UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITEDHEALTHCARE INSURANCE COMPANY, et al.,)))
Plaintiffs,)
v.) Civil Action No. 16-157 (RMC)
ALEX M. AZAR II, Secretary of the)
Department of Health and Human Services, et al.,))
Defendants.)))

MEMORANDUM OPINION

This Court vacated a final rule issued by the Centers for Medicare & Medicaid Services (CMS) to determine when certain private insurers were overpaid by Medicare because it did not comply with the statutory requirement of "actuarial equivalence." *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.D.C. 2018). The government moves for reconsideration. Although the government does not ask to reinstate the rule, it does ask the Court to narrow its decision based on new empirical analysis. Because the data underlying that analysis has long been in CMS' possession but was not litigated and because the analysis does not persuade, the Court will deny the motion.

I. BACKGROUND

A more robust description of the statutory scheme, regulatory scheme, and facts of this case can be found in the Court's previous decision. *See id.* at 176-83. A brief recap is necessary for context.

Under the Medicare Advantage program, Medicare-eligible beneficiaries can elect to receive health insurance coverage through private insurance companies instead of through

traditional Medicare programs administered by CMS. CMS reimburses hospitals participating in traditional Medicare a fixed amount based on each patient's diagnosis at discharge, and it reimburses doctors a fixed amount based on the specific services provided. By comparison, CMS reimburses insurers participating in Medicare Advantage a fixed amount for each patient they enroll, based in part on various risk factors including diagnosis on discharge.

Although different reimbursement schemes are at play, by statute CMS must pay Medicare Advantage insurers in a manner that ensures "actuarial equivalence" with payments to traditional Medicare providers. *See* 42 U.S.C. §1395w-23(a)(1)(C)(i). CMS accomplishes this feat by using a complex risk-adjustment model, the CMS Hierarchical Condition Category (CMS-HCC) model, to regress total traditional-Medicare expenditures onto traditional-Medicare beneficiaries' risk factors. The output of this model is a marginal dollar cost associated with each risk factor, reduced to a "normalized" risk coefficient that takes as its starting point the "average beneficiary." Medicare Advantage insurers are paid based on the cumulative risk scores of their patients. The underlying logic is that developing risk coefficients from traditional Medicare data, and then adjusting a Medicare Advantage beneficiary's risk score, will render the cost to CMS under traditional Medicare and the cost to the insurer under Medicare Advantage actuarily equivalent.

As part of its oversight of the Medicare Advantage program, CMS audits a sample of reimbursement requests submitted by Medicare Advantage insurers. Costs associated with

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¹ For example, the model might determine that the average beneficiary receives \$10,000 per year in reimbursable expenses and that the marginal cost of a given risk factor is \$2,000. By definition the average beneficiary has a risk score of 1.0, so the risk factor would have a normalized risk coefficient of 0.2.

² For example, a patient with a cumulative risk score of 1.2 costs 20% more than the average beneficiary and the Medicare Advantage insurer would be reimbursed 120% the average benchmark rate.

unsupported diagnoses must be reported to CMS. But reimbursement is not limited to only those audited cases. As of 2008, CMS applies a "Risk Adjustment Data Validation" (RADV) audit to extrapolate the error rate in the audited sample across an entire insurance contract, and the insurer is responsible for returning all overpayments calculated based on that extrapolated rate.

RADV audits introduce a complication in this payment scheme. RADV audits extrapolate an error rate based on audited data from a Medicare Advantage insurer, but Medicare Advantage payment rates are based on data drawn from traditional Medicare, which is itself unaudited and admittedly prone to some degree of error. This has the effect of making traditional Medicare patients appear healthier, and cost less per diagnosis code, than their Medicare Advantage counterparts.³ For years CMS counterbalanced this effect by implementing a fee-for-service adjuster (FFS Adjuster), which estimated the error rate present in traditional Medicare diagnoses; insurers were only responsible for repayment of RADV audit errors exceeding the estimated traditional Medicare error rate. In early 2014, however, CMS finalized a rule which eliminated the FFS Adjuster and upset this balance. *See* 79 Fed. Reg. 29,844 (May 23, 2014) (Overpayment Rule). UnitedHealthcare challenged the Overpayment Rule in January 2016. *See* Compl. [Dkt. 1].

This Court made three findings relevant to the instant motion when it ruled on summary judgment. First, the Court determined that "two figures are actuarially equivalent when they share the same set of actuarial assumptions." *UnitedHealthcare*, 330 F. Supp. 3d at 186 (citing *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011)). "Different assumptions behind the elements of a calculation would, necessarily, result in actuarially non-

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³ This is because the CMS regresses total Medicare expenditures onto both audited and unaudited diagnosis codes. Put another way, costs are spread out among a larger set of diagnoses, such that each individual diagnosis takes up a smaller share of the costs.

equivalent results." *Id.* Thus, an "inevitable" result of relying on unaudited data to set payment rates but audited data to determine overpayment is that CMS "will pay less for Medicare Advantage coverage because," unlike traditional Medicare settings, "essentially no errors would be reimbursed." *Id.* at 187. This violates the actuarial equivalence requirement of 42 U.S.C. § 1395w-23(a)(1)(C)(i).

Second, the statutory scheme requires CMS to establish risk factors for Medicare Advantage patients "using the same methodology as is expected to be applied in making payments under" traditional Medicare. 42 U.S.C. § 1395w-23(b)(4)(D). However, beneficiary risk factors in traditional Medicare were developed using unaudited diagnoses. So, for the same reason, the Court determined that CMS failed to use the "same methodology" and violated this statutory requirement when it subsequently applied RADV audits to Medicare Advantage payments without accounting for the "crucial data mismatch" between audited and unaudited data. *UnitedHealthcare*, 330 F. Supp. 3d at 187.

Third, CMS stated as part of prior rulemaking that the FFS Adjuster was necessary to "account[] for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the [Medicare Advantage] risk-adjustment model (FFS claims)." *Id.* at 188 (quoting RADV Final Methodology at AR5314-15) (emphasis and internal quotations omitted). Although "Medicare Advantage insurers should [not] be permitted knowingly or recklessly to bill CMS for erroneous diagnosis codes," *id.* at 189, the Court determined that this concern did not adequately explain why, as a technical matter, the FFS Adjuster was no longer necessary and why the agency had changed its position. This absence of adequate explanation

rendered the Overpayment Rule arbitrary and capricious. *Id.* (citing *Republic Airline Inc. v. U.S. Dept. of Transp.*, 669 F.3d 296 (D.C. Cir. 2012)).

For each of these three reasons, the Court vacated the Overpayment Rule. *Id.* at 192. Sixty days later, the government moved for partial reconsideration under Federal Rule of Civil Procedure 60(b). See Defs.' Rule 60(b) Mot. for Partial Recons. (Mot.) [Dkt. 76]. The government does not dispute that the Overpayment Rule failed to explain the shift in policy, was arbitrary and capricious, and should remain vacated. *Id.* at 1. But the government notes that just weeks after the Court's decision, CMS finalized an FFS Adjuster Study which concluded that, as an empirical matter, "diagnosis error in FFS claims data does not lead to systematic payment error" in the Medicare Advantage program. CMS, Fee for Service Adjuster & Payment Recovery for Contract Level Risk Adjustment Data Validation Audits at 6 (Oct. 26, 2018) (FFS Adjuster Study), available at https://tinyurl.com/ve3737d; see also 83 Fed. Reg. 54,982 (Nov. 1, 2018) (publishing FFS Adjuster Study and soliciting comments on its conclusions). The government contends that this conclusion calls into question the Court's own findings regarding the "inevitable" consequences of a data mismatch between audited and unaudited records, and further asks the Court, as a matter of judicial prudence, to reconsider its opinion and reserve a decision on the necessity of the FFS Adjuster until CMS has an opportunity to further investigate the issue through regular rulemaking processes.

UnitedHealthcare signaled its intent to oppose, but briefing was stayed pending the release of the data underlying the FFS Adjuster Study. *See* 12/20/2018 Minute Order. CMS publicly released some data on April 25, 2019. Shortly thereafter, CMS noticed its intentions to release "[a]dditional data . . . to all parties who have entered in an applicable data use agreement" and to "replicate" the FFS Adjuster Study and publish the results. 84 Fed. Reg. 18,215, 18,216

(Apr. 30, 2019). CMS published that replicated study—which explained certain methodological decisions and confirmed the FFS Adjuster Study's conclusions—on June 28, 2019, and further extended the comment period for the FFS Adjuster Study. *See* Defs.' Reply in Supp. of Their Rule 60(b) Mot. for Partial Recons. (Reply), Ex. A, FFS Adjuster Study Addendum [Dkt. 97-1]; *see also* 84 Fed. Reg. 30,983 (June 28, 2019) (2019 FFS Adjuster Study Rule). Although that rulemaking process has not yet completed, briefing resumed and the motion is now ripe for review.⁴

II. LEGAL STANDARD

The government asks the Court for relief pursuant to Federal Rule of Civil Procedure 60(b). Rule 60(b) provides as follows:

On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons:

- (1) mistake, inadvertence, surprise, or excusable neglect;
- (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);
- (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;
- (4) the judgment is void;
- (5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
- (6) any other reason that justifies relief.

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⁴ See Mot.; United's Brief in Opp'n to Defs.' Rule 60(b) Mot. for Partial Recons. (Opp'n) [Dkt. 91]; Reply [Dkt. 97].

Fed. R. Civ. P. 60(b). The government specifically moves for relief under provisions (b)(2) and (b)(6).

"In considering a Rule 60(b) motion, the district court 'must strike a delicate balance between the sanctity of final judgments . . . and the incessant command of a court's conscience that justice be done in light of *all* the facts." *PETA v. HHS*, 901 F.3d 343, 354-55 (D.C. Cir. 2018) (quoting *Twelve John Does v. District of Columbia*, 841 F.2d 1133, 1138 (D.C. Cir. 1988)) (internal quotations omitted). To that end, a district court considering a Rule 60(b) motion "is vested with a large measure of discretion." *Id.* at 355. Notwithstanding, "[m]otions for reconsideration are 'disfavored," *Walsh v. Hagee*, 10 F. Supp. 3d 15, 18 (D.D.C. 2013) (citation omitted), and the D.C. Circuit has cautioned that Rule 60(b) "should be only sparingly used." *PETA*, 901 F.3d at 355.

III. ANALYSIS

A. Rule 60(b)(2)

The government first argues that its Rule 60(b) motion is appropriate because the FFS Adjuster Study constitutes "new evidence" that would have been relevant to the Court's decision. UnitedHealthcare responds that the data underlying the FFS Adjuster Study has been in CMS' possession for many years now and that the agency has not shown that with "reasonable diligence" the study "could not have been discovered" before judgment. In turn, the government does not contest the age of the data but asserts that the study is the culmination of an extended review, that it is commonplace for agencies to review previous decisions, and further that the agency is entitled to a presumption of regularity when performing such a review. *See Allied Mech. Servs., Inc. v. NLRB*, 668 F.3d 758, 770-71 (D.C. Cir. 2012).

The government's response misses the mark. Although CMS is entitled to a presumption of regularity in its review of prior decisions, the development of facts central to this

litigation does not call merely for regularity—it calls for the exercise of "reasonable diligence." Compare Reasonable Diligence, Black's Law Dictionary (11th ed. 2019) ("A fair degree of diligence expected from someone of ordinary prudence under the circumstances like those at issue."), with Ordinary Diligence, Black's Law Dictionary (11th ed. 2019) ("The diligence that a person of average prudence would exercise in handling his or her own affairs."). Here, CMS was aware of actuarial criticisms of the Overpayment Rule when it first responded to comments. See Overpayment Rule at 29,844. It was similarly aware that those criticisms were at the heart of this lawsuit when the Complaint was filed in early 2016. See generally Compl. And it remained aware of the importance of this issue through over two years of litigation in this Court.

By contrast, the underlying data sets CMS used for its FFS Adjuster Study were developed in 2004, 2005, 2008, and 2011, respectively. See 2019 FFS Adjuster Study Rule at 30,983. The FFS Adjuster Study itself is only sixteen pages long. There is no indication in the record or from the government that the timeline for completion of the FFS Adjuster Study was informed in any way by its potential evidentiary value in this litigation. After CMS received criticisms of the FFS Adjuster Study, it only took some four months for the agency to replicate that study. See 2019 FFS Adjuster Study Rule. Given the years available to CMS, the Court cannot conclude that the completion of the FFS Adjuster Study after the 11th hour is the result of "reasonable diligence" under the circumstances. See In re Neurontin Mkg. & Sales Practices Litig., 799 F. Supp. 2d 110, 114-15 (D. Mass. 2011) (holding a new meta-analysis of existing scientific studies was not new evidence because the defendant "could have performed a similar meta-analysis prior to the trial"); see also Good Luck Nursing Home, Inc. v. Harris, 636 F.2d 572, 577 (D.C. Cir. 1980) ("[A] party that . . . has not presented known facts helpful to its cause when it had the chance cannot ordinarily avail itself on [R]ule 60(b) after an adverse judgment

has been handed down."); *cf. Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596-97 (1993) ("Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.").⁵

B. Rule 60(b)(6)

The government argues that relief is nonetheless warranted under Rule 60(b)(6), which permits relief from judgment for "any other reason that justifies relief." Fed. R. Civ. P. 60(b)(6). But not just any reason will do; such relief is reserved for "extraordinary circumstances." *Ackermann v. United States*, 340 U.S. 193, 199 (1950). This is a weighty burden that is best satisfied when "the interest that litigation must someday end [is] only slightly impinged, while the countervailing interest that justice be done [is] seriously at stake." *Good Luck Nursing Home*, 636 F.2d at 577-78. For example, "[w]hen a party timely presents a previously undisclosed fact so central to the litigation that it shows the initial judgment to have been *manifestly unjust*, reconsideration under [R]ule 60(b)(6) is proper even though the original failure to present that information was inexcusable." *Id.* at 577 (emphasis added). And for the reasons below, the Court finds these criteria are not satisfied.

1. Unjust Outcome

In response to the government's motion, UnitedHealthcare has gone to great lengths to explain why the conclusions of the FFS Adjuster Study are incorrect. For its part, the government has done little to substantiate the findings of the FFS Adjuster Study to the Court. Without getting too much into the weeds, UnitedHealthcare argues:

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⁵ As the government suggests, provision (b)(2) is an odd fit with the administrative record and rulemaking process because there is no "evidence"; analysis under provision (b)(6) may be more appropriate. *See* Reply at 10-11.

First, that the FFS Adjuster Study answers the wrong question. The FFS Adjuster Study concluded that "errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to [Medicare Advantage] organizations." FFS Adjuster Study at 5. But problems with the Overpayment Rule arise because it operates in two steps: (1) payment to insurers; and (2) recoupment of overpayment by CMS. The Court determined that the Overpayment Rule created a "crucial data mismatch" between the first step and the second. UnitedHealthcare, 330 F. Supp. 3d at 187. That is, unaudited data was used to develop risk coefficients for the first step, but audited data was used to determine when insurers had been overpaid. The FFS Adjuster Study addresses only the effect of audited data on the development of risk factor coefficients for payments, i.e., only the first step. It does not examine the effect of using only audited data to determine overpayment amounts to Medicare Advantage insurers, i.e., the second step, and so does not speak to the "crucial data mismatch" identified by the Court.

Second, and more fundamentally, that the FFS Adjuster Study mixes audited and unaudited data when analyzing payments to insurers and so actually negates its authors' conclusions. Simplified, the CMS-HCC risk model also proceeds in two steps: (1) regression of total Medicare Parts A and B expenditures for each beneficiary onto all risk factors, producing a marginal dollar cost for each risk factor; and (2) normalization of those marginal costs against the average beneficiary cost, producing a risk coefficient. While the FFS Adjuster Study used audited data to generate the marginal dollar costs in step one, it then normalized those coefficients against unaudited data. See CMS, Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Validation Audits - Technical Appendix at 13 (Oct. 26, 2018), available at https://tinyurl.com/rte2b61 ("In the next step, we take the new coefficients

and apply them on the original FFS data set."). This was accomplished by mathematically correcting—*i.e.*, adjusting downwards—the results using audited data to conform to the results using unaudited data. Without this correction, the coefficients *over* predict total Medicare costs, which is exactly what one would expect if higher marginal dollar costs generated from only audited diagnoses were applied to a beneficiary population that includes both audited and unaudited diagnoses. But this correction plays the same role as the FFS Adjuster, only proving the FFS Adjuster's necessity in the payment scheme. *See* Opp'n, Ex. 7, Decl. of Julia Lambert [Dkt. 91-7] ¶¶ 40-42.

The Court need not linger on the details of these arguments. On a motion to reconsider, it is sufficient to say that the arguments are fully explained and the government does not adequately respond. Indeed, the government asserts that it would be improper to "fully address United's criticisms outside of the rulemaking process." Reply at 23. Instead, the government offers the FFS Adjuster Study not "for the validity of its conclusions, which are still tentative, but rather as evidence that the Court's conclusions may not necessarily be accurate, [and] to demonstrate the technical complexity of the questions that the study addresses." *Id.* at 24.

In the regular course of rulemaking pending comments, the government is entitled to withhold its final conclusions until its review process is completed. But the government cannot be coy when it seeks extraordinary relief. Having already argued and lost its case after two years of litigation and careful consideration by the Court, merely hinting at possible inaccuracies and suggesting technical complexity is not enough to now convince the Court that the interests of justice are "seriously at stake" or that the outcome was "manifestly unjust." True, this case is technically complex, but it did not somehow become *more* technically complex after

the Court's decision than it was before. In the face of robust argument that the Court's initial decision was correct—which itself followed only after extensive briefing from both parties—the government's new arguments to the contrary must be both convincing and definitive.

2. Interest of Finality

On the other hand, the stakes for Plaintiffs are high. As the government itself previously argued, merely vacating the Overpayment Rule without addressing the merits of the CMS methodology "would provide plaintiffs no relief" because it "would not necessitate any change to the Secretary's risk adjustment methodology." Defs.' Mem. of P. & A. in Supp. of Their Mot. to Dismiss for Lack of Subject Matter Jurisdiction [Dkt. 12-1] at 19. The government motion for reconsideration demonstrates the problem: without the finality of a decision, the government seems intent on re-litigating the Court's findings.

C. Deference to the Regulatory Process

The government nonetheless counsels deference to the CMS administrative process and asks the Court to give UnitedHealthcare "time . . . to 'convince the agency to alter a tentative position" and provide the agency "an opportunity to correct its own mistakes and to apply its expertise,' potentially eliminating the need for (and costs of) judicial review." *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 387 (D.C. Cir. 2012) (quoting *Pub. Citizen Health Research Grp. v. FDA*, 740 F.2d 21, 30-31 (D.C. Cir. 1984)). But the factors discussed in *American Petroleum Institute* do not support reconsideration when applied to this case.

In *American Petroleum Institute*, EPA promulgated a final rule that exempted some hazardous materials from regulation, but not others. The petitioners argued that the final rule should have exempted a broader range of materials. During the pendency of litigation, however, EPA backtracked and proposed a rule eliminating the exemption entirely which, if adopted, would have mooted the petitioners' claims. Alternatively, the comment process on the

proposed rule gave the petitioners another avenue to argue their case to the agency, before any judgment by the court. Accordingly, the D.C. Circuit held the case in abeyance, reasoning that "waiting to resolve this case allows EPA to apply its expertise and correct any errors, preserves the integrity of the administrative process, and prevents piecemeal and unnecessary judicial review." *Id.* at 388.

Essentially all those facts cut in the opposite direction here. For one, CMS is no longer writing on a blank slate: UnitedHealthcare had plenty of time to convince CMS and the Court of its position; CMS had plenty of time to consider and finalize its interpretation; and whatever the costs of judicial review, after two years of litigation, multiple rounds of briefing, and three decisions by the Court, they have already been expended. For another, if the Court modifies its decision and CMS adopts its proposed rule, the effect would be to expand the scope of litigation, not contract it. That is, the proposed rule is not a "complete reversal of course" by the agency that might otherwise end this litigation. *Id*. To the contrary, CMS is doubling down on its position. Thus, instead of mooting UnitedHealthcare's claims, CMS seeks to *re-open* a matter which has already been decided. Further, this expansion would occur even if the Court modifies its decision and CMS does *not* adopt the proposed rule. Under those circumstances, the most that could be said is that the regulatory landscape would revert to the same condition as before any of this litigation began, setting the parties up for another four years of conflict.

"Put simply, the doctrine of prudential ripeness ensures that Article III courts make decisions only when they have to, and then, only once." *Id.* at 387. The government does not contest that this matter was properly ripe when it was litigated or when it was decided. The Court carefully considered the matter and issued its decision, and that decision was crafted to give practical, not merely nominal, relief to the prevailing party. Having lost, the government

now seeks to reset the process. But "an agency [cannot] stave off judicial review of a challenged

rule simply by initiating a new proposed rulemaking that would amend the rule in a significant

way." Id. at 388. By that same token, an agency clearly cannot undo judicial review of a

challenged rule by initiating proposed rulemaking after an adverse decision has already been

handed down.

CONCLUSION IV.

For the reasons stated, the Court will deny the government's Rule 60(b) Motion

for Partial Reconsideration, Dkt. 76. A memorializing Order accompanies this Memorandum

Opinion.

Date: January 27, 2020

ROSEMARY M. COLLYER United States District Judge

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