ROPES & GRAY

HOSPITAL AND HEALTH SYSTEMS

QUARTERLY REIMBURSEMENT CHECK

NOVEMBER 2023

ROPES & GRAY ATTORNEYS share their analysis of administrative and court litigation, regulatory developments and other key developments affecting federal program payments to hospitals and health systems. Below are the takeaways from our latest review.

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FOCUS ON

D.C. Circuit Addresses SSI Fraction of DSH Calculation and Upholds District Courts on Another Chance for Agency to Defend Fraction Calculation Method and Inconsistent Interpretation of "Entitled"

This feature describes two recent decisions of the D.C. Circuit Court of Appeals concerning one of two fractions, the Supplemental Security Income ("SSI") fraction or Medicare fraction, used to calculate the Medicare disproportionate share hospital ("DSH") payment adjustment: *Pomona Valley Hospital Medical Center v. Becerra*, No. 20-5350, 2023 WL 5654315 (D.C. Cir. Sep. 1, 2023); *Advocate Christ Medical Center v. Becerra*, 80 F.4th 346 (D.C. Cir. 2023). Hospitals have long argued that the calculation of the SSI fraction contains errors and omissions and that the inconsistent interpretation of "entitled" to SSI benefits understates DSH payments. In addition, the SSI entitlement data used in the DSH calculation is not shared with hospitals, preventing them from authenticating the SSI fractions calculated by the agency.

The first case, *Pomona Valley*, builds on the seminal D.C. District Court *Baystate* case, which held that that agency's calculation of the SSI fraction was fatally flawed and must be recalculated due to several systemic errors and omissions that uniformly reduced the resulting SSI fractions. *See Baystate Med. Ctr. v. Leavitt*, 545 F. Supp. 2d 20, 57–58, *amended in part*, 587 F. Supp. 2d 37, *judgment entered*, 587 F. Supp. 2d 44 (D.D.C. 2008). *Pomona Valley* concerns the continued validity of the agency's continued black-box approach to calculating the SSI fraction that does not afford hospitals any means of verifying that the agency's calculations are accurate. The second case, *Advocate Christ*, addresses whether the agency's inconsistent interpretation of the word "entitled" as to Medicare Part A versus SSI benefits in the DSH calculation is valid. These decisions on the calculation of the SSI fraction reflect that the decades-long quest to establish the inaccuracy of the calculation continues.

Pomona Valley

In *Pomona Valley*, the plaintiff hospital sought to increase its SSI fractions and DSH payments for fiscal years 2006 through 2008 by obtaining the SSI data of its Medicare beneficiaries and proving that those fractions were under-

stated. After the Centers for Medicare and Medicaid Services ("CMS") refused to provide the underlying data from the SSI eligibility file, the hospital obtained State of California benefit data, including "aide codes" that indicate whether patients are eligible for SSI, and provided expert testimony about that data to show that the hospital's SSI fractions were understated by $3 million. The plaintiff hospital appealed CMS's determination to the Provider Reimbursement Review Board ("Board"), which concluded that the hospital "did not submit sufficient quantifiable data in the record to prove that the SSI [fractions] calculated by CMS . . . were flawed."

The D.C. District Court held that the Board's decision was not supported by substantial evidence because CMS failed to provide any data or evidence to rebut the hospital's showing that the SSI fractions were improperly calculated. The Court remanded the case back to the Board for further proceedings but declined to issue specific instructions on how to do the calculation on remand or to impose an adverse inference against the agency for not rebutting the hospital's evidence or furnishing the relevant underlying SSI data.

The D.C. Circuit agreed. It characterized the hospital's evidence, including State of California benefit data and witness testimony, as "substantial" and found that "[g]iven the strength of the hospital's showing, and the absence of any countervailing evidence, the Board's conclusion that Pomona had failed to prove an undercount was unreasonable." The D.C. Circuit held that "the [D]istrict [C]ourt correctly set aside the Board's order and remanded to the Board for further proceedings." It explained that the hospital's "showing was robust enough to require some response from the agency." The D.C. Circuit also affirmed the District Court's decision not to apply an adverse inference against the agency for failing to rebut the hospital's evidence or provide the underlying data and instead stated that "CMS may be able to dispute [the hospital's showing] successfully" in which case the burden would shift to the hospital.

Advocate Christ

In *Advocate Christ*, a group of hospitals argued that the agency's interpretation of "entitled to [SSI] benefits" in the SSI fraction is contrary to the statute as well as arbitrary and capricious 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 agency contended, however, that because SSI is a cash benefit, only a person who is actually paid SSI benefits can be considered "entitled" to these benefits. Plaintiffs also sought to compel the agency to provide them with the payment status codes from the Social Security Administration ("SSA") for all persons enrolled in the SSI program so that they could verify and challenge CMS's calculation of their DSH adjustments.

The District Court ruled in favor of the agency, and the D.C. Circuit affirmed. The D.C. Circuit agreed with the agency that "entitled to [SSI] benefits" "cover[s] only Medicare beneficiaries who are entitled to SSI cash payments at the time of their hospitalization." It also rejected Plaintiffs' reliance on *Becerra v. Empire Health Foundation*, 142 S. Ct. 2354 (2022), due to "key distinctions between the Part A and SSI schemes." Among its conclusions, the Court found that unlike SSI benefits, "Part A benefits extend well beyond payment for specific services at specific times" and "individuals rarely, if ever, lose this eligibility over time" to Part A benefits but "routinely ping-pong in and out of [SSI] 'eligibility' depending on fluctuations in their income or wealth from one month to another." The D.C. Circuit further found that Section 951 of the Medicare Prescription Drug, Improvement, and Modernization Act "cannot mean . . . that [the Department of Health and Human Services] must give hospitals data that it never received from SSA in the first place," including "the specific codes assigned to individual patients."

The hospitals have until December 29, 2023, to request review by the Supreme Court. The validity of the agency's interpretation of "entitled to [SSI] benefits" in the DSH statute is also being considered by the Eastern District Court of Washington, where briefing remains stayed pending a final non-appealable decision in *Advocate Christ*. *See* Order, *Empire Health Found. v. Becerra*, No. 2:16-cv-209 (E.D. Wash. May 18, 2023), ECF No. 107. If that Court and, in turn, the Ninth Circuit in *Empire Health* issue a decision contrary to the D.C. Circuit's decision, it is more likely that the Supreme Court will consider the agency's inconsistent interpretation of the word "entitled."

Conclusion

Looking forward, the agency's response on remand in *Pomona Valley* could shape hospitals' approach to challenging the validity of the agency's black-box calculation of their Medicare DSH payments in the future. The validity of the agency's inconsistent interpretation of the word "entitled" in the DSH calculation also remains a live issue. The Supreme Court may assess this interpretation if the hospitals in *Advocate Christ* seek certiorari, especially if the Ninth Circuit in *Empire Health* reaches a different decision than the D.C. Circuit.

What market trends have our hospital and health system lawyers been analyzing?

- On October 19, in a *Financial Times Health Payer Specialist* article, "Oregon Regulators Could Prolong SCAN, Other Regional Payer Mergers," health care partner and co-chair **TIM MCCRYSTAL** and health care counsel **JOHN SARAN** discussed the implications of Oregon's Health Care Market Oversight program that adds new administrative requirements for providers and payers seeking to engage in mergers and acquisitions and other business deals.
- On October 10, in a *Modern Healthcare* Q&A column, health care partner **CHRISTINE MOUNDAS** examined the Federal Trade Commission's ("FTC") changes and enforcement of its Health Breach Notification Rule and its impact for hospitals and health systems and digital health companies.
- On September 21, we launched a new podcast series, "*Recent Trends and Developments in Health Care Joint Ventures*." With increased regulatory scrutiny by state and federal regulators of mergers and acquisitions in the health care industry, joint ventures present a valuable alternative to traditional acquisition strategies for expansion and diversification of services, access to capital, and deployment of technological, business, and management resources. Follow the links below to listen to past episodes, and click here to sign up for future alerts.
  - *Recent Trends and Developments in Health Care Joint Ventures*, featuring health care partners **STEPHANIE WEBSTER**, **BEN WILSON** and **ADRIANNE ORTEGA**
  - *Five Key Considerations for a Successful Joint Venture*, featuring health care partners **DEVIN COHEN** and **BEN WILSON**
  - *Nonprofit/For-Profit Joint Ventures*, featuring health care partners **TIM MCCRYSTAL** and **ADRIANNE ORTEGA**
  - *Payor/Provider and Provider/Provider Joint Ventures*, featuring health care partners **DEVIN COHEN** and **BRETT FRIEDMAN**
- On July 13, antitrust partner **JANE WILLIS** and litigation associate **DAVID YOUNG** discussed the intersection between federal antitrust enforcement and state regulatory review of health care transactions on the Value-based Care Collides with Competition: Antitrust and Enforcement Considerations podcast episode.
- In a *Healthcare Risk Management article* published July 5, health care partners **BRETT FRIEDMAN** and **DEVIN COHEN** examined the legal and compliance risks of hospital-at-home programs since the COVID-19 public health emergency has ended. They noted that compliance may become more challenging, and hospitals should adequately plan to implement the necessary transitional efforts to move from a pandemic to post-pandemic environment so they remain in compliance.

DOCKET UPDATES

In addition to *Pomona Valley* and *Advocate Christ* discussed above, federal courts have also issued the following decisions in the past few months concerning (1) rules implementing the No Surprises Act; (2) the calculation of a hospital's Provider Relief Fund ("PRF") Phase 3 General Distribution payment; (3) the regulation addressing the timetable for consideration by the Provider Reimbursement Review Board of requests for expedited judicial review and the right to bring a court action on a reimbursement dispute; and (4) the ability to appeal to the Board based on CMS's publication of DSH SSI fractions.

1. NO SURPRISES ACT LITIGATION

Two federal courts recently issued three decisions addressing the validity of the agency's rules implementing the No Surprises Act. By way of background, the No Surprises Act established an independent dispute resolution ("IDR") process for resolving payment disputes between certain out-of-network providers on the one hand, and group health plans and health insurers on the other hand. The Act also directed the Departments of the Treasury, Labor, and HHS ("Departments") to issue regulations governing the IDR process, which are the subject of the three cases below and prior litigation. In February 2022, the Texas Eastern District Court found that the challenged portions of the IDR provisions addressing the balancing of factors for calculating the payment amount in the Departments' October 7, 2021, interim final rule must be set aside under the Administrative Procedure Act ("APA") because they conflicted with the plain text of the No Surprises Act. *See Texas Med. Ass'n v. HHS*, 587 F. Supp. 3d 528 (E.D. Tex. 2022), *appeal dismissed*, No. 22-40264, 2022 WL 15174345 (5th Cir. Oct. 24, 2022). According to the Court, instead of considering all factors prescribed by the No Surprises Act, the rule improperly imposed a rebuttable presumption in favor of the offer closest to the qualifying payment amount ("QPA"). The Court also found the rule invalid because the agency failed to provide notice and comment as required by the APA. Then, in July 2022, the Texas Court concluded that the parallel IDR process for air ambulance services, also established in the October 2021 final rule, violated the APA and the Court thus vacated those portions of the rule. *See LifeNet, Inc. v. HHS*, 617 F. Supp. 3d 547 (E.D. Tex. July 26, 2022). In response to those two rulings, the Departments issued new final rules under the No Surprises Act on August 19, 2022. The three cases below reflect further challenges to the agency's implementation of the No Surprises Act.

a. *Texas Medical Association v. HHS*, No. 6:23-cv-59-JDK, 2023 WL 4977746 (E.D. Tex. Aug. 3, 2023)

On August 3, 2023, health care providers successfully challenged two features of the arbitration process established under the No Surprises Act that they argued increased the cost of the IDR process and limited their ability to address related claims in a single IDR proceeding. First, the Texas Eastern District Court agreed with the hospitals that the agency's increase in the administrative fee for participating in the arbitration process from $50 for calendar year ("CY") 2022 to $350 for CY 2023 violated the APA's notice-and-comment rulemaking requirements, primarily because the fee increase was announced in agency guidance and not in the October 2021 final rule. Second, the Court found that the agency's October 2021 batching rule, which made it difficult to "batch" or consider jointly in a single IDR proceeding related claims for resolution by requiring that the claims have the same service code, violated the APA because it similarly was implemented without notice and comment. The Court ultimately vacated both rules but did not order the agency to refund the hospitals' previously paid fees, which the agency initially set at $50 for calendar year 2022 before raising it to $350 for CY 2023. The government did not appeal. As a result of this decision, HHS continues to suspend the federal IDR process for all batched disputes.

b. *Association of Air Medical Services v. HHS*, No. 21-cv-3031 (RJL), 2023 WL 5094881 (D.D.C. Aug. 9, 2023)

On August 9, 2023, an association of air ambulance providers unsuccessfully challenged the methodology established in a July 13, 2021, interim final rule for calculating the QPA as improperly decreasing their payments. The D.C. District Court disagreed, holding that this portion of the rule complied with the APA and reflected a reasonable exercise of statutory authority.

More specifically, the association argued, among other things, that the rule was invalid because the prescribed method of calculating the QPA intentionally lowered payments to air ambulance providers by 1) excluding most types of contracted rates between air ambulance providers and plans or issuers; 2) treating hospitals and independent air ambulance services as providers in the "same or similar specialty"; and 3) using overbroad geographic regions to calculate QPAs. The Court rejected these claims. It found that the exclusion of single case agreements was reasonable and consistent with the plain text and intent of the No Surprises Act, which sought "to address the market failure stemming from air ambulance providers' ability to remain out-of-network and charge high out-of-network rate." The Court also found the Departments reasonably justified in treating independent air ambulance providers and hospitals providing air ambulance services as being under the same "single provider specialty" for the purposes of QPA calculations. And the Court concluded that Congress deferred to the Departments to define the geographic regions, and the Departments' use of broad "census divisions" was reasonable because a narrower approach would be more likely to produce insufficient information to calculate the QPA.

c. *Texas Medical Association v. HHS*, No. 6:22-CV-450-JDK, 2023 WL 5489028 (E.D. Tex. Aug. 24, 2023)

While the D.C. District Court upheld the Departments' July 2021 interim final rule pertaining to the QPA methodology, the Eastern District Court of Texas, for the most part, did not in a decision issued two weeks later, that found that certain portions of the rule and the Departments' August 2022 guidance violate the APA. With respect to single case agreements specifically, the Court found the D.C. District Court's analysis "unpersuasive" for "fail[ing] to address that many case-specific or single-case agreements are negotiated under a plan or policy providing coverage for air ambulance transports." The Court ultimately held that "all but one regulation pertaining to the calculation of the QPA violate the plain text of the [No Surprises Act]," and that "the regulations extending the deadline for making an initial payment determination and requiring two proceedings for one air transport conflict with the Act and are unlawful" as well. Among other conclusions, this Court found that the agency's interpretation of "contracted rates" conflicts with the No Surprises Act by improperly including in the calculation of the QPA so-called "ghost rates," "rates for items or services that providers have no intention to provide." The Court also found that the regulation is unlawful because it "improperly allows insurers to include in the QPA calculation rates of providers in different specialties," even though the No Surprises Act "requires insurers to always calculate the QPAs based on the rates of providers 'in the same or similar specialty.'" The government has appealed this decision.

2. *HOSPITAL FOR SPECIAL SURGERY V. BECERRA*, NO. 22-CV-2928 (JDB), 2023 WL 5448017 (D.D.C. AUG. 24, 2023)

This case concerns a hospital's challenge to the calculation of its PRF Phase 3 General Distribution payment by the Health Resources and Services Administration ("HRSA"). On August 24, 2023, the D.C. District Court granted the agency's motion for summary judgment, holding that the issues challenged by the Hospital for Special Surgery were committed to agency discretion and, even if reviewable, were not arbitrary or capricious. The Hospital argued that it should have received an additional $51.2 million from the PRF Phase 3 General Distribution. The Phase 3 General Distribution payment calculation methodology requires HRSA to calculate a "loss ratio" for each applicant using the 2019 and 2020 first and second quarter revenues and

expenses entered on the application, and then, as part of the pre-payment risk mitigation and cost containment safeguards employed by HRSA, capping the loss ratio to that applicant's provider type's mean loss ratio if it is an outlier or above the mean loss ratio plus one standard deviation for the applicant's "provider type."

The Court held that the agency's decisions were unreviewable and committed to agency discretion because Congress had appropriated the funds for a particular purpose with "little to cabin [the agency's] discretion to develop and implement a mechanism for distributing those funds." The Court added that even if the challenged decisions were reviewable, they would not be arbitrary and capricious because the record evidence supported the agency's decision to implement the 27 provider-type categories for Phase 3 as reasoned and based on legitimate rationales. The Court also found that the outlier cap fell under the agency's discretion and thus did not violate Congress's directive because nothing in the statutory language mandates providers be reimbursed for all their lost revenue attributable to COVID-19.

3. *SAINT FRANCIS MEDICAL CENTER V. BECERRA*, NO. 1:22-CV-1960-RCL, 2023 WL 6294168 (D.D.C. SEPT. 27, 2023)

The Medicare statute guarantees hospitals the right to bring a civil action for judicial review of the substantive legal question at issue in an appeal of a Medicare contractor's final payment determination "whenever the [Provider Reimbursement Review] Board determines . . . that it is without authority to decide" the particular question of law or "fails to render such determination within" 30 days after receipt of a request for expedited judicial review ("EJR"). 42 U.S.C. § 1395oo(f)(l). Binding precedent of the D.C. Circuit Court of Appeals confirms this 30-day deadline under the Medicare statute for the Board to determine its authority to decide a legal question for which the provider has requested EJR. *See Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 354 (D.C. Cir. 2017); Allina Health Servs. v. Price, 863 F.3d 937, 941 (D.C. Cir. 2017), *aff'd sub nom. Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019) ("*Allina II*"). In *St. Francis*, however, the Court concluded that the 30-day deadline does not begin to run until the Board finds that it has jurisdiction and that the hospitals thus prematurely filed their action after 30 days without a Board decision because the Board had not yet made that jurisdictional finding. The Court also found that the EJR regulation (42 C.F.R. § 405.1842) establishing this timetable was consistent with the statute and neither arbitrary nor capricious, but notably did not address either *Clarian Health* or *Allina II*. The issue of whether hospitals have the right to initiate a court action when the Board fails to determine its authority to decide a legal question within 30 days is likely to be the subject of additional litigation, including in this case if the hospitals decide to appeal, because EJR is a key avenue for hospitals to seek recourse in court on legal questions that the Board cannot address.

4. *BATTLE CREEK HEALTH SYSTEM V. BECERRA*, NO. 17-CV-0545 (CKK), 2023 WL 7156125 (D.D.C. OCT. 31, 2023)

The D.C. District Court held that Provider Reimbursement Review Board had jurisdiction over the plaintiff hospitals' appeals of CMS's 2009 publication of SSI fractions for fiscal year 2007 because it constituted a "final determination" within the meaning of 42 U.S.C. § 1395oo of the Medicare statute. The Court found that the Board's "primary legal position – only a cost report is a 'final determination' – is foreclosed by appellate precedent." 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 that provides a 'hospital [with] advance knowledge of the amount of payment it will receive' is a 'final determination.'" The Court also 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.'" As applied here, the Court found that "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 concluded that the Board, as a result, "has jurisdiction to consider the decision on DSH calculations in the Transmittal [issuing the SSI fractions], because the Transmittal governed, at that point, 'some aspect of the calculation'" of the DSH payment. 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." The Court, in turn, vacated the Board's jurisdictional decision and remanded the case to the Board to address the merits of the dispute.

5. *POMONA VALLEY HOSPITAL MEDICAL CENTER V. BECERRA*, NO. 20-5350, 2023 WL 5654315, (D.C. CIR. SEPT. 1, 2023)

See Focus On section for further details.

6. *ADVOCATE CHRIST MEDICAL CENTER V. BECERRA*, 80 F.4TH 346 (D.C. CIR. 2023)

See Focus On section for further details.

REGULATORY UPDATES

1. CMS ISSUES FINAL OPPS/ASC RULE

On November 2, 2023, CMS released the final rule for the calendar year 2024 outpatient prospective payment system ("OPPS") and ambulatory surgical center ("ASC") payment system, which is scheduled to be published in the *Federal Register* on November 22, 2023. In August 2023, just after the publication of the OPPS proposed rule, we circulated a client alert summarizing key aspects of CMS's proposals. CMS decided to finalize most of its proposals in this final rule addressing the following topics: A. OPPS Payments; B. Payment for 340B Drugs; C. New Public Reporting Requirements for Hospitals' List of Charges and other Data; D. Policies for Rural Emergency Hospitals; and E. Changes to the Medicare Code Editor. Learn more.

2. CMS ALSO ISSUES FINAL HOME HEALTH PPS RULE

On November 2, 2023, CMS also issued its CY 2024 final rule for the home health prospective payment system, effective January 1, 2024. The rule finalizes the proposed policy to increase home health payments by $140 million, or 0.8percent more in CY 2024 than the prior year. This increase is, in part, the result of a finalized home health productivity-adjusted market basket percentage update of 3.0 percent, increasing payments by $525 million. CMS also increased payments by $70 million by finalizing its adjustment to the fixed-dollar loss ratio for outlier payments. CMS further finalized its behavioral assumption adjustment decreasing payments by $455 million, or 2.6 percent, which is half of what the agency had proposed. Relatedly, the agency's decrease in payments in the CY 2023 home health final rule is the subject of an action filed in July 2023 before this final rule was issued. *See Nat'l Assn for Home Care & Hospice v. Becerra*, No. 23-cv-1942 (D.D.C.). In that case, the complaint alleges that the prior CY 2023 final rule "violates the statute's plain text, reflects an impermissible and unreasonable interpretation, and is arbitrary and capricious" because it improperly cuts payments for home health services. The complaint even cites the then-proposed CY 2024 rule as evidence that the agency "shows no sign of reversing course." Moreover, CMS finalized all proposed changes to the Home Health Quality Reporting Program requirements and the expanded Home Health Value-Based Purchasing Model. This rule takes effect on January 1, 2024.

3. ADMINISTRATION ISSUES PROPOSED RULE WITH CHANGES TO THE NO SURPRISES ACT'S IDR PROCESS

On October 27, 2023, HHS, along with the Labor and Treasury Departments and the Office of Personnel Management, published a proposed rule on changes to the

federal independent dispute resolution ("IDR") process established under the No Surprises Act. To assist parties in determining whether payment disputes are eligible for the federal IDR process, the proposed rule would require payers to provide more information, including standardized codes indicating if claims for items or services furnished by out-of-network providers are subject to the surprise billing provisions. The proposed rule would also centralize the open negotiation process in the federal government's IDR portal to incentivize meaningful negotiations before engaging in the IDR process. The proposed rule would further streamline eligibility determinations and the administrative fee payment process for parties that opt to pursue the IDR process. Finally, the proposed rule would allow parties to bundle certain items or services as separate payment determinations in a single dispute, referred to as a "batched dispute," to improve efficiency and minimize costs. Comments on this proposed rule are due by January 2, 2024.

4. CMS PROPOSES NEW NURSE STAFFING REQUIREMENTS FOR LONG-TERM CARE FACILITIES

On September 6, 2023, CMS issued a proposed rule that would impose federal requirements for nurse staffing in Medicare- and Medicaid-certified long-term care ("LTC") facilities. The proposed rule responds to chronic understaffing concerns in the post-acute setting, which was exacerbated by the COVID-19 public health emergency, and attempts to "improve[] the likelihood that [the 1.4 million LTC facility] residents in the U.S. are provided safe, high-quality care, and that workers have the support they need to provide high-quality care." While the impact of the proposed rule would be state-dependent (as some states have no laws on point while others have similar laws to the proposed rule), it imposes substantial costs on LTC facilities, managers, owners, and other stakeholders. If finalized without changes to the timeline, the staffing proposals would be implemented in three phases over three years, with more flexibility afforded to LTC facilities located in rural areas to comply within a five-year timeline. Learn more.

5. NEW YORK STATE OFFICE OF THE MEDICAID INSPECTOR GENERAL EXPANDS PROVIDER SELF-DISCLOSURE REQUIREMENTS FOR ROUTINE OVERPAYMENTS

On August 21, 2023, the New York State Office of the Medicaid Inspector General ("OIG") released updated guidance for self-disclosures by Medicaid providers. Critically, the Updated Self-Disclosure Guidance introduces a new process for Medicaid providers to report, return and explain self-identified overpayments resulting from "routine and transactional errors" that have already been voided or adjusted through an "abbreviated" process. This abbreviated process is in addition to the pre-existing "full process" available for overpayments due to systematic errors, which remains unchanged. In the past, many routine overpayments have been returned through administrative voids, rather than through formal self-disclosures. The new abbreviated process in the Updated Self-Disclosure Guidance introduces additional procedural requirements and considerations for providers. Learn more.

6. CMS RELEASES 2024 FINAL RULE FOR INPATIENT AND LONG-TERM CARE HOSPITALS' PAYMENT SYSTEMS

On August 1, 2023, CMS released the final rule for the federal fiscal year 2024 inpatient prospective payment system ("IPPS") and LTC hospital payment system, which was published in the Federal Register on August 28, 2023. The final rule addressed the following topics: A. market basket and other base rate updates; B. "health equity" policies; C. wage index, geographic reclassification, and other changes impacting rural hospitals; D. medical education programs; E. disproportionate share hospital payments; F. "quality of care" – ownership disclosures for additional providers as well as hospital performance and data reporting; G. low-volume hospitals' payment adjustment; and H. the Medicare interoperability program. CMS notably decided to finalize a majority of its proposals in this final rule, including its limitation on counting section 1115 waiver days in the Medicare DSH calculation. Learn more.

ENFORCEMENT UPDATES

1. DOJ HEALTH CARE STRIKE FORCE CONTINUES WITH ENFORCEMENT ACTIONS

In the past three-and-a-half years, the Health Care Fraud Strike Force—a longstanding, nationwide initiative in which the Department of Justice ("DOJ") and HHS collaborate to prevent and deter health care fraud and enforce criminal anti-fraud statutes—has investigated health care fraud related to the COVID-19 pandemic and continues to initiate new enforcement actions. For example, on August 18, 2023, a federal jury convicted the former owner and operator of a Mississippi hospice company of making false statements on an attestation in connection with receiving and attesting to the receipt of PRF funds because he no longer owned the company, the company was not eligible for PRF funding, and he transferred the funds to his personal account. As another example, on August 24, 2023, the operator of a California home health agency pleaded guilty to wire fraud after, among other actions, receiving $139,736 in PRF payments that were used for personal purposes and therefore not to prevent, prepare for and respond to COVID-19, or for expenses or lost revenues attributable to COVID-19, as required by the PRF.

2. FINAL RULE ON INFORMATION BLOCKING VIOLATIONS AND PROPOSED RULE ESTABLISHING "DISINCENTIVES" FOR HEALTH CARE PROVIDERS

On July 3, 2023, the long-awaited final rule from HHS-OIG was published in the *Federal Register*, establishing civil monetary penalties ("CMPs") of up to $1 million per "information blocking" violation pursuant to Section 4004 of the 21st Century Cures Act ("Cures Act"). The term "information blocking" is defined as a practice that, except as required by law or specified in an information blocking exception, is likely to interfere with the access, exchange, or use of electronic health information. See 45 C.F.R. § 171.103. Penalties may be imposed on developers of certified health information technology (including entities that offer such technology), health information exchanges, and health information networks beginning on September 1, 2023. The Final Rule concludes the rulemaking process that HHS-OIG began with a proposed rule published in the *Federal Register* on April 24, 2020. Learn more.

On November 1, 2023, HHS, the Office of the National Coordinator for Health Information Technology, and CMS published a proposed rule in the Federal Register titled "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" that, if finalized, would establish long-awaited disincentives under the Cures Act for health care providers' participation in the Medicare Electronic Health Record Incentive Programs and the Medicare Shared Savings Program. The Proposed Rule represents a continuation of efforts by HHS agencies to promote health information exchange and interoperability among health information technology systems. Learn more.

3. HHS AND FTC WARNING LETTERS HIGHLIGHT CONTINUED SCRUTINY OF USE OF ONLINE TRACKING TECHNOLOGIES IN HEALTHCARE

Hospitals need to be wary about the privacy and security risks of online tracking technologies on their websites and mobile applications. On July 20, 2023, HHS's Office for Civil Rights and the FTC sent warning letters to approximately 130 hospital systems and telehealth providers. The letters were intended to warn those entities of the privacy and security risks of online tracking technologies integrated into their websites and mobile applications. The agencies noted that the entities may be impermissibly disclosing consumers' sensitive personal health information to third parties such as Meta/Facebook pixel and Google Analytics through the use of such online tracking technologies, in potential violation of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended, the FTC Act and the FTC Health Breach Notification Rule. Learn more.

VALUE-BASED CARE CORNER

1. CMS ISSUES FINAL PHYSICIAN FEE SCHEDULE RULE

On November 2, 2023, CMS released the final rule for the calendar year 2024 Physician Fee Schedule ("PFS"), which is scheduled to be published in the *Federal Register* on November 16, 2023. In August 2023, just after the publication of the PFS proposed rule, we circulated a client alert summarizing key aspects of CMS's value-based proposals. CMS decided to finalize most of its value-based changes in this final rule concerning the Medicare Shared Savings Program and the Quality Payment Program. Learn more.

2. CMS ANNOUNCES UPDATES TO ACO REACH FOR 2024 AND BEYOND

On August 14, 2023, the CMS Center for Medicare and Medicaid Innovation ("CMMI") announced a number of changes to the Accountable Care Organization ("ACO") Realizing Equity, Access and Community Health ("REACH") Model for the 2024 Performance Year ("PY"). Key changes are as follows:

Increased flexibility for Beneficiary Alignment: CMMI announced three changes to the beneficiary alignment rules that, together, should make it easier for ACO's to satisfy beneficiary alignment minimums. First, CMMI is reducing alignment minimums for New Entrant and High Needs ACOs for PY 2025, and for High Needs ACOs in PY 2026. Second, to protect REACH ACOs against fluctuation in beneficiary alignment, CMMI is implementing a "buffer" that will allow each REACH ACO to temporarily drop as much as 10% below the required minimum beneficiary threshold at a single juncture during the remaining three PYs. Finally, CMMI has expanded the eligibility criteria for aligning beneficiaries to a High Needs ACO to include Medicare beneficiaries with at least 90 Medicare-covered days of home health services utilization or at least 45 Medicare-covered days in a Skilled Nursing Facility ("SNF") within the previous 12 months.

Adjustments to Financial Guarantee Requirements: CMMI's changes to ACO REACH Financial Guarantee requirements offer mixed results for participating ACOs. First, CMMI announced that ACOs participating in Provision Financial Settlement may release their required financial guarantee amount for a given program year after they have paid any Shared Losses reflected in the Provisional Financial Settlement Report. This will reduce carrying costs for ACOs that currently must maintain a financial guarantee until the Final Settlement for each PY, which has resulted in ACOs having to "stack" financial guarantees for successive PYs for as long as six months. On the other hand, however, effective in PY 2024, CMMI is increasing the financial guarantee amount for all ACOs participating in Enhanced Primary Care Capitation and the Advanced Payment Option to 4%, which effectively increases ACOs' operating costs.

Twelve-Month Window for Provisional Financial Settlement: Effective in PY 2024, Provisional Financial Settlement will reflect a full 12 months of PY experience (increased from six months), which will result in a more accurate Provisional Settlement.

Changes to Benchmarking: CMMI announced several important changes to the ACO REACH Model benchmarking methodology. First, CMMI has added two new components—Low-Income Subsidy Status (in combination with dual-eligibility) and State-based Area Deprivation Index—to the Health Equity Benchmark Adjustment ("HEBA"), which are intended to better capture underserved beneficiaries. Relatedly, CMMI will now apply the HEBA to upwards adjust monthly capitation rates for ACOs that fall in the top three deciles (rather than limiting the adjustment to the top decile) and will limit downwards adjustment to capitation rates to ACOs in the bottom three deciles (currently, the bottom five deciles all face downwards adjustment). CMMI also will introduce Retrospective Trend Adjustment ("RTA") risk corridors in an effort to provide greater predictability to ACOs. Unlike the current policy, where CMMI can adjust the RTA if the actual trend varies from the RTA by at

least 1%, CMMI has adopted a three-band risk corridor, whereby ACOs bear full responsibility for any variance of up to 4%. CMS and ACOs bear equal responsibility for variance of four percent to 8%, and CMS assumes full responsibility for variance greater than 8%. These corridors offer little comfort to many ACOs, however, as an upwards adjustment of 4 percent from the RTA might have significant financial repercussions for an ACO. Next, CMMI announced a new 2024 Part C risk adjustment model as an update to the 2020 model; for PY 2024, CMMI will blend the two models and expects a 0.4% reduction to ACO benchmarks. CMMI also announced that, beginning in PY 2024, it will apply a 1 percent cap on the Coding Intensity Factor ("CIF") that is applied to ACO risk score growth, which will serve to limit ACOs' exposure to risk score adjustment due to the CIF. Finally, CMMI will cap risk score and Coding Intensity Factor adjustments for High Needs ACOs to 3% (positive or negative), which may limit ACOs' ability to accurately reflect the risk acuity of their aligned beneficiaries.

Expanded Beneficiary Enhancement: Beginning in PY 2024, Nurse Practitioners and Physician Assistants that are Participant Providers or Preferred Providers with a REACH ACO participating in the NP/PA Benefit Enhancement will be able to certify and order Pulmonary Rehabilitation Care Plans.

3. CMS ANNOUNCES AHEAD MODEL FOR STATES

On September 5, 2023, CMS announced a new voluntary state total cost of care model, called the Advancing All-Payer Health Equity Approaches and Development ("AHEAD") Model. The AHEAD Model aims to increase the resources available to participating states to invest in primary care and to improve statewide population health while leveraging state authority to manage health care quality across all payers to lower overall costs. Participating states will be accountable for state-specific Medicare and all-payer cost growth and primary care investment targets.

The AHEAD Model features three primary components: First, participating states will receive CMS funding to support state efforts in planning and implementing the Model during its initial performance years. Second, states will be expected to recruit hospitals to participate in "Global Hospital Budgets," whereby hospitals agree to fixed annual budgets for specific patient populations or programs (e.g., Medicare fee-for-service beneficiaries); and those global budgets will give participating hospitals greater fiscal certainty while incentivizing them to eliminate avoidable hospitalizations and improve care coordination between other hospitals, primary care providers, and specialists. The long-term goal of the Model is savings generated by hospital global budgets to offset or facilitate expanded state investment in primary care. Finally, primary care practices located in a participating state will be able to participate in "Primary Care AHEAD" by contracting with both the participating state and CMS. Participating practices will be required to engage in state-led Medicaid transformation efforts and the aligned Primary Care AHEAD program and will also receive a Medicare care management fee to meet care transformation requirements. Participating practices will also be responsible for reaching performance goals on Model quality measures. Participation for primary care practices will be at the tax identification number ("TIN") level, and, while CMS has not released a comprehensive model overlap policy, the agency stated in a recent webinar that practices participating in the Medicare Shared Savings Program will also be able to participate in AHEAD. CMS will not allow overlap with Making Care Primary (those states are excluded from AHEAD) or Primary Care First.

CMS is also considering offering participants payment rule waivers similar to those available in the ACO REACH model, including the Part B cost sharing waiver, home health homebound requirement waiver and SNF three-day stay waiver.

The AHEAD Model is slated to run for 11 years from 2023-2034, and CMS anticipates accepting eight states across two application windows in 2023 and 2024. States that apply

will have the option to choose from three different participation cohorts, depending on the state's readiness to implement the Model. The three cohorts will have staggered start dates across 2023 and 2024 and will offer different length "pre-implementation periods." CMS will provide up to $12 million in cooperative funding to each participating state to support Model planning and implementation. Additional details are expected in the Model's Notice of Funding Opportunity, which CMS expects to release later this fall.

COVID-19 PROVIDER RELIEF FUNDING UPDATES

1. FUTURE REPORTING WITH RESPECT TO PRF PAYMENTS

Providers that received more than $10,000 in PRF funds between January 2022 and June 2023 must submit PRF reports. As set forth in sub-regulatory guidance by the Health Resources and Services Administration ("HRSA"), the fifth Reporting Period concluded on September 20, 2023, with four Reporting Period deadlines, covering successive Reporting Time Periods, on the horizon. Consequently, providers in receipt of greater than $10,000 in PRF funds from January 2022 through June 2023 need to keep in mind that, though the COVID-19 public health emergency has now ended, their obligations to continue making PRF reports have not ended, as outlined in the following schedule:

a. Reporting Period 6 (for funds received from July 1, 2022, to December 31, 2022) will be from January 1, 2024, to March 31, 2024;

b. Reporting Period 7 (for funds received January 1, 2023, to June 30, 2023) will be from July 1, 2024, to September 30, 2024;

c. Reporting Period 8 (for funds received July 1, 2023, to December 31, 2023) will be from January 1, 2025, to March 31, 2025; and

d. Reporting Period 9 (for funds received January 1, 2024, to June 30, 2024) will be from July 1, 2025, to September 30, 2025.

Of paramount importance, with the expiration of the public health emergency on May 11, 2023, the ability to apply PRF distributions to lost revenues also expired as of June 30, 2023. Health Res. & Serv. Admin., *Provider Relief Programs: Provider Relief Fund And ARP Payments Frequently Asked Questions*, 8–9 (May 5, 2023). Consequently, in future quarters, providers may retain PRF funds only to the extent that they can report using such funds to reimburse eligible expenses attributable to COVID-19.

2. HHS-OIG AND HHS HRSA CONTINUE TO CONDUCT AUDITS OF PRF RECIPIENTS

The Terms and Conditions governing PRF, as issued and administered by HRSA, generally authorize HHS to audit PRF payment recipients to ensure compliance with PRF requirements. With the Public Health Emergency now officially over and despite Congress's rescission of unobligated PRF funds, the HHS-OIG and HRSA continue to conduct audits of providers that received PRF payments.

To date, these HHS-OIG audits have largely focused on determining whether providers expended funds in accordance with the Terms and Conditions and reported use of those funds correctly. In a separate agency process independent of the HHS-OIG, HRSA has initiated its own "post-payment reviews" of PRF recipients, with a similar scope to HHS-OIG's audits, as well as an apparent focus that extends more broadly to encompass the accuracy of provider application materials and HRSA's data inputs and calculations in awarding such funds. U.S. Gov't Accountability Off., GAO-23-106083, COVID-19 Provider Relief Fund HRSA Continues to Recover Remaining Payments Due From Providers 19 (2023). According to agency officials, in late 2023, HRSA plans to initiate audits of providers that received PRF payments between July 2020 and December 2020. *Id.* HRSA is focusing on those providers that received large payments and are therefore deemed high-risk.

As of May 2023, HRSA has recovered nearly half of the $2.618 billion in overpayments, unused payments, and payments to non-compliant providers that HRSA has iden-

tified for recovery. By April 2024, HRSA intends to recover the remaining payments identified by sending final repayment notices to the providers.

3. *QUI TAM* COMPLAINT UNSEALED RELATED TO PRF COVID-19 HIGH-IMPACT AREA DISTRIBUTIONS

On June 12, 2023, the U.S. District Court for the District of New Jersey unsealed a qui tam complaint (the "Complaint") against several New Jersey hospitals, management services organizations, and the hospitals' chief executive officer and chief financial officer, alleging that the hospitals refused to return PRF money for which they knew they were not eligible and used PRF funds for impermissible purposes. *See United States v. Hudson Hospital OPCO, LLC*, No. 21-cv-19788 (D.N.J. Nov. 5, 2021) [Dkt. No.14]. This is one of the first unsealed qui tam complaints alleging ineligibility for, and misuse of, funds received under PRF. This case is specifically related to the COVID-19 High-Impact Area Distribution, a targeted distribution. HHS allocated $20 billion of the $178 billion available to the COVID-19 High-Impact Area Distribution for hospitals that had incurred disproportionate numbers of COVID-19 inpatient admissions, which were reported to HHS for certain payments per admission.

In the Complaint, the relator—the former system chief medical officer ("CMO") and chief hospital executive for one of the defendant hospitals—alleged that the defendant hospitals received over $50 million in COVID-19 High-Impact Area Distribution payments that were improperly obtained by reporting COVID-19 patient admissions information that included patients who had not tested positive for COVID-19 or otherwise failed to meet HHS's inclusion criteria.

Additionally, the relator alleged that the relator and other defendant hospital CMOs put together a CMO task force to review the alleged overpayment from the COVID-19 High-Impact Area Distribution and confirmed by audit that there had been an overpayment. The relator stated that the defendant hospitals should have self-reported and returned the overpayments, but that the defendant hospitals as well as their chief executive officer and chief financial officer allegedly refused. The relator also alleged that the funds were subsequently used for impermissible expenses, including for renovating the hospital lobby, a medical office building and the radiology center, creating a weight loss center and upgrading the catheter lab and stroke lab. The government declined to intervene in this case.

4. HHS-OIG AUDITS PARTICIPANTS IN THE COVID-19 UNINSURED PROGRAM

In July 2023, HHS-OIG issued a report of an audit it conducted to determine whether claims for COVID-19 testing and treatment services reimbursed through the COVID-19 Uninsured Program complied with federal requirements. The audit covered claims for 19 million patients associated with COVID-19 Uninsured Program payments, totaling $4.2 billion with service dates from March 1, 2020, through December 31, 2020.

As part of its review, HHS-OIG conducted interviews, analyzed health insurance coverage data and reviewed medical and billing records as well as a random sample of 300 patients with associated provider payments totaling $2.8 million. Ultimately, HHS-OIG recommended that HRSA recoup $294,294 in improper COVID-19 Uninsured Program payments found in this sample, as well as identify additional payments provided to insured individuals or services that were unrelated to COVID-19. HHS-OIG estimates that these payments total approximately $784 million. HRSA has agreed with this recommendation and noted that reviews are currently underway. Providers should be aware of potential recoupment of payments received under the COVID-19 Uninsured Program.

340B UPDATES

In light of the Supreme Court's June 15, 2022 decision in *American Hospital Association v. Becerra*, striking down a CMS rule providing payment for prescription drugs that hospitals purchased through the 340B program at average sales price (ASP) minus 22.5%, on November 2, 2023, CMS issued a final rule that would remedy its violation for calendar years

2018 through 2022. In the rule, CMS finalized its proposal to make a one-time lump-sum payment to affected 340B hospitals calculated as the difference between what they were paid for 340B drugs during the relevant time period, and what they would have been paid had the 340B payment policy not applied, without interest. The final rule provides the amounts that each hospital would be paid, with payments totaling $9 billion for 2018 through 2022. CMS states that it is accounting for Medicare beneficiary cost-sharing in the lump-sum payments, and as a result, providers may not bill Medicare beneficiaries for that cost-sharing. CMS plans to issue payment instructions to the Medicare contractors providing a 60-day window for the contractors to make the lump-sum payments to hospitals. CMS estimated that hospitals were paid $7.8 billion more for non-drug items and services during 2018 through 2022 as a result of the invalidated policy. To preserve budget neutrality, CMS will reduce the outpatient prospective payment system conversion factor by 0.5%, beginning in CY 2026 until that $7.8 billion is offset, which CMS estimates will take 16 years.

In addition, in the final outpatient prospective payment system final rule issued also issued on November 2, CMS finalized its proposal to continue the policy from CY 2023 to pay 340B hospitals the statutory default payment rate for separately payable drugs and biologicals, generally ASP plus 6 percent. CMS also finalized its proposal to no longer to require both 340B modifiers of JG and TB and instead, effective January 1, 2025, to permit 340B hospitals to report only the TB modifier.

LOOKING AHEAD

- On December 29, 2022, CMS issued Transmittal 18 to make changes to the Medicare cost report form and instructions (CMS Form 2552-10). Those changes became effective for cost reporting periods beginning on or after October 1, 2022. Hospitals' first cost reporting periods subject to the new instructions have now ended or will be ending soon, and hospitals must ensure compliance with the new instructions or risk a disallowance. For instance, hospitals must adhere to Transmittal 18's revised cost report instructions by reporting Section 1115 waiver days on their cost reports and completing the burdensome identification of Medicare bad debt and Medicaid eligible days on their cost reports.

- On November 16, we will post the final episode in our new podcast series, "*Recent Trends and Developments in Health Care Joint Ventures.*" The new episode, entitled "Different Joint Venture Models" features health care partners **Stephanie Webster, Brett Friedman** and **Ben Wilson** delving into two alternative partnership models for health care joint ventures: clinically integrated networks and professional services agreement models. They look at how these two alternatives compare, and how they both differ from a traditional joint venture partnership as well as share their perspective on why health care entities may choose to enter into any one of these arrangements. The episode will be available wherever you regularly listen to your podcasts, including on Apple, Google, and Spotify.

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