

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

HUMANA INC.,

and

HUMANA BENEFIT PLAN OF TEXAS,  
INC.,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as  
Secretary of the United States Department of  
Health and Human Services,

and

UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

Defendants.

No. 4:23-cv-00909-O

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO TRANSFER VENUE  
OR DISMISS**

**TABLE OF CONTENTS**

	<b>Page</b>
INTRODUCTION .....	1
BACKGROUND .....	3
I.    The Medicare Statute Requires the Centers for Medicare and Medicaid Services to Ensure that Payments to MAOs Are Actuarially Equivalent to the Agency’s Expected Payments for Coverage of the Same Enrollee Population in Fee-for-Service Medicare. ....	3
A.    Medicare Advantage Risk Adjustment .....	3
B.    The RADV Audit Program .....	6
II.   CMS Has Repeatedly Acknowledged that an FFS Adjuster Is Necessary to Accurately Compensate MAOs Subject to Extrapolated RADV Audits. ....	7
III.  CMS Reversed Its Policy on the FFS Adjuster in 2018 and Has Been Searching for Justifications for that Reversal Ever Since. ....	9
IV.  Plaintiffs Challenge the Final Rule under the APA. ....	11
LEGAL STANDARD.....	11
ARGUMENT .....	12
I.    The Government’s Motion to Transfer Venue Should Be Denied. ....	12
II.   The Government’s Motion to Dismiss Should Be Denied. ....	14
A.    Humana Has Established Standing through Two Categories of Distinct and Imminent Injuries. ....	14
1.    The Final Rule injures Humana by harming its competitive standing and imposing new compliance costs on its business. ....	15
2.    Humana is currently subject to RADV audits conducted by HHS-OIG that are covered by the Final Rule and faces a certainty of future RADV audits by CMS and HHS-OIG. ....	19
B.    The Complaint Raises Purely Legal Issues That Are Ripe for Decision. ....	22
CONCLUSION.....	25

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>Cases</b>	
<i>Abbott Lab'ys v. Gardner</i> , 387 U.S. 136 (1967) .....	23, 24, 25
<i>Air Force Major v. Austin</i> , 2022 WL 3698302 (N.D. Tex. Apr. 4, 2022).....	13
<i>Bacchus Imports, Ltd. v. Dias</i> , 468 U.S. 263 (1984) .....	15, 16
<i>Bevill v. City of Quitman</i> , 2019 WL 6492521 (E.D. Tex. Dec. 3, 2019) .....	12
<i>Campbell v. Barr</i> , No. 3:20-cv-01605-G (N.D. Tex. June 19, 2020) .....	13
<i>Campbell v. Garland</i> , No. 3:19-CV-1887-L (N.D. Tex. July 21, 2021).....	13
<i>Clapper v. Amnesty Int'l</i> , 568 U.S. 398 (2013) .....	16, 17
<i>Clinton v. City of New York</i> , 524 U.S. 417 (1998) .....	15, 16
<i>Cochran v. U.S. Secs. &amp; Exch. Comm'n</i> , 20 F.4th 194 (5th Cir. 2021) (en banc).....	24
<i>Czyzewski v. Jevic Holding Corp.</i> , 580 U.S. 451 (2017) .....	19
<i>Dep't of Com. v. New York</i> , 139 S. Ct. 2551 (2019) .....	17
<i>Energy Future Coal. v. E.P.A.</i> , 793 F.3d 141 (D.C. Cir. 2015) .....	23
<i>Garrett v. Hanson</i> , 429 F. Supp. 3d 311 (E.D. Tex. 2019) .....	11
<i>Gen. Land Off. v. Biden</i> , 71 F.4th 264 (5th Cir. 2023).....	11
<i>Hammers v. Mayea-Chang</i> , 2019 WL 6728446 (E.D. Tex. Dec. 11, 2019) .....	14

## TABLE OF AUTHORITIES

(Continued)

	<b>Page(s)</b>
<i>Haverkamp v. Linthicum</i> , 6 F.4th 662 (5th Cir. 2021).....	11
<i>Holmes v. Energy Catering Servs., LLC</i> , 270 F. Supp. 2d 882 (S.D. Tex. 2003).....	13
<i>In re Radmax, Ltd.</i> , 720 F.3d 285 (5th Cir. 2013) (per curiam).....	13
<i>In re Volkswagen of Am., Inc.</i> , 545 F.3d 304 (5th Cir. 2008) (en banc).....	12, 13, 14
<i>Louisiana v. Biden</i> , 55 F.4th 1017 (5th Cir. 2022).....	18
<i>Lujan v. Defs. of Wildlife</i> , 504 U.S. 555 (1992).....	14
<i>Medicaid &amp; Medicare Advantage Prods. Ass’n of P.R., Inc. v. Hernandez</i> , 58 F.4th 5 (1st Cir. 2023).....	5
<i>N.H. Hemp Council, Inc. v. Marshall</i> , 203 F.3d 1 (1st Cir. 2000).....	24
<i>Nat’l Venture Cap. Ass’n v. Duke</i> , 291 F. Supp. 3d 5 (D.D.C. 2017).....	21
<i>Permian Basin Ass’n v. Dep’t of the Interior</i> , 2015 WL 11622492 (W.D. Tex. Feb. 26, 2015).....	13
<i>Pickett v. Tex. Tech Univ. Health Scis. Ctr.</i> , 37 F.4th 1013 (5th Cir. 2022).....	11
<i>Rest. L. Ctr. v. U.S. Dep’t of Lab.</i> , 66 F.4th 593 (5th Cir. 2023).....	18, 19
<i>Sherley v. Sebelius</i> , 610 F.3d 69 (D.C. Cir. 2010).....	17
<i>Superior Shooting Sys., Inc. v. Cole</i> , 2010 WL 11565996 (N.D. Tex. Dec. 20, 2010).....	12
<i>Susan B. Anthony List v. Driehaus</i> , 573 U.S. 149 (2014).....	19, 20
<i>Tex. Bankers Ass’n v. Consumer Fin. Prot. Bureau</i> , 2023 WL 4872398 (S.D. Tex. July 31, 2023).....	18, 19

**TABLE OF AUTHORITIES**

(Continued)

	<b>Page(s)</b>
<i>Tex. Democratic Party v. Benkiser</i> , 459 F.3d 582 (5th Cir. 2006).....	20
<i>Texas v. Becerra</i> , 577 F. Supp. 3d 527 (N.D. Tex. 2021).....	18
<i>Texas v. Biden</i> , 20 F.4th 928 (5th Cir. 2021).....	21, 22
<i>Texas v. United States</i> , 523 U.S. 296 (1998).....	25
<i>Texas v. United States</i> , 787 F.3d 733 (5th Cir. 2015).....	17
<i>Time, Inc. v. Manning</i> , 366 F.2d 690 (5th Cir. 1966).....	12
<i>Tyler v. Hennepin Cnty.</i> , 598 U.S. 631 (2023).....	14
<i>United Transp. Union v. Foster</i> , 205 F.3d 851 (5th Cir. 2000).....	24, 25
<i>UnitedHealthcare Ins. Co. v. Becerra</i> , 16 F.4th 867 (D.C. Cir. 2021) .....	10, 17, 18
<i>Walmart Inc. v. U.S. Dep’t of Justice</i> , 21 F.4th 300 (5th Cir. 2021).....	22, 24
<i>White Oak Realty, L.L.C. v. U.S. Army Corps of Eng’rs</i> , 746 F. App’x 294 (5th Cir. 2018).....	14
<i>Willamette Fam., Inc. v. Allen</i> , 643 F. Supp. 3d 1180 (D. Or. 2022).....	22
<i>Zuazua v. C.R. England, Inc.</i> , 2021 WL 8442046 (W.D. Tex. Aug. 20, 2021) .....	13
<b>Statutes</b>	
28 U.S.C. § 1391(e)(1).....	14
42 U.S.C. § 1395w-23(a)(1)(B)(i) .....	4
42 U.S.C. § 1395w-23(a)(1)(C)(i) .....	4
42 U.S.C. § 1395w-23(a)(1)(E) .....	4

**TABLE OF AUTHORITIES**

(Continued)

	<b>Page(s)</b>
42 U.S.C. § 1395w-23(a)(3) .....	4
42 U.S.C. § 1395w-24(a)(6)(A)(i) .....	15
42 U.S.C. § 1395w-24(a)(6)(A)(iii) .....	15
42 U.S.C. § 1395w-24(b)(1)(C) .....	4
5 U.S.C. §§ 706(2)(A) .....	23
5 U.S.C. §§ 706(2)(C) .....	23
<b>Rules and Regulations</b>	
42 C.F.R. § 422.2 .....	6
42 C.F.R. § 422.254(b) .....	4
42 C.F.R. § 422.254(b)(1) .....	15
42 C.F.R. § 422.254(b)(5) .....	15
42 C.F.R. § 422.310(e) .....	6, 10
42 C.F.R. § 422.310(g) .....	20
42 C.F.R. § 422.311(a) .....	21
70 Fed. Reg. 4588 (Jan. 28, 2005) .....	4
75 Fed. Reg. 19,678 (Apr. 15, 2010) .....	7, 10
79 Fed. Reg. 29,844 (May 23, 2014) .....	6, 21
88 Fed. Reg. 6643 (Feb. 1, 2023) .....	passim
<b>Other Authorities</b>	
2 James Wm. Moore et al., <i>Moore’s Federal Practice</i> § 12.30[3] (3d ed. 2023) .....	11
CMS, <i>Deadline for Submitting Risk Adjustment Data for Use in Risk Score Calculation Runs for Payment Years 2021, 2022, 2023, and 2024</i> (May 18, 2022), <a href="https://www.cms.gov/files/document/py20202021202220232024paymentrunnotice508g.pdf">https://www.cms.gov/files/document/py20202021202220232024paymentrunnotice508g.pdf</a> .....	20
CMS, <i>Frequently Asked Questions</i> , <a href="https://www.cms.gov/files/document/contract-level-radv-faqs.pdf">https://www.cms.gov/files/document/contract-level-radv-faqs.pdf</a> (last updated Nov. 2023) .....	25

**TABLE OF AUTHORITIES**

(Continued)

**Page(s)**

CMS, *Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet* (June 1, 2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Fact-Sheet-2013.pdf> ..... 20

## INTRODUCTION

This case involves complicated actuarial issues relating to how Medicare Advantage Organizations, often called “MAOs,” are compensated for providing Medicare benefits to more than 30 million seniors. But what ultimately happened here is simple: the government failed to justify its desired policy on the facts, so it decided to deem the facts irrelevant and adopt a final rule based solely on new and erroneous legal arguments—to the detriment of Plaintiffs Humana Inc. and Humana Benefit Plan of Texas, Inc. (collectively, “Humana”), other MAOs, and, ultimately, seniors. Now, the government asks this Court to dismiss Plaintiffs’ challenge to that policy, arguing that a rule it has spent more than a decade developing has no actual impact on one of the largest MAOs in the country. That position is wrong, and Plaintiffs’ challenge should proceed in this Court.

In 2010, the government first proposed dramatically expanding a limited audit program by statistically extrapolating the results of what it calls “risk adjustment data validation”—or “RADV”—audits to recalculate payments across entire Medicare Advantage contracts. But the government could not figure out an actuarially sound way to perform that extrapolation, as Congress requires, due to differences between the data the government used to develop payment rates for MAOs and the data from which it planned to calculate post-audit payments. In 2012, the government acknowledged the actuarial problem and committed to address it through a payment adjustment, known as a Fee-for-Service Adjuster (“FFS Adjuster”), that would account for this data mismatch. But in 2018, the government reneged on that promise and proposed to conduct extrapolated RADV audits *without* applying an FFS Adjuster, claiming it had performed a study showing that the FFS Adjuster was unnecessary. Commenters, including Humana, demonstrated that the study was empirically flawed and in fact proved the necessity of the FFS Adjuster. Rather than heed those comments, the government abandoned any effort to defend the actuarial soundness



of its proposed policy. Instead, when the government finally published the final rule more than four years later, in 2023, it declared that it would extrapolate RADV audit results without the FFS Adjuster for purely legal reasons—even if that methodology produced “*systematic payment error*” that undercompensated MAOs.

Humana does not object to reasonable audits of its Medicare Advantage contracts. And it does not even object to extrapolating the results of those audits—if that extrapolation is performed in an actuarially and statistically sound manner that complies with the Medicare statute. But it must object to the government’s about-face in the final rule because the government failed to provide a valid justification for abandoning the FFS Adjuster, and its new policy threatens to systematically underpay Humana for the financial risks it assumed to provide Medicare benefits to millions of seniors. Humana has standing to challenge that policy change because it injures Humana in entirely expected ways. If affirmed as published, the new policy will harm Humana’s business by (1) forcing Humana to account for the inevitable revenue losses from the new policy when submitting new Medicare Advantage bids to the government, making Humana’s benefit plans less competitive against fee-for-service Medicare; (2) forcing Humana to expend resources on new actuarial work to develop those bids; and (3) subjecting Humana to RADV audits that will inevitably produce larger, actuarially unsound recoveries.

Humana’s contention that the government violated the Administrative Procedure Act (“APA”) is ripe for decision now. It presents purely legal questions that require no further factual development for resolution. And more delay will impose hardship on Humana by forcing it to suffer the aforementioned injuries and attendant uncertainty as it tries to account for the government’s unlawful new policy.

Alternatively, the government asks the Court to transfer the case away from Humana’s

chosen venue—while acknowledging that seven of the eight factors relevant to the analysis do not support transfer and misconstruing the eighth factor. That argument is easily rejected, too. The government’s motion should be denied and the case should proceed in this Court.

## **BACKGROUND**

### **I. The Medicare Statute Requires the Centers for Medicare and Medicaid Services to Ensure that Payments to MAOs Are Actuarially Equivalent to the Agency’s Expected Payments for Coverage of the Same Enrollee Population in Fee-for-Service Medicare.**

Congress created what is now the Medicare Advantage program in 1997 to bring to Medicare the “innovations that have occurred in the private sector.” Compl. ¶ 18. Traditional “fee-for-service” Medicare relies primarily on a fee-for-service payment model that compensates healthcare providers for specific services rendered to Medicare beneficiaries. *See id.* ¶ 13. In contrast, Medicare Advantage uses a prospective payment model that incentivizes more efficient care and better benefits. *Id.* ¶¶ 16-17. Seniors can choose between fee-for-service Medicare or enrolling in Medicare Advantage plans offered by private health insurers like Humana, which are required by law to provide *at least* the same benefits offered by fee-for-service Medicare. *Id.* ¶¶ 3, 17, 21. In exchange, the Centers for Medicare and Medicaid Services (“CMS”)—which administers the Medicare program—pays these MAOs a fixed monthly rate reflecting the money that CMS estimates it would pay to provide fee-for-service Medicare benefits to the same population of enrollees. *Id.* ¶ 17. This payment model shifts financial risk to MAOs, which foot the bill when an enrollee consumes more healthcare services than anticipated but retain the savings when an enrollee consumes fewer. *Id.*

#### **A. Medicare Advantage Risk Adjustment**

To compensate MAOs for the financial risks they assume in providing Medicare benefits to Medicare Advantage enrollees, Congress requires CMS to pay MAOs the same amount that fee-

for-service Medicare would expect to pay to cover the same enrollees: Congress commands that CMS “shall adjust” payments to MAOs based on various risk factors, including health status, “so as to ensure *actuarial equivalence*” with fee-for-service Medicare. 42 U.S.C. § 1395w-23(a)(1)(C)(i).<sup>1</sup> Congress thus instructed the agency to develop an actuarially sound method of “risk adjustment,” *id.* § 1395w-23(a)(3)—a way of statistically estimating costs for a particular pool of Medicare Advantage enrollees based on their health and demographic risk factors.

The Medicare Advantage risk-adjustment system sets payments using “base rates” and “risk scores.” Compl. ¶ 23. Each enrollee in a Medicare Advantage plan has the same “base rate”—an estimate of the expected cost to provide fee-for-service Medicare benefits to an enrollee with *average* health and demographic characteristics in the covered locale. *Id.* CMS sets base rates through an annual bidding process. *Id.* ¶ 24. MAOs, including Humana, submit bids for each Medicare Advantage plan, stating the amount of revenue they estimate will be necessary to provide benefits to an enrollee of *average* risk in a given geographic area in the next calendar year. *Id.* The MAOs must certify “based on generally accepted actuarial principles” that projected revenues will cover (1) an average enrollee’s fee-for-service Medicare benefits and (2) any supplemental benefits—services not covered by fee-for-service Medicare—the MAOs commit to provide. *Id.*; 42 C.F.R. § 422.254(b). If a bid comes in under a “benchmark” that CMS sets as a ceiling for base payments, the bid becomes the base rate; if the bid is higher, the CMS benchmark becomes the base rate. Compl. ¶ 25. An MAO with a below-benchmark bid cannot charge premiums and receives a rebate from CMS that it must return to enrollees via supplemental benefits or reduced out-of-pocket costs. *See* Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588, 4589, 4594 (Jan. 28, 2005); 42 U.S.C. §§ 1395w-23(a)(1)(B)(i), (a)(1)(E), 1395w-24(b)(1)(C);

---

<sup>1</sup> All emphasis is added and all quotations, alterations, and citations omitted unless noted.

*Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Hernandez*, 58 F.4th 5, 8 n.1 (1st Cir. 2023). Conversely, an MAO with an above-benchmark bid must charge enrollees a premium to make up the difference between the benchmark and the bid. *Hernandez*, 58 F.4th at 8 n.1. MAOs thus compete for enrollees with fee-for-service Medicare—and each other—based on the value of the supplemental benefits and reduced out-of-pocket costs that below-benchmark bids permit. And the statutory scheme requires MAOs to account for increased revenue needs via higher premiums, higher cost-sharing, or fewer supplemental benefits.

After establishing the base payment rate for a Medicare Advantage plan, CMS then adjusts the base rate to reflect the health and demographic risks of a given MAO's enrollee population. CMS assigns each Medicare Advantage enrollee a “risk score,” which increases or decreases payment based on the enrollee's actual characteristics. Compl. ¶ 23. The agency ultimately pays the MAO the base rate multiplied by the risk score for each enrollee. *Id.* ¶¶ 32-34.<sup>2</sup> CMS calculates enrollees' risk scores in part based on “diagnosis codes” that healthcare providers submit to MAOs, usually in claims forms. *Id.* ¶¶ 27-28. A diagnosis code is a number assigned to a particular medical diagnosis by the International Classification of Diseases manual, which is used for clinical coding and billing by CMS, healthcare providers, and private insurers. *See id.* ¶ 27.

To determine how much to pay MAOs, CMS built its payment model on data from fee-for-service Medicare. The agency estimates the expected marginal costs associated with particular types of diagnosis codes based on how much CMS pays healthcare providers who submitted claims for services rendered to fee-for-service Medicare beneficiaries where *the providers' claims* included those same codes. *Id.* ¶ 29. CMS and MAOs alike commonly refer to this data as “claims data.” So, for example, if CMS on average spent an extra \$3,000 each year providing services to

---

<sup>2</sup> *See* Compl. ¶¶ 26-34 for detailed discussion of how CMS calculates and uses risk scores.

fee-for-service Medicare beneficiaries whose *claims data* included a diagnosis code for diabetes, a diabetes code reported for a Medicare Advantage enrollee would increase that enrollee's risk score. Importantly for purposes of this lawsuit, when calculating the average incremental spending associated with fee-for-service Medicare claims for given diagnosis codes, ***CMS does not review the beneficiaries' medical records*** to confirm that the diagnosis codes in the claims data are documented in those records. *Id.* ¶ 30. CMS could have chosen to build its risk-adjustment payment model based on medical-record documentation, but did not do so; instead, it opted to use ***claims data from fee-for-service Medicare***. *Id.* Because diagnosis codes reported in claims data are not always documented in medical records, using claims data spreads the costs associated with any particular codes across a larger pool of beneficiaries, producing a lower per-beneficiary estimate for the incremental cost of treating that condition. *Id.* ¶¶ 42, 48.

#### **B. The RADV Audit Program**

When constructing this risk-adjustment system, the U.S. Department of Health and Human Services (“HHS”)—CMS’s parent agency—sought to “ensure[] the integrity and accuracy of risk adjustment payment data.” 42 C.F.R. § 422.2 (defining “Risk adjustment data validation (RADV) audit”). In its regulation governing risk-adjustment data, the agency contemplated “validat[ing]” the diagnosis codes that healthcare providers submit to MAOs for their enrollees and that MAOs in turn submit to CMS to calculate those enrollees’ risk scores. *Id.* § 422.310(e). HHS has implemented this regulation with RADV audits. CMS and the Office of the Inspector General for HHS (“HHS-OIG”) audit a subset of Medicare Advantage contracts, requiring the contract administrator to submit medical records for a sample of enrollees. *Id.*; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage Program, 79 Fed. Reg. 29,844, 29,934 (May 23, 2014). CMS or HHS-OIG then reviews those medical records to determine whether they document the conditions corresponding with the diagnosis codes submitted to CMS. Compl.

¶¶ 38-39. CMS recoups payments from MAOs for any diagnosis codes it judges not to be documented in the medical record. *Id.* The agency has described the purpose of the “RADV audit process” as “further[ing] actuarial equivalence” between Medicare Advantage and fee-for-service Medicare. Policy and Technical Changes to the Medicare Advantage Program, 75 Fed. Reg. 19,678, 19,747 (Apr. 15, 2010).

Historically, CMS recouped only payments corresponding to individual diagnosis codes from the enrollee sample. But the challenged rule codifies the agency’s plan to statistically extrapolate audit results across the contract’s entire enrollee population and recover contract-wide repayments based on those estimates. Compl. ¶ 40; *see also* Policy and Technical Changes to the Medicare Advantage Program for Years 2020 and 2021 (“Final Rule”), 88 Fed. Reg. 6643, 6643 (Feb. 1, 2023). CMS estimates that this shift will increase recoveries from MAOs by hundreds of millions of dollars annually, and \$4.5 billion total by 2032. *See* 88 Fed. Reg. at 6664.

## **II. CMS Has Repeatedly Acknowledged that an FFS Adjuster Is Necessary to Accurately Compensate MAOs Subject to Extrapolated RADV Audits.**

When CMS first announced its intent to extrapolate RADV audits in 2010, it sparked a flurry of criticism that the agency’s proposed methodology was actuarially flawed in a way that would systematically undercompensate MAOs. Compl. ¶ 41. As Humana and commenters such as the American Academy of Actuaries explained at that time, the agency would impose a double standard if it developed the risk-adjustment payment model using one documentation standard—unaudited fee-for-service Medicare claims data—but based its extrapolated audit recoveries on a different documentation standard—diagnosis codes documented in medical records. *Id.* Humana explained that the resulting payment reduction would substantially lower the revenue expected to be generated by any given MAO’s bid, requiring MAOs to submit bids with higher estimates of the expected costs of offering Medicare benefits to an average enrollee—and, by extension, to

charge higher premiums, offer fewer supplemental benefits, and/or require increased cost-sharing from enrollees. *Id.* ¶ 46.

CMS initially took these concerns to heart. In internal documents, the agency acknowledged that it would be improper to 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.” *Id.* ¶ 51; *see also* App’x ISO Plfs.’ Opp. to Mot. to Transfer Venue or Dismiss (“App.”) at 88-101. CMS acknowledged that these inconsistent standards “tend[] to reduce the estimated average costs of various conditions and therefore our [Medicare Advantage] risk adjustment factors,” thereby necessarily reducing risk-adjustment payments to MAOs. Compl. ¶ 48. “For our payments to be as accurate as possible,” CMS concluded, “we should be using the same standard for both.” *Id.* ¶ 51.

To remedy this actuarial defect, CMS considered what it called an FFS Adjuster, which would “offset . . . recovery amounts under RADV” audits to account for diagnosis codes in fee-for-service Medicare claims data not documented in beneficiaries’ medical records. *Id.* Given the underpayments threatened by its inconsistent documentation standard, the agency concluded that the FFS Adjuster “makes sense and from a technical point of view is the right thing to do.” *Id.*

In February 2012, CMS published guidance officially adopting the FFS Adjuster. *Id.* ¶ 52. The agency stated that it would calculate the FFS Adjuster “based on a RADV-like review of records submitted to support [fee-for-service Medicare] claims data,” and would apply it “as an offset” to any payments recovered in extrapolated RADV audits. *Id.* Humana subsequently and expressly relied on this promise when developing its Medicare Advantage bids to CMS. *Id.* ¶ 53.

### **III. CMS Reversed Its Policy on the FFS Adjuster in 2018 and Has Been Searching for Justifications for that Reversal Ever Since.**

For more than six years, CMS said nothing else publicly or to Humana about how the FFS Adjuster would work. Then, on November 1, 2018, the agency issued a proposed rule that unexpectedly reversed course, announcing it would *not* apply an FFS Adjuster to extrapolated RADV audits. The agency rested this reversal primarily on a study purporting to show that the use of unaudited fee-for-service Medicare claims data to adjust Medicare Advantage payment rates does not “bias” payments to MAOs. *Id.* ¶ 56. Four days after releasing the proposed rule, CMS rushed that study’s conclusions into court to defend a separate Medicare Advantage regulation (the “Overpayment Rule”) against a then-pending APA challenge. *Id.* ¶ 57. But CMS did not initially release the study or its underlying data, and eventually admitted it had lost key outputs and would need to replicate its analysis. *Id.* ¶¶ 56-58. In June 2019, CMS released its second attempt at the study. *Id.* ¶ 58. Commenters, including Humana, noted its numerous methodological and actuarial flaws, which appeared engineered to support the agency’s litigation positions in the Overpayment Rule litigation. *Id.* ¶¶ 59-60.

On February 1, 2023, four-plus years after issuing the proposed rule and after twice extending its statutory deadline, CMS finally published the Final Rule. In yet another pivot, the Final Rule abandons all prior rationales for eliminating the FFS Adjuster, including the much-maligned study, which even the agency acknowledges had “inherent limitations.” 88 Fed. Reg. at 6659-60; Compl. ¶ 63. In place of the study, the Final Rule offers two new, purely legal arguments for why an FFS Adjuster is “not appropriate.” 88 Fed. Reg. at 6656.

First, CMS asserts that no FFS Adjuster is required because the Medicare statute’s actuarial-equivalence requirement does not apply to RADV audits, and thus even “*systematic payment error*” harming MAOs is irrelevant. 88 Fed. Reg. at 6644, 6659. The agency’s only



support for this assertion was the D.C. Circuit's decision in *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), the aforementioned challenge to the Overpayment Rule. 88 Fed. Reg. at 6656. In that case, the D.C. Circuit held that the actuarial-equivalence requirement did not apply to recovery of individual overpayments under a regulation promulgated outside the agency's risk-adjustment framework. But as the D.C. Circuit made clear—and CMS acknowledged—the *Becerra* decision “did not address the RADV audit context.” *Id.* In fact, the court stated that “[c]ontract-level RADV audits” are “*materially distinct* from the Overpayment Rule,” which “requires only that an insurer report and return to CMS known errors in its beneficiaries’ diagnoses.” *Becerra*, 16 F.4th at 892. CMS ignored that difference as well as RADV audits’ place in the regulatory and statutory scheme for risk adjustment, 42 C.F.R. § 422.310(e); its previous statements that RADV audits “*further* actuarial equivalence,” 75 Fed. Reg. at 19,747; and the threat that extrapolation without an FFS Adjuster would lead to systematic underpayments for MAOs, Compl. ¶ 41 & n.28; *supra* at 7-8. Nor did CMS attempt to explain why, even absent a statutory mandate, it would be reasonable for a critically important health-insurance program to ignore sound actuarial principles.

Second, CMS concluded that an FFS Adjuster is “not appropriate” because the Medicare statute requires CMS to apply a flat adjustment to every Medicare Advantage enrollee’s risk score to account for MAOs’ incentive to report more diagnosis codes than fee-for-service Medicare providers. 88 Fed. Reg. at 6656; Compl. ¶¶ 35-37. The agency argued that this “coding-intensity adjustment” must mean that the actuarial-equivalence requirement does not “requir[e] an offset” to RADV audit recoveries through an FFS Adjuster. 88 Fed. Reg. at 6656. CMS did not explain the reasoning behind that conclusion and did not account for its previous statements distinguishing the functions of the coding-intensity adjustment and RADV audits. Compl. ¶¶ 68-69.

#### **IV. Plaintiffs Challenge the Final Rule under the APA.**

On September 1, 2023, Plaintiffs filed their complaint in the Northern District of Texas, where Humana Benefit Plan of Texas, Inc. resides. ECF No. 1. Plaintiffs bring three claims for relief under the APA, alleging that (1) the Final Rule is arbitrary and capricious and contrary to law because it reverses CMS’s prior policy on the FFS Adjuster without an adequate explanation, relying solely on legal justifications that misinterpret the Medicare statute, Compl. ¶¶ 72-77; (2) CMS abused its discretion in deciding to apply the new policy retroactively beginning in payment year 2018, *id.* ¶¶ 71, 78-87; and (3) CMS promulgated the Final Rule without observance of procedure required by law, *id.* ¶¶ 88-91. On December 15, 2023, the government moved to transfer venue or dismiss the complaint. ECF No. 29 (“Mot.”).

#### **LEGAL STANDARD**

On a motion to dismiss for lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1) or to transfer under 28 U.S.C. § 1404(a), “all well-pleaded facts are taken as true and all reasonable inferences must be made in the plaintiff’s favor.” *Haverkamp v. Linthicum*, 6 F.4th 662, 668-69 (5th Cir. 2021); *see Garrett v. Hanson*, 429 F. Supp. 3d 311, 317 (E.D. Tex. 2019). The Court may consider “undisputed facts” outside the four corners of the complaint, including documents cited therein. *Pickett v. Tex. Tech Univ. Health Scis. Ctr.*, 37 F.4th 1013, 1029 (5th Cir. 2022); *Garrett*, 429 F. Supp. 3d at 317; *see also* 2 James Wm. Moore et al., *Moore’s Federal Practice* § 12.30[3] (3d ed. 2023). The plaintiff need only “allege a plausible set of facts establishing jurisdiction.” *Haverkamp*, 6 F.4th at 668. At the pleading stage, “general factual allegations of injury” suffice to meet the plaintiff’s burden, as the Court will “presum[e] that general allegations embrace those specific facts that are necessary to support the claim [of standing].” *Gen. Land Off. v. Biden*, 71 F.4th 264, 272 (5th Cir. 2023).

## ARGUMENT

### I. The Government's Motion to Transfer Venue Should Be Denied.

The government concedes that venue in the Northern District of Texas is proper under 28 U.S.C. § 1391(e)(1) because Humana Benefit Plan of Texas, Inc. resides in the District. Mot. at 14. Yet the government seeks *discretionary* transfer to the Dallas Division under 28 U.S.C. § 1404(a), which permits a district court to transfer an action “[f]or the convenience of parties and witnesses, in the interest of justice . . . to any other . . . division where it might have been brought.” It is the government’s “significant burden . . . to show” that the Dallas Division is “clearly more convenient” than the Fort Worth Division. *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 314 n.10, 315 (5th Cir. 2008) (en banc). That is because the plaintiff’s “statutory privilege of choosing [a] forum” is “highly esteemed,” *Time, Inc. v. Manning*, 366 F.2d 690, 698 (5th Cir. 1966), and “should be respected” unless the defendant shows that the transferee venue is “clearly more convenient,” *Volkswagen*, 545 F.3d at 315. The government fails to carry this significant burden.

Eight factors are relevant to the § 1404(a) analysis; the government concedes that *seven of them do not support transfer*. Mot. at 15. These factors, such as “the relative ease of access to sources of proof” and the “availability of compulsory process to secure the attendance of witnesses,” *Volkswagen*, 545 F.3d at 316, favor preserving the plaintiff’s “statutory privilege” where, as here, a case raises legal questions that will be decided based on an administrative record, *Time, Inc.*, 366 F.2d at 698. That fact alone justifies denial of the government’s motion to transfer. *See, e.g., Superior Shooting Sys., Inc. v. Cole*, 2010 WL 11565996, at \*5 (N.D. Tex. Dec. 20, 2010) (denying intra-district transfer where only “local interest” and “access to sources of proof” factors weighed in favor of transfer); *Bevill v. City of Quitman*, 2019 WL 6492521, at \*5, \*8 (E.D. Tex. Dec. 3, 2019) (denying intra-district transfer where “local interest” weighed in favor of transfer).

The government is also wrong that the final factor—“the local interest in having localized interests decided at home”—favors transfer. When agency overreach threatens nationwide harms, a “local interest” exists in all venues. For instance, in *Permian Basin Petroleum Ass’n v. Department of the Interior*, 2015 WL 11622492 (W.D. Tex. Feb. 26, 2015), the court denied transfer and held that the “local interest” factor was neutral in a challenge to an agency action affecting “landowners and businesses within [several] relevant states.” *Id.* at \*3. That reasoning applies with even greater force here, where the Final Rule announces a new policy that will adversely impact MAOs and seniors nationwide.<sup>3</sup>

Unable to make the showing required by § 1404(a) that the Dallas Division is “clearly more convenient” than the Fort Worth Division, *Volkswagen*, 545 F.3d at 315, the government asserts that the Court should still transfer the case to the Dallas Division because venue in this District is premised on Humana Benefit Plan of Texas residing in Dallas County, Mot. at 14-15. But Congress expressly authorized plaintiffs to sue federal defendants in the judicial district where the plaintiff resides, without regard to division: “if no real property is involved,” a civil action against

---

<sup>3</sup> None of the government’s cases are to the contrary. Nearly all involve witnesses or evidence located in a particular division, such that the § 1404(a) factors weighed in favor of transfer. *See In re Radmax, Ltd.*, 720 F.3d 285, 287-90 (5th Cir. 2013) (per curiam) (three factors weighed in favor of transfer to division where all relevant events took place and all witnesses resided); *Zuazua v. C.R. England, Inc.*, 2021 WL 8442046 (W.D. Tex. Aug. 20, 2021) (§ 1404(a) factors favored transfer to division where car crash took place, plaintiff resided, and witnesses and potential evidence were found); Order at 8, *Campbell v. Garland*, No. 3:19-CV-1887-L (N.D. Tex. July 21, 2021), ECF No. 50 (transfer to division where alleged misconduct occurred); Order at 1, *Campbell v. Barr*, No. 3:20-cv-01605-G (N.D. Tex. June 19, 2020), ECF No. 6 (same). The remaining case, *Air Force Major v. Austin*, involved a Dallas resident’s individual claims and was decided under 28 U.S.C. § 1406, which applies only when venue is *improper*, not merely inconvenient under § 1404(a). *See* 2022 WL 3698302, at \*1 (N.D. Tex. Apr. 4, 2022); Compl., 2022 WL 1014171, ¶¶ 96-139; *Holmes v. Energy Catering Servs., LLC*, 270 F. Supp. 2d 882, 884-86 (S.D. Tex. 2003) (denying § 1406(a) transfer because venue was proper). Here, Humana asserts only facial challenges to a nationwide policy, and the government concedes venue is proper under § 1391(e), such that § 1406 does not apply at all.

a federal agency or officer acting in official capacity “may . . . be brought in any judicial *district* in which . . . the plaintiff resides.” 28 U.S.C. § 1391(e)(1). Like the court in *Hammers v. Mayea-Chang*, 2019 WL 6728446, at \*3 (E.D. Tex. Dec. 11, 2019), there is no reason to override that congressional authorization by “engrafting a new divisional requirement onto the text of § 1391”; rather, the plaintiff’s choice of forum “should be respected,” *Volkswagen*, 545 F.3d 315.

## **II. The Government’s Motion to Dismiss Should Be Denied.**

### **A. Humana Has Established Standing through Two Categories of Distinct and Imminent Injuries.**

By its plain terms, the Final Rule imposes at least two categories of distinct and imminent injuries on Humana: (1) financial losses and compliance costs caused by necessary changes to Humana’s annual bid submissions to CMS, and (2) financial losses from pending and future RADV audits using the challenged methodology. There is “ordinarily little question” that regulated entities like Humana have standing to “challeng[e] the legality of government action[s],” such as the Final Rule, that target them. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Indeed, the Fifth Circuit has specifically recognized that “courts should not be austere in granting standing under the APA to challenge agency action taken pursuant to a statute.” *White Oak Realty, L.L.C. v. U.S. Army Corps of Eng’rs*, 746 F. App’x 294, 299 (5th Cir. 2018). That principle applies with special force to Humana’s allegation of “classic pocketbook injur[ies]” caused by the government’s regulation of its business. *E.g., Tyler v. Hennepin Cnty.*, 598 U.S. 631, 636 (2023).

The government makes two contrary arguments in its motion; neither is persuasive. It asserts Humana faces no imminent injury because the Final Rule (i) *permits* CMS to extrapolate audit recoveries but does not *require* it to do so, *see, e.g.*, Mot. at 17, and (ii) merely confirms the existing legal regime, *see id.* at 18-19. In other words, the government argues that the Final Rule—a formal rulemaking concluding 14 years of back-and-forth between CMS and its stakeholders—

will not injure Humana because it accomplishes nothing of substance at all. That characterization is not only incorrect but defies common sense given the Final Rule’s history and plain language.

**1. The Final Rule injures Humana by harming its competitive standing in the market and imposing new compliance costs on its business.**

The Final Rule upends the actuarial foundations of Humana’s Medicare Advantage bids, harming Humana competitively and causing it to incur immediate compliance costs.

1. Competitive Harm. Courts “routinely recognize” a party’s right to challenge a regulation that places the party at a competitive disadvantage or “change[s] market conditions” detrimentally. *Clinton v. City of New York*, 524 U.S. 417, 433 (1998). In *Clinton*, for instance, a veto rescinding a “statutory bargaining chip . . . inflicted a sufficient likelihood of economic injury to establish standing” because it undermined plaintiffs’ ability to make a purchase under favorable terms. *Id.* at 432-33. Another example is *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263, 267 (1984), where wholesalers “plainly ha[d] standing” to challenge a tax that, even if passed on to consumers, “increase[d] the price of their products as compared to” competitors.

The Final Rule competitively disadvantages Humana versus fee-for-service Medicare. When Humana submits a bid for one of its Medicare Advantage plans, the Medicare statute requires Humana’s actuaries to certify “based on generally accepted actuarial principles” that the revenues produced—through CMS payments, enrollee premiums, and other sources—will cover enrollees’ fee-for-service Medicare benefits and any supplemental benefits. *See* 42 C.F.R. § 422.254(b)(5), (b)(1); *see also* 42 U.S.C. § 1395w-24(a)(6)(A)(i), (A)(iii). To satisfy that command, Humana must compensate for any expected decline in revenues caused by the Final Rule’s larger RADV audit recoveries. For more than a decade, an FFS Adjuster has been an integral part of Humana’s actuarial equation on that score: An FFS Adjuster would limit CMS’s RADV audit recoveries and thus directly affects the revenue projections on which Humana’s

Medicare Advantage bids rest. *See* Compl. ¶ 74; App. at 56-57. Humana “expressly premised” its annual bids “on the understanding that CMS would use an FFS Adjuster in RADV audits.” Compl. ¶ 53.

The Final Rule disrupts that settled understanding by eliminating the FFS Adjuster, which by definition will increase RADV audit recoveries and reduce Humana’s expected revenues. Compl. ¶¶ 55-56, 63; App. at 56; 88 Fed. Reg. at 6664; *see* Mot. at 17 (not disputing that the “government’s recovery from [RADV] audits will be increased because of the rule”). Accounting for that lost revenue will require Humana to increase premiums for enrollees, increase other forms of enrollee cost-sharing, and/or cut back supplemental benefits, such as vision care. Compl. ¶¶ 25, 46; *see* App. at 56-57. That the Final Rule would alter the underlying actuarial assumptions Humana must consider is not a controversial point; the country’s premier actuarial professional organization, the American Academy of Actuaries, recognized that “the uncertainty related to a plan’s ultimate post-audit risk score could make it difficult for actuaries to . . . certify the plan bid.” Compl. ¶ 46. The resulting changes in Humana’s bids will necessarily make its Medicare Advantage plans less attractive to potential enrollees as compared to fee-for-service Medicare, with which Humana competes. *See id.* ¶¶ 18-20, 47; App. at 15-16, 56-57, 60. Humana therefore has standing to challenge that policy change. *See, e.g., Bacchus Imports*, 468 U.S. at 267; *cf. Clinton*, 524 U.S. at 432-33.

The government’s reliance on *Clapper v. Amnesty International USA*, 568 U.S. 398 (2013), is misplaced. *See* Mot. at 18. In *Clapper*, an organization’s reaction to a “risk of harm” was insufficient to constitute injury-in-fact because the threatened harm “relie[d] on a highly attenuated chain of possibilities.” 568 U.S. at 410, 416. The plaintiffs in *Clapper* challenged a statute authorizing warrantless surveillance of certain non-U.S. citizens, asserting that they were injured

by precautions they took to protect against a “highly speculative fear” that the government would invoke the statute to “target *other individuals*—namely, their foreign contacts.” *Id.* at 410-11. The contested statute in *Clapper* thus impacted the plaintiffs secondarily, if at all. And the plaintiffs could “only speculate as to whether the Government w[ould] seek to use” the challenged statute “(rather than other methods)” to target any such communications. *Id.* at 412-13.

But here, the Final Rule regulates Humana directly. If it is lawful, Humana must adjust its actuarial assumptions not to avoid speculative harms, but to comply with a statutory *command* that it must account for the revenue reductions the Final Rule promises. *See supra* at 4. Humana has standing to challenge the Final Rule because it must respond in a way that causes predictable and imminent harms. *See, e.g., Texas v. United States*, 787 F.3d 733, 752 (5th Cir. 2015) (economic loss from regulation requiring state to issue drivers’ licenses to previously ineligible persons conferred standing); *Sherley v. Sebelius*, 610 F.3d 69, 73-74 (D.C. Cir. 2010) (plaintiffs would “have to invest more time and resources to craft a successful grant application” in response to increased competition); *cf. Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019) (finding injury based on “predictable effect of Government action on the decisions of third parties”).

The government also incorrectly argues that the Final Rule has no injurious effect because, it says, RADV audits are essentially equivalent to the obligation to refund known overpayments, which was codified in the 2014 Overpayment Rule. *Mot.* at 19; *see also id.* at 13 (conflating RADV audits and the Overpayment Rule). The government relies on the D.C. Circuit’s *Becerra* ruling, *see Mot.* at 12; 88 Fed. Reg. at 6656, but the case does not support the government’s argument. In concluding that the Overpayment Rule was not subject to the Medicare statute’s actuarial-equivalence mandate, the D.C. Circuit emphasized the rule’s limited requirement for MAOs to refund discrete payments they know are not supported by medical records. *Becerra*, 16



F.4th at 885, 891. Extrapolated RADV audits are not similarly confined, but would instead effectively impose a documentation standard of perfection by allowing contract-wide recoupments regardless of MAOs' knowledge, and regardless of whether medical records in fact exist to support diagnosis codes beyond the limited group of enrollees sampled. *See id.* at 892; *supra* at 7-8.

By its own terms, the Final Rule *changes* federal policy, reversing CMS's previous guidance and committing that the agency will *not* apply an FFS Adjuster in extrapolated RADV audits. CMS itself estimates that this change will decrease MAOs' revenue by \$4.5 billion over ten years, and, by statute, Humana must account for those anticipated lost revenues, to its competitive detriment. That injury more than suffices to confer standing under Article III.

2. Compliance Costs. Humana will also incur costs for actuarial work to account for the new legal regime ushered in by the Final Rule. A "regulation later held invalid *almost always* produces the irreparable harm of nonrecoverable compliance costs." *Texas v. Becerra*, 577 F. Supp. 3d 527, 556 (N.D. Tex. 2021); *cf. Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (recognizing harm of compliance costs in the preliminary injunction context); *Rest. L. Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023) (same). When compliance costs are "certainly impending," they constitute injury-in-fact even if they will be incurred years later. *E.g., Tex. Bankers Ass'n v. Consumer Fin. Prot. Bureau*, 2023 WL 4872398, at \*6 (S.D. Tex. July 31, 2023) (finding "imminent" injury based on "preparation costs" necessitated by regulation that would not become effective for over two years).

Humana invested in both its existing methodology for calculating bids and its internal compliance processes, which relied on the promise of an FFS Adjuster based on CMS's previous policy. *See* Compl. ¶ 53; App. at 56-57, 61. Because the Final Rule eliminated the FFS Adjuster, Humana must incur costs to change its actuarial calculations. Compl. ¶ 46; App. at 56-57 & n.83

(explaining that actuaries would need to consider “a number of factors” to determine actuarially sound bids in the absence of an FFS Adjuster). Indeed, Humana has consistently explained to CMS that it would be required to use a “different methodology for calculating risk scores” if CMS were to extrapolate RADV audit results without using an FFS Adjuster. App. at 15-16. Humana’s 2024 bids to CMS, which were submitted on June 5, 2023, crystallize this point; Humana explained that “the February 1, 2023 release of CMS’s Final RADV Rule provided insufficient time for industry participants, such as Humana, to internalize and account for the Rule when preparing bid submissions, which were due a mere two months after the Rule went into effect.” *Id.* at 106. The time and expense required to do so is plainly a cognizable injury under Article III. *See Rest. L. Ctr.*, 66 F.4th at 597; *Tex. Bankers*, 2023 WL 4872398, at \*6; *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017) (“loss of even a small amount of money is ordinarily an ‘injury’”).

**2. Humana is currently subject to RADV audits conducted by HHS-OIG that are covered by the Final Rule and faces a certainty of future RADV audits by CMS and HHS-OIG.**

The government’s primary argument is that Humana faces no certainly impending injury because it “may not be selected for a RADV audit, or not for quite some time,” and that, even if it were selected, “CMS may not demand an extrapolated recovery that would be increased by the absence of an ‘FFS Adjuster.’” Mot. at 17. But Humana’s Medicare Advantage plans *are currently* undergoing four RADV audits subject to the challenged audit methodology, and it defies the record and common sense to suggest that these will be the only ones. Such government audits that are substantially certain to occur, even if “not for quite some time,” Mot. at 17, impose a “certainly impending” Article III injury-in-fact, *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158, 164-65 (2014).

First, an audit applying the Final Rule will cause a “quintessential” financial harm to Humana because it will necessarily produce a higher recovery for the government than the same

audit would have produced under the previous policy. *Tex. Democratic Party v. Benkiser*, 459 F.3d 582, 586 (5th Cir. 2006); *see supra* at 7; Compl. ¶¶ 4, 46, 53, 82-83. The Final Rule commits to extrapolate RADV audits results covering “[Payment Year] 2018 and any subsequent payment year”—corresponding to calendar year 2017 and later.<sup>4</sup> 88 Fed. Reg. at 6644. Two Humana Medicare Advantage plans are already undergoing HHS-OIG RADV audits covering calendar years 2017 and 2018, and two more are undergoing audits covering calendar years 2020 and 2021. App. at 110-21. That Humana already faces four audits subject to this new methodology is no surprise, and more such audits are substantially certain: Humana has had at least one contract selected for *every single year* of RADV audits published since the program began in 2007. *See CMS, Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet* (June 1, 2017).<sup>5</sup> RADV audits are “not a rare occurrence” and the government has “not disavowed enforcement” against Humana; thus, “an . . . enforcement action is not a prerequisite to challenging the law.” *Susan B. Anthony List*, 573 U.S. at 158, 164-65.

It does not matter, as the government argues, that CMS and HHS-OIG *might* choose not to “demand” an extrapolated recovery in any particular audit, or that CMS purportedly could have previously audited the entirety of every single contract but elected not to do so. Mot. at 17-18, 20. For one thing, the government’s speculation is contrary to the Final Rule’s text. The Final Rule states, in no uncertain terms, “[the government] *will* begin collection of extrapolated overpayment

---

<sup>4</sup> “Payment year” refers to the year following the calendar year in which services were provided, during which CMS makes the majority of related payments to MAOs. *See, e.g.*, 42 C.F.R. § 422.310(g); CMS, *Deadline for Submitting Risk Adjustment Data for Use in Risk Score Calculation Runs for Payment Years 2021, 2022, 2023, and 2024* (May 18, 2022), <https://www.cms.gov/files/document/py20202021202220232024paymentrunnotice508g.pdf>.

<sup>5</sup> <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Fact-Sheet-2013.pdf>.

findings for any CMS and OIG audits conducted in [Payment Year] 2018 and any subsequent payment year.” 88 Fed. Reg. at 6644; *see* Compl. ¶ 71. The government admits that “CMS currently intends to extrapolate.” Mot. at 17. The only potential exceptions identified in the Final Rule involve “unforeseen circumstances” or other “limited instances”; the Final Rule makes clear that “*extrapolation is expected to be the standard practice* for RADV audits beginning in [Payment Year] 2018.” 88 Fed. Reg. at 6650. The Final Rule further “finaliz[es] a policy whereby CMS will not apply an FFS Adjuster because [the agency has] determined that an FFS Adjuster is not appropriate.” *Id.* at 6644, 6659; Compl. ¶ 63.<sup>6</sup> Whatever details might remain to be determined, the Final Rule is unequivocal that the agency will not apply an FFS Adjuster to RADV audits.

Nor does the theoretical availability of agency discretion in “limited instances” in the future defeat standing. *See, e.g., Nat’l Venture Cap. Ass’n v. Duke*, 291 F. Supp. 3d 5, 13-15 (D.D.C. 2017) (plaintiffs had standing to challenge “overarching agency policy” despite government’s “sole discretion” over enforcement in any case). In *Texas v. Biden*, 20 F.4th 928 (5th Cir. 2021), for example, the Fifth Circuit rejected the government’s argument that enforcement discretion defeated the State of Texas’s standing to challenge termination of a federal policy of “return[ing] certain undocumented aliens to Mexico for the duration of their removal proceedings” rather than releasing them into the U.S. *Id.* at 944, 973-74, *rev’d & remanded on other grounds*, 142 S. Ct. 2528 (2022). The policy’s termination injured Texas by “increas[ing] the number of aliens released . . . into the United States,” which imposed “financial harm by way of driver’s license applications” and healthcare costs. *Id.* at 966, 968-69. The government contended the new policy would have no injurious effect because even under the previous policy, “immigration officers . . .

---

<sup>6</sup> Both HHS-OIG and CMS “conduct RADV audits” and nothing in the record suggests HHS-OIG would apply an FFS Adjuster contrary to the Final Rule’s stated policy. 79 Fed. Reg. at 29,934; 42 C.F.R. § 422.311(a).

would have discretion” to release immigrants rather than sending them to Mexico. *Id.* at 973-74. That discretion did not defeat standing, the court of appeals held, because the new policy’s overall impact still caused injury by increasing the number of immigrants in Texas. *See id.* at 974. Likewise here: The government cannot deprive Humana of standing where it in no way disavows enforcement of the Final Rule as a general matter, but merely dangles the prospect that in some audits it “may not demand” all the money to which the Final Rule claims entitlement. Mot. at 17.

The only case the government cites in support, an Oregon district court decision, is inapposite twice over: the entire cited discussion was *dicta* because the court dismissed the case on abstention grounds, and the court was also addressing irreparable harm in the context of a request for injunctive relief, not standing under Article III. *See Willamette Fam., Inc. v. Allen*, 643 F. Supp. 3d 1180, 1192 (D. Or. 2022); Mot. at 18. The court addressed the asserted harm *on the merits*—raising no suggestion plaintiff lacked standing—and concluded the plaintiff was not irreparably harmed because it could raise its arguments in pending administrative proceedings. *See id.* This lone case does nothing to blunt the overwhelming force of the precedent recognizing Humana’s standing to challenge regulations directly affecting its business. *See supra* at 19-22.

**B. The Complaint Raises Purely Legal Issues That Are Ripe for Decision.**

This APA challenge is ripe for review because it raises purely legal questions and the Final Rule immediately affects Humana’s business. “Ripeness is a twofold inquiry that requires courts to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” *Walmart Inc. v. U.S. Dep’t of Justice*, 21 F.4th 300, 311 (5th Cir. 2021). Fitness for judicial review turns on “whether the issue presented is a purely legal one, whether consideration of that issue would benefit from a more concrete setting, and whether the agency’s action is sufficiently final.” *Id.* Hardship depends on whether the regulations’ impact “is sufficiently direct and immediate as to render the issue appropriate for judicial review at this

stage.” *Abbott Lab’ys v. Gardner*, 387 U.S. 136, 152 (1967). This APA challenge is plainly ripe.

*First*, Humana’s “substantive challenge” is suitable for adjudication now because it challenges the Final Rule’s legal rationales for eliminating the FFS Adjuster.<sup>7</sup> “It is well-established that claims that an agency’s action is arbitrary and capricious or contrary to law present purely legal issues,” making it “unnecessary to wait” for the agency’s “legal conclusion to be applied in order to determine its legality.” *Energy Future Coal. v. E.P.A.*, 793 F.3d 141, 146 (D.C. Cir. 2015). The government incorrectly states that the “core of Humana’s substantive claim” is “that the agency’s extrapolated audit methodology must include an FFS Adjuster to satisfy the statutory mandate of ‘actuarial equivalence,’” and contends this theory “cannot be properly assessed until CMS conducts an audit.” Mot. at 21. The government mischaracterizes Humana’s claim for relief. Humana does not contend—in this action at least—that CMS violated the Medicare statute’s actuarial-equivalence mandate; instead, it contends that neither of the agency’s justifications in the Final Rule “provide an adequate, reasoned explanation” for abandoning the FFS Adjuster. Compl. ¶ 76. Those justifications—(1) that the actuarial-equivalence requirement does not apply to RADV audits and (2) that the coding-intensity adjuster forecloses an FFS Adjuster—are purely legal conclusions. The government does not say how specifics of its ultimate “sampling methodology” could possibly make a difference to this Court’s review of either issue.

In this way, the Final Rule resembles the challenged regulation in *Abbott Laboratories*, which construed a statute to require a drug’s generic name to be printed alongside its trade name. 387 U.S. at 137-38. Whether this regulation exceeded the government’s authority was a question

---

<sup>7</sup> In limiting its ripeness argument to Plaintiffs’ “substantive challenge” and “substantive claim,” Mot. at 20-22, the government appears to be referencing Count I of Plaintiffs’ complaint. Compl. ¶¶ 72-77 (citing 5 U.S.C. §§ 706(2)(A), (C)). The government does not appear to contend that Plaintiffs’ other claims for relief are not yet ripe. *See id.* ¶¶ 78-91.

“purely of congressional intent,” and the government “made no effort to justify the regulation in factual terms,” so resolution of that legal question would not “vary with different circumstances.” *Id.* at 149; *see also N.H. Hemp Council, Inc. v. Marshall*, 203 F.3d 1, 5 (1st Cir. 2000) (“abstract [issue] of statutory interpretation” ripe for review where the enforcing agency had taken an “emphatic position” on the issue). The government’s own cases confirm that “a pure issue of law . . . is fit for judicial decision without any additional fact-finding.” *Cochran v. U.S. Secs. & Exch. Comm’n*, 20 F.4th 194, 212 (5th Cir. 2021) (en banc), *aff’d sub nom. Axon Enter., Inc. v. Fed. Trade Comm’n*, 598 U.S. 175 (2023) (cited at Mot. at 22); *see United Transp. Union v. Foster*, 205 F.3d 851, 859 (5th Cir. 2000) (cited at Mot. at 22) (similar). So too here, Humana’s challenge to CMS’s purely legal rationales for reversing course on the FFS Adjuster—which the agency has “made no effort to justify . . . in factual terms,” *Abbott Lab’ys*, 387 U.S. at 149—does not depend on any factual circumstances and is ripe for immediate judicial review.

**Second**, the same injuries that establish Humana’s standing inflict a “direct and immediate” hardship on Humana. *Abbott Lab’ys*, 387 U.S. at 152; *see Walmart*, 21 F.4th at 313 (standing analysis in “pre-enforcement cases . . . tracks closely with ripeness”). The government contends Humana will suffer no immediate hardship because it is “uncertain when, if ever, CMS will attempt to use sampling and extrapolation” to make contract-wide RADV audit recoveries. Mot. at 21. The motion suggests that CMS may not demand extrapolated audit recoveries even though the agency has spent 14 years laying the groundwork for such recoveries and recently reaffirmed its intentions in a formal rulemaking that consumed more than four years. That suggestion cannot be squared with the Final Rule’s plain text, which expressly states that CMS “will extrapolate RADV audit findings,” and “will not apply an FFS Adjuster in RADV audits because we have determined that an FFS Adjuster is not appropriate.” 88 Fed. Reg. at 6643-44; *see also id.* at 6644 (CMS “will

begin collection of extrapolated overpayment findings for any CMS and OIG audits conducted in [Payment Year] 2018 and any subsequent payment year”); *id.* at 6650 (extrapolation will be the “standard practice”); *see supra* at 20-21. And if any doubt remained about the agency’s intentions, CMS presently states on its website that it “aims to initiate the next RADV audits in the coming months” and “*will* begin the process to collect extrapolated amounts resulting from contract-level RADV audits.”<sup>8</sup> But even if the government drags its feet, Humana does not have the same luxury—it will be required by statute to prepare and certify actuarially compliant bids that account for the revenue impacts of the Final Rule. Regardless of whether the agency delays further in extrapolating RADV audit recoveries, the competitive and compliance injuries that Humana will suffer are certain to accrue, making this case ripe for review. *See supra* at 14-22.

The government’s cited cases only underscore this point. Extrapolated RADV audits are not events that “may never occur,” like the hypothetical “train of events” needed to determine the constitutionality of a statute authorizing drug-testing of crewmembers involved in railroad collisions, *United Transp.*, 205 F.3d at 857-59, or the possibility that a state might, as a last resort, appoint a master to oversee a failing school district, *Texas v. United States*, 523 U.S. 296, 300 (1998) (cited at Mot. at 22). Just like the statutory interpretation in *Abbott Laboratories*, CMS’s assertedly “authoritative interpretation” of the Medicare statute has a “direct effect on [Humana’s] day-to-day business,” 387 U.S. at 152, and “withholding court consideration” of this interpretation would impose significant hardship on Humana, *id.* at 149.

## CONCLUSION

For the foregoing reasons, the government’s motion should be denied.

---

<sup>8</sup> CMS, *Frequently Asked Questions*, <https://www.cms.gov/files/document/contract-level-radv-faqs.pdf> (last updated Nov. 2023).



Dated: February 13, 2024

**O'MELVENY & MYERS LLP**

By: /s/ Timothy S. Durst

K. LEE BLALACK II\*  
lblalack@omm.com  
1625 Eye Street, N.W.  
Washington, D.C. 20006  
Telephone: (202) 383-5300  
Facsimile: (202) 383-5414

TIMOTHY S. DURST  
Texas Bar No. 00786924  
tdurst@omm.com  
2501 N. Harwood Street, Suite 1700  
Dallas, Texas 75201  
T: (972) 360-1900  
F: (972) 360-1901

STEPHEN M. SULLIVAN\*  
ssullivan@omm.com  
JONATHAN P. SCHNELLER\*  
jschneller@omm.com  
ELIZABETH M. BOCK\*  
ebox@omm.com  
HEATHER WELLES\*  
hwelles@omm.com  
400 S. Hope Street  
Los Angeles, California 90071  
Telephone: (213) 430-6000  
Facsimile: (213) 430-6407

JENNIFER B. SOKOLER\*  
jsokoler@omm.com  
7 Times Square  
Times Square Tower  
New York, New York 10024  
Telephone: (212) 326-2000  
Facsimile: (212) 326-2061

DAVID DEATON\*  
ddeaton@omm.com  
610 Newport Center Drive  
Newport Beach, California 92660  
Telephone: (949) 823-6900  
Facsimile: (949) 823-6994

*Attorneys for Plaintiffs Humana Inc. and Humana  
Benefit Plan of Texas, Inc.*

\* Admitted pro hac vice

**CERTIFICATE OF SERVICE**

I hereby certify that on February 13, 2024, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all participating counsel of record.

*/s/ Timothy S. Durst*