ROPES & GRAY

Hospital and Health Systems Reimbursement Check

July 2025

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

FEDERAL AWARD INDIRECT COST RATES: CUTS, CAPS AND IMPLICATIONS

In the early days of the second Trump Administration, several federal funding agencies announced caps to indirect cost ("IDC") rates for federally funded research awards. In many cases, these caps would substantially reduce reimbursements from the federal government to hospitals and health systems for IDC payments supporting their research enterprises. This article reviews how IDC rates are determined, previous attempts to limit IDC reimbursement, recently announced caps to IDC rates and resulting litigation, and the implications of IDC rate caps on federal research awards and Medicare reimbursement.

Overview of IDC Rates

Federally funded research awards often include payment rates for IDCs, also referred to as facilities and administration ("F&A") costs. These costs, which are essential to conducting research, are not directly attributable to a specific funded research project; they include an institution's Information Technology infrastructure, facility maintenance, utilities, general office equipment, and salaries/wages for administrative personnel. Under most federal awards, a percentage of modified total direct costs is allocated toward these expenses as the IDC rate.

The IDC rate for a given federal award is usually determined in one of the following ways, as outlined in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 C.F.R. Part 200 (the "Uniform Guidance") and in federal agency-specific guidance:

1. A fixed rate as specified in statute, regulation, or policy, *e.g.*, an 8% IDC rate for the National Institutes of Health ("NIH") awards to foreign and international organizations). *See* NIH Grants Policy Statement (Apr. 2024), § 16.6;
2. A negotiated rate between the recipient institution and the "cognizant agency for indirect costs"—*i.e.*, the designated federal agency responsible for reviewing, negotiating, and approving IDC proposals on behalf of all federal agencies—memorialized in a Negotiated Indirect Cost Rate Agreement ("NICRA"). *See* 2 C.F.R. § 200.414(c), 45 C.F.R. § 75.414(c);
3. A *de minimis* (default) rate, currently set at 15%, if there is no fixed or negotiated rate. *See* 2 C.F.R. § 200.414(f), 89 Fed. Reg. 80,055, 80,057 (Oct. 2, 2024); or
4. For subrecipients lacking a federally negotiated rate, a rate determined by the prime awardee (pass-through entity) in collaboration with the subrecipient. *See* 2 C.F.R. § 200.332(b)(4).

Most established research institutions that receive federal funding choose to utilize federally negotiated rates, as set forth

in their respective NICRAs with the cognizant agency. This allows research institutions to engage in long-term budgeting and planning but also creates a reliance on federal agencies' consistent application of those negotiated rates.

Past Efforts to Limit IDC Reimbursements

In the mid-1990s, the Clinton Administration proposed capping IDC reimbursements as part of its federal fiscal year ("FFY") 1995 budget request, following a Congressional Research Service report on IDCs. The budget proposed to maintain the status quo by capping IDC reimbursements to FFY1994 levels for those institutions of higher education ("IHEs") receiving over $10 million in federal research funding. Congress did not include this limitation in any appropriations bills.

In 2013, under the Obama Administration, the Office of Management and Budget ("OMB") proposed an unspecified flat IDC rate through the federal rulemaking process, but the effort was withdrawn following successful lobbying from industry stakeholders. Similarly, early in the first Trump Administration, OMB proposed capping all IDC rates at 10% (the *de minimis* rate at the time). In response, Congress held a hearing on IDCs but did not support the Trump Administration's proposal, which lost traction.

The second Trump Administration continues to push for IDC rate caps. Although Project 2025, which has been influential in the administration's policymaking, recommends *Congressional action* to cap IDC rates for IHEs, current attempts have come from *agency-specific action*, without notice and comment rulemaking, as summarized below. *See* Project 2025 at 355.

Recently Announced IDC Rate Caps from Certain Federal Agencies

Since President Trump took office in January 2025, federal funding agencies—including the NIH, the National Science Foundation ("NSF"), the Department of Energy ("DOE"), and the Department of Defense ("DoD")—have announced caps limiting IDC rates to 15%.

NIH was the first of these agencies to move to cap IDC rates, issuing supplemental guidance to the 2024 NIH Grants Policy Statement (NOT-OD-25-068, February 7, 2025, the "Supplemental Guidance") that imposes a 15% rate on all current and new awards. The Supplemental Guidance states that "there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant," to be applied to (1) go-forward expenses for all *current* awards to IHEs; and (2) all *new* awards to all entities issued on or after February 10, 2025.

However, the Supplemental Guidance has been on pause since Judge Angel Kelley of the U.S. District Court for the District of Massachusetts issued a temporary restraining order on February 10 blocking implementation of the IDC rate cap and, later, on April 4, entered final judgment on the dispute granting a permanent injunction. Ropes & Gray helped secure the temporary restraining order and nationwide injunction by filing a complaint on behalf of the Association of American Medical Colleges, American Association of Colleges of Pharmacy, Association for Schools and Programs of Public Health, Conference of Boston Teaching Hospitals, and Greater New York Hospital Association.

Attempts by DOE, NSF, and DoD to impose similar caps have also been blocked by temporary restraining orders or final judgments vacating the policy, although litigation is ongoing:

- On April 11, DOE announced a cap for awards to IHEs, stating its intention to terminate all awards to IHEs that do not conform with the cap. On April 16, Judge Allison D. Burroughs of the U.S. District Court for the District of Massachusetts issued a temporary restraining order blocking the cap from going into effect. On June 30, Judge Burroughs converted the temporary restraining order into a final judgment vacating the DOE cap, with the government having 60 days to appeal.
- On May 2, NSF announced a rate cap to take effect on May 5. The Association of American Universities and several IHEs filed suit on May 5 challenging the rate cap, and NSF stayed implementation through June 20. On June 20, the U.S. District Court for the District of Massachusetts vacated NSF's policy notice of the rate cap and ruled it invalid and arbitrary.
- On May 14, DoD issued a memorandum announcing a rate cap for all new awards to IHEs issued on or after June 12. The memorandum also directs DoD to renegotiate IDC rates on existing awards and, if renegotiation is not possible, terminate and reissue the award under revised terms. On June 17, Judge Brian Murphy of the U.S. District Court for the District of Massachusetts issued a temporary restraining order prohibiting DoD from implementing the rate cap policy. At present, a hearing is set for the morning of September 4, 2025.

Implications of IDC Rate Caps on Federal Research Awards

If implemented, these IDC rate caps would significantly affect

IHEs, teaching and research hospitals, and other institutions that rely on long-term IDC reimbursement. These institutions build their budgets around anticipated levels of IDC support—often projected years in advance. Lower IDC rates would force many institutions to make drastic cuts to staff, programming, and other essential resources. Some independent research institutions might face severe financial distress.

Although litigation to date has stalled federal agency efforts to impose IDC rate caps, the Trump Administration may pursue other avenues to restrict IDC reimbursement such as Congressional action. For example, a leaked U.S. Department of Health and Human Services ("HHS") budget document states that the Trump Administration may ask Congress to eliminate the statutory prohibition on changes to NIH's IDC rate policies. Although the document does not cite the relevant provision, this likely refers to the annual appropriations law, which since 2018, has included a provision prohibiting NIH from altering IDC policies. *See* Further Consolidated Appropriations Act of 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677 (2024). In response to the Trump Administration's efforts, the Joint Associations Group on Indirect Costs ("JAG")—a coalition of 10 higher education associations, including the Association of American Universities ("AAU"), Association of American Medical Colleges ("AAMC"), National Association of Independent Colleges and Universities ("NAICU"), and Council on Governmental Relations ("COGR")—has proposed a new Financial Accountability in Research ("FAIR") model for reimbursement of indirect research costs to OMB, the White House Office of Science and Technology Policy ("OSTP"), and members of Congress. According to an AAU FAQ, the FAIR model would eliminate F&A terminology and the associated rate proposal preparation by creating new trackable costing categories and is intended to increase accountability and transparency, align project costs with the type of work being performed, and align funding structure more closely with that allowed by private foundations by treating more items as direct costs.

IDC Rate Caps and Medicare Reimbursement

Medicare reimbursement is governed by its own statutory and regulatory framework, separate from the Uniform Guidance and IDC rate setting processes outlined above. However, as hospitals typically operate under integrated accounting systems, changes to IDC recovery under federal research awards may lead to internal cost reallocations, potentially affecting the allocation of costs on Medicare cost reports, the data reported for purposes of the area wage index, and Medicare reasonable cost reimbursement for items such as organ acquisition costs and nursing and allied health programs.

Some hospitals and health systems already may incorporate elements of their negotiated IDC rate methodology—such as fringe benefit allocations or administrative overhead assumptions—into their Medicare cost reporting practices. With potential IDC rate caps on federal awards, institutions should reassess these practices to ensure alignment with Medicare's unique cost principles. Any cost allocation changes made in response to IDC rate caps should be evaluated carefully to avoid inadvertent effects on Medicare reimbursement.

We are following closely the Trump Administration's various proposed changes to established law, regulation, and guidance governing federally funded research programs, including actions related to IDC rates with these potential implications.

Docket Updates

1. *Advocate Christ Medical Center v. Kennedy*

On April 29, 2025, the U.S. Supreme Court upheld the government's interpretation that a patient is "entitled to [Supplemental Security Income ("SSI")] benefits" for purposes of the SSI fraction used to calculate the disproportionate share hospital ("DSH") payment adjustment only if "she is eligible to receive a cash payment during the month of her hospitalization." *Advocate Christ Medical Center v. Kennedy*, 145 S. Ct. 1262 (2025).

The Medicare statute requires increased Medicare Part A payments to hospitals that serve a disproportionate number of low-income patients, who are more expensive to treat. To do so, CMS calculates a disproportionate patient percentage for a hospital based on a fraction representing low-income patients the hospital treats. 42 U.S.C. § 1395ww(d)(5)(F)(vi). The numerator of the first fraction of that formula counts patient days for patients who were "entitled to benefits under [Medicare] part A" and were "entitled to [SSI] benefits . . . under subchapter XVI of this chapter. . . ." § 1395ww(d)(5)(F)(vi)(II). The government argued that a person is entitled to SSI benefits only if the person is qualified for an actual payment in a given month, while the hospitals argued that entitlement to SSI benefits is a legal status that a person obtains by meeting the statutory qualifications for the

SSI program more generally, even if she does not receive a payment in a given month.

The Supreme Court rejected the hospital's argument and upheld the government's interpretation that individuals are entitled to SSI benefits only if they qualify for cash payments in a given month. The Supreme Court reasoned that SSI benefits are cash benefits, and that the statutory context indicates that entitlement to these payments is determined on a monthly basis. In reaching this conclusion, the Court distinguished *Becerra v. Empire Health Foundation, for Valley Hospital Medical Center*, 597 U.S. 424 (2022). Characterizing *Empire Health* as "turn[ing] on the specific features of Medicare Part A," the Supreme Court reasoned that there were "critical distinctions" between SSI benefits and Part A benefits.

Justice Jackson, joined by Justice Sotomayor, dissented. She argued that meeting the statutory SSI enrollment criteria is sufficient to make one entitled to benefits. In an impassioned section of her dissent, Justice Jackson recounted the fluctuating fortunes facing low-income Americans, explaining that part of the "benefits" SSI confers is the reassurance that if someone enrolled in the program falls on hard times, SSI payments will support them. In her opinion, that benefit exists even in months when a program enrollee is not actually qualified to receive cash payments.

This case has significant implications for Medicare reimbursement. The inclusion of SSI days in the numerator of the Medicare fraction might have significantly increased qualifying hospitals' DSH payments. But significantly, the Court declined to address the separate issue of whether the use of only particular Social Security Administration ("SSA") status codes to identify patient days attributable to SSI-entitled individuals was reasonable. Continued litigation on this open question is expected.

The full impact of *Advocate Christ* on DSH-related cases is an area to monitor.

2. *Montefiore Medical Center v. Kennedy*

In *Montefiore Medical Center v. Kennedy*, No. 24-cv-1810 (D.D.C. 2024), the parties recently filed their combined opposition and cross-motion for summary judgment and reply and opposition to summary judgment briefs. *Montefiore* is the lead case in the U.S. District Court for the District of Columbia challenging the June 2023 retroactive rule requiring the inclusion of Medicare Part C days in the Medicare DSH calculation for periods prior to October 1, 2013.

In its reply, the government principally argues that the 2023 final rule and the policy it reflects did not violate any provision of the Medicare statute because of the Supreme Court's decision in *Becerra v. Empire Health Foundation, for Valley Hospital Medical Center*, 597 U.S. 424 (2022).

Plaintiff filed its combined opposition and reply brief on June 17, 2025. The brief rebuts the government's argument that *Empire*, which did not address how to treat Part C days in the DSH calculation, resolves the case. The brief argues that the D.C. Circuit's decision in *Northeast Hospital Corp. v. Sebelius*, 657 F.3d 1 (D.C. Cir. 2011)—which found that the DSH statute was ambiguous with respect to the treatment of Part C days and that the agency could not change its interpretation as to Part C days retroactively—remains binding precedent, and that the statutory text is best read as excluding Part C inpatient hospital days from Part A-entitled days in the DSH calculation because patients enrolled in Medicare Part C program health insurance plans are statutorily ineligible for original Medicare Part A fee-for-service insurance program benefits. Plaintiff also argues that the 2023 rule violates the Medicare statute's rulemaking requirements prohibiting retroactive rulemaking except under certain, limited circumstances and is otherwise arbitrary and capricious.

Briefing is currently scheduled to conclude by August 1, 2025.

3. *University of Kansas Hospital Authority. v. Kennedy*

In February 2025, four hospitals filed the first challenge to the inpatient prospective payment system ("IPPS") standardized amount alleging the improper carry-forward of the 1985 budget neutrality provisions in *University of Kansas Hospital Authority v. Kennedy*, No. 25-cv-603 (D.D.C. 2025). The hospitals claim HHS wrongly incorporated 1985 offsets meant to expire, resulting in an ongoing nearly 6% reduction in IPPS payments. After the PRRB dismissed the hospitals' appeals as barred from administrative and judicial review, the hospitals turned to federal court. They invoke the court's reasoning in the district court's December 2024 decision in *St. Mary's Regional Med. Ctr. v. Becerra*, 2024 WL 5186641 (D.D.C. 2024), discussed in the March 2025 Newsletter, holding that the Medicare statute does not preclude judicial review of a challenge to the undercalculation of the IPPS standardized amount calculation resulting from the inclusion of transfers as discharges in the inaugural 1984 IPPS standardized amount.

Congress required the transition to the IPPS from the prior "reasonable costs" reimbursement model to be budget neutral in an attempt to guard against disruptive payment swings resulting from the transition. Under the budget neutrality

provisions, aggregate Medicare payments in FYs 1984 and 1985 were to be equal what they would have been under the reasonable cost payment system. 42 U.S.C. § 1395ww(d)(2)(F), (e)(1)(B). The plaintiff hospitals argue that the budget neutrality provisions put in place at the start of the IPPS were explicitly limited to FYs 1984 and 1985, and no budget neutrality adjustment was to be made to the 1986 IPPS rates. 42 U.S.C. § 1395ww(e)(1)(B). HHS expected that Medicare payments would increase in 1984 and 1985 due to inflation, and thus applied budget neutrality adjustments to offset the projected increases by 3% in 1984 and 6% in 1985. HHS declined to retire the 1985 budget neutrality adjustment in the 1986 standardized amount calculation, which has been carried forward in setting subsequent IPPS rates, including the current rate. HHS's position was that the statute did not explicitly require HHS to make IPPS payments without the 1984 or 1985 budget neutrality offsets. 50 Fed. Reg. 35,646, 35,697 (Sept. 3, 1985).

The plaintiff hospitals in *University of Kansas* allege that the IPPS statute requires that the starting point for post-1985 standardized amounts be the non-budget-neutralized 1985 amount, and the inclusion of the budget neutrality provisions that were supposed to expire in 1985 in later standardized amount calculations violates the statute. 42 U.S.C. § 1395ww(e)(1)(B). The hospitals argue that the result of the improper carry forward of the 1985 budget neutrality provisions into latter standardized amount calculations has resulted in a nearly 6% reduction of IPPS payments since 1985.

The hospitals appealed the budget neutrality offsets carried forward to their FY 2025 IPPS standardized amount calculations to the PRRB. The Board dismissed the hospitals' appeals, stating that the Medicare statute bars administrative and judicial review of HHS's improper carrying forward of the 1985 budget neutrality adjustment to later years. The hospitals argue that the Board's reading of the statute is wrong and that the statute only precluded review of *how* HHS applied the budget neutrality adjustment in FY 1985, not the adjustment's improper carry forward to later years. The hospitals invoked the court's reasoning in the recent *St. Mary's* case on the inaugural IPPS standardized amount error that "no part of the IPPS statute, including the budget neutrality provisions, authorized the Secretary to carry forward the 1985 budget neutrality adjustment to the following year; in fact, the statute forbade him from doing so." *St. Mary's*, 2024 WL 5186641, at 9.

The Secretary's answer to the compliant is due July 21.

4. *Appeals of Board Dismissals of Jurisdictionally Challenged Section 1115 Waiver Days Appeals*

Several lawsuits challenging dismissals of appeals on the exclusion of section 1115 waiver days are closer to resolution now that the deadline to file an appeal has elapsed in *Baylor All Saints Medical Center v. Becerra*, No. 4:24-CV-00156-O, 2025 WL 888500 (N.D. Tex. Mar. 21, 2025) ("*Baylor All Saints II*"), the lead case in a handful of Section 1115 waiver day exclusion challenges. This follows the Northern District of Texas's ("Texas Court") March 21, 2025, dismissal of the provider plaintiff's claims in *Baylor All Saints II* related to the dismissal of an appeal challenging the exclusion of section 1115 waiver days. In *Baylor All Saints II*, the court upheld the PRRB's dismissal of the provider's Section 1115 waiver day claims based on non-compliance with PRRB requirements. Most related cases were stayed pending the appeal deadline in *Baylor All Saints II*.

The plaintiff hospital in *Baylor All Saints II* requested that the district court overrule the PRRB's dismissal of the provider's appeal 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* the Docket Update section of the March 2025 Newsletter for details on Section 1115 Waiver Days Appeals. The hospital raised three arguments in support of its request: (1) the Board's decision was arbitrary and capricious; (2) the Board's decision was contrary to its own rules; and (3) the Board's rules themselves are arbitrary and capricious. The government argued that the PRRB had determined that the provider had not properly appealed the number of section 1115 waiver days as a component of the DSH Medicaid fraction, and that the hospital had not shown it was entitled to relief on section 1115 waiver days. *See id*.

In its March 21 ruling, the Texas Court found that the PRRB's decision was not arbitrary and capricious, and that the PRRB had properly dismissed the hospital's appeal because the hospital did not comply with the PRRB's requirements by raising as a distinct issue under appeal the improper exclusion of section 1115 waiver days in the Medicaid fraction. Having already found for the PRRB, the Texas Court did not address the hospital's final two arguments.

Several lawsuits challenging the PRRB's dismissals of appeals challenging the Secretary's decision to exclude days for patients receiving assistance under a section 1115 waiver in the Medicaid fraction for periods before 2023 remain ongoing in the wake of the *Baylor All Saints II* decision. Many of

these cases were stayed while the appeal deadline in *Baylor All Saints II* was pending, giving parties time to evaluate whether they will attempt to move forward with their respective challenges. However, one case, *Baylor All Saints Medical Center v. Becerra*, No. 4:24-cv-652 (N.D. Tex. 2024) ("*Baylor All Saints I*"), which also challenged dismissal of an appeal regarding section 1115 waiver days with respect to Medicare reimbursement, was not stayed and was terminated pursuant to a joint stipulation of dismissal filed June 5, 2025. *Id*. at ECF No. 19.

5. *Trump v. CASA Inc.*

On June 27, 2025, the Supreme Court issued a decision in *Trump v. CASA Inc.*, No. 24A884, 2025 WL 1773631 (U.S. June 27, 2025) ("*CASA*"). Although the underlying dispute in the case involves a challenge to Executive Order 14160, "Protecting the Meaning and Value of American Citizenship," which purports to interpret the Citizenship Clause of the Fourteenth Amendment to eliminate birthright citizenship, the issue presented to the Supreme Court focused on the broader question of permissibility of so-called "nationwide" or "universal" injunctions. The Court ruled that federal courts lack the authority to issue "universal" or "nationwide" injunctive relief that extends beyond the parties to the dispute. However, the Court recognized that universal injunctions are permitted in class actions or when necessary to provide complete relief to the parties in the litigation. The Court also did not address the authority of federal courts to set aside or vacate agency actions under the Administrative Procedure Act ("APA"), which would have the effect of invalidating the agency action as to both parties to the litigation and non-parties.

The dispute regarding universal injunctions will likely have limited implications on reimbursement issues. The decision concerned the scope of relief for preliminary injunctions and did not address relief available under other statutes, and thus, universal vacatur remains permissible under the APA, at least for now. In addition, the government represented that it generally will follow circuit court judgments within that circuit, and non-parties may be able to file follow-on cases within the same circuit after a favorable ruling to obtain the benefit of a circuit court decision. And since any provider can bring suit in the D.D.C., providers who are not party to a case can file a new suit in the D.D.C. to get the benefit of any D.C. Circuit ruling the government fails to properly follow. Finally, the Supreme Court acknowledged that universal relief remains available through class actions or where necessary to provide complete relief to the parties.

6. *Guardian Flight, LLC v. Health Care Services Corp.*

On June 12, 2025, the U.S. Court of Appeals for the Fifth Circuit issued a decision in *Guardian Flight, LLC v. Health Care Services Corp.*, 140 F.4th 271 (5th Cir. 2025), holding that the No Suprises Act (the "Act") did not provide two air ambulance service providers with a private cause of action to sue an insurer to enforce or confirm an Independent Dispute Resolution ("IDR") award. The case arose from efforts by the providers to negotiate the scope of benefits coverage with Health Care Service Corporation ("HCSC")—a member-owned health insurance company—under the Act. *See Guardian Flight, LLC v. Health Care Serv. Corp*., 735 F. Supp. 3d 742, 747-48 (N.D. Tex. 2024). The providers initially pursued the IDR process established by the Act, which implements the Act's goal of protecting patients from surprise medical bills by creating a non-judicial process for providers to settle billing disputes with insurers.

After the IDR process concluded, the providers brought suit under the Act alleging that HCSC had failed to timely pay providers 33 IDR awards, and also brought claims under ERISA and an unjust enrichment theory. The district court dismissed the providers' claims, and the Fifth Circuit affirmed its dismissal, concluding that the Act does not provide a general private right of action to sue to enforce the terms of IDR awards. The Fifth Circuit reasoned that the Act precludes judicial review of IDR awards except for limited circumstances where the award was procured by fraud or where the arbitrators were not impartial or engaged in misconduct, and that Congress chose not to incorporate the provisions of the Federal Arbitration Act that authorize courts to confirm or enforce arbitral awards.

The Fifth Circuit's ruling conflicts with a recent ruling of the U.S. District Court for the District of Connecticut in *Guardian Flight LLC v. Aetna Life Insurance Co.*, 2025 WL 1399145 (D. Conn. 2025). If courts continue to reach different conclusions on whether the Act contains an implied private right of action to enforce IDR awards, it is more likely that the Supreme Court will consider the issue on certiorari or that Congress will amend the Act to clarify its intent.

7. *State of New York v Kennedy*

On July 1, 2025, the U.S. District Court for the District of Rhode Island granted a preliminary injunction in *State of New York v. Kennedy*, No. 1:25-cv-196, 2025 WL 1803260 (D.R.I. July 1, 2025) ("*State of New York*"), finding that a coalition of 19 states and D.C. had shown irreparable harm and were likely to succeed on claims that the Trump Administration's

proposed large-scale restructuring and reductions-in-force ("RIFs") of HHS were arbitrary, capricious, and contrary to law. Widespread personnel and structural changes at HHS have the potential to significantly disrupt the programs hospitals and health systems rely on for funding and oversight.

On May 5, 2025, Plaintiffs filed a complaint challenging a proposal announced by Secretary Robert F. Kennedy, Jr. in his March 27, 2025 "Make America Healthy Again" directive (the "MAHA Directive") on constitutional and statutory grounds and seeking a court order declaring the directive unlawful and preventing its implementation. *State of New York*, Compl. at 1–5, ECF No. 1. On May 9, 2025, the plaintiffs filed a motion for preliminary injunction, requesting the district court temporarily block the directive while the case is pending. *State of New York*, Mot. for Prelim. Inj., ECF No. 43. Issued pursuant to Executive Order 14210, 90 Fed. Reg. 9669 (2005), the MAHA Directive orders HHS to terminate 10,000 employees, consolidate 28 divisions into 15, and centralize certain functions into newly created offices.

In their complaint and motion for preliminary injunction, the state plaintiffs asserted that the MAHA Directive is unconstitutional, exceeds executive authority, and violates the APA. Specifically, the plaintiffs argued that the directive usurps Congressional authority by incapacitating HHS without legislative approval and exceeds the President's and HHS's legal authority to dismantle or weaken agencies established by Congress. Additionally, the plaintiffs claimed that HHS's refusal to spend appropriated funds violates the separation of powers principles reflected in the Appropriations Clause and codified in the Impoundment Control Act. The plaintiffs also contended that the directive is arbitrary and capricious under the APA due to a lack of reasoned decision-making and failure to consider the consequences of this agency action. According to the plaintiff states, these changes are already causing serious harm. They alleged that essential public health services, such as disease surveillance, laboratory testing, HIV/AIDS prevention, and maternal and infant health programs, are being disrupted. In addition, plaintiff states asserted that the loss of technical support, data, and grant management is constraining their ability to help vulnerable populations. Plaintiffs also alleged that the inability to update federal poverty guidelines is affecting eligibility for benefits, and that as a result, states are facing higher costs and more administrative burdens as they try to make up for the loss of federal support.

In a response filed May 16, 2025, the federal defendants argued that the executive branch has "broad discretion" over its personnel and priorities. *State of New York*, Opp. to Mot. for Prelim. Inj., ECF No. 52. Defendants asserted that the plaintiffs lack standing to challenge the restructuring and RIFs and maintained that any claims for non-payment of grant funds should be brought before the Court of Federal Claims under the Tucker Act. The government also argued that the Civil Service Reform Act precludes judicial review of HHS employment decisions. In addition, the government contended that the plaintiffs were unlikely to succeed on their APA claims because the plaintiffs did not challenge discrete, final agency action and failed to meet the higher standard required for APA challenges to unlawfully withheld agency action. The government urged denial of the motion for preliminary injunction, arguing that plaintiffs' alleged injuries are speculative and that granting the request would cause immense harm to the executive branch.

Following oral argument, D.R.I. granted the plaintiffs' motion for preliminary injunction on July 1, 2025, enjoining HHS and all other named defendants from taking any action to implement or enforce the MAHA Directive. *State of New York*, Mem. & Order, ECF No. 73. The district court rejected defendants' jurisdictional arguments, and concluded that the Trump Administration had "usurped" Congressional authority over public health appropriations such that plaintiffs were likely to succeed on their "contrary to law" claims. *Id.* at 49. The district court declined to reach the constitutional issues, finding that it "need not go further" because alternative grounds for resolution were available. *Id.* In light of the preliminary injunction ordered May 22, 2025, in *American Federation of Government Employees v. Trump*, No. 3:25-cv-3698 (N.D. Cal. 2025) ("*AFGE 2*"), the district court stated it would "preemptively deny" defendants' request to stay the injunctive relief pending any appeal they may file. *Id.* at 57.

Parties filed statements on July 11, 2025, addressing the effect of *CASA* on the *State of New York* preliminary injunction order. While plaintiffs asserted that the Supreme Court's decision does not affect the scope of the *State of New York* preliminary injunction, the federal defendants agreed and requested D.R.I. modify its order to apply only to, and within the boundaries of, the plaintiff states.

The federal defendants filed a status report by July 11, 2025, detailing the status of their compliance with the D.R.I. preliminary injunction order. *State of New York*, Status Report, ECF No. 74. In the status report, defendants emphasized that the D.R.I. order is narrower than the preliminary injunction in *AFGE 2*, which blocked implementation of Executive Order No. 14210 and a joint memorandum from the White House's

Office of Management and Budget and Office of Personnel Management, which directed 22 federal departments and agencies to prepare for RIFs and sweeping reorganizations. On July 8, 2025, the Supreme Court stayed the *AFGE 2* preliminary injunction order, finding the factors weighed in favor of staying the injunctive relief but "express[ing] no view on the legality of any Agency RIF and Reorganization Plan produced or approved pursuant to the Executive Order and Memorandum. *Trump v. American Federation of Government Employees*, 2025 WL 1873449 (2025). While the *AFGE 2* preliminary injunction order applied to 22 federal departments and agencies, the preliminary injunction in *State of New York* only applies to the following HHS programs: Centers for Disease Control and Prevention; (ii) the Food and Drug Administration's Center for Tobacco Products; (iii) the Administration for Children and Families' Office of Head Start and regional offices; and (iv) the Assistant Secretary for Planning and Evaluation. *State of New York*, Mem. & Order, ECF No. 73. To ensure compliance with the *State of New York* preliminary injunction notwithstanding the stay of the broader preliminary injunction in *AFGE 2*, HHS's Office of General Counsel circulated specific guidance to the four components impacted by the D.R.I. order and to additional staff involved in implementing the MAHA Directive. *State of New York*, Status Report, ECF No. 74. Defendants have not appealed the D.R.I. preliminary injunction order as of the date of publication.

State of New York and *AFGE 2* are among several ongoing challenges to the Trump Administration's efforts to significantly reduce the federal budget and workforce. On July 15, 2025, the Supreme Court issued an order in *McMahon v. State of New York*, No. 24A1203, 2025 WL 1922626 (U.S. July 14, 2025), staying a preliminary injunction that ordered the immediate reinstatement of all employees fired from the U.S. Department of Education. The Supreme Court's stay of an agency-specific restructuring plan is notable and may affect ongoing proceedings in *State of New York*.

8. *American Health Care Association et al v. Kennedy*

In, *American Health Care Association et al v. Kennedy*, No. 2:24-cv-00114 (N.D. Tx 2025), the association representing long-term and post-care care providers successfully challenged CMS's nursing home staffing rule. Notwithstanding the Trump Administration's broader deregulatory efforts, the administration continues to defend against certain legal challenges to pre-existing regulations. For example, on April 7, a Biden-era nursing home staffing rule that would require nursing homes to add more direct-care staff and an on-site registered nurse around the clock was vacated by Judge Kacsmaryk in the Northern District of Texas. The rule was expected to place a considerable burden on the nation's 15,000 nursing homes, already struggling with staffing. Judge Kacsmaryk agreed with the nursing home industry that the HHS rule exceeded Congress's statutory intent. The Trump Administration has appealed this decision to the Fifth Circuit Court of Appeals, despite the fact that the rule places a considerable burden on the nursing home industry. This suggests that there are some existing regulations the Trump Administration is willing to defend in court.

9. *Volume-Decrease Adjustment Appeals*

Following the D.C. Circuit's 2024 decision in *Lake Region Healthcare Corp. v. Becerra*, 113 F.4th 1002 (D.C. Cir. 2024) ("Lake Region Healthcare") addressing CMS's methodology for calculating the volume-decrease-adjustment ("VDA") (as discussed in the November 2024 Newsletter), the Provider Reimbursement Review Board ("PRRB" or "Board") has been resolving VDA appeals by remanding appeals to the contractors to calculate the payment based on the Board's longstanding "fixed-fixed" methodology.

Sole Community Hospitals ("SCHs") are entitled 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), VDA payments must "fully compensate" SCHs for their fixed costs, including the "reasonable cost of maintaining necessary core staff and services." Historically, CMS has used several different methodologies for calculating VDA payments. 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 *Lake Region Healthcare*, the MAC denied the hospitals' VDA request, employing the "fixed-total" calculation methodology to conclude that Lake Region had already been fully compensated for its fixed costs. The PRRB reversed the MAC's decision and granted Lake Region the full requested VDA, employing its longstanding "fixed-fixed" methodology. The CMS Administrator reversed the Board, employing the "fixed-total" methodology, and the hospitals appealed to the

D.C. district court. The court ruled in favor of the agency and the Administrator's "fixed-total" approach under *Chevron* deference. But, following the Supreme Court's intervening decision in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024), the D.C. Circuit reversed the district court's decision and rejected the agency's interpretation of the VDA statute and the "fixed-total" methodology.

The Board has been remanding VDA appeals employing its longstanding, and now validated by the D.C. Circuit, "fixed-fixed" methodology. The Board has noted in several decisions that "[i]n the appeals following the D.C. Circuit's *Lake Region* decision, the Administrator has declined review [of the Board's decisions]" and "[t]he Board finds that the "fixed-fixed" methodology is proper for the calculation of the. . .VDA payment. . ."

10. *Marin General Hospital et al. v. Kennedy*

In recent months, hospitals have filed several cases challenging the regulations that limit PRRB group appeals to only a single issue, following the Board's denials of requests for expedited judicial review ("EJR") on the grounds that the appeals contain multiple issues and the Board therefore lacked jurisdiction. *See e.g.*, *Marin General Hospital et al. v. Kennedy*, No. 1:25-cv-881 (D.D.C. 2025). Plaintiffs argue these rules conflict with 42 U.S.C. § 1395oo(b), which describes "*matters* in controversy" in group appeals (emphasis added). They also contend that the Board should have broken their group appeals into multiple appeals if it identified more than one issue. The plaintiff hospitals argue in *Marin*, and in several other identical cases, that (1) the regulation and corresponding PRRB rules that limit group appeals to a single issue are contrary to the plain language of the Medicare statute, and (2) in the alternative, the Board was required to bifurcate the hospitals' group appeals into multiple appeals.

In September 2018, 29 hospitals sought EJR in six separate group appeals on the issue of "whether CMS unlawfully interprets the term 'entitled' in applying differential treatment to the counting of days to compute the Medicare DSH payment." The Board requested the hospitals submit more information in support of the requests for EJR, specifically requesting that it "identify all other regulations. . . that the Providers are challenging." The hospitals responded identifying multiple portions of the DSH regulations relating to different legal questions pertaining to the calculation of the Medicare fraction.

The Board denied the EJR requests, stating it did not have jurisdiction over all of the multiple legal issues raised in the EJR requests. Six years later, the providers wrote to the Board asking for a renewed decision on their EJR requests, which the Board denied, stating that the renewed request did not comply with the Board's rules for filing a new, standalone request for EJR, and reiterating that the EJR requests contained multiple issues.

The hospitals challenged the second EJR request denial, arguing that PRRB Rules 12 and 13, which limit group appeals to a single issue, and the corresponding regulation at 42 C.F.R. § 405.1837, are contrary to the plain language of 42 U.S.C. §1395oo(b), which provides for group appeals to the PRRB "only if the matters in controversy involve a common question of fact or interpretation of law or regulations." The hospitals also argue that the Board was bound by 42 C.F.R. 405.1837(f)(2)(ii), which provides that "[w]hen the appeal is found to involve more than one factual or legal question common to each provider, the Board must assign a separate case number to the appeal of each common factual or legal question and conduct further proceedings in the various appeals separately for each case."

The Secretary's answer to the complaint in *Marin* is due August 1, 2025.

11. *Additional Cases to Watch*

Baylor All Saints Med. Ctr. v. Kennedy, No. 24-10934 (5th Cir.) – The government has appealed the lower court's ruling striking 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 from the count of Medicaid-eligible days used to determine the Medicare DSH payment. Oral argument will be scheduled for the first week of September.

Battle Creek Health System v. Becerra, No. 23-5310 (D.C. Cir.) – The government appealed the lower court's ruling that hospitals can appeal directly from CMS's published Supplemental Security Income ("SSI") fractions, 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"). Oral argument was held in November 2024, and a decision is expected in the coming months.

Regulatory Updates

1. *CMS Seeks Public Comments on Hospital Price Transparency Accuracy and Completeness following Executive Order 14221*

On May 22, 2025, CMS released updated Hospital Price Transparency Guidance to reconcile pre-existing Hospital Price Transparency Guidance with President Trump's February 25, 2025 Executive Order 14221 "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information." Executive Order 14221 (i) ordered the Departments of Treasury, Labor, and HHS to issue new rules or guidance to better standardize reports of price information and enforce price transparency requirements, and (ii) required disclosure of the actual prices of items and services instead of estimates.

Accordingly, the updated guidance (i) requires hospitals to encode a standard charge dollar amount if it can be calculated, and (ii) instructs hospitals to discontinue use of a placeholder (i.e., 999999999) in the estimated dollar amount field, and instead supply an actual dollar amount. CMS clarified that it expects hospitals to encode payor-specific negotiated charges as dollar amounts, and where payor-specific charges are not known (e.g., because the negotiated change is a percentage of a fee schedule), to encode an "estimated allowed amount." With regard to the "estimated allowed amount," in the event that the hospital has no reimbursement data from the prior 12 months for a particular item or service, it should encode an "expected" dollar amount and include a comment that there were no instances of the item or service in the prior 12 months. Executive Order 14221 also details additional transparency enforcement efforts, as described in detail in the Enforcement Updates section, below.

CMS also solicited public comment on several questions related to hospital price transparency reporting, aimed at gathering feedback on how best to ensure accurate, complete, and meaningful data. Comments were due July 21, 2025.

2. *Trump Administration Continues Efforts to Push for Deregulation*

The Trump Administration has announced several initiatives to streamline or eliminate federal (and state) regulations, including (i) the Justice Department's ("DOJ") anticompetitive regulations task force, and (ii) HHS's and the Food and Drug Administration's ("FDA") Request for Information to identify and eliminate outdated or unnecessary regulations. The administration has yet to clarify the specific regulations that will be edited or eliminated.

DOJ Anticompetitive Regulations Task Force

On March 31, 2025, DOJ launched an anticompetitive regulations task force focused on identifying and eliminating federal and state regulations that hinder competition, including within health care. The task force's stated purpose is to "advocate[] for the elimination of anticompetitive state and federal laws and regulations that undermine free market competition and harm consumers, workers, and businesses." DOJ aims to reduce regulatory burdens, in part, to remove barriers and to allow for easier competition by smaller entities within the health care industry. DOJ solicited public comment through May 27 as to specific laws and regulations that are believed to cause barriers to competition, including in health care, and received approximately 400 total submissions. While the DOJ has yet to identify what regulations it will target, in a June 24, 2025, statement to the Senate Subcommittee on Antitrust, Competition Policy, and Consumer Rights, Principal Deputy Assistant Attorney General Roger Alford listed health care regulation as a key area of concern raised in the public comments received by the task force. Two specific examples Alford cited were Certificate of Need laws, which Alford argued could deter entry into health care markets and suppress competitive supply, and onerous licensing requirements that Alford stated worked to suppress competition by preventing the provision of telehealth services across state lines.

This task force is consistent with further pushes by the executive branch to deregulate, including a pair of recent presidential actions, both published April 9, 2025: the first, an Executive Order, directs agency heads to identify anticompetitive regulations within 70 days and submit said lists to the Chairman of the Federal Trade Commission ("FTC") and the Attorney General, and the second, a presidential memorandum, directs agency heads to review regulations with a specific eye toward legality under recent Supreme Court decisions.

In the midst of these efforts to deregulate the health care industry at a federal level, state governments continue to impose additional regulatory requirements that require oversight of health care providers and review of health care players and transactions. For example, an increasing number of states have enacted new or more stringent regulatory review and approval processes for "material" health care transactions (e.g., hospital combinations or physician practice acquisitions), seemingly motivated by a desire to more carefully scrutinize transactions that could reduce competition or access to health care services. Notably, a number of the public comments submitted to DOJ in response to the task force's request were specifically related to purportedly anti-competitive state law regulations of health care entities, including payors, facilities, and providers. Specifically, the

comments called for reforms to state-based regulations related to provider licensing, Certificate of Need ("CON") filings, unrestricted consolidation (specifically by high-profit or private-equity-backed entities), and provider scope of practice laws (especially in states with many rural and underserved areas, e.g., South Carolina). It remains to be seen how the contrasting federal and state approaches to promoting competition within the health care industry may alter the regulatory balance of power between federal and state authorities.

HHS and FDA Request for Information

On May 13, HHS and FDA issued a public Request for Information to identify and eliminate outdated or unnecessary regulations. HHS Secretary Kennedy released an explanatory video detailing the "10-to-1" deregulatory agenda, which requires agencies to repeal 10 existing regulations for every new regulation issued, consistent with Executive Order 14192. HHS will implement the previously described 10-to-1 rule; cap the cost of all new regulations in fiscal year 2025 at less than zero; expand deregulation to guidance documents, memoranda, policy statements, and similar directives; and engage in "radical transparency," publishing annual reports detailing estimated regulatory costs. The comment period runs for 60 days, from May 13 to July 12, with a specific portal created for public submissions. While it is unclear what regulations HHS, FDA or other federal agencies will target as potentially anticompetitive, hospitals and health systems should monitor this effort to see whether the Justice Department or other agency heads identify opportunities to streamline regulations related to reimbursement.

3. *Recent Government Actions Reflect Administration's Efforts to Cut Medicaid Spending*

Congress and CMS have proposed several measures that may result in substantial reductions in Medicaid spending. Three recent examples are detailed below which, if fully implemented, could reduce Medicaid receipts for hospitals and health systems and potentially necessitate alternate funding streams:

- Tightening Medicaid eligibility and coverage, including work requirements and cost-sharing for certain beneficiaries.
- Ending matching of Medicaid funds to the federal matching for Designated State Health Programs ("DSHPs") and Designated State Investment Programs ("DSIPs").
- Restricting provider taxes, which states often use to increase federal matching funds, by prohibiting new taxes or limiting rate increases on existing taxes.

The efforts described below reflect the government's focus on reducing federal spending on Medicaid in favor of shifting the burden back to states. Hospitals and health systems may see higher rates of uninsured individuals, reduced flexibility for non-core mission activities, and potential downward pressure on Medicaid rates. Further, hospitals that qualify for Medicare Disproportionate Share Hospital ("DSH") adjustments may lose eligibility due to reduced numbers of Medicaid patients lowering their DSH Patient Percentage. Hospitals are also likely to face reduced uncompensated care payments with reduced Medicaid eligibility, resulting in increased uncompensated care costs.

Restrictions on Medicaid Eligibility and Coverage

On July 4, 2025, President Trump signed the budget reconciliation bill titled, "One Big Beautiful Bill Act" (the "BBB") into law. The BBB is expected to reduce Medicaid spending by imposing more stringent Medicaid eligibility requirements, thereby reducing the number of individuals covered by Medicaid and, in some instances, reducing Medicaid benefits. The requirements include the imposition of work and "community engagement" requirements, more frequent eligibility checks, cost-sharing requirements for certain beneficiaries, and shortening the open enrollment period. Cost-sharing changes will maintain the 5% of family income cap on out-of-pocket costs but require states to impose cost-sharing of up to $35 per service on expansion adults with incomes between 100% and 138% of the Federal Poverty Level. Legislators project that these restrictions would reduce expenditures by $900 billion over the next decade. While Medicaid home- and community-based services that largely serve disabled individuals were not targeted by the BBB, given the increased financial pressure from lower hospital reimbursements, these programs will likely be targets for hospitals' budget cuts. Accordingly, hospitals and health systems should prepare to revise current cost-sharing for services provided to Medicaid beneficiaries and encounter greater numbers of uninsured individuals.

Restrictions on Provider Taxes

The BBB also targets so-called "provider taxes," which are assessments levied on entities like hospitals and nursing homes. Generally speaking, provider taxes help states draw in greater matching payments from the federal government, while the states make higher Medicaid payments to the

providers in order to even out the burden of the taxes. This practice has recently drawn public scrutiny, particularly by Republicans, and some policy observers cite provider taxes as a contributing factor in Medicaid's rising costs (because, absent a cap on federal matching funds, states can, in theory, use provider taxes to generate limitless increased federal support). However, provider taxes are widely utilized; every state except Alaska currently uses provider taxes as part of their Medicaid financing. Accordingly, any restrictions in states' ability to impose provider taxes could have a meaningful impact on state Medicaid finances.

The BBB prohibits states from establishing any new provider taxes or from increasing the rates of existing taxes. This limit applies to taxes on all provider types, except nursing facilities and intermediate care facilities, and local government taxes in expansion states. The BBB further imposes additional requirements to ensure non-uniform or non-broad-based health care-related taxes are "generally redistributive," including by preventing taxes that impose higher rates on providers that primarily serve Medicaid beneficiaries than on other providers that serve a relatively smaller number of beneficiaries.

Separately, on May 12, 2025, CMS issued a proposed rule to update the rules of engagement for states that impose provider taxes. The proposed provisions overlap with those enacted in the BBB regarding non-uniform and non-broad-based health care-related taxes. CMS is accepting public comments on the proposed rule through July 14, 2025.

Ending Matching of Medicaid Funds to Designated State Health Programs ("DSHPs") and Designated State Investment Programs ("DSIPs")

On April 10, CMS sent a letter to states with DSHPs or DSIPs, notifying them that it would neither approve nor reauthorize federal fund matching for DSHPs or DSIPs. DSHPs and DSIPs are state programs, funded through Section 1115 demonstrations, which offer innovative and experimental programs under the state Medicaid plan. Under the 1115 demonstrations, CMS authorizes states to waive certain federal requirements or authorize federal matching funds for new Medicaid initiatives that are "integral to the state's section 1115 demonstration" (April 10, 2025 CMS Letter "RE: Designated State Health Programs and Designated State Investment Programs"). For example, historical initiatives have included grants to rural health care providers in North Carolina for high-speed internet to support telehealth services, as well as grants to a labor union in New York to reduce costs of health insurance for certain childcare providers. In order to "preserve the core mission of the Medicaid program" and to "safeguard the financial health of the Medicaid program," CMS is reevaluating such initiatives, which it views as removed from Medicaid's "core mission." Hospitals and health systems that currently have any or participate in any DSHP or DSIP will need to reevaluate the financing or provision of such services, without additional federal funding for these programs.

4. *CMS Publishes Federal Fiscal Year 2026 Hospital Payment Proposed Rule*

On April 11, 2025, CMS published its annual proposed rule for the FFY 2026 inpatient prospective payment system ("IPPS") and long-term care hospital ("LTCH") payment system, proposing a 2.4% overall rate increase for IPPS and a 2.6% increase for LTCH. We summarized the proposed rule in a client alert, in which we analyzed key developments on 15 topics related to hospital reimbursement. Although the deadline for submitting comments to CMS has passed, please reach out to your Ropes & Gray advisor if you have any questions about these proposals. Here, we provide a high-level summary of CMS's proposals with respect to (i) DSH payments, (ii) changes in the IPPS and LTCH PPS payment rates for FFY 2026, and (iii) changes to the low-volume hospital definition and payment adjustment:

Medicare DSH

For FFY 2026, CMS proposes to increase total DSH payments by $1.5 billion over FFY 2025, to $7.29 billion. CMS arrived at this figure by revising the three statutory factors that determine DSH payments: (1) CMS's estimate of 75% of the amount of traditional DSH payments that would have been paid under the pre-2014 system; (2) an adjustment to that amount to account for changes in the national uninsured rate; and (3) each eligible hospital's estimated uncompensated care amounts relative to total uncompensated care for all eligible hospitals.

Changes in IPPS Payment Rates and Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FFY 2026.

CMS proposes an increase of 2.4% to the overall IPPS payment rates for FFY 2026, which represents a 3.2% increase to the market basket percentage estimate offset by a 0.8% decrease due to productivity adjustment. CMS also proposes a 2.6% increase in the national standardized amount for LTCHs for FFY 2026, the result of a 3.4% increase to the market basket percentage estimate offset by a 0.8% decrease due to the productivity adjustment. CMS estimates the proposed changes will result in an increase of approximately $4 billion

in FFY 2026 payments to acute care hospitals, primarily driven by changes in operating payments, uncompensated care payments, and capital payments. Additionally, CMS estimates the proposed changes will result in an increase of approximately $61 million in FFY 2026 payments to LTCHs, primarily driven by the market basket update and adjustments for area wage levels and high-cost outlier payments.

Changes to Low-Volume Hospital Definition and Payment Adjustment

The Consolidated Appropriations Act of 2025 ("CAA 2025") extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment through FFY 2025. Unless Congress further extends the low-volume payment adjustment, beginning with FFY 2026, CMS proposes to revert to the definition of "low-volume hospital" and the corresponding payment adjustment methodology in effect between FFY 2005 – FFY 2010. This would require CMS to develop an empirical relationship between (a) the standardized cost-per-case for such hospital and the total number of discharges of such hospitals and (b) the amount of the additional incremental costs (if any) associated with the number of such charges. Additionally, beginning in FFY 2026, a "low-volume hospital" must be more than 25 road miles from another subsection (d) hospital and have fewer than 200 discharges during the fiscal year. CMS proposes that hospitals submit written requests for low-volume hospital status to their MAC by September 1, 2025.

5. *CMS Finalizes Calendar Year 2026 Medicare Advantage and Part D Payment Rates*

On April 7, 2025, CMS finalized its payment policies for CY 2026 for Medicare Advantage ("MA") and Part D programs. In the last edition of the newsletter, we covered the CY 2026 Advance Notice ("Advance Notice") issued January 10, 2025 (see Calendar Year 2026 Advance Notice of Methodological Changes for MA Capitation Rates and Part C and Part D Payment Policies). The CY 2026 finalized payment policies are largely consistent with those proposed in the Advance Notice, although CMS payments to MA plans are now expected to increase by approximately 5.06% from 2025 to 2026, or over $25 billion, as compared to the previously projected 4.33% ($21 billion) increase. This represents the largest increase in MA and Part D payments since CY 2023. CMS notes this increase is largely attributed to the increased effective growth rate, which is 9.04%. With MA plans projected to receive even larger capitated payments from CMS, hospitals and health systems may have an opportunity to negotiate more favorable reimbursement rates with payors.

NOTE: After this newsletter had gone to publication, CMS released its proposed rules for the Physician Fee Schedule and Outpatient Prospective Payment System. Keep your eyes out for future insights from Ropes and Gray.

Enforcement Updates

1. ***DOJ Announces White-Collar Enforcement Priorities and Revised Self-Disclosure Policy***

On May 12, 2025, DOJ announced a new white-collar enforcement plan and accompanying changes to white-collar and corporate enforcement policies, emphasizing health care fraud as a top priority. DOJ plans to expedite investigations, pursue individual wrongdoers, and review corporate agreements for possible early termination. Revisions to the Criminal Division's Corporate Enforcement and Voluntary Self-Disclosure Policy encourage timely disclosures by promising declinations or reduced penalties, even if DOJ is already aware of misconduct, so long as the disclosure meets certain criteria. Hospitals and health systems should take particular note of revisions to incentives for corporate cooperation and whistleblower priorities.

In a memorandum accompanying the announcement, DOJ identified 10 "high-impact areas" on which DOJ will focus its white-collar enforcement efforts, of which health care fraud is the first. The memorandum continues DOJ's prioritization of individual over corporate prosecutions, stating that the "prosecution of individuals, as well as civil and administrative remedies directed at corporations, are often appropriate to address low-level corporate misconduct and vindicate U.S. interests." In line with this individual emphasis, DOJ stated that it will "review the length of all existing agreements with companies to determine if they should be terminated early."

The memorandum also emphasizes the importance of "efficient investigations" that are "swiftly concluded." While this may lower the number of lingering investigations, the directive may also result in premature charging decisions without the benefit of a comprehensive review.

Also on May 12, DOJ revised the Criminal Division's Corporate Enforcement and Voluntary Self-Disclosure Policy ("CEP"). The updated CEP encourages voluntary self-disclosures by being less "stingy" with incentives, guaranteeing declinations for fully cooperative companies that implement remedial measures barring aggravating circumstances. Prosecutors retain discretion in high-impact cases, where companies might still face significant penalties.

The new policies also reduce the rush for companies to self-report. Under the revised guidance, companies that disclose misconduct within 120 days of an internal whistleblower report, and before DOJ contacts the company, will receive a declination, even if DOJ is already aware of the misconduct. Substantial benefits like Non-Prosecution Agreements and fine reductions are possible for timely, good-faith disclosures. Given the environment of DOJ hiring freezes and still unclear level of overall focus on corporate criminal enforcement, however, companies will need to analyze carefully whether or when to self-disclose an issue to the government.

Additionally, DOJ released an updated overview of the Corporate Whistleblower Awards Pilot Program, which builds on the program released in August 2024. The program is a three-year pilot program designed to incentivize individuals to report criminal misconduct by offering awards for original, truthful information about crimes in one or more of the designated areas. The revised program expands the scope of healthcare fraud that qualifies under the pilot program, now including healthcare offenses and related crimes involving both private and public healthcare benefit programs. Consistent with the first iteration of the program, to qualify for a financial award, tips must result in a forfeiture action.

In all, the May 12 guidance demonstrates that health care fraud enforcement remains a top priority for DOJ. While the guidance provides corporate entities with pathways to avoid prolonged investigations and punitive penalties, we anticipate a continued series of large civil and criminal recoveries for corporate liability coinciding with criminal charges for implicated individuals.

2. *Administration Establishes CMS Fraud Prosecutor Program*

On April 15, 2025, President Trump issued a memorandum that will expand federal efforts to prosecute health care fraud claims against both providers and beneficiaries. The memorandum directs the Attorney General to establish a fraud prosecutor program in at least 15 United States Attorneys' Offices focusing on CMS programs. Although it highlights beneficiary fraud particularly by undocumented immigrants, it is not limited to that context and is aligned with the Trump Administration's stated goal of eliminating waste, fraud and abuse in government health care programs.

3. *DOJ and HHS Announce FCA Working Group & Enforcement Priority Areas*

On July 2, 2025, DOJ and HHS announced the formation of the DOJ-HHS False Claims Act Working Group, signaling a continued and coordinated effort to combat health care fraud through robust enforcement of the FCA. The Working Group will include senior leadership from HHS, CMS, HHS-OIG, and DOJ's Civil Division, along with participation from U.S. Attorneys' Offices nationwide. The Working Group announced six priority enforcement areas for FCA investigations and prosecutions: 1) Medicare Advantage; 2) drug, device, or biologic pricing; 3) barriers to patient access to care (including network adequacy violations); 4) kickbacks related to drugs, medical devices, durable medical equipment, and other federally reimbursed products; 5) materially defective medical devices that impact patient safety; and 6) manipulation of EHR systems to drive inappropriate utilization of Medicare-covered products and services. The Working Group also announced that it will leverage data mining and cross-agency collaboration to expedite investigations and identify new leads.

Of particular interest to providers, the announcement mentions that the Working Group will discuss whether HHS should implement payment suspensions in connection with credible allegations of fraud. Although payment suspensions have been a weapon in CMS's arsenal, payment suspensions have not typically accompanied FCA investigations in recent years. Their mention in the Working Group announcement may signal a shift toward use of this powerful tool, which can deprive companies of much needed revenue while potentially lengthy investigations proceed. HHS's pursuit of payment suspensions could further complicate already complex government investigations and negotiations.

4. *Focus on Health Care Price Transparency Enforcement*

Consistent with Executive Order 14221 (discussed in the Focus On article, above), HHS, Treasury, and Labor have begun more aggressive enforcement of hospital price transparency regulations. CMS's new guidance requires actual prices instead of estimates, and it has issued more frequent monetary penalties against non-compliant hospitals. Hospitals should ensure that posted price disclosures are accurate and comprehensive to mitigate compliance risks.

On February 25, 2025, President Trump signed Executive Order 14221, directing HHS and the departments of Treasury and Labor "to rapidly implement and enforce" health care price transparency regulations that require hospitals to disclose prices on their websites. The Executive Order directs these agencies to "update their enforcement policies" and "ensure hospitals and insurers are in compliance with requirements to

make prices transparent." In response to the Executive Order, CMS released updated guidance regarding the hospital price transparency requirements. This new guidance requires hospitals to post the actual prices of items and services, rather than estimates. CMS also issued a Request for Information ("RFI") to gather public feedback on how to boost hospital compliance and enforcement and ensure data shared is accurate and complete. These actions build on an initiative of the first Trump Administration. In 2019, the president issued Executive Order 13877, which ordered HHS to propose a regulation to require hospitals to publicly post standard charge information. In November 2020, the Transparency in Coverage final rule was promulgated pursuant to that Executive Order, and the Trump Administration is already ramping up enforcement efforts of the regulation. From Inauguration Day through May 13, 2025, CMS issued nine notices of monetary penalties, ranging from $32,000 - $310,000. This is a marked increase from the prior administration, which noticed only three monetary penalties in all of 2024. As federal agencies ramp up these enforcement efforts, hospitals and health systems should continue to ensure the accuracy and completeness of their price disclosures.

5. *Major HHS Reorganization Efforts Underway*

On March 27, 2025, HHS announced it will undergo "a dramatic restructuring" in accordance with President Trump's February 26, 2025 Executive Order, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative." HHS plans a major restructuring. In additional to the workforce reduction announced earlier this year, HHS plans to create a new Assistant Secretary for Enforcement who will lead agency efforts to combat fraud, waste, and abuse in federal health programs. The new Assistant Secretary for Enforcement will oversee offices responsible for key enforcement and dispute resolution activities: the Departmental Appeals Board (which manages coverage and payment disputes between the federal government and providers, state payers, and beneficiaries, and mediates civil monetary penalties), Office of Medicare Hearings and Appeals (which manages coverage and payment disputes from Medicare enrollees and providers), and Office for Civil Rights (which investigates and enforces violations of nondiscrimination and HIPAA). Important details have yet to be announced, such as the structure and staffing of the new office, but its creation may more efficiently focus on the administration's health care enforcement priorities.

Further, CMS recently launched the Fraud Detection Operation Center ("FDOC") to fight waste, fraud, and abuse. To detect fraud, the FDOC leverages the Fraud Prevention System ("FPS"), a tool that uses artificial intelligence and machine learning models to flag potentially fraudulent behavior by providers, such as suspicious billing patterns. On a new webpage, CMS lists "recent success stories" in its fight against fraud, including stopping Medicare payments to a provider who billed for services provided to a deceased patient; removing 18 Medicare providers "convicted of a serious crime" from the Medicare program; and CMS's efforts to review claims prior to payment for new hospices in four high-risk states.

While HHS is rolling out new fraud-fighting initiatives, the department is planning to close regional offices in Boston, Chicago, New York, San Francisco, and Seattle. Oversight and enforcement activities will be absorbed by the remaining offices in Atlanta, Dallas, Denver, Philadelphia and Kansas City. HHS separately announced a reorganization of the Office of General Counsel ("OGC") that will include the closure of six regional OGC offices. It is unclear how these changes will impact health care fraud enforcement, as OGC, HHS and CMS regional offices have traditionally collaborated on enforcement. Hospital and health systems should continue to monitor developments in HHS's reorganization plans as they are announced.

6. *Recent Supreme Court Cases Could Lower Health Care Fraud Litigation Costs*

Recent rulings by the Supreme Court are expected to shift the prosecution of civil monetary penalties ("CMP") from administrative law proceedings to federal court. The court held in *Securities and Exchange Commission v. Jarkesy*, 114 S. Ct. 2117 (2024) that a jury trial is required under the Seventh Amendment when the Securities and Exchange Commission ("SEC") brings securities fraud cases seeking CMP. Additionally, in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), the court overturned what is known as *Chevron* deference, effectively shifting the power to interpret statutes from federal agencies to the courts. These cases have implications for HHS and CMS, which assess civil monetary penalties under several authorities (e.g., the False Claims Act, No Surprises Act) through administrative law proceedings and a robust internal appeal process. If the agencies attempt to bring CMP claims against a provider that are "legal in nature," such as fraud claims, the Seventh Amendment requires a jury trial.

As a result, hospitals and health systems could see lower fraud litigation costs. When a hospital or health system disputes

penalties, it will have greater leverage to challenge agencies in court, which could cause more agencies to settle claims as juries are known to be far less agency-friendly than administrative law judges. Additionally, more protections are available to defendants in court than in an administrative setting, including an expanded discovery process through which parties gather evidence to prepare for trial. In the face of agency actions to impose CMP liability for health care fraud, hospitals and health systems will have newfound leverage to push CMS and HHS to settle claims and avoid costly litigation.

Federal Awards and Grants Updates

1. *Federal Award Terminations*

For several months, the Trump Administration has decreased drastically federal support for research activities through unprecedented award terminations led by federal funding agencies. NIH alone has terminated over $2 billion in award funding, with many other federal fundings agencies following suit, including NSF, the National Endowment for the Humanities, the Department of Education, and DoD. Termination notices often state that the research projects "no longer effectuate[ ] program goals and agency priorities," selecting from a finite group of topics that the awarding agency states are outside of its current priorities—gender identity; diversity, equity, and inclusion; vaccine development and/or hesitancy, including COVID-19-focused programs; health equity or health disparities; environmental justice; and HIV/AIDS. In some instances, awards have been terminated not because of the subject matter of the project, but rather because the underlying program through which an agency issued awards has been terminated altogether, including, for example, programs that support the development of promising, young, diverse researchers, including women, people of color, and people from low socioeconomic backgrounds. IHE recipients of federal funding also have received numerous award terminations based on the Trump Administration's determination that these institutions have permitted "antisemitism and bias" on their campuses.

Affected institutions and investigators have submitted and continue to submit award-level administrative appeals challenging agencies' adverse determinations and requesting reconsideration of those decisions. Some agency responses to requests for reconsideration have begun to trickle in. NIH, for example, has provided many institutions with a three-paragraph form denial letter, containing only the same information included in the original termination notices that does not address specific merits of the terminated award or the institution's arguments against termination. Other institutions have had their terminated awards reinstated following submission of an administrative appeal. However, when reinstated, the awarding agency often does not state the reason for reinstatement, and because some of these reinstated awards are within the scope of certain court orders (discussed below), it is difficult to decipher a clear pattern or logic in agencies' reinstatement actions.

These award terminations also are being challenged in court. In two cases, plaintiffs (in one case, the American Public Health Association, and in another, a coalition of states) brought claims against HHS and NIH in the U.S. District Court for the District of Massachusetts alleging that the Trump Administration is canceling unlawfully federal awards that fund medical and scientific advancements based on agency directives to terminate grants and cooperative agreements that relate to "diversity," "transgender issues," "vaccine hesitancy," and other topics disfavored by the Administration. These cases have been joined and sit before Judge William G. Young. On June 16, Judge Young ruled that the challenged agency directives, as well as the resulting award terminations, are arbitrary and capricious. In the court's findings of fact and rulings of law issued July 2, Judge Young noted that the Trump Administration's award terminations were "creating chaos and promoting an unreasonable and unreasoned agenda of blacklisting certain topics" and that these actions have "absolutely nothing to do with the promotion of science or research." *American Public Health Association v. National Institutes of Health*, No. 1:25-cv-10787, slip op. at 14 (D. Mass. July 2, 2025). Judge Young limited relief to the parties before the court and the terminated awards identified by the plaintiffs. However, following the order, NIH has reinstated a number of awards, including some awards not expressly covered by Judge Young's order and some not challenged by recipients through the administrative appeals process. The Trump Administration has appealed Judge Young's decision to the U.S. Court of Appeals for the First Circuit.

Other lawsuits have challenged terminations from other agencies, such as the U.S. Agency for International Development and Institute of Museum and Library Services, and have received temporary restraining orders or preliminary injunctions. However, the injunctive relief has been reversed on appeal in several cases.

2. *Curtailment in Federal Award Funding; Shift to MAHA-Supported Research*

The Trump Administration's recommendations on discretionary spending for FFY 2026 propose double-digit percentage cuts across several research-funding agencies, including a 56% cut at NSF, a 46% cut at the National Aeronautics and Space Administration (though funds for space exploration would increase), a 37% cut at NIH, and a 14% cut at DOE. While the administration's budget request is only an expression of the president's spending priorities, it may influence Congress's appropriations legislation. If approved, such funding cuts would affect, directly and negatively, hospitals and academic medical centers that regularly apply for, receive, and rely on awards from these federal science agencies to support critical research endeavors that ultimately inform clinical care interventions and improvements.

One potential pathway to continued federal funding support is to promote research initiatives that align with the Trump Administration's Make American Healthy Again ("MAHA") Commission, to which the administration recommends a $500 million allotment. Supported research could focus on chronic illnesses and lifestyle interventions, such as promoting nutrition and physical activity. NIH has yet to publish any funding opportunities specific to MAHA but the administration has proposed that NIH focus on implementing the President's Executive Orders and MAHA priorities, including by promoting research of certain chronic diseases.

3. *Updates to Provider Relief Fund ("PRF") Guidance*

The Health Resources & Services Administration ("HRSA") recently clarified providers' post-payment reporting requirements under the PRF. The FAQ states that "[p]roviders need to retain original documentation for three years after the date of submission of the final expenditure report, in accordance with 2 CFR 200.333." HRSA recently sent email notices to providers emphasizing that all PRF recipients must retain all records pertinent to PRF payments until September 30, 2027, reflecting the HRSA's interpretation that the date of the "final expenditure report," as required in the Post-Payment Notice of Reporting Requirements, corresponds to the date that the last Reporting Period ended, which was September 30, 2024, rather than the date when the funds first were initially received, beginning in 2020.

This policy suggests that the Trump Administration is allowing time to consider whether to conduct further auditing of PRF recipients. Accordingly, providers should continue to maintain documentation demonstrating compliance with PRF terms and conditions, including the reports submitted via the reporting portal and expense reports substantiating the COVID-19-related expenses reimbursed by PRF payments.

4. *June 11, 2025 HHS OIG Audit Report on PRF Compliance*

On June 11, 2025, the HHS Office of Inspector General ("OIG") published a report with its audit findings regarding PRF compliance among 30 hospitals that received PRF grants. The audit identified unallowable expenditures totaling $63 million and inaccurately reported lost revenues of $645.6 million in 11 hospitals. Most of the "unallowable expenditures" were attributed to clerical errors, inadequate documentation, duplication of costs, and payments exceeding the Executive Level II salary cap required for any salary-related expenditures. With respect to the "inaccurately reported lost revenues," the report notes that one hospital duplicated reported lost revenues because the parent hospital and its subsidiary hospitals reported the same lost revenues and that another hospital used incorrect 2019 patient care service revenues as a baseline for its 2020 lost revenues. The report also commented on HRSA's allowance of the more flexible "Option iii" alternative methodology for calculating lost revenues, noting that if a stricter year-over-year comparison had been required, as available under "Option i," 27 hospitals would not have been able to claim $3.5 billion in lost revenue and instead would have needed to rely on documented COVID-19 expenses.

The report indicates that intensified scrutiny of PRF compliance is likely, as OIG has provided HRSA with a detailed roadmap for potential recoupment actions. These actions are expected to focus on salary-cap overages, duplicate or unsupported expense entries, and duplicative or aggressive lost-revenue calculations. The findings suggest that maintaining contemporaneous documentation of PRF expenditures, ensuring fringe benefit and salary allocations comply with federal caps, and evaluating lost revenue models against the more conservative "Option i" baseline may help identify areas of potential exposure. Conducting rigorous internal reviews may reduce the likelihood of refund demands, negative audit findings, and related enforcement repercussions.

Value-Based Care Corner

1. *New CMS Innovation Agenda Proposes Value-Based Programs Take on Downside Risk*

In a May 13, 2025 blog post, Center for Medicare and Medicaid Innovation ("CMMI") Director Abe Sutton

announced the Trump Administration's new value-based care strategy, aligning with HHS's Make America Healthy Again agenda. While pulling back from the Biden Administration's goal of having all fee-for-service patients in value-based care by 2030, CMMI stated that it will "double down" on value-based care through models that mandate downside risk for both model participants (e.g., ACOs) and providers. All proposed model features support one of CMS's new "strategic pillars": (1) promote evidence-based prevention; (2) empower people to achieve their health goals; and (3) drive choice and competition for people.

Promote Evidence-Based Prevention. Prevention efforts are threefold, including preventing disease, early detection of disease, and slowing progression of diseases. CMMI envisions direct engagement with providers and beneficiaries on prevention efforts, such as through community-based organizations. Future models will incentivize preventative care to providers, such as by offering waivers or by reducing cost-sharing for high-value or preventative services. Models may also offer access to evidence-based alternative medicine and evaluate for preventive outcomes.

Empower People to Achieve their Health Goals. CMMI emphasizes the importance of access to data. CMMI's strategic vision for this pillar focuses mostly on financial data, for example, by proposing that future models publish data about the cost and quality of provider services in order to inform beneficiary decision-marking. Other plans to increase price transparency include issuing waivers to support predictable cost-sharing for certain services, drugs, or devices. CMMI is also considering requiring a minimum percentage of provider payments be risk-based in order to support patient-centered payments. The emphasis on data access also includes health data; CMMI envisions increased utilization of mobile applications for disease management and symptom tracking.

Drive Choice and Competition for People. New design models may expand advanced shared savings and prospective payments in order to enable independent provider practices to participate. For example, models may collect losses over longer periods for independent providers. CMMI further proposes reallocating hospital capacity in outpatient and community clinics by modifying certificate of need requirements. CMMI will also test approaches such as modifying risk scoring and regional benchmarks for specialty-focused longitudinal care.

Protecting the Federal Taxpayer. New design models could require that all alternative payment models involve downside risk and/or require that providers bear some of the financial risk. CMMI is further deliberating on ways to improve and simplify benchmarking methodology and reduce the role of state governments in establishing reimbursement rates.

2. *IOTA Model Set to Kick Off July 2025*

CMMI's Increasing Organ Transplant Access Model ("IOTA Model"), finalized November 2024, began on July 1, 2025 and will run through June 20, 2031, for a total of six performance years ("PY"). This model builds off CMMI's previous work in the chronic kidney disease and End Stage Renal Disease area with the Kidney Care Choices and ESRD Treatment Choices models. The IOTA Model will test whether performance-based incentives can increase the number of both living donor and deceased donor kidney transplants performed by participating transplant hospitals. IOTA participants will be measured by (1) the number of kidney transplants performed, (2) the kidney acceptance rate ratio, and (3) post-transplant outcomes—relative to the outcomes across all kidney transplant hospitals. Participants will receive a score based on these measures and at the end of each PY. Based on the score, CMS will pay an upside risk payment to the participant for meeting performance goals; the participant will fall into a neutral zone where no incentive payment will be paid to or owed by the participant; or the participant will owe a downside risk payment to CMS. Downside risk payments will begin in PY2 to give participants the opportunity to assess value-based care solutions to improve outcomes.

The model includes other measures designed to increase transparency around transplants, as well. To increase transparency, participants will be required to publish the criteria they use when determining whether to add a patient to the kidney transplant waitlist on a public facing website. Further, participants are subject to data-sharing requirements and incentives to improve the patient experience. These measures collectively aim to holistically improve the kidney transplant process, while reducing expenditures.

CMS selected all eligible kidney transplant hospitals in half of the participating donation service areas to participate in the mandatory model, for a total of 103 kidney transplant hospitals. The eligible kidney transplant hospitals in the other half of donation service areas will serve as the comparison group for evaluation purposes.

3. ***HHS Layoffs and Reorganization Could Spell Trouble for PACE Providers***

The Program of All Inclusive Care for the Elderly ("PACE")

is a decades old CMS managed care program that provides home and community center-based care primarily to Medicare and Medicaid dual eligible patients. PACE was designed to promote participants to remain in their communities, rather than moving into facilities. While established as a care model in the 1970s and implemented into a permanent Medicare model in the Balanced Budget Act of 1997, it was not until recent years that the program began to take off. The expansion in the PACE market can be attributed in part to CMS's allowance of for-profit PACE organizations in 2016, as seen in the 116% increase of PACE programs from 2010 to 2022, from 69 to 149, and the 211% increase in the number of PACE enrollees, from approximately 18,100 to 56,350.

Despite its successes, HHS included PACE in the Department's reorganization efforts (described in greater detail in the Focus On article, above). Recent HHS layoffs (~20,000 people) and statements on "planned productivity enhancements for the PACE management department" from an HHS spokesperson, however, have put PACE providers on edge. The Trump Administration also relocated the PACE program from the Center for Medicare to CMMI. According to the National PACE Association, there are currently more than 180 PACE organizations and approximately 120 more interested in opening programs. The process to apply for and become a PACE organization is already lengthy and complicated, involving state and federal applications and approvals. Current backlogs and approval times for new PACE organizations are a deterrent to entering the market or expanding as an operating organization. Further barriers to entry and HHS restructuring concern industry leaders that delays in the approval of new PACE organizations will slow the program's promising growth over the past few years.

4. *Medicare Drug Price Negotiation Program Updates*

On March 14, 2025, CMS published the manufacturers of the 15 drugs selected for the Medicare Drug Price Negotiation Program ("Negotiation Program"). The next step in the process is a negotiation period between the manufacturers and CMS, which will also involve stakeholder input including a patient-focused roundtable event for each drug and a town hall for clinicians and researchers. CMS was scheduled to send initial proposals for the maximum fair price ("MFP") no later than June 1, 2025, and the manufacturer was required to respond to such proposal within 30 days. During the 30-day period between the initial proposal and the manufacturer's acceptance or counteroffer, CMS would invite the manufacturer to meet for negotiations. If no agreement was reached in the first response from the manufacturer, CMS would invite the manufacturer to up to two meetings for continued negotiations before the negotiation periods ends on November 1, 2025.

Separately, on May 12, 2025, CMS issued a draft guidance for public comment on the third cycle of negotiations under the Negotiation Program. Notably, the draft guidance includes drugs payable under Part B as part of the Negotiation Program for the first-time. It further sets forth CMS's considerations for identifying drugs that were negotiated for applicability in years 2026 and 2027 for renegotiating. In the third cycle of negotiations, CMS will announce, by February 1, 2026, up to 15 additional drugs covered under Part D or payable under Part B and drugs selected for the first cycle of renegotiations. Negotiated or renegotiated MFPs for the drugs published in February 2026 will be effective on January 1, 2028.

The draft guidance effectuates President Trump's Executive Order "Lowering Drug Prices by Once Again Putting Americans First" by including policies that prioritize the selection of prescription drugs with high costs to the Medicare program. CMS accepted comments on the draft guidance that were submitted on or before June 26, 2025. Comments are now closed.

5. *CMS Revises and Extends Kidney Model*

On May 27, 2025, CMS announced changes to and extension of the Kidney Care Choices ("KCC") Model to reduce net spending as well as an extension of the model through 2027. CMMI will revise the financial methodology and participation options. While CMMI states the KCC Model has shown significant improvements in quality of care, including an increase in home dialysis and living donor transplants, it expressed concerns about an increase in spending, resulting in net losses of approximately $304M in PY 2023.

CMMI will implement the following changes in 2026 with the stated goal of maintaining the quality of care while reducing spending:

- 1% discounts for participants that meet certain chronic kidney disease (CKD) and end-stage renal disease benchmarks;
- Cutting in half the Quarterly Capitation Payment (QCP) for CKD from approximately 2/3 more than fee-for-service (FFS) for evaluation & management claim payments to 1/3 more than FFD;
- Removing the $15,000 kidney transplant bonus for successful transplants by the Kidney Care First (KCF) Practices and Kidney Care Entities; and

- Terminating the KCF option one year earlier than originally planned at the end of performance year 2025.

6. *CMS Introduces First Technology-Based Innovation Model for Original Medicare*

On June 27, 2025, CMS announced the Wasteful and Inappropriate Service Reduction ("WISeR") Model, which is a voluntary model testing the use of Artificial Intelligence ("AI") and Machine Learning ("ML") to streamline the prior authorization process for certain items and services that CMS determined are most vulnerable to fraud, waste and abuse. Participants will be technology companies specializing in medical necessity recommendations for payers. Items and services subject to this model are those that CMS has determined 1) may pose concerns related to patient safety if delivered inappropriately; 2) have existing publicly available coverage criteria; and 3) may involve prior reports of fraud, waste and abuse. Examples of selected items and services include skin and tissue substitutes; implantation of electrical nerve stimulators; and knee arthroscopy for knee osteoarthritis. The WISeR Model excludes inpatient-only services, emergency services, and services that would pose a substantial risk to patients if significantly delayed. Participants are required to have clinicians with the expertise to conduct medical reviews to validate determinations. Importantly, final decisions that a service does not meet Medicare coverage requirements must be made by licensed clinicians. Model participants will receive payments based on their ability to reduce medically unnecessary or non-covered services and lower spending in Original Medicare. Each participant will cover a Medicare Administrative Contractor ("MAC") jurisdiction or region. Participants' payments will be adjusted based on performance measures across three categories: (1) process quality, (2) provider or supplier and beneficiary experience, and (3) clinical quality outcomes.

The WISeR Model will not change Medicare coverage or payment criteria. Further, payment to providers and suppliers for covered items and services will not change under the model. Providers and suppliers in selected regions will have the choice of submitting a prior authorization request for the model's selected items and services or go through a post-service/pre-payment review. Those providers and suppliers that choose to submit a prior authorization may either submit their request directly to model participants or to their MAC to forward the request to the participant responsible for that region. Providers and suppliers in participating regions should anticipate initial slows in payment authorization for select items, as the model is implemented. Given the intent of the model to reduce payment for unnecessary services, providers and suppliers may experience higher rates of denials for selected services during the model period. The model will run for six performance years from January 1, 2026 to December 31, 2031.

7. *CMS Announces Proposed Chronic Condition Payment Model*

On July 14, 2025, CMS announced a new proposed payment model in the 2026 Physician Fee Schedule ("PFS") Notice of Proposed Rulemaking. The Ambulatory Specialty Model ("ASM") focuses on upstream management and prevention of chronic diseases, specifically heart failure and lower back pain. Participants would be specialists in the two target areas that treat individuals in Original Medicare in outpatient settings, those in accountable care organizations ("ACOs"). For heart failure, participants would be physicians specialized in general cardiology; for low back pain, participants would be physicians specialized in anesthesiology, pain management, interventional pain management, neurosurgery, orthopedic surgery, or physical medicine and rehabilitation.

The model aims to reduce avoidable hospitalizations and unnecessary procedures, improve patient experience and outcomes, and lower costs to Original Medicare through interventions like screening, increasing transparency by making provider performance assessments more widely available. Participants would be rewarded for improving patient health outcomes and facilitating better coordination with primary care providers. Participant performance would be measured based on (1) quality, (2) cost, (3) improvement activities, and (4) improving interoperability by encouraging the adoption of technology. CMS modeled these measures off the Merit-based Incentive Payment System (MIPS) Value Pathways (MVP). ASM participants would be subject to a two-sided risk arrangement, such that participants will receive higher, neutral, or lower reimbursement rates on future Medicare Part B claims for covered services, based on their performance relative to the performance of peers. This model, if passed as proposed, would be mandatory and would begin on January 1, 2027 and run for five performance years through December 31, 2031. Comments on the model will be received for 60 days from the publication date in the Federal Register, which is scheduled for July 16, 2025.

Transaction Trends

Hospital transaction activity decreased in the first quarter of

2025 as compared to previous years, but economic uncertainty has impacted distressed hospitals and resulted in more merger activity involving these facilities and systems. Of the five merger and acquisition ("M&A") transactions announced during the first quarter of 2025, four involved a distressed hospital or health system.

Market factors such as increasing labor and supply costs and uncertainty around federal health care program reimbursement are likely to impact or threaten potential transactions. The recently passed BBB dramatically impacts federal Medicaid spending and limits certain tools states use to raise matching Medicaid funds, including enhanced Medicaid rates through so-called "State Directed Payments," limits on provider taxes, requiring states to undertake more frequent Medicaid eligibility assessments, and requiring enhanced patient cost-sharing for Medicaid-covered patients. The impact of these Medicaid cuts may, immediately, be unevenly experienced across hospitals and health systems, with Medicaid-dependent facilities experiencing the first, most immediate hits. Many of these facilities may already be struggling against existing headwinds, and it remains to be seen whether the broader impact of Medicaid reductions limits the opportunities for transactions, results in increasing pressures to close hospitals, particularly in rural, Medicaid-dependent communities, or presents an opportunity for enterprising health systems to expand their footprint capitalizing on the distressed nature of these facilities.

Evidence that economic uncertainty-is limiting hospital M&A is already present in the market. For example, two providers announced on May 5, 2025, that the parties had decided to terminate their previously announced merger, after careful consideration of the evolving operating environment. Both organizations had endured financial struggles, and one of the providers noted in Frequently Asked Questions that priorities at the federal level are evolving and reimbursement is not keeping up with cost increases, leading to increasing financial challenges. The proposed transaction was also under review by the Oregon Health Authority Health Care Market Oversight program and, as part of that process, a community review advisory board unanimously recommended against approving the deal due to likely increases in cost of care. The provider went on to state that in the future its board may decide to identify a strategic partner that is aligned with its not-for-profit and community-based mission.

Ropes & Gray continues to track real-time updates on state health care transaction laws related to competition, quality, access, cost and more. Leveraging our sector expertise, RG HealthTrax – A Health Care Transaction Laws Tracker provides clients with current and reliable information to maintain a competitive advantage in investments.

340B Updates

1. *Trump Administration Issues Executive Order Aiming to Lower Drug Prices*

On April 15, 2025, President Trump signed Executive Order 14273 ("Lowering Drug Prices by Once Again Putting Americans First") which includes two initiatives that potentially implicate prices under the 340B drug discount program ("340B Program") and that also recall initiatives from the first Trump Administration.

One initiative directs the HHS Secretary, within 90 days of the Executive Order, to ensure that future grants to federally qualified health centers under section 330(e) of the Public Health Service Act are conditioned upon the health centers establishing practices to make insulin and injectable epinephrine available to low-income health center patients *at or below* the discounted price paid under the 340B Program. Such individuals must either have a high cost-sharing requirement for insulin or injectable epinephrine, have a high unmet deductible, or have no health insurance.

President Trump had issued a similar Executive Order at the end of his first term that would have conditioned grant funding to federally qualified health centers on their establishment of practices to provide access to insulin and injectable epinephrine to low-income health center patients at the discounted price paid under the 340B Program. A final rule implementing the Executive Order was issued in December 2020, with an effective date of January 22, 2021. After delaying the implementation of the rule, the Biden Administration ultimately rescinded the rule in October 2021 because of its concerns that the administrative burden and cost necessary to comply with the rule had the potential to constrain health centers' ability to provide ongoing primary care services to medically underserved and vulnerable populations.

Another initiative requires the HHS Secretary, within 180 days of the order, to publish a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Social Security Act to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. Following the conclusion of this survey, the HHS Secretary must consider and propose any appropriate adjustments that would align

Medicare payment with the cost of acquisition, consistent with the budget neutrality requirement in section 1833(t)(9)(B) of the Social Security Act and other legal requirements.

Although this initiative does not expressly reference the 340B Program, action by the previous Trump Administration suggests that the acquisition cost survey could presage reductions in Medicare reimbursement for drugs. In 2018, President Trump had reduced Medicare payment to hospitals by 28.5% for drugs purchased at 340B prices, after which litigation ensued. In 2022, the Supreme Court decided in *AHA v. Becerra* that the HHS Secretary lacked discretion to cut Medicare's reimbursement for selected hospitals without first conducting a drug acquisition cost survey.

2. *Trump Administration Proposes to Shift 340B Program Responsibility from HRSA to CMS*

On May 30, 2025, President Trump issued a budget proposal for Federal Fiscal Year 2026. Among other things, the budget proposes that HRSA and other agencies be reorganized into a new unified agency, called the Administration for a Healthy America, with the stated goal of improving coordination of health resources for Americans by increasing operational efficiency. In addition, in accordance with the HHS reorganization plan, the budget proposal recommends shifting responsibility for the 340B Program from HRSA to CMS to allow for streamlined processes and the ability to utilize in-house drug pricing resources and expertise.

3. *CMS Announces Plan to Accelerate Clawback of "Windfall" after 340B Supreme Court Decision*

In the calendar year 2026 Medicare OPPS proposed rule, CMS announced that the agency intends to accelerate the recapture of funds from hospitals that realized what the agency called a "windfall" following *AHA v. Becerra*. After the Supreme Court invalidated HHS's payment reductions for 340B drugs in that case, CMS issued repayments to hospitals that had been underpaid for 340B-acquired drugs. While those reductions were in effect, however, CMS had increased the payment rate for non-drug items and services by 3.19 percent, redirecting approximately $7.8 billion to OPPS hospitals to preserve budget neutrality. CMS had previously planned to claw back this windfall through a 0.5-percent annual reduction in the OPPS conversion factor for non-drug services, beginning in calendar year 2026 and continuing for a projected 16 years. In the newly issued proposed rule, CMS seeks to accelerate the repayment schedule by increasing the annual reduction to either two or five percent, which would recover the required amount in six or three years, respectively.

4. *Minnesota Court Sides with Minnesota over Manufacturers in Contract Pharmacy Litigation*

As discussed in our prior November 2024 newsletter, in recent years, several state legislatures have enacted 340B contract pharmacy-mandate laws, which generally restrict pharmaceutical manufacturers from interfering with the delivery of the 340 drugs to a pharmacy under contract with a 340B covered entity. Manufacturers and Pharmaceutical Research and Manufacturers of America ("PhRMA") have brought challenges to these various mandates in the courts, with litigation ongoing in many instances. In the latest update on several ongoing legal challenges to state contract pharmacy mandates, on April 15, 2025, a Minnesota state court granted the state of Minnesota's motion to dismiss PhRMA's complaint related to a Minnesota state law that prohibits pharmaceutical manufacturers from restricting, prohibiting, or otherwise interfering with the delivery of 340B covered drugs to a 340B contract pharmacy.

PhRMA brought this lawsuit, in September 2024, against the State of Minnesota, the Minnesota Attorney General, and members of the Minnesota Board of Pharmacy, alleging that Minnesota Statute § 62J.96 was preempted by federal law, violated the U.S. Constitution's Commerce and Due Process Clauses, and violated the Minnesota Constitution's Single Subject and Title Clause.

The defendants moved to dismiss PhRMA's complaint, arguing, among other points, that the court lacked subject matter jurisdiction because PhRMA failed to allege a redressable injury traceable to a defendant and that the Minnesota law does not explicitly grant any enforcement authority to the state Attorney General or Board of Pharmacy. The district court granted that motion. PhRMA will have an opportunity to appeal the state court ruling. As of the date of this publication, no appeal has been filed.

On April 15, 2025, the court granted the motion to dismiss, finding that the state statute was not preempted by federal law; did not engage in unconstitutional extraterritorial regulation; and did not violate the Minnesota Constitution. Specifically, the court stated that the Minnesota law regulated the delivery of drugs to contract pharmacies without setting or enforcing drug pricing or requiring manufacturers to provide 340B prices to contract pharmacies. Further, the court found that the Minnesota law did not violate the Commerce Clause because, under U.S. Supreme Court precedent, a state law does not necessarily violate the dormant Commerce Clause merely because its regulation of in-state activity had out-of-

state effects. Rather, according to the court, the Minnesota law merely required any pharmacy that conducts business in Minnesota to be licensed in Minnesota.

Other legal challenges to similar state laws remain pending nationwide, including in the Fifth Circuit, where, on April 2, 2025, a panel heard arguments related to the Mississippi contract pharmacy mandate law.

5. *Litigation over 340B Rebate Models between Manufacturers and HRSA Continues*

As discussed in the prior reimbursement newsletters, Johnson & Johnson ("J&J") and other pharmaceutical manufacturers have separately filed lawsuits against HRSA, arguing that HRSA has violated the APA by failing to approve the manufacturers' proposed 340B rebate models. J&J's rebate models would generally require DSH hospitals to purchase products from wholesalers at commercial prices and to then submit rebate claim data to the manufacturers in order to receive a rebate payment equal to the difference between the list price and the 340B ceiling price.

On February 3, 2025, five months after filing its complaint for declaratory and injunctive relief against HHS and HRSA, 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.

HHS and HRSA filed their opposition to J&J's motion on April 2, 2025, and cross-moved for judgment—the latest development in this ongoing litigation. HHS and HRSA argued that the text of the 340B statute supported their position that approval from the HHS Secretary was required before a manufacturer could initiate a rebate-based discount pricing mechanism. Specifically, according to the agency, the HHS Secretary has discretion to determine whether a manufacturer may sell drugs to a covered entity at the ceiling price through an upfront discount or a rebate. HHS reiterated that a rebate system could comply with the requirements of the 340B statute, but any such model would require initial approval from the HHS Secretary.

Further, HHS argued that J&J's implementation of its proposed rebate model without the agency's approval would violate the "must offer" provision of the 340B statute, which requires each pharmaceutical pricing agreement ("PPA") to require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at such price. HHS contended, relying on *Astra v. Santa Clara*, that the PPA is not a transactional, bargained-for contract. Rather, the PPA is a uniform agreement that recites the responsibilities that the 340B statute imposes on drug manufacturers and the HHS Secretary, respectively. As such, HHS stated that when a manufacturer signs a PPA, the manufacturer agrees to the terms and conditions of the program as stated in the statute and failure to comply with such terms and conditions could warrant the manufacturer's termination from the 340B Program and civil monetary sanctions.

J&J filed its opposition to HRSA's summary judgment motion on April 16, 2025, restating its prior arguments made in its complaint and summary judgment motion. On April 30, 2025, HHS and HRSA filed a reply in further support of their motion for summary judgment, arguing that legislative rulemaking was not required for the agency to block the manufacturers' rebate models and defending the agency's action as neither arbitrary nor capricious given the potential disruptions to the 340B Program that could occur if manufacturers could independently alter 340B pricing mechanisms. Briefing on the cross-motions remains ongoing, with various DSHs intervening as well. On June 5, 2025, the intervening DSHs filed a reply in support of their cross-motion for summary judgment, arguing that the 340B statute does not permit rebate models.

As discussed in our prior newsletter, several other pharmaceutical manufacturers filed similar lawsuits in the wake of J&J's complaint. On April 29, 2025, a D.C. district court judge heard arguments from HHS, manufacturers, and intervening hospital associations, while presiding over several lawsuits (brought by several pharmaceutical manufacturers) on a joint briefing schedule. At oral argument, the judge seemed concerned that, under a rebate model, the federal government would be helpless to interfere if manufacturers violated the rules of the 340B Program. May 2, 2025, HHS submitted a notice to the U.S. District Court for the District of Columbia stating that the agency would issue guidance on rebate models by June 1, 2025. Based on the Office of Budget and Management ("OMB") website, HHS submitted its "340B Rebate Guidance" to OMB for regulatory review on June 1, 2025, but such guidance has not yet been made public. On May 15, 2025, the court denied the manufacturers' motions (although granting Sanofi's motion in part on other grounds) and granted HHS's motion for summary judgment finding that HRSA did not act contrary to law by requiring the manufacturers to obtain approval before implementing their

proposed rebate models. The court stopped short of issuing a declaration, requested by the intervenor-hospital systems, stating that rebates are categorically prohibited under the 340B statute. On May 20, 2025, several pharmaceutical manufacturers filed a notice of appeal to the D.C. Circuit. Eli Lilly filed a similar notice on June 12, 2025.

6. *Nevada Clinic Seeks Injunction over Removal from Drug Discount Program*

On March 27, 2025, Sagebrush Health Services ("Sagebrush"), a Nevada-based STD clinic, filed its latest complaint against HRSA, challenging HRSA's refusal to reinstate 20 different Sagebrush sites into the 340B Program that the agency had terminated in January and its decision to terminate, effective March 31, 2025, the two remaining Sagebrush sites that participated in the 340B Program.

This is the latest development in a dispute that has been ongoing since December 2024, when HRSA first advised Sagebrush that 20 of its clinic sites were ineligible for the 340B Program because they had not received the requisite federal grant funding. At the time, Sagebrush sued HRSA, arguing that the terminations would cause the imminent destruction of Sagebrush. On February 21, a court denied Sagebrush's motion for a temporary restraining order and dismissed the case without prejudice, allowing HRSA's decision to remove the clinics from the 340B Program to stand.

In its latest complaint and accompanying motion for a preliminary injunction, Sagebrush argues that HRSA exceeded its statutory authority in removing Sagebrush's clinics from the 340B Program and ordering Sagebrush to repay discounts they received from pharmaceutical manufacturers. Sagebrush also argued that these HRSA decisions were arbitrary, capricious, and an abuse of discretion. In Sagebrush's motion, Sagebrush asked the court to reinstate into the 340B Program the Sagebrush clinics that were previously removed and to prevent HRSA from removing the remaining two active Sagebrush clinics from the 340B Program. On April 7, 2025, Sagebrush was able to provide HRSA and the court evidence of one of the active Sagebrush clinic's eligibility, and therefore HRSA agreed that such clinic could continue to participate in the 340B Program. As it concerns the two active Sagebrush clinics, the merits of the lawsuit now only relate to one Sagebrush clinic.

On April 22, 2025, HRSA filed a response to Sagebrush's motion for a preliminary injunction. HRSA argued that Sagebrush was not eligible to participate in the 340B Program as an STD clinic because the clinic based its eligibility on the purchase of HIV test kits for use in the treatment of STDs. To qualify as a 340B-covered entity, however, STD clinics must receive federal funds under Section 318 of the Public Health Service Act for the treatment of STDs, and the relevant test kits were purchased with state funds only. HRSA also argues that Sagebrush is unable to demonstrate irreparable harm because Sagebrush only alleges economic loss from loss of access to discounted drugs and Sagebrush remained operational after the other clinics were terminated from the 340B Program.

On May 20, 2025, Amgen, Inc. and other manufacturers who have all also separately sued HRSA with respect to its handling of Sagebrush's eligibility, filed an amicus brief in support of HRSA's opposition to Sagebrush's motion for a preliminary injunction. The manufacturers argued that none of the Sagebrush subcontractors that HRSA terminated from the 340B Program satisfied the 340B statutory requirement that an entity only qualifies as an STD subgrantee if it is receiving funds "through a State or unit of local government." Instead, according to the manufacturers, the Sagebrush subcontractors received funds only from other subgrant recipients.

Separately, in Amgen's own case against HRSA, in which Amgen alleges that the agency has not fulfilled its obligations to oversee the 340B Program by allowing certain ineligible clinics to participate in the 340B Program, briefing remains ongoing. On April 14, 2025, HRSA filed a partial motion to dismiss, arguing that the court lacked subject matter jurisdiction, that the plaintiffs failed to exhaust the required regulatory administrative remedies for allegations based on 340B drug diversion before initiating their lawsuit, and that the challenge was moot with respect to those Sagebrush entities that were already terminated. The plaintiffs responded on May 13, 2025 arguing that a live controversy remained and that the case should proceed. HHS and HRSA filed their reply on May 28, 2025. The parties await a ruling from the court.

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

Ropes & Gray attorneys regularly analyze and advise clients on shifting health care legal and policy developments policies advising clients and hosting webinars on pressing developments. Our recent thought leadership includes:

- Alert: July 15: Closeout Requirements During Appeals of Terminations of NIH Research Grants
- Alert: April 30: CMS Publishes Federal Fiscal Year 2026 Hospital Payment Proposed Rule
- Article: May 2: Medicare Advantage Enforcement Strong Amid Agency Cuts
- Webinar: May 14: Civil Rights Compliance as Term or Condition of NIH Awards: What Should We Do Now?
- Alert: May 14: NYS Fails to Pass Expanded Health Care Transaction Notice Requirements Bill
- Webinar: May 22: Executive Branch Updates: What to Know About the Federal Grant Termination Trend
- Webinar: June 13: Salvaging Minority Health Programs in the New Title VI Enforcement Environment
- Alert: July 8: DOJ and HHS Announce False Claims Act Working Group & Enforcement Priority Areas

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