SPECIAL REPORT

NO SURPRISES ACT UPDATE

Litigation Developments, Enforcement Trends, Agency Guidance and Future Rulemakings

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SPECIAL REPORT

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OVERVIEW

The No Surprises Act (NSA) has been in effect since January 2022, and has faced litigation ever since from healthcare providers. States and federal agencies are also examining surprise billing and consumer protection laws related to some provisions of the NSA. Here we review the state of NSA litigation, oversight activities, and rulemaking and guidance as we approach Q4 2023, and share our views on what lies ahead for healthcare providers.

IN DEPTH

The No Surprises Act (NSA) was enacted in 2020 and became effective January 1, 2022. Yet the US Departments of Health and Human Services, Labor, and Treasury (collectively, the departments), have published only a few rules implementing the NSA. Healthcare providers quickly challenged those rules under the Administrative Procedure Act (APA). The APA litigation remains pending in multiple courts across the country, with new developments arising as recently as August 3, 2023, when the district court in *Texas Medical Association, et al. v. U.S. Department of Health and Human Services* (*TMA IV*) vacated the administrative fee guidance and regulatory text governing the batching of claims for the federal independent dispute resolution (IDR) process. On August 4, 2023, the departments announced a temporary suspension of the IDR process, signaling that they plan to comply with the district court's judgment and order. They did not rule out an appeal.

Air ambulance providers have also filed actions challenging awards by IDR entities (IDREs) in the federal IDR process. Those actions remain pending as well.

Meanwhile, states are conducting oversight under their surprise billing and consumer protection laws. The Centers for Medicare & Medicaid Services' (CMS) Center for Consumer Information and Insurance Oversight (CCIIO) is conducting similar oversight of provider compliance with the balance billing and good-faith estimate (GFE) provisions of the NSA.

What lies ahead for providers for the remainder of 2023? We expect to see more litigation developments, greater oversight, and new rulemakings and guidance. Providers should stay mindful of these trends and increase their efforts to maintain compliance with the NSA.

We discuss the key litigation, oversight activities, and rulemaking and guidance below.

TEXAS MEDICAL ASSOCIATION (TMA) LITIGATION

The TMA and various co-plaintiffs have filed four APA actions in the US District Court for the Eastern District of Texas challenging the rules and guidance implementing the NSA. We refer to these four actions as *TMA I, II, III* and *IV*.

TMA I challenged the departments' interim final rule implementing the statutory circumstances that IDREs must consider when determining which offer is the out-of-network rate in federal IDR. The interim final rule required IDREs to treat the offer closest to the plan's or issuer's qualifying payment amount (QPA) as the presumptive out-of-network rate. The district court found that the presumption was contrary to the statute and set aside the regulatory text.[1]

The departments responded to *TMA I* by issuing a final rule that required IDREs to consider the QPA first, forego the consideration of additional statutory circumstances accounted for in the QPA, and explain in writing why any additional circumstances were considered.[2]

[1] *See Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 587 F. Supp. 3d 528, 549 (E.D. Tex. 2022), appeal dismissed, 2022 WL 15174345 (5th Cir. Oct. 24, 2022); *LifeNet, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 617 F. Supp. 3d 547 (E.D. Tex. 2022).
[2] 87 Fed. Reg. 52618 (Aug. 26, 2022); *see also* 45 C.F.R. 149.510(c)(4)(iii).

TMA II challenged the final rule on the ground that it too was contrary to the statute. The district court agreed and set aside the regulatory text.[3] The departments have appealed.[4] For now, the IDREs must apply the plain language of the statute and determine the out-of-network rate without giving any statutory circumstance special weight.

TMA III challenges the departments' interim final rule establishing the methodology for determining the QPA. The plaintiffs contend that several aspects of the QPA methodology combine to artificially deflate the QPA and, by extension, out-of-network rates. Notably, the plaintiffs assert that the QPA methodology incorporates ghost rates, meaning contracted rates with providers that do not actually provide the contracted service.[5] The district court heard oral arguments on the merits of *TMA III* on April 19, 2023.[6]

As discussed at the outset, *TMA IV* challenged the guidance setting the administrative fee to participate in federal IDR. All parties to federal IDR must pay the non-refundable administrative fee. The fee was initially $50.[7] For 2023, the departments increased the fee to $350 per party, per dispute, through guidance. The plaintiffs argued that the guidance was a substantive rule that had to go through notice and comment rulemaking, and was also contrary to law and arbitrary and capricious because it restricted access to IDR, among other reasons.[8]

TMA IV also challenged part of the regulatory text implementing the provisions of the NSA that authorize the batching of items and services in federal IDR. The NSA requires that batched items and services be "related to the treatment of a similar condition."[9] The regulatory text went further, requiring that the items and services be "the same or similar items or services . . . ." Items and services were "considered to be the same or similar items or services if each [was] billed under the same service code, or a comparable code under a different procedural code system . . . ."[10] The plaintiffs argued that the regulatory text was unlawful because it did not go through notice and comment rulemaking. The plaintiffs further argued that the regulatory text was contrary to law and arbitrary and capricious for reasons similar to the guidance.[11]

The district court in *TMA IV* vacated both the guidance and the regulatory text[12] and remanded the case to the departments on August 3, 2023. It did so on the ground that the departments failed to conduct notice and comment rulemaking.[13] The district court

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[3] *Tex. Med.* Ass'n *v. U.S. Dep't of Health & Hum. Servs.*, -- F. Supp. 3d --, 2023 WL 1781801, at *13 (E.D. Tex. Feb. 6, 2023).
[4] Notice of Appeal, *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:22-cv-00372-JDK (E.D. Tex., filed Apr. 6, 2023), ECF No. 101 at 1.
[5] Complaint, *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:22-cv-00450-JDK (E.D. Tex. filed Nov. 30, 2022), ECF No. 1 at ¶ 11.
[6] Minute Entry, *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:22-cv-00450-JDK (E.D. Tex. filed Apr. 19, 2023), ECF No. 57.
[7] *See* Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act (Sept. 30, 2021); available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Technical-Guidance-CY2022-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf.
[8] Complaint, *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:23-cv-00059-JDK (E.D. Tex., filed Jan. 30, 2023), ECF No. 1 at ¶ 6.
[9] 42 U.S.C. § 300gg-111(c)(3)(A)(iii).
[10] 45 C.F.R. § 149.510(C)(3)(i)(c).
[11] Complaint, *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:23-cv-00059-JDK (E.D. Tex., filed Jan. 30, 2023), ECF No. 1 at ¶¶ 151-158.
[12] Memorandum Opinion and Order, *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:23-cv-00059-JDK (E.D. Tex., filed Aug. 3, 2023), ECF No. 50 at 2 (vacating the regulations previously at 45 C.F.R. § 149.510(c)(3)(i)(C), 26 C.F.R. § 54.9816-8T(c)(3)(i)(C), and 29 C.F.R. § 2590.716-8(c)(3)(i)(C)).
[13] *Id.* at 14.

did not reach the plaintiffs' other arguments for why the guidance and the regulatory text violated the APA.

The following day the departments announced that "[e]ffective August 3, 2023, the Departments have temporarily suspended the Federal [IDR] process, including the ability to initiate new disputes and have directed [IDREs] to pause all IDR-related activities." The departments explained that they "are currently reviewing the court's decision [in *TMA IV*] and evaluating current IDR processes, templates, and system updates that will be necessary to comply … ." They committed to "issue these updates in the near future and … provide specific directions to certified IDR entities for resuming all IDR-related activities in a manner consistent with the court's judgment and order."[14] The departments' statement strongly suggests that it will return to the $50 administrative fee and permit increased batching, but did not rule out an appeal.

Effective August 8, 2023, the Departments have directed certified IDR entities to resume processing single and bundled disputes initiated in 2022, as well as single and bundled disputes initiated in 2023 where the administrative fees have been paid (or the deadline for collecting fees expired) before August 3, 2023. Additionally, the Departments have directed certified IDR entities to resume processing batched disputes where the IDR entity determined that the batched dispute was eligible and administrative fees have been paid (or the deadline for collecting fees expired) before August 3, 2023. Processing of other disputes remains temporarily suspended.

We expect the district court in *TMA III* to issue a decision this year or early next year.

ACTIONS CHALLENGING IDR AWARDS

Multiple air ambulance providers have filed actions challenging IDR awards. The actions name as defendants not only the plan or issuer in the IDR proceeding but also the IDRE itself. The plaintiffs argue that the IDREs have demonstrated partiality, committed prejudicial misbehavior and exceeded their powers. The defendant IDREs have filed motions to dismiss, arguing that they are entitled to arbitrator immunity and that plaintiffs lack Article III standing. Those motions to dismiss remain pending.[15]

The US Department of Justice has filed a statement of interest on behalf of the United States in three cases consolidated in the US District Court for the Middle District of Florida. The United States takes the position that IDREs are improper parties for several reasons:

- The NSA does not create a cause of action against IDREs themselves, but instead allows judicial review only of their award determinations.
- IDREs should be entitled to arbitrator immunity. The legislative history of the NSA shows that Congress understood the IDR process to be a form of arbitration.
- There are potential consequences of requiring IDREs to defend themselves against such lawsuits. Participation by IDREs in the federal IDR process is voluntary, and their per-dispute

[14] *See* CCIIO, Federal IDR Process Temporarily Paused (Aug. 4, 2023).
[15] *Med-Trans Corp. v. Capital Health Plan, Inc.*, No. 3:22-cv-01077-TJC-JBT (M.D. Fla., filed Oct. 4, 2022); *Med-Trans Corp. v. Blue Cross and Blue Shield of Fla., Inc.*, No. 3:22-cv-01139-TJC-JBT (M.D. Fla., filed Oct. 21, 2022) (dismissed with prejudice); *REACH Air Med. Servs., LLC v. Kaiser Found. Health Plan Inc.*, No. 3:22-cv-01153-TJC-JBT (M.D. Fla., filed Oct. 26, 2022); *Guardian Flight, LLC v. Aetna Health Inc.*, No. 4:22-cv-03805 (S.D. Tex., filed Nov. 1, 2022); *REACH Air Med. Servs., LLC v. Kaiser Found. Health Plan Inc.*, No. 4:22-cv-03979 (S.D. Tex., filed Nov. 16, 2022).

compensation modest. Therefore, the entities may have little incentive to continue their participation if required to engage in costly and time-consuming litigation.[16]

The plaintiffs argue that judicial review is meaningless unless the IDRE is a party bound by the district court's ruling. The plaintiffs also argue that IDREs collect substantial revenue from adjudicating tens of thousands of disputes and should be responsible for serious errors.[17]

We expect the district courts to adjudicate the motions to dismiss this year or early next. If the plaintiffs defeat those motions, then we expect to see more healthcare providers challenge IDR awards in federal court on similar grounds.

STATE ENFORCEMENT

Beyond the IDR process, we have seen some state attorneys general and insurance commissioners investigate alleged surprise billing by providers and alleged noncompliance with surprise billing laws by issuers. For example, the Office of the New York State Attorney General announced a settlement with a commercial ambulance service provider related to the state's surprise billing law.[18] The agreement required the provider to make restitution to eligible consumers, pay a penalty to the state and adhere to certain business practices going forward.[19]

To date, enforcement actions against providers and issuers have been limited. We expect state attorneys general and regulators to increase enforcement—particularly on the provider side—heading into 2024.

FEDERAL ENFORCEMENT

CCIIO is investigating provider compliance with the NSA, including the GFE requirements. We are aware that CCIIO has sent letters to some hospitals requesting information demonstrating compliance with the law. For example, hospitals have received inquiries related to the number of scheduled appointments for uninsured or self-pay patients and, for those appointments, whether patients received a GFE. CCIIO has also sent inquiries to hospitals requesting information on the scripts used when patients call requesting GFEs. We are aware that other providers have received inquiries regarding compliance with the balance billing prohibition in the NSA.

According to CCIIO, providers have also raised that in some cases health plans have not calculated the QPA accurately. Further, providers argue that some health plans are not abiding by the 30-day timeline laid out in the statute for paying what they owe in arbitration when the IDRE rules in the provider's favor. CCIIO has investigated these complaints, including conducting audits of QPA calculations. However, the results of these audits and other investigations have not been publicly disclosed. There is also a backlog of complaints that CCIIO has not yet fully addressed.

CMS has not yet announced the imposition of civil monetary penalties (CMPs) or other consequences on

[16] *See* Statement of Interest, *Med-Trans Corp. v. Capital Health Plan, Inc.*, No. 3:22-cv-01077-TJC-JBT (M.D. Fla., filed May 12, 2023), ECF No. 58.
[17] *Id.* at ECF No. 60 (filed May 26, 2023).
[18] *See* New York State Attorney General, Attorney General James Secures Relief for Patients Illegally Charged by Ambulance Company (Oct. 6, 2022), available at: https://ag.ny.gov/press-release/2022/attorney-general-james-secures-relief-patients-illegally-charged-ambulance.
[19] *See* New York State Attorney General, In the Matter of Mobile Life Support Services, Inc. Assurance No.: 22-051 (Sept. 14, 2022), available at: https://ag.ny.gov/sites/default/files/2022.09.14_aod_mobile_life_fully_executed.pdf.

noncompliant providers. It remains to be seen whether CMS will do so before finalizing its enforcement rule, which it published nearly two years ago.[20] The imposition of CMPs before finalization of the enforcement rule would be subject to potential legal challenge under the APA. For that reason, and given the nature of CMS enforcement to date, we expect that CMS will finalize the rule before it starts imposing CMPs on providers.

NEW NSA GUIDANCE AND PUBLICATIONS

On July 7, 2023, the departments published three NSA guidance documents:

- Frequently Asked Questions (FAQs): The Departments issued new FAQs clarifying that cost sharing for services furnished by nonparticipating providers, facilities or providers of air ambulance services is considered cost sharing for out-of-network services for purposes of assessing consumers' maximum out-of-pocket limit. If a plan or issuer has a direct or indirect contractual relationship with a provider, facility or provider of air ambulance services, then the entity is considered participating, even if the plan or issuer does not consider the entity to be part of its network. The departments also clarified that facility fees are "items and services" that should be included in GFEs.
- First Annual Report: The NSA requires the secretary, in consultation with the Federal Trade Commission and the US attorney general, to produce five annual reports analyzing the impact of the NSA on matters such as trends in market consolidation and concentration, healthcare costs, and access to items and services. The report did not reach any immediate conclusions but described the framework that will be used in future reports to evaluate the market effects of the NSA.[21]
- Request for Information (RFI): Consistent with the administration's goal of reducing patients' unexpected healthcare costs, HHS joined with the Consumer Financial Protection Bureau and Department of the Treasury to issue an RFI seeking comment on (i) the prevalence, nature and impact of medical credit cards, loans and other financial products used to pay for healthcare, and (ii) options to address practices by companies and providers offering such products that may result in excess costs and medical debt. The RFI aims to better understand how certain financial products that are used to pay for healthcare affect patients across different demographic groups. The RFI also seeks information on the prices or standard charges offered to patients who use these products, and whether such charges are properly disclosed in accordance with hospital price transparency and GFE requirements.

FUTURE RULEMAKINGS

We expect to see additional NSA rulemaking within the next year. The administration published its Spring 2023 Unified Agenda on June 13, 2023. It listed the regulatory and deregulatory actions planned for the next 12 months, included three NSA rulemakings:

[20] *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement*, 86 Fed. Reg. 51730 (Sept. 16, 2021)

[21] For example, the report notes that prior to the NSA's enactment, 33 states had enacted surprise billing protections. Existing studies suggest that these state protections have had an impact on in- and out-of-network prices; these impacts will be taken into account in future reports.

- A proposed rule on Independent Dispute Resolution Operations (CMS-9897), planned for June 2023
- The final rule on Requirements Related to Air Ambulance Services, Agent and Broker Disclosures and Provider Enforcement (CMS-9907), planned for August 2023
- A proposed rule on Requirements Related to Advanced Explanation of Benefits and Other Provisions Under the Consolidated Appropriations Act 2021 (CMS-9900), planned for March 2024.

While the timeframes for the first and second planned rulemakings have lapsed, it is plausible that the administration will move at least one of the three rulemakings between now and the next presidential inauguration in January 2024. It is also plausible that the administration will address the vacatur in *TMA IV* through rulemaking during the same timeframe.

The departments have not yet announced plans for rulemakings on numerous other issues presented by the NSA. Those issues include good-faith estimates for insured individuals; insurance ID card requirements; payer balance billing disclosure requirements; provider directory requirements; and continuity of care requirements. It remains to be seen whether and when the departments will conduct rulemakings on those issues.

EMERGING PRIVATE SECTOR SOLUTIONS?

We frequently receive inquiries from providers seeking more robust data on contract rates for use in their negotiations and federal IDRs with plans and issuers. Many providers hoped the Transparency in Coverage rules for plans and issuers—which entered the enforcement phase in July 2022—would usher in a new era of data-driven compromise. That new era has not yet fully materialized due to the challenges inherent in using the voluminous and complex data. We are, however, beginning to see start-up companies such as After Transparency find ways to access and deliver the data in usable formats. We expect to see providers in 2023 and 2024 benefit from continued increases in the usability of contract-rate data.

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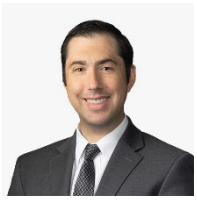

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