Medicare+Choice) to "allow beneficiaries to have access to a wide array of private health plan choices" and allow Medicare "to utilize innovations that have helped the private market contain costs and expand health care delivery options." H.R. Rep. No. 105-217, at 585 (1997). Congress has been successful in fulfilling those goals, and the Medicare Advantage program has consequently become a vital part of the nation's health care system.

Indeed, examples of the program's success abound: The average premium for a Medicare Advantage plan is lower today than it was a decade ago, and the program's cost-savings have allowed plans to deliver supplemental benefits not covered by FFS Medicare, including vision and dental care, hearing aids, and over-the-counter drug benefits. *See* Meredith Freed et al., *Medicare Advantage in 2024: Premiums, Out-of-Pocket Limits, Supplemental Benefits, and Prior Authorization*, KFF (Aug. 8, 2024). The number of seniors choosing to enroll in Medicare Advantage plans has steadily climbed over the past two decades. *See* Meredith Freed et al., *Medicare Advantage in 2024: Enrollment Update and Key Trends*, KFF (Aug. 8, 2024). From 2023 to 2024 alone, enrollment increased by 2.1 million beneficiaries, or 7 percent. *Id.* The majority of eligible Medicare beneficiaries now receive their Medicare benefits through a Medicare Advantage plan. *Id.* According to CMS's most recent data, released in September 2024, the number of Medicare beneficiaries enrolled in Medicare Advantage has gone up to 33.8 million. *See* CMS, *Monthly Summary Report* (September 2024). Enrollees also highly value the program, with 90 percent reporting satisfaction with their plan. *See* AHIP, *America's Seniors Speak: Medicare Advantage Delivers Value, Affordable Coverage, and Saves Money* (Feb. 27, 2024).

In addition to its popularity with Medicare beneficiaries, the Medicare Advantage program enjoys strong bipartisan congressional support. In advance of CMS's announcement of 2025 Medicare Advantage plan payment rates, more than sixty senators from both parties wrote to CMS, urging the agency to avoid payment cuts and maintain stable coverage options. *See* Letter from Senator Catherine Cortez Masto et al. to CMS Administrator Chiquita Brooks-LaSure (Jan. 26, 2024).

The reason for the program's popularity is simple: Medicare Advantage plans deliver better care at lower costs. They coordinate physician services, hospital care, and prescription drug benefits through an integrated approach, ensuring that beneficiaries receive streamlined treatment in a timely and efficient manner. *See* AHIP, *Statement for the Record Submitted to the House Ways and Means Committee, Subcommittee on Health* 2 (June 26, 2024). They also focus on preventing illness, managing chronic conditions, and employing best practices to improve health. One study found that Medicare Advantage enrollees have fewer hospital readmissions, fewer preventable hospitalizations, and lower rates of high-risk medication use than beneficiaries in FFS Medicare. *See* Christie Teigland et al., *Harvard-Inovalon Medicare Study: Utilization and Efficiency Under Medicare Advantage vs. Medicare Fee-for-Service* (June 2023). Another revealed that enrollees "were more likely … to receive preventive care services, such as annual wellness visits and routine checkups, [and] screenings." Nancy Ochieng & Jeannie Fuglestein Biniek, *Beneficiary Experience, Affordability, Utilization, and Quality in Medicare Advantage and Traditional Medicare: A Review of the Literature*, KFF (Sept. 16, 2022). Researchers have also found Medicare Advantage has spillover effects for FFS spending: Medicare Advantage growth from 2010 to 2017 was associated with decreased spending and emergency department visits in beneficiaries with six or more chronic conditions. *See* Sungchul Park et al., *Association of Medicare Advantage Penetration With Per Capita Spending, Emergency Department Visits, and*

Readmission Rates Among Fee-for-Service Medicare Beneficiaries with High Comorbidity Burden, 78 Med. Care Rsch. & Rev., no. 6 (Aug. 26, 2020). And increased Medicare Advantage enrollment is associated with reduced use of post-acute care in FFS Medicare. *See* Fangli Geng et al., *Increased Medicare Advantage Penetration Is Associated with Lower Postacute Care Use for Traditional Medicare Patients*, 42 Health Aff. 488, 492 (Apr. 2023).

Given the significant contributions of the Medicare Advantage program, its continued success is important to America's health care system and the health of the American people.

II. THE FINAL RULE IS IMPERMISSIBLY RETROACTIVE

As with any public-private partnership, the success of the Medicare Advantage program depends on the government "honor[ing] its obligations." *Maine Cmty. Health Options v. United States*, 590 U.S. 296, 329 (2020). For more than a decade CMS promised to apply an FFS Adjuster to offset extrapolated payment recoveries in RADV audits by accounting for inaccuracies in the FFS data used to calculate risk adjustment payments to MAOs. MAOs explained, and until 2023 CMS appeared to agree, that the Medicare statute requires such an adjustment as a matter of "actuarial equivalence." Each year for that entire time, MAOs submitted bids to participate in the Medicare Advantage program in accordance with CMS policy and actuarial guidance. They cannot go back in time to account for the impacts that CMS's new approach would have on those bids. By reneging on CMS's commitment to apply an FFS Adjuster, the Final Rule upsets MAOs' settled expectations and unfairly and unlawfully harms MAOs, to the detriment of the Medicare Advantage program as a whole and the millions of enrollees it serves.

A. The Final Rule Upsets Settled Expectations That Have Helped Determine Medicare Advantage Organizations' Bids To CMS

The Medicare Advantage payment model is complex, but the harm done by changing it retroactively—years later—should be obvious. The fundamental bargain at the heart of Medicare

Advantage is that MAOs assume the financial risk of providing Medicare benefits in exchange for a fixed monthly amount per enrollee. For the Medicare Advantage program to work as Congress intended and provide high-quality care to beneficiaries across the eligible population, MAOs need to know the rules of the road that will govern CMS payments in the years covered by their bids and contracts with CMS. The Final Rule changes critical assumptions on which MAOs based their bids to participate in the Medicare Advantage from 2012 to 2023.

1. The Medicare Advantage payment model requires MAOs to submit actuarially sound bids based on CMS guidance

The Medicare statute mandates that CMS adjust payments to MAOs based on the demographic characteristics and health status of each MAO's plan enrollees—demographics and health status that may vary substantially from plan to plan—"so as to ensure actuarial equivalence" with the expected costs CMS would have incurred if it had been required to provide benefits to that specific set of beneficiaries under FFS Medicare. 42 U.S.C. § 1395w-23(a)(1)(C)(i). This actuarially based payment model—which includes modifications reflecting the health of an MAO's enrollees known as "risk adjustment"—is intended to guarantee that MAOs have the resources they need to ensure beneficiaries have adequate access to high-quality health care. The payment model is also meant to eliminate structural incentives that might otherwise favor enrollment of younger and healthier people, and thus furthers Congress's goal of making Medicare Advantage plans broadly available to all eligible beneficiaries, regardless of demographics and health status. *See* American Academy of Actuaries, Risk Assessment and Risk Adjustment 1 (May 2010) ("A well-designed risk-adjustment system is one that properly aligns incentives, limits gaming, and protects risk-bearing entities (e.g., insurers, health plans).").

An annual bid submission process determines the base monthly amount CMS will pay per member, reflecting anticipated risk adjustment payments, as well as any rebates from bids below

CMS-determined county benchmarks, which MAOs use to offer supplemental benefits or reduce cost-sharing or premiums. *See* 42 U.S.C. § 1395w-23(a)(1)(B), (E). MAOs' bids to CMS set forth actuarially based estimates of the amount of revenue the MAO needs in order to provide "coverage to [a Medicare Advantage] eligible beneficiary with a national average risk profile." 42 C.F.R. § 422.254(b)(1); *see also* 42 U.S.C. § 1395w-24(a)(6)(A).

To craft and certify bids, MAOs and their actuaries must of course rely heavily on CMS guidance. Bids "must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles." 42 C.F.R. § 422.254(b)(5). And a "qualified actuary"—who "must be a member of the American Academy of Actuaries"—"must certify [each] plan's actuarial valuation." *Id.* In addition to requiring "careful estimates of anticipated risk adjustment revenue," bids "must specify the benefits and cost-sharing requirements that will apply to enrollees" and "must also show that the plan will operate within narrow margin tests imposed by CMS." App. 1584 (Cigna).

For that reason, the Medicare statute requires that CMS publish an annual announcement that includes the necessary information for MAOs' bids, including payment rates as well as "[t]he risk and other factors to be used in adjusting … rates." 42 U.S.C. § 1395w-23(b)(1)(B). In the annual announcement, the statute also requires CMS to explain its payment assumptions and methodology. *Id.* § 1395w-23(b)(3). And it must give 60 days' advance notice of "proposed changes … in the [payment] methodology from the methodology and assumptions used in the previous announcement," so that MAOs have an adequate opportunity to comment on CMS's proposed changes before they are finalized and incorporate any methodological changes into their bids. *Id.* § 1395w-23(b)(2). The final announcement must then be published by the first Monday in April each year, so bids can be submitted by the first Monday in June. *Id.* §§ 1395w-23(b)(1)(B)(i); 1395w-24(a)(1).

2. MAOs' bids to participate in the Medicare Advantage program from 2012 to 2023 reasonably relied on CMS's commitment to apply an FFS Adjuster in RADV audits

Beginning in 2012, MAOs' bids relied on CMS's promise that it would apply an FFS Adjuster to extrapolated RADV audit recoveries. CMS previewed its proposed elimination of an FFS Adjuster for the first time in November 2018—long after bids had already been submitted and accepted for payment years 2018 and 2019.[2] Even after 2018, MAOs reasonably relied on the application of an FFS Adjuster for potential extrapolated RADV audits in the future both because it was grounded in actuarial equivalence—a statutory requirement—and because there was no sound empirical or actuarial basis for eliminating the FFS Adjuster. CMS had never previously questioned that the actuarial-equivalence requirement applied to RADV Audits; indeed, the proposed rulemaking assumed it did apply. *See* App. 738; ECF No. 44 at 17-18. The only reason CMS gave for abandoning the FFS Adjuster consistent with actuarial equivalence was a deeply flawed study that CMS later abandoned. *See id.* The uniform consensus of professional actuaries who evaluated CMS's underlying data in comments on the proposed rulemaking was that actuarial equivalence required CMS to continue to apply an FFS Adjuster to any audits. *See, e.g.*, App. 2412, 2482-2498 (Winkelman Report); App. 1500 (Pipich Report); App. 5334 (Lambert Report). And MAOs had no reason to foresee that the Final Rule would entirely abandon that statutory requirement. During the period before CMS finalized the rule in February 2023, CMS never issued actuarial guidance directing MAOs to consider the proposed change when submitting bids for any

[2] Bids for payment year 2018 were due in June 2017, and contracts were fully executed in September 2017. *See* 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* 72-74 (Apr. 3, 2017). Bids for payment year 2019 were due in June 2018, and contracts were fully executed in September 2018. *See* CMS, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 117-119 (Apr. 2, 2018).

of the payment years—2020, 2021, 2022, and 2023—for which they submitted bids over the four-year period of time that the proposed rulemaking was pending.

The need for an FFS Adjuster also makes sense from a bid standpoint. In their bids, MAOs must estimate revenue to provide coverage to an eligible person with "a national average risk profile," 42 C.F.R. § 422.254(b)(1)—that is, an FFS beneficiary with a risk score of 1.0. "Critical to this process is a valid and consistent definition of a beneficiary with a 'national average risk profile.'" App. 2427; *see* App. 7498. Bids are required to include projected risk scores for the MAO's enrollees. *See* CMS, *Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2018*, at 83-84, 106-107 (Apr. 7, 2017). This projection is used to standardize bids for an average Medicare beneficiary. *See* CMS, *Medicare Managed Care Manual*, ch. 7, § 70 (rev. 2014). Because FFS claims are unaudited, the national average risk profile means an FFS beneficiary with a 1.0 risk score based on the conditions *reported* by providers. In a RADV audit, however, CMS calculates risk scores based only on conditions *confirmed* in a medical record. An extrapolated RADV audit—with no FFS Adjuster—thus moves the target by requiring a more demanding form of documentation than is assumed in the national average risk profile that MAOs use to determine estimated revenue and standardize their bids. As the American Academy of Actuaries explained, this inconsistency "may create systematic underpayment" and "make it difficult for actuaries to estimate the plan's risk score and certify the plan bid." App. 7625.

CMS agreed and responded in 2012 by announcing that it would apply an FFS Adjuster. App. 7703-7704. The "FFS Adjuster," CMS explained, would function "as an offset to the preliminary recovery amount" determined in a RADV audit. App. 7703. And by "account[ing] 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)," it would address the actuarial concerns raised by the American Academy of Actuaries, AHIP, and others. App. 7703-7704.

MAOs took CMS at its word. Several MAOs and actuaries with expertise in the Medicare Advantage program explained their reliance on CMS guidance and the unfairness of reneging on the FFS Adjuster in comments on CMS's proposed rulemaking. In "preparing and submitting bids," MAOs "were given guidance to rely on by CMS in early 2012 that any RADV audits subject to extrapolation would include" an FFS Adjuster. App. 2427-2428 (Winkelman Report). "Any change to assumptions and methodologies after the bid submission jeopardizes the basis of the actuaries' certifications of those bids, and therefore the appropriateness of those bids." App. 2426. For more than a decade, MAOs' bids and plan benefits incorporated CMS's commitment to address "actuarial equivalence concerns" and relied "on CMS's and HHS OIG's repeated determinations not to pursue extrapolation or contract-level recoveries in the absence of a[n] FFS Adjuster." App. 1584 (Cigna). CMS's about-face more than a decade later "upsets settled expectations" and "fundamentally and retroactively alter[s] that bargain." *Id.* The MAOs "and [their] actuaries reasonably based their bids … on the latest final guidance from CMS," which from 2012 to 2023 was that "any RADV audit would include a Fee-for-Service Adjuster." App. 4224 (Anthem).

Plans and experts also made clear to CMS that "[c]hang[ing] this key assumption," and basing bids instead on extrapolated RADV audits with no FFS Adjuster, would have required estimating lower revenue to "submit bids with potentially greater member premiums or fewer supplemental benefits." App. 4224-4225 (Anthem); *see also* App. 5235 (UnitedHealth) ("Had CMS announced a different policy on RADV recoveries, plans may well have determined that they needed to submit higher bids in order to satisfy their revenue requirements and … obtain actuarial certification of their bid."); App. 2426 (Winkelman Report) ("Any change to assumptions and

methodologies after the bid submission jeopardizes the basis of the actuaries' certifications of those bids, and therefore the appropriateness of those bids."). In reliance on CMS's commitment to apply an FFS Adjuster, MAOs provided the government and beneficiaries "increased savings, more generous benefits, and lower premiums." App. 4225 (Anthem). CMS's about-face more than a decade later "upsets settled expectations" and "fundamentally and retroactively alter[s] that bargain." App. 1584 (Cigna).

In sum, during a twelve-year period, from 2012 to 2023, CMS policy was to apply an FFS Adjuster, and MAOs relied on that policy in developing their bids. CMS now claims that such reliance should be disregarded "because any funds recovered under RADV would be for payments to which the MAO was never entitled." App. 7357. That new assertion is wrong. The agency's decision in 2012 reflected a sound determination that MAOs are entitled in RADV audits to retain payments below an FFS Adjuster and that only amounts in excess of that offset constitute overpayments. *See* App. 728. CMS's prior policy was reasonably understood and relied upon as a means for the agency to meet the statutory requirement that it pay MAOs in a manner that "ensure[s] actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). "When an agency changes course … it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'" *DHS v. Regents of Univ. of Cal.*, 591 U.S. 1, 30 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 213 (2016)). The Final Rule disrupts MAOs' settled expectations. But far from taking those settled expectations into account, CMS unreasonably and unfairly discounted them.

B. The Final Rule's Application To Prior Payment Years Is Contrary To The Medicare Statute And Unfairly Penalizes Medicare Advantage Organizations' Reasonable Reliance On Prior CMS Policy

This case illustrates precisely why "[r]etroactivity is not favored in the law." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). "[D]ealing with administrative agencies is

all too often a complicated and expensive game, and players like [MAOs] are entitled to know the rules." *Inhance Techs., LLC v. EPA*, 96 F.4th 888, 895 (5th Cir. 2024) (citation omitted). In changing the rules, agencies must also "be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Regents of Univ. of Cal.*, 591 U.S. at 30 (quoting *Encino Motorcars*, 579 U.S. at 213 (quotation marks omitted)). This is especially true where a change is retroactive because the "power … to regulate retroactively … is limited to circumstances in which retroactive application would not result in 'injury or prejudice.'" *Calumet Shreveport Refining, LLC v. EPA*, 86 F.4th 1121, 1134 (5th Cir. 2023). Accordingly, courts in this Circuit "balance the ills of retroactivity against the disadvantages of prospectivity" with no deference to the agency's own retroactivity determination. *Id.* (quoting *Microcomputer Tech. Inst. v. Riley*, 139 F.3d 1044, 1050 (5th Cir. 1998)). In *Calumet Shreveport Refining*, for example, the Fifth Circuit reviewed the EPA's decision to apply a "novel" interpretation of the Clean Air Act to refineries' "years-old petitions" for exemptions from certain requirements. 86 F.4th at 1127. The court rejected retroactive application of the EPA's new interpretation, explaining that it "harshly penalize[d] petitioners for their good-faith and justified reliance on the agency's prior approach." *Id.* at 1136.

That same reasoning applies with equal force here. Since 2012, MAOs' bids have incorporated the reasonable expectation that CMS would apply an FFS adjuster to offset any extrapolated RADV recoveries. Those bids cannot now be revised to reflect CMS's retroactive transformation of its longstanding regulatory interpretation on which MAOs relied. The agency's reversal more than a decade later will impose vast liability that conflicts with how the agency has operated the RADV program for years. The Final Rule's penalty on MAOs' "good-faith and justified reliance on the agency's prior approach" is therefore impermissibly retroactive. *Id.*

The Medicare statute explicitly prohibits CMS from making "substantive changes" retroactive "by extrapolation or otherwise" 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). CMS argues that the Final Rule does not make any substantive changes because it does not change the "documentation standard for diagnosis coding." App. 7352. But that argument ignores the substantive changes the Final Rule makes both by applying extrapolation for the first time to RADV audit recoveries dating back to payment year 2018 and by eliminating the FFS Adjuster that CMS had previously committed to apply if, and when, it ever applied extrapolation. CMS promised the use of an FFS Adjuster in 2012, appearing to endorse the conclusion of commenters, including professional actuaries, that actuarial equivalence required such an adjustment when the agency calculates an extrapolated RADV audit amount. The Final Rule reverses that policy by implementing extrapolation while simultaneously construing actuarial equivalence not to apply to RADV audits. The decision to expose MAOs to financial liability through a regulation that imposes new audit requirements for prior years is obviously a "substantive change" within the meaning of the Medicare statute's bar on retroactive rulemaking. 42 U.S.C. § 1395hh(e)(1)(A).

In the rulemaking, CMS claimed that even if the elimination of an FFS Adjuster is substantive, it was necessary to comply with the agency's obligations under the Payment Integrity Information Act of 2019 ("PIIA") and serves the public interest. Neither rationale is persuasive.

First, no statute requires CMS to apply any RADV methodology retroactively to audits of prior payment years before the Final Rule was announced. The PIIA addresses "improper payments." *See* Pub. L. No. 116-117, § 2, 134 Stat. 113, 113-133 (2020). As explained above, and in Humana's brief, this is not a case involving audits to recover amounts for settled obligations. ECF No. 44 at 46; *supra* pp. 9-11. Regardless, nothing in the PIIA applies retroactively, nor does

it even mandate payment recovery in any particular form. As the title of the statute suggests, the PIIA is an information-forcing statute, which expressly defines "compliance" by reference to various reporting, self-assessment, and publication requirements. 31 U.S.C. § 3351(2). The Final Rule's lack of citation to any of those requirements is telling—because none of them authorize, let alone compel, CMS to rescind payment policies it had previously determined were actuarially, and thus statutorily, required.

Second, retroactive application will actually harm the public interest by reneging on CMS's prior commitment, upending MAOs' settled expectations, and undermining the bargain at the heart of the Medicare Advantage program. CMS's assertion that the Final Rule "serves the public interest by reducing the improper allocation of taxpayer dollars" (App. 7352) is both conclusory and wrong. The allocation of taxpayer dollars was proper under CMS's prior policy and has not become improper now. *See* ECF No. 44 at 46 (explaining that "the RADV audits at issue here do not resemble typical 'recovery tools' rooted in settled obligations" precisely because "the Final Rule *changes* MAOs' settled expectations by altering the actuarial foundations underpinning bids submitted to CMS long before the Final Rule's effective date"). More importantly, that policy was priced into the plan benefits, including supplemental benefits and reduced premiums and cost-sharing, that MAOs already provided for those prior payment years. The Government received value commensurate with its payments.

CMS also fails to address the harm to the public interest by retroactive application of these changes. The Final Rule ignores "a principle as old as the Nation itself: The Government must honor its obligations." *Maine Cmty.*, 590 U.S. at 328. Governments that do not are neither "respected" nor "trusted." *Id.* As AHIP explained in its comments on the proposed rulemaking, "[a] lack of trust injects significant uncertainty and risk into the system, undermines how the free market and public programs work together, and fundamentally weakens the integrity of the

[Medicare Advantage] program." App. 1436. The public-interest exception here must be construed "narrowly in order to preserve the primary operation of" the Medicare statute's bar on retroactive rulemaking. *Maracich v. Spears*, 570 U.S. 48, 60 (2013) (quoting *Commissioner v. Clark*, 489 U.S. 726, 739 (1989)). Reading the exception as CMS does—to allow retroactive changes to payment or audit policies any time they would reduce federal spending—would swallow the general rule. *See* ECF No. 44 at 47; *Clarke v. CFTC*, 74 F.4th 627, 643-644 (5th Cir. 2023) ("[T]he public interest is served when administrative agencies comply with their obligations under the APA."). Indeed, subjecting MAOs to unfair retroactive audits itself threatens the public interest. *Supra* pp. 11-12 (discussing possible increases in premiums and reduced coverage options for Medicare Advantage beneficiaries caused by retroactive application of the RADV Rule).[3]

III. THE CODING-INTENSITY ADJUSTMENT DOES NOT ELIMINATE THE NEED FOR A FEE-FOR-SERVICE ADJUSTER

In the Final Rule, CMS abandoned any effort to satisfy actuarial equivalence with the new argument that this statutory requirement does not apply to RADV audits at all. As one of two grounds for its decision, CMS claimed that "it would be unreasonable to interpret" "the actuarial equivalence provision" to "requir[e] an offset to the recovery amount" in a RADV audit when

[3] Moreover, as AHIP explained in its comments, CMS has long cited the interest of finality as a principal reason not to upset Medicare payment determinations. App. 1472. As CMS explained to the D.C. Circuit, the interest of finality reflects "evidentiary and administrability considerations," given that "[r]ecords grow stale, memories fade, personnel move on, and retention is costly." App. 1472 (quoting Sec'y Br. at 47, *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290 (D.C. Cir. 2018)). This is especially true in the case of RADV audits, which are predicated on the review of medical records related to services that may have been provided many years earlier. The operational barriers are significant—due to the passage of time, records may not exist or may be nearly impossible for plans to retrieve. App. 1472-1473.

another provision of the Medicare statute requires CMS to apply a Coding-Intensity Adjustment that reduces payments. App. 7355. That reasoning is fundamentally flawed.[4]

There is nothing "unreasonable" in having two distinct adjustments that address different actuarial issues, and both adjustments here follow directly from CMS's statutory mandate to "ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). "Actuarial equivalence" in this context means the application of actuarial principles to achieve equivalence between CMS's payments to an MAO for its enrolled population and the government's expected costs for the same population in FFS Medicare. One such principle—codified in an actuarial standard of practice that is "binding on members of the U.S.-based actuarial organizations," Actuarial Standards Board, Actuarial Standard of Practice No. 1 § 1 (Mar. 2013)—requires data consistency in the development and application of risk-adjustment payment models. *See* Actuarial Standards Board, Actuarial Standard of Practice No. 45 § 3.2 (Jan. 2012). That means the plan data to which CMS applies the risk-adjustment model must be "reasonably consistent" with the FFS data the agency used to develop the model. *Id.* If it is not consistent, then CMS must make an adjustment to account for the inconsistency. *Id.*

The Coding-Intensity Adjustment and FFS Adjuster each address inconsistencies between the data used in Medicare Advantage and FFS Medicare, but the two adjustments address different inconsistencies. *See* ECF 44 at 33-34 (articulating the distinct inconsistencies addressed by the Coding-Intensity Adjustment versus the FFS Adjuster). "Coding intensity" addresses the relative completeness of patient diagnosis coding, or "the difference between the [risk] scores that a group of beneficiaries would have if enrolled in MA and their scores in FFS." Richard Kronick & W.

[4] CMS also cited the D.C. Circuit's decision in *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 869, 891-992 (D.C. Cir. 2021), *see* App. 7355, which is irrelevant for the reasons explained in Humana's brief. *See* ECF No. 44 at 29-32.

Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4 Medicare & Medicaid Res. Rev. E1, E4 (2014) (also at App. 8873). CMS began studying coding intensity as a result of the Deficit Reduction Act of 2005, which directed the agency to "conduct an analysis" and ensure that the risk-adjustment model "reflects differences" in the completeness of diagnosis coding between Medicare Advantage plans and FFS Medicare. Pub. L. No. 109-171, § 5301, 120 Stat. 4, 51; 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I)-(II). In 2010, Congress then imposed a statutory minimum adjustment, which will expire if CMS begins relying on Medicare Advantage data to calibrate the model, rather than FFS data, and thereby eliminates the problem of different degrees of completeness in coding between FFS and Medicare Advantage. *See* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1102(e), 124 Stat. 1029, 1046; 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III)-(IV).

CMS adopted an FFS Adjuster in 2012 to address an entirely different data inconsistency: not the relative completeness of coding but the relative accuracy of diagnosis codes relied on in the payment process (where "accuracy" here refers to the degree to which codes reported by providers are confirmed by medical records in a RADV audit). In FFS Medicare, providers are paid based on the services they provide patients, not the diagnoses they report, so it is recognized that as a general matter the diagnoses they report for FFS patients are less accurate. *See* Gregory C. Pope et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*, Health Care Fin. Rev. Summer 2004, at 129. Nevertheless, while holding MAOs to codes audited against patient medical records for purposes of *payment*, for purposes of calibrating the risk-adjustment model CMS chose *not* to validate the less reliable diagnoses reported on FFS claims at all. *See* ECF No. 44 at 32-33. Extrapolating a RADV audit to an entire contract (as the Final Rule authorizes), without an adjustment for the disparity, would severely distort the actuarially appropriate payment CMS owes to the MAO.

The Coding-Intensity Adjustment does nothing about that disparity, and thus an FFS Adjuster is necessary to address it. Indeed, CMS adopted an FFS Adjuster in 2012, against the backdrop of the agency's ongoing implementation of the Coding-Intensity Adjustment. And from 2012 to 2023, CMS recognized that there is no incompatibility or redundancy in implementing both adjustments. As CMS explained in 2018, in response to similar arguments that the Coding-Intensity Adjustment itself was unnecessary because of coding oversight through RADV audits, "RADV audits … have the purpose of validating whether diagnosis codes submitted for risk adjustment are documented in the medical record" and do not "address the impact on risk scores of differences in MA and FFS coding patterns." CMS, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 38-39 (Apr. 2, 2018). Based on CMS's rationale, the converse here is equally true: The Coding-Intensity Adjustment does not address any actuarial issues specific to RADV extrapolation. The Final Rule scarcely acknowledges CMS's longstanding position that both adjustments are required as a matter of sound actuarial practice.[5]

In the Final Rule, CMS provided no reasonable justification for its new position that the application of the Coding-Intensity Adjustment obviates the need for the FFS Adjuster. Nor does it make sense as a matter of statutory interpretation. The requirement in 42 U.S.C. § 1395w-

[5] Indeed, CMS has long maintained that even more adjustments are required. For example, CMS has long implemented a "normalization factor" to account for year-over-year trends in FFS risk scores between the year in which the risk-adjustment model was last calibrated and the payment year to which the model will be applied. *See* CMS, *Medicare Managed Care Manual* § 90 (rev. 2014). Like the Coding-Intensity Adjustment, that factor results in a "downward adjustment[] to risk scores." *Id.* But CMS has never suggested that it should not be applied on top of the Coding-Intensity Adjustment and has explained, to the contrary, that it "does not adjust for … different coding patterns" and instead addresses a separate inconsistency between the model's calibration in one year and application in another. *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 38-39.

23(a)(1)(C)(ii) to apply a Coding-Intensity Adjustment does not purport to limit the scope of Congress's broader actuarial-equivalence mandate in 42 U.S.C. § 1395w-23(a)(1)(C)(i) or exempt CMS from addressing actuarial inequivalence if it arises in an audit. On its face, the coding-intensity provision is simply one application of a general rule that requires CMS to ensure actuarial equivalence; it does not carve out other applications of the rule.[6]

The Supreme Court has made clear that "courts must exercise independent judgment in determining the meaning of statutory provisions," but agency "interpretations issued contemporaneously with the statute at issue … may be especially useful in determining the statute's meaning," particularly if they "have remained consistent over time." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2262 (2024). CMS's apparent interpretation of the Medicare statute for more than a decade—by far "the best reading of the statute"—was that it requires CMS to address actuarial equivalence in the RADV context, alongside and in addition to any other actuarial issues such as coding intensity. *Supra* pp. 9-11. CMS's departure from that approach was neither "reasonable [n]or reasonably explained." *Nat'l Ass'n of Mfrs.*, 105 F.4th at 815.

CONCLUSION

The Court should grant summary judgment to Humana and vacate the Final Rule.

[6] If CMS were correct that the Coding-Intensity Adjustment is relevant to the RADV audit methodology, the agency would need to have considered the degree to which extrapolated audits reduce payments already reduced by adjusting for coding intensity, but it did not. CMS's reliance on the Coding-Intensity Adjustment to eliminate the FFS Adjuster with no consideration of any actual overlap with RADV audits was "not … reasonable or reasonably explained." *Nat'l Ass'n of Mfrs. v. SEC*, 105 F.4th 802, 815 (5th Cir. 2024). The Final Rule is "arbitrary and capricious for this additional reason" as well. *Id.*

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Respectfully submitted,

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