United States Court of Appeals

for the

Fifth Circuit

Case No. 25-11293

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, FORT WORTH

BRIEF OF APPELLEES

K. LEE BLALACK, II
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, DC 20006
(202) 383-5300
lblalack@omm.com

DAVID DEATON
O'MELVENY & MYERS LLP
Two Embarcadero Center, 28th Floor
San Francisco, California 94111
(415) 984-8700
ddeaton@omm.com

STEPHEN SULLIVAN
JONATHAN SCHNELLER
ELIZABETH BOCK
HEATHER WELLES
O'MELVENY & MYERS LLP
400 South Hope Street, Suite 1900
Los Angeles, California 90071
(213) 430-6000
ssullivan@omm.com
jschneller@omm.com
ebock@omm.com
hwelles@omm.com

JENNIFER B. SOKOLER
O'MELVENY & MYERS LLP
1301 Avenue of the Americas, Suite 1700
New York, New York 10019
(212) 326-2000
jsokoler@omm.com

TIMOTHY S. DURST
O'MELVENY & MYERS LLP
2801 North Harwood Street, Suite 1600
Dallas, Texas 75201
(972) 360-1900
tdurst@omm.com

Attorneys for Plaintiffs-Appellees

CP COUNSEL PRESS (800) 4-APPEAL • (393192)

No. 25-11293

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

Plaintiffs-Appellees,

vs.

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
Northern District of Texas, Fort Worth Division
Civil Action No. 4:23-cv-00909-O

CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order for the judges of this Court to evaluate possible disqualification or recusal:

Plaintiffs-Appellees

1. Humana Inc. No parent corporation or publicly held corporation owns 10% or more of Humana Inc.'s stock.

2. Humana Benefit Plan of Texas, Inc. Humana Benefit Plan of Texas, Inc. is a wholly owned subsidiary of Plaintiff-Appellee Humana Inc.

Counsel for Plaintiffs-Appellees

K. Lee Blalack II
O'MELVENY & MYERS LLP
1625 Eye Street, N.W.
Washington, D.C. 20006
[Tel.] (202) 383-5300

Timothy S. Durst
O'MELVENY & MYERS LLP
2801 N. Harwood Street, Suite 1600
Dallas, Texas 75201
[Tel.] (972) 360-1900

Stephen M. Sullivan
Jonathan P. Schneller
Elizabeth M. Bock
Heather Welles
O'MELVENY & MYERS LLP
400 S. Hope Street, 19th Floor
Los Angeles, California 90071
[Tel.] (213) 430-6000

Jennifer B. Sokoler
O'MELVENY & MYERS LLP
1301 Avenue of the Americas, 17th Floor
New York, New York 10019
[Tel.] (212) 326-2000

David Deaton
O'MELVENY & MYERS LLP
Two Embarcadero Center, 28th Floor
San Francisco, California 94111
[Tel.] (415) 984-8700

Defendants-Appellants

Defendants-Appellants are all governmental entities and therefore not required to be listed on a certificate of interested persons. 5th Cir. R. 28.2.1(a).

Counsel for Defendants-Appellants

Brett A. Shumate
Assistant Attorney General
Michael S. Raab
Weili J. Shaw
Attorneys, Appellate Staff Civil Division, U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530
[Tel.] (202) 514-1371

Other Interested Entities

1. Subsidiaries of Humana Inc., including: Arcadian Health Plan, Inc.; CarePlus Health Plans, Inc.; Cariten Health Plan Inc.; CHA HMO, Inc.; CompBenefits Insurance Company; Emphesys Insurance Company; Humana Benefit Plan of Illinois, Inc.; Humana Employers Health Plan of Georgia, Inc.; Humana Health Benefit Plan of Louisiana, Inc.; Humana Health Company of New York, Inc.; Humana Health Insurance Company of Florida, Inc.; Humana Health Plan of California, Inc.; Humana Health Plan of Ohio, Inc.; Humana Health Plan of Texas, Inc.; Humana Health Plan, Inc.; Humana Health Plans of Puerto Rico, Inc.; Humana Insurance Company; Humana Insurance Company of Kentucky; Humana Insurance Company of New York; Humana Insurance of Puerto Rico, Inc.; Humana Medical Plan of Michigan, Inc.; Humana Medical Plan of Pennsylvania, Inc.;

Humana Medical Plan of Utah, Inc.; Humana Medical Plan, Inc.; Humana Regional Health Plan, Inc.; Humana Wisconsin Health Organization Insurance Corporation; HumanaDental Insurance Company; Independent Care Health Plan; and other Humana Inc. subsidiaries that provide services and products other than in connection with the Medicare Advantage program.

/s/ K. Lee Blalack II
K. Lee Blalack II

STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs-Appellees do not believe that oral argument is necessary, but do not oppose Defendants-Appellants' request for argument.

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(continued)

Page(s)

Statutes

Other Authorities

TABLE OF AUTHORITIES
(continued)

Page(s)

Regulations

INTRODUCTION[1]

The district court below correctly vacated a rule that threatened the future of the Medicare Advantage program, which provides healthcare to more than 35 million seniors across the country. That program depends on private health insurers, known as Medicare Advantage Organizations or "MAOs," offering Medicare benefits to seniors as an alternative to the traditional Medicare program. The MA program has produced better health outcomes and a broader menu of benefits for seniors than they would otherwise receive in traditional Medicare. As a result, the MA program has become enormously popular, and now more than fifty percent of Medicare beneficiaries choose to enroll in the MA program rather than traditional Medicare.

Though the MA program is complex—as is the Final Rule's five-year regulatory history—this appeal is straightforward: The district court held that the Centers for Medicare and Medicaid Services, which administers the MA program, violated the Administrative Procedure Act by proposing a rule based on one set of rationales and finalizing the regulation based on entirely different ones—without affording the public the opportunity to comment on the agency's new reasoning.

---

[1] This brief refers to Medicare Advantage as "MA"; Medicare Advantage Organizations as "MAOs"; the Centers for Medicare and Medicaid Services as "CMS"; the Administrative Procedure Act as the "APA"; Appellees Humana Inc. and Humana Benefit Plan of Texas, Inc. as "Humana"; the Notice of Proposed Rulemaking published at 83 Fed. Reg. 54,982 (Nov. 1, 2018) as the "Proposed Rule"; the Final Rule published at 88 Fed. Reg. 6643 (Feb. 1, 2023) as the "Final Rule"; and Appellants' Opening Brief as "AOB."

The district court's decision is correct and compelled by controlling precedent. In *Texas Association of Manufacturers v. U.S. Consumer Product Safety Commission*, 989 F.3d 368, 383 (5th Cir. 2021), this Court held that an agency violates the APA's notice-and-comment requirement by failing to "allow[] for comment after . . . chang[ing] its primary justification for [a] rule . . . before adopting a final rule." That is precisely what CMS did here.

Texas Association of Manufacturers is dispositive, and the Final Rule's history validates this Court's reasoning in that case. In 2010, CMS first proposed a new methodology for its Risk Adjustment Data Validation ("RADV") program, which the agency uses to audit payments under MA contracts. The agency, both internally and publicly, acknowledged that the new audit methodology would violate actuarial standards and cause MAOs to be underpaid unless CMS included an actuarial adjustment in the audit process. MAOs explained at the time that this adjustment was needed because the Medicare statute—42 U.S.C. § 1395w–23(a)(1)(C)(i)—requires "actuarial equivalence" between the MA program and traditional Medicare. CMS and the MA industry referred to this actuarial adjustment as the Fee-for-Service Adjuster ("FFS Adjuster").

Six years later, CMS abruptly reversed course and proposed a rule that abandoned the FFS Adjuster that the agency had previously recognized was required. To justify this reversal, the Proposed Rule relied primarily on an empirical study

that—according to the agency—demonstrated that the new audit methodology posed no risk of systematic payment error. But CMS withheld much of the study's underlying data from the public and ultimately admitted that the agency had lost key outputs and would need to replicate its analysis.

When CMS finally released a new version of the study accompanied by the applicable methodology and underlying data, numerous commenters including Humana demonstrated that the study was empirically flawed. Rather than disproving the need for a FFS Adjuster, the data underlying CMS's study *confirmed* that, absent such an actuarial adjustment, the new audit methodology would cause MAOs to be systematically underpaid in violation of the Medicare statute. Remarkably, Appellants' brief entirely omits this misadventure, which vividly illustrates the virtues of the notice-and-comment rulemaking process.

After granting itself multiple extensions over nearly five years, CMS published the Final Rule in 2023. The Final Rule did not rely on the study—or any other rationale in the Proposed Rule—as a basis for jettisoning CMS's previous policy that the agency would adjust RADV audit recoveries through the FFS Adjuster. Instead, the Final Rule rested on entirely new, purely legal rationales, including a new contention that the Medicare statute does not require the agency to adopt a FFS Adjuster, even if failure to do so disrupts actuarial equivalence between the MA program and traditional Medicare.

As Humana argued in the district court, CMS's belatedly announced interpretation of a long-standing statute is just as flawed as its disavowed empirical study. But for this appeal, what matters is that CMS denied Humana any meaningful opportunity to comment on this new statutory construction, leading the district court to correctly hold that the Final Rule violated the APA.

In response, Appellants principally contend that *Texas Association of Manufacturers* only controls when an agency fails to afford an opportunity to comment on *technical* rationales for a policy. This is a brand-new argument on appeal, and it is meritless. Appellants cite no case adopting their reinterpretation of the APA nor grapple with the obvious risks of a judicial rule that disincentivizes agencies from undertaking technical analyses by subjecting those analyses to scrutiny that would not apply to other agency justifications for rulemaking. Indeed, in this case, CMS abandoned its empirical study when the underlying data did not support its thesis—behavior that should be cause for concern, not a mechanism for successfully avoiding judicial scrutiny. In their brief, Appellants also attempt to revisit their argument that cherry-picked phrases from the Proposed Rule previewed the ultimate rationale in the Final Rule, but offer no persuasive rejoinder to the district court's analysis.

Appellants' other principal argument is that the Medicare statute limits the APA's "logical outgrowth" doctrine solely to "provision[s]" of "final regulations,"

which they interpret to include text in the Code of Federal Regulations, but exclude the rules adopting those regulations. This argument is also undisputably forfeited, as it too appears for the first time on appeal. But regardless, it changes nothing. The Medicare statute does not exempt CMS's rules from the requirement that agencies must provide meaningful notice and an adequate opportunity to comment on their reasoning. On the contrary, the cited statute *limits* CMS's authority to enforce improper rules. Nor do Appellants explain why regulatory text would qualify as a "provision," yet portions of the Final Rule explaining the agency's policies would not.

In their brief, Appellants repeatedly stress the importance of protecting taxpayers through audits of MA program payment data. Humana shares those program-integrity goals and has no objection to payment audits. Humana simply insists that CMS conduct those audits in a manner that is both actuarially sound and compliant with the Medicare statute. This Court should affirm.

STATEMENT OF ISSUES

1. Whether the district court properly concluded that the Final Rule, 88 Fed. Reg. 6643 (Feb. 1, 2023), *see* ROA.17069-91, violated the APA because it was not a logical outgrowth of the Proposed Rule, 83 Fed. Reg. 54,982 (Nov. 1, 2018), *see* ROA.10453-59, when the Final Rule relied on new rationales not disclosed in the Proposed Rule.

2. Whether Appellants forfeited the argument that the APA's notice-and-comment requirements do not apply to an agency's non-technical rationales when Appellants did not present that argument to the district court.

3. Whether Appellants forfeited the argument that 42 U.S.C. § 1395hh(a)(4), a section of the Medicare statute, provides the applicable legal standard and that the Final Rule complied with that statute, when Appellants never argued or even cited § 1395hh(a)(4) to the district court.

STATEMENT OF THE CASE

Though the legal issue before the Court is quite narrow, Humana provides the Court with a complete account of the factual and procedural record because Appellants' brief supplies a selective history that at times omits material information from the record below.

I. Legal and Factual Background

A. The Medicare Advantage Program

This case concerns CMS's administration of one part of Medicare, the MA program. Under Parts A and B of the Medicare statute—known as "traditional Medicare" or "fee-for-service Medicare"—CMS directly pays healthcare providers to treat Medicare beneficiaries. *See* 42 U.S.C. § 1395c *et seq.*; *id.* § 1395j *et seq.* Under Part C of the statute, which authorizes the MA program, Medicare beneficiaries can instead choose to enroll in health plans offered by private insurers like Humana. *See id.* § 1395w–21 *et seq.* MA enrollees are legally entitled to receive

at least the same benefits they would receive in fee-for-service Medicare, and may also receive supplemental benefits from their MAOs, such as vision and dental benefits and prescription drug coverage. *See* ROA.8598.

In establishing Part C, Congress sought to leverage "the health benefit design, delivery, and cost containment innovations that have occurred in the private sector." H.R. Rep. No. 105-217, at 585 (1997).[2] The MA program has proven remarkably successful: As Congress anticipated, the MA program today offers more comprehensive benefits and better clinical outcomes than fee-for-service Medicare, and 90 percent of MA beneficiaries express satisfaction with their health coverage. *See* ROA.1483-84, 4386-87. More than half of all seniors choose to enroll in the MA program rather than participate in traditional, fee-for-service Medicare.[3]

The program's design creates strong incentives for MAOs to provide cost-effective care as compared to fee-for-service Medicare. In fee-for-service Medicare, CMS directly pays healthcare providers to treat Medicare beneficiaries, largely by reimbursing providers retrospectively for each specific service rendered. *See* ROA.8982; 42 U.S.C. § 1395ww(d)(1)-(4) (Part A); *id.* § 1395*l*(a)(1) (Part B). In MA, though, CMS prospectively pays an MAO a fixed monthly amount based on

[2] https://www.congress.gov/105/crpt/hrpt217/CRPT-105hrpt217.pdf.

[3] *Medicare Enrollment Dashboard*, CMS, https://data.cms.gov/tools/medicare-enrollment-dashboard (last updated Jan. 2026); *see also* ROA.26170 (providing older figure).

the estimated cost of providing fee-for-service Medicare benefits to the MAO's particular enrollee population. *See* 42 U.S.C. § 1395w–23. And MA payments are untethered to the volume of medical care that enrollees ultimately receive, which eliminates any incentive to provide unnecessary services. *See* ROA.9169. Rather, the MA program's fixed-payment structure shifts financial risk to MAOs, which bear the cost when enrollees consume more medical services than anticipated, but retain the savings when enrollees consume fewer services than expected. *See* 42 U.S.C. § 1395w–23.

B. The Medicare Statute's "Actuarial Equivalence" Mandate

In return for MAOs' commitment to provide at least the same benefits that enrollees would receive in fee-for-service Medicare, Congress requires CMS to "pay 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." *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 883 (D.C. Cir. 2021). The Medicare statute codifies this foundational bargain by requiring "'actuarial equivalence' between payments to MAOs and the payments that CMS would expect to make for the same enrollees' healthcare expenses in the fee-for-service Medicare program." ROA.26913 (quoting 42 U.S.C. § 1395w–23(a)(1)(C)(i)).

To "ensure actuarial equivalence," 42 U.S.C. § 1395w–23(a)(1)(C)(i), Congress required CMS to develop and apply an actuarially sound method of "risk adjustment," *id.* § 1395w–23(a)(3). Risk adjustment in the MA program works by adjusting payments to MAOs to account for differences in "enrollee health status and demographic factors," ROA.8731-32, so that CMS pays MAOs "more to care for ill beneficiaries and less to care for healthy ones," ROA.9003. The Medicare statute's actuarial-equivalence requirement applies whenever CMS "adjust[s] the payment amount . . . for such risk factors as age, disability status, gender, institutional status, and . . . *health status* under paragraph (3)." 42 U.S.C. § 1395w–23(a)(1)(C)(i) (emphasis added).

C. Risk Adjustment and the CMS-HCC Model

CMS implements this statutory command by measuring the costs associated with various risk factors in fee-for-service Medicare, *see* ROA.9351, and then compensating MAOs based on the prevalence of those risk factors in their enrollee populations, ROA.8356-57, 8528-29.

CMS calculates its risk-adjusted payments to MAOs for each enrollee by multiplying two components: (1) a "base rate" representing the agency's estimate of the expected cost to provide fee-for-service Medicare benefits to an MA enrollee of average risk in a given locale, and (2) a "risk score" unique to each MA enrollee that

accounts for that enrollee's actual demographic and health characteristics. ROA.8529.

The first of these components—the "base rates"—are set each year by CMS through an annual bidding process, whereby MAOs submit bids to the agency estimating the revenue needed to provide fee-for-service Medicare benefits to an MA enrollee of average risk in a given locale. *See* 42 U.S.C. § 1395w–24(a); 42 C.F.R. § 422.254(a)(1), (b). For the second component, CMS calculates risk scores for each MA enrollee using a risk-adjustment methodology called the "CMS-HCC Model." ROA.8529-30, 8550-51.

In fee-for-service Medicare—as in MA—providers record and report their patients' medical diagnoses using industry-standard "diagnosis codes" associated with different health conditions. *See* ROA.9351. In fee-for-service Medicare, "physician and outpatient services are paid generally based on *procedure* codes, and diagnosis codes serve only to *justify* the procedures provided," ROA.9351 (emphasis added), while diagnosis codes serve a more direct function in the MA payment system. Under the CMS-HCC Model, the agency groups diagnosis codes into what it calls "Hierarchical Condition Categories" ("HCCs"), each of which represents a set of related health conditions. ROA.8550.

To quantify the "expected medical expenditures"—that is, the risk—associated with each HCC, CMS analyzes the claims for payment ("claims data")

that healthcare providers submitted in connection with fee-for-service Medicare for medical care those providers rendered to beneficiaries with those conditions. ROA.9351. Based on that calculation, the agency assigns a coefficient to every HCC. ROA.9351. The coefficients for an MA enrollee's reported health conditions can be aggregated, along with demographic and other risk coefficients, to calculate the enrollee's risk score. ROA.8302-03. CMS normalizes the coefficients so that the average fee-for-service Medicare beneficiary will have a risk score of 1.0, ROA.8302, which ensures that payments in fee-for-service Medicare and MA are actuarially equivalent.

In a simplified example, a 74-year-old man whose healthcare providers report to his MA plan diagnosis codes for diabetes with chronic complications, congestive heart failure, and acute myocardial infarction would have a risk score of 1.920. ROA.8750. That risk score represents CMS's *estimate* that his healthcare expenses will be 92 percent (0.920) higher than the average fee-for-service Medicare beneficiary (1.0). ROA.8750.[4]

Risk Score	Risk Coefficient
Male, age 70-74	0.597
Diabetes with chronic complications (HCC 18)	0.344
Congestive heart failure	0.355

[4] CMS included this example in a December 2018 report to Congress based on then-applicable risk factors. ROA.8720, 8750. For simplicity, this reproduction omits three HCCs that do not contribute to this hypothetical enrollee's risk score.

(HCC 85)	
Acute myocardial infarction (HCC 86)	0.410
Interaction between diabetes and congestive heart failure	0.214
Total Risk Score	**1.920**

If the base rate for the MA plan in this example were $1,000 per month, CMS would pay the MAO that administers the plan $1,920 per month for this MA enrollee—the $1,000 base rate multiplied by the enrollee's risk score of 1.920. *See* ROA.8530.

CMS has chosen to set these HCC coefficients based entirely on the diagnosis codes that *fee-for-service* Medicare providers report to the agency in claims for payment; although it could do so, CMS does not use MA claims or encounter data to set MA payment rates. ROA.4220. Moreover, the agency's calculation of the coefficients measures the expected cost associated with a fee-for-service Medicare provider's *reporting* of the diagnosis codes, rather than the cost associated with medical conditions *documented* in the beneficiary's medical record. ROA.4220. This fact is central to the underlying dispute in this case.

Critically, because CMS does not routinely audit reported diagnosis codes in fee-for-service Medicare, the agency does not systematically ensure that diagnosis codes reported in fee-for-service claims data are actually documented in the beneficiaries' medical records. ROA.4220. Accordingly, the risk coefficients in the CMS-HCC Model in no way account for the acknowledged fact that the fee-for-

service Medicare *claims* data do not always match the underlying *medical records*. *See* ROA.2206, 2223.

D. Extrapolated RADV Audits and the FFS Adjuster

MAOs receive the vast majority of the diagnosis codes they must ultimately submit to CMS "from the provider . . . that furnished the item or service," 42 C.F.R. § 422.310(d)(3), but the MAOs *do not* typically receive the underlying medical records from the healthcare providers, *see* ROA.8304. CMS has always acknowledged that MAOs "cannot reasonably be expected to know that every piece of [MA] data is correct," 65 Fed. Reg. 40,170, 40,268 (June 29, 2000), especially when the program serves millions of seniors and involves the submission of tens of millions of diagnosis codes each year.

Because some submitted diagnosis codes may not be documented in the MA enrollees' medical records, CMS periodically conducts RADV audits to "validat[e]" submitted diagnosis codes in the associated medical records. 42 C.F.R. § 422.310(e). 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," ROA.7900. The agency audits MA contracts for each payment year and requires the MAOs that administer those contracts to collect medical records from the providers for a sample of their enrollees and then submit those records to CMS. *See* ROA.7864; 42 C.F.R. § 422.310(e). CMS then evaluates whether the

medical records document the diagnosis codes reported for those enrollees according to applicable diagnosis coding guidelines. ROA.7864.

In 2010, CMS announced that it would start using RADV audits to calculate "payment error estimate[s]" for the entire enrollee population of the audited MA contract—and to recover extrapolated contract-wide repayments based on those estimates. ROA.7929-31. Under this new proposal, CMS would audit diagnosis codes for only a sample of a contract's enrollees, but would use the results to recoup an extrapolated payment associated with an estimated rate of undocumented diagnosis codes for the entire MA contract. ROA.7931.

Commenters identified a critical flaw in this approach. Humana and others explained that the agency's proposal was "actuarially unsound . . . because it would simultaneously use two very different sets of data to measure diagnoses: (1) *non-validated* [fee-for-service Medicare] Claims Data" that does not incorporate medical records for "the development of payment rates" on the "front end," and (2) "*validated* MA Claims Data," documented in medical records, "on the back end of [the RADV] audit[]." ROA.8013 (emphasis added). The result, commenters explained, would be a RADV audit methodology that was "inconsistent with the actuarial equivalence requirement" of the Medicare statute. ROA.8013. The American Academy of Actuaries warned CMS that this "data inconsistency" could

"create systematic underpayment [to MAOs], undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities." ROA.8145.

As the district court explained, "CMS's proposal would have estimated the agency's costs associated with a given diagnosis code based on claim forms submitted by fee-for-service Medicare providers but would pay audited MAOs based only on diagnosis codes documented in the enrollees' medical records." ROA.26915-16. Appellants misstate this concern by suggesting that MAOs merely "characterized" fee-for-service data as "'unaudited.'" AOB 11. In reality, CMS itself has acknowledged that "some portion of diagnoses [listed] on [fee-for-service Medicare] claims are not documented in medical records." ROA.2206.

Although Appellants now downplay this actuarial problem as an "exceedingly complex" "theory," AOB 10, internal agency documents confirm that CMS understood the problem all too well. The agency knew that setting risk coefficients using unaudited fee-for-service Medicare claims data inflates the prevalence of medical conditions among Medicare beneficiaries, which "*tends to reduce the estimated average costs of various conditions* and therefore our [HCC] risk adjustment factors." ROA.2223 (emphasis added).

In its internal communications, agency personnel acknowledged that CMS 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." ROA.2222. The agency admitted that "we should be using the same standard for both." ROA.2222.

CMS devised a solution to this actuarial problem: an "FFS Adjuster" that would "offset . . . recovery amounts under RADV" audits to account for undocumented diagnosis codes in fee-for-service Medicare claims data. ROA.2210. 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 "[e]nsure[] that RADV and MA [prospective] payments are on the same documentation standard." ROA.2210. It would not, as Appellants now suggest, "allow [MAOs] to keep some payments that CMS would otherwise recover through RADV audits," AOB 11, but instead would calibrate the overall RADV audit recovery to remedy the inconsistent documentation standard, ROA.2210. In light of these threatened underpayments, the agency's leadership concluded that the FFS Adjuster "makes sense and from a technical point of view is the right thing to do." ROA.2223.

In February 2012, CMS issued a public notice adopting the FFS Adjuster in a revised RADV audit methodology. ROA.8223-24. Consistent with its internal analysis, the agency's notice 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. ROA.8223-24. 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 RADV audit recoveries. ROA.8223-24.

E. The Coding-Intensity Adjustment

There is an additional wrinkle in the statutory framework governing MA payment rates. The so-called Coding-Intensity Adjustment is a statutorily required adjustment to MA risk scores that is designed to account for the differing incentives between the MA and fee-for-service Medicare programs to achieve complete diagnosis coding.[5]

Fee-for-service Medicare providers are typically paid based on services they render to beneficiaries rather than diagnosis codes they report to CMS, so those providers have "no incentive to report more than one" sufficient diagnosis code. ROA.9392; *see also* ROA.1291 (noting that MAO documentation is "more robust and accurate" than fee-for-service Medicare provider documentation), ROA.9279.

[5] As discussed *infra* at 25, the Final Rule asserted for the first time that it would be unreasonable to interpret the Medicare statute as requiring an FFS Adjuster in light of the Coding-Intensity Adjustment, but Appellants do not contest on appeal that CMS provided inadequate notice of this new rationale. *See* AOB 19 n.1.

MAOs, by contrast, are incentivized to "find and report as many diagnoses as can be supported by the medical record," which helps improve clinical outcomes by capturing a fuller picture of enrollees' health conditions, informs the agency's understanding of beneficiaries' health status and anticipated healthcare costs, and "legitimately increase[s] [MAO enrollees'] risk scores" to reflect the full financial risk MAOs bear. *See* ROA.9392-93.

Shortly after CMS implemented its risk-adjustment model, Congress became concerned that this asymmetrical incentive structure could lead to "risk scores that are [not] consistent across both fee-for-service and Medicare Advantage settings," which could threaten actuarial equivalence between the two programs. 152 Cong. Rec. H54 (daily ed. Feb. 1, 2006) (statement of Rep. Thomas); *see* 152 Cong. Rec. S438 (daily ed. Feb. 1, 2006) (statement of Sen. Grassley) (same); *see also* ROA.8272 (CMS rate notice quoting Senator Grassley's statement), ROA.8935. CMS analyzed the issue and ultimately determined in 2009 that such differences existed, and that those differences warranted an across-the-board downward adjustment of MA risk scores to "better assure financial neutrality" between the two programs. ROA.8271; *see also* ROA.8270-72, 8279. Congress responded in 2010 by amending the Medicare statute to institute a minimum adjustment to MA risk scores, the Coding-Intensity Adjustment. *See* Health Care & Education Reconciliation Act, Pub. L. No. 111-152, § 1102(e), 124 Stat. 1029, 1046 (2010).

The Coding-Intensity Adjustment applies to all MA enrollees; it lowers their respective risk scores by a uniform percentage and does not involve any examination of medical records. *See id.*

CMS has consistently recognized that the Coding-Intensity Adjustment addresses coding *completeness*, not coding accuracy, and is thus distinct from RADV audits and the FFS Adjuster. For example, in 2010, CMS denied that the Coding-Intensity Adjustment was "duplicative of any RADV audit-related adjustments" or that the agency was "double counting the impact of inaccurate [diagnosis] coding"; it publicly stated that the Coding-Intensity Adjustment was "not intended to adjust for inaccurate coding." ROA.8296-97; *accord, e.g.*, ROA.1168 ("[S]ection 1853(a)(1)(C)(ii) addresses the incentive for all [MAOs] to identify *more valid, supported codes* on all HCCs, and therefore report more diagnoses . . . .") (emphasis added), ROA.4228.

II. Procedural History

A. The 2018 Proposed Rule Reversed CMS Policy on the FFS Adjuster Based on a New Empirical Study and Purported Inequities Between Audited and Unaudited MA Plans

For more than six years after announcing the FFS Adjuster, CMS provided no additional detail about how it would function. *See* ROA.4216; *see generally* ROA.1246-7861. Then in 2018, the agency unexpectedly reversed course, issuing a Proposed Rule to retract the FFS Adjuster. *See* ROA.1246-52.

The Proposed Rule's primary rationale for abandoning the FFS Adjuster was an empirical one: CMS asserted that a new agency study demonstrated that "errors in [fee-for-service Medicare] claims data do not have any systematic effect" on risk scores or payments to MAOs. ROA.1250. The Proposed Rule also offered an alternative rationale that applying an FFS Adjuster "would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans." ROA.1251.

Initially, CMS did not adequately explain the methodology underlying the study or release much of its underlying data. ROA.1265-66, 1313. Nor did the agency's Chief Actuary certify the study, as required by agency guidelines. ROA.13475-76, 13501.

In response to the Proposed Rule, a host of commenters observed that CMS had not provided adequate information about the study to permit meaningful review by the public. *See, e.g.*, ROA.1266, 1313-14, 1524, 1581-82, 1734. The agency then released some data, but eventually admitted that it had lost key outputs of the study and would need to replicate its analysis. *See* ROA.1260. In June 2019, CMS released a new version of the study, reasserting that "diagnosis error in . . . FFS [claims] data does not" lead to systematic "payment bias" in the MA program. ROA.7928.

Commenters, including Humana, then identified a series of methodological errors guaranteeing that the study would produce the finding of no payment bias—regardless of what the underlying data actually showed—thereby undermining actuarial equivalence. *See* ROA.2081-82, 4236-48, 4739-40, 5727-54. When expert actuaries retained by various commenters replicated CMS's analysis and corrected these errors, they uniformly found that diagnosis codes lacking medical-record documentation in fee-for-service Medicare claims data would systematically deflate MA payment rates. *See, e.g.*, ROA.1965-69, 13477 (report from a member of the American Academy of Actuaries explaining that correcting just two of many methodological flaws in CMS's study would result in a finding of a 9.9% deflation of MA payment rates).

B. CMS Repeatedly Delayed the Final Rule

In their brief, Appellants blithely characterize the years between the 2018 Proposed Rule and the 2023 publication of the Final Rule as a time of "further dialogue with the public." AOB 13-14. In reality, much of that five-year period consisted of CMS belatedly publishing data underlying the agency's flawed study and then granting itself multiple extensions of time to publish the Final Rule. *See* ROA.17073-74.

In 2019, CMS requested "comment on whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C)"—which contains the Medicare statute's actuarial-

equivalence requirement—"mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology." ROA.1261 (84 Fed. Reg. 30,983, 30,983 (June 28, 2019)). This request gave no hint that CMS was reconsidering whether the actuarial-equivalence requirement applied in the first instance—it asked only how that requirement should inform the agency's proposal. *See* ROA.26923 (district court found "no specific indication . . . that would alert the reader to the fact that CMS was considering abandoning [its] justifications for a finding that actuarial equivalence does not apply"). Commenters understood CMS to be seeking comment on whether eliminating the FFS Adjuster would *violate* the actuarial-equivalence requirement—not whether that statutory requirement applied to RADV audits at all. *See, e.g.*, ROA.1973 (arguing that CMS could satisfy the statutory actuarial-equivalence requirement by applying an FFS Adjuster or by developing the risk-adjustment model using audited FFS claims data); ROA.4438-39 (similar).

After this 2019 request, CMS said nothing else until October 2021, when it extended the timeline for the Final Rule's publication by an additional year. ROA.7858-59. A further extension notice followed in November 2022, before CMS finally published the Final Rule the following year. *See* ROA.7860-61, 7862-84.

C. The Final Rule Abandoned the Flawed Study and Instead Adopted a Different, Purely Legal Rationale to Support CMS's New Policy

CMS published its Final Rule on February 1, 2023, "finalizing that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings," beginning retroactively with payment year 2018 and without applying an FFS Adjuster. ROA.7862-63; *see* ROA.7862-84.

The Final Rule abandoned both of the Proposed Rule's rationales for eliminating the FFS Adjuster. Contrary to Appellants' assertion that "the Proposed Rule and the Final Rule rested on the same rationale," AOB 2, the agency expressly disavowed the empirical study that had been the Proposed Rule's chief justification, acknowledging its "inherent limitations." ROA.7878 ("[T]he finalization of our proposal not to apply an FFS Adjuster does not depend on the results of our study."). The agency likewise declined to rely on the Proposed Rule's only other rationale for discarding the FFS Adjuster—the contention that applying an FFS Adjuster would "introduce inequities between audited and unaudited plans." ROA.1251; *see* ROA.26922.

CMS in fact abandoned *any* defense of the actuarial soundness of its new policy, choosing instead to declare that actuarial soundness was irrelevant. The Final Rule concluded that "[e]ven if systematic payment error exists"—that is, even if the inconsistent documentation standard does in fact systematically undercompensate MAOs for the risks they assume—an FFS Adjuster was not required because that

underpayment "does not impact the requirement that submitted [diagnosis codes] must be adequately supported by medical records." ROA.7878. The agency justified that conclusion with two purely legal rationales.

First, the Final Rule relied on the D.C. Circuit's decision in *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), to conclude that extrapolated RADV audits need not comply with the Medicare statute's actuarial-equivalence requirement. ROA.7863. *UnitedHealthcare* involved an APA challenge to a separate MA regulation, the Overpayment Rule. It did not involve RADV audits, and the D.C. Circuit expressly distinguished its holding relating to the Overpayment Rule from RADV audits. *UnitedHealthcare*, 16 F.4th at 893 n.1. CMS nonetheless asserted that the D.C. Circuit's decision was "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 MAOs and not to the obligation of MAOs to return improper payments (for example, payments for unsupported diagnosis codes)." ROA.7863. The Final Rule did not address or even acknowledge the D.C. Circuit's observation that the RADV audit context is "materially distinct" from payment recoveries under the Overpayment Rule. *UnitedHealthcare*, 16 F.4th at 892. The agency also never sought public comment on *UnitedHealthcare*'s significance to the Proposed Rule. ROA.7858-61.

Second, CMS cited the Coding-Intensity Adjustment to support its new position. The agency concluded that "it would be unreasonable to interpret the [Medicare] 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 . . . longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits)." ROA.7875. While the Final Rule repeated this assertion multiple times, ROA.7863, 7875-77, 7879, it never articulated *why* such a reading would be unreasonable. Nor did the Final Rule acknowledge CMS's previous statements distinguishing between the functions served by the Coding-Intensity Adjustment and RADV audits. For instance, the Final Rule did not address the agency's previously stated position that the Coding-Intensity Adjustment was not "duplicative of any RADV audit-related adjustments" and that the Coding-Intensity Adjustment and RADV audit recoveries would not "double count[] the impact" of undocumented diagnosis codes in the medical records because the Coding-Intensity Adjustment is "not intended to adjust for inaccurate coding." ROA.8296-97; *see supra* at 19.

While CMS stated that it "do[es] not agree" with commenters' concerns that the Final Rule would create an actuarially unsound discrepancy between fee-for-service Medicare and MA payments, it made no serious attempt to respond to those

comments; it merely asserted, without explanation, that the comments were "not adequate[]" to overcome its disagreement. ROA.7878.

D. The District Court Vacated the Final Rule

Humana filed this action in the Northern District of Texas on September 1, 2023, challenging the Final Rule under the APA. ROA.1-60. Humana asserted three claims for relief: (1) that the Final Rule is arbitrary and capricious and contrary to law because it reversed CMS's FFS Adjuster policy in violation of the Medicare statute's actuarial-equivalence mandate and without adequate explanation; (2) that CMS abused its discretion in deciding to apply the new policy retroactively; and (3) that CMS promulgated the Final Rule without observance of procedure required by law because the agency provided insufficient notice and "deprived [Humana] of a meaningful opportunity to comment on a central justification for the Final Rule." ROA.51-55.

On September 25, 2025, following cross-motions for summary judgment, the district court granted Humana's motion and denied the government's motion. ROA.26912-27. The district court vacated and remanded the Final Rule, holding that it violated the APA's procedural requirements because it was not a "logical outgrowth" of the Proposed Rule. ROA.26918. The district court's decision rested exclusively on those narrow procedural grounds, and because it held the Final Rule

"procedurally invalid," the district court found no need to "address the other claims." ROA.26918.

The court held that the Final Rule's conclusion not to use an FFS Adjuster because "actuarial equivalence does not apply" to RADV audits was not a "logical outgrowth" of the agency's justifications stated in the Proposed Rule. ROA.26918. The court assessed both of the agency's declared rationales. Taking the second reason first, the district court explained that "Defendants do not and cannot assert that their second justification (the Coding-Intensity Adjustment) logically flowed from the Proposed Rule's justifications." ROA.26920.[6]

The district court therefore focused the remainder of its analysis on CMS's first justification—that actuarial equivalence "does not apply." ROA.26920. The court first rejected the government's argument that the Proposed Rule put commenters on notice of the Final Rule's ultimate conclusion because it stated that "RADV audits do not address issues with the accuracy of payments" and thus should not be used to "correct any systematic payment error." ROA.26921. The court explained that the government's argument relied on selective quotations from the Proposed Rule which stated that applying an FFS Adjuster could introduce

[6] Appellants do not contend on appeal that CMS provided adequate notice of this rationale. *See supra* at 17 n.5; *see also* AOB 19 n.1.

"inequities" between audited and unaudited MA plans—a rationale that CMS abandoned in the Final Rule. ROA.26920-22.

Second, the district court assessed the government's contention that "any procedural defects were remedied when CMS requested comment on 'whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C) . . . mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform [its] proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology.'" ROA.26922 (alteration in original). The court explained that the agency's call for additional comments cited the actuarial-equivalence provision in a manner suggesting "to the reader that CMS believes the sub-sections are *applicable* to RADV audits," consistent with the agency's previous policy, and therefore would not "alert the reader to the fact that CMS was considering abandoning the [Proposed Rule's two] justifications" in favor of "a finding that actuarial equivalence does not apply." ROA.26923 (emphasis added).[7]

Notably, the district court *did not* address whether the Final Rule complied with the "logical outgrowth" requirement in the Medicare statute's notice-and-comment provision, *see* 42 U.S.C. § 1395hh(a)(4), or how that "logical outgrowth" requirement applied to "a provision" of "a final regulation." *See* AOB 28-29. That

[7] The district court also rejected various arguments that Appellants do not raise before this Court. *See* ROA.26924-25.

is because, as explained *infra* at 50-51, the government never presented that argument to the district court and it appears for the first time on appeal.

SUMMARY OF THE ARGUMENT

In *Texas Association of Manufacturers*, this Court ruled that if an agency "change[s] its primary justification for [a] rule" without seeking further public comment, it violates the APA's notice-and-comment requirement. 989 F.3d at 383. As the district court correctly held, that is what happened here: CMS proffered two justifications for the Proposed Rule, then abandoned them both and offered two new, distinct justifications in the Final Rule. It therefore violated the APA under a straightforward application of this Court's precedent.

Appellants offer two primary arguments to resist this conclusion, both of which are forfeited and neither of which has merit. *First*, Appellants attempt to limit the holding in *Texas Association of Manufacturers* to new substantive requirements or *technical* rationales that fail to disclose underlying data or analysis, arguing that the APA does not require notice of non-technical justifications. As a threshold matter, Appellants never made this argument in the district court. They cite no precedent to support it. Nor do they offer any normative reasoning for a legal rule that would incentivize agencies to avoid producing technical analysis to support rulemaking, even though the APA's goal is to ensure that agency decision-making is adequately informed by both its own analysis and commenters' expertise. The

district court also correctly rejected Appellants' contention that cherry-picked phrases from the Proposed Rule provided adequate notice of CMS's ultimate reasoning in the Final Rule.

Second, Appellants argue that under the Medicare statute, notice is required only for "provisions" of new regulations, not the agency's rationales. This argument is also plainly forfeited, as they never presented it to the district court. Even if this Court were to consider the new argument, it changes nothing. The Medicare statute says that a final rule that is not a "logical outgrowth" of a proposed rule cannot be enforced absent further opportunity for comment. That statute limits the agency's discretion once it has violated the APA. Yet Appellants' argument would require this Court, for the first time, to hold that Congress intended that statute to impose a *less* stringent notice-and-comment obligation for rulemaking in the Medicare program than the APA requires. No court has ever suggested that the cited section of the Medicare statute frees CMS from its distinct statutory obligation under the APA to provide adequate notice of its policymaking rationales; on the contrary—and as even Appellants recognize—courts interpret the Medicare statute to incorporate the APA's notice-and-comment requirement. Under the APA, CMS's notice was plainly inadequate.

Humana fully recognizes that it is a steward of public resources and does not object to RADV audits to further payment accuracy. Humana merely insists that

CMS conduct these audits in a manner that complies with the Medicare statute and the protections afforded by the APA. The district court rightly held that CMS violated the APA's procedural requirements and, thus, this Court should affirm.

ARGUMENT

I. The District Court Correctly Concluded That the Final Rule Was Not a Logical Outgrowth of the Proposed Rule

A. The APA Required CMS to Provide Clear Notice of the Rationale for the Final Rule

In notice-and-comment rulemaking, the "agency's rationale for [a] rule must be made clear and subjected to public comment." *Tex. Ass'n of Mfrs.*, 989 F.3d at 382; *see* 5 U.S.C. § 553(c). Where an agency fails to "allow[] for comment after . . . chang[ing] its primary justification for [a] rule but before adopting a final rule," it violates the APA's notice-and-comment requirement. *Tex. Ass'n of Mfrs.*, 989 F.3d at 383.

To satisfy this requirement, a final rule need not be identical to the proposed rule that preceded it. But the proposed rule must have provided "fair notice" of any potential change, such that "interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Id.* at 381 (quoting *Am. Coke & Coal Chemicals Inst. v. EPA*, 452 F.3d 930, 938-39 (D.C. Cir. 2006)). The notice-and-comment requirement is satisfied in such circumstances because the final rule is deemed the "logical outgrowth" of the proposed rule. *Id.* at 381-82.

In cases involving a "change[] in the justification for the Proposed Rule and the justification for the Final Rule," the Court asks whether the new justification was "made clear and subjected to public comment." *Id.* at 382. Thus, if the agency wishes to base the final rule on a new justification, the agency must issue a notice "mak[ing] clear it [is] inviting comments on [that] new justification" *before* issuing the final rule. *Id.* at 382-83. If the agency fails to do so, the final rule has been promulgated "without observance of procedure required by law," and must be set aside. 5 U.S.C. § 706(2)(D).

B. The District Court Correctly Concluded That CMS Failed to Provide Clear Notice of Its New Rationale

Applying *Texas Association of Manufacturers*, the district court correctly held that the Final Rule was procedurally invalid because it did not make CMS's "intention to switch justifications 'clear and subjected to public comment.'" ROA.26923.

As the district court noted, the Final Rule expressly relied on two justifications for not applying an FFS Adjuster to extrapolated RADV audit recoveries: (1) that the Medicare statute's actuarial-equivalence requirement does not apply to RADV audits, "consistent with [the] *UnitedHealthcare*" decision on the Overpayment Rule; and (2) that the Coding-Intensity Adjustment forecloses the use of an FFS Adjuster. ROA.26920; *see* ROA.17070. And as the district court further observed, the government did not and could not assert that the Proposed Rule provided adequate

notice of the Coding-Intensity Adjustment rationale, ROA.26920, a conclusion that Appellants do not contest on appeal, AOB 19 n.1. Thus, the Final Rule could pass procedural muster under the APA only if the agency provided clear notice of the Final Rule's first justification—that the actuarial-equivalence requirement does not apply as a matter of law to RADV audits. The district court properly concluded that CMS did not provide the required clear notice.

The Proposed Rule articulated two *different* justifications for not applying an FFS Adjuster to extrapolated RADV audit recoveries: (1) the FFS Adjuster study, which according to CMS showed that "diagnosis error in FFS claims data does not lead to systematic payment error in the MA program," ROA.1251; and (2) CMS's "finding that it would be inequitable to correct the payments made to audited plans but not to non-audited plans," ROA.26916. The study purported to show that the inconsistent documentation standards implicated by extrapolated RADV audits did not, as an empirical matter, result in systematic underpayments to MAOs. It said nothing about whether the Medicare statute's actuarial-equivalence provision applies to RADV audits; in their brief, Appellants do not contend otherwise.

And as the district court correctly found, the second rationale in the Proposed Rule—about inequities between audited and unaudited MA plans—did "not give the reader any indication that CMS" was considering an announcement that the Medicare statute's actuarial-equivalence provision does not apply to RADV audits.

ROA.26922. After all, that rationale concerned equity "between . . . MAOs," whereas actuarial equivalence involves the relationship between an individual MAO and fee-for-service Medicare rates. ROA.26922 n.25.

The district court also correctly concluded that the agency's supplemental notice requesting comment on 42 U.S.C. § 1395w–23(a)(1)(C)—which contains the actuarial-equivalence requirement—did not "alert the reader to the fact that CMS was considering abandoning" the justifications articulated in the Proposed Rule in favor of a "finding that actuarial equivalence does not apply." ROA.26923. Indeed, as the district court explained, ROA.26923, CMS's request for comment signaled that it believed that § 1395w–23(a)(1)(C) *was* applicable to RADV audits, consistent with the agency's longstanding acknowledgment that an FFS Adjuster was required to ensure payment accuracy for audited MAOs and its previous statements that RADV audits "*further* actuarial equivalence."[8] That impression is further confirmed by the fact that the Final Rule rested its new statutory analysis on *UnitedHealthcare*, which was decided two years after CMS's supplemental notice and "after the comment period closed." ROA.26924 n.31. CMS's failure to provide clear notice of its changed justification undeniably hamstrung Humana's comments on the

[8] 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) (emphasis added).

Proposed Rule, which could observe only that the agency had provided no analysis of how the Proposed Rule "could possibly satisfy" the actuarial-equivalence requirement. *See* ROA.283. The district court thus correctly applied this Court's precedent that "merely informing the public, in a generic sense, of the broad subjects and issues the Final Rule would address is insufficient." *Mock v. Garland*, 75 F.4th 563, 584 (5th Cir. 2023).

The district court's reasoning faithfully applied *Texas Association of Manufacturers*. There, as here, the agency abandoned its original technical justification for a proposed rule when that justification was called into question. *See* 989 F.3d at 382. This Court held that the agency violated the APA's notice-and-comment requirement because it relied on a different justification—which was never before "clearly communicated as a new justification"—to finalize the rule. *Id.* at 382-83. That is precisely what happened here—CMS abandoned its empirical study and pivoted to purely legal justifications in the Final Rule when the overwhelming actuarial and statistical evidence presented by commenters discredited the study and showed conclusively that the facts failed to support the agency's preferred policy outcome. Because the agency never "ma[d]e clear that it was inviting comments" on a "new justification" for the Final Rule, *id*. at 383, the district court properly concluded that under *Texas Association of Manufacturers*, CMS failed to provide

adequate notice of its new justification for reversing the agency's long-standing policy favoring a FFS Adjuster, ROA.26924.

C. Appellants' Attempts to Sidestep the APA's Clear Notice Requirement Are Unavailing

1. *The APA's Notice-and-Comment Requirement Applies to Non-Technical Rationales*

Appellants concede, as they must, that *Texas Association of Manufacturers* is binding law in this Circuit. AOB 25. They nevertheless argue that the APA's notice requirements generally do not apply to an agency's articulation of a rule's rationale. *See id.* at 22-29. In Appellants' view, this Court's holding that an "agency's rationale for [a] rule must be made clear and subjected to public comment," *Tex. Ass'n of Mfrs.*, 989 F.3d at 382, applies *only* to justifications based on previously undisclosed "technical data or studies." *See* AOB 24-26. Thus, they appear to argue that a proposed rule can provide insufficient notice under the APA in only two circumstances: (i) where the substantive requirements of the final rule differ from those of the proposed rule, *see id.* at 23-24; and (ii) where the final rule relies on "undisclosed technical data or studies," *id.* at 28.

This argument fails at the outset because Appellants never raised it below. In their consolidated opposition to Humana's motion for summary judgment and opening brief in support of their cross-motion for summary judgment, Appellants never argued that *Texas Association of Manufacturers* did not apply in this case or

that CMS had no obligation to make its "rationale for the rule" "clear and subjected to public comment" as that case requires; instead, they argued only that CMS satisfied the test announced in *Texas Association of Manufacturers* and that any procedural error was harmless. *See* Dist. Ct. Dkt. No. 62 at 44-46.

In their reply in support of their cross-motion for summary judgment, Appellants appeared to argue for the first time that *Texas Association of Manufacturers* stood for the narrow proposition that "an agency must notify the public of the factual basis on which it proposes to exercise its regulatory discretion," not CMS's statutory interpretation. Dist. Ct. Dkt. No. 74 at 27. But even then, Appellants nowhere suggested, as they do on appeal, that the APA's notice-and-comment requirements simply do not apply to an agency's non-technical rationales. As a result, the district court's opinion nowhere addressed that contention. Appellants have thus forfeited that argument. *See, e.g.*, *Rollins v. Home Depot USA*, 8 F.4th 393, 397 (5th Cir. 2021) ("A party forfeits an argument by failing to raise it in the first instance in the district court . . . ."); *Lifemark Hosps., Inc. v. Liljeberg Enters., Inc. (In re Liljeberg Enters., Inc.*), 304 F.3d 410, 427 n.29 (5th Cir. 2002) (to preserve argument for appeal, party must brief argument "before the district court" in a manner "sufficient to permit the district court to rule on it").

In any event, Appellants' attempt to rewrite this Court's precedent fails. The agency at issue in *Texas Association of Manufacturers* violated the APA because it

"changed its primary justification for the rule" but did not "clearly communicate[]" its "new justification" or "make clear it was inviting comments on the . . . new justification" before issuing the Final Rule. 989 F.3d at 382-83. Although it is true that the new rationale at issue in *Texas Association of Manufacturers* involved data, nothing in the opinion suggests that the Court's reasoning turned on that fact, or that the Court's holding was limited to justifications involving undisclosed data or technical analysis. Rather, the Court held that an "agency's rationale for [a] rule must be made clear and subjected to public comment," full stop. *Id.* at 382.

Appellants cite no case establishing their supposed rule that the APA's notice-and-comment requirement applies only to technical justifications. Rather, they rely on two treatises, neither of which supports any such rule. *See* AOB 23-25 (citing 1 Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 5.3 (7th ed. 2024), and 32 *Wright & Miller's Federal Practice & Procedure* § 8183 (2d ed.)). The first treatise states that the "vast bulk of challenges to the adequacy of agency notices of proposed rulemaking" fall into the two categories identified by Appellants—(1) where the final rule's substantive requirements differ from the proposed rule and (2) where the final rule relies on previously undisclosed technical data. 1 Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 5.3 (7th ed. 2024). The treatise nowhere states or even implies that these two categories are exclusive. The second treatise identifies the same "two lines of

judicial precedent" but similarly does not suggest that those cases represent the *only* situations in which the notice provided in a proposed rule is deemed inadequate under the APA. 32 *Wright & Miller's Federal Practice & Procedure* § 8183 (2d ed.).

Nor do Appellants endeavor to explain *why* rationales involving technical data would be subject to the APA's notice-and-comment requirements, but non-technical justifications would be excused. That proposition is inconsistent with the very purpose of the APA, which requires agencies to "disclose in detail the thinking that has animated . . . a proposed rule," thereby "mak[ing] its views known to the public in a concrete and focused form so as to make criticism . . . possible." *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977). The entire point of the APA's notice requirement is to provide the public with an "accurate picture of the reasoning that has led the agency to the proposed rule," so that interested parties can "comment meaningfully" by "communicat[ing] information, concerns, and criticisms to the agency during the rule-making process" in a collective effort to improve policy outcomes. *Conn. Light & Power Co. v. Nuclear Reg. Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982). And the final rules that are eventually promulgated must indicate the "significant issues faced by the agency" and the "rationale of their resolution," so as to disclose "what major issues of policy were ventilated . . . and why the agency reacted to them as it did"—a requirement that cannot be satisfied if the agency's reasoning was never "ventilated" through the notice-and-comment process. *Home*

Box Off., 567 F.2d at 36 (quoting *Auto. Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1967)).

The agency's rationales for a rule may involve technical data or studies, the agency's non-technical views on policy or law, or some combination. The APA's notice requirement can provide an "accurate picture" of the agency's "reasoning"—thereby allowing interested parties to "comment meaningfully"—only if it applies to both technical and non-technical justifications. *Cf. Little Sisters of the Poor Saints Peter & Paul Home v. Pa.*, 591 U.S. 657, 686 (2020) (agencies satisfied notice-and-comment requirements because proposed rules requested comment on the "basis for the [agencies'] legal authority" and the "rationales for the [rules]"). Adopting Appellants' cramped reading of *Texas Association of Manufacturers* would allow agencies to simply dodge unfavorable facts, rather than account for them. In their brief, Appellants offer no explanation for why Congress would have endorsed such a perverse legislative outcome. And as other courts have recognized, a "novel" legal interpretation is precisely the sort of agency decision making that a regulated industry must be given a chance to address during the rulemaking process. *Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1274-75 (D.C. Cir. 1994) (agency failed to give adequate notice of new interpretation of "public water system"). There is no good reason—legal or normative—to retrospectively limit the holding of *Texas Association of Manufacturers*.

Appellants also suggest that applying the logical-outgrowth test to a rule's justifications is inconsistent with *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158 (2007). AOB 27, 29. But Appellants overread that case. There, the agency's proposed rule included an exception to the regulation that its final rule ultimately did not adopt. *Long Island Care at Home*, 551 U.S. at 174-75. The Supreme Court held that the agency provided adequate notice of the change, reasoning that the exception's presence in the proposed rule meant the agency "might choose . . . to withdraw it." *Id.* at 175.

Appellants contend that under *Long Island Care at Home*, the APA's notice-and-comment requirement does not apply to rationales at all because the Supreme Court "did not suggest that the proposed rule needed to provide notice of the explanation the agency gave in the final rule." AOB 27. But as the opinion makes clear, the Court never had reason to address that issue and thus never endorsed such a sweeping proposition. The regulation at issue in *Long Island Care at Home* interpreted a statutory provision exempting from minimum-wage rules "any employee employed in domestic service employment to provide companionship services for individuals . . . unable to care for themselves." 551 U.S. at 161-62 (quoting 29 U.S.C. § 213(a)(15)). Although the agency considered a regulation that would carve out certain workers employed by third-party agencies from the statutory exemption, the agency ultimately decided against the carveout. *Id.* at 174-75.

In the final rule, the agency stated that eliminating the carveout was "more consistent" with the statutory language, which extended the exemption to "any employee" engaged in the enumerated services. *Id.* at 175. Unlike here, though, no one argued that commenters were deprived of the opportunity to comment on *the explanation*, just that the agency adopted an impermissible substantive change. *See* Resp't's Br., *Long Island Care at Home, Ltd. v. Coke*, 2007 WL 930417, at *46-47 (Mar. 27, 2007) (arguing that notice was defective because the final rule was the inverse of the proposed rule, and that the new interpretation was contrary to statute and thus not entitled to *Chevron* deference). The Court held that the agency's decision not to adopt its proposal was foreseeable. *See Long Island Care at Home*, 551 U.S. at 175. As to the explanation itself, the parties only disputed whether it satisfied the APA's arbitrary and capricious standard—and so the Court, unsurprisingly, reached only that issue, finding the explanation was "reasonable, albeit brief." *Id.*

Here, by contrast, CMS's shifting justifications themselves were unforeseeable. Unlike in *Long Island Care at Home*, nothing in the Proposed Rule or CMS's later request for comment indicated that the agency was considering adopting the statutory interpretation on which it ultimately relied in the Final Rule. Rather, "after commenters poked many holes in the replicated study, CMS abandoned it entirely when promulgating the Final Rule," ROA.26916 n.3, instead

proffering brand new legal justifications for the same discredited policy. *Long Island Care at Home* in no way suggests that an agency is free to unforeseeably "change[] its primary justification for [a] rule" without seeking comment on the new justification, as CMS did here. *Tex. Ass'n of Mfrs.*, 989 F.3d at 383.[9]

2. *Appellants' Cherry-Picked Statements from the Proposed Rule Do Not Establish the Requisite Clear Notice*

In the alternative, Appellants argue that both the Proposed Rule and CMS's request for additional comment gave the public sufficient notice that CMS might conclude that the Medicare statute's actuarial-equivalence provision "does not limit or bear on RADV audit recoveries." AOB 29-34. But as the district court correctly recognized, these arguments wrench CMS's statements from their context and distort them in an attempt to support the Final Rule. ROA.26923-24. Upon even cursory inspection, none of these statements comes close to providing the clear notice of CMS's eventual rationale that is required by *Texas Association of Manufacturers*.

Appellants first point to the following passage in the Proposed Rule, ROA.10458:

[9] Appellants do not acknowledge, much less reconcile, the obvious inconsistency between their interpretations of *Long Island Care at Home* and *Texas Association of Manufacturers*. Their reading of *Long Island Care at Home*—that a proposed rule need not "provide notice of the explanation the agency gave in the final rule," AOB 27—would necessarily mean that *Texas Association of Manufacturers*, which they admit required such an explanation, *see id.* at 25-26, was wrongly decided.

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

Appellants, though, noticeably omit the last sentence of the paragraph, which concludes: "Doing so would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans." ROA.10458; *see* AOB 30.

Appellants argue that the rationale in the block-quoted passage was "identical" to the rationale on which CMS relied in the Final Rule, which they characterize as follows: "even if . . . payment rates [a]re too low, payment-accuracy concerns do not bear on RADV audits, which are instead intended to recover payments to which MAOs are not entitled because they were made based on diagnoses unsupported by medical records." AOB 31-32.

But as the district court astutely noted, "context is important," ROA.26921, and "courts regularly reject the cherry picking of sentences to satisfy the notice requirements of the APA," ROA.26922 n.23. Appellants ignore these admonitions.

To begin, they mischaracterize CMS's rationale for the Final Rule. That rationale was not simply that "payment-accuracy concerns do not bear on RADV audits," AOB 31, which is a *factual* conclusion, albeit an erroneous one. The Final Rule's justification was instead a *legal* conclusion that the statutory requirement of actuarial equivalence does not apply to RADV audits. Throughout the Final Rule, CMS repeatedly explained that this legal conclusion was the "first basis for [its] decision" not to apply an FFS Adjuster. ROA.17082; *see also* ROA.17070, 17084, 17086. Nothing about the cited passage from the Proposed Rule prefigures that legal conclusion or so much as mentions the statute's actuarial-equivalence requirement—much less "make[s] clear [CMS] was inviting comments on the" legal rationale on which it ultimately relied. *Tex. Ass'n of Mfrs.*, 989 F.3d at 383.

Appellants also mischaracterize the Proposed Rule's justifications. The omitted concluding sentence of the paragraph upon which they rely—and the rationale on which CMS relied in the Proposed Rule—was that applying an FFS Adjuster would supposedly "introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans." ROA.10458. And lest there be any doubt, the *very next paragraph* summarized the two rationales that CMS offered in the Proposed Rule for not including an FFS Adjuster: "Because our study suggests that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program *and because we believe it would be inequitable to*

correct any systematic errors in the payments made to audited plans only, we would not include an FFS Adjuster in any RADV extrapolated audit methodology." ROA.10458 (emphasis added). CMS's prefatory comments supporting that conclusion cannot suffice to satisfy its burden to "make clear it was inviting comments on" the foundational legal assertion that the Medicare statute's actuarial-equivalence requirement does not apply to RADV audits. *Tex. Ass'n of Mfrs.*, 989 F.3d at 383.

For similar reasons, it is irrelevant that certain passages in the Final Rule referred to the "inequity" rationale from the Proposed Rule. *See* AOB 36. The Final Rule referred to that rationale three times—twice while summarizing the Proposed Rule, *see* ROA.17082, 17086, and once while responding to public comments that not applying an FFS Adjuster would disadvantage audited plans, *see* ROA.17083. But the Final Rule relied on CMS's legal conclusions about the statute's actuarial-equivalence requirement and the Coding-Intensity Adjustment—not the "inequity" rationale—to justify not applying an FFS Adjuster in extrapolated RADV audits. *See* ROA.17070.

Other passages from the Proposed Rule and Final Rule underscore CMS's defective notice. The agency asserted repeatedly in the Final Rule that the actuarial-equivalence provision "applies only to how CMS risk adjusts the payments it makes to MAOs" in the first instance, and not to RADV audit recoveries. ROA.17070,

17082, 17084. But in the Proposed Rule, CMS rested its decision on a factual conclusion that there was no "systematic effect on the risk scores calculated by the CMS-HCC model," and thus no "systematic effect on the payments made to MA organizations." ROA.10457. If anything, this justification in the Proposed Rule confirmed to commenters that the agency *agreed* that it was obligated to satisfy the actuarial-equivalence requirement—otherwise, there was no reason for CMS to invest the considerable time and money to produce a study that supposedly demonstrated compliance. That inference was particularly strong given CMS's previous recognition in its 2012 public notice that the FFS Adjuster would "account[] for" the difference between "the documentation standard used in RADV audits to determine a contract's payment error (medical records)" and "the documentation standard used to develop the Part C risk-adjustment model (FFS claims)." ROA.8223-24.

Appellants attempt to muddy the waters by asserting that references to "systemic payment error" and "payment accuracy" in the Proposed Rule should be understood as implicitly referring to the statute's actuarial-equivalence requirement. AOB 32. But while the three terms are sometimes related, they are not synonymous. Generic references to payment "error" and "accuracy" did not provide clear notice that CMS was considering adopting a new legal position that the Medicare statute's actuarial-equivalence provision does not apply to RADV audits at all. *Cf. Am. Water*

Works Ass'n, 40 F.3d at 1274-75 (agency's reference to "control" of water pipes in proposed rule did not sufficiently foreshadow final rule's adoption of broad, "novel definition" that extended to third-party infrastructure).

The comments that CMS received on the Proposed Rule confirm the agency's procedural default. In comment after comment, Humana and other industry participants focused on the validity and efficacy of the study on which CMS relied in its Proposed Rule. *See, e.g.*, ROA.4215-62. And while some commenters repeated the widely accepted understanding that the actuarial-equivalence provision applies to RADV audits, they almost invariably did so in passing while arguing that failing to apply an FFS Adjuster would *violate* actuarial equivalence. *See, e.g.*, ROA.2081-82. Of course, none addressed the Final Rule's statutory analysis because CMS never articulated it. Thus, even after the agency's request for additional comment in 2019, interested parties were demonstrably unaware that CMS was "chang[ing] its primary justification" for the rule. *Tex. Ass'n of Mfrs.*, 989 F.3d at 383; *see* ROA.2101 (commenter noting that CMS had not "advanc[ed] a statutory interpretation" in its supplemental request for comment).[10]

[10] Even if some commenters had been able to "divine" the agency's "unspoken thoughts," which they clearly did not, that would not mean the agency satisfied its obligation to provide fair notice. *Mexican Gulf Fishing Co. v. U.S. Dep't of Commerce*, 60 F.4th 956, 975 (5th Cir. 2023) ("These comments show only that a few members of the public happened to 'divine' the Government's 'unspoken thoughts.'") (citation omitted); *see also Tex. Ass'n of Mfrs.*, 989 F.3d at 383 ("The

II. Appellants' New Reliance on the Medicare Statute's Notice-and-Comment Requirement Is Both Forfeited and Immaterial

For the first time in this litigation, the government on appeal now argues that the Medicare statute supplies the required legal framework for judicial review of the agency's compliance with the procedural requirements for notice-and-comment rulemaking. *E.g.*, AOB 28. Appellants further argue that the Medicare statute's logical-outgrowth requirement, 42 U.S.C. § 1395hh(a)(4), is narrower in scope than the APA's logical-outgrowth test. *See id.*[11] Appellants contend that the Final Rule satisfied § 1395hh(a)(4) because the text of the actual regulation did not change from the Proposed Rule and § 1395hh(a)(4) did not require CMS to provide notice of its reasoning in the Final Rule. *Id.* at 28-29.

In their brief, Appellants leave unspoken the true implications of this novel argument. To sustain the Final Rule on this basis, this Court would have to hold that, in adopting § 1395hh(a)(4), Congress intended to impose a lesser notice-and-

---

fact that one commenter suggested that data above the 95th percentile is too unstable for rulemaking does not relieve the Commission of its burden to provide notice and an opportunity to comment on the clearly articulated justification for its use of such data.").

[11] Section 1395hh(a)(4) provides in full: "If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation."

comment obligation for rulemaking in the Medicare program than is required by the APA and that, if CMS satisfies that lesser standard, the agency is relieved of complying with the APA's more demanding requirements. Appellants offer no evidence suggesting that Congress intended such an extraordinary result. They cite no case endorsing this argument, and Humana's own research has identified none. As with their new gloss on the APA, Appellants forfeited this argument by failing to raise it before the district court, and it is meritless in any event.

A. Appellants Forfeited Any Argument Based on the Medicare Statute's Notice-and-Comment Procedures by Failing to Raise It Before the District Court

To preserve an argument for appeal, the argument must have been raised "before the district court" in a manner "sufficient to permit the district court to rule on it.'" *Lifemark*, 304 F.3d at 427 n.29; *see also Rollins*, 8 F.4th at 397 ("A party forfeits an argument by failing to raise it in the first instance in the district court—thus raising it for the first time on appeal . . . .").

Appellants never point this Court to a record citation where they relied in the district court on § 1395hh(a)(4) because no such citation exists. The government did not cite that statute in its answer or in its motion to dismiss. Nor did the government rely on § 1395hh(a)(4) in summary judgment briefing, even though the parties briefed the "logical outgrowth" issue extensively. On the contrary, the government relied exclusively on the APA. *See* Dist. Ct. Dkt. No. 62 at 44. Having

chosen to deny the district court the opportunity to consider their § 1395hh(a)(4) argument, Appellants cannot now present that argument in this Court.

B. Appellants' New Argument Would Not Change the Result

Even if the Court were to consider Appellants' new argument, it changes nothing, for three distinct reasons.

First, every court to have considered the issue has found that § 1395hh(a)(4) codifies within the Medicare statute the APA's *existing* logical-outgrowth test. *See Stringfellow Mem'l Hosp. v. Azar*, 317 F. Supp. 3d 168, 185 n.6 (D.D.C. 2018) ("As relevant to this dispute, the requirements of the APA and the Medicare Act are substantially similar [under § 1395hh(a)(4)]. . . . Thus, the conclusions reached on the APA claim are equally applicable to the Medicare Act claim."); *Empire Health Found. for Valley Hosp. Med. Ctr. v. Azar,* 958 F.3d 873, 882-83 (9th Cir. 2020) ("The key inquiry is whether the changes in the final rule are a 'logical outgrowth of the notice and comments received.' The Medicare statute echoes this standard[.]"), *rev'd on other grounds sub nom. Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 597 U.S. 424 (2022).[12] Indeed, Appellants concede that "[t]he [Medicare]

[12] In other contexts, courts have similarly noted that, because "the Medicare Act was drafted after the APA," it "places notice and comment requirements on the Secretary's substantive rulemaking similar to those created by the APA." *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001); *see Clarian Health W., LLC v. Burwell*, 206 F. Supp. 3d 393, 408 (D.D.C. 2016) (Jackson, J.) ("courts use the APA's standards" for evaluating Medicare Act notice-and-comment

statute's 'logical outgrowth' language refers to case law developed under the APA," AOB 23, and they rely exclusively on APA cases in their brief, *id.* at 23-27, 29, 31.

That concession is consistent with the Final Rule itself. When commenters pointed out that "the RADV provisions violated the Administrative Procedure[] Act (APA) due to the disclosure of insufficient methodology or data to support these policies," ROA.17084-85, CMS did not respond that the APA was inapplicable or that § 1395hh(a)(4) furnished a materially different test. Instead, the agency simply argued that "[t]he data and methodology we disclosed should sufficiently allow for stakeholders to evaluate and comment." ROA.17084-85.

Second, § 1395hh(a)(4) does not lessen the APA's otherwise-applicable requirement that CMS provide sufficient notice of its policy rationales. Rather, it constrains the agency's authority to act once any "provision" of a final rule violates the APA's logical-outgrowth test, regardless of whether commenters were prejudiced by the violation. 42 U.S.C. § 1395hh(a)(4). Any such provision "shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation."

---

claims because "the Medicare statute's notice-and-comment rulemaking requirements are substantially similar to those of the APA"), *rev'd on other grounds sub nom. Clarian Health W., LLC v. Hargan*, 878 F.3d 346 (D.C. Cir. 2017). Congress adopted the Medicare statute's requirements to ensure that "notice and comment . . . become a matter not merely of administrative grace, but of statutory duty." *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019).

Id. "In other words . . . that provision may not become legally operative until it has gone through notice and comment rulemaking." *Allina Health Servs. v. Price*, 863 F.3d 937, 945 (D.C. Cir. 2017) (Kavanaugh, J.) (holding that, after the court vacated a 2004 rule under the logical-outgrowth doctrine, the agency violated § 1395hh(a)(4) by reimposing the rule without further comment); *see also Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109 (D.C. Cir. 2014) (§ 1395hh(a)(4) eliminates the APA's harmless error exception for a notice-and-comment violation).

Thus, even under Appellants' cribbed understanding of "provision," which they limit to "the text of a regulation," AOB 26, the point of § 1395hh(a)(4) was to make notice-and-comment procedures under the Medicare statute *more* rigorous, not less, by ensuring that regulatory text that was not the logical outgrowth of a proposed rule could not "take effect" even if the error was harmless.[13] That statutory reference in no way suggests, as Appellants contend, that Congress intended to license CMS to withhold public notice of the agency's reasoning that would otherwise be required under the APA. Notably, in their brief, Appellants cite no case adopting their proffered interpretation of § 1395hh(a)(4). This Court should reject their bid to read the statute's run-of-the-mill reference to the word "provision" as mandating such an

[13] The Medicare statute is also more procedurally rigorous than the APA in that it imposes a longer minimum comment period and applies notice-and-comment requirements to interpretive rules. *Allina*, 587 U.S. at 570, 573-79.

"absurd or unreasonable result." *United States v. Female Juv.*, 103 F.3d 14, 16-17 (5th Cir. 1996).

Third, Appellants' interpretation of § 1395hh(a)(4) is unpersuasive on its own terms. They cite solely *Black's Law Dictionary* to support their theory that "the text of a regulation is a 'provision' of that regulation," but other parts of the Final Rule are not. AOB 26. To begin, the dictionary's definition—"[a] clause in a statute, contract, or other legal instrument"—equally applies to the entire Final Rule, which is by any understanding a "legal instrument." *Provision*, Black's Law Dictionary (12th ed. 2024). Other dictionaries similarly suggest that any portion of the Final Rule could be correctly termed a "provision." *See Provision (n.)*, Oxford English Dictionary (2007 ed.) (def. 5) ("[e]ach of the clauses or divisions of a legal or formal statement; a legal or formal statement providing for some particular matter").[14]

Nor do Appellants cite any legislative history of § 1395hh(a)(4) to corroborate that Congress intended for the term "provision" to carry the significant weight that Appellants urge. Had Congress intended for the term "provision" to encompass the regulatory text and nothing else, it is reasonable to expect evidence of that design in the legislative record—which, if anything, suggests the opposite. *See* H.R. Rep. No.

[14] https://www.oed.com/dictionary/provision_n?tab=meaning_and_use.

108-74, pt. 1 at 38-39 (2003)[15] (explaining that the bill would "provide protections for beneficiaries and providers by requiring *new matter* introduced in a final rule that is not a logical outgrowth of previously published *material* to be treated as a proposed regulation until there is public comment") (emphasis added); *id.* at 41-42 (statute applies to a "rulemaking document").

To the extent Appellants' actual argument is that CMS did not change its substantive policy on the FFS Adjuster between the Proposed Rule and the Final Rule, that makes even less sense, as the regulatory text does not refer to an FFS Adjuster at all. *See* ROA.10459 (Proposed Rule), ROA.17091 (Final Rule). Yet CMS undisputedly adopted a new policy abandoning the FFS Adjuster. *See* ROA.10458 ("[W]e propose not to include an FFS Adjuster in any final RADV payment error methodology."), ROA.17070 ("We are also finalizing a policy whereby CMS will not apply an FFS Adjuster in RADV audits[.]"). It cannot plausibly be correct that CMS can avoid APA review by simply announcing a new policy decision in a final rule rather than regulatory text, and again Appellants offer no persuasive authority for such a formalistic conclusion.

[15] https://www.congress.gov/committee-report/108th-congress/house-report/74/1.

CONCLUSION

For the foregoing reasons, this Court should affirm the judgment of the district court.

Date: May 20, 2026 Respectfully submitted,

By: */s/ K. Lee Blalack II*

K. Lee Blalack II
O'MELVENY & MYERS LLP
1625 Eye Street, N.W.
Washington, D.C. 20006
[Tel.] (202) 383-5300
[Fax] (202) 383-5414
lblalack@omm.com

Timothy S. Durst
O'MELVENY & MYERS LLP
2501 N. Harwood Street, Suite 1700
Dallas, Texas 75201
[Tel.] (972) 360-1900
[Fax] (972) 360-1901
tdurst@omm.com

Stephen M. Sullivan
Jonathan P. Schneller
Elizabeth M. Bock
Heather Welles
O'MELVENY & MYERS LLP
400 S. Hope Street, 19th Floor
Los Angeles, California 90071
[Tel.] (213) 430-6000
[Fax] (213) 430-6407

ssullivan@omm.com
jschneller@omm.com
ebock@omm.com
hwelles@omm.com

Jennifer B. Sokoler
O'MELVENY & MYERS LLP
1301 Avenue of the Americas, 17th Floor
New York, New York 10019
[Tel.] (212) 326-2000
[Fax] (212) 326-2061
jsokoler@omm.com

David Deaton
O'MELVENY & MYERS LLP
Two Embarcadero Center, 28th Floor
San Francisco, California 94111
[Tel.] (415) 984-8700
[Fax] (415) 984-8701
ddeaton@omm.com

Counsel for Plaintiffs-Appellees

CERTIFICATE OF SERVICE

This is to certify that the foregoing instrument has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure, on May 20, 2026, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

/s/ K. Lee Blalack II

K. Lee Blalack II

CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limit and the word limit of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 12,637 words.

This document complies with the typeface requirements of Fed. R. App. P. 32(a)(7)(B)(i) and Fed. R. App. P. 32(a)(5), and the type-style requirements of Fed. R. App. P. 32(a)(6), because this document has been prepared in a proportionally spaced typeface using Microsoft Word in size 14 point font in Times New Roman.

/s/ K. Lee Blalack II

K. Lee Blalack II

Counsel for Plaintiffs-Appellees