Hospital and Health Systems

Reimbursement Check

MARCH 2025

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

Focus On Trump 2.0: Implications for Hospitals and Health Systems

In the short time since taking office on January 20, President Donald Trump has taken executive actions calling for sweeping changes affecting the health care sector. While new administrations always bring changes, the speed and breadth of reforms the Trump Administration has introduced through executive orders and other actions have been striking. Although the current administration has only begun to implement its health care priorities, it has signaled that the next four years may significantly reshape health care reimbursement—and health care writ large.

HHS Leadership

Department of Health and Human Services. On February 13, the Senate confirmed Robert F. Kennedy, Jr. as Secretary of the U.S. Department of Health and Human Services ("HHS") after a highly debated confirmation process. Secretary Kennedy will oversee a vast public health system with a budget nearing $2 trillion. At HHS, Kennedy is expected to focus on reforms to the U.S. Food and Drug Administration ("FDA"), Centers for Disease Control and Prevention ("CDC"), and National Institutes of Health ("NIH").

Centers for Medicare & Medicaid Services. President Trump nominated Mehmet Oz, MD, as CMS Administrator, highlighting Dr. Oz's focus on disease prevention and reducing perceived fraud and waste at CMS. If confirmed, Dr. Oz has stated he will focus on chronic conditions and may push for an expansion of Medicare Advantage. He has publicly supported expanding Medicare Advantage, even proposing a "Medicare Advantage for All" plan during his 2022 Senate campaign but has also spoken of his intent to scrutinize plan risk coding practices.

Executive Orders and Other Government Actions

Deregulation and Decreasing Federal Spending. On January 20, President Trump signed Executive Order 14158 to establish the U.S. Department of Government Efficiency ("DOGE") as a temporary organization within the Executive Branch. Led by Elon Musk, DOGE's stated goal is to reduce federal spending and eliminate regulations. In coordination with DOGE, HHS has reportedly canceled $182 million in contracts and offered employee buy-outs to accompany its forced workforce terminations. On March 7, HHS revealed that 2,908 HHS employees had been fired, factoring in 591 employees who were later rehired. As of early March, the DOGE website claimed that, among federal agencies, HHS experienced the ninth largest savings due to DOGE spending reductions.

On January 31, Executive Order 14192 mandated that agencies repeal 10 existing regulations for each new one, purportedly aiming for a net reduction in regulatory costs. Notably, the executive order applies only to discretionary rulemaking, not to mandatory payment rules, such as the Medicare Physician Fee Schedules or Hospital Inpatient Prospective Payment System. More specifically, for the purpose of this executive order, a "regulation" includes an agency statement intended to

implement, interpret, or prescribe law or policy, or to describe agency procedure or practice requirements. This excludes regulations related to, among other areas, agency organization, management, and personnel.

Immigration. Executive Order 14159, signed on January 20, states that the Secretary of the Department of Homeland Security ("DHS") may authorize state and local law enforcement to perform the federal immigration enforcement functions and aims to block federal funding for so-called "sanctuary" cities. On the same day, Acting DHS Secretary Benjamine Huffman rescinded previous Biden-era restrictions on immigration-related enforcement actions in sensitive areas like hospitals and schools. Although the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and other federal and state privacy laws apply to undocumented individuals, patients may be more reluctant to disclose certain personal information to providers necessary for submitting reimbursement claims. Additionally, on February 25, Executive Order 14218 directed agencies to exclude "ineligible aliens" from public benefits and further restrict federal funding to undocumented immigrants, potentially affecting health care reimbursement.

Diversity, Equity, and Inclusion ("DEI"). In Executive Orders 14151 and 14173, President Trump directed executive departments and federal agencies to terminate any DEI programs. Pursuant to this directive, the CDC issued memos on January 29 to recipients of grant funding directing grantees to "immediately terminate, to the maximum extent, all programs, personnel, activities, or contracts promoting [DEI]," but later rescinded the memo to comply with a temporary restraining order ("TRO") issued by a federal court.

Artificial Intelligence. On January 23, President Trump signed Executive Order 14179 mandating the creation of an AI Action Plan that the executive order states is necessary to maintain U.S. global AI dominance, promote economic competitiveness, and bolster national security. While this executive order does not automatically repeal all Biden-era AI measures, it calls for the suspension or revision of actions conflicting with its stated goals of enhancing the country's "global AI dominance" to promote economic competitiveness and national security. Advancements in AI could potentially enhance diagnostic accuracy, facilitate personalized treatment plans, and improve operational efficiencies, ultimately improving patient outcomes and reducing costs. Hospitals and health systems should continue to monitor developments in this area, given the implications of AI policy for reimbursement.

Make America Healthy Again ("MAHA") Movement. On February 13, President Trump signed Executive Order 14212, establishing the MAHA commission with Secretary Kennedy as its Chair. According to the Executive Order, the commission's mission will be to "advise and assist the President on how best to exercise his authority to address the childhood chronic disease crisis." A few weeks later, Executive Order 14221 stated that it was building on efforts to advance the MAHA movement by mandating certain federal agencies to take specific action to promote health care price transparency. In line with the executive order, Secretary Kennedy has stated his intent to shift the focus of HHS to addressing chronic illness, in part by revising FDA approval guidelines and shifting NIH research priorities. The Center for Medicare and Medicaid Innovation also intends to implement new payment models aimed at chronic conditions and nutrition. In Executive Order 14221, President Trump also referenced Executive Order 13877 of June 24, 2019 ("Improving Price and Quality Transparency in American Healthcare to Put Patients First"), under which the first Trump Administration issued regulations requiring hospitals to maintain "consumer-friendly" pricing information and requiring health plans to post publicly their negotiated rates, out-of-network payments to providers, and certain prescription drug pricing information. Specifically, the new Executive Order 14221 instructs the HHS Secretary to require the disclosure of the actual prices of items and services, not estimates, so that, according to the executive order, patients have access to clear and actionable pricing information. The later Executive Order also directs the Secretary Kennedy to issue updated guidance or proposed regulatory action to help ensure that pricing information is standardized and easily comparable across hospitals and health plans.

Trade Policy. The Trump Administration has taken swift action on tariffs as part of its "America First" initiatives. On February 1, 2025, President Trump announced 25% tariffs on imports from Canada and Mexico and 10% tariffs on imports from the People's Republic of China. While the tariffs on Canada and Mexico were later put on hold, President Trump has moved forward with additional tariffs. On February 10, he proclaimed that, effective March 12, all steel and aluminum imports would be subject to a 25% tariff. The European Union has announced countermeasures, but the tariffs remain in place at the time of publication. These moves are likely to affect companies and consumers by escalating health care costs, disrupting supply chains, and creating affordability challenges through, for instance, higher prices of medical devices imported into the United States.

Research Funding. On February 7, Acting NIH Director Matthew J. Memoli, MD, MS issued Notice No. NOT-OD-25-068 announcing a 15% cap on indirect facilities and administration costs for all future federal research grants and for existing grants to institutions of higher education. However, on February 10, a federal court issued a TRO blocking these cuts from taking effect, followed by a nationwide preliminary injunction issued on March 5 that enjoins the NIH from taking any steps to implement, apply, or enforce the cap on indirect cost payments—for all grant recipients, not only the named plaintiffs—while the judge hears lawsuits affecting billions in federal funds for universities and medical centers.

Antitrust in Mergers and Acquisitions. On February 18, new Federal Trade Commissioner Chair Andrew Ferguson announced that the Trump Administration will retain certain Biden-era merger guidelines, signaling that there may be greater continuity with Biden-era competition policy than previously anticipated.

Expected Future Activity

Prescription Drug Costs. The Trump Administration has rescinded a Biden-era executive order requiring HHS to develop drug pricing models for Medicare and Medicaid enrollees, potentially hindering implementation of CMS's Innovation Center models. Further, although the Inflation Reduction Act limits certain changes to the Medicare Drug Price Negotiation Program, President Trump may attempt to weaken the law. Project 2025 recommends repealing the Inflation Reduction Act Medicare negotiation program, but it is likely to be preserved due to its projected cost savings and difficulty in replacing. 340B reform could be revisited (the first Trump administration made significant cuts to 340B reimbursement), however Senate Majority Leader John Thune (R-SD) is a strong supporter of the 340B program. The Administration is also expected to promote access to generics and biosimilars as part of President Trump's efforts to decrease federal spending on health care programs.

Medicare Advantage. While "Medicare Advantage for All" is unlikely, President Trump will likely support policies favorable to Medicare Advantage plans. At the same time, reforms to address concerns regarding prior authorization, utilization management techniques, and marketing strategies may continue. Changes to Star Ratings and risk adjustment are also possible. The health equity index, which will be incorporated into Star Ratings beginning in performance year 2028, will likely be rebranded or reframed rather than repealed outright, given its potential to benefit rural communities and its alignment with MAHA movement priorities such as improving health through focusing on aspects beyond the traditional health care system, including food safety, nutrition, and the environment.

Medicaid. On January 30, CMS announced a review of states' Section 1115 Medicaid waivers, which could lead to the revocation of waivers approved during the final days of the Biden Administration. Additionally, recent debates in Washington have reportedly focused on Medicaid reforms. While there is support among Republicans in the Executive Branch for implementing work requirements, premiums, and eligibility restrictions, some are concerned that Congress's $2 trillion in spending cuts will require reductions to Medicaid. Republican legislators in competitive districts worry about electoral backlash from constituents reliant on Medicaid. According to experts, spending cuts could result in the potential loss of health insurance coverage for millions of enrollees due to work requirements, reduced federal matching rates (if states opt to undo their Medicaid expansions), and per capita caps (if states reduce optional services and implement more restrictive eligibility requirements).

Conclusion

The Trump Administration has already begun to reshape the health care landscape, and future actions by the Administration and Congress could significantly impact hospitals and health systems. Ropes & Gray is staying on top of these developments and their implications. The firm will continue to provide updates on such developments through distribution of client alerts, which you may sign up for here.

Docket Updates

1. *Montefiore Medical Center v. Becerra*, No. 24-cv-1810

The lead case in the U.S. District Court for the District of Columbia ("D.D.C.") challenging the June 2023 final rule governing the treatment of part C days in the Medicare disproportionate share hospital ("DSH") calculation for periods prior to October 1, 2013, *Montefiore Medical Center v. Becerra* (D.D.C. Case No. 24-cv-1810), has now entered the merits briefing stage.

Unlike in other cases attempting to challenge the 2023 rule or published SSI fraction without first receiving NPRs, the government in *Montefiore* did not challenge the Court's jurisdiction to review the hospital's challenge to the application of the 2023 final rule in its NPR.

The hospital's opening brief in *Montefiore* argues that the 2023 rule violates the Medicare statute's prohibitions on retroactive rulemaking, where the agency seeks to establish or change a substantive legal standard or where the final rule is not a logical outgrowth of the proposed rule. The brief further argues that the limited carve-out for retroactive rulemaking does not save the 2023 rule because retroactive rulemaking is only permitted to change, not to establish, a substantive payment standard, and the agency, in its rulemaking, not only claimed to be establishing a policy, but also flatly denied (again) any change.

The brief argues that the specific provisions requiring advance notice and comment after logical outgrowth failures and prohibiting actions against providers for services prior to a rule's effective date also control over the general authorization for retroactive rulemaking. Regardless, the brief argues that neither of the limited exemptions permitting retroactive rulemaking, as historically construed by the agency, justifies the 2023 rule's retroactivity. Consistent with the agency's decision to adopt the same policy only prospectively in 2013, the brief argues that applying the rule prospectively is not contrary to the public interest, particularly where the 2023 rule harms the public interest in lawful DSH payments. Further, the brief argues that retroactivity is not required to make DSH payments, where the restored pre-2004 standard could be applied and DSH payments had concededly already been made. The brief also argues that the agency cannot avoid these strict prohibitions on retroactivity based on its new embrace of *Becerra v. Empire Health Foundation for Valley Hospital Medical Center*, 597 U.S. 424 (2022), because the agency has repeatedly recognized that the statute does not require a particular reading on Part C days, and no court has found otherwise (including *Empire*, which did not disturb the D.C. Circuit law that the statute is ambiguous as to Part C).

In addition, the brief argues that the new rule is arbitrary and capricious for a variety of reasons, including that the agency failed (1) to acknowledge, let alone explain, that the policy adopted retroactively in the 2023 rule (which had previously been adopted as prospective-only in 2013) departed from the pre-2004 rule and practice; (2) to consider properly the reliance of hospitals nationwide on the agency's longstanding, pre-2004 position; or (3) to contend with the enormous adverse financial

impact on hospitals and other inconsistencies brought about by the agency's policy change.

The government's opposition and cross-motion for summary judgment is due March 28, and briefing is currently scheduled to be completed by late June.

2. *St. Mary's Regional Med. Ctr. v. Becerra*, No. 23-01594

On December 20, 2024, the D.D.C. held that the Medicare statute does not preclude judicial review of a challenge to the undercalculation of the Inpatient Prospective Payment System ("IPPS") standardized amount calculation resulting from an alleged error in the 1983 IPPS rule. The Court remanded the case to the Provider Reimbursement Review Board ("PRRB" or "Board") to adjudicate the hospitals' request for expedited judicial review.

The plaintiff hospitals filed administrative appeals with the PRRB and sought expedited judicial review, seeking recalculation of their FY 2019 IPPS payments. The hospitals argue that CMS incorrectly counted transfers as discharges in determining the initial standardized amount calculated for the 1983 base year, an error that was carried forward in the standardized amount calculations for all subsequent years. The hospitals argue that because the error in the standardized amount has been carried forward to later periods, their FY 2019 IPPS payments have been understated.

The PRRB dismissed the hospitals' appeals. The Board claimed that it lacked subject matter jurisdiction because the standardized amounts are "inextricably intertwined" with certain budget neutrality adjustments, *see* 42 U.S.C. §§ 1395oo(g)(2), 1395ww(d)(7), of which the Medicare statute precludes review. The hospitals challenged the Board's dismissal, and the Court held the PRRB has jurisdiction to rule on the hospitals' expedited judicial review ("EJR") request. In remanding the appeals to the PRRB, the court held that the IPPS standardized amounts are not inextricably intertwined with the Secretary's budget neutrality adjustments, reasoning that "[n]one of the Preclusion Provisions affords any textual support whatsoever for the proposition that Congress meant to preclude review of the Secretary's inaugural standardized amount calculation. Such a reading is not even plausible, let alone compelling enough to surmount the presumption of reviewability."

There are several other similar challenges that have been stayed pending the final result of *St. Mary's*, including *Adena Regional Medical Center et al v. Becerra*, Case No. 24-cv-3336 (D.D.C. Nov. 26, 2024), involving 500 hospitals, and *Acadia Gen. Hosp. v. Becerra*, Case No. 24-cv-0936 (D.D.C. April 1, 2024) involving 30 hospitals. The hospitals in *St. Mary's* have now cleared a major jurisdictional hurdle and are therefore closer to reaching a ruling on the merits of their claims challenging the calculation of the standardized amount.

3. *Sanford Bismarck*, No. 23-cv-114 & *Banner Health* No. 23-cv-00962

Two potential settlements, *Sanford Bismarck v. Becerra*, No. 23-cv-114 (D.D.C. Jan. 13, 2023) ("Sanford Bismarck") and *Banner Health v. Becerra*, No. 23-cv-962 (D.D.C. Apr. 7, 2023) ("*Banner Health*"), may soon help pave the way for increased capital DSH payments for hospitals with appeals pending for periods prior to October 1, 2023.

In both cases, groups of hospital plaintiffs challenge the continued enforcement of a 2006 rule that rendered ineligible to receive capital DSH adjustments geographically urban hospitals that had been reclassified under Section 401 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (42 U.S.C. § 1395ww(d)(8)(E)) as rural for operating purposes.

Previously, on September 30, 2021, the D.D.C. ruled in another case that the 2006 rule excluding reclassified urban hospitals from eligibility for capital DSH payments was arbitrary and capricious. The D.D.C. found that the rule misrepresented the Secretary's previous policy on the matter and failed to consider the capital costs across different geographic areas. *See Toledo Hosp. v. Becerra*, No. 19-cv-3820, 2021 WL 4502052 (D.D.C. Sept. 30, 2021). However, the D.D.C. rejected *Toledo's* arguments that the 2006 Rule violated the plain language of the Medicare Act. On that point, the Court found the statute permits CMS to treat hospitals as rural for capital PPS purposes, rejecting *Toledo's* claim that the statute should only apply to operating PPS. *Id*. In addition, the D.D.C. concluded that the statute does not require the Secretary to pay hospitals for the greater capital costs that they incur, but rather that the capital PPS provision of the statute "merely requires the Secretary to 'take into account' variations in the relative capital costs." *Id*.

The agency has since acquiesced in the *Toledo* decision on a prospective basis in the Fiscal Year 2024 IPPS rule and revised the capital DSH regulations so that hospitals reclassified as rural will no longer be considered rural for purposes of determining eligibility for capital DSH payments, effective for discharges occurring on or after October 1, 2023 (88 Fed. Reg. 59117 (Aug. 28, 2023)).

Despite the *Toledo* ruling and the new rule acquiescing to that decision for periods on or after October 1, 2023, CMS continued to apply the 2006 rule, and litigation on the issue thus continued, including the *Sanford Bismarck* and *Banner Health* cases. The plaintiff hospitals in *Sanford Bismarck* and *Banner Health* seek judicial review of the application of the 2006 rule to pre-October 1, 2023, cost years. Both cases have been stayed for nearly a year pending settlement negotiations, and in January 2025, the government indicated that a final settlement in both cases is imminent. The resolution of *Sanford Bismark* and *Banner Health* may pave the way for other hospitals to receive capital DSH payments for pre-2023 cost years.

4. *Baptist Healthcare System v. Fink*, No. 25-205

In January 2025, hospitals sued the Secretary of Health and Human Services alleging that the PRRB improperly dismissed their appeals challenging the Secretary's inconsistent interpretation of "entitled" to benefits in the SSI fraction used to calculate the hospitals' DSH adjustment in the June 2023 Part C days final rule. *See Baptist Healthcare System v. Fink*, No. 25-cv-205 (D.D.C. Jan. 23, 2025). The hospitals appealed from revised NPRs issued pursuant to the February 2024 transmittal instructing the MACs to implement the June 2023 Part C days final rule (discussed above). *See Change Request (CR) to Implement the Medicare Program Final Action: Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage*, CMS Manual System, Pub. 100-20, Transmittal 12513, CR 13294 (Feb. 1, 2024) (instructing Medicare contractors to apply the June 9, 2023 final rule in revised NPRs for remanded appeals of pre-October 1, 2013 cost reporting periods).

In addition to challenging the inclusion of Part C days in their SSI fractions, the hospitals also argued the number of SSI-entitled days included in the SSI fraction numerator have been understated because "the Secretary's dissimilar construction of the term 'entitled' in the DSH statute" violates the plain meaning and intent of the Medicare statute. A similar argument is currently being reviewed by the Supreme Court in *Advocate Christ Medical Center v. Becerra*, cert. granted, 144 S. Ct. 2629 (June 10, 2024) (No. 23-715) . The hospitals in the Baptist case are trying to appeal the understatement of the SSI days included in the SSI fraction numerator from their revised NPRs implementing the June 2023 part C days rule.

The Board held that it lacked jurisdiction over the appeals challenging the understatement of the SSI fraction because "under 42 C.F.R. § 405.1889(b)(1), an appeal from a revised final determination is limited in scope to 'only those matters that are specifically revised,' and the revised NPRs from which the Plaintiffs appealed only afforded appeal rights 'with respect to the treatment of Part C Days in the calculation,' and 'the reasonableness of the Secretary's interpretation set forth in [the Part C Days Final Rule]'" *Id*. at 9.

The hospitals then petitioned a federal district court in the District of Columbia to vacate the Board's decision and, on the merits, set aside the payments issued to the Plaintiffs and find the "Secretary's manner of counting SSI Days in the Medicare fraction numerator of the [disproportionate patient percentage]" contrary to statutory law. *Id*. at 10. Briefing in the case is not yet scheduled.

5. *Baylor All Saints Medical Center, et al., v. Kennedy*, No. 24-10934

On January 22, 2025, the government filed its opening brief in the Fifth Circuit Court of Appeals in its appeal of the U.S. District Court for the Northern District of Texas's (the "Texas Court") ruling striking down the section 1115 waiver days provision of the FFY 2024 IPPS rule (effective October 1, 2023). *Baylor All Saints Medical Center, et al., v. Becerra*, No. 24-cv-432 2024 WL 3833278 (N.D. TX, 2024). That provision 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 (the "Exclusion Rule"). *See Baylor All Saints Medical Center, et al., v. Becerra* in the Docket Update section of the November 2024 Newsletter for details on the section 1115 waiver days policy. The Texas court granted the plaintiff hospitals' request for a preliminary injunction and vacated the portion of the 2024 IPPS rule excluding section 1115 waiver days for patients whose care is provided through uncompensated care pools. The Texas court held that under *Forrest General Hosp. v. Azar*, 926 F.3d 221, 228–29 (5th Cir. 2019), 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 government appealed the decision to the Fifth Circuit. In its opening brief, the government argued that the Secretary has "always had. . .broad discretion" under the Medicare statute "to determine whether (and to what extent) to include patients covered by a [section 1115 waiver] project in the Medicaid fraction numerator." The government argued that the availability of section 1115 waivers as "supplemental funding should have no bearing on a hospital's disproportionate share calculation" because the waivers do not actually provide insurance coverage for patients. The government argued that the Exclusion Rule in the FFY 2024 IPPS rule aims to "amend[] the regulatory text to better comport with the agency's original intent" of the waiver days policy. *See* 88 Fed. Reg. 58,640, 59,015 (Aug. 28, 2023) ("[I]t was never our intent . . . to include in the . . . Medicaid fraction numerator days of patients that benefited so indirectly from a demonstration"), despite contrary holdings in *Forrest General* and a related case, *Bethesda Health, Inc. v. Azar*, 980 F.3d 121 (D.C. Cir. 2020) dealing with an earlier version of the same regulation. The government also argued that the plaintiffs did not properly channel their challenge through the administrative appeals process because the Board had dismissed the appeals on the ground that the portion of the rule being challenged was not a "final determination," and the district court therefore lacked jurisdiction to enjoin the Exclusion Rule. Plaintiff hospitals argued in their response that the court's holding in *Forrest General* is not limited to its application to the prior waiver days rule as the government argued but is instead about the requirements of the Medicare statute and precludes the Secretary's interpretation of the statute in the now vacated rule.

The rule remains vacated pending appeal, and the government's reply brief was due March 21.

6. Appeals of Board Dismissals of Jurisdictionally Challenged Section 1115 Waiver Days Appeals

Since last fall, several providers have sued in federal district court challenging PRRB dismissals of appeals challenging the Secretary's decision not to include days for patients receiving assistance under a section 1115 waiver in the Medicaid fraction for periods before 2023. See, e.g., Compl. at 19, Steward Melbourne Hospital v. Becerra, No. 6:24-cv-01906 (M.D. Fl. 2024), ECF No. 1 (challenging the calculation of payments for the fiscal years ending in 2015). These cases follow recent steps the agency has taken to resolve section 1115 waiver days appeals, including the issuance of a technical direction letter directing MACs to accept amended cost reports including section 1115 waiver days in the DSH calculation, and transmittal directing MACs to resolve pending waiver days appeals by May 2025. *See* Change Request 12,669 (directing MACs to resolve section 1115 waiver days appeals within 24 months of transmittal's May 2023 implementation date).

In each of these cases, the providers timely appealed the exclusion of Medicaid eligible days in their DSH adjustments but later sought to include a challenge to the exclusion of section 1115 waiver days from the DSH calculation in their Medicaid eligible days appeal. The Board dismissed the hospitals' challenges specifically relating to the section 1115 waiver days issue. The Board reasoned that the section 1115 waiver days issue was a distinct issue that the providers did not raise before the appeal deadline. The hospitals, in contrast, claim that this issue was properly before the Board as part of its appeal challenging the exclusion of Medicaid eligible patient days in the Medicaid fraction because all Section 1115 Waiver days are necessarily Medicaid eligible days.

Accordingly, the providers challenge the Board's dismissals as "ultra vires, arbitrary and capricious, an abuse of discretion, and otherwise contrary to the Medicare Act." *Id*. at 19. Most of these cases have been stayed pending a decision in *Baylor All Saints Medical Center v. Becerra*, No. 4:24-cv-156 (N.D. Tex.), which presents a similar jurisdictional issue. *See, e.g.,* Joint Mot. Stay, *Bayfront Health v. Becerra*, No. 24-2491 (M.D. FL. Jan. 15, 2025). While there is long-standing precedent for the hospitals to overcome in raising a "new" issue later in the administrative appeals process, these cases could potentially create a pathway for hospitals to receive increased DSH payments through resolving section 1115 waiver days appeals via appeals of the Medicaid eligible days issue.

7. *Texas Medical Association v. HHS*, No. 23-40605

The Texas Medical Association ("TMA") challenged the implementation by the Departments of the Treasury, Labor, and Health and Human Services (collectively, the "Departments") of the No Surprises Act's dispute resolution provisions in four separate cases (commonly referred to as TMA I, TMA II, TMA III and TMA IV). The No Surprises Act limits the amount out-of-network providers can charge patients for emergency and certain non-emergency services, attempting to protect patients from "surprise" bills. We described the several TMA actions relating to the No Suprises Act in the May 2024 Newsletter.

TMA III challenged whether HHS's original July 2021 interim final rules artificially deflate the qualifying payment amount ("QPA"), an amount that helps to determine patients' and insurers' obligations to out-of-network providers under the Act. TMA argued that the final rules deflate the QPA by, among other things, accounting for ghost rates (*i.e.*, contract rates with physicians and others who are not actually providing the particular health services and thus have no incentive to fairly negotiate reasonable reimbursement rates) during QPA calculations.

In October 2024, the Fifth Circuit reversed the district court's vacatur of the QPA calculation provisions, affirmed the vacatur of the deadline provision (30-day statutory deadline for health plans to provide an initial payment or notice of denial that "begins on the date the plan or issuer receives the information necessary to decide a claim for payment for such services"), and affirmed the district court's holding that the QPA disclosure provisions were not arbitrary and capricious or contrary to law. *Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.*, 120 F.4th 494 (5th Cir. 2024).

On December 16, 2024, TMA motioned for a rehearing *en banc*, alleging that in reversing the district court's vacatur of the QPA calculation provisions, the Fifth Circuit improperly "revived the Departments' unlawful rules with minimal analysis, largely ignor[ed] the NSA's text and misconstru[ed] plaintiffs' arguments." The Fifth Circuit has yet to rule on the motion for *en banc* review.

Regulatory Updates

1. HHS Recission of the Richardson Waiver and the Impacts on Agency Rulemaking

On February 28, 2025, HHS Secretary Kennedy announced HHS's recission of a long-standing Nixon-era policy referred to as the "Richardson Waiver," effective immediately, through the issuance of the Policy on Adhering to the Text of the Administrative Procedures Act ("APA") (the "Policy"). Pursuant to the Richardson Waiver, HHS voluntarily agreed to undertake APA notice-and-comment procedures for "matter(s) relating to agency management or personnel or to public property, loans, grants, benefits, or contracts," despite the APA's waiver of those requirements for such matters (*see* 5 U.S.C. 553(a)(2)), and to forego notice and comment under the good-cause exception "sparingly." 36 FR 2532 (Feb. 5, 1971).

In the Policy, HHS asserts that the long-standing Richardson Waiver is "contrary to the clear text of the APA and imposes on [HHS] obligations beyond the maximum procedural requirements specified in the APA," citing Supreme Court case *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 100 (2015), which found that courts lack authority to impose obligations "beyond the 'maximum procedural requirements' specified in the APA." While Medicare rules, requirements, and other statements of policy affecting substantive legal standards are otherwise subject to statutory notice-and-comment requirements even more stringent than the APA's requirements (*see Azar v. Allina*

Health Services, 239 S. Ct. 1804, 1809 (2019)), the Policy has potentially significant implications for policy changes regarding other HHS programs and funding sources.

2. Bipartisan Lawmakers Introduce Bill Boosting Medicare Physician Pay by 6.6%

On January 31, 2025, a bipartisan group of representatives introduced a bill to increase physician payments under Medicare. The bill, the Medicare Patient Access and Practice Stabilization Act, would roll back payment cuts that were implemented under the CY 2025 Medicare Physician Fee Schedule, finalized November 1, 2024, and provide a 2% increase to physician reimbursements under the fee schedule. The proposed bill would adjust Medicare physician payments, beginning on April 1, 2025, through the remainder of 2025, leaving the current Medicare pay rate in place for services furnished from January to March 2025. Services furnished after the cutoff, however, would see a 6.62% increase—offsetting the pay cut, adjusting for inflation, and prorating the first three months of pay cuts. Though the text of this bill has not been made public, hospitals and health systems that include physician networks subject to the Medicare Physician Fee Schedule should monitor its progress.

3. Biden Administration's Final HHS Regulatory Agenda Officially Withdrawn While Fate of Proposed Health Care Regulations Remains Unclear

On January 20, 2025, the President issued a memorandum entitled "Regulatory Freeze Pending Review," freezing the publication of all new rules and regulations, pending review and approval by department or agency heads designated or approved by the new President (the "Memorandum"). The Memorandum requires the withdrawal of rules sent to the Office of the Federal Register that have yet to be published, and for the first 60 days following the date of the Memorandum (on or around March 21, 2025), also recommended that executive departments and agencies consider postponing the effective date of rules that had been published in the Federal Register, but had yet to go into effect to allow for further notice and comment.

While the specific impact of the Memorandum on health care reimbursement remains unclear, it will likely, at a minimum, delay passage of several pending CMS regulations as the agency conducts the further internal review required by the Memorandum. As of the date of this publication, the effective dates of a number of reimbursement-related rules have been postponed. For example, on February 11, 2025, HHS delayed until April 14, 2025 the effective date of its pending "Modification of the Medicaid Pharmacy Subrogation Standard" rule that adopts a new standard for State Medicaid subrogation transactions. And on February 14, 2025, the Drug Enforcement Agency ("DEA") and HHS jointly issued a delay of the effective date of two final rules, "Expansion of Buprenorphine Treatment via Telemedicine Encounter" and "Continuity of Care via Telemedicine for Veterans Affairs Patients," until March 21, 2025. The fate of other final rules pending release still remains to be seen. For example, CMS had been due to issue the final version of the Medicare Advantage ("MA") and Part D rule for 2026, which the agency had proposed in December 2024 and then further supplemented on January 10, 2025 (see further discussion of rule substance in Calendar Year 2026 Advance Notice of Methodological Changes for MA Capitation Rates and Part C and Part D Payment Policies; *see also* Ropes & Gray, "CMS Proposes Beneficiary Protection and Marketing Updates for Medicare Advantage and Part D Plans in 2026" (Dec. 9, 2024)). Additionally, updates to the No Surprises Act, such as the October 27, 2023 Federal Independent Dispute Resolution Operations Proposed Rule, are also to be determined.

The Memorandum is only one of the many methods through which the new administration is attempting to alter the regulatory landscape. The last Biden-era Unified Agenda, titled the "Fall 2024 Unified Agenda of Regulatory and Deregulatory Actions" ("Unified Agenda"), was officially withdrawn by the Trump Administration on February 5, 2025, shortly before expected publication in the Federal Register. Fall editions of the Unified Agenda present agency statements of regulatory priorities for the coming year. The HHS Statement of Regulatory Priorities included items such as Medicare coverage of preventative services and streamlining the prior authorization process. At this time, a replacement Agenda has not been provided by the new Administration.

Additionally, the incoming Congress is expected to use the Congressional Review Act ("CRA") to upend nearly final regulations proposed during the end of the Biden administration. Per the CRA, federal agencies must submit all final rules to Congress prior to the rule taking effect; Congress then has 60 session days to overturn the rule by joint resolution of disapproval, during which time the agency may not issue a substantially similar rule. In the President's first term in office, the CRA was used to overturn more than a dozen rules promulgated by the Obama administration, and similar action is expected, given the single-party control of the current Congress. The House also recently passed the "Midnight Rules Relief Act," which, if enacted, would streamline the disapproval process by allowing Congress to disapprove multiple regulations under one joint resolution of disapproval if the regulations were submitted for review during a portion of the final year of a President's term.

In addition, certain health care programs and flexibilities extended under the last administration are soon to expire and face an uncertain future with a new Congress. On December 20, 2024, Congress, as part of the American Relief Act, enacted a three-month extension through March 31, 2025, on certain post Public Health Emergency Medicare telehealth flexibilities. These flexibilities include continuation of allowances permitting (a) all eligible Medicare providers to continue providing eligible services remotely via telehealth, (b) Medicare patients receiving services for non-behavioral/mental health care in their home, and (c) continued suspension of geographic restrictions for originating site for Medicare non-behavioral/mental telehealth services. While this extension allowed time for further discussions on how to structure telehealth coverage and reimbursement in the long term—with Congress now under single-party control, it remains to be seen whether further extensions will be granted.

4. Uncertain Future for HHS Strategic Plan for the Use of Artificial Intelligence in Health, Human Services, and Public Health

On January 10, 2025, the HHS Office of Inspector General ("HHS-OIG") released a Strategic Plan for the Use of Artificial Intelligence in Health, Human Services, and Public Health ("Strategic Plan"), pursuant to Biden's October 30, 2023 Executive Order 14110, "Safe, Secure and Trustworthy Development and Use of Artificial Intelligence." Among other items, Executive Order 14110 directed federal agencies (including HHS) to take a number of steps to ensure that Artificial Intelligence ("AI") is deployed in a safe and secure manner, consistent with the Biden Administration's "dedication to advancing equity and civil rights." While the Strategic Plan does not have any immediate regulatory or reimbursement implications, it sets forth HHS's "vision and goals for AI" in the health care industry, including the use of AI in reimbursement and revenue cycle functions. Notably, the Strategic Plan discusses AI's potential role in submitting claims and managing billing to ensure timely and accurate payment, reduce denials, and optimize revenue cycle management, including the use of AI in prior authorization, clinical review assessments, utilization management, and claims adjudication. In particular, HHS guides that AI should be (1) accountable to human oversight ("viewed as a tool to support and inform efforts"); (2) monitored to prevent the introduction or exacerbation of bias (e.g., inaccurate eligibility denials to patient populations with historically more complicated coverage); and (3) monitored to avoid the potential for inappropriate outcomes (e.g., an increase in adverse coverage decisions). With the rapid rise of the advancement and implementation of AI in billing, coding, and reimbursement-related practices, hospitals and health systems should be aware of HHS's guidance and potential AI uses that may be subject to regulatory and enforcement scrutiny in the future.

The future of the Strategic Plan itself, however, is uncertain. On January 20, 2025 the President issued Executive Order 14148, "Initial Rescissions of Harmful Executive Orders and Actions," which included among the list of rescinded Biden-era executive orders, Executive Order 14110, pursuant to which the Strategic Plan was developed. Shortly after, on January 23, 2025, the President then issued Executive Order 14179, "Removing Barriers to American Leadership in Artificial Intelligence," which called on agencies to "identify any actions taken pursuant to Executive Order 14110 that are or may be inconsistent with, or present obstacles to," the policy goal of "America's global AI dominance in order to promote human flourishing, economic competitiveness, and national security." In addition, this Executive Order called for the creation of an AI Action Plan to achieve the above stated policy goal; public comments on said AI Action Plan were due by March 15, 2025. Soon after the issuance of Executive Order 14148, the Strategic Plan was removed from the HHS website. Because the Strategic Plan is not a formal legislative rule, it need not go through formal notice and comment procedures to be rescinded by the Trump Administration. Further, given the Strategic Plan's specific objective of "advancing equity," AI policies developed for such a purpose will likely be rescinded under Executive Order 14173. However, this Administration's focus on deregulation and private sector involvement in the development of AI indicates that current HHS plans around the use of AI in health, human services, and public health will likely change.

5. Calendar Year 2026 Advance Notice of Methodological Changes for MA Capitation Rates and Part C and Part D Payment Policies

On January 10, 2025, CMS released the Calendar Year ("CY") 2026 Advance Notice of Methodological Changes for MA Capitation Rates and Part C and Part D Payment Policies (the CY 2026 Advance Notice). If finalized, the proposed policies are projected by CMS to result in a net increase of 4.33% in payments made to MA plans in CY 2026 (or over $21 billion), on average, year over year. This represents the largest increase in payments since CY 2023.

CMS anticipates that the net increases will be largely driven by (a) estimated growth in overall MA spending, including through a technical adjustment including direct and indirect medical education costs, and (b) updates to the MA risk score trend for CY 2026 by calculating risk score trends over just a two-year period (2022 to 2023), rather than a three-year period (2021-2023), in order to avoid skewing the risk data over 2020 and 2021, when spending was reduced due to the COVID-19 Public Health Emergency. Notably, this increase is expected to occur notwithstanding projected *decreases* in average payments to MA plans by as much as 4.31% as a result of changes to the MA risk adjustment model. For example, CMS proposes to complete the three-year phase-in of the updated MA Risk Adjustment model (non-Program of All-Inclusive Care for the Elderly), finalized in the CY 2024 Rate Announcement ("2024 CMS-HCC Model") in 2026. Among other developments, the 2024 CMS-HCC Model will complete the restructuring of condition categories from ICD-9 to ICD-10.

If finalized, hospitals and health systems may consider opportunities for negotiation of favorable reimbursement rates with MA plans, as MA plans are projected to receive increased payments over time. As CMS noted in the Fact Sheet accompanying the Advance Notice, per statute, MA payment rates must be finalized by April 7, 2025; it remains unclear whether the regulatory freeze imposed by the new Administration will impact this timetable. If the changes are not finalized, MA plans may seek to reduce reimbursement rates given that prior adjustments to the MA risk adjustment model had reduced MA payments.

6. Congressional Reauthorization of the Hospital Low-Volume Adjustment

The low-volume adjustment was set to sunset on December 31, 2024, however, a continuing resolution passed on December 21, 2024, H.R. 10545, extending the low-volume adjustment until March 31, 2025. The Medicare low-volume hospital adjustment, codified at 42 C.F.R. § 412.101, is a payment adjustment applied to hospitals with low Medicare discharge rates that also meet certain distance requirements from other hospitals. This payment adjustment increases the reimbursement rate for such hospitals on a sliding scale, dependent on the hospital's discharge and mileage qualifications. On March 14, 2025, Congress passed a continuing resolution to fund the government through September 30, 2025, which preserved the adjustment.

7. HHS-OIG Scrutinizes Medicare's Rural Nursing Repayment Rates

In December 2024, HHS-OIG issued a report of its findings from an audit of the utilization of swing-bed services at Critical Access Hospitals ("CAHs"). HHS-OIG found that the swing-bed utilization for skilled nursing services at CAHs increased by 2.8% from cost years 2015 through 2020, while the average daily reimbursement amount increased by 16.6% over the same period. To conduct this audit, HHS-OIG randomly selected 100 CAHs to determine where enrollees would have had access to the same skilled nursing services provided by CAHs at alternative facilities. Eighty-seven out of 100 CAHs surveyed were within a 35-mile driving distance of an alternative facility that had cheaper care available. HHS-OIG estimated that Medicare could have saved up to $7.7 billion over a six-year period if payments made at CAHs were reimbursed at skilled nursing facility ("SNF") prospective payment system ("PPS") rates. HHS-OIG therefore recommended that CMS seek legislative change that will allow CMS to reimburse CAHs at rates that align with those paid to alternative facilities when it determines that similar care is available at alternative facilities. Back in 2015, HHS-OIG issued a similar report, with similar recommendations to CMS to adjust reimbursement rates for CAHs to the lower SNF rates at alternative facilities. Nearly 10 years later, HHS-OIG continues to recommend that CMS lower the SNF PPS rate; however, CMS has not yet done so. In its October 30, 2024 response to the report, CMS declined to adopt HHS-OIG's recommendations, citing concerns that changes to current payment policies could jeopardize the viability of rural hospitals and access to care in other underserved areas. Additionally, CMS cited its concern that the random sample of 100 CAHs included in the report are not representative of the total population of CAHs that provide swing-bed services.

Enforcement Updates

1. Changing Health Care Fraud Enforcement Priorities under the Trump Administration

President Trump's many executive actions in the early days of his second term suggest a broad shift in health care fraud enforcement. While targeting waste, fraud and abuse has been a common refrain from the new administration, the government has also terminated government employees, and specifically those focused on combating health care fraud. Health care providers must be alert to changing priorities, which will impact where and how the government focuses its enforcement efforts.

President Trump also injected significant uncertainty into the enforcement landscape with a continued reduction in the federal workforce. On January 24, 2025, President Trump fired over a dozen inspectors general, including HHS Inspector General Christi Grim. HHS-OIG has significant oversight of fraud and abuse in Medicare and Medicaid, including by issuing advisory opinions and safe harbor regulations, accepting self-disclosures, and entering into corporate integrity agreements with providers. The President followed with Executive Order 14210, ordering agencies to terminate thousands of probationary employees, including over 5,000 probationary employees at HHS. While these probationary employee terminations are being challenged in court, if they stand, they could curtail the administration's ability to investigate and prosecute enforcement actions as well as its ability to collaboratively engage with health care industry stakeholders.

Additionally, the Department of Justice ("DOJ") has also signaled that it is shifting away from the white collar enforcement priorities of past administrations. Instead, newly confirmed Attorney General Pamela Bondi has issued 14 first-day directives, which outline DOJ's focus on violent crime, illegal immigration, cartels, human trafficking, and DEI policies. The DOJ appears to be using its increasingly limited resources to tackle priorities other than health care fraud.

2. First Circuit Sets High Bar for Causation under the Anti-Kickback Statute

On February 18, 2025, a three-judge panel on the U.S. Court of Appeals for the First Circuit unanimously decided *U.S. v. Regeneron Pharmaceuticals, Inc.*, a case with significant implications for health care companies facing allegations of FCA violations premised on Anti-Kickback Statute ("AKS") violations. In a win for health care companies, the First Circuit joined two other Circuits in adopting a stringent "but-for" causation standard for proving causation under the AKS.

The AKS criminalizes knowingly offering or paying any person any remuneration to induce that person to purchase a good, facility, or service for which payment may be made under a federal health care program. A 2010 amendment to the AKS added that a claim for payment from a federal health care program "that includes items or services *resulting from* a violation of [of the AKS] constitutes a false" claim for purposes of the FCA. With this language, the government may turn an AKS violation into an FCA violation, which exposes the defendant to treble damages. The FCA may also allow private individuals to bring claims on behalf of the government, which they may not do for stand-alone AKS violations.

In *Regeneron*, the First Circuit interpreted the phrase "resulting from" to mean that an illicit kickback was the but-for cause of a claim submitted to the government. The First Circuit joins the Sixth and Eighth Circuits in agreeing on the but-for causation standard. Meanwhile, the Third Circuit maintains that only a "causal link" between the kickback and the claim is necessary. The but-for standard sets a high bar for the government and relator's counsel. Instead of needing to prove simply that provider referrals are in some way connected to kickbacks received, they must prove that the referrals would not have occurred absent the kickbacks. This actual causation standard should help providers as they seek to push back against unviable FCA claims premised on the AKS.

3. New OIG Special Fraud Alert Concerning Marketing Arrangements with MAOs

On December 11, 2024, HHS-OIG issued a special fraud alert concerning MA marketing arrangements with Medicare Advantage Organizations ("MAOs"), Health Care Professionals ("HCPs"), and brokers and agents that it views as carrying a risk of fraud and abuse. The special fraud alert focuses on two types of marketing arrangements: (1) those between MAOs and HCPs, and (2) those between HCPs and agents and brokers. OIG intends to scrutinize payments from MAOs to HCPs, which can implicate the AKS by providing items like gift cards or in-kind payments to HCPs and their staff in exchange for referring or recommending individuals for a particular MA plan. HHS-OIG warns that these tactics have resulted in enrollment of beneficiaries in an MA plan, sometimes without their consent, when they wanted to stay in original Medicare or another MA plan.

The alert also addresses arrangements between HCPs and agents/brokers. Coming on the heels of the $60 million Oak Street Health settlement, the alert also highlights payments by HCPs to agents and brokers in exchange for patient referrals. The Oak Street Health settlement resolved claims that Oak Street Health violated the AKS by paying kickbacks to third-party insurance agents in exchange for recruiting seniors to Oak Street Health's primary care clinics. The alert asserts that MA enrollees are often unaware of these financial arrangements and may rely on the recommendation of an agent or broker in making HCP selection decisions regarding their individual treatment needs. As the government continues to scrutinize these types of arrangements, HCPs and MAOs should carefully review their arrangements to ensure they are structured appropriately.

Updates on Relief Funding for Major Disasters and Public Health Emergencies

1. Los Angeles Wildfires and the Future of the Federal Emergency Management Agency under the Trump Administration

On January 10, 2025, HHS declared a public health emergency for California to address the health impacts of the ongoing wildfires in Los Angeles County, and, on January 31, 2025, the Federal Emergency Management Agency ("FEMA") announced that private nonprofits impacted by the Los Angeles County Wildfires may be eligible for Public Assistance to help restore their damaged or destroyed facilities. The Requests for Public Assistance ("RPA") were due by March 9, 2025. Providers of critical services, such as hospitals, await FEMA's decision on their RPA.

However, President Trump suggested via public statements and on Truth Social that he may take executive action to reform, overhaul, or dismantle FEMA. In furtherance of these objectives, President Trump issued an executive order on January 24, 2025, establishing a FEMA Review Council to, among other objectives, assess the adequacy of FEMA's response to disasters and whether FEMA could provide federal public assistance or whether the states should better serve this function. Any drastic changes to FEMA's role in response to major disasters and declared emergencies would have a significant impact on funding for hospitals and health systems providing support in response to such disasters and emergencies. In addition to Public Assistance funding that hospitals can request to help restore facilities that were destroyed in the Los Angeles wildfires, hospitals and health systems continue to await reimbursement from FEMA in connection with claims for COVID-19-related expenses and costs, including costs associated with setting up COVID-19 testing centers and contracting additional labor, as well as other hospitals and health systems that have responded to recent declared emergencies and disasters, such as the areas impacted by the hurricanes in North Carolina and Florida late last year.

2. COVID-19 Provider Relief Fund Reporting, Auditing, and Enforcement

As set forth in the HRSA's subregulatory guidance, the "Provider Relief Fund Distributions and American Rescue Plan Rural Distribution Post-Payment Notice of Reporting Requirements," which was last updated on April 22, 2024, the seventh and final Reporting Period for providers who received more than $10,000 in Provider Relief Fund ("PRF") payments between January 1, 2023, and June 30, 2023, closed on September 30, 2024. For any providers who applied for and were approved to submit a late report, the seventh and final Reporting Period closed on December 6, 2024.

HRSA has continued to issue Final Repayment Notices ("Notice") to PRF payment recipients who did not report in an applicable PRF Reporting Period, as required by the PRF terms and conditions, and such noncompliant providers must now repay any funds that were received and not reported on. Providers have 60 days from the date of receiving a Notice to either (i) repay the funds or (ii) request a Decision Review. The Decision Review Process is only available to providers that have received a Notice and disagree with either the amount to be repaid to HRSA or the reason(s) for repayment contained in the Notice. All decisions made by HRSA in connection with a Decision Review are final. Providers who did not report on eligible funds should be prepared to return the unreported amounts as soon as possible to avoid being sent to debt collection.

At the same time, HRSA and HHS OIG have continued to issue audit requests to providers, as well as follow-up questions to open audit requests, regarding provider compliance with certain terms and conditions, including the Single Audit requirement. Separately, with respect to expected enforcement regarding PRF payments received, there was at one point a general expectation that such enforcement, including False Claims Act-based enforcement, would be vigorous; however, most recent HHS OIG and DOJ enforcement for COVID-19-related funding appears to be focused on COVID-19-related funding other than the PRF and on general bad actors (e.g., misappropriation of funds) rather than the more technical noncompliance issues that were expected to be the subject of enforcement. Ropes & Gray LLP is staying tuned to any potential shift in the cadence of audits or the appetite for enforcement under the new Trump Administration.

Value-Based Care Corner

1. Drug Pricing EO and Impact on the CMMI Drug Pricing Models

On January 28, 2025, President Trump issued Executive Order 14148, "Initial Recission of Harmful Executive Orders and Actions," rescinding former President Biden's Executive Order 14087 of October 14, 2022 (Lowering Prescription Drug Costs for Americans). Executive Order 14087 directed implementation of the new health care payment and delivery models from the Center for Medicare and Medicaid Innovation ("CMMI") that would "lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care." In response to this order, CMMI developed three drug pricing models: (1) Medicare $2 Drug List Model; (2) Cell & Gene Therapy ("CGT") Access Model; and (3) Accelerating Clinical Evidence Model.

While E.O. 14148 rescinds Biden's directive that created these models, the new E.O. does not direct CMMI to terminate the programs. Rather, the Trump order merely removes the executive mandate, leaving the future of the models uncertain. The Trump Administration has not explicitly stated whether these programs will continue, and a significant reduction in the federal work force led by DOGE, including cuts to CMMI, could leave the agency without sufficient resources to continue the models' implemen-tation. While each of these three models were at various stages of planning and implementation when President Trump issued E.O 14148, the CGT Access Model, aimed at creating multi-state purchasing agreements to help state Medicaid programs pay for expensive gene therapies is the only currently active model of the three and has already begun the process of enrolling states. On March 12, 2025, CMS announced in a released Fact Sheet that CMMI will no longer pursue the Medicare $2 Drug List Model and the Accelerating Clinical Evidence Model pursuant to E.O. 14087, officially rescinding these models.

2. Certified Community Behavioral Health Clinic Demonstration

On January 7, 2025, the Substance Abuse and Mental Health Services Administration ("SAMHSA") announced the award of one-year Certified Community Behavioral Health Clinic ("CCBHC") Demonstration planning grants to 14 states and Washington, D.C. in the amount of $1 million per recipient as authorized by the Bipartisan Safer Communities Act ("BSCA") of 2022 to address the ongoing national mental health and substance use disorder crises.

The states selected are Alaska, Colorado, Connecticut, Delaware, Hawaii, Louisiana, Maryland, Montana, North Carolina, North Dakota, South Dakota, Utah, Washington, and West Virginia, as well as the District of Columbia. As planned, in 2026, up to 10 of these states will be selected to participate in the CCBHC Medicaid demonstration program and receive enhanced Medicaid reimbursement. CCBHCs must see people in crisis immediately (24 hours a day, seven days a week) and provide timely routine outpatient care. CCBHCs must ensure access to a comprehensive range of services, providing care coordination when needed and incorporating evidence-based practices and other supports based on a community needs assessment. The demonstration will provide reimbursement through Medicaid for the full cost of services that CCBHCs provide, at higher, more competitive rates than community mental health centers previously received. This sustainable funding also aims to ensure the clinics can provide a more comprehensive range of services, rather than fragmented services driven by billing codes.

At this point, given this program is still in its early stages, it is unclear whether this program will go forward as planned under the new administration.

3. 2025 Accountable Care Organization Initiatives and the New Administration Continue to Increase Participation in ACOs

The Trump Administration is inheriting a CMS initiative that has made significant strides toward its stated goal for all traditional (fee-for-service) Medicare beneficiaries to be in a "value-based care" relationship with providers that participate in accountable care measures for quality and total cost of care by 2030. In a January 15, 2025 update, CMS reported that 53.4% of people with Traditional Medicare are in an accountable care relationship with a provider. This represents more than 14.8 million people and a 4.3% increase from January 2024. This represents the largest annual increase since CMS began tracking accountable care relationships.

The increases are driven in large part by the continued popularity of the Medicare Shared Savings Program ("MSSP"). For 2025, CMS approved 228 applications for MSSP, including 55 new ACOs and 173 renewing or reentering Accountable Care Organizations ("ACOs"), the largest annual number of renewals in the 12-year history of the program. This brings the total number of ACOs participating in the MSSP to 476. CMS has also seen a 16% increase in the number of Federally Qualified Health Centers, Rural Health Clinics, and Critical Access Hospitals participating in MSSP from last year.

In an effort to continue the expansion of accountable care options, CMS also introduced the ACO PC Flex Model for CY 2025, which includes 24 ACOs serving 349,000 people with traditional Medicare. This new model tests a new payment scheme for primary care within MSSP to support primary care as the foundation of accountable care.

Conversely, participation in the other ACO program, the ACO Realizing Equity, Access, and Community Health Model ("ACO REACH"), declined by 3.8%. CMS has not said whether it will extend this program after 2026, when it is scheduled to sunset, or whether it will be replaced with a successor CMMI model. As the only full-risk model, and one that offers full capitation, it is likely that at least some of these components would continue either in MSSP or in its successor model.

ACOs and value-based care, generally, have remained largely bi-partisan initiatives, and the current form of MSSP was implemented through President Trump's "Pathways to Success" revisions. Accordingly, the Trump Administration will likely continue these efforts, but with significant updates to align with the administration's priorities, including a likely replacement of the current health equity requirements and renewed focus on effective use of health care data.

4. CMS Launches Transforming Maternal Health Model

On January 1, 2025, CMS launched the new Transforming Maternal Health (TMaH) Model, which is designed to improve maternal health care for people enrolled in Medicaid and the Children's Health Insurance Program ("CHIP"). CMMI first announced the model in December 2023, and, on January 6, 2025, CMS announced the 15 following states selected to participate in the new model: Alabama, Arkansas, California, District of Columbia, Illinois, Kansas, Louisiana, Maine, Minnesota, Mississippi, New Jersey, Oklahoma, South Carolina, West Virginia, and Wisconsin. The TMaH Model will run for 10 years and focuses on three key elements, which include (i) access to care, infrastructure and workforce capacity, (ii) quality improvement and safety, and (iii) whole-person care delivery. The model has a three-year pre-implementation period where states will receive targeted technical assistance to advance each model element and a seven-year implemental period to execute the model.

The model seeks to address limited access to maternal health care providers, including community-based maternity services, and outdated data collection methods with limited information sharing among community-based organizations and other agencies. The model will implement protocols that promote the reduction of avoidable procedures, encourage shared decision-making between the mothers and providers, and promote medical risk screenings for conditions such as depression and health-related social needs ("HRSNs"). Lastly, the model will encourage participating states to extend Medicaid and CHIP postpartum coverage to 12 months to promote preventive care, overall health, and reduction of cost care.

5. CMS Finalizes Mandatory Kidney Transplant Demo with Higher Bonus

In December 2024, CMS finalized the rule establishing the mandatory six-year Increasing Organ Transplant Access Model ("IOTA Model") with several changes from the proposed version. As described in our May 2024 newsletter, CMMI had issued a proposed rule announcing the model, which will test whether performance-based payment improves access to kidney transplants for patients with end-stage renal disease.

To allow participant hospitals additional time to prepare, the model will now start on July 1, 2025. Additional changes from the proposed rule include increasing the upside risk payment from $8,000 to $15,000 and removing the requirement for providers to review organ offers declined on the attributed patient's behalf. The final rule also (i) modifies the transplant target to reflect the average number of deceased or living donor transplants during the baseline years rather than the highest count, (ii) adjusts the quality strategy to allow for additional time for measure identification and stakeholder input, eliminating three equality measures from the quality domain; and (iii) removes the health equity payment adjustment while making health equity plans voluntary.

As CMMI is implementing this model via formal rulemaking, any change to the model, including a decision by the Trump Administration to delay or terminate it, would require further regulatory action.

6. CMS Announces Ending Four Payment Models Early by the End of 2025

On March 12, 2025, CMS announced that several payment models will end payments by the end of 2025, including the (i) Maryland Total Cost of Care ("TCOC") Model, (ii) Making Care Primary ("MCP") Model, (iii) End-Stage Renal Disease ("ESRD") Treatment Choices ("ETC") Model, and (iv) Primary Care First ("PCF") Model. Additionally, CMS also is considering reductions to the Integrated Care for Kids ("InCK") Model.

The TCOC Model was created to expand on the Maryland All-Payer Model and create incentives for health care providers to coordinate with each other and set a per capita limit on Medicare total cost of care. Maryland's TCOC Model was the first model that held a state fully accountable for risk for the total cost of care for Medicare beneficiaries. The performance period of the TCOC Model began on January 1, 2019, and was set to conclude on December 31, 2026, but CMS now intends to end the model as of December 31, 2025. Instead, the model will transition to the States Advancing All-Payer Health Equity Approaches and Development ("AHEAD") Model and begin its implementation period in January 2026. See below for more information on the AHEAD Model.

The MCP Model is a voluntary primary care model that launched on January 1, 2024, with the stated goal of improving care management and care coordination for primary care services. This model was intended to be a 10.5-year model where CMS would work with the state Medicaid agencies to engage in full care transformation across payers. The MSP Model is focused on supporting less experienced primary care practices and organizations by helping them build advanced care delivery capabilities, help coordinate specialty partners and, over time, assume prospective payments and accountability for cost and quality outcomes. Eight states were selected to participate in this model after reviewing criteria related to geographic diversity, health equity opportunity, and ability to align with state Medicaid agencies. These states are Colorado, Massachusetts, Minnesota, New Mexico, New Jersey, New York, North Carolina, and Washington. CMS announced that the MCP Model will end early, although the end date is still unknown.

The ETC Model began on January 1, 2021, and is a mandatory model designed to promote increased use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD. The ETC Model also reduces Medicare costs and maintains/improves the quality of care provided to these beneficiaries.

Under the ETC Model, CMS implements specific payment adjustments to incentivize participating ESRD facilities and Managing Clinicians to ensure that ESRD beneficiaries are informed and have access to treatment options. The ETC Model was set to end June 30, 2026, but CMS has stated it intends to conduct future rulemaking to end the model as of December 31, 2025.

The PCF Model is a voluntary five-year payment model that began in January 2021 for Cohort 1 and January 2022 for Cohort 2. The PCF Model incentivizes value and quality by offering an innovative payment structure to support advanced primary care delivery. The PCF Model is offered in 26 regions but is now set to conclude on December 31, 2025.

Lastly, the InCK Model is a child-centered local service delivery and state payment model designed to reduce costs and improve quality of care for children under 21 covered by Medicaid. Launched in early 2020, this seven-year model has allocated approximately $126 million in funding to participating states and organizations, including Connecticut, Illinois, North Carolina, New Jersey, New York, and Ohio. CMS is exploring options to reduce the size of InCK awards or make other adjustments to the model, though these changes are still uncertain.

7. AHEAD Model

CMMI continues its implementation of the States Advancing All-Payer Health Equity Approaches and Development ("AHEAD") Model. As described in a previous client alert, the state-based AHEAD Model is a voluntary multi-payer model, in which states partner with hospitals and primary care providers to provide value-based care to Medicare and Medicaid beneficiaries. Notably, participating hospitals will agree to operate on a global budget.

CMS has selected several states to participate in the AHEAD Model across three cohorts. The first cohort (Maryland and Vermont) is set to begin in January 2026 for nine performance years, with an 18-month pre-implementation period from July 2024 to December 2025. The second cohort (Connecticut and Hawaii) will begin in January 2027 for eight performance years, with a 30-month pre-implementation period from July 2024 to December 2026. Lastly, the third cohort (Rhode Island and a sub-state region of New York, which includes the Bronx, Kings, Queens, Richmond, and Westchester Counties) will begin in January 2027 for eight performance years, with a 24-month pre-implementation period from January 2025 to December 2026. The AHEAD Model holds states and participating providers accountable for state-specific Medicare and all-payer cost growth and primary care investment targets, and for population health and health equity outcomes.

8. TEAM Mandatory Medicare Payment Causes Hospitals to Seek Partnership

On January 1, 2026, CMS plans to launch the five-year Transforming Episode Accountability Model ("TEAM"), which is a mandatory, episode-based, alternative payment model designed to improve care coordination and reduce costs for certain surgical procedures. Selected acute care hospitals will take on downside risk for traditional (fee-for-service) Medicare beneficiaries undergoing certain surgical procedures, including lower extremity joint replacement, major bowel procedures, and spinal fusions. Acute Care Hospitals are selected through CMS's Core-Based Statistical Areas ("CBSAs") to identify selected geographic regions for the model test. Hospitals paid under the IPPS and located in the selected CBSAs are required to participate in TEAM. Selected hospitals assume responsibility for the cost and quality of care through the first 30 days after the Medicare beneficiary leaves the hospital.

In preparation for participation, selected hospitals are actively seeking collaborations with post-acute care providers to better manage care and financial risk in the 30-day episode-based payments to maximize CMS reimbursement. Hospitals are incentivized to lower costs for designated services to meet regional benchmarks or bear the costs that exceed payments. CMS believes that hospital success requires developing robust partnerships with post-acute care providers to ensure seamless patient transition and comprehensive care. As a result, the model allows hospitals to enter into gainsharing arrangements with providers that can help improve care continuity.

340-B Updates

1. J&J and Other Pharmaceutical Manufacturers Sue HRSA over 340B Rebate Models

On November 12, 2024, pharmaceutical manufacturer Johnson & Johnson ("J&J") filed a lawsuit against HHS and HRSA in the U.S. District Court for the District of Columbia. In its complaint, J&J, a participant in the 340B drug discount program ("340B Program"), challenges HRSA's determination that J&J was prohibited from using a rebate model to provide 340B pricing to DSH hospitals as arbitrary, capricious, and an abuse of discretion.

The lawsuit is the latest development in the ongoing dispute between J&J and HRSA. As discussed in our November newsletter, J&J had announced that it would be implementing a rebate model to meet its 340B pricing obligations and minimize duplicate discounts and diversion. Under the proposed J&J rebate model, DSH hospitals would purchase certain of J&J's pharmaceutical products from wholesalers at the commercial price. Upon a DSH hospital's submission of rebate claim data, J&J would validate that the purchases were made by an eligible covered entity and dispensed from eligible 340B locations and then, if satisfied that the requirements for 340B pricing were met, make a rebate payment to the hospital equal to the difference between the list price and the 340B ceiling price. In communications between the two parties, HRSA stated that J&J's rebate model would require DSH hospitals to purchase

covered outpatient drugs at prices above the 340B ceiling price and threatened to terminate J&J from the 340B Program. J&J subsequently announced that it would forgo plans to implement the rebate model but reserved the right to pursue legal action.

In its lawsuit, J&J argues that the 340B statute permits manufacturers to select the mechanism for offering reduced-priced drugs to covered entities and that such mechanisms need not be approved by HRSA, noting that the 340B statute's legislative and regulatory history suggests that both rebates and discounts are options for furnishing the 340B price to covered entities and that the statute does not specify which mechanism manufacturers must use. Similarly, J&J also notes that the Pharmaceutical Pricing Agreement entered into by manufacturers and HRSA does not specify the type of mechanism to be used to effectuate 340B ceiling prices. J&J further reiterates in its complaint that its rebate model would alleviate concerns related to duplicate discounts and diversion.

On February 3, 2025, J&J moved for summary judgment arguing that (i) the 340B statute allows rebate models, which manufacturers can select at their discretion; and (ii) HRSA unlawfully rejected J&J's rebate model. HRSA's deadline to respond to the summary judgment motion is April 2, 2025.

The lawsuit has provoked action from DSH hospitals. On January 30, 2025, a hospital group asked the district court to allow the hospital group to join the J&J lawsuit to defend the federal government's authority to block the J&J rebate model.

Other manufacturers are also joining the fray. In the wake of the J&J suit, three other pharmaceutical manufacturers have filed similar lawsuits against HRSA: (i) Eli Lilly & Co. sued HRSA seeking a declaratory judgment that its "cash replenishment" rebate model was lawful; (ii) Sanofi-Aventis U.S. LLC sued HRSA seeking a declaratory judgment that its proposed rebate model was permitted under the 340B Program and an order enjoining HRSA from taking enforcement action against the company for implementing the model; and (iii) Novartis Pharmaceuticals sued HRSA seeking a declaratory judgment that its proposed rebate model was permitted under the 340B Program, an order enjoining HRSA from taking enforcement action against the company for implementing the model and an order vacating HRSA published policy regarding rebate models generally.

2. Pharmaceutical Manufacturers Sue HRSA over Clinic Eligibility

On December 20, 2024, Amgen Inc., Eli Lilly & Co., and UCB Inc. filed a lawsuit against HRSA in the U.S. District Court for the District of Columbia, alleging that the agency has not fulfilled its obligations to oversee the 340B Program by allowing certain ineligible clinics to participate in the 340B Program. The clinics named in the lawsuit are nine clinics operated by Sagebrush Health Services ("Sagebrush") that participated in the 340B Program as sexually transmitted disease ("STD") clinics.

As a general matter, under the 340B statute, STD clinics are eligible to participate in the 340B Program if the clinics receive funds through a state or unit of local government under certain federal grants relating to the treatment of STDs. Like with other covered entities, STD clinics may participate in the 340B Program and access 340B pricing only after HRSA has certified their eligibility, which is done on an annual basis. And STD clinics may provide drugs purchased at 340B prices to patients only if the patients receive a health care service from the clinic consistent with the services funded by the federal grants.

The lawsuit alleges that HRSA repeatedly certified numerous clinics as covered entity STD clinics even though these clinics were ineligible for the 340B Program because the clinics (i) use 340B drugs for purposes other than STD prevention and treatment; (ii) engage in diversion by transferring 340B drugs to individuals who are not covered entity patients; (iii) do not receive federal grant funding directly from state or local governments but indirectly from other entities that receive the funding from the state or local governments; and (iv) receive only in-kind contributions rather than "funds."

The plaintiffs allege that HRSA's certification and recertifications of these entities are arbitrary, capricious, and not in accordance with law, and also exceed the agency's statutory authority. Among other relief, the plaintiffs request that the court invalidate HRSA's determination that these clinics are covered entities under the 340B Program. Notably, even though the Sagebrush clinics are the only clinics named in the lawsuit, the plaintiffs ask the court to declare that all 340B registrations of all STD clinics that use 340B drugs for non-STD conditions or that only receive in-kind contributions are contrary to law. HRSA has until April 14, 2025, to respond to the complaint.

On the same day the lawsuit was filed, HRSA advised Sagebrush that 20 clinic sites, including eight of the nine clinics identified in the Amgen complaint, were not eligible covered entities and would be terminated from the 340B Program because the clinics had not received the requisite federal grant funding. On January 13, HRSA confirmed that the relevant sites would be terminated by close of business, advising Sagebrush to determine the full scope of non-compliance and repay affected manufacturers. In response, on January 16, 2025, Sagebrush sued HRSA, challenging the termination of the various covered entities, arguing that such termination would "cause the imminent destruction of Sagebrush, which relies on the 340B Program to sustain its operations." Sagebrush's motion for a temporary restraining order and preliminary injunction was denied.

On January 31, 2025, Genentech, Inc. also sued HRSA, challenging HRSA's decision to allow allegedly ineligible Sagebrush clinics to participate in the 340B Program—including the same clinics named in the Amgen complaint plus additional clinics. Specifically, Genentech argues that such clinics were unlawfully certified and obtained reduced prices on Genentech drugs that do not treat or prevent STDs, therefore constituting unlawful diversion as the drugs were used for non-STD patients. In addition to the nine Sagebrush clinics named in Amgen's lawsuit, Genentech named two other Sagebrush clinics as

ineligible for participation in the 340B Program. Genentech noted that, for example, these clinics purchased drugs used to treat rheumatoid arthritis and certain cancers and autoimmune disorders at 340B pricing.

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

A new administration brings change—and change means new rules and policies out of Washington that can have significant implications for hospitals and health systems. A team of Ropes & Gray associates, counsel, and partners are diligently sharing insights with our health care clients on the implications of the new Executive Orders released by the Trump Administration concerning topics such as DEI programs, immigration, gender affirming care, and NIH and USAID funding. Since January, we have hosted the following webinars:

- March 7: Responding to CDC's "Foreign Assistance Questionnaire"
- March 6: Trump Administration Efforts to Discourage DEI and Cancel USAID Grants: Notices of Grant Termination and Demands for "No DEI" Certifications
- February 9: NIH Caps Indirect Costs at Flat Rate: Critical Implications for Research Institutions
- February 5: Pressures on Research Funding under the Trump Administration: Indirect Cost Recovery and Other Restrictions
- January 29: The Trump Administration's DEI-Related Executive Orders: Implications for Recipients of Federal Funding

To receive timely updates and exclusive event invitations on the relevant issues for hospitals and health systems, we invite you to sign up for the Health Care "Health Systems/Hospitals/AMCs" mailing list.

Ropes & Gray continues to track real-time updates on state health care transaction laws related to competition, quality, access, cost and more. By leveraging our sector expertise, our latest innovation, RG HealthTrax, provides users with the most current and reliable information, helping clients maintain a competitive advantage in their investments.

Ropes & Gray health care partner Christine Moundas and associates Gideon Palte and Carolyn Lye published an article in *WestLaw Today* discussing two final rules that HHS published to establish health data interoperability and information-blocking regulations.

Looking Ahead

On Wednesday, March 26, Ropes & Gray will host a networking reception at The Bygone during the AHLA Institute on Medicare and Medicaid Payment Issues. For more information on the event, please contact Marnine.Wilensky@ropesgray.com.

Ropes & Gray partner Stephanie Webster will also speak at the conference on Medicare DSH, Worksheet S-10, and other cost reporting issues.

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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