No. 25-11293

UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

HUMANA, INCORPORATED; HUMANA BENEFIT PLAN OF TEXAS, INCORPORATED,
Plaintiffs-Appellees,

v.

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

On Appeal from the United States District Court
for the Northern District of Texas, No. 4:23-cv-00909-O (O'Connor, J.)

BRIEF FOR AMERICA'S HEALTH INSURANCE PLANS AND BLUE CROSS BLUE SHIELD ASSOCIATION AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

PETER A. KURTZ
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

ADELA LILOLLARI
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

KEVIN M. LAMB
Counsel of Record
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000
kevin.lamb@wilmerhale.com

Counsel for Amici America's Health Insurance Plans and Blue Cross Blue Shield Association

May 27, 2026

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Circuit Rule 28.2.1, in addition to those disclosed in the parties' certificates of interested persons, have an interest in the outcome of this case. These representations are made so that members of the Court may evaluate possible recusal.

- America's Health Insurance Plans, Amicus Curiae
- The Blue Cross Blue Shield Association, Amicus Curiae
- Kevin M. Lamb, Wilmer Cutler Pickering Hale and Dorr LLP, Counsel
- Peter A. Kurtz, Wilmer Cutler Pickering Hale and Dorr LLP, Counsel
- Adela Lilollari, Wilmer Cutler Pickering Hale and Dorr LLP, Counsel

/s/ *Kevin M. Lamb*
KEVIN M. LAMB

CORPORATE DISCLOSURE STATEMENT

America's Health Insurance Plans is a national trade association that represents the health insurance plan community. It has no parent company, and no publicly traded company owns 10 percent or more of its stock.

The Blue Cross Blue Shield Association is a non-profit association that promotes the national interests of thirty-one independent, community-based, and locally operated Blue Cross Blue Shield health insurance companies. It has no parent corporation, and no publicly traded corporation owns stock in it.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES AND RULES

REGULATIONS AND ADMINISTRATIVE MATERIALS

LEGISLATIVE MATERIALS

OTHER AUTHORITIES

INTEREST OF AMICI 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 ("MA") 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 MA.

AHIP's members include health insurer companies that contract with the Centers for Medicare & Medicaid Services ("CMS") to provide health care coverage to enrollees through the MA program, a public-private partnership that offers an alternative to federally administered fee-for-service ("FFS") Medicare. Fifty AHIP members offer MA plans.

The Blue Cross Blue Shield Association ("BCBSA") is the non-profit association that promotes the national interests of thirty-one independent, community-based, and locally operated Blue Cross Blue Shield health insurance companies ("Blue Plans"). Together, the Blue Plans provide health insurance for

---

[1] No counsel for a party authored this brief in whole or in part, and no entity or person other than amici, their members, and their 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).

over 118 million people—one in three Americans—in every zip code in all fifty states, the District of Columbia, and Puerto Rico. Blue Plans offer a variety of health insurance products to all segments of the population, including federal employees, large employer groups, small businesses, and individuals. As leaders in the health care community for more than eighty years, Blue Plans have extensive knowledge of and experience with the health insurance marketplace. Blue Plans also offer plans through the MA program.

AHIP and BCBSA are thus well situated to explain how the CMS rule in question (the "Final Rule") will severely damage the MA program to the detriment of the tens of millions of Americans who depend on it for high-quality, low-cost health care.

INTRODUCTION AND SUMMARY OF ARGUMENT

By offering MA plans, insurers known as Medicare Advantage organizations ("MAOs") commit to providing at least the same benefits as traditional FFS Medicare to eligible individuals in exchange for fixed monthly payments per enrollee from CMS. By statute, CMS must adjust these capitated payments to account for the enrollees' health status and demographics relative to the average Medicare beneficiary—a process known as "risk adjustment." To ensure that the process works as intended, Congress mandated "actuarial equivalence" between CMS's payments to an MAO and the expected costs CMS would incur for the

same individuals in traditional FFS Medicare. 42 U.S.C. § 1395w-23(a)(1)(C)(i). The requirement of "actuarial equivalence" ensures that MA plans are broadly available to beneficiaries regardless of their health status and that MAOs have the resources to offer comprehensive benefits and are paid fairly for the risks they assume.

The actuarial-equivalence requirement has enabled MA to become the preferred choice for tens of millions of beneficiaries, particularly those living on low and fixed incomes. If left to stand, the Final Rule would break this lynchpin of the payment model. Indeed, as the district court noted, "[f]rom 2012 to 2018," CMS recognized the need for a fee-for-service adjuster ("FFS Adjuster") "to ensure actuarial equivalence." ROA.26916, 26923. The Final Rule unexpectedly reversed course, preventing the public from meaningfully addressing why the actuarial equivalence that Congress codified—and the Final Rule ignores—necessarily governs risk adjustment data validation ("RADV") audits. For the reasons explained in Humana's brief, CMS's procedural violation alone requires vacatur of the Final Rule. *See* Humana Br. 31-43. AHIP and BCBSA write separately to make three points on behalf of the broader health insurance plan community.

First, the MA program improves health outcomes for millions of Americans while promoting cost-saving practices. It is therefore critical to the nation's health

care system. MA plans deliver numerous benefits that are superior compared to FFS Medicare, including substantially reduced cost sharing for beneficiaries and supplemental benefits such as dental and vision care not covered by FFS Medicare. As a result, enrollment in MA has steadily increased since the program's inception in 1998. Today, a majority of eligible Medicare beneficiaries are enrolled in MA plans. Any disruption to the program will harm those beneficiaries.

Second, the RADV rulemaking process at issue in this case underscores the importance of requiring any final rule to be a "logical outgrowth" of the proposed rule. 42 U.S.C. § 1395hh(a)(4). CMS did not disclose in the proposed rulemaking (the "Proposed Rule") that it was considering abandoning actuarial equivalence in RADV audits as a matter of law and excluding an FFS Adjuster on that basis. Because of that omission, CMS deprived the public of fair notice and an opportunity to comment on the reasoning behind an enormously consequential policy implemented by the Final Rule, which, by CMS's own estimates, will likely affect billions of dollars in payments to MAOs over the next decade. 88 Fed. Reg. 6643, 6663 (Feb. 1, 2023). It also deprived CMS of the benefit of public comments—comments that would have highlighted and required CMS to squarely confront the shortcomings of the Final Rule.

Third, CMS's new rationales in the Final Rule for eliminating the FFS Adjuster fall woefully short. CMS's contention that an FFS Adjuster is not

necessary because actuarial equivalence does not apply as a matter of law defies Congress's contrary instruction and violates the basic actuarial principle that data used in the calibration and application of risk-adjustment models like the MA model must be reasonably consistent. The Final Rule's implementation of this actuarially unsound model would lead to the systematic underpayment of audited MAOs. CMS fares no better in asserting that Congress's enactment of a separate adjustment, focused on remedying differences in the relative completeness of patient diagnosis coding between FFS Medicare and MA (the "Coding-Intensity Adjustment"), somehow forecloses the FFS Adjuster. In fact, the opposite is true. Congress's enactment of the Coding-Intensity Adjustment shows that Congress means what it says: CMS must ensure actuarial equivalence between FFS Medicare and MA.

ARGUMENT

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

In 1997, Congress created MA or Medicare Part C (originally called Medicare+Choice) to "allow beneficiaries to have access to a wide array of private health plan choices" and to 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 MA program has consequently become a vital part of the nation's health care system.

Examples of the program's success in serving Medicare beneficiaries abound: The average premium for an MA 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* Ochieng et al., *Medicare Advantage in 2025: Premiums, Out-of-Pocket Limits, Supplemental Benefits, and Prior Authorization*, KFF (July 28, 2025). Likewise, a recent study found that annual health care expenditures per MA beneficiary from 2021 to 2023 were almost $6,300 lower on average than the per beneficiary costs for their FFS peers. AHIP, *Medicare Advantage Leads to Savings for Seniors and Taxpayers* 4 (Feb. 2026). The number of seniors and people with disabilities choosing to enroll in MA plans has steadily climbed over the past two decades. *See* Ochieng et al., *Medicare Advantage in 2025: Enrollment Update and Key Trends*, KFF (July 28, 2025). From 2024 to 2025 alone, enrollment increased by 1.3 million beneficiaries, or 4 percent. *Id*. Indeed, the majority of eligible Medicare beneficiaries now receive their Medicare benefits through an MA plan. *Id*. According to CMS's most recent data, released in May 2026, the number of Medicare beneficiaries enrolled in MA plans now totals 35.8 million. *See* CMS, *Monthly Contract Summary Report* (May

2026). Enrollees also highly value the program, with 90 percent reporting satisfaction with their plans. *See* AARP, *Enrollees' Views of Medicare Advantage* 4, 6 (Apr. 2025); AHIP, *America's Seniors Speak: Medicare Advantage Delivers Value, Affordable Coverage, and Saves Money* (Feb. 27, 2024).

The reason for the program's popularity is simple: MA plans deliver better care at lower costs than FFS Medicare. 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, e.g.,* AHIP, *Statement for Hearing on "Improving Value-Based Care for Patients and Providers" 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 MA enrollees have fewer hospital readmissions, fewer preventable hospitalizations, and lower rates of high-risk medication use than beneficiaries in FFS Medicare. *See* Teigland et al., *Harvard-Inovalon Medicare Study: Utilization and Efficiency Under Medicare Advantage vs. Medicare Fee-for-Service* 2, 10 (June 2023). Another revealed that enrollees "were more likely than beneficiaries in traditional Medicare to receive preventive care services, such as annual wellness visits and routine checkups" and "screenings." Ochieng & 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 that, by contrast, FFS Medicare beneficiaries had 11% higher total costs than MA enrollees with the same "sociodemographic, enrollment, geographic, clinical, and social drivers of health … characteristics," experiencing 52% more emergency department visits, 40% more hospital admissions, 30% more inpatient days, 126% more readmissions, and 71% more preventable hospitalizations. Teigland & Bilder, *Medicare Advantage vs. Traditional Fee-for-Service Medicare: Different Populations, Different Outcomes* 4, 8 (May 28, 2025).

Researchers have likewise found that MA has beneficial spillover effects for FFS Medicare spending: MA growth from 2010 to 2017 was associated with decreased FFS Medicare spending and decreased emergency department visits in beneficiaries with six or more chronic conditions. *See* 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. 703 (2020); *see also* Alfrey et al., *Medicare Advantage Enrollment and Total Medicare Program Spending*, 63 J. of Health Care 1 (2026) (finding that higher MA enrollment showed lower standardized Medicare spending). And MA enrollment is associated with reduced use of post-acute care in FFS Medicare. *See* Geng et al.,

Increased Medicare Advantage Penetration Is Associated with Lower Postacute Care Use for Traditional Medicare Patients, 42 Health Aff. 488, 491-492 (2023); Roy et al., *Postacute Care Use and Outcomes Among Medicare Advantage vs Traditional Medicare Beneficiaries*, JAMA Network Open (Oct. 29, 2025).

Given the significant contributions of the MA program, its continued stability and broad availability are critical to America's health care system and the health of America's seniors and people with disabilities.

II. THE RADV AUDIT RULEMAKING UNDERSCORES THE IMPORTANCE OF REQUIRING THAT ANY FINAL RULE BE A LOGICAL OUTGROWTH OF THE PROPOSED RULE

A. To Ensure Meaningful Public Comment, Final Rules Must Be A Logical Outgrowth Of Proposed Rules

"Congress has told the government that, when it wishes to establish or change a 'substantive legal standard' affecting Medicare benefits, it must first afford the public notice and a chance to comment." *Azar v. Allina Health Servs.*, 587 U.S. 566, 568 (2019) (quoting 42 U.S.C. § 1395hh(a)(2)). Notice and comment serves a critical purpose in the rulemaking process: It "assure[s] fairness and mature consideration of rules of general application." *Brown Express, Inc. v. United States*, 607 F.2d 695, 701 (5th Cir. 1979) (quoting *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764 (1969) (plurality opinion)). It does so by allowing "the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated." *Id*. "If an agency

promulgates a rule without affording interested parties a fair opportunity to comment, it deprives itself of that education." *Global Van Lines Inc. v. ICC*, 714 F.2d 1290, 1299 n.9 (5th Cir. 1983). Congress understood "that an agency's judgment would be only as good as the information upon which it drew," which is why it prescribed procedures "to ensure that the broadest base of information would be provided to the agency by those most interested and perhaps best informed on the subject of the rulemaking at hand." *Brown Express*, 607 F.2d at 701.

Congress has paid special attention to the notice-and-comment rules applicable to Medicare regulations, no doubt reflecting Congress's understanding that "[o]ne way or another, Medicare touches the lives of nearly all Americans" and that "even seemingly modest modifications to the program can affect the lives of millions." *Allina Health Servs.*, 587 U.S. at 568-569 (quoting 42 U.S.C. § 1395hh(a)(2)). Congress thus enacted a notice-and-comment provision, 42 U.S.C. § 1395hh, that imposes obligations beyond those required by the Administrative Procedure Act ("APA"). For example, section 1395hh "require[s] the government to provide public notice and a 60-day comment period (twice the APA minimum of 30 days)" not just for any rule or requirement but also for any "other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits,

the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare]." *Id.* at 570.

In 2003, Congress amended the Medicare notice-and-comment statute to explicitly require that all final rules be a "logical outgrowth" of proposed rules that are subject to notice and comment. Medicare Prescription Drug and Modernization Act of 2003, Pub. L. No. 108-173, § 902, 117 Stat. 2066, 2375 (codified at 42 U.S.C. § 1395hh(a)(4)). According to the committee report accompanying the amendment, this new requirement would prohibit regulations from taking effect "until public comment occurred." H.R. Rep. No. 108-178, pt. 2, at 254 (2003). The report noted, approvingly, that courts had "repeatedly held that new matter in final regulations must be a logical outgrowth of the proposed rule" under the APA, and that this requirement was "an inherent aspect of notice and comment rulemaking." *Id.*; *see also* H.R. Rep. No. 108-391, at 754-755 (2003) (same). And unlike the APA, "the Medicare statute has no harmless error exception," *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109 (D.C. Cir. 2014), so its logical-outgrowth provision, too, was more stringent than the APA because it eliminated the possibility that a rule that was not a logical outgrowth might still take effect under the harmless-error doctrine.

As this Court has explained, the "objective" of the logical outgrowth requirement "is fair notice." *Texas Ass'n of Mfrs. v. U.S. Consumer Prod. Safety*

Comm'n, 989 F.3d 368, 381-382 (5th Cir. 2021). To satisfy the logical-outgrowth requirement, the agency must "adequately frame the subjects for discussion [in the proposed rule] such that the affected party should have anticipated the agency's final course in light of the initial notice." *Mock v. Garland*, 75 F.4th 563, 583 (5th Cir. 2023) (quoting *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021)). If a final regulation is not a logical outgrowth of the proposed rule, then the regulation "shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation." 42 U.S.C. § 1395hh(a)(4).

B. The Public Had No Opportunity To Comment On CMS's Decision To Reject Actuarial Equivalence In RADV Audits As A Matter Of Law

The rulemaking process for the Final Rule underscores the importance of the logical-outgrowth requirement. In the Final Rule, CMS implemented enormously consequential changes to the MA program: It concluded that "actuarial equivalence"—the bedrock principle that CMS will pay MAOs an amount to care for members equivalent to the cost CMS would expect to pay for those same members if they were enrolled in traditional FFS Medicare, 42 U.S.C. § 1395w-23(a)(1)(C)(i)—does not apply to RADV audits. 88 Fed. Reg. at 6660. Based on that conclusion, CMS declined to adopt an FFS Adjuster for RADV audits that is necessary to ensure actuarial equivalence between payments for FFS Medicare and

audited MAOs. If allowed to stand, CMS's decision would result in the systematic underpayment of audited MAOs for the care they provide their enrollees. *See infra* pp. 18-24.

CMS, however, never disclosed in the Proposed Rule that it was considering taking the unprecedented step of declining to apply the actuarial-equivalence requirement to RADV audits as a matter of law, thereby reversing the agency's "long-standing finding that actuarial equivalence applies" to RADV audits. ROA.26923; *see supra* p. 3.[2] The Proposed Rule assumed that the actuarial-equivalence requirement *did* apply and purported to show why CMS did not need to adopt an FFS Adjuster to ensure actuarial equivalence. CMS offered two rationales: (1) The agency had conducted a study that showed that "diagnosis error in FFS claims data does not lead to systematic error in the MA program"; and (2) "it would be inequitable to correct any systematic errors in the payments made to audited plans only." 83 Fed. Reg. 54982, 55041 (Nov. 1, 2018).

In four subsequent notices published in the Federal Register, the agency likewise neglected to disclose that it was considering not applying the actuarial-equivalence requirement to RADV audits. *See* 83 Fed. Reg. 66661 (Dec. 27, 2018); 84 Fed. Reg. 8069 (Mar. 6, 2019); 84 Fed. Reg. 18215 (Apr. 30, 2019);

[2] Citations to the "record on appeal" will be designated as citations to the "ROA."

84 Fed. Reg. 30983 (June 28, 2019). In the last notice, CMS identified the same rationales from the Proposed Rule as grounds for not applying an FFS Adjuster. CMS's proposal, the agency said, "rested on two grounds. First, [CMS] conducted a study which indicated that diagnosis error in FFS claims data does not lead to systematic payment error in the … MA program. Second, … it would be inequitable to correct any systematic errors made in the payments to audited plans only." 84 Fed. Reg. at 30983.[3]

Public comments on the Proposed Rule understandably responded to CMS's proffered reasons for not applying an FFS Adjuster. In comment after comment, members of the public focused their responses on the study that CMS identified as the primary basis for the agency's proposed policy. Commenters, including AHIP, took issue first with CMS's failure to disclose the "data, assumptions, and methodology" underlying the study, urging the agency "to release this information as soon as possible." ROA.1481; *see also, e.g.*, ROA.1264-1266 (Cigna comment identifying 13 categories of data and analyses that were "either undisclosed or only

[3] CMS's disregard of notice-and-comment requirements is not limited to the Final Rule. Indeed, CMS has subsequently modified core aspects of the RADV audit methodology through sub-regulatory guidance without notice-and-comment. For example, CMS has changed audit sampling frames, medical record submission limits, and hardship exemption procedures, each of which materially affects the financial exposure of audited MAOs. *See* CMS, *Update on Status of Medicare Advantage Risk Adjustment Data Validation Audits* (Jan. 27, 2026).

incompletely disclosed"); ROA.1313 (American Academy of Actuaries comment "encourag[ing] CMS to be fully transparent as to its methods"); ROA.1524 (Anthem comment noting that it had "sent a letter to CMS explaining that the Agency's failure to release … critical information [regarding the study] impedes Anthem's right to comment on the Proposed Rule"). And after CMS belatedly released the data, commenters addressed the study's myriad actuarial and statistical shortcomings, which the data exposed. As BCBSA explained, the study contained "technical problems and faulty assumptions and conclusions," including, among others, a failure to normalize data, inconsistent use of comparison data, data conversion errors, and use of an inappropriate sample size. ROA.1933-1935. Multiple MAOs submitted lengthy expert reports opining on the report's errors. *See, e.g.*, ROA.3167-3204 (report prepared for Humana); ROA.4137-4203 (report prepared for Aetna, Anthem, Cigna, Humana, and Kaiser Permanente).

Commenters assumed that actuarial equivalence applies to RADV audits for good reason: Since at least 2012, as the district court found, CMS operated under the "long-standing principle that actuarial equivalence applies" to RADV audits, ROA.26916, 26923, 26925, and had committed to conducting RADV audits in an actuarially sound manner. Commenters thus focused on why the Proposed Rule would violate actuarial principles that everyone understood CMS was required to follow. AHIP, for example, explained in its comment that an "FFS adjuster, or

other similar adjustment, is necessary to ensure actuarial equivalence between payments to MA plans and payments under the FFS program," and it attached an expert analysis showing how the rejection of the FFS Adjuster undermined the actuarial-equivalence requirement that is "fundamental to the proper functioning of the MA risk adjustment model." ROA.1955-1957. MAOs likewise assumed actuarial equivalence would apply in the proposed RADV audit methodology. *See, e.g.*, ROA.4222 (Humana) ("CMS's Proposal to Eliminate a FFS Adjuster from the RADV Audit Methodology Violates the Medicare Act's Actuarial Equivalence Requirement"); ROA.4546 (Aetna) (similar); ROA.4732 (Anthem) (similar).

Commenters did not seriously consider that CMS might abandon actuarial equivalence as a legal matter in the Final Rule. Had CMS issued the Proposed Rule based on that fundamentally different rationale, commenters would have responded accordingly. This is not, as the government suggests in its opening brief, a minor dispute about "differences in how the preambles to the proposed and final rules explained the agency's reasoning." Opening Br. 26. By CMS's own estimates, extrapolated RADV audit recoveries will likely affect nearly $5 billion in payments to MAOs over the next decade. 88 Fed. Reg. at 6663. And that number almost certainly underestimates the impact of the Final Rule because CMS has more recently announced an "aggressive" "expansion of its auditing efforts" that would apply the Final Rule to "all eligible MA contracts … for payment years

2018 through 2024." CMS, *CMS Rolls Out Aggressive Strategy to Enhance and Accelerate Medicare Advantage Audits* (May 21, 2025). Indeed, for payment year 2020, CMS recently announced that *471* contracts were selected for RADV audits. *See* CMS, *Payment Year 2020 List of Audited Contracts* (visited May 27, 2026).

The intent of Congress to require that RADV audits, including the calculation and recoupment of overpayments, comply with the statute's actuarial-equivalence requirement for CMS payments thus carries immense consequences for MAOs and the integrity of the MA program. The absence of comments on *that* issue from the public only confirms the rulemaking's obvious deficiency: CMS failed to "adequately frame the subjects for discussion," *Mock*, 75 F.4th at 583, as it was required to do to satisfy the logical-outgrowth requirement in section 1395hh(a)(4).

III. CMS'S NEW RATIONALES FOR EXCLUDING AN FFS ADJUSTER DEFY SOUND ACTUARIAL PRACTICE AND CONGRESSIONAL DESIGN

Because this appeal presents the narrow procedural question whether the Final Rule is a logical outgrowth of the Proposed Rule, the merits of the Final Rule are not at issue. It nonetheless bears emphasizing that the Final Rule's rationales for excluding an FFS Adjuster—(1) that the actuarial-equivalence requirement does not apply to RADV audits as a matter of law and (2) that Congress's enactment of the Coding-Intensity Adjustment obviates the need for the FFS Adjuster—are meritless.

A. The Final Rule's Exclusion Of An FFS Adjuster Violates Basic Actuarial Principles And Is Contrary To The Medicare Statute

CMS's abandonment of the FFS Adjuster in RADV audits violates the actuarial-equivalence requirement that Congress imposed and that is necessary for an actuarially sound risk-adjustment payment system. Congress has mandated that CMS's payments to MAOs for their enrollees be adjusted for risk factors, including health status, to ensure that the payments are "actuarial[ly] equivalen[t]" to the expected costs that CMS would have incurred had it been required to provide traditional FFS Medicare benefits to the same set of enrollees. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Parity with FFS Medicare costs guarantees that MAOs will have the resources they need to harness efficiencies to offer attractive coverage to the populations enrolled in their plans. Parity also eliminates structural incentives that might otherwise favor enrollment of a younger and healthier population, furthering Congress's goal of making MA plans broadly available to all otherwise-eligible Americans. *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).").

"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).

The Final Rule violates this actuarial principle by holding MAO data to a different documentation standard than the FFS Medicare data that CMS uses to develop the risk-adjustment payment model. The FFS Medicare dataset that CMS uses—diagnoses reported on medical claims to CMS by providers—is known to contain a substantial rate of diagnosis codes that are not supported by patient medical records according to CMS's documentation and coding standards. *See* Winkelman, *Actuarial Report on CMS' November 1, 2018 Proposed Rule* 10-11 (Aug. 2019) (available at ROA.4150-4152). RADV audits, by contrast, are conducted against the patient's medical records and do not credit diagnoses reported on provider claims. 42 C.F.R. § 422.310(e).

The effect of an extrapolated RADV audit is that the same patients will appear healthier and less costly for MAOs than they do in the unaudited FFS Medicare data that includes unsubstantiated diagnoses. That is, for a given patient population, CMS will estimate expected costs—and thus set risk-adjustment

factors—according to diagnosis codes reported in FFS Medicare claims data, regardless of whether the diagnoses are documented in medical records. But CMS will then discredit undocumented codes for an MAO's members in an extrapolated RADV audit. CMS will accordingly pay the MAO less than the expected cost it would incur for the same individuals in FFS Medicare. And because the Final Rule authorizes CMS to recoup payments on an extrapolated, contract-wide basis—rather than just for the unsupported diagnoses identified during the audit—the result will be an actuarially unsound payment model that systematically underpays MAOs for their members.[4]

An FFS Adjuster in RADV audits is necessary to remedy the data inconsistency between FFS Medicare and RADV audit data and ensure actuarial equivalence, as CMS itself long recognized. ROA.26916, 26923, 26925; *supra* p. 3. But in the Final Rule, CMS now claims that the actuarial-equivalence

[4] Extrapolating underpayments at the contract-level will produce aggregate recoupment demands in the billions for the industry, which do not necessarily bear any relationship to actual payment error. The effect of extrapolation is clear from one recent HHS-OIG audit, which, applying the same extrapolation methodology as the Final Rule, extrapolated enrollee-level overpayments of approximately $165,000 to an estimated contract-level figure of $59 million—a ratio exceeding 350:1. *See* HHS-OIG, *Medicare Advantage Compliance Audit of Diagnosis Codes that MMM Healthcare, LLC, (Contract H4003) Submitted to CMS* 6 (Aug. 13 2024).

requirement does not apply to RADV audits as a matter of law and thus abandons the FFS Adjuster.[5]

Not only is this conclusion actuarially unsound, it is also contrary to the Medicare statute. Congress has mandated a risk-adjustment payment model that "ensure[s] actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). To apply the risk-adjustment model, the statute mandates data collection by MAOs. *See, e.g.*, *id.* § 1395w-23(a)(1)(I)(ii), (3)(B), (3)(C)(iii).

The Final Rule amends the risk-adjustment data regulation, 42 C.F.R. § 422.310, under CMS's authority to prescribe Medicare regulations. *See* 88 Fed. Reg. at 6665 (citing 42 U.S.C. § 1395hh). Section 422.310 implements section 1395w-23 by regulating "all data … used in the development and application of a risk adjustment payment model." It prescribes MAOs' data collection and sources, 42 C.F.R. § 422.310(b)-(c), and submission to CMS, *id.* § 422.310(d), as well as CMS's use of the data, including to "determine the risk adjustment factors used to adjust payments" and to "update risk adjustment models," *id.* § 422.310(f)(1)(i)-(ii). These provisions all tie directly back to section 1395w-23. As relevant here, section 422.310 also addresses the "[v]alidation of risk adjustment data" through

[5] BCBSA has urged CMS to reintroduce the FFS Adjuster on precisely this basis, recommending that CMS "audit FFS data in a similar manner over the same [dates of service] to benchmark MA error rates against the underlying FFS error rate." BCBSA, *RADV Audit Recommendations to CMS* 3 (June 2025).

"RADV audits," *id.* § 422.310(e), making clear that such audits likewise exist to implement section 1395w-23's requirements for developing and applying an actuarially sound risk-adjustment payment model.

Because the Final Rule revises regulations that implement section 1395w-23, its provisions must comply with the statute's actuarial-equivalence requirement. "[W]hen Congress provides express rulemaking authority to an agency in order to carry out the substantive provisions of a statute, a regulation promulgated under such authority [must be] 'reasonably related to the purposes of the enabling legislation,'" meaning that "the regulation is not inconsistent with the statute and serves to prevent circumvention of that statute." *Graham Eng'g Corp. v. United States*, 510 F.3d 1385, 1389 (Fed. Cir. 2007) (quoting *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973)). There is only one reading of the Final Rule that comports with Congress's delegation of authority to CMS: In revising how CMS validates the data it uses to "develop[] and appl[y]" its payment model, 42 C.F.R. § 422.310(a), the Final Rule must adhere to Congress's directives, including "ensur[ing] actuarial equivalence," 42 U.S.C. § 1395w-23(a)(1)(C)(i).

CMS's attempt to draw a timing-based distinction between its implementation of the risk-adjustment model (which CMS accepts is subject to actuarial equivalence) and its later payment recovery through RADV audits (which

it claims is unbound by actuarial equivalence) is meritless. The model is intended to "adjust the payment amount" to an MAO based on the "health status" of an MA plan's enrollee population. 42 U.S.C. § 1395w-23(a)(1)(A)(i). That is precisely what RADV audits purport to accomplish by recouping payment for diagnoses that are not supported by medical record documentation. Indeed, in the Final Rule, CMS describes recouping payments through the audits as "[p]ayment adjustments." 88 Fed. Reg. at 6646.

Finally, CMS's reliance on *UnitedHealthcare Insurance Company v. Becerra* is misplaced. 16 F.4th 867 (D.C. Cir. 2021). In *UnitedHealthcare*, the D.C. Circuit held that actuarial equivalence did not apply to a 2014 rule CMS promulgated requiring MAOs to return "identified overpayments" for unsupported diagnosis codes ("Overpayment Rule"). *Id.* at 870-871. The court reasoned that because the actuarial-equivalence requirement applies "at the group or population level, not the individual level," it does not apply to the Overpayment Rule, which corrects only "particular mistaken payments" to MAOs—namely, individual "payments they *are aware* lack support in a beneficiary's medical records." *Id.* at 884, 886. But of course, extrapolated RADV audits *are* at the population level, which the D.C. Circuit acknowledged in observing that the Overpayment Rule was "materially distinct from contract-level RADV audits." *Id.* at 892.

UnitedHealthcare is distinguishable for a second reason. To support its conclusion that actuarial equivalence did not apply there, the court relied on the fact that the Overpayment Rule was not promulgated under the statutory subchapter where the actuarial-equivalence requirement is set out. *Id.* at 883. Here, CMS *is* implementing the RADV audit rule pursuant to section 1395w-23(a)(1)(C), the "statutory home" of the actuarial-equivalence requirement. *Id.* 870.

In short, *UnitedHealthcare* is "plainly distinguishable" from the present case, as the court itself acknowledged, 16 F.4th at 893 n.1, and does not support CMS's conclusion that extrapolated RADV audits are exempt from the statute's actuarial-equivalence requirement.

B. The Coding-Intensity Adjustment Confirms That CMS Must Ensure Actuarial Equivalence Between FFS Medicare And Medicare Advantage

The Final Rule cites the Coding-Intensity Adjustment as grounds for not implementing an FFS Adjuster. In particular, 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 another provision of the Medicare statute requires CMS to apply a Coding-Intensity Adjustment that reduces payments. 88 Fed. Reg. at 6656.

There is nothing unreasonable, however, 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). The Coding-Intensity Adjustment 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." Kronick & Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4 Medicare & Medicaid Res. Rev. E1, E4 (2014) (available at ROA.9403, 9406). To account for this difference, the Coding-Intensity Adjustment imposes a statutory minimum adjustment. Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5301, 120 Stat. 4, 51 (codified at 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I)-(II)). It will expire if CMS begins relying on MA data to calibrate the risk-adjustment model, rather than FFS data, and thereby eliminates the problem of different degrees of completeness in coding. *See* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1102(e)(3)(D), 124 Stat. 1029, 1046 (codified at 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III)-(IV)). The FFS Adjuster, meanwhile, was adopted to address an entirely different data inconsistency—not the relative *completeness* of coding but the relative *accuracy* of diagnosis codes reported in FFS Medicare as compared to diagnosis codes supported by medical record documentation. *See supra* pp. 18-24.

CMS has acknowledged that the Coding-Intensity Adjustment and the FFS Adjuster serve different purposes. Indeed, CMS proposed the FFS Adjuster in 2012 against the backdrop of the agency's ongoing implementation of the Coding-Intensity Adjustment. And from 2012 to 2023, CMS never suggested there was any incompatibility or redundancy in implementing both adjustments. To the contrary, in 2018, CMS acknowledged that the adjustments address different issues in responding to arguments that the Coding-Intensity Adjustment was unnecessary because of coding oversight through RADV audits. As CMS explained, "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 differences between documentation of diagnoses in FFS Medicare and audited MA data.

The D.C. Circuit has reached the same conclusion. The Coding-Intensity Adjustment, the court said, "does not … address unsupported … [diagnosis] codes reported by MA insurers, but only the practice, relative to traditional Medicare, of

overreporting [diagnosis] codes that are nonetheless accurate." *UnitedHealthcare*, 16 F.4th at 877.

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-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 agency audits. 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.

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*, 603 U.S. 369, 394 (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 satisfy the actuarial-equivalence requirement in the RADV context, alongside and

in addition to any other actuarial issues such as coding intensity. *Supra* pp. 18-24, 26. CMS's departure from that approach was neither "reasonable [n]or reasonably explained." *National Ass'n of Mfrs. v. SEC*, 105 F.4th 802, 815 (5th Cir. 2024).

CONCLUSION

The Court should affirm the vacatur of the Final Rule.

Respectfully submitted.

/s/ *Kevin M. Lamb*

KEVIN M. LAMB
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000
kevin.lamb@wilmerhale.com

PETER A. KURTZ
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

ADELA LILOLLARI
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

Counsel for Amici America's Health Insurance Plans and Blue Cross Blue Shield Association

May 27, 2026

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 6,090 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word for Office 365 in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ *Kevin M. Lamb*
KEVIN M. LAMB

May 27, 2026

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of May, 2026, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ *Kevin M. Lamb*
KEVIN M. LAMB