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

HUMANA INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:23-cv-909-O
	)	
XAVIER BECERRA, et al.,	)	
	)	
Defendants.	)	
	)	

MOTION TO TRANSFER VENUE OR DISMISS

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INTRODUCTION

Under Medicare Advantage, the federal government pays private insurers a predetermined sum to cover beneficiaries who participate in the program. The size of those payments varies based on the health characteristics of each covered individual. Insurers must therefore report the medical conditions with which each beneficiary has been diagnosed. To be valid, a reported diagnosis must be documented in the beneficiary's medical record. Insurers are "not entitled" to payments based on undocumented diagnoses. 42 U.S.C. § 1320a-7k(d)(4)(B); *see* 79 Fed. Reg. 29,844, 29,921–22 (May 23, 2014). Because insurers are paid more for covering beneficiaries with certain medical conditions, the federal government conducts audits to confirm the accuracy of some reported diagnoses. Any payments based on diagnoses that are not documented in the beneficiary's medical record are then recouped. Historically, the recoveries made through this audit program have been a tiny fraction of the estimated overpayments to Medicare Advantage insurers.

For more than a decade, the Centers for Medicare & Medicaid Services (CMS) have considered the use of statistical sampling and extrapolation in Medicare Advantage audits, to allow the government to recoup a larger portion of its overpayments. CMS published a rule concerning those audits earlier this year, which Humana and its Texas subsidiary challenge here. Under that rule, the agency may use statistical sampling and extrapolation in future Medicare Advantage audits, beginning with payment year 2018. The complaint alleges that this rule is (1) substantively invalid, because it disclaims the use of a particular adjustment factor in calculating those future audit recoveries; (2) impermissibly retroactive, because it applies that policy to previous payment years; and (3) procedurally invalid, because it discusses a decision by a federal court of appeals on which public comment was not sought.

CMS has not begun—much less completed—any audits under the challenged rule. It has not chosen the contracts to be audited under the rule for any payment year, nor selected a statistical sampling and extrapolation methodology for any such audits. It is therefore uncertain (1) whether or when Humana or its Texas subsidiary will be audited under the challenged rule, (2) whether any such audit will identify overpayments to be recouped, and (3) how CMS will calculate any such overpayments. The complaint does not, and could not, contain any such allegations. And in their absence, Humana and its Texas subsidiary cannot establish standing to press their challenge now. Nor are certain aspects of that challenge currently ripe for adjudication. For those reasons, the complaint should ultimately be dismissed.

But rather than dismissing the case now, the Court should transfer it to the Dallas Division. Humana has its principal place of business in Louisville, Kentucky, and its Texas subsidiary is based in Dallas. Yet plaintiffs have filed in the Fort Worth Division, where no party resides and nothing giving rise to their claims occurred. The case should be transferred, so that the arguments for dismissal can be heard in the proper Division.

BACKGROUND

A. Traditional Medicare and Medicare Advantage

Through the Medicare program, the federal government provides health insurance to the elderly and disabled. Medicare covers hospitalizations under Part A of the statute, 42 U.S.C. §§ 1395c to 1395i-6, outpatient medical care under Part B, *id.* §§ 1395j to 1395w-6, and prescription drugs under Part D, *id.* §§ 1395w-101 to 1395w-154. This case concerns Medicare

Advantage—formerly known as Medicare+Choice—which Congress established in Part C of the statute, *id.* §§ 1395w-21 to 1395w-29.[1]

Under Medicare Advantage, the federal government pays insurers to provide the coverage that participating beneficiaries would otherwise receive through Parts A and B (collectively, though somewhat inaccurately, known as "fee-for-service" Medicare,[2] or else "traditional" Medicare). 42 U.S.C. § 1395w-22(a). Medicare Advantage insurers contract to provide coverage in a particular geographic area; most Medicare Advantage insurers have many such contracts. Each beneficiary can then choose among the plans available where he or she resides. *Id.* § 1395w-21(b). The insurers receive a predetermined sum for providing coverage to each beneficiary, which varies to account for the anticipated cost of covering a given individual. *See UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 873–76 (D.C. Cir. 2021) ("*United*") (discussing the Medicare Advantage payment model).

B. Medicare Advantage Payments

To calculate the payment owed to a Medicare Advantage insurer, the government first determines its "benchmark" (or "capitation rate"). The benchmark is based on the per capita cost of covering Medicare beneficiaries under Parts A and B in the relevant geographic area. 42 U.S.C.

[1] Medicare Advantage is sometimes referred to as "MA," just as Medicare+Choice was abbreviated "M+C," and both have been called "Part C" for short.

[2] In Medicare Part A, hospitals are no longer paid on the basis of the services provided. Instead, hospitals are paid at prospectively determined rates, depending on the "diagnosis-related group" to which each patient is assigned. 42 U.S.C. § 1395ww(d)(1)–(4); 42 C.F.R. § 412.60. This payment model aims to compensate hospitals for "the average cost of treating such a diagnosis, 'regardless of the [actual] number of conditions treated or services furnished during the patient's stay.'" *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1051 (D.C. Cir. 1997) (quoting 42 C.F.R. § 412.60(c)(2)). In Medicare Part B, providers are still paid for the particular services provided, under a pre-determined fee schedule in most cases. *See United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 967 (D.C. Cir. 1999) (citing 42 U.S.C. § 1395w-4(g)(2)(C), (D)).

§ 1395w-23(n); 42 C.F.R. § 422.258. Each participating insurer then submits a "bid," telling the government what payment the insurer will accept to cover a beneficiary with an average risk profile in that area. 42 C.F.R. § 422.254. If the insurer's bid is less than the benchmark, the bid becomes its "base payment"—the amount it is paid for covering a beneficiary of average risk—and the insurer receives a portion of the difference between its bid and base payment as a "rebate" that funds supplemental benefits otherwise unavailable to Medicare beneficiaries, or reduces the premiums they would otherwise owe. 42 U.S.C. § 1395w-24(b)(1)(C); 42 C.F.R. § 422.260. If the insurer's bid is greater than the benchmark, then the benchmark becomes its base payment and the insurer must charge beneficiaries a premium to make up the difference. *See* 42 U.S.C. §§ 1395w-23(a)(1)(B)(ii), 1395w-24(b)(2)(A).

Finally, the insurer's base payment is "risk-adjusted" for each covered beneficiary. The statute requires CMS to "adjust" each Medicare Advantage payment "for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including . . . health status . . . so as to ensure actuarial equivalence" between the payments made to insurers and the expected cost of coverage. 42 U.S.C. § 1395w-23(a)(1)(C)(i). In implementing this requirement, CMS generally "aims to pay the same amount to Medicare Advantage insurers for their beneficiaries' care as CMS would spend on those same beneficiaries if they were instead enrolled in traditional Medicare." *United*, 16 F.4th at 883; *see Berger v. Xerox Ret. Income Guar. Plan*, 338 F.3d 755, 759 (7th Cir. 2003) (explaining, in a different statutory context, that "actuarial equivalence" implies the comparison of "a present and a future value"). In the absence of risk adjustment, insurers would be overpaid for covering relatively healthy beneficiaries, and underpaid for covering sicker ones.

"To adjust the monthly payments, CMS uses a model—called the CMS-Hierarchical Condition Category, or CMS-HCC, risk-adjustment model—that it periodically studies and improves based on clinical information and cost data." *United*, 16 F.4th at 874. This "risk-adjustment model applies a regression analysis to the mass of data from traditional Medicare for a previous year to convert each demographic and health characteristic into an expected cost of coverage." *Id.* Those expected costs are then expressed as "relative factors"—sometimes called "risk factors"—assigned to each demographic and health characteristic.

The government periodically publishes tables of these numerical risk factors, which are added to produce a "risk score" for each beneficiary.[3] The beneficiary's risk score is multiplied by the insurer's base payment to calculate the amount owed to the insurer for covering that specific beneficiary. A risk score of 0.8 indicates that providing coverage to the beneficiary in question is expected to cost 80% as much as covering an average beneficiary. An insurer covering that beneficiary would therefore receive 80% of its base payment.[4]

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[3] *See, e.g.*, CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates (Apr. 1, 2019) ("2020 Rate Announcement"), *available at* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf. Medicare Advantage payments for calendar year 2023 are based on the risk factors published in the 2020 Rate Announcement.

[4] The insurer's payment is subject to two further adjustments, which are ignored in this simplified example and the more detailed example immediately below. The statutory coding pattern adjustment reduces an insurer's payment by at least a fixed amount. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III). And because the data used to calibrate the Medicare Advantage payment model is always several years old, the normalization factor accounts for intervening changes in treatment and diagnostic coding patterns. In 2023, the combined effect of the two adjustments reduces each insurer's payment by approximately 16.5%. The insurer therefore does not receive its full base payment multiplied by the beneficiary's risk score, but rather 83.5% of that amount. *See* CMS, Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates at 55, 59 (Apr. 4, 2022), *available at* https://www.cms.gov/files/document/2023-announcement.pdf.

To take a concrete example, in 2023, an 80-year-old man continuing his enrollment in Medicare Advantage was assessed to be 55.6% as risky as an average beneficiary, if he had not been diagnosed with any relevant conditions (and was neither institutionalized nor eligible for Medicaid). 2020 Rate Announcement at 74. An insurer would therefore be paid 55.6% of its base rate for covering him. A diagnosis of diabetes without complication would add another 10.5%, for a total risk score of 0.556 + 0.105 = 0.661. *Id.* at 75. An insurer would now receive 66.1% of its base payment for covering this hypothetical beneficiary. Diagnosis with rheumatoid arthritis adds another 42.1%, for a total risk score of 0.556 + 0.105 + 0.421 = 1.082. *Id.* at 76. An insurer would receive 108.2% of its base payment for covering this beneficiary, whose medical conditions and demographic characteristics combine to make covering him a slightly above-average risk. *See United*, 16 F.4th at 875 (discussing a similar example).

C. The Requirement of Medical Record Documentation

For this system of risk adjustment to function, Medicare Advantage insurers must report diagnosis data for each of their covered beneficiaries. The "accuracy" of that data must be certified by the insurer, 42 C.F.R. § 422.504(*l*), because reporting certain diagnoses constitutes a claim for the associated payments. Under the terms of the Medicare Advantage program, a reported diagnosis is only accurate if it is documented in the beneficiary's medical record. *See* 42 C.F.R. § 422.310(d)(1); 45 C.F.R. § 162.1002(c)(2)–(3). Diagnoses that are not documented in the medical record are not a valid basis for payment. *See United*, 16 F.4th at 869 ("Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer."); *United States ex rel. Swoben v. United Health Ins. Co.*, 848 F.3d 1161, 1176 (9th Cir. 2016) (noting that "CMS requires medical diagnosis codes to be supported by a medical record"); *United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d

1010, 1067 (N.D. Cal. 2020) ("A properly documented medical record must support each diagnosis code."). Plainly stated, when an insurer tells the government that a certain beneficiary has diabetes, and collects the additional payment associated with that diagnosis, the insurer must be able to show that the beneficiary does in fact have a documented case of diabetes.

This basic programmatic requirement of medical record documentation for reported diagnoses is enforced in several ways. Self-policing by Medicare Advantage insurers is the first means of enforcement. "CMS has long made clear that, under [42 C.F.R.] § 422.504(*l*), Medicare Advantage organizations have 'an obligation to undertake "due diligence" to ensure the accuracy, completeness, and truthfulness' of the [diagnosis] data they submit to CMS and 'will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness' of these data." *Swoben*, 848 F.3d at 1166–67 (quoting 65 Fed. Reg. 40,170, 40,268 (June 29, 2000)); *see also id.* at 1174. When an insurer reports a diagnosis that is not documented in a beneficiary's medical record, any resulting payment is an "overpayment"—that is, one to which the insurer "is not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B). Insurers must promptly return any overpayments that they identify. *Id.* § 1320a-7k(d)(1)–(2). When CMS issued a regulation implementing this statutory provision in 2014, it noted the "long-standing . . . requirement that a diagnosis submitted . . . by an MA organization for payment purposes must be supported by medical record documentation," and emphasized that an "invalid" diagnosis would "result in an overpayment." 79 Fed. Reg. 29,844, 29,921–22 (May 23, 2014) ("Overpayment Rule").

Civil actions are the second means of enforcing the requirement of medical record documentation for diagnoses reported in the Medicare Advantage program. An insurer's failure to promptly return an overpayment results in a false claim, and subjects the insurer to treble damages. 42 U.S.C. § 1320a-7k(d)(3).

D. RADV Audits, Extrapolation, and the Challenged Rule

Government audits are the third, and final, means of enforcement. "To supplement the regulatory obligations on Medicare Advantage insurers to certify the accuracy of the diagnosis codes . . . they report to CMS, . . . CMS seeks to confirm that its payments to insurers are correct by spot-checking the data submissions going back several years." *United*, 16 F.4th at 877. CMS reviews the diagnosis data on which payments are based through its "Risk Adjustment Data Validation" (or "RADV") audits. At its core, the RADV audit process is quite simple. First, the government chooses a Medicare Advantage contract to audit. Then it selects particular individuals receiving benefits under that contract. Next, the insurer submits medical records to substantiate the reported diagnoses for those beneficiaries. The government then compares the reported diagnoses—which are "risk adjustment data"—to the submitted medical records, against which the diagnoses are "validated." *See* 75 Fed. Reg. 19,678, 19,749 (Apr. 15, 2010) (explaining that validation of reported diagnoses "that result in additional payment" is achieved by confirming "the existence of clear, unambiguous diagnostic information in a beneficiary's medical record" that "provides the written support for the diagnosis that was made"). Any payment based on an unsupported diagnosis is identified as an overpayment that must be returned to the government. *See United*, 16 F.4th at 877. This audit process has been in place for many years. *See* 42 C.F.R. § 422.310(e) (2005); 42 C.F.R. § 422.257(e) (1999). Humana does not challenge its lawfulness here. *See* Compl. ¶¶ 38–39.

For more than a decade, CMS has been discussing the possibility of collecting not only the particular overpayments identified through RADV audits, but also using the audited sample as the

basis for a statistical extrapolation.[5] Such an extrapolation would allow the government to estimate and recoup more of the overpayments made to Medicare Advantage insurers, without having to inspect an unmanageably large volume of beneficiary medical records. *See, e.g.*, *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005) (noting that "sampling of similar claims and extrapolation from the sample is a recognized method of proof" when the government seeks to recover overpayments). But to date, the government has never demanded that any audited insurer repay more than the particular overpayments identified through a RADV audit.

Earlier this year, CMS published a final rule concerning extrapolated RADV audits, which Humana challenges here. 88 Fed. Reg. 6643 (Feb. 1, 2023) ("RADV Rule"). The RADV Rule was the culmination of a process that began in 2010, with the publication of an informal proposal to conduct extrapolated audits. CMS requested comment on that informal proposal, and in 2012 published a "Notice of Final Payment Error Calculation Methodology" for RADV audits on its website. Under the terms of that methodology, a sample of beneficiaries would be selected for each audited contract, and then used to calculate an estimated payment error for the entire Medicare Advantage contract.[6]

In 2018, CMS issued a notice of proposed rulemaking that discussed the agency's use of sampling and extrapolation in RADV audits. 83 Fed. Reg. 54,982, 55,037–41 (Nov. 1, 2018) ("NPRM"). CMS explained that, in addition to the methodology outlined in 2012, the agency had

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[5] *See, e.g.*, CMS, Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates at 22 (Apr. 7, 2008), *available at* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2009.pdf.

[6] CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) ("2012 Notice"), *available at* https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/recovery-audit-program-parts-c-and-d/other-content-types/radv-docs/radv-methodology.pdf.

"identified other potential methodologies for sampling and extrapolation, which would calculate improper payments made on the audited MA contract for a particular sub-cohort or sub-cohorts" of beneficiaries "in a given payment year." *Id.* at 55,039. Such a "sub-cohort" might, for example, be the beneficiaries diagnosed with a particular medical condition.

CMS finalized its proposal this year. In doing so, the agency announced that it was "not adopting any specific sampling or extrapolated audit methodology." RADV Rule, 88 Fed. Reg. at 6643. Instead, CMS would "rely on any statistically valid method for sampling and extrapolation that is determined to be well-suited to a particular audit." *Id.* The agency therefore does not have any official sampling or extrapolation methodology for RADV audits, and the 2012 Notice is no longer in effect.

Throughout these years, CMS continued to conduct RADV audits. For payment years 2011, 2012, and 2013, audits were conducted as described in the 2012 Notice. NPRM, 83 Fed. Reg. at 55,038. For payment years 2014 and 2015, CMS conducted RADV audits of particular "sub-cohorts" of interest. *See id.* at 55,039 n.26. Although each of these audits was designed to support the calculation of extrapolated audit recoveries, in the challenged rule CMS announced that the agency would "not extrapolate RADV audit findings" for these payment years, but only "collect the non-extrapolated overpayments" specifically identified in those years, just as it had done before. RADV Rule, 88 Fed. Reg. at 6644. CMS expects to begin issuing those audit findings in the coming year. And, in accordance with the challenged rule, CMS intends to "begin extrapolation with the [payment year] 2018 RADV audit," which the agency has not yet conducted. *Id.* There are no pending RADV audits from which CMS intends to make extrapolated recoveries.

The RADV Rule addressed one other issue: the use of a "fee-for-service adjuster" in extrapolated audits. When the government has attempted to enforce the requirement that diagnoses

submitted for payment be supported by medical record documentation—whether through the statutory overpayment provision, 42 U.S.C. § 1320a-7k(d), false claims actions, 31 U.S.C. § 3729 *et seq.*, or RADV audits—Medicare Advantage insurers have unsuccessfully argued that the requirement is not enforceable absent an "adjustment" to increase their payment rates or lower the documentation standard for their claims. Their theory is that erroneous diagnoses in the "fee-for-service" data used to calibrate the Medicare Advantage payment model suppress the risk scores produced by that model, and therefore reduce payments to Medicare Advantage insurers. To require medical record documentation of all reported diagnoses while paying insurers at the published rates, the argument goes, would violate the statutory requirement of "actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). Essentially, insurers claim that the published risk factors underestimate the costs borne by Medicare Advantage insurers. To achieve "actuarial equivalence," the argument concludes, CMS must either raise the payments to Medicare Advantage insurers or lower the documentation standard applied to their reported diagnoses, so that some number of payments could be lawfully premised on diagnoses absent from a beneficiary's medical record. That increase in payments or reduction in documentation standards has come to be known as a "Fee-for-Service Adjuster," often written as "FFS Adjuster."

When CMS promulgated its Overpayment Rule in 2014, the agency made clear that any payment based on a diagnosis not documented in the beneficiary's medical record is an "overpayment" to which the insurer "is not entitled" within the meaning of 42 U.S.C. § 1320a-7k(d)(4)(B).[7] 79 Fed. Reg. at 29,921. A commenter suggested that, even when an insurer identifies

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[7] In doing so, the Overpayment Rule merely reaffirmed the longstanding programmatic requirement of medical record documentation of all diagnoses submitted for payment. 79 Fed. Reg. at 29,923 ("CMS has required for many years that diagnoses that MA organizations submit for payment be supported by medical record documentation."); *see* 42 C.F.R. §§ 422.310(d)(1), 422.504(*l*); 45 C.F.R. § 162.1002(c)(2)–(3).

a diagnosis unsupported by medical record documentation, it need not return the associated payment unless "an appropriate FFS Adjuster" is "applied to the entire [MA] contract." *Id.* at 29,921. CMS rejected the argument that its statutory mandate to achieve "actuarial equivalence" required the agency to make such an adjustment before recouping overpayments.

The D.C. Circuit upheld the agency's decision in *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (June 21, 2022) (No. 21-1140). As the *United* court explained, "[t]he 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 Medicare Advantage insurers." 16 F.4th at 870. The insurer challenging the Overpayment Rule argued that "the actuarial-equivalence principle . . . impose[s] an implied—and functionally prohibitive—legal precondition on the requirement to return known overpayments." *Id.* But the D.C. Circuit held that the obligation to return such overpayments does not "depend on a prior determination of actuarial equivalence." *Id.* Instead, "the actuarial-equivalence requirement is . . . limited to the specified context of CMS's calculation and disbursement of monthly payments in the first instance." *Id.* at 885; *see id.* at 870–71 ("Actuarial equivalence is a directive to CMS" that "describes the goal of the risk-adjustment model Congress directed CMS to develop.").

CMS similarly rejected the use of an FFS Adjuster in the RADV Rule. Although its 2012 Notice (at 4) said that CMS would "apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset" to the recoveries calculated through an extrapolated RADV audit, the challenged rule provides that "CMS will not apply an FFS Adjuster in RADV audits," 88 Fed. Reg. at 6644, 6656. Humana brought this suit to challenge that decision and other aspects of the RADV Rule.

E. Procedural Background

The complaint asserts three claims. First, Humana alleges that the decision not to apply an FFS Adjuster in extrapolated RADV audits is unlawful. Compl. ¶¶ 72–77. Second, the insurer asserts that the application of that decision to RADV audits for payment years 2018 through 2023 is impermissibly retroactive. *Id.* ¶¶ 78–87. Third, and finally, Humana alleges that the challenged rule is invalid on procedural grounds, because CMS did not seek comment on the applicability of the D.C. Circuit's *United* decision to the challenged rulemaking. *Id.* ¶¶ 88–91.

CMS now moves to transfer the case or, in the alternative, to dismiss the complaint for lack of jurisdiction.

LEGAL STANDARD

Rule 12(b)(1) requires dismissal of a complaint where the court "lacks the statutory or constitutional power to adjudicate the case." *Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998) (citation omitted). As the parties asserting federal jurisdiction, plaintiffs bear the burden of proof. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992); *Choice Inc. v. Greenstein*, 691 F.3d 710, 714 (5th Cir. 2012).

ARGUMENT

In the challenged rule, CMS announced its intention to use statistical sampling and extrapolation in future Medicare Advantage audits, and not to include a certain adjustment factor in its audit calculations. The agency did not choose any particular methodology for selecting a sample or calculating an extrapolated recovery. *Cf.* Compl. ¶ 74 (alleging that the rule established a "final RADV audit methodology"). The agency has previously discussed the possibility of estimating all payment error across an entire Medicare Advantage contract, or estimating error for only a subset of payments—for example, those associated with particular categories of diagnoses.

CMS has not decided whether it will use either approach, or some other design, in any future RADV audit. No audits have been conducted under the challenged rule, and no contracts have been selected for audit.

Humana and its Texas subsidiary bring a facial challenge to the RADV Rule. That challenge should be transferred to the Dallas Division, where Humana's Texas subsidiary has its principal place of business. No party resides in the Fort Worth Division of this District, and none of the events giving rise to the case occurred here. But if the Court declines to transfer venue, it should dismiss the complaint for lack of standing and ripeness.

A. Venue should be transferred to the Dallas Division.

Humana lays venue in the Northern District of Texas under 28 U.S.C. § 1391(e)(1) which, as relevant here, provides that suits against "an officer or employee of the United States or any agency thereof acting in his official capacity . . . , or an agency of the United States, . . . may . . . be brought in any judicial district in which (A) a defendant in the action resides, (B) a substantial part of the events or omissions giving rise to the claim occurred, . . . or (C) the plaintiff resides." A corporation bringing suit is "deemed to reside . . . only in the judicial district in which it maintains its principal place of business." *Id.* § 1391(c)(2). Venue in the Northern District is proper because Humana Benefit Plan of Texas, Inc. has its principal place of business in Dallas County. Compl. ¶ 8. No other parties reside in this District, and nothing giving rise to the claims occurred here.

Although venue rests on one party's residence in Dallas County, Humana has filed this case in the Fort Worth Division. Defendants now move to transfer the case to its natural home in the Dallas Division under 28 U.S.C. § 1404(a), which applies "as much to transfers between divisions of the same district as to transfers from one district to another." *In re Radmax, Ltd.*, 720

F.3d 285, 288 (5th Cir. 2013) (per curiam). Where, as here, a case has "no apparent connection" to the Division in which it was filed, it is properly transferred to the Division in which venue is grounded. Indeed, some courts make such transfers *sua sponte*. *See Zuazua v. C.R. England, Inc.*, 2021 WL 8442046, at *3 (W.D. Tex. Aug. 20, 2021) (transferring venue *sua sponte* to another Division upon finding that "this case has no apparent connection to San Antonio," where it was filed); Order at 8, *Campbell v. Garland*, No. 3:19-CV-1887-L (N.D. Tex. July 21, 2021), ECF. No. 50 (Lindsay, J.) (transferring a suit *sua sponte* under § 1404(a) after finding "no apparent connection between this case and the Dallas Division"); Order, *Campbell v. Barr*, No. 3:20-CV-1605-G (N.D. Tex. June 19, 2020), ECF No. 6 (Fish, J.) ("There being no apparent connection between this case and this division, on the court's own motion, this case is TRANSFERRED to the Fort Worth Division . . . .").

The Fifth Circuit has set out an eight-factor balancing test for evaluating when transfer is appropriate under 28 U.S.C. § 1404(a). *In re Radmax*, 720 F.3d at 288 (citing *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 315 (5th Cir. 2008) (en banc)). Those factors are largely inapplicable here because, if this case is not ultimately dismissed (as it should be), then it would be decided on an administrative record, rather than proceeding through discovery to trial, and would not involve foreign law nor present any choice-of-law issues. Neither the Dallas Division nor the Fort Worth Division is more familiar with the federal statute and regulations at issue here. Nor are Defendants aware of any difference in the relative congestion of the dockets between the two Divisions. *See In re Radmax*, 720 F.3d at 288. The final factor, "the local interest in having localized interests decided at home," favors transfer to the Dallas Division, because venue is grounded on one party's residence there. *Id.* (quoting *In re Volkswagen*, 545 F.3d at 315).

When the plaintiff asserting venue "is a resident of Dallas" and "fails to allege any facts that could establish a connection between this case and the Fort Worth Division," then the "case belongs in the Dallas Division." Order, *Air Force Major v. Austin*, No. 4:22-cv-0248-P, 2022 WL 3698302, at *1 (N.D. Tex. Apr. 4, 2022) (Pittman, J.) (quotation omitted) (explaining that "judges in the Fort Worth and Dallas Divisions have a duty to analyze whether the cases on their dockets are being filed in the proper division"). The Fifth Circuit has required transfer between divisions "where only the plaintiff's choice weighs in favor of denying transfer and where the case has no connection to the transferor forum," among other considerations. *In re Radmax*, 720 F.3d at 290 (footnote omitted). Because no parties reside within this Division, and none of the "events or omissions giving rise to the claim occurred" here, 28 U.S.C. § 1391(e)(1), transfer to the only Division with any connection to this case is "clearly more convenient." *In re Radmax*, 720 F.3d at 288 (quoting *In re Volkswagen*, 545 F.3d at 315).

B. Humana and its Texas subsidiary lack standing.

The Supreme Court has "established that the irreducible constitutional minimum of standing contains three elements." *Lujan*, 504 U.S. at 560. These elements are "(1) an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent; (2) a causal connection between the injury and the conduct complained of; and (3) the likelihood that a favorable decision will redress the injury." *Croft v. Governor of Texas*, 562 F.3d 735, 745 (5th Cir. 2009) (citing *Lujan*, 504 U.S. at 560–61).

The complaint does not specifically allege an injury for either plaintiff, but it seems to imply two theories of injury: (1) that the government will make larger recoveries from plaintiffs in future audits under the challenged rule than it would have in the rule's absence, and (2) that the

rule altered the documentation standard in the Medicare Advantage program. Neither theory suffices.

i. Possible future audit demands do not provide standing.

The first theory of injury rests on the assumption that Humana or its Texas subsidiary will eventually be subject to RADV audits under the challenged rule, and that the government's recovery from those audits will be increased because of the rule. *See, e.g.*, Compl. ¶ 65 (suggesting that the RADV Rule will lead to unlawfully large "audit recoveries"). That injury is not "certainly impending," and is therefore "too speculative for Article III purposes." *Clapper v. Amnesty Int'l*, 568 U.S. 398, 409 (2013) (citing *Lujan*, 504 U.S. at 565, n.2 (internal quotation marks omitted)). The Supreme Court has "repeatedly reiterated that 'threatened injury must be *certainly impending* to constitute injury in fact,' and that '[a]llegations of *possible* future injury' are not sufficient." *Clapper*, 568 U.S. at 409 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (internal quotation marks omitted)). But "possible future injury" is all that plaintiffs can allege here.

Humana may not be selected for a RADV audit, or not for quite some time. And that is all the more true for its Texas subsidiary. If and when they are eventually audited, plaintiffs may not be found to have received any overpayments. (RADV audits have previously returned such a finding for some Medicare Advantage contracts.) And even if they are audited and found to have received overpayments, CMS may not demand an extrapolated recovery that would be increased by the absence of an "FFS Adjuster." Although CMS currently intends to extrapolate, its regulations say only that the agency "may" collect extrapolated recoveries. 42 C.F.R. §§ 422.310(e), 422.311(a)(2); *see* RADV Rule, 88 Fed. Reg. at 6650 (explaining that "extrapolation is expected to be the standard practice for RADV audits beginning in [payment year] 2018," but that extrapolation is not required by the challenged rule). CMS has previously

conducted audits from which it intended to make extrapolated recoveries, then chosen to demand only the particular overpayments specifically identified in those audits, rather than an extrapolated sum. For these reasons, a possibly increased recovery from a possible future audit under the RADV Rule does not amount to a concrete injury that is certainly impending now. *See Willamette Family, Inc. v. Allen*, 643 F. Supp. 3d 1180, 1192 (D. Or. 2022) (holding, on a motion for preliminary injunction, that alleged injuries from "incomplete audits" are too "speculative" to support standing).

Nor can Humana salvage this theory of injury by describing it as the need to account for increased recoveries in future audits when formulating its bids. *See* Compl. ¶ 74 (suggesting that the rule affects "the revenue that Humana . . . can reasonably project when certifying bids for benefit plans"). Because the harm of such audits "is not certainly impending," as discussed above, Humana cannot establish standing through "a reasonable reaction" to that "risk of harm." *Clapper*, 568 U.S. at 416. To hold otherwise "would be tantamount to accepting a repackaged version of [Humana's] first failed theory of standing." *Id.* The second-order effects of hypothetical audit recoveries cannot constitute an imminent, concrete injury when such recoveries themselves do not.

ii. The challenged rule did not change the documentation standard in the Medicare Advantage program.

The second theory of injury is that the challenged rule impermissibly altered the documentation standard that applies throughout the Medicare Advantage program, eliminating Humana's ability to submit unsupported diagnoses for payment. *See, e.g.*, Compl. ¶ 40 (alleging that, prior to the challenged rule, CMS paid "Medicare Advantage organizations based on *reported* diagnosis codes they obtain[ed] from healthcare providers," without regard to medical record documentation); *id.* ¶ 44 (alleging that, prior to the challenged rule, the "documentation standard

used to calculate [Medicare Advantage] payments" was "diagnosis codes reported in claims forms," regardless of support in a beneficiary's medical record).

But injury based on a purported change in the documentation standard does not establish standing to pursue this case. Even if a change in the documentation standard under which Medicare Advantage insurers may claim and retain payments for covering beneficiaries diagnosed with certain medical conditions would constitute an injury-in-fact, such an injury is not fairly traceable to the challenged rule, which did not change that documentation standard.

Before the RADV Rule was promulgated, CMS required every diagnosis submitted for payment by a Medicare Advantage insurer to be supported by medical record documentation. *See United*, 16 F.4th at 869 ("Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer."); *Swoben*, 848 F.3d at 1176 (noting that "CMS requires medical diagnosis codes to be supported by a medical record"); *Ormsby*, 444 F. Supp. 3d at 1067 ("A properly documented medical record must support each diagnosis code."). Under the 2014 Overpayment Rule, every single payment based on an unsupported diagnosis constitutes an "overpayment" that the insurer "is not entitled" to retain. 42 U.S.C. § 1320a-7k(d)(4)(B); *see* 79 Fed. Reg. at 29,921–22. Insurers are required to certify the accuracy of the diagnoses they submit for payment, 42 C.F.R. § 422.504(*l*), and to promptly return payments based on unsupported diagnoses whenever such payments are identified, 42 U.S.C. § 1320a-7k(d)(1)–(2). Insurers have no right to retain any such payments. Though some insurers, including Humana, disputed that definition of "overpayment," the Overpayment Rule was upheld when challenged and remains in effect today. *Cf.* Compl. ¶ 53 n.35 (suggesting that Humana's 2017 bid was premised on "the assumption that . . . overpayments will be determined" under a more lenient documentation standard).

Similarly, before the RADV Rule was promulgated, CMS had an unfettered right to audit the diagnoses submitted for payment and recoup any overpayments that the audit identified. *See id.* ¶ 39 ("For many years after launching the RADV audit program in 1999, CMS recouped the payments corresponding . . . to those . . . diagnosis codes in the audited sample that were not documented in medical records."). There were, of course, practical limitations on the agency's ability to conduct those audits, which restricted their number and scope. But only such practicalities kept CMS from auditing every single diagnosis reported for payment, if it had wished to do so. Insurers had no right to a particular level of enforcement activity.

Because insurers had no right to claim or retain payments based on unsupported diagnoses before the promulgation of the challenged rule, the rule did not alter the documentation standard by eliminating such a right. Any such injury therefore is not fairly traceable to the challenged rule.

Humana has not alleged standing to bring this facial challenge, and so the Court should dismiss the complaint for lack of subject matter jurisdiction.

C. Humana's substantive challenge is not ripe.

"The ripeness doctrine is drawn from both Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction . . . ." *Nat'l Park Hosp. Ass'n v. Dep't of the Interior*, 538 U.S. 803, 808 (2003) (quotation omitted). The doctrine "separates those matters that are premature because the injury is speculative and may never occur from those that are appropriate for judicial review." *United Transp. Union v. Foster*, 205 F.3d 851, 857 (5th Cir. 2000). It "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies." *Nat'l Park*, 538 U.S. at 807 (quotation omitted). It also "protect[s] the agencies from judicial interference until an

administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* at 807–08 (quotation omitted).

Even if Humana can allege an injury fairly traceable to the RADV Rule—which it cannot—its substantive challenge is unripe. *See* Compl. ¶¶ 72–77. 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." 42 U.S.C. § 1395w-23(a)(1)(C)(i). That claim cannot be properly assessed until CMS conducts an audit according to the "statistically valid method for sampling and extrapolation that [it] determine[s] to be well-suited to [that] particular audit." RADV Rule, 88 Fed. Reg. at 6643. In its complaint, Humana notes the distinction that the *United* court drew between the Overpayment Rule, "which requires only that an insurer report and return to CMS known errors in its beneficiaries' diagnoses that it submitted as grounds for upward adjustment of its monthly capitation payments," and "[c]ontract-level RADV audits, which would effectively eliminate—and require repayment for—all unsupported codes in a Medicare Advantage insurer's data." 16 F.4th at 892. *See* Compl. ¶¶ 57, 64. The D.C. Circuit said that "the contexts of contract-level RADV audits and overpayment refunds are plainly distinguishable," 16 F.4th at 893 n.1, and "materially distinct," *id.* at 892. Humana's substantive claim rests on the argument that this distinction makes a significant difference.

But it is currently uncertain when, if ever, CMS will attempt to use sampling and extrapolation to "effectively eliminate—and require repayment for—all unsupported codes in a Medicare Advantage insurer's data." *Id.* CMS has not decided whether to design any future RADV audits according to such a methodology, or to employ a methodology that would only seek to eliminate and require repayment for a subset of unsupported codes in a Medicare Advantage

insurer's data, or to use some other methodological design altogether. RADV Rule, 88 Fed. Reg. at 6654 ("We are not adopting any particular statistical sampling methodology in this final rule.").

A party's claim "is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (quotation omitted). The use of RADV audits to seek repayment for all unsupported diagnoses "may never occur." *United Transp. Union*, 205 F.3d at 857. And Humana cannot show the hardship necessary to establish ripeness. *See Cochran v. SEC*, 20 F.4th 194, 212 (5th Cir. 2021). As discussed above, the RADV Rule will not have a "direct and immediate impact" upon Humana until the insurer is actually audited. *Energy Transfer Partners, L.P. v. FERC*, 567 F.3d 134, 140 (5th Cir. 2009). Its substantive claim should therefore be dismissed as unripe.

CONCLUSION

For the reasons set forth above, this case should be transferred to the Dallas Division of this District. If the Court does not transfer the case, the complaint should be dismissed for lack of jurisdiction.

Respectfully submitted,

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Dated: December 15, 2023 *Counsel for Defendants*

CERTIFICATE OF CONFERENCE

Defendants' counsel conferred with Plaintiffs' counsel by electronic mail and telephone from December 13 through 15, 2023. Plaintiffs' counsel authorized Defendants' counsel to represent that Plaintiffs oppose transfer of venue to the Dallas Division.

/s/ James Bickford