1	IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA
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3	Association of Air Medical) Services, et al.,) Civil Action
4 5) No. 21-cv-3031 Plaintiffs,)) ORAL ARGUMENT
6 7 8	Vs.) Washington, DC U.S. Department of Health and) March 21, 2022 Human Services, et al.,) Time: 3:00 p.m.) Defendants.)
9 10 11	TRANSCRIPT OF ORAL ARGUMENT HELD BEFORE THE HONORABLE JUDGE RICHARD J. LEON UNITED STATES DISTRICT JUDGE
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1 THE COURTROOM DEPUTY: Good afternoon, Your Honor. 2 This afternoon we have civil action No. 21-3031, 21-3231, 3 Association of Air Medical Services v. the United States Department of Health and Human Services, et al. 4 5 Will counsel for the plaintiffs please approach the 6 lectern, identify yourself for the record and name the party or parties that you represent, and then defense counsel. 7 8 MR. STIMSON: Brian Stimson and my law partner 9 Sarah Hogarth. 10 THE COURT: Speak up, please. The mask is not helpful. If you've been vaccinated, take the mask off. 11 12 MR. STIMSON: Great. I'm Brian Stimson, Your Honor. 13 And my colleague, Sarah Hogarth, and I represent the 14 Association of Air Medical Services. 15 THE COURT: Welcome. 16 MR. STIMSON: Thank you. 17 MR. TYSSE: Good afternoon, Your Honor. James Tysse. 18 I'm with my colleague, Kristen Loveland. We represent the 19 American Medical Association. And also appearing at counsel 20 table today are my co-counsel, representing the American Hospital Association, Stephanie Webster and Douglas 21 22 Hallward-Driemeier. 23 THE COURT: Welcome. 24 MR. TYSSE: Thank you. 25 MR. McELVAIN: Good afternoon, Your Honor. Joel

McElvain for the defendants.

THE COURT: Welcome.

MR. McELVAIN: Thank you.

THE COURT: All right. Counsel, I sent out a -- as I'm sure you're well aware, sent out a minute order earlier today breaking down the speaking rules and times -- not as to who would speak from the specific counsel members, but what party. And so we'll start with the AMS challenges, the methodology of the calculation of the QPA. And that should be McDermott Will, someone from McDermott Will.

MR. STIMSON: It will be me, Your Honor.

THE COURT: You have 20 minutes.

MR. STIMSON: Your Honor, my client, AMS, represents 93 percent of the air ambulance industry.

THE COURT: You got to speak up, sir. It's hard to hear you. With all this plastic and everything, you got to speak up.

MR. STIMSON: My client, AMS, represents 93 percent of the air ambulance industry. They have more than 300 members operating more than 1,000 rotor-wing air ambulances and more than 200 fixed-wing air ambulances. And they include nonprofit, for-profit providers, local, regional and national providers, and hospital and nonhospital providers. They've supported the enactment of the No Surprises Act because they share Congress's goal of ending surprise air ambulance billing.

And today they're challenging only discrete parts of both

Interim Final Rule Part 1 and Interim Final Rule Part 2 that
bear on the payment for the services that they rendered to the public.

As you directed, I'll begin by addressing the Part 1 challenge. And Part 1 implements § 2799A-1 of the Public Health Service Act. Section 2799A-1 sets forth the direction to the departments to establish a qualified payment methodology, and it also defines the QPA as the median of the contracted rates recognized by the issuer as the total maximum payment under such coverage for the same or similar item or service in the same or similar specialty in the geographic region in which the item or service is furnished.

So you've got to have a contracted rate, recognized by a planner issuer in the same or similar specialty for the same or similar service in the same geographic area.

The problems with Part 1 on the QPA methodology are threefold. First, it excludes contracted rates and single case agreements from the median. Second, it carves air ambulance, and air ambulance alone, out of the definition of provider in the same or similar specialty, which turns on the usual business practices of the issuer, meaning the contracting practices of the issuer.

And then, thirdly, it uses geographic regions that are unduly broad to the point of being arbitrary.

So, on the first point, single case agreements, the departments define them as contracts used to supplement the network of the coverage for a specific beneficiary under unique circumstances. The departments acknowledge, in their own regulation defining contracted rate, that single case agreements are network agreements and, in the very same regulation, they say that rates in those network agreements cannot count towards the median, which is internally inconsistent. And they rationalize that inconsistency by saying the term "contracted rate" really means rates negotiated with providers that are contracted to participate with the issuer under the generally applicable terms of coverage.

The words "generally applicable terms of coverage"

don't appear in the statute. And the departments' efforts to

add them to the statute by regulation is contrary to law. What

the statute says is that the median is determined using

contracted rates recognized by the issuer as the total maximum

payment under such coverage. So, if an issuer contracts with a

provider for a rate in a single case and then pays that rate,

it's recognized that rate as the total maximum payment under

the coverage. And it's that simple.

The departments try to overcome that simple statutory language by doing a couple of things. The first is that they cite to some journal articles that they assert support their interpretation and addition of the phrase "under generally

applicable terms of the regulation." But when you look at those journal articles at JA-739 and JA-346, neither one of them says that single case agreements are outside of coverage or generally applicable terms of coverage.

The departments also make a congressional intent argument. They say that Congress intended for the QPA to be reflective of market rates reached under typical contract negotiations, and their interpretation supposedly advances that more so than the plain text.

And the problem with that is that when you look at the record, it shows that single case agreements are negotiated. Typically, in the air ambulance industry, they're the product of typical contract negotiations. And I point you to a study at JA-337 through JA-346 that looked at data from three commercial payers from 2014 to 2017. And what that data shows in that study is that 22 percent of air ambulance transports are in network and 72 (sic) percent are out of network. And of the 78 percent that are out of network, 48 percent are out-of-network paid-in-full. Which means that approximately 37 percent of transports are out-of-network paid-in-full, in comparison to 22 percent that are reached --- in which payment is reached on a network basis.

What that means is that providers and issuers reach agreement on the rate of payment more often in single case situations than they do on a network basis, and that alone

shows that the departments' reasoning is arbitrary.

That arbitrariness is underscored by how the departments approach single-case agreements in the context of balanced billing protections. They say that a single-case agreement is a contract that triggers the application of the balanced billing protections for patients, but it's not a contract when it comes to the determination of the QPA. A contract is either a contract or it's not. It either contains rates or it doesn't. And we submit that single case agreements are contracts that do contain contracted rates that should count towards the median and for that reason the definition should be vacated.

Moving on to the --

THE COURT: Would the approach that they're taking for this rule, the agencies, would have that have disproportional impact on certain states and certain hospital centers?

MR. STIMSON: In terms of the payment that the hospital centers get for providing air ambulance services or --

THE COURT: Well, the air ambulance services. I'm thinking states that have larger distances between hospital centers where air ambulance services may be necessary or states where there's a higher percentage of use of some kind of emergency transportation necessary. Would those states be more seriously impacted by the way the agencies define this?

MR. STIMSON: Generally, yes. Because rule states, where you have to fly people long distances to get to hospitals, are more dependent on air ambulance services. And if you narrow the band of contracted rates that are used to determine the median, that has the potential effect of reducing the payments that are ultimately made to the providers, regardless of how the -- the component of the rule addressed in the IDR process shakes out. So it is a bigger issue for rural areas.

On the second issue that I mentioned, the determination of provider specialty, the departments carved air ambulance, and air ambulance alone, out of their definition of provider in the same or similar specialty, which is the practice specialty defined by the issuer consistent with the issuer's usual business practice. So, the department said for all providers, except air ambulance, the specialty of the provider is going to be determined by the issuer's approach and contract.

Now, how the issuer views the provider when they sit across the table from them and contract with them, but for air ambulance, they're all a single specialty. The problem is the rationale that the departments used for that carve-out, and it is they want cost-sharing for air ambulance transports to be the same across-the-board, with no variation. That rationale applies equally to all provider types and it's irrational to

single out air ambulance providers on that basis and treat them differently from everyone else.

MR. STIMSON: They say that enrollees should not be required to pay higher cost-sharing amounts solely because the air ambulance provider assigned to them has negotiated higher contracted rates or because it has a different revenue model. But that's an issue that arises with every other provider specialty. There's natural variations amongst all providers, some of which is clinical and some of which is economic, and it's not a basis on which to differentiate air ambulance from other providers.

The arbitrariness of that is underscored by how the departments approach independent, freestanding emergency departments, or IFEDS. IFEDS are nonhospital emergency departments. They have historically low levels of network contracting, and in that respect they're similar to many air ambulance providers.

The departments applied their general definition of provider in the same or similar specialties to IFEDS, but not air ambulance. And the ultimate result is you have two similarly situated providers, one of which is subject to the general rule and one of which is being singled out, which we submit is arbitrary and a basis for vacating that definition.

Third issue, Your Honor, is geographic regions. And

the departments have told issuers that they, in calculating the QPA, need to first look at all of the metropolitan statistical areas in the state or all of the other areas within the state. And if they can't find three contracted rates in the area of the state where the patient was picked up, they bump up to a census division. And when they bum up to a census division, with a constellation of multiple states, they look at all the metropolitan statistical areas in the census division, or all the other areas in the census division depending on the point of pick up.

The rationale they provide for bumping up to census divisions is that Congress intended for the QPA to represent market dynamics. Market dynamics are the basis for using census divisions. The problem is census divisions were designed to aid in the presentation of census data, they weren't designed to approximate the geographic markets for air ambulance services.

THE COURT: Isn't the market dynamics reflected in the contractual dispute -- contractual negotiations?

MR. STIMSON: Well, there are certainly some commonalities across geographic markets, but the problem is that when you have a census division like the Pacific division, which spans Alaska, Hawaii, California, Oregon, and Washington, there is vastly different conditions on the ground across the division and there aren't shared market dynamics from one end

of the division to the other.

I'll take, as an example, in that division, San
Diego, California and Seattle, Washington. They're both within
the metropolitan statistical areas of the Pacific census
division. A rotor-wing in San Diego is not going to fly to
Seattle because it's 1,000 miles to get there and it's beyond
its range and it wouldn't make clinical sense to fly the
patient there anyway. That rotor-wing is in the California
insurance market, not the Washington insurance market, which is
separated by the state of Oregon. And there's a host of unique
things that the San Diego provider has to take into account
operating in San Diego. It's got unique costs, unique
workforce, unique demographics, unique taxes and regulations.
It's got unique weather conditions, unique traffic patterns,
and a unique health care structure, none of which are shared
with Seattle.

And the departments' position is that they can somehow divine market dynamics within a census division by lumping Seattle and San Diego together. It just doesn't work. And the arbitrariness of that becomes more apparent if you go a level out and compare someplace like Anchorage, Alaska to San Diego. Those are two totally different markets.

This is, unfortunately, a problem of the departments' own making. When they removed single-case agreements from median, they reduced the number of contracted rates that you

would count when looking at the MSAs in other portions of individual states. So they had no choice but to move to a larger geographic region.

At the same time, Congress provided a solution in this situation, and that is the use of a third-party database to determine the QPA. And the departments have defined the allowed amounts that can be used to populate those databases in a limited way. They've limited them to in-network allowables, as opposed to allowed amounts more generally. And so they've limited the inputs into the QPA and they've limited the use of the alternative that Congress provided.

The solution here is not to use arbitrary geographic regions, it's to vacate those geographic region definitions and to implement the statute that Congress enacted by allowing single-case agreements to count towards the median and allowing the use of third-party databases when there's insufficient contracted rates.

I think I'm close to my time, Your Honor, so I'm happy to answer any questions that you have. And if you have none, I'll reserve.

THE COURT: You can save it. You've still got two minutes -- about two or three minutes left. You can save it for your rebuttal, if you would like.

MR. STIMSON: That would be great. Thank you.

THE COURT: Mr. McElvain.

MR. McELVAIN: Thank you, Your Honor, and may it please the Court. Congress enacted the No Surprises Act to address a market failure. In a free market parties negotiating at arms-length arrive at a fair price for a product. In many instances, however, the health market has not worked in this way. In an emergency, a patient may have no way to shop for a facility or for an air ambulance that is in his health plan. Or, a patient might schedule a procedure at her in-network facility only to later find that part of her care was performed by an out-of-network physician.

In cases like these, the market has broken down, providers could drive their prices up, knowing that their services could not be rejected no matter what they charged. The result has been devastating medical debt for individual patients and an explosion in health care costs that has driven up both insurance premiums and federal deficits. Congress addressed this crisis through several interlocking reforms.

First, the Act bans providers from balance billing their patients in the circumstances I've just described.

Providers are referred, instead, to an arbitration process with the patient's health plan.

Congress also directed departments, who are the defendants here, to establish the process under which an arbitrator will determine the payment amount. And Congress set forth a sequence for the arbitrator's decision-making. That

sequence begins with what is known as the "qualifying payment amount." This is a term of art in the statute. It is the median of in-network contract rates for a given service in a given region. The statute treats this amount as the proxy for what the price for the service would have been if the provider and the plan had negotiated a fair price in advance.

The Air Ambulance plaintiffs take issue with the July rule, the first interim final rule, which sets the methodology for the qualifying payment amount. None of their challenges has merit.

First, the rule properly bases the calculation of the QPA off of the generally applicable rates set under the plan documents themselves, rather than ad hoc agreements for out-of-network services that are entered into outside of the plan documents.

Second, the rule properly treats all ambulance providers as performing the same medical specialty.

Third, the rule appropriately defines the geographic regions for air ambulances in a way that promotes the use of actual market data to set the QPA.

And, finally, rule properly bases patients' cost sharing on the in-network rates that are set in plan documents. Therefore, summary judgment should be awarded to the defendants on the Air Ambulance challenge.

Turning to the first argument that the plaintiffs

have presented regarding single case agreements. I would like to begin just by taking a step back and reminding the Court what we're talking about with regard to single-case agreements. Typically you would expect a provider in a plan or a heath policy issuer to enter into negotiations and reach an in-network agreement in advance that would cover this service for this facility at this price with a -- you know, set of -- a table of setting those rates, you know, down the line of what all those prices are, which may or may not include a particular air ambulance provider. If the air ambulance provider remains out of network, the insurer or the plan issue -- I'm sorry, the issurer or the plan would not have a legal obligation to pay for that out-of-network service. That would fall on the patient.

However, often the payers, the insurers, the plans make a business judgment that it's better to pay that charge in whole or in part, rather than dumping the entire cost onto the patient, as a matter of business judgement, as a matter of public relations, what have you. So what will happen is even in the absence of a legal compulsion to do so, the payers will enter into a one-off, a single-case agreement where they will pay the air ambulance operator or the other provider for that particular service for that particular patient.

THE COURT: Is there a distinction between emergency services versus nonemergency services?

MR. McELVAIN: Not for this purpose, no. Well, we do get to the freestanding emergency departments issue, which is actually a separate issue resting on different authority. I'm sorry. I may be confusing issues. There is an issue involving freestanding emergency departments. With regard to the question of single-case agreements, there's no distinction. The rule, across-the-board, is that the relevant rates are the rates that are set under the plan documents themselves in advance, not ad hoc agreements that are entered into outside of the plan, whether it's emergency services or air ambulance services or for any other service otherwise subject to the act.

So the statute defines the qualifying payment -excuse me, the qualifying payment amount generally is the
median of the contract rates recognized by the planner-issuer
under such plans or coverage -- I skipped a little bit of the
statutory language, but that's the statutory language -- under
such plans or coverage, respectively, as of January 31st, 2019
and then adjusted for inflation.

So the departments have interpreted that language to mean that the contracted rates that the statute refers to for setting the qualifying payment amount are the rates under the plan documents themselves. So they've included those rates. But, again, as I've said, they've excluded the rates that are separately set under one-off agreements, single-case agreements. And as the departments explained in the rule-

making, this definition most closely aligns with the statutory intent of ensuring that the qualifying payment amount reflects the market rates under typical contract negotiations -- meaning typical negotiations for in-network services -- a central purpose of the act, after all, is to ensure that patients do not owe more for out-of-network services than what they would have paid for in-network services. And you can find that in the text of the statute itself under 300gg-111(a)(1) for most providers and 300gg-112(a)(1) with respect specifically to air ambulances.

So the statute does not refer to any contract, instead, rates under the plan or coverage. And what does "under the plan" mean? A payment arises under a plan or coverage if it is governed by or is owed by reason of the authority of the terms of the plan or policy documents themselves. We've cited to the Ardestani case in our brief. That's not, obviously, a health insurance case, but interpreted the word "under" and applied that dictionary definition of the word "under."

So it has to be the plan documents themselves that tell you what the rate is for that service, what the in-network rate for that service is. If there's some separate agreement entered into after the fact, that just simply does not count under the statute.

As I mentioned previously, the distinction between

single-case agreements and the generally applicable rates under the plan documents themselves turns on the fact that insurers sometimes will essentially voluntarily agree to pay charges, in whole or in part, even if they're not under a legal compulsion to do so.

And I would refer the Court, if the Court is interested in further reading on this topic, to the Zack Cooper article, which is page 1073 of the administrative record, page 739 of the joint appendix. Also, the Erin C. Fuse Brown article, page 2860 of the administrative record, page 340 of the joint appendix, which both discuss this phenomenon, where insurers will enter into agreements even though they're not legally compelled to do so, even though the plan documents themselves do not compel the payment.

One additional point on this argument is, just to remind the Court, as I'm sure you're aware, that the statute does not set the QPA on the basis of any contracts whatsoever, it's on the basis of contract rates under the plans or policies that are in effect as of January 31st, 2019, and then subject to an inflation adjustment.

So this makes sense when you think of what Congress was trying to accomplish. They wanted to get the universe of contracted rates under plans that were out there as of a snapshot in time. Plaintiffs are not always on the same plan year; some are on calendar years, some are on other fiscal

years. But any plan in force as of January 31st, 2019, whether that was the end of that particular plan's year or the beginning of the plan's year, would count for that particular snapshot in time for purposes of this calculation. And that makes sense when you're talking about plans in general.

Under the plaintiffs' theory this qualifier doesn't make any sense whatsoever because there's no reason to think that Congress would have thought that a single-case agreement that just happened to be entered into on the day of January 31st, 2019 had any particular relevance to it. It just simply does not make sense under the statutory language.

Finally, on this point, the plaintiffs have argued that the defendants have acted inconsistently with regard to the definition of a participating facility. And, again, to take a step back as to why this phrasing is relevant under the statute. Under some circumstances the No Surprises Act will apply for a patient only if they have scheduled an in-network appointment at a, quote, participating facility. And that if it turns out that the patient later receives care from an out-of-network physician at that facility, the Act kicks in and protects the patient from balance billing.

So the definition of which facilities are participating facilities matters quite a bit for the purposes of that determination, although less so for the purposes of why we're arguing here today.

The definition in the statute of a participating facility is different from the definition of a qualifying payment amount. Statute defines a participating facility as a facility with a direct or indirect contractual relationship with the plan or issuer with respect to the furnishing of such an item or service at the facility. So there's not the same language, there's not the "under the plan" language that we see in the qualifying payment amount. It's simply a different statute. So the disparate treatment makes sense, given the different statutory requirements.

Turning to the second argument with regard to treating all air ambulance providers as within the same medical specialty. The statute provides that a qualifying payment amount is the median contracted rate for the service that is provided by a provider in the same or similar specialty. So the departments, of course, needed to define who is within a same or similar specialty, who were in different specialties.

The departments considered the matter and decided that all providers of air ambulance services are considered to be a single provider specialty, whether they are owned by hospitals, whether they are owned by independent entities.

Now, this is important to the plaintiffs, as I understand their theory, because hospital-based services may have lower rates but independent air ambulance operators, who in recent years have been acquired -- in frequent cases have been acquired by

private equity, have adopted a business model of driving up their rates and charging more for the same service.

So the departments reason that from the perspective of a patient, if you're picked up by an air ambulance and taken to a hospital or what have you, you are receiving the same service, the same medical specialty is being performed from the perspective of the patient, no matter who is the operator of that airplane or that helicopter or who have you. The patient would have no reason to care whether it's the hospital's air ambulance or whether it's an independent operator's air ambulance; they're receiving the same service either way.

THE COURT: There's a difference between that happening if it's an emergency situation versus a nonemergency situation. In a nonemergency situation there's an opportunity to think through in advance the financial consequences of being air ambulanced somewhere. In an emergency situation the person frequently isn't even conscious or is under such adverse circumstances that he or she can't possibly be processing anything of that kind.

MR. McELVAIN: Correct. And I think in the typical case it would be an emergency that a patient is using an air ambulance. I don't have precise statistics, but I think it's relatively rare that it would be a nonemergency situation where air ambulance services came into play. But regardless, Congress made the judgment that air ambulance services

categorically, across the board, are the types of service where the No Surprises Act applies and the law should apply to all such services.

And the question here, of course, is simply what does it mean to be in the same or similar specialty from the perspective of hospital-based ambulances versus independent ambulances? The departments reasonably treated that phrase in the statute as referring to the practice specialty of a provider, which as a, you know, cardiology or urology. The type of medicine that a provider provides, or the type of service that is provided, rather than the ownership structure of the entity.

The plaintiffs have made an issue of a separate treatment of freestanding emergency departments and hospital—owned emergency departments. The rule does permit insurers to treat those types of facilities separately if they have a standard practice of allowing separate billing from those types of entities. And the plaintiffs' theory is that this same disparate treatment should, therefore, have been allowed for air ambulances.

But this treatment arose under a separate statutory provision. There's language in the statute 300gg-111(a)(2) that directs the departments to take into account payment adjustments that -- payment adjustments that take into account the quality or the facility type, including higher acuity

settings. The departments found that there was some evidence to believe that there was a difference in the acuity of patients that go to one type of emergency department or the other and so, therefore, permit a disparate treatment to account for the fact that there was that relevant distinction.

There's no evidence in the record that there's a similar distinction to be drawn among these types of air ambulance providers. And in any event, air ambulance providers are not facilities within the meaning of this language.

"Facility" is a term of art in the statute that refers to hospitals, freestanding clinics, I believe ambulatory surgical centers, an actual facility that has a building, say, not an air ambulance provider. So this separate statutory authority just simply did not come into play for air ambulance providers at all.

Turning to the third argument that the plaintiffs have raised, going to the scope of the geographic regions. So, again, to remain the Court, the qualifying payment amount is the median of the contracted rates for service provided in the geographic region in which the item or service is furnished. And the Act also directs the departments to issue regulations that would establish the methodology to determine the qualifying payment amount and, specifically, to define these geographic regions.

So, the departments exercises authority to say, in

the first instance, the relevant geographic regions for air ambulances would be all of the metropolitan statistical areas in one state and all of the areas within that state outside of those MSAs, if that does not provide sufficient data. And by sufficient data, that means at least three in-network rates that you could find to set a median, because you need at least three -- one, two, three -- to set the median of number two in the middle.

If you cannot get at least those three contract rates from the geographic region so defined, then the fallback -- which is what the plaintiffs challenge -- the fallback is to go to all the MSAs within the larger census region or all the non-MSA areas within the census region.

So the question is, if you don't get enough data from within that one particular state, is it permissible to draw this larger geographic region? Or were the departments required to accept the plaintiffs' proffered alternative, which was to draw price figures, pricing data from a database.

I think the first response to that is simply that no such database exists. The departments could not have committed -- could not have acted arbitrarily or capriciously if they declined to rely on a database that simply does not exist. And I'll refer the Court to the letter from Cameron Curtis, who is, himself, the president of the Association of Air Medical Services, the plaintiff here. There's one such

letter, which is ECF 5-8. It's with the plaintiffs' summary judgment papers. And there's a second letter from Mr. Curtis at pages 291 and 292 of the joint appendix that makes the same point, that no such database exists. The air ambulance providers were volunteering to create this database for the departments. The departments -- that was a very kind offer, but the departments reasonably declined that kind offer and chose to go with actual market data from actual contracts that exist outside and, you know, among actual providers and actual payers instead.

Turning to the final point, the plaintiffs have also taken issue with the departments' use of the qualifying payment amount to set patients' cost-sharing payments. So, to remind the Court, the qualifying payment amount plays two roles under the statute.

First, it is used to base what cost-sharing a patient will owe for a particular service and then, separately, it forms the basis -- as I believe we'll be talking about later this afternoon, will be it forms the basis of setting payments between providers and insurers.

This argument goes to the first purpose; it goes to how do you go about setting the patients' cost sharing? Under 300gg-112, which is the air ambulance statute, the statute specifies that a patient's cost sharing should be based on the amount that would apply if such services are provided by a

participating provider. But the statute does not itself directly specify how do you go about determining what that amount would have been if there were a participating provider. So the departments reasonably chose to fill that gap by looking to the parallel structure in 300gg-111, which applies to other providers. And under that statute cost sharing ultimately turns, absent a statutory exception, on the qualifying payment amount.

And so, the departments look at gg-111, applied the same framework to gg-112 and said if we use the qualifying payment amount, that would be a fair approximation of what the in-network price would have been for the service.

Now, the plaintiffs take issue with this treatment. They read the statute -- their argument, as I understand it, is 300gg-111 explicitly bases this calculation on the qualifying payment amount. There is no such explicit language in 300gg-112. Therefore, the plaintiffs argue, under the expressio unius canon Congress must have meant to foreclose the departments from using the qualifying payment amount for this calculation.

But there is a host of authority in D.C. Circuit that states that the expressio unius canon has little force in the administrative setting. Van Hollen versus FEC, from 2016, is one such case from the Circuit. Catwaba County versus EPA, a 2009 case from the D.C. Circuit, makes the same point. A

congressional mandate in one section and silence in another often suggests not a prohibition, but simply a decision not to mandate any solution in the second context, i.e., to leave the questioning to agency discretion. And that exactly describes 300gg-111 and 300gg-112 and the circumstances here.

The alternative under which, as I understand the plaintiffs' argument, the patients' cost-sharing would ultimately turn on whatever agreement is ultimately arrived at between the provider and the payor, would essentially return patients back to the middle of these payment disputes. And that would put -- the central purpose of the No Surprises Act was to take patients out of those disputes, after all, and make sure that patients had fiscal certainty, rather than facing uncertain medical debt from the types of medical services to which the No Surprises Act applies.

So for these reasons we believe that the AMS's challenges to the rule should be rejected and summary judgment should be awarded to the defendants. And I would invite any questions from the Court.

THE COURT: We'll get to the rebuttal, then we'll take a break.

MR. McELVAIN: Thank you.

THE COURT: You'll have seven minutes.

MR. STIMSON: Thank you, Your Honor. I want to talk, first, about the contracted rate issue and then talk about the

database point. So, I think there's a perhaps a misunderstanding of the relationship between plan documents and network contracts that is animating the discussion.

The plan documents are between the plan and the enrollee. The coverage would be between the issuer and the beneficiary. A network contract is between the planner issuer and the provider that delivers the services, and it sets forth the rate that the planner issuer pays to the provider.

The plan documents will typically say something along the lines of we will pay our in-network or out-of-network allowable for the services on your behalf, enrollee or beneficiary. What they don't do is unilaterally impose contracted rates on providers. They can't, because the providers are not party to the plan documents. It's a tripartite arrangement.

So what the government is arguing in the real world doesn't make logical sense. They're saying that you would only look to contracted rates in plan documents when the contracted rates, whether it's on a network basis or a single case basis, set forth in the agreement between the planner issuer and the provider. The plan documents simply obligate the planner issuer to pay the provider on the enrollee or beneficiary's behalf.

The government seems to be positing that plans and issuers pay out-of-network charges out of the goodness of their

hearts. And that can't possibly be true. Because you or I or anyone else goes to plans and issuers and buys out-of-network benefits so that those charges are paid in whole or in part. They're not paid out of the goodness of the plan's or issuer's hearts. They're paid because there's an obligation to do so.

And the Cooper and Brown articles say just that, actually. If you go to the Cooper and Brown articles, they're at JA-739 and JA-346, they acknowledge the reality that plans and issuers under the plan documents are obligated to pay amounts on behalf of their beneficiaries. Sometimes they pay the full bill charges, sometimes they pay a portion of the bill charges, and sometimes they pay nothing, if they don't believe that the service is covered. That's all the -- all those articles stand for and they don't support the government's interpretation.

On the database issue, it is true that AMS has -- has acknowledged in comments that there is not presently a database of allowed amounts. But, two points are worth noting. One, that's the answer that the government -- that Congress prescribed to the issue of the lack of contracted rates.

Congress didn't prescribe the use of census divisions so that you could compare rates -- you could use rates in Seattle as a comparator for rates in San Diego. The government prescribed the use of a database.

AMS, in its comments, offered to assist the

government in developing a database of allowed amounts. And that's at JA-292. And the government did not take AMS up on that offer. Instead, the government narrowed its reading of the plain language of allowed amounts to exclude out-of-network allowed amounts, which would have enabled the building of robust database that would have solved the geographic region problem. So, again, that issue is a problem of the government's own making.

Thank you, Your Honor.

See you in ten minutes.

THE COURT: All right. We're going to take a ten-minute break. My court reporter has been working awfully hard, deserves a rest. And we'll be back in ten minutes and then we'll hear from the parties on the status of the Texas order, where the government sees it going, what the government's position is going to be with regard to that, and get whatever response the American Medical Association -- I think Akin Gump's counsel is prepared to address that issue.

(Recess.)

THE COURT: All right, Counsel. Let's start with the government.

What's the government doing on the appeal of that decision in Texas? Are they appealing it or not appealing it?

MR. McELVAIN: I don't have a definite answer for

that, Your Honor, just yet. I recognize that's not an entirely

1 satisfactory answer, but we --2 THE COURT: It's been about a month. MR. McELVAIN: We have not appealed yet. 3 we've -- as we've previously stated --4 5 THE COURT: In fact, it's almost exactly a month. MR. McELVAIN: That sounds about right, yes, Your 6 7 Honor. I can tell you that we haven't appealed yet. I can say, as we previously said in our papers, that we are working 8 9 on a final rule and our anticipation, our intent is to issue a 10 final rule no later than May. THE COURT: You have, under the rules in that 11 12 circuit, right, 60 days or 90 days? 13 MR. McELVAIN: 60 days. So the appeal time hasn't 14 run yet. And I'm sorry, I just cannot make a definitive 15 representation to you as to whether we will appeal or not. All 16 I can tell you, as you're already aware, that we have not yet 17 appealed, And we're working on a file rule. 18 THE COURT: Is that -- the opinion of the judge in 19 Texas, it's a national -- ruling of national proportions, 20 right? 21 MR. McELVAIN: We urged the Court not to enter a 22 ruling with nationwide implications, with nationwide effect. 23 He reject that suggestion and vacated the particular portions 24 of the rule across the board. So, yes, we do understand his 25 ruling to have nationwide effect.

1 THE COURT: So as to the portion of this case that the American Medical Association is involved in, dicta is in 2 place? 3 4 MR. McELVAIN: The dicta is in place. We just spoke 5 to the AMA, which is also challenging 149.510. I guess there 6 are some asterisks to offer there. First, with respect to the 7 Air Ambulance challenge, they are challenging --8 THE COURT: Those issues weren't raised in the Texas 9 case, right? 10 MR. McELVAIN: Correct, 149.520 is a separate 11 regulation which was not addressed by the Texas court. I 12 should note, it's a little bit more complicated than that 13 because 149 --14 THE COURT: Is that possible? 15 MR. McELVAIN: Could it possibly be more complicated? 16 THE COURT: This is like something out of a fake 17 courts exam. 18 MR. McELVAIN: That's a fair point. 19 149.520, in part, incorporates 149.510, so that 20 complicates the issue to a certain extent. The agencies are 21 working on guidance that would address what standards are under 22 the remaining portions of the regulations for both air 23 ambulances and other providers. That quidance isn't out yet. 24 We're working as fast as we can to get that out for the

arbitrators. So, you know, that guidance is forthcoming.

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But, I think the bottom line is that, yes, there is a live dispute that remains with the air ambulance providers.

149.520 was not addressed by the Texas court and so we would urge that summary judgment be awarded for the defendants in the air ambulance challenge for the reasons we've expressed in our briefs. And I would be happy to go into them, if the Court was inclined to hear argument.

THE COURT: Of course the other alternative is to wait and see what happens with the appeal and the new rule you said that they're working on.

MR. McELVAIN: Right. We're working on a final rule. Our intent is to issue a final rule no later than May. That is our intent. I cannot make that 100 percent guarantee. There are no 100 percent guarantees in life, but that is what we're hoping to achieve.

THE COURT: The DOJ's thinking is it's preferable for the Court to go ahead and issue a ruling, rather than wait until May?

MR. McELVAIN: I think if the Court is inclined to wait, then we would be perfectly amenable to that. There's — this case has diminishing relevance as each day goes by and there will be a final rule in the near future, which I imagine we may very well be back in this courtroom on, depending on if the providers —

THE COURT: Well, I think that's probably a fair

assumption, that there might be reason to challenge that, too.

MR. McELVAIN: I can't make any representations as to what the content of the rule may be. Maybe the providers will be unhappy, maybe insurers will be unhappy and we would get a lawsuit in a different direction. I just simply can't make any representations one way or the other.

THE COURT: All right. Let me hear from AMA's counsel.

MR. TYSSE: Good afternoon, Your Honor. James Tysse on behalf of plaintiffs in the American Medical Association,
American Hospital Association matter.

This Court, Your Honor, can and should go ahead and enter summary judgment in favor of plaintiffs on their claims challenging the September rule in both the AMS matter and in our matter. It has the power to do so. As the government just said, it acknowledged that it can and could do so with respect to the AMS claims. It should do so on the claim in our matter as well. And I'm happy to explain why in some detail.

THE COURT: Yeah, because, look, we don't just whip off opinions around here.

MR. TYSSE: Of course not.

THE COURT: You want me to pump out a 60-, 70-page opinion, or longer, when there's a new rule coming out in May, which you may want to amend your complaint and challenge that for whatever reasons -- at least I'm talking hypothetically. I

1 don't know what's going to happen, obviously. 2 MR. TYSSE: Of course. THE COURT: You know, we do more than enough writing 3 around here as it is. 4 5 MR. TYSSE: I understand, Your Honor. THE COURT: More than enough. 6 7 MR. TYSSE: I understand, Your Honor. I think it could be a quite short opinion, though, in our view. 8 9 THE COURT: I'm sure if you were writing it. 10 MR. TYSSE: I think the Eastern District of Texas got 11 it right. It's -- the statute is clear. Congress sets the 12 policy, not the departments. And that's essentially what the 13 opinion can say; that's about as simple as it is. 14 But let me give you --15 THE COURT: I don't think the D.C. Circuit would like 16 an opinion like that. The D.C. Circuit likes things with 17 ribbons and bows on it. This is my 20th anniversary, this 18 week. So I'm used to how the D.C. Circuit operates and they 19 like things, you know, jot and tittle, ribbons and bows, laid 20 out. So we're talking probably, in a case of this complexity 21 and magnitude, somewhere between 40 and 60 pages or 40 and 75 22 That's a lot of work, especially if it's going to all pages. 23 be thrown up in the air and changed in May. 24 MR. TYSSE: Well, I appreciate that point, Your

Honor. I understand it is a lot of work. At the same time, if

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you would indulge me, let me provide a few reasons why I think, notwithstanding that fact, we would still urge you to rule and not wait until May.

And the first is that, I think as the government just acknowledged, the Court, unquestionably, has a live controversy with respect to the AMS claims. The reason is, AMS is challenging, as we just discussed, a separate provision, it's 45 CFR 149.520(b)(2), in particular. And what that language says in that particular provision, it actually borrows some of the offending language that the Eastern District of Texas stuck out. In particular, that information provided by a party to the arbitration must also, quote, clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate. That is an existing regulation right now that is extent and binding parties to arbitrations. And while this regulation is in place, there is a live controversy on that issue.

Now, because the Court is going to -- needs to adjudicate that issue, we submit there's no reason why it should not also adjudicate the exact same issue in the companion case that this Court consolidated at the government's urging on judicial economy grounds. And I think the reason is, of course, any opinion in that case is likely to be appealed. It would make no sense for only a portion of -- the AMS portion of the claim to go up on appeal and not have the rest of the

consolidated case go up. So we think that, again, this is an operative provision right now that is offensive for the exact same reason --

THE COURT: And, of course, if there was a circuit conflict at some point, it could go to the Supreme Court.

MR. TYSSE: Sure enough, Your Honor. But either way, I think my plaintiffs -- my clients, excuse me, and the American Hospital Association clients would like to be part of that appeal process. We feel strongly about -- that this rule is injuring our clients daily, threatens to impose serious injuries, and we want to be part of explaining to both this Court, as well as the D.C. Circuit and any Court that will have jurisdiction why this rule is plainly contrary to the statute. So it just doesn't make sense, we think, to kind of double-track the cases.

We also seek broad relief, Your Honor. We seek to invalidate a couple of provisions that were not invalidated in the Texas case. They're set forth in our notice of supplemental authority. Both of them are, sort of, part and parcel of the broader rule. And I think another, kind of, important consideration is that unlike in the Texas action, the American Medical Association and American Hospital Association plaintiffs have nationwide membership and indisputable standing.

One of the arguments that the government has raised

in the Texas action is that the plaintiffs in that suit lack standing. And if they appeal, which we -- so far they've vigorously defended this case, we have assumed they will appeal. But if they do, they could also seek a stay of that judgment pending appeal, they could seek to overturn the judgment based on the lack of standing of those members.

Obviously, that would immediately -- the harms that my clients face would spring into effect immediately, as soon as that were to happen.

THE COURT: I don't know in the Fifth Circuit loves standing issues the way the D.C. Circuit does. The D.C. Circuit loves those issues.

MR. TYSSE: That is possible true, Your Honor, but I do think it is a threshold issue that would have to be adjudicated in that case. That does not have to be adjudicated here, where the parties clearly have standing.

And I think the final reason, that this probably really gets to your point, is why issue a ruling in this at all. Like I said, I think because the AMS regulation is outstanding, there is a live dispute there. You know, the Court should go ahead and rule on both. But, I think, you know, part of the issue is that even now the departments are working on a final rule, as they've said. It's presumably going to try to, you know, tweak this in some respect or another. But I think a ruling from this Court that was in

accordance with the ruling of the Eastern District of Texas or even, perhaps, built on that ruling would help the situation that my clients are facing by giving -- you know, sending a clear message, essentially, to the agency about why they have gone so far astray in their statutory construction.

I think, given it's a live controversy, there's no reason why this Court, which has, you know, virtually unflagging jurisdiction to adjudicate controversies within its jurisdiction could not go ahead and adjudicate the controversy and then, you know, the agency would have to take that into account when it promulgated its rule.

I think, beyond that, there's two other, kind of, harms that are kind of ongoing. One is that, as we've set forth in our papers, particularly our initial stay papers, there are negotiations right now going on between health care providers on the one hand and commercial insurers on the other hand over the appropriate payment rates. Part of those negotiations, you know, for contracts, for in-network contracts, have to do with, well, how are out-of-network payments going to be decided upon under the No Surprises Act.

So it's actually important to get clarity on that issue sooner or later. And just kind of kicking the can down the road for a few months, to May, prejudices those negotiations.

I think there is a third point, which is under the

statutory scheme, there's a 30-day open negotiation period before we get to the arbitration process. So our briefs are really focused on the arbitration process and what happens there. But, before that happens, there's a 30-day period where insurers and health care providers can try to negotiate a fair price.

Well, obviously, when there's this much uncertainty over the status of this rule, what the government is going to do, those negotiations are going to come to a halt. The parties can't know what is going to be a fair price to offer if this elephant in the room is out there where, you know, all these cases are stayed, the appeal process is not going forward. So I think that's yet another reason why it's important to rule on this issue now, rather than kicking the can down the road.

And I think I'll make one more point on that, too, which is that I think the government said something to the effect of, you know, there's a fair assumption that we'll just be back here again in a few months. And I think it's -- from our perspective, we don't want to be back here in a few months. We think Congress already made its choice. We think the choice it made was very clear. It, in pretty unusually detained language, I think, set forth the specific factors and standards that it wants the independent arbitrators to consider. It did not, unlike in several other provisions throughout 300-111, you

know, provide the department shall issue regulations that, you know, will go to the balancing of these factors or the weighing of the factors.

And Congress used language -- in fact, it borrowed language: Shall consider or shall take into consideration direct language from D.C. Circuit case law, particularly the American Corn Growers case and the Public Service Commission of Indiana case, where courts have said, oh, when Congress used that language, we assumed that the decision-maker is going to get discretion to make the ultimate decision and that an agency can't come over the top until, for example, in the American Corn Growers case, they state how to exercise its discretion.

So we assume, in other words, that Congress legislates against a backdrop of existing case law. And in this circumstance they borrowed language that says Congress is not imposing a particular structure, go ahead and adjudicate the claim based on your own expertise. And these are all certified independent expert arbitrators.

So, again, that's -- that's all to say that, again, the government said that there's a fair assumption that we'll be back in a few months. And we don't want to be back in a few months and have to litigate this all over again. We think a decision in this Court that makes clear that they can't do what they've done, they can't impose a presumption, create a presumption out of thin air -- that's obvious, that's nowhere

in the statute -- and they can't say that the arbitrator must select one offer over another based, you know, again, where it's nowhere to be found.

But even just the fact that the agencies have, sort of, extracted one factor -- to borrow the language from American Corn Growers extracted one factor out of a list and treated it completely differently, I think, again, goes to show that they've gone far astray in their rulemaking power and there's no reason to delay relief.

So, again, we don't want to be back here litigating, in six months, a revamped but still a legal rule. So, to the extent that this Court is willing, we think that the appropriate course is to go ahead and adjudicate the live controversy involving AMS and the live controversy involving the American Medical Association and the American Hospital Association.

If the Court has further questions, I'm happy to address any of them. I'm also happy to address the merits, to the extent the Court is interested. But I defer to the Court's judgment on what, if any, questions it has.

THE COURT: Let me give AMS a chance to speak a few words on this matter.

MR. TYSSE: Thank you, Your Honor.

THE COURT: Thank you, sir.

How does it strike you, sir?

MR. STIMSON: I'm sorry, Your Honor?

THE COURT: How does it all strike you?

MR. STIMSON: We generally concur with the points made by the AMA, and I would just double down on two of those.

The first is that the defects in the rules are primarily legal in nature and they're not things that can be fixed through tweaking in the margins. There's a core statutory construction issue on Part 2 that the government got wrong and then there's a core statutory construction issue on Part 1 that the government got wrong and we think that it would be a waste to come back and litigate the same issues in six months.

There's also some urgency on the part of my clients for clarity, both in the litigation and in the rulemaking and in their business operations generally. This is affecting their negotiations with payers, plans and issuers, it's affecting the resources and the time and the personnel that they're deploying to prepare for independent dispute resolution. And the absence of a ruling that speaks to \$ 149.520 in advance of April has the potential to prejudice them in IDR proceedings that occur between now and the issuance of a new rule. And for that reason it's very important to them, if Your Honor chooses to address 149.520 before the first IDR decisions start to role in.

With that, I'm happy to answer any questions.

THE COURT: No, that's fine.

MR. STIMSON: Thank you, Your Honor.

MR. McELVAIN: Your Honor, may I have 30 seconds?

THE COURT: You may. You can actually have a couple minutes. How is that? Seems only fair.

MR. McELVAIN: I negotiated against myself. I should

7 never do that.

Just a couple of quick points with regard to

Mr. Tysse's comments on behalf of the AMA plaintiffs. If I

understood his position correctly, I believe he was urging this

Court to issue an opinion which would be helpful on the

rulemaking process because it would serve in an advisory

capacity for the agencies to take into account for the next

rule.

If there's one issue that is absolutely core to the notion of Article III jurisdiction, it's that Courts do not issue advisory opinions. They decide live controversies. And I think it's quite doubtful, with respect to the AMA plaintiffs, that there is still a live controversy.

To be fair, the AMA plaintiffs do say that they are challenging two additional sentences of the regulation that were not vacated by the Texas court. But if you look at those particular provisions, one is 149.510(a)(2)(v), which is the definition of credible information. It tells the arbitrator only consider credible information.

I'm having trouble understanding what the plaintiffs' objection is to that argument. If the question is: Are arbitrators prohibited from considering information that is incredible, that is not credible, that is a merits argument that I am very comfortable having. But even before we get to the merits, I have genuine doubt that there is a live controversy and that they suffer any harm from that particular provision.

Similarly, they also seek the vacatur of the third sentence of 149.510(c)(4)(ii)(A), which reads as follows: In these cases, the certified IDR entity -- the arbitrator -- must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR items or services, which could be either offer.

Again, I'm having trouble understanding what the plaintiff's objection is to that particular sentence, when it's a stand-alone sentence. I had understood up to this point the plaintiffs' claim that they were prejudiced by the rule because the rule did not allow the arbitrators to determine fair value if they're -- after the conclusion of merits briefing, if they seek to recast their theory, to claim that they're harmed because they are not permitted to gain unfair value from the arbitrator, I guess I would like to know what that claim is and have the opportunity to respond to it, that's all.

THE COURT: Well, I have a practice, which you may or

may not be aware of, in cases that are complex and have substantial issues, and especially novel issues, I give the parties a chance -- based on my own experience years ago as a litigator, where invariably would go out for a beer afterwards and said, I wish I'd said this, I wish I'd said this, I wish I'd said this.

So, well, you'll get a transcript in this case, obviously, and when you've reviewed the transcript, invariably you'll said, I wish I'd said this, I wish I'd said this, I wish I'd said this. So I'll give you a chance to supplement your pleadings. I'll give you ten days from the date you get your copy of the transcript. And it won't be cross -- you know, back and forth.

Each side can do one supplemental, limited to what was asked or said here in the courtroom, and not new issues, not raising new issues. And we'll put a 12-page limit. That's it. It's got to be 12 pages or less. And it's got to be limited to what was discussed here in the courtroom. And all three parties, the government and the two plaintiffs can submit something, and just to supplement or clarify something you've said or wish you'd said during the course of the hearing today.

It's very heavily briefed and very well argued. I commend all of you on your pleadings and for the briefing and the arguments today. I wish we had more of those quality briefs and arguments more frequently. But, obviously, it's an

important matter, it has tremendous ramifications and consequences to the parties involved, and the government. so, it's something that's going to take some serious, careful thought, and hard work at some point. So the only question is when and under what circumstances. And if you need to flesh that out a little more, both sides are welcome to do that, too. Thank you, Counsel. MR. McELVAIN: Thank you, Your Honor. THE COURT: Have a good day.

CERTIFICATE OF OFFICIAL COURT REPORTER I, JANICE DICKMAN, do hereby certify that the above and foregoing constitutes a true and accurate transcript of my stenographic notes and is a full, true and complete transcript of the proceedings to the best of my ability. Dated this 22nd day of March, 2022 Janice E. Dickman, CRR, CMR, CCR Official Court Reporter Room 6523 333 Constitution Avenue, N.W. Washington, D.C. 20001