IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES, *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civ. No. 1:21-cv-3031 (RJL)

PLAINTIFF AAMS'S POST-HEARING BRIEF

Plaintiff Association of Air Medical Services (AAMS) respectfully submits this post-argument brief pursuant to the Court's invitation at the conclusion of the March 21, 2022, oral argument in this case. Dkt. 57 (Hearing Tr.) at 47:7-21.

At the hearing, this Court considered whether and when to issue a decision on the cross-motions in view of the court's vacatur in *Texas Medical Association v. U.S. Department of Health & Human Services*, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022) (*TMA*), of certain elements of the Interim Final Rule Part II; and also in view of the government's representation that it is "hoping to achieve" the issuance of a final rule in May. *See* Hearing Tr. 31:20–46:24.

The issuance of a decision as soon as practicable remains critical for AAMS members and the patients they serve. On that point, three considerations warrant emphasis.

1. Interim Final Rule (IFR) Parts I and II are Harming AAMS Members.

The challenged provisions of IFR Parts I and II, which create the methodology for the qualifying payment amount (QPA) and grant special weight to the QPA in the independent dispute resolution (IDR) process, respectively, are presently in force and therefore are presently harming AAMS members. Only a prompt ruling by the Court on those provisions will stop the ongoing

harm to AAMS members and protect patient access to air ambulance services, particularly in rural areas, where patients are great distances from hospitals.

AAMS challenges three aspects of the QPA methodology—contracted-rate exclusions, arbitrary similar-specialty treatment, and overbroad geographic regions—that, when combined, have the purpose and effect of deflating the QPA. Many plans and issuers are currently paying the deflated QPA to AAMS members. Those payments are pushing AAMS members into open negotiations, and towards the IDR process. During IDR, the Departments will still require arbitrators to treat the deflated QPA as the presumptive out-of-network rate under IFR Part II. AAMS members, therefore, must presently meet a counter-textual, heightened evidentiary burden to overcome the QPA presumption and obtain the appropriate out-of-network rate from the plan or issuer in IDR.[1] The one-sided process drains the resources and time of AAMS members and negatively impacts their business operations.

The harm to AAMS members increases daily as they move forward under the procedures established by the No Surprises Act (NSA). The IDR process applies to services furnished during plan years beginning on or after January 1, 2022. When a dispute arises, a party must initiate open negotiations within 30 business days after the provider receives a payment denial or initial payment. 45 C.F.R. § 149.510(b)(1)(i). The open-negotiation period lasts 30 business days. *Id.* The IDR process must then be initiated within 4 business days after open negotiations fail. *Id.* § 149.510(b)(2)(i). The parties have 3 business days to select an IDR entity and 10 business days thereafter to submit an offer. *Id.* §§ 149.510(c)(1)(i), (c)(4)(i). The arbitrator then has 20 more

[1] The experience of some AAMS members is that some plans and issuers are declining to pay or send them a notice of denial of payment—and then declining to engage in open negotiations—while the judicial challenges to IFR Parts I and II are ongoing. Such plans and issuers apparently realize that they can stymie the IDR process in its entirety if they refuse to acknowledge receipt of "clean claims" while the Federal IDR portal is inaccessible.

business days to issue a decision. *Id.* § 149.510(c)(4)(ii). For plan years starting January 1, 2022, those deadlines line up the first IDR proceedings for resolution in April 2022.

At this point, many AAMS members have been in open negotiations with plans or issuers for months and continue to enter open negotiations as payment disputes arise. The current playing field—on which plans and issuers pay the deflated QPA and ride out the process under the presumption that the deflated QPA is the appropriate out-of-network rate, or decline to pay or send a notice of denial of payment to allow an AAMS member to initiate the IDR process—is crippling providers' ability to promptly recover fair payment through open negotiations. The Departments have made matters worse by delaying the opening of the Federal IDR portal, which providers must access to initiate the IDR process when open negotiations fail. The Departments have not provided a date certain on which the portal will open, or even stated they will toll the deadline for initiating the IDR process until the portal is open. AAMS members are thus in limbo, with no mechanism for vindicating their rights when open negotiations fail. The lack of a Federal IDR portal further skews the playing field against AAMS members in open negotiations because, unlike plans and issuers, AAMS members need to promptly recover fair payment to maintain cash flow adequate to sustain the delivery of services to patients.[2]

In addition to harming AAMS members' ability to conduct open negotiations, the challenged provisions of IFR Parts I and II also harm AAMS members in three additional ways. The first is, of course, IDR decisions that select the issuer's or plan's lower offer based on the QPA. In each individual IDR proceeding, the deflated QPA and presumption in favor of the QPA

[2] The same dynamics are likewise crippling the ability of AAMS members to negotiate in-network contracts with plans and issuers at rates that sustain service delivery. The experience of AAMS members is that many plans and issuers are insisting on unsustainable in-network rates because the alternative is a one-sided playing field with no mechanism for accessing the IDR process. *See* Dkt. 5-2 (Sannerud Decl.) ¶¶ 12-13.

will combine to steer the arbitrator to the plan's or issuer's offer and away from the appropriate out-of-network rate.

The second harm comes from the longer-term effects of an IDR process that turns on a deflated QPA and presumption in favor of the QPA. An AAMS member cannot institute IDR against the same party for 90 days following an IDR determination. *See* 42 U.S.C. § 300gg-112(b)(5)(D) (incorporating *id.* § 300gg-111(c)(5)(E)). As such, the arbitrator's determination based on the deflated QPA will drive the plan's or issuer's market conduct for at least the next 90 days, amplifying the impact of the determination on the AAMS member.

Third, as AAMS members have previously declared (Dkts. 1-5, 1-6, 1-7, 5-2), they are likely to see reductions in revenue, fail to cover their costs, and have no choice but to close air ambulance bases. Base closures would disproportionately harm patients in rural areas who are at great distances from hospitals, especially trauma centers. Dkt. 5-1 at 4.

These harms warrant the Court's prompt vacatur of the offending provisions of IFR Parts I and II.

2. Arbitrary Treatment of AAMS Members Continues.

The government's treatment of AAMS members after the *TMA* decision is arbitrary and capricious. Neither *TMA*, nor the statute, nor even the government's own regulations support a regulatory regime in which *only* air ambulances (but no other providers) are subject to the QPA presumption. The position that the QPA presumption applies solely to air ambulances (but not to other providers) is nonsensical.

First, the logic and rationale of the *TMA* decision applies in full force to the use of the QPA presumption in air ambulance IDRs.

TMA vacated parts of 42 C.F.R. § 149.510, which governs the IDR process from initiation to completion. Specifically, *TMA* vacated parts of § 149.510 that create the QPA presumption.

Dkt. 53-1 (*TMA* Decision) at 35-36.[3] The government concedes that *TMA* is binding as to § 149.510. *See* Hearing Tr. 32:18-25 (noting vacatur in *TMA* has nationwide effect).

After *TMA*, the government is left primarily with 42 C.F.R. § 149.520. *See* Hearing Tr. 34:1-7 ("[T]here is a live dispute that remains with the air ambulance providers. 149.520 was not addressed by the Texas court . . . ."); Dkt. 56 ("[The *TMA*] order did not address 45 C.F.R. § 149.520, which governs arbitration procedures for out-of-network air ambulance services. That provision remains operative after the vacatur order . . . ."). Section 149.520 incorporates §149.510 and applies to air ambulance providers. *See* 45 C.F.R. § 149.520(b)(1) (IDR process for air ambulances must "*comply with the requirements of § 149.510*.") (emphasis added).

The *TMA* order did not vacate Section 149.520. But the decision itself makes perfectly clear that the QPA presumption is an impermissible deviation from the intent of Congress. There is no way to read the *TMA* decision and conclude that the QPA presumption should nevertheless remain in place for air ambulance providers.

Second, the continued application of the QPA presumption to air ambulances is contrary to the statute, which gives no indication whatsoever that Congress intended the QPA to play a different role, in air ambulance IDRs, from the role it plays in all other IDRs. On the contrary, the statutory section concerning air ambulance IDRs directs that the procedures followed in air ambulance IDRs should be the same, for all purposes relevant here, as the procedures followed for

[3] *TMA* vacated 45 C.F.R. § 149.510(c)(4)(ii)(A), which required the IDR entity to select the offer closest to QPA "unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate." *TMA* also vacated 45 C.F.R. § 149.510(a)(2)(viii) (second sentence); 45 C.F.R. § 149.510(c)(4)(iii)(C) (final sentence); 45 C.F.R. § 149.510(c)(4)(iv); and 45 C.F.R. § 149.510(c)(4)(vi)(B).

all other providers. *See* 42 U.S.C. § 300gg-112(b)(5) (containing near-identical language to Section 300gg-111).

Third, even the government's own regulations confirm that the procedures for air ambulance IDRs should be the same (in all respects relevant here) to the procedures followed in all other IDRs. As noted above, the regulation that the government now relies on—§ 149.520—incorporates § 149.510. *See* 45 C.F.R. § 149.520(b)(1) (IDR process for air ambulances must "*comply with the requirements of § 149.510*.") (emphasis added). Section 149.510 applies to all providers and contains the QPA presumption.[4]

Neither *TMA,* the statute, nor the regulations support the position that the QPA plays a different role in air ambulance IDRs than in all other IDRs. It is arbitrary for the government to treat air ambulances as the only providers subject to the QPA presumption.

The government represented to the Court that the Departments intend to issue sub-regulatory guidance setting forth their view on how *TMA* impacts the IDR process for all providers, including air ambulance providers. Hearing Tr. 33:19-25. The Departments have still not issued such guidance. Nor have they committed to issue it by a date certain.

The lack of guidance, coupled with the Departments' litigation position, underscores why any deferral of a decision in this case will prejudice AAMS members. The Departments continue to single out air ambulance providers and treat them differently from all other providers by forcing them to operate under a rule that has been vacated. No statements by the Departments suggest they will more likely than not accept the *TMA* decision or change course with respect to AAMS

[4] Section 149.520 describes the "additional information" that an arbitrator must consider in an air ambulance IDR. This "additional information" differs from the "additional information" considered in other providers' IDRs. *Compare* 45 C.F.R. § 149.520(b)(1) (air ambulance "additional information"), *with* 45 C.F.R. § 149.510(c)(4)(iii)(C).

members (even in the short term). The Court should remedy this manifest inequity by vacating the offending provisions of IFR Parts I and II now.[5]

3. Future Rulemaking Is No Reason to Defer a Decision.

The government's statements concerning the publication of a final rule in May are at best aspirational. At the *TMA* hearing on February 4, 2022, the government represented that "the agencies intend to issue a final rule no later than May of this year." *TMA*, No. 6:21-cv-425 (E.D. Tex. Feb. 4, 2022), ECF No. 112, Hearing Tr. 59:7-12 (excerpts attached hereto as Exhibit A). On March 3, 2022, when seeking a stay in another lawsuit, the government stated that it "anticipate[s] that a final rule will be issued no later than May 2022." *Am. Soc'y of Anesthesiologists v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-6823 (N.D. Ill. Mar. 3, 2022), ECF No. 19. And at the March 21 hearing in this case, the government stated that the "intent is to issue a final rule no later than May. That is our intent. I cannot make that 100 percent guarantee." Hearing Tr. 34:11-15. We do not question the government's good faith on this front, but there are ample reasons to doubt that the government will actually be able to publish a final rule in the next 60 days, let alone the next 30 days.

For starters, the Departments never planned to publish a final rule in 2022. The Office of Management and Budget (OMB) published its Fall 2021 Unified Regulatory Agenda and Regulatory Plan—which sets forth the Administration's short and long-term regulatory and deregulatory actions—on December 10, 2021.[6] OMB listed only IFR Part II in the Unified

[5] If the government appeals *TMA* by its deadline on April 25, 2022, then any arguments for deferring a decision on the grounds of judicial economy and efficiency will lose force. An appeal of *TMA* means that the government will continue to defend the QPA presumption.

[6] Fall 2021 Unified Agenda of Regulatory and Deregulatory Actions, *available at* https://www.reginfo.gov/public/do/eAgendaMain, (last visited March 31, 2022).

Regulatory Agenda,[7] and the U.S. Department of Health and Human Services did not mention IFR Part I or Part II or any final rule in the Regulatory Plan.[8] In the Unified Regulatory Agenda, OMB stated only that the deadline for reviewing comments on IFR Part II was "to be determined." The representations by government counsel in this case are a clear departure from official government statements of regulatory planning just a few short months ago.

At this point, the Departments have received more than 8,000 comments on Part I,[9] and more than 5,000 comments on Part II.[10] To publish a final rule "no later than May," the Departments must review more than 13,000 total comments, craft a final rule, and clear the draft through their intra-departmental processes and OMB. At OMB, the Office of Information and Regulatory Affairs (OIRA) must review it under Executive Order (EO) 12866, which may take up to 90 days. The EO 12866 review includes stakeholder meetings with any organizations that request them. Given the magnitude of this rulemaking, AAMS will request a meeting and expects myriad stakeholders to do the same. Once the EO 12866 review is done and OMB clears the final draft of the rule, the final rule must still go to the Federal Register for formatting and publication, which can take days or sometimes weeks.

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[7] *Id*. at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0938-AU62m.

[8] *Id*. at https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/202110/Statement_0900_HHS.pdf.

[9] Requirements Related to Surprise Billing; Part I CMS-9909-IFC, *available at* https://www.regulations.gov/docket/CMS-2021-0117, (last visited March 31, 2022).

[10] Requirements Related to Surprise Billing; Part II CMS-9908-IFC, *available at* https://www.regulations.gov/docket/CMS-2021-0156, (last visited March 31, 2022).

It is our understanding based on a review of government websites that OIRA is not yet reviewing a final rule.[11] If that is indeed the case, the likelihood of the Departments running the regulatory gauntlet and publishing a complex final rule in the next 30 or 60 days is vanishingly slim. In the experience of undersigned counsel, publication of a final rule in the next 5-7 months would be consistent with inter-agency norms and therefore more realistic, despite the government's stated but uncertain intentions for a faster schedule. And all the while AAMS members will be subjected to months of potentially catastrophic, business-ending harms. Against this backdrop, the Court should grant full relief to AAMS as expeditiously as possible.

Dated: April 4, 2022

Respectfully submitted,

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[11] List of All Regulatory Actions Currently Under Review (Agency: HHS), *available at* https://www.reginfo.gov/public/jsp/EO/eoDashboard.myjsp?agency_cd=0000&agency_nm=All&stage_cd=4&from_page=index.jsp&sub_index=0, (last visited March 31, 2022).

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF TEXAS

TYLER DIVISION

TEXAS MEDICAL ASSOCIATION AND DR. ADAM CORLEY, PLAINTIFFS, VS. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, DEFENDANTS.	) (	CIVIL ACTION NO. 6:21-CV-425-JDK TYLER, TEXAS FEBRUARY 4, 2022 2:03 P.M.

MOTION FOR SUMMARY JUDGMENT HEARING

BEFORE THE HONORABLE JUDGE JEREMY D. KERNODLE

UNITED STATES DISTRICT JUDGE

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THE COURT: Okay. Do you want to address the remedy?

MR. MCELVAIN: Sure.

So -- and there are two points. First, is if the Court were to disagree with us, the appropriate course of action would be to remand without vacatur.

But because there's no -- there's at least a serious chance that the agencies would be able to remedy any identified defect on -- in the rulemaking -- and, in fact, the rulemaking has already initiated. The agencies' intend to issue a final rule no later than May of this year.

So they've taken comments on the interim final rule in the process of considering those comments, including the Plaintiffs' comments, and will respond appropriately in the final -- final ruling.

So this interim final rule will be short-lived, and there's every reason to think that the agencies are capable of responding to any defects that the Court identifies in the rule as it currently exists.

To the contrary, vacatur -- the intent would be quite destructive. I've spoken just now about why insurers needed the rules to be in place ahead of time, and the reason that they needed those rules to be in place ahead of time was not because the arbitration itself has become