Hospital and Health Systems

Quarterly Reimbursement Check

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ROPES & GRAY

Ropes & Gray attorneys share their analysis of administrative and court litigation, regulatory developments, key developments affecting federal program payments to hospitals and health systems, and other reimbursement related issues.

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Focus On

CMS Expands Reconciliation of Outlier Payments

On April 26, 2024, the Centers for Medicare and Medicaid Services ("CMS") issued Transmittal 12594 with Change Request 13566 (the "Transmittal") implementing outlier reconciliation Cost-to-Charge Ratio ("CCR") updates that add new criteria for determining which hospitals will be subject to so-called "reconciliation" of their outlier payments under the inpatient prospective payment system ("IPPS") and long-term care hospital prospective payment system ("LTCH PPS").

Under existing Medicare regulations and manuals, CMS reconciles outlier payments upon cost report settlement to account for differences between the CCR used to pay the claim at its original submission by the provider and the CCR determined at final settlement of the cost reporting period during which the discharge occurred. Historically, CMS has required reconciliation of a hospital's outlier payments if the actual operating CCR was a minimum 10 percentage point change (e.g., a change from 0.5 to 0.4) between the CCR used during the time period to make the outlier payments and the sum of operating and capital outlier payments in the cost reporting period exceeds $500,000.

The Transmittal, however, adds an additional criterion that, if satisfied, would require a MAC to refer cost reports for outlier reconciliation. For cost reporting periods starting October 1, 2024, MACs must refer cost reports to CMS if the difference between the actual operating CCR and the CCR used during the time period to make outlier payments is more than a 20% fluctuation. The example CMS provides is a change from an original CCR of 0.085 to 0.05. While this change, of just 3.5%, would not meet the 10 percentage point change that triggered reconciliation historically, since the 3.5% fluctuation is a more than 40% fluctuation from the original CCR (0.035 / 0.085), the cost report would be referred for reconciliation under the new criterion if it also meets the sum threshold of $500,000, which remains unchanged. Additionally, all new hospitals will have outlier payments reconciled for their first cost reporting period. MACs also maintain discretion to pursue reconciliation of a hospital's outlier payments even if the hospital does not meet these criteria for reconciliation. CMS states it believes this change will make reconciliation more responsive to fluctuations in CCRs.

Docket Updates

1. ***Mercy Health-St. Vincent Medical Center d/b/a Mercy St. Vincent Medical Center v. Becerra*, Case No. 1:22-cv-3578 (D.D.C. Feb. 9, 2024).**

On February 9, 2024, the D.C. District Court granted five hospitals' motion for summary judgment in a case challenging CMS's Medicare pass-through reimbursement for nursing and allied health education ("NAHE") programs. The core

dispute centered on the method of calculating Administrative and General Costs ("A&G Costs"), which are part of the NAHE programs' "net cost" that Medicare reimburses.

The hospitals argued that A&G Costs are assessed before any offset for tuition revenue. The Department of Health and Human Services ("HHS") disagreed, arguing that A&G Costs are calculated after offsetting direct costs with the tuition revenue. Siding with the hospitals, the Court concluded that the text of CMS's regulation, 42 C.F.R. § 413.85(d)(2)(i)–(ii), authorizes hospitals to calculate A&G Costs before "deducting the revenue that a provider receives from tuition and student fees."

Pointing to the text of the regulation, the Court ruled HHS may deduct for tuition revenue "*only after* determining a hospital's 'total allowable educational costs.'" That means the hospitals must be permitted to factor in A&G Costs based on the accumulated cost of the hospitals' educational program. "This order of operations," the Court explained, "comes straight from the regulation—one the Secretary devised, and one he must follow."

The Court rejected the Provider Reimbursement Review Board's reliance on the cost report instructions in its ruling because the regulation itself carries the force of law. The Court also concluded that the hospitals did not need to request the use of an alternate cost finding methodology because the hospitals "merely seek to get paid in accordance with the Secretary's own regulation."

The Court further criticized HHS's restrictive interpretation that limits net costs to costs that are "allowable" and "directly related to approved educational activities." HHS's reading, the Court noted, effectively reduces total allowable educational costs to direct costs and, therefore, conflicts with the definition of total allowable educational costs in the regulation. That definition, the Court explained, includes both direct and indirect costs, like A&G Costs.

The Court remanded the case back to the Board for further proceedings consistent with the Court's opinion, and the Secretary did not file an appeal to the D.C. Circuit.

2. *Advocate Christ Medical Center v. Becerra*, 80 F.4th 346 (D.C. Cir. 2023).

On December 29, 2023, hospitals petitioned for the Supreme Court's review of the D.C. Circuit's decision, holding that "entitled to [Social Security Income ("SSI")] benefits" "cover[s] only Medicare beneficiaries who are entitled to SSI cash payments at the time of their hospitalization." *See* Petition for Writ of Cert., *Advocate Christ,* No. 23-715 (Dec. 29, 2023). Hospitals have historically challenged the inconsistent interpretation of the term "entitled to benefits" in the Disproportionate Share Hospital ("DSH") calculation as between the Medicare program and the SSI program. The hospitals argue that the agency's interpretation of "entitled to [SSI] benefits" in the SSI fraction is contrary to the statute because it differs from the agency's interpretation of "entitled to benefits under [Medicare] part A." In their view, the phrase "entitled to [SSI] benefits" must include all patients enrolled in the SSI program at the time of hospitalization, even if they did not receive a cash payment at that time. The hospitals contend that "[t]he Secretary's internally inconsistent reading of 'entitled to benefits'—within the same sentence of the same statute—deprives [] hospitals of the compensation Congress intended for serving a disproportionate share of low-income patients."

On April 18, 2024, the government filed its opposition brief, arguing that the writ of certiorari should be denied as the D.C. Circuit correctly concluded that the Medicare fraction's use of "entitled to supplementary security income benefits . . . under [title XVI]" covers only beneficiaries who are entitled to SSI cash payments at the time of their hospitalization. The government stated that "what matters is whether the individual was entitled to an SSI payment for the month, not the timing of the actual receipt of such payment." The hospitals responded on May 3, 2024, with an assertion that hospitals, patients, and communities would face "billion-dollar-plus" financial consequences if the Supreme Court does not review the D.C. Circuit's decision and that the government ignores that some patients entitled to receive benefit checks are not counted under the government's interpretation of the meaning of "entitled to benefits." The Supreme Court has not issued its decision on the petition.

3. *Battle Creek Health System*, No. 23-5310 (D.C. Circuit 2023).

On December 28, 2023, the Secretary of HHS filed an appeal of the D.C. District Court's decision in *Battle Creek Health System v. Becerra* to the D.C. Circuit Court. See Notice of Appeal to D.C. Circuit, *Battle Creek Health System v. Becerra*, No. 1:17-cv-0545 (D.D.C. Jan. 2, 2024). The D.C. District Court held that the Provider Reimbursement Review Board had jurisdiction over the plaintiff hospitals' appeals of CMS's 2009 publication of SSI fractions for fiscal year 2007 and, in turn, vacated the Board's jurisdictional decision and remanded the case to the Board to address the merits of the dispute. In reaching its decision, the Court reasoned that CMS's publication of the SSI fractions at issue constituted a "final determination" within the meaning of 42 U.S.C. § 1395oo of the Medicare statute. Relying on *Washington Hospital Center v. Bowen*, 795 F.2d 139 (D.C. Cir. 1986), and *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011), the Court stated that "any administrative action" providing a hospital with "advance knowledge of the amount of payment it will receive" is a "final determination." The Court explained that "section 1395oo permits providers to prospectively appeal what they will, in the future, receive as a result of services provided to eligible patients" and "eliminates the requirement that [a provider] file a cost report prior to appeal." The Court found that the Board had jurisdiction over the appeal because "the publication provided, with some finality, 'advance knowledge of the amount of [the DSH] payment'" and "clearly instructed [MACs] in how to calculate DSH payments." The Court also found that the providers' "injury accrues for the purposes of the relevant statutory subsection when [they] are informed

that they will receive a smaller reimbursement based on a particular fractional determination," and that, "through the Transmittal, CMS . . . made a final decision with the meaning of the statute, because CMS definitively alerted providers to forthcoming reimbursements."

On April 30, 2024, the government filed is brief before the D.C. Circuit, arguing the Provider Reimbursement Review Board ("PRRB") properly concluded that it lacked jurisdiction to hear plaintiffs' appeal because the Medicare fractions that plaintiffs challenged did not determine an "amount of the payment" available under the prospective payment system and they were not "final." Battle Creek's brief is due on July 1, 2024, with the government's reply brief to follow. The Court has not yet scheduled oral argument.

4. *American Hospital Association et al. v. Becerra,* No. 4:23-cv-1110 (N.D. Tex. Nov. 2, 2023).

The AHA and several hospital systems filed suit in Texas, challenging a new HHS Health Insurance Portability and Accountability Act ("HIPAA") rule as contrary to law and arbitrary and capricious. *See* Complaint, *American Hospital Association et al. v. Becerra,* No. 4:23-cv-1110 (N.D. Tex. Nov. 2, 2023).

The rule, issued by HHS as a Bulletin in December 2022, purports to extend HIPAA's disclosure restrictions to technology that connects an individual's IP address with a visit to an Unauthenticated Public Webpage that addresses specific health conditions or health care providers. HHS deems this a "Proscribed Combination" that falls within the category of individually identifiable health information" ("IIHI"). See Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates (Bulletin), https://perma.cc/58V6-NTMG.

In their summary judgment motion, the hospitals argue that the rule exceeds HHS's authority because the webpage visitor's computer IP address "is not even remotely 'information' that provides a reasonable basis to identify 'the individual' (if any) whose own health, health[ ]care, or payment for health[ ]care actually 'relates to' the visit." See Mot. and Mem. for Summary J. filed by Petitioners, *American Hospital Association et al. v. Becerra,* No. 4:23-cv-1110 (N.D. Tex. Jan. 5, 2024). There are many "generic reasons," the hospitals contend, as to why a person, such as a public-health researcher or hospital employee, may visit a hospital's webpage "entirely unrelated to the health, health[ ]care, or payment for health[ ]care of any particular individual." And even if the visit to the webpage related in some way to an individual's particular health care need, the hospitals note that the webpage visitor could be a family member, friend, or countless other unrelated third parties. The hospitals argue that HHS's inference that the visitor's IP address is IIHI raises serious First Amendment concerns because it restricts the hospitals' right to provide data from their public-facing webpages to their technology vendors to improve communication tools.

Even if the Court concludes that the rule is permissible under the IIHI definition, the hospitals argue that HHS's rationale for the rule was arbitrary and capricious because HHS did not provide any reasoning to support its assertion that the Proscribed Combination is IIHI. The hospitals fault HHS for its failure to consider the "myriad motivations" that individuals may have for visiting an Unauthenticated Public Webpage, especially when HHS's position conflicts with the federal government's own use of third-party technologies on agency webpages.

The hospitals argue that the rule is also procedurally defective under the APA. HHS, shortly after issuing the Bulletin, began systematically enforcing it, warning entities to comply and threatening civil penalties. However, the rule did not go through the required notice-and-comment rulemaking, even though it carries the force of law by "significantly altering covered entities' obligations and conduct."

Prior to the government filing its response, on March 18, 2024, the Office for Civil Rights ("OCR") updated the guidance first issued in December 2022 regarding the use of online tracking technologies in the public-facing websites of HIPAA-regulated entities, including hospitals and health systems (the Revised Bulletin). OCR has clarified that, without more, the connection between an individual unauthenticated website user's IP address or other identifying information with the information that the user visited the covered entity's website is not sufficient to constitute IIHI.

In light of the updated guidance, the matter is currently stayed pending settlement negotiations between the parties.

5. *Texas Medical Association v. HHS*, 2023 WL 1781801 (Feb. 6, 2023), *appeal filed*, No. 23–40217 (5th Cir. Apr. 6, 2023).

Since the passage of the No Surprises Act in 2021, the Texas Medical Association ("TMA") has challenged the implementation by the Departments of the Treasury, Labor, and Health and Human Services ("HHS") (collectively, the "Departments") of the No Surprises Act's dispute resolution provisions in four separate cases (commonly referred to as TMA I, TMA II, TMA III and TMA IV).

Case	At Issue	Latest Status
TMA I[1] Case No.: 6:21-cv-425-JDK; filed on October 28, 2021.	Whether the Departments' original July 2021 interim final rules[2] imposed unlawful guardrails on the arbitration process (e.g., requiring arbitrators to "rebuttably presume" the offer closest to the qualifying payment amount ("QPA") was the appropriate out-of-network rate). The QPA is the basis for determining individual cost-sharing for items and services covered by the balance-billing protections.	**Concluded.** On February 23, 2022, the U.S. District Court for the Eastern District of Texas ("District Court") ruled in favor of TMA, vacating certain provisions of the interim final rules related to the independent dispute resolution process ("IDR Process") and the QPA. On April 22, 2022, the Departments appealed this decision in the Fifth Circuit Court of Appeals. However, on October 20, 2022, the Departments voluntarily dismissed their appeal. As a result of this case, the Departments issued new final rules in August 2022, which TMA is challenging in TMA II.
TMA II[3] Case No.: 6:22-cv-372-JDK); filed on September 22, 2022.	Whether the Departments' August 2022 revised final rules[4] (which were published in response to the TMA I ruling) conflict with the statute by requiring arbitrators to consider the QPA first and requiring certain regulatory criteria to be met before an arbitrator could give weight to any other circumstance or factor. These new requirements unlawfully elevate the QPA over the other statutory factors and make QPA the de facto benchmark rate.	**Ongoing.** On February 6, 2023, the District Court ruled in favor of TMA and vacated certain provisions of the interim final rules addressing information that an arbitrator must consider when deciding the proper payment amount, remanding such provision for further review. On April 6, 2023, the Departments appealed this decision in the Fifth Circuit Court of Appeals. More details regarding this appeal are provided further below.
TMA III[5] Case No.: 6:22-cv-450-JDK; filed on November 30, 2022.	Whether the Departments' original July 2021 interim final rules artificially deflate the QPA by, among other things, accounting for ghost rates (i.e., contract rates with physicians and others who are not actually providing the particular health services, thus have no incentive to fairly negotiate reasonable reimbursement rates) during QPA calculations.[6]	**Ongoing.** On August 24, 2023, the District Court ruled in favor of TMA and vacated certain challenged provisions of the July 2021 interim final rules related to calculating QPA. The Departments, once again, appealed to the Fifth Circuit Court of Appeals seeking to overturn the District Court's decision vacating the regulations outlining the methodology used to calculate the QPA. The parties are currently submitting briefs in the appeal.
TMA IV[7] Case No.: 6:23-cv-59-JDK; filed on January 30, 2023.	Whether the Departments' decision to increase the nonrefundable administrative fee for each IDR proceeding from $50 to $350, through amending the latest 2023 Federal IDR Guidance, effectively established a barrier to accessing the IDR process for many providers.[8] Also, whether the Departments' batching rule itself also unduly restricts access to IDR because the Departments adopted a service-code-only approach to batching, which permitted only a narrow set of circumstances to be reviewed as one proceeding.	**Concluded.** On August 3, 2023, the District Court, once again, ruled in favor of TMA and vacated and remanded certain challenged provisions of the September 2021 interim final rules related to implementing the IDR process. In response to the Court's ruling, the Departments published new proposed rules[9] on November 3, 2023.

As described in more detail in the chart above, each case challenges a rule or guidance issued by the Departments implementing the No Surprises Act.

New Developments

In TMA II, the parties recently presented arguments to the Fifth Circuit Court of Appeals. The Departments challenged the district court's decision, arguing they acted within their authority in the August 2022 final rules that continue to favor the significance of QPA as a factor when making a determination on the appropriate payment amount for the items and services in dispute. The Departments contend that, with the removal of the vacated October 2021 final rules as a result of TMA I, there is no lingering effect of the "rebuttable presumption" in favor of using QPA as the final amount. TMA countered that the August 2022 final rules effectively (and improperly) created a new QPA presumption, by:

- precluding any factor from consideration, if it is already accounted for by the QPA (45 C.F.R. § 149.510(c)(4)(iii)(E)),
- requiring the arbitrator to provide a written explanation if any weight was given to a factor other than the QPA (45 C.F.R. § 149.510(c)(4)(vi)(B)),
- requiring the arbitrator to review QPA first, before reviewing any other factor (45 C.F.R. § 149.510(c)(4)(iii)(B)),
- establishing a narrow "related to" requirement that prohibits an arbitrator to give any weight to a factor that is not related to either party's offer (45 C.F.R. § 149.510(c)(4)(iv)(B)), and
- requiring an arbitrator to first decide on the credibility of a non-QPA factor, before giving weight to its utility in a determination (45 C.F.R. § 149.510(a)(2)(v)).

As the parties await a decision from the Fifth Circuit Court of Appeals in TMA II, they are currently submitting briefs in the TMA III appeal.

Regulatory Updates

1. CMS Releases FY 2025 IPPS Proposed Rule

On April 10, 2024, CMS published its annual proposed rule for the federal fiscal year ("FY") 2025 IPPS and LTCH payment systems. Notable proposed changes include an increase of 2.6% to the IPPS payment rates for FY 2025, 0.2% lower than the 2.8% increase that was enacted for FY 2024, and a proposal to pay a total of $6.498 billion in DSH uncompensated care payments to hospitals, marking a decrease of 3.29% from the $6.712 billion in payments for FY 2024, due mainly to a decline in the estimated uninsured rate for FYs 2024 and 2025. CMS also proposed a new mandatory episodic payment model for acute care hospitals in certain areas to be selected by CMS. Comments on these proposals are due to CMS by June 10, 2024. Learn more.

2. Change Healthcare Cyberattack: HHS OCR Publishes Early Guidance on Breach and United-Health Group Provides Critical Status Update

On March 13, 2024, the HHS Office for Civil Rights ("OCR") announced that it had opened an investigation into the monumental cyberattack on Change Healthcare ("Change"), a unit of UnitedHealth Group ("UHG"). The attack is one of the largest assaults against the U.S. health care system, with far-reaching effects on hospitals, physicians, and other health care providers across the nation. On April 19, OCR published a new FAQ webpage about the cybersecurity incident and the implications for covered entities and business associates with business associate relationships with Change. OCR does not provide any new bombshell details—the agency confirms it has not yet received breach reports from Change/UHG—though the site does include background information and early guidance for covered entities beginning to evaluate possible notification obligations.

3. CMS Issues New Ruling Retroactively Eliminating "Total Days" Option in SSI Fraction

On March 4, 2024, CMS issued Ruling 1498-R3, revising the patient categories included in the SSI fraction used by the agency in calculating DSH payments. The ruling states it revokes and replaces Ruling 1498-R2, which had allowed hospitals to apply a revised SSI fraction with or without part A non-covered days included in the numerator and denominator, i.e., based either on "total" or "covered" days, for cost reporting periods with discharges prior to October 1, 2004. In Ruling 1498-R3, CMS states it revoked 1498-R2 "to comply with" the Supreme Court's decision in *Becerra v. Empire Health Foundation,* which "approve[d]" the agency's new interpretation of "entitled to benefits under part A" of Medicare as applied to the counting of inpatient hospital days for "patients whom Medicare insures but does not pay for on a given day" in the Medicare DSH payment calculation. 142 S. Ct. 2354, 2361 (June 24, 2022). Ruling 1498-R3 now "requires, for each properly pending claim in a DSH appeal or open cost report, including those involving patient discharges pre-dating October 1, 2004, that the agency and MACs calculate or recalculate the provider's Medicare fraction. . . based on total days, not covered days." CMS states it "recognize[s] that hospitals may have anticipated receiving greater Medicare reimbursement for still-open pre-FY 2005 cost reporting periods... where the 'covered' days limitation would have resulted in a larger DSH adjustment," and that "providers... will have the right to appeal" their Notices of Program Reimbursement ("NPRs") and revised NPRs reflecting the withdrawal of CMS Ruling 1498-R2.

4. CMS Publishes Instructions Regarding Issuing NPRs and Revised NPRs Following the 2023 Part C Final Rule and *Allina II* decision

On February 21, 2024, CMS published a Change Request ("CR") with instructions to MACs on the treatment of

Medicare Part C Days in the Medicare DSH payment. The instructions direct MACs on how and when to issue new NPRs and revised NPRs ("RNPRs") following the Part C Final Rule published in June 2023. MACs had until March 22 to identify the number of cost report settlements placed on hold pending the instructions, and the number of cost reports with pending appeals or appeals that were remanded challenging the treatment of Part C days in DSH payments before October 1, 2013. The CR also directs MACs to issue NPRs by September 25, 2024 for all cost reports on hold pending the instructions that had not received an initial NPR, as well as issue RNPRs for all cost reports that had a Notice of Reopening Issued to the provider for the purpose of holding the cost report open pending the results of the *Allina II* decision in *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (June 3, 2019). The CR also directs MACs to issue RNPRs for DSH payment-related appeals that have been or will be remanded by the CMS Administrator or PRRB within one year from the date of the CR (Feb. 21, 2025) if the remand has already been issued by Feb. 21, 2024, or six months from the date of the remand for remands received after the publication of the CR.

5. CMS Finalizes Changes to Medicaid DSH Calculation Resulting in Reduced Payments

On February 20, 2024, CMS finalized proposed changes to how states calculate the hospital-specific cap for Medicaid DSH. *See* 89 Fed. Reg. 13,916. The final rule went into effect on April 27, 2024 (60 days after its February 23, 2024 Federal Register publication date). The rule implements changes to the calculation under the Consolidations Appropriations Act of 2021 (Pub. L. 116–260, December 27, 2020) ("CAA") by limiting hospitals to accounting only for patients with Medicaid as the primary payer when estimating annual Medicaid shortfalls. CMS expects the new calculations to result in an $8 billion reduction in DSH payments annually for fiscal years 2024-2027. The rule also clarifies the timing and availability of certain data, for example, the detailed supplemental payment reporting data required under Section 202 of the CAA 2021 will be available starting with the 2022 fiscal year.

6. Departments' Supplemental Background on the Independent Dispute Resolution ("IDR") Process

On February 15, 2024, HHS and the U.S. Treasury Department (collectively, the "Departments") jointly published a Supplemental Background on Federal Independent Dispute Resolution ("IDR") Public Use Files. The No Surprises Act and its implementing regulation establish a Federal IDR process that providers and insurers may use to determine the out-of-network rate for qualified IDR items or services after an unsuccessful open negotiation period.

The publication is the first time that the Departments have released the full scope of statutorily required information from the first two calendar quarters of 2023. As part of ongoing efforts to streamline and improve the full federal IDR process, the Departments continue to make ongoing technical and operational enhancements to the process to facilitate throughput. As such, in addition to the statutorily required information, the Departments confirmed that future reports will include number of payment disputes initiated, closed, and the reasons for closure. Ultimately, CMS states these additions are intended to promote transparency in the federal IDR process and be responsive to the Departments' obligations to the public.

Although the Departments issued five times the number of payment determinations in the first half of 2023 than in all of 2022, they recognize there are disputing parties that continue to await eligibility and payment determinations. The Departments noted the primary cause of delay in processing disputes is the considerable amount of time and resources required by IDR entities to make eligibility determinations. In efforts to continue improving the efficiency of certified IDR entities, the Departments continue to propose new changes to policy and operations. *See* Federal Independent Dispute Resolution Operations, 88 Fed. Reg. 75,744 (November 3, 2023).

Notably, although currently inconclusive, the data provided in the update may prove useful in assessing whether the August 2022 final rules are, as the Departments seem to be suggesting, effective at making the federal IDR process more efficient in making final payment determinations. (See discussion under Docket Updates for *Texas Medical Association v. HHS*, No. 23-40217, (5th Cir. Argued Feb. 5, 2024)).

7. CMS Publishes Final Rule on Interoperability and Electronic Prior Authorization Requirements for Payers and Providers

On February 8, 2024, CMS published a final rule on interoperability and prior authorization requirements for payers and providers.[10] Beginning in 2027, providers that attest "no" or fail to report on a new "Electronic Prior Authorization" measure will lose "meaningful user" status under the Merit-Based Incentive Payment System and Promoting Interoperability Program. Specifically, providers must attest to requesting prior authorization electronically via a prior authorization application programming interface using data from certified electronic health record technology ("CEHRT") for at least one medical item or service (excluding drugs) ordered during the applicable performance/reporting period, subject to certain exceptions. These are similar consequences to the "appropriate disincentives" for information blocking by health care providers proposed by HHS Office of the National Coordinator for Health Information Technology ("ONC") and CMS in the proposed rule described below.

8. CMS Issues Proposed Rule on Appeal Rights for Certain Changes in Patient Status for Medicare Beneficiaries

On December 21, 2023, CMS released a proposed rule that would implement an order from the Federal District Court for the District of Connecticut in *Alexander v. Azar* that requires HHS to establish appeals processes for certain

Medicare beneficiaries who are initially admitted as hospital inpatients but are subsequently reclassified as outpatients receiving observation services during their hospital stay and meet other eligibility criteria.

The proposed processes include: 1) Expedited appeals, for certain beneficiaries who disagree with the hospital's decision to reclassify their status that will be conducted by a Beneficiary & Family Centered Care – Quality Improvement Organization ("BFCC–QIO"); 2) Standard appeals, for beneficiaries who do not file an expedited appeal within the expedited timeframe but are otherwise eligible for the expedited appeal; and 3) Retrospective appeals, for certain beneficiaries to appeal denials of Part A coverage of hospital services, and certain skilled nursing facility services, as applicable, for status changes that occurred prior to the implementation of the prospective appeals process, dating back to January 1, 2009. The comment period for this proposed rule closed February 26, 2024.

9. CMS Proposes Rule for Strengthening Oversight of Accrediting Organizations

On February 15, 2024, CMS published a proposed rule, 89 Fed. Reg. 11,996, to bolster oversight of organizations that accredit health care providers certified by the Medicare and Medicaid programs. The proposed rule would set forth a number of provisions to strengthen the oversight of accrediting organizations ("AOs") by addressing conflicts of interest among AO owners, surveyors, and other employees; establishing consistent standards for AOs, processes and definitions; and updating the validation and performance standards systems. The proposed rule would hold AOs accountable to the same standards as state Survey Agencies that also conduct surveys on behalf of CMS to bolster AO performance and oversight to ensure providers meet health and safety standards. The comment period for the proposed rule ended April 15, 2024.

10. New York State Proposes New Cybersecurity Program and Incident Reporting Requirements for Hospitals

On November 13, 2023, New York released proposed statewide hospital cybersecurity regulations that would require state-licensed hospitals to establish cybersecurity programs, policies and procedures (the "Proposed Regulations"). The Proposed Regulations would also require appointing a Chief Information Security Officer ("CISO") and engaging qualified cybersecurity personnel, using appropriate authentication methods for access to hospital information systems, undertaking annual risk assessments that include penetration tests and scans or reviews of information systems to identify cybersecurity vulnerabilities, adopting incident response plans, and reporting to the New York State Department of Health ("NYSDOH") within two hours of a determination that a cybersecurity incident has occurred and has had a material adverse impact on the hospital.

If approved by the New York State Public Health and Health Planning Council ("PHHPC") and subsequently finalized, the Proposed Regulations would supplement federal HIPAA Security Rule requirements but would be broader in some respects, including what information is subject to the requirements. The new requirements would take effect one year after their finalization, except for new security incident reporting requirements, which would take effect immediately. To comply, hospitals would need to update their cybersecurity policies and procedures, hire cybersecurity professionals, change their incident response procedures, and revise their planned security risk assessments. The Proposed Regulations are pending approval of PHHPC.

11. ONC and CMS Publish Proposed Rule with New Consequences for Information Blocking by Certain Health Care Providers

On November 1, 2023, ONC and CMS published a proposed rule that, if finalized, would establish disincentives under the 21st Century Cures Act to deter health care providers from engaging in information blocking practices and could reduce hospital payments by restricting "meaningful user" status.[11] Under the proposed rule, any hospitals or critical access hospitals ("CAHs") that participate in the Medicare Promoting Interoperability ("PI") Program and are determined to have committed information blocking would not be considered "meaningful users" of ONC-certified electronic health record technology ("CEHRT") under the PI Program. Similarly, clinicians that participate in the Merit-Based Inventive Payment Systems ("MIPS") and are determined to have committed information blocking would not be considered "meaningful users" of CEHRT under MIPS. For hospitals participating in the PI Program, losing "meaningful user" status would lead to a 75% lower annual increase in Medicare payments based on an inflation market basket update or rate of increase for hospitals that CMS publishes each year. For a CAH, losing "meaningful user" status would lead to a reduction in payments received from CMS under the Medicare PI Program from 101% to 100% of its reasonable costs. For clinicians participating in MIPS, losing "meaningful user" status would result in a Promoting Interoperability category score—which represents 25% of the total MIPS score—of zero. Eligible clinicians with a MIPS score below the CMS-established benchmark may incur a penalty of up to 9% of their Medicare payments. ONC and CMS also propose disincentives-related ACO performance in the Medicare Shared Savings Program. Comments on the proposed rule were due on January 2, 2024, and we anticipate a final rule later this year.

Enforcement Updates

Hospitals Press CMS to Lower Star Rating on Plans that Repeatedly Deny Care on Appeal

The Federation of American Hospitals ("Federation") issued a recommendation in CMS's 2023 Measures Under Consideration ("MUC") list, which CMS publishes in the

pre-rulemaking process to make proposed measures publicly available and to seek input from stakeholders in upcoming proposed rules. The MUC List is a list of quality and efficiency measures CMS is considering adopting for use in the Medicare program. The MUC list is made publicly available by December 1 each year for categories of measures described in section 1890(b) (7) (B) (i) (I) of the Social Security Act ("SSA") as amended by Section 3014 of the Patient Protection and Affordable Care Act. The Federation's proposal pressures CMS to take action against Medicare Advantage plans that repeatedly deny care. The Federation asked CMS to add a quality measure to star rating calculations to be adjusted up or down depending on how often plans uphold or overturn initially denied prior authorization requests by adding prior authorization appeal rates to ratings. The pressure on CMS to reel in Part C plans' denial of care is one effort by the association to address the financial toll on hospitals from care denials. If the Federation's proposals were adopted, consumers would be able to see how often Part C plans uphold or overturn denied prior authorizations and would thus have more visibility into the practices of Part C plans they may enroll in.

Value-Based Care Corner

CMS Proposes Mandatory Episodic Payment Model for Hospitals

On April 10, 2024, the Center for Medicare and Medicaid Innovation ("Innovation Center") proposed in its annual IPPS rule a new mandatory episode-based alternative payment model that would require participation of all hospitals in selected Core-Based Statistical Areas. The Transforming Episode Accountability Model ("TEAM") would be tested for five years, from January 1, 2026, to December 31, 2030, over which time CMS projects a net cost to hospitals of over $400 million. Selected acute care hospitals would coordinate care for people with Traditional Medicare who undergo one of the surgical procedures included in the model (initiate an episode) and assume responsibility for the cost and quality of care from surgery through the first 30 days after the Medicare beneficiary leaves the hospital. Hospitals would receive target prices for included episodes prior to each performance year. While similar to the Comprehensive Care for Joint Replacement Model, TEAM includes a broader array of episodes, including coronary artery bypass grafting and major bowel procedures. Hospitals will also take on increased financial risk (up to +/- 20%, beginning in 2027) for episodes, with additional adjustments for quality performance. Given the Innovation Center's broad preclusion of administrative and judicial review, hospitals should carefully review the proposal and submit comments by the June 10, 2024 deadline.

CMS Approves Groundbreaking and Innovative 1115 Waiver Amendment for New York State Medicaid Program

On January 9, 2024, CMS announced its approval of the New York Health Equity Reform ("NYHER") waiver amendment under Section 1115(a) of the Social Security Act. The waiver provides substantial upfront funding to safety net and distressed New York hospitals, a move that signals that CMS may act to offer similar support to hospitals in other states seeking Medicaid waivers.

CMS approval of NYHER follows a waiver design process that spanned almost three years and required more than 17 months of negotiations between CMS and the New York State Department of Health ("DOH"). The result is a significant expansion to the New York State Medicaid Program that will deploy approximately $7.5 billion in funding over 3.25 years, transforming how New York State promotes health equity and works to reduce health disparities for the more than 7.6 million individuals with health coverage under the State Medicaid Program. NYHER has a particular focus on addressing Health-Related Social Needs ("HRSN"), but also will have significant implications for safety net and distressed hospitals as they transform care delivery models into global value-based payment structures, in alignment with recent federal opportunities from the Centers for Medicare & Medicaid Innovation. Finally, NYHER will provide funding to address unprecedented health care workforce challenges emanating from the COVID-19 pandemic. Learn more.

CMS Releases Financial Specifications and Fact Sheet for AHEAD Model

On February 12, 2024 CMS released financial specifications for the hospital global budget methodology for Medicare fee-for-service patients under the States Advancing All Payer Health Equity Approaches and Development ("AHEAD") Model, and a fact sheet detailing the AHEAD Model's policy regarding participation overlapping with current CMS models and programs that will be concurrently operating.

AHEAD is CMS's most significant effort to date to engage providers and States in multi-payor payment reform aimed at curbing health care cost growth, improving population health, and advancing health equity. The voluntary total cost of care model was announced late last year and, in partnership with Health Resources and Services Administration ("HRSA"), CMS issued the Notice of Funding Opportunity setting forth the State participation requirements. This spring, CMS will select up to eight states to participate and share in $96 million of grant funding. Participating States, which will act as value-based care "hubs," will partner with hospitals and primary care providers as well as organizations addressing HRSN. Learn more.

Disaster Relief Funding Updates

HHS OIG Report Finding HRSA Made Potential Overpayments in Phase 2 General Distributions

In March 2024, HHS OIG published a report summarizing its findings in an audit that reviewed whether: (i) HRSA correctly calculated Provider Relief Fund ("PRF") payments under the Phase 2 General Distribution, (ii) these payments were supported by appropriate documentation, and (iii) HRSA made payments to eligible providers. The audit covered 73,449 tax-filing taxpayer identification numbers ("TINs") for Medicaid and CHIP providers, dental providers, and assisted living facilities for which each provider had received a total of $10,000 or more from July 3, 2020, through June 21, 2021, under the Phase 2 General Distribution. HRSA disbursed $4.8 billion to these providers. Of the TINs covered by the audit, HHS OIG selected a statistical sample of 150 providers that were each represented by a TIN. *See* Off. of Inspector Gen., A-09-22-06001, "HRSA Made Some Potential Overpayments to Providers Under the Phase 2 General Distribution of the Provider Relief Fund Program (2024)," pp. 7-8 (the "2024 Report").

Summary of Findings, Recommendations, and HRSA Responses

HHS OIG found that HRSA made PRF payments to eligible providers for all 150 sampled providers. However, for 17 of the 150 providers, HRSA made PRF payments that either were not correctly calculated (15 providers) or were not supported by appropriate documentation (2 providers). *See* 2024 Report, p. 8. For the remaining two sampled providers, HRSA made payments based on revenue that was not supported by federal income tax returns. *See* 2024 Report, p. 9.

Specifically, for the 15 sampled providers for which PRF payments were not correctly calculated, HRSA made payments:

- without subtracting payments that had previously been made to providers' subsidiary organizations,
- based on incorrectly calculated patient care revenue,
- based on revenue information that providers incorrectly entered on PRF applications, and
- based on revenue information for which bad debt was not subtracted. *See* 2024 Report, pp. 8-9.

As a result of the incorrect calculations, HRSA made $18.4 million in potential overpayments to the 17 sampled providers. HHS OIG has estimated that HRSA made $159.4 million in potential overpayments to providers, or 3.3 percent of the total PRF payment amounts that were subject to the audit. *See* 2024 Report, p. 9.

Based on the foregoing, HHS OIG made three recommendations to HRSA, including that HRSA conduct a review of the 17 sampled providers that the agency identified that had potential overpayments of $18.4 million and determine the amount of and seek repayment of any overpayments. *See* 2024 Report, p. 18. HRSA stated that it had identified 16 sampled providers with potential overpayments totaling $7,241,390 instead of 17 sampled providers with potential overpayments totaling $18,381,187.

Additionally, HHS OIG recommended that HRSA identify other providers with subsidiary organizations that had revenues included in the providers' federal tax returns to determine whether the payments made to the subsidiary organizations were correctly accounted for when calculating the payments for providers under the Phase 2 General Distribution and seek repayments if required. Lastly, HHS OIG recommended identifying other providers for which payments under the Phase 2 General Distribution were approved and withheld, determine whether their subsidiary organizations received additional payments during the period when the payments were withheld, and seek repayments if necessary. See 2024 Report, p. 19. HRSA concurred with these recommendations, noted that it maintains a list of post payment discrepancies that it tracks and works to resolve, and depending on the availability of resources, it will consider adding these recommendations to this list. *See* 2024 Report, p. 20.

HHS OIG also provided some guardrails that HRSA should follow should it need to rapidly disburse similar payments to providers in response to a future national emergency. *See* 2024 Report, p. 19.

HRSA Issues New and Modified PRF FAQs

On February 16, 2024, HRSA issued updated PRF FAQs reflecting that no further payments, including reconsideration payments, will be made to providers. In accordance with the end of the PRF program, FAQs on topics such as eligibility, payment amounts, payment attestation, payment status, phase-specific distributions and requirements, terms and conditions, extensions and targeted distributions were removed. Further, FAQs on topics such as returning payments, unused funds, auditing requirements, lost revenue, and commercial audit reports were added or modified.

Notably, Reporting Periods 8 and 9 were removed, likely because no payments were received after June 30, 2023. Thus, the Period of Availability for eligible expenses under Reporting Period 7 will end on June 30, 2024, and the Reporting Time Period will end on September 30, 2024. Moreover, as per the revised FAQs, now if an entity received one or more General and Targeted Distributions and/or ARP Rural Distribution payments exceeding $10,000 in the aggregate during a payment-received period, the entity is required to report in each applicable Reporting Time Period, instead of during a single time period.

Additionally, a new FAQ was added to note that a Reporting Entity may not, in response to an audit finding, amend its Report after the applicable Reporting Period has passed. However, a few other options are available to these providers:

- For providers required to report in subsequent Reporting Periods and that choose to replace their unallowable expense with their unreimbursed lost revenues in the Reporting Period in question:
  - Providers would update their previously entered lost revenues information in the next available reporting period.
  - Providers are required to enter a justification for the change with a description (including the notation that they were making this change to replace an unallowable expense as part of their audit-finding corrective action plan, adding the audit and/or finding number).
- For providers that were not required to report in subsequent Reporting Periods and chose to replace their unallowable expenses with their unreimbursed lost revenues in the reporting period in question:
  - In the corrective action plan, the providers would indicate that the unallowable expense was "replaced" by unreimbursed lost revenues.

Complaint Filed Relating to Phase 4 General Distribution Reconsideration Payments

On January 10, 2024, Presbyterian Healthcare Services ("PHS") filed a complaint in the United States District Court of New Mexico against HHS and HRSA, as well as the HHS Secretary and HRSA Administrator (the "Complaint"). *See Presbyterian Healthcare Services vs. Becerra,* Case No. 1:24-cv-00034 (D.N.M., Jan. 10, 2024). The Complaint alleges that HRSA violated the Administrative Procedure Act ("APA") when it arbitrarily and capriciously (i) denied PHS's PRF Phase 4 General Distribution reconsideration request without first considering whether doing so was reasonable under the circumstances; and (ii) announced in a three-sentence update to its website the ending of all reconsideration payments due to the rescission of appropriations of unobligated PRF dollars by the passage of the Fiscal Responsibility Act of 2023 ("FRA").

PHS submitted a Phase 4 General Distribution application during the eligible time period through HRSA's online portal and received $15,539,766.42 in Phase 4 payments. While HRSA calculated such payments using an imputed loss ratio, as it determined that the application's supporting files lacked documentation substantiating PHS's actual losses in one of the six quarters reviewed, PHS contends that actual quarterly losses should have been used. Had HRSA used the actual quarterly losses calculation methodology, PHS would have received a total Phase 4 payment of $26,102,272.84. PHS thus argues that HRSA deprived it of $10,562,495.52.

Accordingly, in November 2022, PHS provided HRSA with a file that substantiated all figures for actual quarterly losses from the Phase 4 application. HRSA encouraged PHS to submit a Phase 4 reconsideration request, allegedly noting that a similarly situated provider had obtained relief through the reconsideration process. The Phase 4 reconsideration request was filed on November 9, 2022. The Complaint alleges that approximately eight months later, in June 2023, HRSA summarily denied PHS's Phase 4 reconsideration request without a reasonable explanation. This denial occurred nearly concurrently with the passage of the FRA on June 3, 2023, which ended all reconsideration payments.

PHS argues that the denial of PRF dollars has diminished its ability to fulfill its mission, and the threat of losing access to PRF dollars would cause irreparable harm. As such, PHS seeks that the court restrain HRSA from enforcing its Phase 4 payment determination against HRSA and immediately set aside $10,562,495.52 to be disbursed to PHS subject to the proper adjudication of the Phase 4 reconsideration request. Importantly, PHS also seeks for the court to set aside HRSA's policy change ending all payments of PRF funds in connection with the FRA.

HHS OIG Audit Report Finding Generally Effective Oversight of PRF Program and Suggesting Improvements

In October 2023, HHS OIG published a report summarizing its audit of HHS's measures to ensure that the Phase 1 General Distribution automatic PRF payments were (1) properly calculated and (2) disbursed only to eligible providers. The audit reviewed approximately $39 billion in automatic PRF payments distributed to 319,468 providers between April 10, 2020 and April 24, 2020, but did not assess how HHS and HRSA designed the automatic PRF payment controls. *See* Off. of Inspector Gen., A-02-20-01025, HHS's Oversight of Automatic Provider Relief Fund Payments Was Generally Effective But Improvements Could Be Made (2023), p. 1 ("Report").

Summary of Findings, Recommendations, and HRSA Responses

Overall, HHS OIG found in its Report that HHS implemented generally effective oversight to ensure that PRF payments were appropriately calculated and distributed to eligible providers and provided some recommendations for improving oversight efforts in the future. Specifically, the audit found the following:

- HHS did not ensure that approximately $2.19 billion (5.5%) in automatic PRF payments were properly calculated.
- HHS did not prevent more than $274 million (less than 1%) from being distributed to ineligible providers.
- HHS did not ensure that all Tranche 1 automatic PRF payments to Medicare providers were properly calculated. Specifically, when calculating such payments, HHS did not always (i) apply a 2% sequestration reduction amount for Medicare Part B carrier providers and durable medical equipment suppliers, (ii) exclude managed care claim amounts for Medicare Part A hospital inpatient providers, (iii) include all pass-through reimbursement amounts for Medicare Part A hospital inpatient providers and (iv) include beneficiary coinsurance liability and deductible

amounts when it calculated Medicare Part B hospital outpatient providers' 2019 Medicare Fee-for-Service reimbursements.

- HHS did not identify all ineligible providers and exclude them from receiving PRF payments.
- HHS did not ensure that all Tranche 2 automatic PRF payments to Medicare providers were properly calculated. Specifically, HHS improperly calculated automatic PRF payments to renal dialysis providers and did not identify providers that had provided duplicate net patient revenue amounts before it calculated automatic provider relief fund payments. *See* Report, p. 12-13.

As a result of its findings in this audit, HHS OIG recommended that HRSA (i) perform post-payment reviews of certain providers with multiple subsidiary organizations and certain renal dialysis providers that attested to and kept automatic PRF payments and recoup any outstanding overpayments from these providers; (ii) perform post-payment reviews of certain providers that attested to and kept automatic PRF payments for which they were not eligible and recoup any outstanding overpayments from these providers; and (iii) strengthen its procedures that may apply to similar future programs to ensure that providers receive their intended share of financial assistance, financial assistance payments are properly calculated, data and data sources are complete and accurate, revisions are made as necessary to properly calculate financial assistance, and all available data sources are used to identify providers ineligible to receive financial assistance. See Report, pp. 22-23. HHS OIG also noted in the Report that it believes HHS accepted the risk of engaging in looser oversight of the PRF program than it would for a similar program under normal circumstances because of the unprecedented challenge to provide emergency financial assistance to providers in a timely manner. As a result, some providers received improper or unallowable payments. *See* Report, p. 12.

In response to the audit findings, HRSA confirmed that it had already reviewed the renal dialysis providers in December 2020 as part of its post-payment quality control review process and that, based on such review, HRSA sent out repayment notices to providers and will continue to seek repayment for overpayments. Additionally, HRSA noted that, after finalizing its review of providers with multiple subsidiary organizations and ineligible providers, the agency will seek repayment for overpayments. Lastly, HRSA stated that it has reviewed and continues to review and update, as applicable, its pre- and post-payment policies and procedures to identify and address payment issues. *See* Report, p. 23.

340B Updates

CMS Issues Final Rule for 340B Administrative Dispute Resolution

On April 18, 2024, the Department of Health and Human Services ("HHS") Health Resources & Services Administration ("HRSA") issued a final rule revising the 340B Drug Pricing Program administrative dispute resolution ("340B ADR") process for covered entities and pharmaceutical manufacturers to resolve 340B disputes involving overcharging, duplicate discounts, and diversion. Our 2022 client alert summarized key aspects of the proposed rule. Below, we summarize notable changes from the final rule.

Structure of ADR Panel: HHS will establish a roster of staff, including staff from HRSA's Office of Pharmacy Affairs, to serve on the ADR board. Each ADR panel will then consist of three staff members on the ADR board. These ADR panel members will undergo conflicts screenings to ensure that there are no conflicts of interest involving the parties in the dispute.

Scope of Permissible Claims: 340B ADR claims may include: (1) claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered drugs at or below the 340B ceiling price; and (2) claims by a manufacturer, after it has conducted an audit of a covered entity, that the covered entity has violated the diversion and/or duplicate discount prohibition. HRSA specifies that all claims must be specific to the parties identified in the claim and provides an illustrative list of examples of the types of claims that may be eligible for the ADR process.

ADR Process: In an effort to increase flexibility, the $25,000 minimum threshold for accessing the 340B ADR process was eliminated. HRSA also finalized specific process requirements, including the content of the filed claim (such as good faith efforts to resolve the dispute), a three-year deadline for filing the claim, requirements for "discovery" and deadlines for responding to filings. The ADR panel must then provide a decision within one year from the date of receiving a complete claim.

Federal Courts and the ADR Process: HRSA did not implement its proposal directing ADR panels to conduct an "initial review" of submitted claims to determine whether they are the same or similar to issues pending in a federal court, and if they are, to suspend further review. In deciding not to adopt its proposal, HRSA acknowledged the commenters' feedback that suspending review would be inconsistent with the statute and with the Supreme Court's ruling in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), which held that covered entities do not have a cause of action to sue manufacturers for 340B Drug Pricing Program violations, but must instead rely on the ADR process.

Administrative Appeal Rights: The final rule creates an administrative appeal process within HRSA for parties dissatisfied with decisions of the ADR panels. Parties will have 30 business days from receipt of the decision to request reconsideration on the basis that there was an error in the decision, including any deviation from policy, guidance, or statute.

This rule takes effect on June 18, 2024.

Bipartisan group of U.S. senators released a discussion draft of 340B legislation, requesting stakeholder comments on highly debated issues in the 340B program

On February 2, 2024, a bipartisan group of U.S. senators released a discussion draft of legislation, titled Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act ("SUSTAIN 340B Act"), for stakeholder feedback. According to U.S. senators sponsoring the legislation, the draft legislation seeks to preserve the 340B Drug Pricing Program ("340B Program") and codify key HRSA guidance. The draft legislation was accompanied by an explanatory statement and a request for information. Comments were due by April 1, 2024, and the senators indicated that these would not be posted publicly. To the extent there are any comments publicly posted (e.g., AHA Comments), it is because the commentor posted it, not the senators.

Contract Pharmacies: Since the inception of the 340B Program, covered entities have used contract pharmacies. HRSA released guidance on contract pharmacies in 2010, see 75 Fed. Reg. 10272 (Mar. 5, 2010), and there has been litigation challenging HRSA policy on contract pharmacies. The draft legislation would expressly provide that contract pharmacies have access to 340B drugs for dispensing to eligible patients without additional manufacturer restrictions and authorize civil money penalties for manufacturers that seek to restrict access. Covered entities would be required annually to register contracts with contract pharmacies for HRSA review to ensure compliance with 340B Program requirements. Provisions from HRSA guidance for contracts with contract pharmacies would be codified and expanded. Covered entities would be required to extend their financial assistance policy to patients that pick up their medications at a retail pharmacy or receive prescriptions in the mail (as well as at child sites). Additionally, the request for information inquires about what other, if any, restrictions should be applied while simultaneously ensuring that patients have access to 340B drugs if the drugs are only available through a limited distribution network or patients are in rural and underserved areas.

Patient Definition: The request for information states that while "eligible patient" is mentioned in the statute's 340B drug diversion prohibition, the term is not defined in the statutory language, leading to confusion regarding the administration of the 340B Program. In fact, that statutory definition for "eligible patient" has also spawned litigation, with a court in South Carolina recently ruling, with regard to a specific covered entity, that the 340B statute does not require a covered entity to have initiated a healthcare service resulting in a prescription filled with 340B drugs (*See Genesis*, below). The request for information sought stakeholder feedback on how the patient definition should be established, including the factors that should inform whether a patient-covered entity relationship exist; the length of time involved in defining the patient relationship; and issues surrounding patients of (and potentially competing claims from) multiple covered entities.

Child Sites: The draft legislation establishes several requirements for a covered entity location to be considered a "child site," expanding upon recent HRSA guidance. See 88 Fed. Reg. 73859 (Oct. 27, 2023). These requirements include that child sites must be registered with HRSA and be owned by and have operations closely integrated with the covered entity.

Transparency: The draft legislation also would require covered entities to report, and HRSA to publish, information about the use of the 340B Program, including the number of patients, their demographics, number of prescriptions classified by payor, charity care costs, the use of contract pharmacies, and a description of the covered entity's use of 340B savings.

Program Integrity: The draft legislation would also require HRSA to issue additional guidance regarding its audits of covered entities, their contract pharmacies and child sites, and manufacturers.

Duplicate Discounts: To address manufacturer concerns that prohibited duplicate discounts exist because there is no system to appropriately identify 340B drug claims, the draft legislation would establish a duplicate discount data clearinghouse to be operated by a third-party vendor and impose obligations on covered entities to report claims-level data. Additionally, covered entities would be required to repay manufacturers for duplicate discounts in the Medicaid program, whether those arose from Medicaid fee-for-service or managed-care payment arrangements.

Equitable Treatment. Health plans and pharmacy benefit managers would not be permitted to discriminate against covered entities, contract pharmacies or patients in the 340B Program through differential payment rates, refusal to contract, or interfering with a patient's choice to receive a 340B drug.

Patient Assistance. Covered entities would be required to extend their financial assistance policy to patients served by contract pharmacies and child sites.

User Fees: The draft legislation includes a user fee program, paid by covered entities, to assist with 340B Program administration. The proposed fee would be 0.01% of the savings the covered entity receives under the 340B Program, calculated as the average difference over a specified period between the wholesale acquisition cost and the 340B price of the drugs purchased under the 340B Program.

Miscellaneous: The draft legislation would also require various studies and reports, and also authorize additional funds for purposes of 340B Program oversight and enforcement.

Genesis Health Care, Inc. Challenges HRSA Definition of Eligible Patient Under 340B

(*Genesis Health Care, Inc. v. Becerra*, No. 4:19-CV-01531 (RBH), 2023 WL 7549156 (D.S.C. Nov. 3, 2023))

On November 3, 2023, the U.S. District Court of South Carolina granted Genesis Healthcare, Inc.'s ("Genesis") motion for summary judgment in its challenge to the HRSA definition of an eligible patient under the 340B statute. 42 U.S.C. § 256b(a)(5)(B). The Court held that the 340B statute does not require a covered entity to initiate a prescription for it to be filled with a 340B drug.

In 2017, after HRSA audited Genesis and found that 340B drugs were dispensed to individuals the agency regarded as ineligible patients, it excluded Genesis from the 340B program because of the alleged noncompliance. At the time, Genesis considered as eligible any patient who received care from Genesis within the previous two years, regardless of whether the individual's prescription was related to health care services provided at Genesis. In issuing its adverse audit finding, HRSA said the fact that Genesis may have provided health care services to the same individual at another point in time did not establish Genesis' ongoing responsibility for subsequent health care services provided by other providers because the covered entity must have *initiated* the health care service resulting in the prescription.

In 2018, Genesis filed suit challenging its removal from the program and argued that HRSA's narrow definition was not supported by the 340B statute, which does not define the term "patient," and was not articulated in any regulatory guidance. As a result of the litigation, HRSA reinstated Genesis in the 340B program and filed a motion to dismiss, arguing the case was rendered moot by such reinstatement. While the district court granted the motion to dismiss, the U.S. Fourth Circuit of Appeals disagreed, citing persistent problems relating to HRSA's application of the eligible patient definition, and remanded the case back to the district court.

On remand, the district court found that the 340B statute does not require a covered entity claiming a 340B discount to have been responsible for *originating* the relevant prescription or providing any health care service related to that prescription. Specifically, the district court found that the fact that Congress had the tools to define the term "patient" but did not do so meant that HRSA's position was unpersuasive under *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). The district court said that covered entities could potentially use 340B drugs to fill any prescription originating from any source, as long as the individual receiving the prescription has separately received services from the covered entity and has an "ongoing relationship" with the covered entity.

The ruling neither attempted to define an "ongoing relationship," nor did it attempt to articulate a reasonable number, or timing, of encounters with the covered entity in order to substantiate an ongoing relationship, as the district court acknowledged that this issue was not before the court.

While HRSA is only enjoined from enforcing its narrow "eligible patient" definition against Genesis, the district court left open the possibility that HRSA could formally define the term "patient" through future notice-and-comment rulemaking, consistent with the plain language of the statute and Congressional intent.

Hospitals Seek 340B Drug Compensation from Medicare Advantage Organizations

Hospitals have begun seeking compensation for 340B underpayments from Medicare Advantage Organizations ("MAOs") following the Supreme Court's 2022 decision in *American Hospital Association v. Becerra* (142 S. Ct. 1896 (2022)) invalidating the OPPS 340B-acquired drug payment policy for 2018-2022 and remanding back to the District Court, which instructed CMS to identify a remedy to the underpayments.

Under CMS's final rule promulgated in response to the Supreme Court decision, CMS issued a one-time lump sum payment to hospitals that were improperly reimbursed under traditional Medicare. However, for Medicare Advantage, CMS declined to direct MAOs to reimburse hospitals for their decrease in reimbursements (during the 2018-2022 time period) despite providers expressing concerns about MAOs' "realizing a windfall" as a result of reducing outpatient payments without making corresponding payments to hospitals. CMS referred commenters to its memo requiring MAOs to "pay non-contract providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules, in accordance with section 1852(a)(2) of the Act."

Hospitals, therefore, are left to contractual remedies pursuant to their agreements with MAOs. In what is likely the first of many cases, Baptist Health recently filed a lawsuit against Humana seeking payment from a Humana MAO. In addition to a demand for repayments based on Baptist Health's contract with Humana, Baptist Health seeks relief under equitable remedies, including unjust enrichment. *Baptist Health v. Humana, et al.,* No. 2-24-cv-00777 (M.D. Ala. March 25, 2024).

Looking Ahead

Making Care Primary Demonstration Program Launches July 1

On July 1, 2024, Making Care Primary ("MCP"), a 10.5-year voluntary multi-payer model aimed at improving the quality of primary care and reducing overall health care spending is launching in the states of Colorado, Massachusetts, Minnesota, New Jersey, New Mexico, New York (certain upstate counties), North Carolina and Washington. The program is designed to create a new pathway for organizations, and particularly smaller primary care practices and Federally Qualified Health Centers, operating under a fee-for-service payment system to shift to a value-based payment model involving prospective, capitated payments. MCP will allow participants to receive funding and support to build a value-based care practice. Learn more.

Anticipating ORI's Final Rule on Research Misconduct

The U.S. Department of Health and Human Services' Office of Research Integrity ("ORI") recently proposed revisions to federal regulations on research misconduct (falsification, fabrication, or plagiarism) that, if adopted, would compel academic medical centers and other recipients of funding from the National Institutes of Health to implement many resource-intensive changes to existing practices for investigating allegations of research misconduct. ORI officials have recently indicated that they expect to publish the final changes to the research misconduct regulations by the end of 2024.

ORI received approximately 300 responses to the proposed revisions during the public comment period, with many commenters emphasizing the significant new administrative burdens and other challenges that would result if the proposed changes are implemented. ORI's assessment of whether modifications to the proposed revisions are warranted will undoubtedly be informed and influenced by the recent wave of significant public interest and scrutiny of federally funded research, as allegations of falsification or fabrication of data against prominent leaders within health care and higher education have recently garnered significant media attention as well as scrutiny from Congress and federal funding agencies.

The Future of *Chevron*

A decision on the future of *Chevron* deference to agency (including HHS and CMS) interpretations of statutes is expected this Supreme Court term in two cases: *Loper Bright Enters. v. Raimondo*, No. 21-5166 (filed Nov. 10, 2022); and *Relentless, Inc. v. Dept. of Commerce*, No. 22-1219 (filed Jun. 14, 2023). Learn more.

CLE Programs

We maintain an updated library of CLE programs on various topics of interest to our hospital and health system clients—from primers on Medicare and Medicaid to new developments related to value-based care programs. Potential topics include:

- Reimbursement issues in the context of transactions
- Value-Based Care
- 340B updates
- Federal Programs

If you are interested in any of the above topics or would like to see a full list of topics, please contact: sabrina.halloran@ropesgray.com.

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Endnotes

1 *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 587 F. Supp. 3d 528 (E.D. Tex. 2022), appeal dismissed, 2022 WL 15174345 (5th Cir. Oct. 24, 2022).

2 *Requirements Related to Surprise Billing: Part I*, 86 Fed. Reg. 36,872 (July 13, 2021), https://www.govinfo.gov/content/pkg/FR-2021-07-13/pdf/2021-14379.pdf.

3 *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 654 F. Supp. 3d 575 (Feb. 6, 2023), appeal filed, No. 23-40217 (5th Cir. filed Apr. 6, 2023).

4 *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618 (Aug. 26, 2022), https://www.govinfo.gov/content/pkg/FR-2022-08-26/pdf/2022-18202.pdf.

5 *Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.*, No. 6:22-CV-450-JDK, 2023 WL 5489028 (E.D. Tex. Aug. 24, 2023).

6 The Air Ambulance Plaintiffs (LifeNet, Inc.; East Texas Air One, LLC; Rocky Mountain Holdings, LLC; and Air Methods Corporation) jointly challenged with TMA the federal government's implementation of the No Surprises Act. In TMA III, the Air Ambulance Plaintiffs challenged guidance published August 2022 that was specific to air ambulance service that required one air transportation service to be arbitrated as two separate proceedings due to the use of two distinct service codes when billing a patient for reimbursement of one air ambulance transport service. *See Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities*, Ctrs. For Medicare & Medicaid Servs. (Aug. 16, 2022), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Technical-Assistance-IDR-Entities-August-2022.pdf.

7 *Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.*, No. 6:23-CV-59-JDK, 2023 WL 4977746 (E.D. Tex. Aug. 3, 2023).

8 *Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act: Change in Administrative Fee*, CTRS. FOR MEDICARE & MEDICAID SERVS. (December 23, 2022), https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/amended-cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.

9 *Federal Independent Dispute Resolution Operations*, 88 Fed. Reg. 75744 (Nov. 3, 2023), https://www.govinfo.gov/content/pkg/FR-2023-11-03/pdf/2023-23716.pdf.

10 Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program, 89 Fed. Reg. 8,758 (February 8, 2024).

11 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking, 88 Fed. Reg. 74,947 (November 1, 2023).