No. 25-11293

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

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

REPLY BRIEF FOR APPELLANTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulation:

Other Authorities:

INTRODUCTION AND SUMMARY OF ARGUMENT

1. Humana asks this Court to take the unprecedented step of striking down an entire rule solely because reasoning in the preamble to the final rule purportedly was not a logical outgrowth of the preamble to the proposed rule. But even now, Humana cannot identify any decision of any court vacating a rule on that ground. This Court should decline Humana's invitation to be the first to do so, which would dramatically expand the logical-outgrowth doctrine in contravention of both the Medicare statute and the Administrative Procedure Act (APA).

Notice-and-comment rulemaking in the Medicare program is governed by express provisions of the Medicare statute. By its plain text, the statutory clause governing logical outgrowth applies only to a "provision" of a "regulation." Humana's argument that courts can nevertheless apply the logical-outgrowth test to reasoning in a preamble contradicts the common understanding of those terms and would produce nonsensical results. Case law applying the logical-outgrowth standard under the APA, where the concept originated, recognizes the same distinction; the D.C. Circuit expressly rejected a similar request to extend the logical-outgrowth standard to agency reasoning in a preamble. This Court should accordingly decline Humana's invitation to depart from the statutory text. *Texas Ass'n of Manufacturers v. U.S. Consumer Product Safety Commission*, 989 F.3d 368 (5th Cir. 2021), applies the separate requirement that agencies disclose critical

data and methodologies. That case should not be read to mark an unprecedented expansion of the logical-outgrowth doctrine without any supporting discussion or analysis.

Humana's invocation of forfeiture to avoid the correct legal standard is unavailing. The government argued to the district court, in its reply in support of summary judgment, that the logical-outgrowth standard did not apply to the agency's reasoning about the actuarial-equivalence requirement. The district court accepted Humana's position on the merits, so the issue is squarely before this Court. Moreover, this antecedent and purely legal question concerns the proper construction of the statute to be applied in this case, and it would be a miscarriage of justice to affirm the vacatur of an entire rule based on a legal standard that does not apply. This Court therefore can and should determine for itself the correct legal standard to apply.

2. Even if this Court applies the logical-outgrowth standard to the reasoning in the preamble to the Final Rule, the Centers for Medicare & Medicaid Services (CMS) gave more than sufficient notice of that reasoning. In both the Final Rule and the Proposed Rule, CMS explained that concerns about actuarial equivalence do not bear on recoveries in Risk Adjustment Data Validation (RADV) audits, which are only intended to enforce the medical-record documentation requirement by recovering invalid payments; it was therefore

inappropriate to limit audit recoveries to address underpayment concerns. Humana's response mischaracterizes the Proposed Rule's analysis by reducing it to a single point about inequities between plans, but inclusion of that point in the Proposed Rule does not diminish the notice given by the rest of CMS's analysis.

In addition to informing the public that it intended not to limit audit recoveries to address payment-accuracy concerns, the agency also sought additional comment specifically on whether the actuarial-equivalence requirement should inform that proposal. If any commenters believed that the actuarial-equivalence requirement applied to RADV audits and required CMS to limit recoveries to address systematic payment error, CMS's position would necessarily be unlawful under their view. Those commenters therefore had sufficient notice to submit comments contending that, contrary to CMS's position, the actuarial-equivalence requirement obligates CMS to limit RADV audit recoveries to address any systematic payment error. That notice is all the logical-outgrowth doctrine requires.

ARGUMENT

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

A. The Medicare Statute Does Not Permit Vacatur of a Rule on the Grounds Relied on by the District Court

As the government's opening brief explained, the notice-and-comment requirement Congress established for the Medicare program requires only that the provisions of a final regulation be a logical outgrowth of the proposed rule. Congress did not require that reasoning in the *preamble* to a final rule be a logical outgrowth of the preamble to the proposed rule. That reading is confirmed by decisions applying the logical-outgrowth doctrine in the APA context. Humana's mélange of arguments for avoiding the statute's plain meaning lack merit.

1. The Medicare statute does not apply the logical-outgrowth standard to reasoning in the preamble to a final rule

a. The Supreme Court made clear in *Azar v. Allina Health Services*, 587 U.S. 566 (2019), that rulemaking in the Medicare program is governed by "the notice-and-comment statute Congress drafted specially for Medicare in 1987." *Id.* at 569, 572. That statute provides:

> 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.

42 U.S.C. § 1395hh(a)(4).

The plain meaning of the statute is that a final rule violates this requirement only if a "provision" of the "final regulation"—that is, a clause of the operative regulatory text—is "not a logical outgrowth" of the proposed rule. *Id.*; *see Provision*, Black's Law Dictionary (12th ed. 2024) ("A clause in a statute, contract, or other legal instrument."); 42 U.S.C. § 1395hh(a)(1) (defining "regulations"); *Regulation*, Black's Law Dictionary (12th ed. 2024) ("An official rule or order, having legal force … .").

Reasoning in a preamble to a final rule is not a "provision" of a "final regulation." The D.C. Circuit has held, for example, that "[t]he principles governing interpretation of the preamble of a regulation are no different" than those applicable to the preamble to a statute, and that "'[t]he operative *provisions* of statutes are those which prescribe rights and duties and otherwise declare the legislative will.'" *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999) (emphasis added). In contrast, the "'preamble no doubt contributes to a general understanding of a statute'" but "'is not an operative part of the statute.'" *Id.*; *see also Peabody Twentymile Mining, LLC v. Secretary of Lab.*, 931 F.3d 992, 998 (10th Cir. 2019). The logical-outgrowth requirement therefore does not apply to reasoning in the preamble to a final rule.

b. This textual reading is confirmed by APA cases applying the "logical outgrowth" standard referenced in § 1395hh(a)(4). "The traditional APA 'logical outgrowth' test applies where an agency changes its final regulation in some way from the proposed regulation for which it provided notice and requested comment, as required under the APA." *City of Waukesha v. EPA*, 320 F.3d 228, 245 (D.C. Cir. 2003) (per curiam).

Courts have never understood this test to require that reasoning in the preamble to the final rule be a "logical outgrowth" of the preamble to the proposed rule, and indeed the D.C. Circuit has expressly rejected that argument. The petitioners in *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 509 (D.C. Cir. 2019), argued that "even if the EPA's *decision* not to" ultimately promulgate certain requirements "is a logical outgrowth of the Proposed Rule, its *reasons* for changing course are not." Specifically, the petitioners argued that "the Proposed Rule did not put interested parties on notice that the EPA intended to embrace a new construction of" a statutory term "or to 'dramatically narrow[] the evidence it deemed relevant.'" *Id.* (alteration in original). The D.C. Circuit held that the petitioners' arguments about the agency's changes in reasoning were irrelevant to the logical-outgrowth analysis. Even if the final decision is based on a "changed view of the governing law or underlying facts," "[s]uch a changed view does not

alter whether an agency's decision" not to promulgate requirements from the proposed rule "is a logical outgrowth of the proposal." *Id.*

c. Humana offers no contrary authority. The government's opening brief pointed out (at 26) that Humana had not cited "any decision of any court striking down a rule solely because of differences in how the preambles to the proposed and final rules explained the agency's reasoning, as opposed to a failure to disclose critical technical data or studies." Notably, Humana still cannot identify a single decision to that effect. Humana cites only *Texas Ass'n of Manufacturers v. U.S. Consumer Product Safety Commission*, 989 F.3d 368 (5th Cir. 2021), but as this Court has since recognized, that decision reflects the separate principle that agencies must disclose critical data or methodologies underlying a rule. *See infra* pp. 12-17. Nor is Humana the first litigant that has tried and failed to find support for the district court's approach. Another recent plaintiff similarly sought "to apply the logical-outgrowth doctrine to a change in reasoning behind the rule" but could "cite[] no case in which a court has applied the logical-outgrowth doctrine to an analogous situation." *Center for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 698 F. Supp. 3d 39, 60 (D.D.C. 2023), *aff'd*, 146 F.4th 1144 (D.C. Cir. 2025). Concluding that the plaintiff's argument was "unsupported by caselaw," the district court instead adhered to "the logical-outgrowth doctrine as it is usually formulated: a change in the rule's substance, or

binding legal requirements, from those suggested in the notice of proposed rulemaking." *Id.*

2. Humana cannot evade the correct legal standard on forfeiture grounds

Humana invokes forfeiture (at 36-37, 50-51) to avoid application of the correct legal standard, but the government did raise the issue in the district court, and in any event forfeiture doctrine does not justify vacatur of the Final Rule based on an incorrect legal standard.

a. Humana concedes (at 37) that the government's summary-judgment reply brief argued that *Texas Ass'n of Manufacturers*—Humana's only purported precedent for extending the logical-outgrowth standard to reasoning in a preamble—stood only for "the proposition that an agency must notify the public of the *factual basis* on which it proposes to exercise its regulatory discretion." ROA.10429 (emphasis added). In other words, the government contended that *Texas Ass'n of Manufacturers* merely applies the principle that agencies must disclose critical data and methodologies underlying a rule. *See infra* pp. 12-17. The government further argued that CMS had no "obligation to seek comment on [the] statutory interpretations" in the preamble to the final rule. ROA.10429.

The government therefore argued in the district court that the logical-outgrowth standard does not apply to CMS's reasoning in the preamble about whether the actuarial-equivalence requirement limits RADV audit recoveries. The

district court did not hold that the government forfeited the argument. Instead, the court agreed with Humana on the merits, concluding that *Texas Ass'n of Manufacturers* applied the logical-outgrowth standard to reasoning in preambles to final rules. ROA.26919. The question was therefore "'pressed or passed upon' in the tribunal *a quo*" and is properly before this Court. *Lopez Ventura v. Sessions*, 907 F.3d 306, 311 (5th Cir. 2018).

b. Forfeiture doctrine would not prevent this Court from applying the correct legal standard in any event. "Once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below." *Yee v. City of Escondido*, 503 U.S. 519, 534 (1992). Thus, "[w]hen an issue or claim is properly before the court, the court is not limited to the particular legal theories advanced by the parties, but rather retains the independent power to identify and apply the proper construction of governing law." *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 99-100 (1991). Likewise, "a court may consider an issue 'antecedent to … and ultimately dispositive of' the dispute before it, even an issue the parties fail to identify and brief." *U.S. Nat'l Bank of Or. v. Independent Ins. Agents of Am., Inc.*, 508 U.S. 439, 447 (1993) (alteration in original). This Court has further held that it has "discretion to consider a forfeited issue if 'it is a purely legal matter and failure to consider the issue will result in a miscarriage of justice.'" *Harris v. FedEx Corp.*

Servs., Inc., 92 F.4th 286, 296 (5th Cir. 2024). Similarly, "[f]orfeiture does not apply when the court is interpreting a statute." *Colony Ins. Co. v. Wright ex rel. Wrongful Death Beneficiaries of Wright*, 16 F.4th 1186, 1191-92 (5th Cir. 2021) (Costa, J., concurring). "Put another way, what a lawyer argues cannot change what the legislature wrote." *Id.* at 1192.

In this case, identification of the legal standard applicable to Humana's notice-and-comment claim is a question of statutory interpretation "'antecedent to … and ultimately dispositive of' the dispute before" the Court, *U.S. Nat'l Bank of Or.*, 508 U.S. at 447 (alteration in original), and therefore falls within the Court's "independent power to identify and apply the proper construction of governing law," *Kamen*, 500 U.S. at 99. *See also Djie v. Garland*, 39 F.4th 280, 286 n.3 (5th Cir. 2022) ("[T]he Government cannot forfeit or waive the proper interpretation of the [statute] in this case."). Upholding vacatur of a regulation based on the incorrect legal standard would also result in a "'miscarriage of justice,'" justifying this Court's consideration of a "'purely legal matter'" regardless of any forfeiture. *Harris*, 92 F.4th at 296. That is particularly so because Humana invokes forfeiture to avoid application of the statute the Supreme Court says governs this case—that is, the notice-and-comment provisions of the Medicare statute.

3. Humana's textual argument lacks merit

Humana also misreads the text of the Medicare notice-and-comment requirement. Humana contends (at 54) that reasoning in the preamble to a final rule can itself be a "provision" of a "final regulation" within the meaning of the statute, and therefore that such reasoning is subject to the logical-outgrowth standard. 42 U.S.C. § 1395hh(a)(4). But even if some dictionary definitions of "provision" are capacious enough to encompass any "statement" in other kinds of documents, Humana Br. 54, that interpretation violates common understandings of the statutory terms in the rulemaking context. As discussed, "'[t]he operative *provisions* of'" regulations "'are those which prescribe rights and duties and otherwise declare the legislative will.'" *Wyoming Outdoor Council*, 165 F.3d at 53 (emphasis added); *see supra* p. 5. Reasoning in the preamble to a regulation generally lacks legal effect and does not determine rights or duties, *see Natural Res. Def. Council v. EPA*, 559 F.3d 561, 564-65 (D.C. Cir. 2009), and therefore is not a "provision" of the "final regulation," 42 U.S.C. § 1395hh(a)(4).[1]

[1] Humana mistakenly suggests (at 55) that the government's position would allow CMS to evade review of the omission of a Fee-for-Service Adjuster (FFS Adjuster) because that omission is noted in the preamble and not in the regulation itself. But Humana can obviously challenge a rule on the ground that omission of a requested provision from the regulatory text is arbitrary, capricious, or contrary to law, assuming Humana satisfies other prerequisites for judicial review. Humana has done just that in claims not resolved by the district court.

Humana's interpretation also conflicts with the remainder of § 1395hh(a)(4), which concerns whether the "provision" shall "take effect." Humana's reading would mean that, if reasoning in the preamble is not a "logical outgrowth" of a notice of proposed rulemaking, that portion of the preamble must be "be treated as a proposed regulation" that "shall not take effect" without further notice and comment. 42 U.S.C. § 1395hh(a)(4). But the preamble to a rule already lacks legal effect, and it is nonsensical to "treat[]" a preamble "as a proposed regulation" or have it "take effect" after further comment. That remedy would also provide Humana no effective relief; treating the preamble as a "proposed rule" would not invalidate the provisions of the Final Rule that Humana principally challenges.

4. *Texas Ass'n of Manufacturers* does not require the district court's approach

Humana further errs in arguing (at 31-32) that *Texas Ass'n of Manufacturers* requires this Court to apply the "logical outgrowth" test to reasoning in the preamble to the Final Rule. That decision does not establish the scope of the logical-outgrowth standard under either the Medicare statute or the APA. Instead, the decision embodies a separate line of APA authority holding that agencies must disclose data and data-analysis methodologies critical to the agency's decisions.

As the government's opening brief explained (at 23-25), APA cases hold that an agency fails to give sufficient notice in two circumstances. "The first type of argument is potentially available (and is frequently made) any time a final rule

includes a requirement that differs in some respect from the analogous requirement in the proposed rule or includes a requirement that was not included at all in the proposed rule." 1 Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 5.3.1, at 686 (7th ed. 2024). In such cases, notice is sufficient if the final rule "is a 'logical outgrowth' of the proposed rule." *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021).[2]

The second "line of precedent requires agencies to disclose scientific and technical information that they have relied upon in developing a rule in order to allow effective comments." 32 *Wright & Miller's Federal Practice & Procedure* § 8183 (2d ed.), Westlaw (database updated Apr. 2026); *see, e.g.*, *Airlines for Am. v. U.S. Dep't of Transp.*, 166 F.4th 487, 488 (5th Cir. 2026) (en banc) (per curiam) (accepting concession that agency "violated the APA when it failed to provide additional notice and the opportunity to comment on a study that was 'critical to the Rule's issuance'"). This duty to disclose does not depend on whether the final rule is a "logical outgrowth" of the proposed rule; it applies even if the proposed rule, the final rule, and their preambles are identical. *See infra* pp. 19-20.

Texas Ass'n of Manufacturers falls squarely within this second category. There, the Court held that the public had insufficient notice and opportunity to

[2] *American Water Works Ass'n v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994), on which Humana relies (at 40, 47-48), falls within this category because the agency adopted an interpretation of a statutory term in the final regulatory text.

comment on data and methodologies critical to the rule. The Court described the petitioners as "argu[ing] that the Commission did not provide an adequate opportunity to comment on its use of data at the 99th percentile to justify its prohibition." *Texas Ass'n of Mfrs.*, 989 F.3d at 381. The Court reasoned that the agency "relied on … new data when promulgating the [f]inal [r]ule" and that the agency "did not provide fair notice when it changed its justification for the [final rule] from data showing that the average [hazard index] was greater than one in the 95th percentile to data including individual spot samples with [hazard indexes] greater than one." *Id.* at 382.[3]

The Court has since characterized its decision in precisely this way. In *Airlines for America v. Department of Transportation*, the Court explained that "[a]gencies have a duty … 'to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.'" 127 F.4th 563, 579 (5th Cir.), *vacated per curiam*, 154 F.4th 323 (5th Cir. 2025), *on reh'g en banc per curiam*, 166 F.4th 487 (5th Cir. 2026). This duty exists when an agency makes its original proposal and continues to apply if an agency develops new data that "'supplant[s]' or 'replace[s]'" the original data. *Id.* (alterations in original). The Court then cited

[3] Although the opinion sometimes used "logical outgrowth" language, doing so "confuse[s] the two types of notice deficiencies" because the "logical outgrowth test does not apply to an agency's failure to make" data or methodologies available for comment. *See* 1 Hickman & Pierce, *supra*, § 5.3.2, at 713.

Texas Ass'n of Manufacturers as a decision finding a violation of this duty and remanding to "'afford interested parties an opportunity to challenge the underlying factual data relied upon.'" *Id.* That principle does not apply here because Humana does not claim that CMS failed to disclose any data or methodologies critical to the Proposed Rule or the Final Rule.

c. Humana cites the opinion's statement that an "agency's rationale for [a] rule must be made clear and subjected to public comment," Br. 36 (alteration in original) (quoting *Texas Ass'n of Mfrs.*, 989 F.3d at 382), but there is no indication that the Court intended that language to establish the broad holding Humana seeks. The only authority the opinion cited for that statement was *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1212 (5th Cir. 1991) (per curiam), which held that the agency failed to give adequate notice "as to its intended methodology" of "us[ing] 'analogous exposure' data to calculate the expected benefits of certain product bans." The principal problem in that case was not that any part of the final rule was not a "logical outgrowth" of the proposed rule, but rather that the agency held its intended data analysis "in reserve" rather than disclose it to the public. *Id.* *Corrosion Proof Fittings* therefore falls squarely within the category of cases requiring disclosure of data and methodologies, and there is no reason to believe that the Court in *Texas Ass'n of Manufacturers* misread its prior decision to extend any further than that principle.

Nor does *Texas Ass'n of Manufacturers* suggest that the Court gave any thought to whether the logical-outgrowth standard should apply to all agency reasoning in the preamble to a final rule. If the panel had considered that question, it would at least have had to evaluate how to square such a rule with *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 524 (1978), which held that courts generally may not impose procedural requirements for rulemaking in addition to those required by the text of 5 U.S.C. § 553. *See infra* p. 19.

The panel had no reason to consider or decide the broader question because *Texas Ass'n of Manufacturers* concerned only undisclosed data and methodologies, and the decision should be read accordingly. Both the Supreme Court and this Court have adhered to "Chief Justice Marshall's sage observation that 'general expressions, in every opinion, are to be taken in connection with the case in which those expressions are used.'" *Arkansas Game & Fish Comm'n v. United States*, 568 U.S. 23, 35 (2012). "'If they go beyond the case, they may be respected, but ought not to control the judgment in a subsequent suit when the very point is presented for decision.'" *Id.* For the same reason, even if *Texas Ass'n of Manufacturers* could properly be read to state the broad position Humana proposes, such language would be dicta unnecessary to the Court's judgment. *See United States v. Segura*, 747 F.3d 323, 328-29 (5th Cir. 2014).

If, as Humana argues, *Texas Ass'n of Manufacturers* is the first (and only) decision to hold that the logical-outgrowth test applies to reasons stated in a preamble to a final rule, that decision would squarely conflict with the D.C. Circuit's decision in *Idaho Conservation League*, 930 F.3d at 509. That result would be remarkable given the opinion's lack of discussion or analysis on this point and the D.C. Circuit's dismissal of such a contention as "[k]icking against the goads." *Id.* This Court should decline Humana's invitation to retroactively impute such an anomalous intention to a prior decision.

5. Humana's remaining arguments concerning the legal standard lack merit

Humana asserts (at 38) that "[a]ppellants cite no case establishing their supposed rule that the APA's notice-and-comment requirement applies only to technical justifications." But as discussed above, the D.C. Circuit has expressly rejected the argument that the logical-outgrowth test applies to reasons stated in the preamble to a final rule. *See supra* pp. 6-7.

Moreover, as the cited treatises indicate, the body of case law on this subject reflects a shared judicial understanding regarding the limits of the doctrine. *See supra* p. 13. Thus, for example, the Supreme Court upheld a final rule against a logical-outgrowth challenge in *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007), even though the agency's rationale for the challenged provision—that it was "more consistent" with the statute—never appeared in the notice of

proposed rulemaking. Humana contends (at 41-42) that the parties challenging the regulation never argued that this rationale should be subject to the logical-outgrowth test. But the fact that neither the litigants nor the courts raised the issue when it would have been obvious to do so only reinforces that the logical-outgrowth doctrine simply does not extend to such claims. *See Long Island Care*, 551 U.S. at 175 ("We do not understand why [the provision in the final rule] was not reasonably foreseeable. Neither can we find any significant legal problem with the Department's explanation for the change." (citations omitted)).

Humana argues (at 38-39) that the cited treatises and decisions do not exclude the possibility of finding a notice-and-comment violation in circumstances other than the two discussed above. *See supra* pp. 12-13. But even if a hypothetical third category were possible, Humana fails to show that such a category exists and that this case falls within it. As discussed, Humana cannot cite a single case vacating a final rule on the sole ground that the agency's reasoning in the preamble to the final rule was not a logical outgrowth of that in the proposed rule.

Finally, Humana proposes policy reasons for its approach, but those reasons cannot override the statutory text, *see Beatty v. Lumpkin*, 52 F.4th 632, 636 (5th Cir. 2022) (per curiam), and lack merit in any event. Humana questions (at 39) why Congress would have intended to require disclosure of data and

methodologies critical to a rule but not subject an agency's reasons for the final rule to the logical-outgrowth test. But it is not clear that Congress ever intended to require disclosure of data and methodologies. As then-Judge Kavanaugh explained:

> Put bluntly, the *Portland Cement* [*Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973),] doctrine cannot be squared with the text of § 553 of the APA. And *Portland Cement*'s lack of roots in the statutory text creates a serious jurisprudential problem because the Supreme Court later rejected this kind of freeform interpretation of the APA. In its landmark *Vermont Yankee* decision, … the Supreme Court forcefully stated that the text of the APA binds courts: Section 553 of the APA "established the *maximum procedural requirements* which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures."

American Radio Relay League, Inc. v. FCC, 524 F.3d 227, 246 (D.C. Cir. 2008) (Kavanaugh, J., concurring in part, concurring in the judgment in part, and dissenting in part).

In any event, courts describing policy reasons for this requirement have limited that reasoning to technical studies and data: "Public notice and comment regarding relied-upon technical analysis, then, are '[t]he safety valves in the use of … sophisticated methodology.'" *American Radio Relay League*, 524 F.3d at 236 (alterations in original); *see also id.* at 236-37 (explaining that doctrine "ensures that an agency does not 'fail[] to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary'" and does not "'allow[] an agency to play hunt the peanut with technical information'" (first

alteration in original)). That is in part because the disclosure requirement does not turn on differences between the proposed rule and the final rule but rather on the general proposition that the public should have access to critical data and studies, including those underlying the *proposed* rule. *See Connecticut Light & Power Co. v. Nuclear Regul. Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982) ("[I]t is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.").

Moreover, strong policy reasons weigh against limiting agencies' ability to evolve their reasoning in response to public comments. As the government's opening brief explained, "the very premise of" notice-and-comment rulemaking is "that rules evolve from conception to completion." *Brennan v. Dickson*, 45 F.4th 48, 69 (D.C. Cir. 2022). Thus, even with respect to the actual substance of a regulation's text, "the APA does not require that rules be subjected to multiple cycles of notice and comment until the version adopted as final is identical to the last notice of proposed rulemaking." *Id.* That principle applies with even greater force to an agency's *explanations* for a regulation's requirements, which do not in themselves have legal effect or establish rights and obligations. *See supra* pp. 5, 11.

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

Even if this Court were to apply the "logical outgrowth" test to CMS's reasoning in the Final Rule, notwithstanding the lack of basis for that approach in the Medicare statute or the APA, the RADV Rule would still more than pass muster. The preamble to the Proposed Rule "'adequately frame[d] the subjects for discussion' such that 'the affected party "should have anticipated" the agency's final course in light of the initial notice.'" *Huawei Techs.*, 2 F.4th at 447.

1. The Final Rule relied on the same rationale as the Proposed Rule

Humana's underlying complaint is that CMS declined to include an FFS Adjuster in the Final Rule. As the government's opening brief explained (at 10-11), Medicare Advantage Organizations (MAOs) had asked for such an adjuster because they believed they were underpaid relative to the statutory standard of "actuarial equivalence" and therefore should be allowed to keep some of the invalid payments discovered in RADV audits. In other words, MAOs wanted to limit RADV audit recoveries to compensate for alleged systematic payment error.

In both the Proposed Rule and the Final Rule, CMS reasoned that it was inappropriate to incorporate an FFS Adjuster because MAOs' concerns about underpayment—labelled as actuarial equivalence, payment accuracy, or systematic payment error—do not bear on recoveries in RADV audits, which are only

intended to enforce the medical-record-documentation requirement by recovering payments for unsupported diagnoses. *See* Gov't Br. 30-32. It was accordingly improper to use RADV audits to address actuarial-equivalence concerns. *See id.* The Proposed Rule's reasoning therefore more than "'adequately frame[d] the subjects for discussion'" such that plaintiffs "'"should have anticipated" the agency's final course in light of the initial notice.'" *Huawei Techs.*, 2 F.4th at 447.

2. Humana mischaracterizes CMS's rationales

Humana's contrary argument rests primarily on a mischaracterization of the preamble to the Proposed Rule. The preamble to the Proposed Rule explained:

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

83 Fed. Reg. 54,982, 55,041 (Nov. 1, 2018) (ROA.10458). Ignoring CMS's extensive discussion of the propriety of limiting RADV audit recoveries to address actuarial equivalence, Humana reduces (at 33) this entire analysis to the

concluding point—that incorporating an FFS Adjuster "would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans." Having eliminated most of the reasoning in the Proposed Rule, Humana then contends (at 33-34) that the Proposed Rule failed to give notice of Final Rule's reasoning that actuarial-equivalence concerns do not bear on RADV audits.

Humana's approach represents the precise "'cherry picking of sentences'" that it attributes (at 44) to the government. Although the concluding point about inequities followed from the preceding analysis, CMS never suggested that the inequity point represented the entirety of the analysis or made it irrelevant. Humana ignores the Proposed Rule's reasoning that "RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation" and that, "[c]onsequently, an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate." 83 Fed. Reg. at 55,041 (ROA.10458). But that language gave more than adequate notice for the same reasoning in the preamble to the Final Rule, which states:

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

88 Fed. Reg. 6643, 6658 (Feb. 1, 2023) (ROA.17084). The preamble to the Final Rule further elaborates:

> [W]e believe that the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to MAOs, and not to the obligation to return improper payments for diagnosis codes submitted by MAOs to CMS lacking medical record support. … "The role of the actuarial-equivalence provision is to require CMS to model a demographically and medically analogous beneficiary population in traditional Medicare to determine the prospective lump-sum payments to [MAOs]." … The purpose of RADV audits is to recover payments that were made improperly based on diagnoses not supported by medical record documentation. If a payment is made to an MAO based on a diagnosis code not supported by medical record documentation, the entire payment for that code is in error and should be recovered in full because the payment standard has not been met.

88 Fed. Reg. at 6656-57 (ROA.17082-83) (third alteration in original) (citations omitted).

More generally, the question is not whether every point made in the preamble to the Proposed Rule also appears in the preamble to the Final Rule, but rather whether the notice of proposed rulemaking "'adequately frame[s] the subjects for discussion' such that 'the affected party "should have anticipated" the agency's final course in light of the initial notice.'" *Huawei Techs.*, 2 F.4th at 447. Thus, if the agency makes points A, B, and C in the proposed rule but keeps only A and B in the final rule, the agency has still given sufficient notice of its reasoning, notwithstanding its omission of C. Humana's contrary approach would mean that, by including additional point C in the proposed rule, the agency

somehow gave *less* notice and invalidated the notice it gave for points A and B. That position is illogical.

In any event, CMS did not omit the concluding point about inequities. Humana does not dispute (at 46) that the preamble to the Final Rule did rely on that point, contrary to the district court's mistaken assertion that the government abandoned it. *See* ROA.26922.

3. Humana's remaining notice arguments are unavailing

a. Humana baldly asserts (at 47-48) that "systematic payment error" and "payment accuracy" as used in the Proposed Rule are different concepts than "actuarial equivalence" as used in the Final Rule, but Humana can provide no alternative explanation for what these concepts mean. As the government's opening brief explained (at 32), both actuarial equivalence and payment accuracy refer to the statutory objective that the risk adjustment model produce appropriate payments to MAOs—currently, payments that approximate what CMS would otherwise spend on the same beneficiaries—and systematic payment error refers to payments that are biased downwards or upwards such that they fail to achieve actuarial equivalence.

b. Humana's remaining arguments are easily answered. Humana argues (at 45) that the rationale that payment-accuracy concerns do not bear on RADV audits is a factual conclusion, whereas the rationale that the actuarial-equivalence

requirement does not apply to RADV audits is a legal conclusion. Humana also suggests (at 47) that, by relying on the results of a study that indicated that there was no systematic payment error in Medicare payment rates, CMS "*agreed* that it was obligated to satisfy the actuarial-equivalence requirement" in RADV audits. Finally, Humana suggests (at 48) that notice was inadequate because many industry commenters failed to address whether actuarial equivalence applies to RADV audits.

These arguments fail for the same reasons. The relevant question is not whether the Proposed Rule and the Final Rule contain identical reasoning, but rather whether notice was sufficient such that parties "'reasonably should have filed [their] comments on the subject during the notice-and-comment period.'" *Huawei Techs.*, 2 F.4th at 447. Whether characterized as "legal" or "factual," the notice of proposed rulemaking plainly indicated CMS's view that actuarial-equivalence concerns do not bear on RADV audits and that "an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate." 83 Fed. Reg. at 55,041 (ROA.10458). That position cannot be reconciled with the view Humana wrongly attributes (at 47) to the Proposed Rule—that CMS agreed

that it "was obligated to satisfy the actuarial-equivalence requirement" in RADV audits.[4]

Similarly, if Humana or other commenters took the view that the actuarial-equivalence requirement requires CMS to limit RADV audit recoveries to address payment accuracy concerns, then CMS's position that it would *not* do so would necessarily be unlawful under their view. Those commenters therefore had sufficient notice to submit comments explaining why the actuarial-equivalence requirement does limit audit recoveries and that CMS's contrary position was unlawful.

Finally, Humana offers no meaningful response to the government's argument (at 33-34) that any doubts about sufficient notice were resolved by CMS's 2019 request for additional comment. That request sought "comment on whether 42 U.S.C. [§] 1395w-23—and in particular clause (a)(1)(C)," which contains the actuarial-equivalence requirement—"mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology." 84 Fed. Reg. 30,983, 30,983 (June 28, 2019) (ROA.10468). Thus, having informed the

[4] Humana suggests (at 13) that 42 C.F.R. § 422.2 reflects the view that the actuarial-equivalence requirement governs RADV audits, but that provision merely explains that RADV audits "ensure[] the integrity and accuracy of risk adjustment payment data" and does not address actuarial equivalence.

public that it intended not to limit RADV audit recoveries to address concerns about systematic payment error, CMS specifically asked whether the statutory actuarial-equivalence provision should inform that proposal. Any commenter who took the view that the actuarial-equivalence provision obligated CMS to limit RADV audit recoveries to address payment-accuracy concerns therefore had sufficient notice to submit comments to that effect. That is all the logical-outgrowth standard requires.

CONCLUSION

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

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,499 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Times New Roman 14-point font, a proportionally spaced typeface.

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