Hospital and Health Systems

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

Supreme Court Overrules *Chevron* and Directs Federal Courts to "Exercise Independent Judgment" In Construing Statutory Meaning

Given the significant financial implications within the health care industry, the issuance of regulations and other related administrative decisions governing federal health care reimbursement often lead to legal challenges against the U.S. Department of Health and Human Services ("HHS") and its agency, the Centers for Medicare & Medicaid Services ("CMS"). For decades, HHS appeared to have an upper hand in these cases, as courts employed the so-called "two-step framework" established in the landmark Supreme Court case *Chevron v. Natural Resources Defense Council, 467 U.S. 837* (1984) ("*Chevron*"), which required federal courts to defer to "reasonable" agency interpretations of ambiguous statutory provisions when challenged under the Administrative Procedure Act ("APA"). This June, however, the Supreme Court explicitly overruled *Chevron*. In *Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244* (2024) ("*Loper Bright*"), an opinion that has attracted significant attention in the health care industry, the Court held that courts are responsible for interpreting statutes without giving deference to agency interpretations of ambiguous provisions. While courts have only just begun to explore how *Loper Bright* may impact administrative litigation, the landmark decision has the potential to reshape reimbursement litigation by providing a more level playing field to parties who challenge federal agency actions, which may also influence the process by which HHS develops and writes regulations.

As discussed in our previous client alert, the *Loper Bright* decision held that courts "must exercise their independent judgment" when determining the meaning of statutes rather than presumptively deferring to reasonable agency interpretations, as was required under *Chevron*. The Supreme Court stated that "statutes, no matter how impenetrable, do—in fact, must—have a single, best meaning[,]" and courts are required to "use every tool at their disposal to determine the best reading of the statute" and resolve any ambiguity. The Supreme Court ruled that this is true even when a statutory ambiguity implicates technical matters within an agency's subject matter expertise. Under *Loper Bright*, technical complexity does not absolve a court of its responsibility to interpret statutes. The Court explained that "Congress expects courts to do their ordinary job of interpreting statutes, with due respect for the views of the Executive Branch[,]" and although an agency's expertise may *inform* the court's judgment, an agency's interpretation cannot bind a court.

Loper Bright has the potential to alter dramatically how HHS and CMS operate—including in matters of reimbursement—by making it more difficult for the government to prevail in APA actions challenging agency interpretations.

Case Study on *Loper Bright*'s Potential Impact on Health Care Reimbursement Litigation: *Lake Region Healthcare Corp. v. Becerra*, 113 F.4th 1002 (D.C. Cir. 2024)

Loper Bright has already begun to reshape legal challenges to health care reimbursement regulations. This feature spotlights *Lake Region Healthcare Corp. v. Becerra*, 113 F.4th 1002 (D.C. Cir. 2024) ("*Lake Region Healthcare*"), which illustrates one example of how the Supreme Court's overruling of *Chevron* can materially change—or even completely reverse—the outcome of Medicare reimbursement litigation.

In *Lake Region Healthcare*, a Minnesota hospital ("Lake Region") challenged CMS's interpretation of a Medicare statute that entitles qualifying hospitals to receive so-called "volume-decrease adjustment" ("VDA") payments, alleging that the government's calculation methodology failed to "fully compensate" the hospital for "fixed costs" that it incurred during the relevant period, to which it was entitled under the statute. In its pre-*Loper Bright* decision, the district court, applying *Chevron*, deferred to the agency's interpretation of the Medicare statute and granted the agency's motion for summary judgment. After the hospital appealed this decision, but before the circuit court ruled on the appeal, the Supreme Court issued its opinion in *Loper Bright*, and the circuit court—no longer bound by *Chevron*—reversed the district court's decision and granted the *hospital's* (rather than the agency's) motion for summary judgment.

While hospitals are generally compensated by the Medicare program through fixed, prospectively determined payments based on diagnosis-related groups ("DRGs"), the Medicare statute entitles hospitals classified as Sole Community Hospitals ("SCHs") to VDA payments for "fixed costs" they incur in providing inpatient hospital services while experiencing a qualifying decrease in cases. To comply with 42 U.S.C. § 1395ww(d)(5)(D)(ii), these VDA payments must "fully compensate" SCHs for their fixed costs, including the "reasonable cost of maintaining necessary core staff and services," though Congress did not prescribe a specific method for calculating the VDA. Historically, CMS has used several different methodologies for calculating VDA payments: the "fixed-total" approach, "fixed-fixed" approach, and a third method not at issue in *Lake Region Healthcare*. Under the fixed-total approach, the VDA is the difference between the hospital's fixed costs for treating Medicare beneficiaries and the total DRG payments the hospital has received. In contrast, the fixed-fixed approach permits higher VDA payments by defining the VDA as the difference between the hospital's fixed costs for treating Medicare beneficiaries and an *estimated* portion of its DRG payments allocable to its fixed costs.

In FFY 2013, Lake Region experienced a qualifying decrease in Medicare inpatient discharges and sought a VDA payment calculated using the fixed-fixed approach. The Medicare Administrative Contractor ("MAC") denied Lake Region's request, using a fixed-total calculation method to conclude that Lake Region had already been fully compensated for its fixed costs. The Provider Reimbursement Review Board ("PRRB") reversed the MAC's decision, and granted Lake Region the full requested VDA. The CMS Administrator subsequently reversed the PRRB, affirming the MAC's denial of Lake Region's VDA request.

Lake Region sought judicial review, arguing HHS failed to fulfill its mandate under 42 U.S.C. § 1395ww(d)(5)(D)(ii). The U.S. District Court for the District of Columbia ("D.C. District Court") ruled for the government on cross-motions for summary judgment. Adhering to pre-*Loper Bright* precedent as required at the time, the D.C. District Court granted *Chevron* deference to HHS's statutory construction after finding the agency's interpretation to be "reasonable, even if it might not be the best[.]"

The D.C. District Court was not the first court to deny a hospital's challenge to the fixed-total calculation method on the grounds that HHS's interpretation of the statute was reasonable under *Chevron*. For example, in *Trinity Reg'l Med. Ctr. v. Azar*, No. 17-CV-03029 LRR, 2018 WL 1558451 (N.D. Iowa Mar. 19, 2018), *report and recommendation adopted in part*, No. 17-CV-3029-LRR, 2018 WL 4295290 (N.D. Iowa Sept. 10, 2018), an Iowa acute care hospital requested a VDA which was denied by the MAC and appealed the MAC's decision to the PRRB which, applying the fixed-fixed method, granted the hospital a VDA payment, only for the CMS Administrator to apply the fixed-total method and conclude that the hospital was not entitled to a VDA payment. The hospital sought judicial review, arguing that HHS's methodology for calculating VDA payments violated the plain language of the statute and was thus arbitrary and capricious. The magistrate judge conceded that the hospital's preferred interpretation "seems more in line with the purpose of the VDA payment" but concluded that HHS's interpretation of the statute "[was] reasonable and thus owed deference[.]" Similarly, in *St. Anthony Reg'l Hosp. v. Azar*, 294 F. Supp. 3d 768 (N.D. Iowa 2018), *aff'd sub nom. Unity HealthCare v. Azar*, 918 F.3d 571 (8th Cir. 2019), a hospital challenged the CMS Administrator's application of the fixed-total calculation method as unlawful. As the statute does not directly address the question of how the VDA payment should be calculated, the court found that this left "an explicit gap" in the statute for HHS to fill. Applying *Chevron*, the court then found that the fixed-total calculation method was reasonable and, as such, *Chevron* required the agency's reasonable interpretation to be given controlling weight. In *Stephens Cnty. Hosp. v. Becerra*, No. 19-CV-3020 (DLF), 2021 WL 4502068 (D.D.C. Sept. 30, 2021), the D.C. District Court had similarly found for the government. The court invoked *Chevron* and upheld the *CMS Administrator's* decision, stating that the statute did not prescribe a formula to calculate the VDA payment and that the agency's interpretation was reasonable.

On September 3, 2024, the U.S. Court of Appeals for the District of Columbia ("D.C. Circuit Court") reversed the lower court's decision. The D.C. Circuit Court noted that in the aftermath of *Loper Bright*, it was required to "exercise independent judgment" in construing the Medicare statute. No longer bound by *Chevron*, the D.C. Circuit Court rejected the agency's statutory interpretation, concluding that CMS's fixed-total approach failed to "fully compensate" Lake Region for its FFY 2013 "fixed costs" as required by the Medicare statute. The D.C. Circuit Court ruled that "a method that ignores *all* compensation for

variable costs is not one that reasonably approximates full compensation for fixed costs." According to the D.C. Circuit Court, by "effectively treat[ing] all DRG payments as compensation for fixed costs, at least up to the amount of the hospital's total fixed costs[,]" the fixed-total approach endorsed by CMS leads to an overstatement of the amount of fixed costs already reimbursed by baseline DRG payments and thus ineligible for reimbursement through a VDA, "shortchanging" hospitals.

Potential Impact of *Loper Bright*

Lake Region Healthcare provides a dramatic example of *Loper Bright* altering the course of Medicare reimbursement litigation. However, trends in administrative law jurisprudence suggest that the overall impact of *Loper Bright* for health care reimbursement may be more muted. As the Supreme Court became increasingly skeptical of agency interpretive authority in the years prior to *Loper Bright*, appellate courts had already begun to bypass *Chevron* deference in adjudicating HHS challenges—either due to finding that *Chevron* deference was unwarranted because the statute at issue was unambiguous or because the agency had not explicitly requested deference. For example, despite extensive *Chevron* analysis in both the district court and appellate court opinions, the Supreme Court did not invoke *Chevron* in its opinion for *Becerra v. Empire Health Found.*, 597 U.S. 424 (2022). Subsequently, the D.C. Circuit Court, citing *Empire* for the proposition that "[reviewing courts] need not apply the *Chevron* framework[,]" expressly rejected the district court's use of *Chevron* in considering a reimbursement dispute. *See Advocate Christ Med. Ctr. v. Becerra*, 80 F.4th 346, 351 (D.C. Cir. 2023) ("*Advocate Christ*"). (See our Bloomberg Law article: *Implications of Loper Bright & Relentless for HHS-Regulated Entities*, Bloomberg L. (May 2024)).

Several cases highlighted in this issue's Docket Updates reflect this judicial trend of declining to find ambiguity in contested statutory language, regardless of whether such language could plausibly be read in more than one way. In *Advocate Christ*, the D.C. Circuit Court—possibly anticipating the result of *Loper Bright*, in which certiorari had been granted several months prior—analyzed the contested statutory language without even mentioning *Chevron*. Similarly, in *Am. Hosp. Ass'n v. Becerra*, No. 4:23-CV-01110-P, 2024 WL 3075865 (N.D. Tex. June 20, 2024), the court struck down an HHS rule after finding that it "exceed[ed] HIPAA's unambiguous text," briefly addressing deference owed to the agency only to say that deference could not save HHS's interpretation. Following *Loper Bright*, the trend has continued. In *Baylor All Saints Medical Center v. Becerra*, No. 4:24-cv-00432 P, 2024 WL 3833278 (N.D. Tex. Aug. 15, 2024), the court acknowledged that the agency's interpretation was "far from an implausible interpretation[,]" but ultimately concluded that "the governing statute [at issue] is clear." And in *Bridgeport Hosp. v. Becerra,* No. 22–5249, 2024 WL 3504407 (D.C. Cir. July 23, 2024), the D.C. Circuit Court concluded that the contested section of the Medicare statute speaks with "remarkable specificity," and as a result, determined that HHS's action was unlawful.

In short, although *Loper Bright* certainly marks a noteworthy shift in legal doctrine, the case represents the continuation of longstanding trends in administrative law jurisprudence, not a sudden paradigm shift. Given that appellate courts' willingness to apply *Chevron* deference had been waning for some time, the impact of *Loper Bright* on how courts resolve reimbursement litigation may be more limited.

Conclusion

Although the full effects of *Loper Bright* will only become clear in time, the loss of *Chevron* deference may embolden litigants to challenge agencies' constructions of statutes, including in the realm of reimbursement. Lower courts will likely see an uptick in challenges to agencies' statutory constructions as regulated entities see *Loper Bright* as ushering in a more equal playing field for administrative litigation. However, likelihood of success will continue to depend on the agency's adherence to the statute and the strength of interpretive arguments. Because reviewing courts will be compelled to exercise independent judgment on questions of law rather than deferring to agency interpretations of ambiguous language, HHS and CMS actions that are not clearly grounded in the statutory language are at greater risk of being struck down by federal courts.

Docket Updates

1. *Bridgeport Hospital v. Azar*

On July 23, 2024, the D.C. Circuit Court vacated CMS's 2019 rule that increased the Medicare wage index for hospitals in the lowest quartile and offset that adjustment by reducing IPPS payments for all other hospitals (the "Redistribution Rule"). *Bridgeport Hosp. v. Becerra*, No. 22–5249, 2024 WL 3504407 (D.C. Cir. July 23, 2024). In the final FFY 2025 inpatient prospective payment system ("IPPS") rulemaking issued August 28, 2024, CMS renewed the low wage index policy, but stated that it was aware of the *Bridgeport* decision and still was "considering options" for next steps. In its subsequent September 30 interim final rule, CMS changed course, removing its low wage index policy that had increased the wage index for hospitals in the lowest quartile while simultaneously reducing payments for all other IPPS hospitals. (*See* Regulatory Updates)

As background, to address concerns about wage disparity between high-wage and low-wage hospitals, CMS adopted the Redistribution Rule in 2019. This rule increased Medicare reimbursement for hospitals in the lowest quartile while decreasing reimbursement for all other hospitals to maintain budget neutrality. A group of hospitals challenged the Redistribution Rule, and the D.C. District Court found that CMS had exceeded its statutory authority in adopting the Redistribution Rule. The D.C. District Court did not vacate the rule, however, deciding that the agency's deficiency was not serious enough to warrant vacatur and that vacating the policy would create significant disruption. The D.C. District Court also emphasized the deference owed to HHS in administering "such a complex statutory and regulatory regime."

On appeal, the D.C. Circuit Court affirmed the D.C. District Court's decision that CMS had exceeded its statutory authority and found that the D.C. District Court should have also vacated the Redistribution Rule. The D.C. Circuit Court highlighted that *Chevron* deference would not have applied in this matter even before *Loper Bright* because no statutory ambiguity required gap-filling. The D.C. Circuit Court reasoned that the Medicare statute speaks with "remarkable specificity" as to the intricate formulas that are used to reimburse hospitals for care. It held that the Medicare statute does not authorize HHS to depart from Congress's established formula "simply because HHS wants those favored hospitals to be able to pay their employees higher wages in the future." The D.C. Circuit Court concluded that HHS's proposed policy "distorts the [statutorily imposed] uniform factor, jettisons the definite, objective data, and departs from the actual disparities between regional and national wages. And it does so despite a mandatory duty to follow the formula Congress chose." The D.C. Circuit Court found that Congress did not paint with "broad strokes," leaving the difficult decisions to an agency. Instead, the court found that the Medicare statute is a "regime of highly specific formulas. And HHS does not 'complement' [the statute] when it jettisons one of those formulas." Rather, the D.C. Circuit Court determined that HHS replaced it with "a new regime entirely." The D.C. Circuit Court decided that vacatur of the Redistribution Rule would be the appropriate remedy, as HHS "cannot 'cure' the fact that it lacks the authority to take a certain action."

Following the Court's decision in *Bridgeport*, CMS initially attempted to double down on its low wage index policy, but ultimately rescinded the policy beginning with FFY 2025. 89 Fed. Reg. 80405 (Oct. 3, 2024). The end of the low wage index policy means lower payments for hospitals in the lowest quartile, while other IPPS hospitals would receive higher payments due to the removal of the corresponding budget neutrality adjustment that CMS applied when it adopted the low wage index policy.

2. *Baylor All Saints Medical Center, et al., v. Becerra*

On August 15, 2024, the U.S. District Court for the Northern District of Texas (the "Texas Court") struck down the provision of the FFY 2024 IPPS rule (effective October 1, 2023), that excluded patients whose care is provided through uncompensated care pools under a Section 1115 Waiver (defined herein) from the count of Medicaid-eligible days used to determine the Medicare DSH payment. *Baylor All Saints Medical Center, et al., v. Becerra*, No. 24-cv-432 (Aug. 15, 2024) Under Section 1115 of the Social Security Act, states can submit pilot Medicaid programs to CMS and, with the approval of the Secretary of HHS ("the HHS Secretary"), waive certain Medicaid program requirements ("Section 1115 Waivers"). 42 U.S.C. § 1315(a).

The Medicare DSH regulation historically provided that hospitals could include within the Medicaid-eligible days in the Medicare DSH calculation "all days attributable to populations eligible for Title XIX matching payments through" a Section 1115 Waiver. 42 C.F.R. § 412.106(b)(4)(ii) (2022). In the FFY 2024 IPPS final rule, however, CMS amended the DSH regulation to restrict the number of Section 1115 Waiver days that may be counted in the Medicaid fraction by excluding days of all patients whose care is provided through uncompensated care pool payments, like those in Texas (42 C.F.R. § 412.106(b)(4)(iii)), as well as patients whose Section 1115 premium assistance covers less than 100% of their premium costs (42 C.F.R. § 412.106(b)(4)(ii)(B)). The Texas Court referred to these new exclusions of patients whose care is provided via such Section 1115 Waivers under the FFY 2024 IPPS final rule as the "Exclusion Rule."

On May 10, 2024, a group of Texas hospitals filed a complaint challenging the FFY 2024 IPPS final rule as conflicting with the Medicare statute, arguing that the statute requires the HHS Secretary to include such individuals covered under Section 1115 Waivers within hospitals' Medicare DSH payments. The plaintiff hospitals moved for a preliminary injunction to stay the application of the challenged portion of the rule. In support of their motion, the hospitals asserted that the Fifth Circuit Court of Appeals' decision in *Forrest General Hosp. v. Azar*, 926 F.3d 221, 228–29 (5th Cir. 2019), barred the HHS Secretary's interpretation of the DSH statute. The plaintiff hospitals argued that under *Forrest General*, the Medicare statute requires the HHS Secretary to make Medicare DSH payments attributable to individuals he deemed to be "Medicaid-eligible" when he approved a Medicaid state waiver that grants such individuals Medicaid-like benefits. The hospitals argued that the provision of the FFY 2024 final rule excluding waiver days associated with uncompensated care pools from the DSH calculation "unlawfully carve[d] out a sub-population of patients who receive inpatient benefits through an approved [Section 1115 Waiver]," in plain violation of the Fifth Circuit's holding. The HHS Secretary argued that the statute's permissive language allowed the HHS Secretary the discretion to definitively exclude Section 1115 Waiver patient-days from the DSH calculation. Further, the HHS Secretary argued that the hospitals did not face the threat of irreparable harm and thus, were not entitled to preliminary injunction because they could seek relief from unfavorable determinations pursuant to the rule through the administrative appeals process.

The Texas Court ruled in favor of the hospitals on August 15, 2024, holding that the Fifth Circuit's decision in *Forrest General* settled the case – rejecting CMS's interpretation of the DSH statute to exclude Section 1115 Waiver days from the numerator of the Medicaid fraction for purposes of the DSH calculation. The court did not issue a permanent nationwide injunction but vacated the Exclusion Rule as unlawful. The court held that the Fifth Circuit's decision in *Forrest General* "directly control[led] the Court's inquiry—and clarifies that the Exclusion Rule contradicts the [Medicare] statute's plain text." The Texas Court followed the Fifth Circuit's reasoning and concluded that because the HHS Secretary had approved Texas's Section 1115 Waiver plan, CMS was required to include in the numerator of the Medicaid fraction patient days for those treated pursuant to the Section 1115 plan. Accordingly, the court declared as invalid the Exclusion Rule, which excluded patients treated via uncompensated care pools from the Medicaid fraction. The Texas Court's decision does not directly address a different provision of the FFY 2024 rule that limited the days associated with Section 1115 premium assistance programs that could be counted in the DSH calculation.

Notably, while the *Baylor All Saints* holding was issued following *Loper Bright*, the Texas Court's decision does not reference *Chevron* or *Loper Bright* at all; instead, it found that the HHS Exclusion Rule contradicts the plain text of the applicable statute, as well as the binding interpretations of the D.C. Circuit Court and Fifth Circuit of the same. However, the Texas Court also stated that HHS's interpretation was "far from an implausible interpretation," suggesting that, were it not for binding circuit precedent or *Loper Bright*, the court very well may have found the statute to be ambiguous, granted deference, and found in favor of the agency.

On October 15, the government appealed the decision to the Fifth Circuit. So, while the rule remains vacated pending appeal, it remains unclear whether days associated with uncompensated care pools under a Section 1115 waiver will ultimately count as Medicaid-eligible days in the DSH calculation.

3. *Battle Creek Health System v. Becerra*

The D.C. Circuit Court has scheduled oral argument in *Battle Creek v. Becerra*, No. 23-5310 (D.C. Cir.), on November 22, 2024, a case concerning whether hospitals can appeal directly from CMS's published Supplemental Security Income ("SSI") frac-tions, one of the two fractions used to calculate the Medicare DSH payment, before the agency applies the SSI fractions in a notice of program reimbursement ("NPR"). The government appealed an October 31, 2023 ruling by the D.C. District Court, holding that the PRRB had jurisdiction over the plaintiff hospitals' appeals of CMS's 2009 publication of SSI fractions for FFY 2007. The D.C. District Court, in turn, vacated the PRRB's jurisdictional decision and remanded the case to the PRRB to address the merits of the dispute. In reaching its decision, the district court found 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, explaining 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 pro-vider] file a cost report prior to appeal." The D.C. District 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, "CMS . . . made a final decision with the meaning of the statute, because CMS definitively alerted providers to forthcoming reimbursements" when it published the SSI fractions in Transmittal 1774, Change Request 6530 (July 24, 2009).

On December 28, 2023, the HHS Secretary filed an appeal of the D.C. District Court's decision in *Battle Creek* 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). On April 30, 2024, the government filed its brief, arguing the PRRB was correct to conclude that it lacked jurisdiction over the appeal because the challenged Medicare fractions did not determine an "amount of the payment" available, and they were not "final." Battle Creek filed its response brief on July 22, 2024, arguing that "Congress expressly provided for DSH payment appeals without [NPR]," when it added DSH payments to the prospective payment system statute at 42 U.S.C. § 1395ww(d). The hospital also argues that D.C. Circuit Court precedent establishes that a hospital can pursue an appeal of a prospective payment before receiving an NPR, citing *Washington Hosp. Ctr. v. Bowen*, 795 F.2d 139, 145 (D.C. Cir. 1986). The hospital also relies on the Supreme Court's recognition in *Azar v. Allina Health Servs.* ("*Allina II*") that the HHS Secretary's SSI fractions are not only final determinations but affect amounts of payment. 587 U.S. 566, 572 (2019) (stating that "the government's 2014 announcement of the 2012 Medicare fractions governed 'payment for services'"). The government replied on September 3, 2024, arguing that the SSI fractions at issue amount to "a decision that merely affects—but does not finally determine" the final payment.

The D.C. Circuit Court has scheduled oral argument in the case for November 22, and a decision is expected next year.

4. *Advocate Christ Medical Center v. Becerra*

Advocate Christ is scheduled for oral argument before the Supreme Court on November 5, 2024. 80 F. 4th 346, cert. granted, 2024 WL 2883751 (U.S. June 10, 2024) (23-715). The Supreme Court will review the D.C. Circuit Court's decision holding that the term "entitled to [SSI] benefits" extends only to Medicare beneficiaries who received SSI cash payments at the time of their hospitalization. *See Advocate Christ*. In a longstanding conflict with CMS, hospitals have historically challenged the inconsistent interpretation of the term "entitled to benefits" in the DSH calculation as between the Medicare program and the SSI program. In *Advocate Christ*, the latest iteration of this kind of challenge, the hospitals argue that the Medicare DSH statute requires that "entitled to [SSI] benefits" extends to all patients enrolled in the SSI program at the time of hospitalization, even if they did not actually receive any cash benefits under the SSI program. The hospitals argue this outcome is consistent with the Supreme Court's decision in *Becerra v. Empire Health Foundation*, 597 U.S. 424 (2022). The government, on the other hand, argues that entitlement to SSI benefits requires actual receipt of SSI cash benefits. The government also invoked the Court's recent holding in *Loper Bright* to characterize its preferred interpretation as a "contemporaneous, longstanding, and consistent agency interpretation" of a technical provision that "warrants the Court's respect." A decision in *Advocate Christ* is expected in the first half of next year.

5. *American Hospital Assoc. v. Becerra*

On June 20, 2024, the U.S. District Court for the Northern District of Texas ruled in favor of the hospital association plaintiffs in a case challenging recent HHS guidance regarding the Health Insurance and Portability and Accountability Act ("HIPAA") (the "Guidance"). *See Am. Hosp. Ass'n v. Becerra*, No. 4:23-CV-01110-P, 2024 WL 3075865 (N.D. Tex. June 20, 2024) ("AHA v. Becerra"). The Guidance, issued in a December 2022 Bulletin, purported to extend HIPAA's disclosure restrictions to "tracking technologies" that effectively connect an individual's IP address with a visit to an Unauthenticated Public Webpage that addresses specific health conditions or health care providers. The matter first arose in November of 2023, when the American Hospital Association ("AHA") and others brought suit

against the Director of the HHS Office for Civil Rights ("OCR") and the HHS Secretary to stop enforcement of the Guidance. In its June 2024 decision, the court ruled that key portions of the Guidance were unlawful and exceeded the scope of the agency's administrative authority. The Texas Court granted the plaintiffs' motion for declaratory judgment to vacate the Guidance's classification of such information gathered from tracking technologies as "individually identifiable health information" ("IIHI"), but rejected the plaintiff's simultaneous request for a permanent injunction. Specifically, the court ruled that metadata (*e.g.*, IP address), input by website users into a HIPAA-regulated entity's unauthenticated, publicly facing webpage does not constitute IIHI, because such information neither relates to an individual's health condition, health care or payment for health care, nor does it identify or can it be used to reasonably identify that individual. The Texas Court reasoned that "[t]o hold otherwise would empower HHS and other executive entities to take increasingly expansive liberties with the finite authority granted to them." Notably, however, the ruling does not vacate the entire Guidance, which may imply that OCR's characterization that an IP address in combination with activity on an authenticated webpage constitutes IIHI, and thus, remains enforceable. HHS initially appealed the Texas Court's ruling but withdrew its appeal on August 29, 2024. Learn more.

While the decision in *AHA v. Becerra* preceded the decision in *Loper Bright* by one week, the *AHA v. Becerra* court emphasized that it was the statute's text, rather than any agency deference, which ultimately led the court to its decision. By stating that any *Chevron* "deference does not give HHS interpretive carte blanche to justify whatever it wants irrespective of violence to HIPAA," this ruling previewed the landscape to come. *AHA v. Becerra* underscores that as agency authority continues to be challenged, agencies will have to more carefully consider the scope of their statutory authority before making determinations or promulgating rules that may be seen as inappropriately stretching its limits. Learn more.

Regulatory Updates

1. Final Rule Provides Appeal Process for Patients Reclassified as Outpatient Observation

On October 11, 2024, CMS finalized a rule establishing a new appeals process for Medicare patients initially admitted as hospital inpatients but whose status is later reclassified to outpatient observation status, thereby effectively denying Medicare part A coverage for their stay. CMS issued the rule in response to the 2020 decision in *Alexander v. Azar*, 613 F. Supp. 3d 559 (D. Conn. 2020), which ordered the agency to create appeals processes for such individuals. The final rule creates three pathways for patients to appeal a hospital's reclassification decision: (1) expedited, (2) standard, and (3) retrospective. Appeals will be conducted by a Beneficiary & Family Centered Care - Quality Improvement Organization ("QIO").

The expedited appeal pathway requires patients to submit requests for appeal prior to their discharges from the hospital. For these appeals, once the patient has received notice of their appeal rights and submitted a timely request for appeal, the QIO has one calendar day to make its decision. Hospitals may not bill patients for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed. The standard appeal pathway follows the same process as expedited appeals; however, patients may submit appeal requests at any time after leaving the hospital. Standard appeals are also referred to as "untimely" appeal requests and QIOs must issue their decisions within two (2) calendar days of receiving all relevant requested information.

The retrospective appeal pathway allows patients to appeal reclassification decisions dating back to January 1, 2009. This process is similar to the current claims appeal process: MACs will perform the first level of appeal, followed by Qualified Independent Contractor ("QIC") reconsiderations, Administrative Law Judge ("ALJ") hearings, review by the Medicare Appeals Council, and then judicial review. Beneficiaries will only have 365 days from the implementation date of the rule to file a request for a retrospective appeal. CMS is projecting implementation in early 2025 and states that it will announce the implementation date on the cms.gov or medicare.gov websites.

2. CMS Updates FFY 2025 Hospital IPPS Rates Due to D.C. Circuit Decision in *Bridgeport Hospital v. Becerra*

In response to the D.C. Circuit Court's decision in *Bridgeport Hosp. v. Becerra* (*See* the Docket Update), on September 30, 2024, CMS issued an Interim Final Rule recalculating the IPPS hospital wage index to remove the low wage index hospital policy and related budget neutrality adjustments.

In FFY 2020, CMS had finalized a policy temporarily increasing the wage-index values for hospitals with a wage index below the 25th percentile range. In doing so, CMS used a budget-neutral methodology that decreased reimbursement for all other hospitals outside of the lowest 25th percentile. The policy was to be effective for four years; however, in the IPPS FFY 2025 proposed rule, CMS adopted an extension of the low wage index hospital policy and the related budget neutrality adjustment for at least three more years, beginning in FFY 2025.

On July 23, 2024, the D.C. Circuit Court of Appeals ruled that CMS's manipulation of the wage-index rates unlawfully disregarded the congressionally required formula. As such, on September 30, CMS issued an interim final rule recalculating the IPPS hospital wage index to undo the low wage index hospital policy including the budget neutrality adjustment for FFY 2025. This means that the standardized amount will increase by about 0.29% or $18.75 for all hospitals.

Overall, 768 hospitals will receive a lower wage index in FFY 2025 than expected under the FFY 2025 IPPS Final Rule. However, for hospitals in the lowest quartile of low wage index hospitals – whose wage index would decrease by more than 5% from its FFY 2024 wage index – CMS included a one-time transitional adjust whereby CMS will limit the decrease in the wage index to ensure these hospitals receive 95% of their final wage index from the prior fiscal year. CMS will not apply budget-neutrality to this transition.

The removal of the bottom quartile budget neutrality adjustment applies generally to the FFY 2025 IPPS, affecting the calculation of the capital rate, which increases to $512.14, and the fixed loss outlier threshold, which increases to $46,217.

The comment period on the interim final rule runs through November 29, 2024.

3. Change Request 13413/Transmittal 12785 Provide Instructions for Hospitals as CMS Resumes the Processing of Realignment Requests Post-*Allina II*

On August 13, 2024, CMS issued Transmittal 12785 to provide information and implementation instructions for hospitals that have requested realignment of the SSI fractions used to calculate the Medicare DSH payment for years beginning before October 1, 2013. Transmittal 12785 replaced the earlier Transmittal 12747, issued July 26, 2024, but the only change in the latter transmittal is a mandate that the SSI fraction files must be formatted such that the "SSI Ratio" column in the files is consistently rounded to four decimal places.

The SSI fractions used to calculate Medicare DSH payments are calculated by CMS based on discharges in the respective federal fiscal year, but hospitals are permitted under 42 C.F.R. § 412.106(b)(3) to request that CMS recalculate, or "realign," their SSI fractions based on discharges in the hospital's cost reporting period. According to CMS, realignment requests for periods beginning prior to October 1, 2013, had been on hold for a number of years pending the outcome of the *Allina II* litigation challenging the treatment of Medicare part C days in the Medicare DSH calculation. In Transmittal 12747, issued more than a year after CMS's June 2023 final rule (CMS-1739-F) purporting to implement the Supreme Court's decision in the *Allina II* case, CMS is resuming the processing of realignment requests for cost reporting periods starting before October 1, 2013. In conjunction with Transmittal 12747, CMS also published updated SSI fractions on the CMS website. Those SSI fractions include part C days, consistent with the June 2023 rule, and the revised files show hospitals' SSI fractions calculated both on the basis of discharges in the federal fiscal year and cost reporting period. The Transmittal provides that hospitals must affirm that they want to proceed with any realignment requests filed before the July 31, 2024 effective date of the Transmittal or alternatively, file new requests. After receiving confirmation of an earlier request or a new realignment request, the respective MAC has 24 months to issue a new NPR.

4. Inpatient Psychiatric Facility FFY 2025 Rule Estimated to Result in $65 Million in Increased Payments to IPFs during FFY 2025

On August 7, 2024, CMS published the final rule for inpatient psychiatric facilities ("IPF") prospective payment system ("PPS") for FFY 2025, updating the IPF PPS payment rates by 2.8% and updating the outlier threshold so that estimated outlier payments remain at 2.0% of total payments. As a result of the final rule, the total estimated payments to IPFs are estimated to increase by $65 million, in FFY 2025. 89 Fed. Reg. 64582. CMS is also revising the IPF PPS patient-level adjustment factors, such as Medicare Severity DRG assignment of the patient's principal diagnosis and selected comorbidities, while also seeking input on potential revisions to the IPF PPS facility-level adjustments, including adding a potential adjustment based on the Medicare Safety Net Index. Additionally, CMS increased the IPF PPS electroconvulsive therapy per treatment amount from $385.58 to $661.52 in order to improve treatment access. CMS is adopting the Core Based Statistical Area ("CBSA") Labor Market Areas for the IPF PPS wage index as defined in the Office of Budget and Management ("OMB") Bulletin 23-01 and will also implement a transition period for providers moving from rural to urban based on these CBSA revisions. CMS also finalized changes to the IPF Quality Reporting Program, including introducing a claims-based measure which will assess the proportion of patients 18 and older who have an emergency department visit within 30 days of discharge from an IPF without subsequent admission, with patients who are admitted represented on a pre-existing measure. However, CMS did not finalize its proposal to require IPFs to submit patient-level quality data for certain measures on a quarterly basis due to concerns of causing data strain on IPFs. As such, reporting will remain annual.

5. CMS Publishes FFY 2025 Medicare IPPS Final Rule

On August 1, 2024, CMS published its annual final rule ("Final Rule") for the FFY 2025 IPPS and long-term care hospital ("LTCH") payment system. 89 Fed. Reg. 68986. The Final Rule finalizes certain aspects of the May 2024 proposed rule, which we previously summarized in an alert. Key provisions of the Final Rule include a net increase of 2.9% to the IPPS payment rates for FFY 2025, which is more than the 2.6% increase proposed but still less than the 3.1% increase for FFY 2024. CMS also finalized a net increase of 3.0% in the national standardized amount for long-term care hospitals for the next fiscal year, which is more than the 2.8% increase proposed but less than the 3.3% increase for FFY 2024. CMS continued its trend of reducing overall uncompensated care payments, reducing the overall pool of DSH uncompensated care funds from $6.498 billion to $5.705 billion between the proposed and Final Rule, and marking a decrease of 4.07% from the overall DSH uncompensated care funds from the FFY 2024 Final Rule. Additionally, CMS finalized its proposal to implement the new OMB labor market area delineations for the FFY 2025 wage index, which will result in some hospitals currently classified as urban counties becoming classified as rural hospitals and therefore, subject to the maximum DSH payment adjustment of 12%.

Among other changes, CMS also:

- Finalized a new separate payment to reimburse small, independent hospitals (with 100 beds or fewer that are not part of a chain) for the additional costs that they incur in establishing and maintaining access to certain "essential medicines."
- Extended the Medicare-Dependent Hospital Program and the temporary changes to the low-volume hospital qualifying criteria and payment adjustments for a portion of FFY 2025.
- Issued the Nursing and Allied Health Education Medicare Advantage rates for calendar year ("CY") 2023 consistent with the methodology first established in FFY 2023, and also presented a number of initiatives to increase health equity, such as requesting information on improving maternity care and obstetrical services.
- Modified a number of reporting programs, including measures for hospital Inpatient Quality Reporting and the hospital Value-Based Purchasing Program.

6. CMS Publishes FFY 2025 Outpatient Prospective Payment System / Physician Fee Schedule Final Rule

On November 1, 2024, CMS finalized the rule for the CY 2025 outpatient prospective payment system ("OPPS") and physician fee schedule ("PFS") (the "OPPS/PFS Final Rule"). The OPPS/PFS Final Rule is not yet published in the Federal Register. CMS finalized an overall increase factor of 2.9% to the OPPS conversion factor. Given this update, CMS estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case mix) for CY 2025 would be approximately $87.7 billion, $4.7 billion more than estimated CY 2024 OPPS payments.

The OPPS/PFS Final Rule updates Medicare payment rates for intensive outpatient program ("IOP") and partial hospitalization program ("PHP") services furnished in hospital outpatient departments and community mental health centers. CMS will maintain the existing rate structure with two IOP and PHP ambulatory payment classifications for each provider type: one for days with three services per day and one for days with four or more services per day.

CMS initially proposed to continue voluntary reporting of the core clinical data elements ("CCDE") and linking variables for both the Hybrid Hospital-Wide Readmission and Hybrid Hospital-Wide Standardized Mortality measures for the performance period of July 1, 2023, through June 30, 2024, impacting the FFY 2026 payment determination for the Hospital IQR Program. But in the OPPS/PFS Final Rule, CMS extended the continued voluntary reporting of the CCDEs and linking variables another year through June 30, 2025, impacting the FY 2027 payment determination. In addition, CMS finalized updates to the Conditions of Participation (CoPs) for hospitals and Critical Access Hospitals ("CAHs") for obstetrical services, including new requirements for maternal quality assessment and performance improvement, maternal health data reporting, baseline standards for the organization, staffing, and delivery of care within obstetrical units, and staff training on evidence-based best practices on an annual basis.

For the PFS, CMS finalized an overall conversion factor of $32.35 for CY 2025, a decrease of 2.9%, representing a 2.8% ($0.93) decrease when compared to the CY 2024 conversion factor of $33.29. CMS also finalized provisions relating to telehealth services, including the addition of several new services to the Medicare Telehealth Services list on a provisional basis, as well as the addition of two new services on a permanent basis (PrEP for HIV counseling and safety planning intervention). CMS also finalized the continued suspension of frequency limitations on telehealth visits for certain services, including subsequent inpatient visits and critical care consultations for CY 2025. Further, beginning in CY 2025, real-time two-way audio-only communication for telehealth services will be permitted for any telehealth service if the patient is not capable of, or does not consent to, the use of video technology and will no longer be limited to diagnosis, evaluation, or treatment of a mental health disorder. For the Quality Payment Program, CMS also finalized six new, optional Merit-based Incentive Payment System Value Pathways for reporting beginning in 2025: ophthalmology, dermatology, gastroenterology, pulmonology, urology, and surgical care. CMS also finalized changes to the Medicare Shared Savings Program ("MSSP") requirements to further advance Medicare's value-based care strategy.

7. CMS, HHS, and ONC Release Final Rule on Information Blocking

On June 24, 2024, the HHS Office of the National Coordinator for Health Information Technology ("ONC") and CMS released a final rule titled "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" (the "Information Blocking Final Rule"). The Information Blocking Final Rule implements disincentives for providers who violate information blocking rules, and could have significant consequences for eligible hospitals, CAHs, eligible clinicians' participation in the Medicare Electronic Health Records ("EHR"), Incentive Programs and accountable care organizations ("ACOs"), ACO participants, and ACO providers/suppliers participating in the MSSP that are found to have engaged in information blocking. One of the disincentives in the new rule involves the Medicare Interoperability Program. Under the Medicare Promoting Interoperability Program, an eligible hospital, CAH or clinician that HHS's Office of Inspector General ("OIG") determines to have committed information blocking, would not be considered by CMS to be a "meaningful EHR user" in an applicable EHR reporting period. The impact on eligible hospitals would be the loss of 75% of the annual market basket increase, and for CAHs, payment would be reduced to 100% of reasonable costs instead of 101%. CMS stated in the Information Blocking Final Rule that these disincentives will provide significant deterrents to information blocking, given the steep financial impact to eligible providers. Learn more.

8. Potential Further Extension of COVID-19 Public Health Emergency ("PHE") Medicare Telehealth Waivers

Congress is currently considering further extending through 2026 certain telehealth flexibilities that were initially introduced during the PHE and that were subsequently extended through 2024 by the Consolidated Appropriations Act, 2023. The House Ways and Means Committee unanimously passed the Preserving Telehealth, Hospital and Ambulance Access Act (H.R. 8261) on May 8, 2024, which would extend key telehealth provisions, including preserving telehealth accessibility for Medicare recipients; permitting audio-only telehealth services; exempting the geographic and originating site restrictions to expand access to urban, suburban and rural Medicare patients receiving telehealth services; and continuing add-on payments for urban, rural, and super-rural areas to preserve access to emergency ambulance services. The proposed act would also continue the suspension of the requirement for an in-person visit within six months of the beneficiary receiving their first tele-mental health service. Finally, the act would further extend Acute Hospital at Home Waiver flexibilities allowing hospitals to expand their capacity to provide inpatient care in an individual's home through 2029. Given the widespread provision of and reliance on telehealth services following the end of the PHE, we are continuing to closely monitor the status of the proposed law.

Updates on Relief Funding for Major Disasters and Public Health Emergencies

1. The Impact of Hurricanes Helene and Milton

Hurricanes Helene and Milton have had devastating impacts on communities throughout the southeastern United States, including Tennessee, North Carolina, Florida, and Georgia. The storms continue to wreak havoc in hospitals across the region, particularly in neighboring states. Floodwaters impacted infrastructure and pose continued issues to access to patients and providers.[1]

Beginning on September 26, 2024, HHS Secretary Xavier Becerra determined that a Public Health Emergency exists in Florida, Georgia, North Carolina, South Carolina, and Tennessee, which gives health care providers greater flexibility in meeting emergency health needs of federal health care program beneficiaries and allows the deployment of resources from the Administration for Strategic Preparedness and Response. Additionally, beginning on September 29, 2024, President Biden issued Major Disaster Declarations for Alabama, Georgia, Florida, North Carolina, South Carolina, Tennessee and Virginia for Hurricane Helene, authorizing the Federal Emergency Management Agency ("FEMA") to provide various methods of disaster relief, including assistance to private nonprofit organizations through FEMA's Public Assistance ("PA") Program. In response to Hurricane Helene, FEMA has provided PA funding and provided infrastructure at critical facilities, including hospitals. In particular, hospitals across the United States have also been impacted by a shortage of intravenous solutions at hospitals, after a plant involved in producing intravenous solutions for Baxter International, one of the United States' largest intravenous solutions manufacturers, was flooded due to the storm.

On October 8, 2024, HHS Secretary Xavier Becerra determined that a Public Health Emergency exists in Florida and has existed since October 5, 2024 due to Hurricane Milton. Additionally, on October 11, 2024, President Biden approved a Major Disaster Declaration in Florida due to the emergency conditions resulting from Hurricane Milton.

There are multiple reimbursement- and funding-related lessons that recipients have learned about managing major disasters after these devastating storms and the PHE, including through maximizing the benefits of the federal grants or other assistance programs aimed at supporting disaster recovery efforts. These lessons can apply to disasters and other public health emergencies in the future, including natural disasters such as Hurricanes Helene and Milton, and include:

- Monitoring and tracking compliance and the dates associated with any 1135 waivers extended by CMS in response to a public health emergency. CMS may extend 1135 waivers to waive certain Medicare, Medicaid, and Children's Health Insurance Program requirements to ensure (i) sufficient health care items and services are available to meet the needs of individuals enrolled in these programs in the emergency area and time periods and (ii) providers who give such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).[2] 1135 waivers typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the HHS Secretary extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period. Monitoring and tracking compliance with federal, state, and local government declarations to ensure compliance with certain health care directives and waivers (*e.g.*, whether beds need to be reserved for certain patients, Emergency Medical Treatment & Labor Act ("EMTALA") obligations, restrictions on elective surgeries).
- Understanding the terms and conditions and reimbursement-related restrictions attached to any disaster relief funding (*e.g.*, whether funds can be used towards certain labor expenses, whether lost revenues will be reimbursed), noting, for example, the restrictions that may apply to publicly funded versus privately funded hospitals, particularly as they coordinate with state and local governments in response to the major disaster or PHE (*e.g.*, FEMA PA fundings has specific terms and conditions for "private nonprofits" or "PNPs").
- Ensuring continued compliance with these requirements and any documentation-related restrictions (e.g., requirements related to use of funds and maintenance of proper records).
- Maintaining updated emergency plans.

Unfortunately, despite the distress and exigency attached to any major disaster, failure to adhere to these various requirements could have serious financial ramifications.

2. Enforcement of COVID-19 Funding Laws

Enforcement activity related to the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), including the Department of Justice's COVID-19 Fraud Enforcement Task Force, continues to focus on Paycheck Protection Program funds and the Employee Retention Tax Credit program. There has been minimal enforcement of CARES Act funding to health care providers, including the Provider Relief Fund ("PRF"). PRF recipients should maintain any records to the funds received in the event of an audit by the Health Resources and Services Administration ("HRSA") or the OIG. Additionally, strategic investors investing in hospitals or other organizations that may have received PRF funds should continue to conduct diligence on and understand the risks of acquiring these entities by ensuring continued compliance with PRF requirements, including timely reporting on PRF funding, retention of any potential overpayments, and compliance with terms and conditions attached to receipt of the funds, including that the health care provider does not balance bill COVID-19-positive patients.

Enforcement Updates

DOJ Increases Stark Law Enforcement

Over the past year, the Department of Justice ("DOJ") has significantly increased its enforcement efforts related to the Physician Self-Referral Law, also known as the Stark Law. The Stark Law generally prohibits a physician from making a referral to an entity for the furnishing of designated health services ("DHS") payable by Medicare if that physician or an immediate family member has a financial relationship with the entity, unless an exception applies. The Stark Law is a strict liability statute, meaning a defendant can be held liable for even an unintentional violation of the law. Common issues giving rise to Stark Law liability include providing compensation to physicians that is above fair market value or that takes into account the volume or value of their referrals.

In an apparent response to the increase in enforcement actions, Stark Law self-disclosures have also drastically increased. According to the CMS Voluntary Self-Referral Disclosure Protocol ("SRDP"), in 2021, providers self-disclosed and settled 27 Stark Law self disclosures for $1.9 million. In 2023, those numbers increased nearly sevenfold, to 176 settled self-disclosures for over $12.5 million. Not all self-disclosures resulted in a settlement with CMS. CMS notes that an additional 267 disclosures to SRDP were withdrawn, closed without settlement, or settled by DOJ.

The DOJ settled several high-value Stark Law-predicated False Claims Act ("FCA") settlements with various health care providers in 2023, including: (1) a health system in Michigan that settled claims for $69 million in March 2023; (2) an imaging company in Illinois that settled Stark-based FCA claims for $85 million in October 2023; (3) a Delaware-based health system that settled claims for $42.5 million in December 2023; and in the largest Stark Law settlement ever, (4) an Indiana-based health system settled Stark Law claims for $345 million in December 2023. In general, these cases settled allegations that providers paid physicians above fair market value for their services in order to receive referrals from the physicians.

The high-value settlement trend has continued in 2024. In March, a neurology practice settled claims for $1.8 million, and in September, a South Dakota hospital settled a Stark and Anti-Kickback Statute-related claim for $12.7 million.

While the Stark Law is a strict liability statute, for DOJ to succeed in bringing an FCA case predicated on a Stark violation, DOJ must prove that the defendant had the necessary specific intent to violate the law. But that additional requirement has not prevented DOJ from litigating Stark Law issues when pre-intervention settlements are not achieved.[3] Further, while the full implications of *Loper Bright* for Stark Law enforcement remain to be seen, one recent FCA *qui tam* action premised on alleged Stark Law violations saw both the relator and the defendant submit briefing to the court arguing that *Loper Bright* was not relevant, each contending that the Stark Law is not ambiguous and that the statute permits CMS to issue regulations with regard to the law. *See United States ex rel. Kyer v. Thomas Health Sys., Inc.*, 2024 WL 4165082 (S.D.W. Va. Sept. 12, 2024).

The recent increase in enforcement actions and potential for steep financial penalties should serve as a warning to providers. Even providers acting in good faith can be ensnared and face enforcement actions related to this technical statute. Providers should take this opportunity to revisit compliance safeguards and review physician compensation arrangements to ensure compliance.

SCOTUS's *Jarkesy* Decision Threatens HHS's Enforcement of Civil Monetary Penalties

On June 27, 2024, the Supreme Court issued its decision in *Securities and Exchange Commission v. Jarkesy*, 144 S. Ct. 2117 (2024) ("*Jarkesy*"), which has the potential to significantly narrow the types of enforcement cases that HHS and other federal agencies can pursue using their administrative proceedings. Writing for the majority, Chief Justice John Roberts held that a jury trial is required under the Seventh Amendment when the Securities and Exchange Commission ("SEC") brings securities fraud cases seeking civil monetary penalties. The Court determined that these types of claims are akin to common law fraud actions and the civil penalties are those traditionally awarded in a court of law. Therefore, the Court reasoned, because the claims are "legal in nature," the Seventh Amendment guarantees the right to a jury trial. Before the decision, the SEC had the option of bringing enforcement actions in federal district court or before SEC administrative law judges ("ALJs"). Practically, this means that when the SEC seeks to enforce civil penalties for securities fraud, those cases must now proceed in federal court, where juries are likely to be less agency-friendly than ALJs.

HHS is facing the implications of this ruling. Like the SEC, OIG assesses civil monetary penalties through ALJ proceedings and appeals through its internal Department Appeals Board ("DAB"), with sources of authority coming from the Social Security Act ("SSA"), Health Care Quality Improvement Act ("HCQIA"), and Public Health Security and Bioterrorism Preparedness and Response Act ("PHSBPR"). Following the *Jarkesy* decision, HHS will need to justify that its civil monetary penalties are not "legal in nature," or face a potential jury trial. This threat of a federal jury trial to contest the issuance of civil monetary penalties will empower health care providers to potentially challenge HHS's interpretations of the statutory authorities upon which the penalties are based.

HHS Makes Significant Updates to Research Misconduct Regulations

On September 12, 2024, the HHS Office of Research Integrity ("ORI") issued its highly anticipated final rule under 42 C.F.R. Part 93 ("Part 93"), revising the procedures and requirements for research misconduct proceedings. Part 93 provides the framework for reviewing allegations of research misconduct (falsification, fabrication, or plagiarism) associated with research supported by U.S. Public Health Service ("PHS") funds—including funding by the National Institutes of Health ("NIH"). The Part 93 framework requires academic medical centers and other institutions that receive PHS funding to investigate allegations of research misconduct in a highly prescriptive fashion and to provide detailed written reports of their internal investigations to ORI.

In the final rule, ORI generally sought to implement changes that will allow institutions to conduct more efficient and timely investigations. Notably, this approach diverges from ORI's proposed rule issued in October 2023. In the final rule, ORI walked back a series of changes contained in the proposed rule that research institutions found particularly problematic and burdensome, including proposals to (i) require unanimous investigation committee decisions for a finding of research misconduct; (ii) require that institutional assessments proceed automatically to inquiry if not completed within 30 days; and (iii) require that all determinations of honest error or difference of opinion be resolved only at investigation and not during the earlier inquiry or assessment stages.

Value-Based Care Corner

1. TEAM Model

On August 1, 2024, CMS finalized its new mandatory payment model—the Transforming Episode Accountability Model ("TEAM") – to be implemented by CMS's Center for Medicare and Medicaid Innovation ("Innovation Center"). This model is mandatory for all acute care hospitals in 205 CBSAs selected by CMS. *See* TABLE X.A.-07 in the final rule. TEAM, an episode-based alternative payment model, requires participating hospitals to coordinate care for people with traditional Medicare who undergo one of the specified surgical procedures included in the model (initiation of an episode). CMS will pay hospitals a "target price" for each episode, which builds a 3% discount to ensure savings to Medicare. Hospitals assume the responsibility for the cost and quality of care from surgery through the first 30 days after the Medicare beneficiary leaves the hospital (conclusion of an episode). Part of this responsibility includes connecting patients to primary care services to establish more accountability in the care relationship.

TEAM will run for five years, from January 1, 2026, to December 31, 2030. The first year of the Model is a "glide path," easing all TEAM participants into full financial risk. After the "glide path," participants will enter one of three tracks: Track 1 has no downside risk and lower levels of reward for the first year, or up to three years for safety net hospitals; Track 2 will maintain lower levels of risk and reward for certain TEAM participants, such as safety net hospitals or rural hospitals, for years two through five; and Track 3 has higher levels of risk and reward for years one through five. The TEAM Model, as finalized, differs from the proposed version in that, it will allow safety net hospitals to participate in a track with lower levels of risk and a pricing methodology that accounts for underserved individuals, in order to promote health equity.

2. Changes to MSSP under the OPPS/PFS Final Rule

CMS announced in its OPPS/PFS Final Rule significant changes to the MSSP but declined to make several sought-after improvements to the program. Notably, despite continued pressure from ACOs, CMS did not finalize its proposals to offer a full risk option. CMS also declined to finalize a policy allowing ACOs to full or partial capitation, which would have provided an up-front and predictable funding stream that has been a key component of recent Innovation Center ACO models. CMS stated that they are continuing to consider feedback on these proposals and may implement them at a later date.

CMS finalized a new "prepaid shared savings" option to assist eligible ACOs that historically earn shared savings. This option permits eligible and approved ACOs to receive shared savings as advances, in order to use the funds for investments that would aid beneficiaries. Appropriate investments include "investments in direct beneficiary services and investments to improve care coordination through staffing or healthcare infrastructure." CMS earmarked at least 50% of prepaid shared savings to be spent on direct beneficiary services not otherwise payable by traditional Medicare. CMS also specified that up to 50% of the prepaid shared savings may be used for staffing and infrastructure.

Additionally, in response to perceived increased exposure to ACOs from ongoing Medicare fraud, CMS finalized, as proposed, its narrow policy excluding Significant, Anomalous, and Highly Suspect ("SAHS") billing from MSSP calculations. CMS defined SAHS as cases where "a given HCPCS or CPT code exhibits a level of billing that represents a significant claims increase either in the volume or dollars (for example, dollar volume significantly above prior year, or claims volume beyond expectations) with national or regional impact (for example, not only impacting one or few ACOs) and represents a deviation from historical utilization trends that is unexpected and is not

clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services." This policy gives CMS sole discretion to identify and exclude SAHS billing activity from MSSP calculations. CMS will remove SAHS claims from the benchmark calculations (*e.g.*, baseline and trend) as well as the ACO's expenditures. CMS stated its intent to only use "rare and extreme cases," where the SAHS activity has "regional or national impact" and affects "more than one or a few" ACOs.

3. CMS Has Yet to Finalize the Proposed Mandatory Organ Transplant Payment Model

In October 2024, the Innovation Center indefinitely delayed the implementation of its proposed Increasing Organ Transplant Access Model ("IOTA Model"). In an announcement posted on the model website, the Innovation Center stated that it was "continuing its work" on the model and anticipates "a later start date for the model than the proposed start date of January 1, 2025."

In May 2024, the Innovation Center issued a proposed rule announcing a mandatory six-year Medicare payment model for kidney transplant hospitals, with a comment period that closed July 16, 2024. The IOTA Model would test whether performance-based payment improves access to kidney transplants for patients with end-stage renal disease. Participation would be mandatory for all transplant hospitals with an active kidney transplant program – defined as eleven transplants over a three-year period – within donation service areas ("DSA") to be selected by the Innovation Center. The Innovation Center intends to select half of all DSAs in the country and all eligible hospitals would be selected to participate in the model.

As proposed, participating hospitals would receive a performance score based on three criteria: (1) the number of kidney transplants; (2) the organ offer acceptance rate; and (3) performance on quality measures. Based on this performance score, hospitals would receive an additional payment, owe a downside risk payment to CMS, or fall into a neutral zone in which it neither receives nor owes any additional payment. For each transplant, the maximum upside risk payment would be $8,000 and the maximum downside risk payment would be $2,000 per transplant. The IOTA Model would also include a health equity performance adjustment, for transplants performed for patients in pre-defined, low-income populations.

Since the issuance of the proposed rule, many hospitals have pushed back against the model, citing various concerns, including the impact of a mandatory model on eligible hospitals at a time when transplant hospitals are already facing significant change as a result of the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative and Securing the U.S. Organ Procurement and Transplantation Network Act. Given the Innovation Center's indefinite delay of the model, its future remains uncertain.

In a June 20 podcast episode, "Hospital & Health System Value-Based Care Strategy Update: Lightning Round with Practitioners in the Trenches," health care partners Stephanie Webster, Devin Cohen, Ben Wilson and counsel Dave Ault addressed the financial viability of Accountable Care Organizations (ACOs), the implications of transactions on ACO participation, whistleblower allegations within ACOs, the necessity of separate legal entities for program participation, data sharing compliance, leveraging AI for ACO administration, and new compliance risks in value-based care arrangements.

340-B Updates

CMS Issues Medicaid Drug Rebate Program Final Rule

On September 20, 2024, CMS issued a long-awaited final rule entitled Medicaid Program; Misclassification of Drugs, Program Integrity Updates Under the Medicaid Drug Rebate Program ("MDRP"). Of note, the final rule updated components of the covered outpatient drug definition, allowing for rebates to be collected on certain drugs subject to reimbursement as part of a "bundle."

The statutory definition of covered outpatient drug "does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of [a list of services set forth in the regulation] (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug)." Historically, this provision has been understood to foreclose rebates where payment for a drug is "bundled" with payment for a service. However, the final rule defines "direct reimbursement" as "includ[ing] both (i) reimbursement for a drug alone or (ii) reimbursement for a drug plus the service, in a single inclusive payment if: (A) the drug, charge for the drug, and number of units of the drug are separately identified on the claim; and, (B) the inclusive payment includes an amount directly attributable to the drug; and, (C) the amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan."

CMS noted that modifying the definition of covered outpatient drug will support states' ability to collect rebates on various physician-administered drugs, making these therapies more affordable to the Medicaid program. The rule, which goes into effect on November 19, may make it more attractive for state Medicaid programs to pursue bundled reimbursement methodologies for drugs and related services. The rule itself only applies to covered outpatient drugs under the MDRP, but raises questions regarding the scope of drugs eligible for discounts under the 340B program, which draws upon the same legal definition for purposes of defining 340B covered drugs.

HRSA Rejects J&J's Proposed Rebate Model

HRSA continues to engage with Johnson & Johnson ("J&J") on the pharmaceutical company's contemplated model to adhere to the 340B drug discount program ("340B Program"), with J&J announcing on September 30, 2024 that it would not continue to pursue the model at this time. A brief history of this engagement follows.

On August 23, 2024, an affiliate of J&J announced a controversial proposed model for allowing one category of covered entity to obtain 340B discounts on two drugs. The manufacturer's model would have applied to Stelara, a drug used to treat psoriasis and Crohn's disease, and Xarelto, a blood thinner, in connection with purchases by DSH hospitals participating in the 340B Program. Under the proposed model, a DSH hospital would have needed to purchase Stelara and Xarelto at a commercial price through wholesalers and, upon a DSH hospital's submission of rebate claim data, J&J would have validated that the purchases were made by an eligible covered entity and dispensed from eligible 340B locations and then, where satisfied, made a rebate payment to the hospital equal to the difference between the list price and the 340B ceiling price. J&J intended to implement the 340B rebate model beginning on October 15, 2024.

J&J had clarified that this model would only apply to Stelara and Xarelto, and that it would honor the 340B price for eligible DSH hospital claims, which would be automatically validated and paid within 7-10 days of validation. As a result, J&J said it expected that DSH hospitals would receive their rebate before needing to pay wholesalers for the drugs, easing cashflow concerns while minimizing J&J-perceived 340B Program abuses such as diversion.

In a September 17, 2024 open letter to J&J's chairman and chief executive officer, HRSA stated that J&J's plan was impermissible under the federal 340B statute because it would result in setting mandatory purchase prices above the statutory 340B ceiling price. HRSA said the HHS Secretary must approve of any rebate mechanism and has not done so for this rebate model. HRSA distinguished J&J's rebate model from other HRSA-designated-permissible "replenishment" processes. HRSA said that, under a typical replenishment model, a covered entity may voluntarily make an initial purchase of a prescription drug at a higher price, but subsequent purchases of that drug are then made at the 340B ceiling price. Under J&J's model, HRSA argued that every drug purchase *must* be at the list price, creating higher up-front costs for covered entities.

In its September 17 letter and then again on September 27, 2024, HRSA advised J&J to cease implementation of its 340B rebate model immediately and to send notice to the agency by September 30, 2024, indicating that the company had halted implementation of its 340B rebate model. On September 27, 2024, HRSA informed J&J that if J&J did not cease implementation of the rebate model and inform HRSA of having done so by the given deadline, HRSA would begin the process to terminate J&J from the 340B Program and initiate a referral to the OIG to initiate civil monetary penalties.

On September 30, 2024, J&J informed HRSA that "due to HRSA's unwarranted threats of excessive and unlawful penalties," it decided to forgo implementation of the rebate model, pending resolution of the issues, while reiterating that it believes the rebate strategy would improve transparency through real-time data validation.

Eighth Circuit Sides with Maryland over Manufacturers on Contract Pharmacy Issue

On September 5, 2024, the U.S. District Court for the District of Maryland declined a request by Novartis Pharmaceuticals, AbbVie, AstraZeneca Pharmaceuticals, and the Pharmaceutical Research and Manufacturers of America ("PhRMA") to enjoin a Maryland state law that requires manufacturers in the 340B Program to provide drugs at a discounted price to pharmacies that contract with 340 Program covered entities. The judge did not provide written reasoning for his decision to side with the State of Maryland, but instead referenced discussions that took place in open court during the motion hearing. This Maryland court action is only one recent action in an ongoing, multi-jurisdictional controversy regarding whether states can require manufacturers to honor 340B discounted prices.

With federal litigation ongoing, several state legislatures have enacted these contract pharmacy-mandate laws, starting in 2021 with Arkansas. Arkansas's law survived a legal challenge brought by PhRMA. The Court of Appeals for the Eighth Circuit found that the 340B statute did not preempt the Arkansas law. Manufacturers and PhRMA have filed suit to challenge such state mandate laws in other jurisdictions, including Arkansas, Mississippi, and West Virginia.

Under the 340B Program, covered entities must offer covered outpatient drugs at discounted pricing to an enumerated list of covered entities. Rather than distributing 340B drugs through their own in-house pharmacies, some covered entities dispense drugs through third-party pharmacies with which they have a contractual relationship (so-called "contract pharmacies"). HRSA has issued guidance permitting covered entity use of contract pharmacy arrangements. 75 Fed. Reg. 10272 (Mar. 5, 2010). Manufacturers have contended that the 340B statute does not expressly mandate, or even permit, the use of contract pharmacies and that restrictions are necessary to prevent duplicate discounts and diversion. Manufacturers have responded to expansion in the use of contract pharmacies by imposing restrictions on the use of contract pharmacies, including limiting contract pharmacies to a particular number or to a certain geographic proximity from the covered entity.

Litigation focused on the right of manufacturers to impose such restrictions has ensued, with the Third Circuit finding that manufacturers are not mandated to comply with contract pharmacy requirements and are permitted to impose restrictions, since the 340B statute is silent on the use of contract pharmacies. *See Sanofi Aventis v. U.S. Department of Health and Human Services*, 58 F.4th 696 (3rd Cir. 2023).

Prescription Drug Affordability Boards

In 2019, Maryland became the first state to authorize a prescription drug affordability board ("PDAB") to study and regulate the costs of prescription drugs in the state. Some state PDABs have authority to institute upper payment limits ("UPLs") that cap what the state or other payors may reimburse for identified drugs. To date, nearly a dozen states, including Massachusetts, New York, and Washington, have enacted laws authorizing PDABs. As states continue to mobilize their PDABs to examine and to set UPLs, there are open questions regarding the lawfulness of the PDAB statutes and their potential spill-over consequences for multiple stakeholders, including whether UPLs may under-reimburse health care providers. In enacting statutes that create PDABs, states such as Maryland appear to be attempting to avoid the pitfalls that Maryland confronted when it attempted to penalize price increases on generic drugs, (a practice that the Fourth Circuit held violated the Dormant Commerce Clause under the Constitutional), by limiting *reimbursement* rather than drug *prices*.

Colorado's PDAB is the furthest along in its UPL-setting process. In late 2023, Colorado's PDAB selected five prescription drugs for affordability review: Amgen's Enbrel for rheumatoid arthritis/autoimmune diseases; Gilead Science's Genvoya for human immunodeficiency virus; Novartis's Cosentyx for psoriasis/psoriatic arthritis; Janssen Biotech's Stelara for psoriasis/psoriatic arthritis; and Vertex's Trikafta for cystic fibrosis. The PDAB later determined that Genvoya and Trikafta are not "unaffordable" and therefore will not be subject to a UPL at this time. The PDAB has begun the price-capping process for the remaining three drugs. Amgen has legally challenged the Colorado statute authorizing the PDAB and granting it price-control authority. Briefing in this case remains ongoing.

What Have Our Hospital & Health System Lawyers Been Up To?

On October 5, health care partner Ranee Adipat presented at the International Performance Management Institute's Healthcare Law & Compliance Institute conference on "How State Regulations on Health Care Costs, Market Concentration, and Health Care Quality Impact the Industry's Transactions."

Ropes & Gray's hospital and health system lawyers launched HealthTrax, an interactive map that offers real-time updates on state health care transaction laws related to competition, quality, access, cost and more. We continue our exploration of these critical developments in health care regulation of health care transactions in a six-part podcast series that launched on September 17: *Health Care Transaction Laws Unwrapped*.

- The first episode, "Navigating Expanding Government Oversight of Health Care Investments," featured partners Debbie Gersh, Tim McCrystal and Jennifer Romig analyzing the current regulatory climate and its implications for investments in health care.
- The second episode, "Recent Developments in the Midwest," featured partners Debbie Gersh, Jennifer Romig and associate Shanzeh Daudi discussing recent developments and trends related to state health care transactions in the Midwest including in Illinois, Indiana and Minnesota.
- The third episode, "Recent Developments on the East Coast," featured partners Brett Friedman and Ben Wilson, and associate Sharon Jaquez discussing recent developments in New York, Massachusetts, Connecticut and Pennsylvania, including practical insights on navigating the evolving regulatory landscape, the impact on deal timelines, confidentiality, and strategic considerations for health care entities and private equity investors.
- The fourth episode, "Recent Developments on the West Coast," featured partners Ranee Adipat and Jennifer Romig and associate Jaclyn Freshman discussing recent developments in California and Oregon, including California's AB 3129 and Oregon's proactive enforcement.

On August 12, health care partner Brett Friedman shared an op-ed article in *Crain's New York Business* examining what success might look like for the $7.5 billion Medicaid 1115 Demonstration Waiver Program, including metrics that might measure success such as rate of screen for unmet social needs, emergency department utilization in patient admissions, and impact on total cost of care for Medicaid beneficiaries.

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 Jennifer Henderson, *Hospitals Still Feeling Impacts of Hurricane Helene*, MEDPAGE TODAY (Oct. 3, 2024); Susanna Vogel, *Hurricane Milton disrupts infrastructure, could trigger more hospital evacuations in Florida*, HEALTHCAREDIVE (Oct. 10, 2024).

2 Examples of requirements that may be waived or modified include: (a) Conditions of participation or other certification requirements (b) Program participation and similar requirements; (c) Preapproval requirements; (d) Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure); (e) Emergency Medical Treatment and Labor Act; (f) Stark self-referral sanctions; (g) Performance deadlines and timetables may be adjusted (but not waived); (h) Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers.

3 *See, e.g.*, https://www.justice.gov/usao-ma/pr/united-states-files-complaint-against-st-elizabeths-medical-center-steward-medical-group; https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-erlanger-health-system.