ROPES & GRAY

# Hospital and Health Systems Reimbursement Check

## October 2025

**ROPES & GRAY ATTORNEYS share their analysis of federal court and administrative litigation, regulatory developments, other key developments affecting federal program payments to hospitals and health systems, and related issues affecting reimbursement.**

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## Focus On

### NEW AI GUIDANCE FOR HOSPITALS AND HEALTH SYSTEMS FROM THE JOINT COMMISSION AND THE COALITION FOR HEALTH AI

On September 17, 2025, Joint Commission ("JC") and Coalition for Health AI ("CHAI") jointly released *Guidance on the Responsible Use of AI in Healthcare* (the "Guidance"). JC is the oldest and largest standards-setting and accrediting body in health care in the United States. CHAI is a coalition of nearly 3,000 organizations, including health systems, patient advocacy groups, and a wide range of industry leaders and start-ups across the health care and technology ecosystems. CHAI's stated mission is to be the trusted source of guidelines for responsible use of artificial intelligence ("AI") in health that serves all, and it aims to ensure high-quality care, foster trust among users, and meet growing health care needs. The Guidance is instructive for hospitals and health care systems considering implementation of AI in various settings, including operations, finance, and administration. As hospitals pursue AI-driven efficiencies and cost savings, the Guidance provides a critical framework for ensuring that the drive for operational improvements does not compromise patient safety or data security.

The Guidance makes recommendations to health care organizations regarding use and deployment of AI. The JC developed the Guidance based on surveys of its accredited hospitals and health systems to address their specific needs in implementing AI responsibly. The Guidance's focus on recommendations for health care provider organizations sets it apart from many other AI standards and requirements, which have primarily focused on AI technology developers and health insurers. The Guidance addresses the full spectrum of organizational responsibilities, from establishing governance structures and data security protocols to monitoring AI performance, assessing bias, and training staff on appropriate use.

#### Guidance Overview

The Guidance states that JC and CHAI developed the Guidance based on industry standards for development, deployment, and use of AI and communications with industry stakeholders. The Guidance addresses the entire life cycle of an AI tool, from initial procurement and validation to ongoing monitoring and staff training. This holistic approach establishes a comprehensive framework for managing the technology's risks and benefits. The Guidance is structured around the following seven foundational elements that JC and CHAI say they have designed to create a comprehensive framework for responsible use of AI in health care:

1. AI Policies and Governance Structures. Health care organizations should have formal oversight of AI across the health care organization with clear accountability, risk-based review, life cycle

management, and regular reporting to their governing bodies.

2. Patient Privacy and Transparency. Health care organizations should define how data are accessed and used, notify patients when AI directly influences care, and educate patients and staff on AI's role and benefits.

3. Data Security and Data Use Protections. When deploying AI, health care organizations should ensure that all information is used and disclosed in accordance with applicable health care privacy laws, including the Health Insurance Portability and Accountability Act ("HIPAA"). Organizations should also implement security measures for data used in AI, such as encrypting data in transit and at rest, applying strict access controls, and performing regular vulnerability assessments. Agreements governing use and disclosure of data should support these controls and principles. The Guidance also recommends that organizations consider adopting the JC's *Responsible Use of Health Data* framework.

4. Ongoing Quality Monitoring. Health care organizations should establish processes to monitor and to evaluate routinely the safe performance of AI-enabled clinical tools. Organizations should validate the tools pre-deployment and monitor their performance post-deployment based on risk and context. Organizations should also use existing quality and safety structures, define responsibilities with vendors, and maintain feedback loops for model updates and issues.

5. Voluntary, Blinded Safety Reporting. There should be a process for confidential, blinded reporting of AI-related safety events to monitor and to evaluate regularly the safe performance of AI tools. The Guidance suggests that reporting findings both within and outside the organization may be useful.

6. Risk and Bias Assessment. Health care organizations should have a process to identify and to document risks and biases in AI tools. According to the Guidance, CHAI's Applied Model Card may be a helpful way to collect relevant information and ensure ongoing assessment of risks and biases.

7. Education and Training. Health care organizations should provide role-specific training on AI tools and organization-wide AI literacy. They should emphasize safe use of AI, intended use cases and limits of specific tools being used, and pathways for reporting issues.

The Guidance indicates that, in the coming months, the JC and CHAI intend to release a series of Responsible Use of AI Playbooks to build on and to operationalize the Guidance, and the JC intends to develop a voluntary Responsible Use of AI certification.

## Comparison to Other Health AI Requirements and Guidance

The Guidance joins myriad other requirements and guidance regarding the use of AI in health care. For example, the Food and Drug Administration ("FDA") regulates AI in medical devices (including certain software products it considers medical devices). Health information technology ("health IT") certification under the Health IT Certification Program of the Office of the National Coordinator for Health IT within the U.S. Department of Health and Human Services requires disclosures of certain source attributes specified in federal health IT certification criteria, and developers must adopt certain risk management practices to assess, mitigate, and oversee risk presented by AI tools. The Centers for Medicare & Medicaid Services ("CMS") has issued guidance on the use of AI tools by Medicare Advantage plans. And some states have passed laws regulating the use of AI in health care. For example, Cal. Health & Safety Code § 1339.75 (known as the Artificial Intelligence in Health Care Services Bill) requires health care facilities, clinics, and physician offices to disclose when generative AI is used to communicate clinical information to patients. Texas's Responsible Artificial Intelligence Governance Act, effective January 2026, is a comprehensive AI regulation that applies across multiple sectors, including health care. For health care providers specifically, the law mandates disclosure to patients when AI is used in diagnosis or treatment and requires licensed practitioners to review all AI-generated records and retain ultimate responsibility for clinical decisions. Utah requires regulated occupations, including licensed health care professionals, to prominently disclose when AI is used in "high-risk" interactions involving health information or medical advice. These state laws emphasize transparency, human oversight, and accountability in clinical AI deployment.

The Guidance provides a different perspective than many of the pre-existing sources by recommending a comprehensive framework for use of AI tools in health care, with a focus on hospitals and health systems. The involvement of the JC, which accredits the majority of U.S. hospitals and sets widely recognized standards for health care quality and safety, gives the Guidance additional gravitas.

## Looking Ahead

The Guidance on the Responsible Use of AI in Healthcare arrives at a pivotal moment for health AI. AI is rapidly

transforming health care, from automated image analysis and predictive analytics to intelligent chatbots that support patient communication. According to the JC, nearly half of U.S. health care organizations have implemented some form of generative AI, and that share is expected to grow. The global AI in health care market, valued at $26.6 billion in 2024, is projected to reach $187.7 billion by 2030. To date, the proliferation of AI in health care has occurred largely in a fragmented regulatory environment, creating uncertainty for health care organizations seeking to deploy AI responsibly.

The Guidance seeks to address this gap by providing a unified and comprehensive health care focused framework. It represents an important step in creating a shared understanding for responsible use of AI in health care, establishing a baseline that can evolve as technologies mature and the health care community learns from real-world AI implementation. This framework is particularly timely as hospitals and health systems navigating financial constraints and staffing challenges turn to AI for compelling opportunities to improve efficiencies, streamline workflows, and better allocate limited resources. However, realizing these benefits requires thoughtful implementation.

The Guidance emphasizes AI's transformative potential (e.g., improved diagnostics, personalized care, operational efficiency) while also highlighting corresponding risks (e.g., patient harm, algorithmic bias, privacy breaches, security threats, and opacity of decision-making). By offering clear framework principles, the Guidance signals that responsibility in deployment and use of AI tools in health care is increasingly an expectation of health care organizations. As hospitals and health systems pursue these operational improvements and cost savings, establishing AI governance structures and developing comprehensive policies for AI implementation and use in accordance with the Guidance's framework can help ensure these benefits are realized while maintaining patient safety, equity, and trust.

## Docket Updates

### *1. Favorable Decision in DSH Part C Days Litigation*

On September 30, 2025, the U.S, District Court for the District of Columbia recently granted summary judgment for the Plaintiff-hospital in Montefiore *Medical Center v. Kennedy*, No. 24-cv-1810 (D.D.C. 2024), the lead case challenging CMS's June 2023 retroactive rule requiring the inclusion of Medicare Part C days as Part A-entitled days in the Medicare Part A disproportionate share hospital ("DSH") calculation for periods prior to October 1, 2013.

The court held that the June 2023 rule retroactively adopting this policy is unlawful, as CMS did not satisfy either of the conditions for exercising its limited retroactive rulemaking authority under the Medicare statute. The court rejected the government's arguments that the retroactive rule was necessary to make DSH payments and that failing to apply the 2023 rule retroactively would be contrary to public interest. The court reasoned that finding these conditions met here would "turn a statutory limitation [on retroactive rulemaking] into a floodgate favoring retroactivity." In addition, the court concluded that the rule was arbitrary and capricious because the agency failed to reasonably address the significant financial impact of its rule.

The court has ordered the parties to brief the appropriate remedy for the agency's unlawful action. Given the federal government shutdown, the schedule for that briefing is not yet set.

### *2. D.C. Circuit Upholds PRRB Jurisdictional Finding That SSI Fractions Not Appealable Final Determinations*

On August 22, 2025, in a significant ruling regarding jurisdiction of the Provider Reimbursement Review Board ("PRRB"), the D.C. Circuit held in *Battle Creek Health System v. Kennedy*, 151 F.4th 464 (D.C. Cir. 2025) that the PRRB properly found that it lacked jurisdiction to hear the plaintiff hospitals' challenges to the calculation of the supplemental security income ("SSI") fraction of the DSH payment adjustment calculation prior to receiving their Notices of Program Reimbursements ("NPRs"). Reversing the district court, the D.C. Circuit concluded that CMS's publication of hospital-specific SSI fractions does not constitute a "final determination of the Secretary as to the amount of the payment" under 42 U.S.C. § 1395oo(a)(1)(A)(ii) and, as such, the PRRB correctly determined that it "lacked jurisdiction over the hospitals' appeal."

*Battle Creek* concerned whether hospitals can appeal directly from CMS's published SSI fractions of the Medicare DSH calculation, before the agency applies the SSI fractions in a hospital's NPR. The government appealed an October 31, 2023, ruling by the U.S. District Court for the District of Columbia, holding that the PRRB had jurisdiction over the plaintiff hospitals' appeals of CMS's 2009 publication of SSI fractions for Federal Fiscal Year ("FFY") 2007. The district court found that CMS's publication of the SSI fractions at issue constituted a "final determination" within the meaning of 42 U.S.C. § 1395oo of the Medicare statute, explaining that "section 1395oo permits providers to prospectively appeal what they will, in the future, receive as a result of services provided to eligible patients" and "eliminates the requirement that [a provider] file a cost report prior to appeal." The district court vacated the PRRB's jurisdictional decision and remanded the case to the PRRB to address the merits of the dispute.

On appeal, the D.C. Circuit held that the PRRB lacked jurisdiction, as CMS's publication of the hospital specific SSI fractions was not a "final determination of the Secretary as to the amount of the payment" within the meaning of 42 U.S.C. § 1395oo(a)(1)(A)(ii). The court drew a distinction between prospectively fixed prospective payment system ("PPS") components—such as the federal rate or other prospectively finalized adjustments—that can be challenged pre NPR, and retrospective, hospital specific adjustments like the DSH adjustment, which depend on year end cost reports, audit adjustments, and interpretive determinations, and thus are only finalized in an NPR (42 U.S.C. § 1395ww(d); 42 C.F.R. § 412.106). Distinguishing its prior decision in *Washington Hospital Center v. Bowen*, 795 F.2d 139 (D.C. Cir. 1986), the court explained that pre NPR appeals are permissible only when "the only variable factor" in the per patient PPS amount has been firmly established. Here, the court found, the Medicaid fraction, audit adjustments, and DSH eligibility and payment amount had not been settled. The court rejected the hospitals' argument that there was no need to wait for an NPR because they could "do the math themselves" upon publication of the SSI fraction, concluding that § 1395oo vests the "final determination" in the Secretary, not providers, and because unresolved interpretive issues remain within agency purview until the issuance of an NPR.

### 3. *Oral Argument Held in Case Challenging 2024 Rule Excluding Uncompensated Care Pool Waiver Days from DSH Calculation*

In September, the Fifth Circuit held oral argument in *Baylor All Saints Medical Center v. Kennedy*, No. 24-10934 (5th Cir.). The case concerns a challenge to a 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. In an August 15, 2024 decision, the U.S. District Court for the Northern District of Texas granted a preliminary injunction and struck down this provision of the 2024 IPPS rule. The government appealed to the Fifth Circuit, arguing that the Secretary had discretion to determine whether to include patients covered by a Section 1115 waiver and that the court lacked jurisdiction because the plaintiffs have not received a "final determination," and thus have not satisfied the channeling requirements to challenge the rule. The rule remains vacated pending appeal, and a decision is expected in the coming months.

### 4. Post *Advocate Christ* Litigation on SSI Fraction

The landscape of litigation concerning the meaning of entitlement for SSI benefits for purposes of the DSH adjustment continues to come into clearer focus in the wake of the Supreme Court's decision in *Advocate Christ Medical Center v. Kennedy*, 605 U.S. 1 (2025). A number of cases concerning entitlement for SSI benefits that had been stayed pending resolution of *Advocate Christ* have now been voluntarily dismissed, in whole or in large part after the Supreme Court's April 29, 2025 decision in *Advocate Christ*. *See, e.g.*, *Anderson Hosp. v. Kennedy*, No. 1:25-cv-1118 (D.D.C. 2025); *Cmty. Hosp. East v. Azar*, No. 20-cv-891 (D.D.C. 2025); *Ascension Saint Thomas Highlands Hosp. v. Becerra*, No. 21-cv-2453 (D.D.C. 2025).

The Supreme Court's April 2025 decision in *Advocate Christ* upheld the agency's interpretation of the phrase "entitled to supplementary security income [SSI] benefits" in the DSH provisions of the Medicare statute to mean that a patient is "entitled to SSI benefits" for purposes of the SSI fraction used to calculate the DSH payment adjustment only if the patient is eligible to receive an SSI cash payment during the month of hospitalization. *See* July 2025 Docket Updates for more on the Supreme Court's decision in *Advocate Christ*.

The Supreme Court in *Advocate Christ* declined to address the separate issue of whether the use of only three particular Social Security Administration ("SSA") status codes to identify patient days attributable to SSI-entitled individuals was reasonable. However, notably, the U.S. District Court for the District of Columbia recently dismissed a consolidated action (that had consolidated two cases) challenging the reasonableness of CMS's limited use of status codes. *See HMH Hosps. Corp. v. Kennedy*, Nos. 24-cv-1901 & 24-cv-3261 (D.D.C. 2025). The court dismissed the action on jurisdictional grounds, concluding that it lacked subject matter jurisdiction over the plaintiff hospitals' substantive claims challenging the alleged undercounting of their SSI fractions, due to the hospitals' failure to exhaust their administrative remedies. The court rejected the plaintiffs' argument that they could appeal in one case from a denial of a request for expedited judicial review, concluding that the denial was not a final determination. The court also declined to permit the plaintiffs in both cases to avoid the exhaustion requirement on the grounds that continuing their PRRB proceedings would be futile. Because the court's ruling was on jurisdictional grounds, it did not reach the merits of the challenge to the agency's use of status codes.

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

### 5. *Trump v. CASA Inc.* and Related Litigation on Federal Workforce Reductions

In recent months, federal courts have addressed Trump administration efforts to sharply reduce the U.S. Department of Health and Human Services ("HHS") budget and workforce. Recent rulings may limit immediate disruption to programs that hospitals and health systems depend on for funding and workforce support, as litigation proceeds in various jurisdictions.

On September 17, 2025, the First Circuit left in place the preliminary injunction issued in State of *New York v. Kennedy*, No. 1:25-cv-196 (D.R.I. filed May 5, 2025) ("*State of New York*"). As noted in our last Newsletter, the U.S. District Court for the District of Rhode Island issued an order on July 1, 2025, temporarily blocking HHS's implementation of reorganizations and reductions-in-force ("RIFs") announced in Secretary Kennedy's Make America Healthy Again ("MAHA") Directive. *State of New York v. Kennedy*, 2025 WL 1803260 (D.R.I. 2025). The First Circuit denied the government's request to stay the preliminary injunction pending appeal, finding the district court reasonably applied the law. *State of New York v. Kennedy*, 2025 WL 2658233 (1st Cir. 2025). In its ruling, the First Circuit distinguished the Supreme Court's prior decisions to stay injunctions pending appeal in *Trump v. American Federation of Government Employees*, 145 S. Ct. 2635 (2025) ("*AFGE 2*") and *McMahon v. State of New York*, 145 S. Ct. 2643 (2025) ("*McMahon*"). *See* July 2025 Docket Updates for details on those rulings. As the appeal moves forward, briefing on the government's motion to dismiss continues in the district court and is currently scheduled to be completed by November 24, 2025.

*State of New York* unfolds alongside other challenges to the Trump administration's agency reorganization plans. Both *AFGE 2* and *McMahon* continue to be litigated in district courts, following recent Supreme Court rulings, and the U.S. District Court for the District of Columbia is also considering the legality of RIFs at the National Institute for Occupational Safety and Health ("NIOSH"), an HHS component. In *National Nurses United v. Kennedy*, No. 1:25-cv-01538 (D.D.C. filed May 14, 2025), worker associations and unions allege that the vast majority of NIOSH employees remain on administrative leave despite NIOSH being subject to the preliminary injunction ordered in *State of New York*. The government moved to dismiss on August 20, 2025, and briefing is ongoing. The court's ruling could affect the availability of federal expertise in hospital occupational safety compliance and workforce risk management.

Building on these ongoing disputes, federal employee unions have brought a new lawsuit challenging the Trump administration's workforce reductions at HHS and other agencies during the ongoing federal government shutdown. On October 15, 2025, the U.S. District Court for the Northern District of California issued a temporary restraining order in *American Federation of State County and Municipal Employees, AFL-CIO v. OMB*, No. 3:25-cv-8302 (N.D. Cal. 2025) blocking further RIFs during, or because of, the shutdown. On October 28, 2025, the court issued a preliminary injunction effectively extending the block on further RIFs because of the shutdown.

While recent injunctions have temporarily limited certain Trump administration restructuring efforts, operational continuity at HHS remains at risk as litigation continues in multiple federal courts.

### 6. *Oral Argument in Chiles v. Salazar*

The U.S. Supreme Court recently heard oral argument in *Chiles v. Salazar*, which concerns a First Amendment challenge to Colorado's ban on conversion therapy. Conversion therapy, as the 10th Circuit observed below, is defined by the Colorado statute and "generally refers to therapeutic attempts by a mental health professional to change a client's sexual orientation or gender identity." Chiles, a licensed professional counselor in Colorado, alleges that she seeks to engage in discussion with patients that could be considered conversion therapy and that the Colorado statute prohibiting her from doing so violates the Free Speech Clause of the First Amendment. In response, Colorado argues that the ban on conversion therapy is a permissible regulation of conduct in the form of medical treatment. At oral argument, the Court questioned whether Chiles—a licensed counselor—has standing to bring the case in the absence of state enforcement and whether the counseling at issue is speech that is merely incidental to regulated conduct, or itself, medical treatment. The oral argument also touched on how to distinguish this case from *United States v. Skrmetti*, where the Court recently upheld a Tennessee law banning puberty blockers. Ultimately, if the Court decides this case based on the First Amendment issue, it may have implications for the power of state and federal governments to restrict or limit certain types of speech-based therapy or medical treatment.

### 7. *Federal Grant and Other Funding Award Litigation*

There is ongoing litigation seeking to challenge several of the Trump administration's actions relating to federal awards and federally funded research programs. See detailed updates, below, in the Federal Awards and Grants Updates section of the newsletter.

### 8. *340B Litigation*

Both drug manufacturers and 340B hospitals continue to litigate

the 340B drug discount program, including: challenges by pharmaceutical manufacturers over the government's rejection of the manufacturers' proposed 340B rebate model; a challenge to the government's decision to terminate certain sites from the 340B drug discount program; and lawsuits challenging state legislation requiring manufacturers to offer 340B drug prices on products purchased for dispensing at contract pharmacies. See detailed updates, below, in the 340B section of the newsletter.

## Regulatory Updates

### 1. *Ongoing Showdown in Congress over ACA Premiums and Undoing Medicaid Cuts*

The passing of the One Big Beautiful Bill Act ("OBBB") has led to a congressional battle over the rollback of ACA premium tax-credits and significant cuts to Medicaid, primarily through the more stringent eligibility requirements included in the OBBB. As an initial response, Senate Democrats introduced the Protecting Healthcare And Lowering Costs Act on July 30, 2025, which includes the following provisions: (1) permanent extension of ACA premium tax credits, preventing a significant increase in health insurance premiums for millions of Americans at the end of 2025, (2) reversal of the nearly $1 trillion in spending cuts on Medicaid, and (3) repeal of enhanced work requirements and eligibility checks. While there has not been movement on this bill since its introduction, it signals the potential trend of efforts to reverse some of the impacts of the OBBB on Medicaid spending and enrollment. The fight over the enhanced tax-credits and Medicaid cuts has contributed to the federal government shutdown.

The effects of the shutdown have been far-reaching. For example, certain payment provisions, including for telehealth and Acute Hospital Care at Home programs, have now expired, leading CMS to direct Medicare contractors to withhold payments for those services on dates of service on or after October 1, 2025, which in turn has led impacted providers to pause or scale back operations. Acute Hospital Care at Home is a Medicare waiver program developed during the COVD-19 pandemic to permit acute care hospitals that are paid under the inpatient prospective payment system to provide inpatient care in patients' homes. Continued funding for Medicare reimbursement for these programs, which was originally set to terminate in 2024, has been contingent upon extensions to the program in annual government spending bills. The uncertainty of the availability of such funding moving forward has caused participating institutions to rethink their participation in the program, which could lead to capacity concerns for facilities, as these patients will now require beds in facilities. States have also begun responding to the OBBB's Medicaid cuts through adjustments to their budgets, lowering Medicaid payments to providers. As this debate continues, hospitals and health systems should anticipate fluctuations in Medicaid reimbursement. See detailed updates, below, in the 340B Updates section of the newsletter.

### 2. *CMS Publishes Federal Fiscal Year 2026 Hospital Payment Final Rule*

On April 11, 2025, CMS published its annual proposed rule for the FFY 2026 inpatient prospective payment systems ("IPPS") and long-term care hospital ("LTCH") payment system, proposing a 2.4% overall rate increase for IPPS and a 2.5% increase for LTCH. On August 4, 2025, CMS published the final FFY 2026 IPPS and LTCH rules, which took effect on October 1, 2025. In our July 2025 newsletter, we analyzed key developments of CMS's proposal with respect to DSH payments, changes in the IPPS and LTCH PPS payment rates for FFY 2026, and the low-volume hospital definition and payment adjustment. We now note the changes from the proposed rule in the final rule.

#### DSH and Uncompensated Care Payments

In the final rule, CMS increased the size of the uncompensated care payment pool relative to the proposal. The proposed uncompensated care pool was approximately $7.19 billion; the final pool is approximately $7.82 billion, about 9% higher than proposed and roughly 35% higher than FFY 2025. CMS derived the final amounts by updating the three DSH uncompensated care factors—the national pool, the uninsured rate adjustment, and each hospital's S 10 share—using more recent data to allocate uncompensated care payments. The separate statutory 25% "empirically justified" DSH payment did not change in the final rule.

#### IPPS and LTCH PPS Payment Update

Under IPPS, CMS finalized an overall rate increase of approximately 2.6% for hospitals that meet quality reporting and electronic health record requirements, compared to the 2.4% increase proposed. CMS now estimates total Medicare payments to acute care hospitals will increase by $5 billion in FFY 2026 relative to FFY 2025, up from a $4 billion increase estimated in the proposed rule. The final update reflects CMS's market basket estimate of hospital cost inflation, reduced by the statutorily required productivity adjustment. For LTCHs, CMS finalized a 2.7% update to the standard federal rate, up from 2.6% proposed, and estimates aggregate LTCH PPS payments will increase by approximately $83 million in FFY 2026, compared to $61 million in the proposal.

Low-Volume Hospital Definition and Payment Adjustment

Beginning in FFY 2026, CMS is returning to the pre-2011 low-volume hospital definition. A "low volume hospital" will be a hospital that is more than 25 road miles from another Medicare subsection (d) hospital and has fewer than 200 total discharges in the fiscal year. Hospitals that qualify will receive a 25% add on to their IPPS payments. To be considered, hospitals were required to submit a written request to their Medicare Administrative Contractor ("MAC") by September 1, 2025, for the adjustment to apply beginning October 1, 2025. CMS also finalized the discontinuation of the low wage index hospital policy and implemented related budget neutral wage index adjustments.

For a more detailed overview of the final IPPS rule, see our full summary.

### 3. *Trump Administration Healthcare Technology Initiatives*

On July 30, 2025, CMS announced the Trump administration's plan to improve and advance interoperability in health care through the "Make Health Tech Great Again" initiative. This initiative furthers the goals of the 2020 CMS Interoperability and Patient Access final rule, which mandated CMS-regulated payers to implement standardized Patient Access Application Programming Interface ("API") for the exchange of health information. The announcement focused on two voluntary CMS-sponsored efforts: (1) the "Interoperability Framework" and (2) "CMS Aligned Networks." The Interoperability Framework requires participants, such as health care networks, Electronic Health Records ("EHR") companies, providers, payers, and digital health product companies to adhere to the criteria that define data sharing principles to facilitate the sharing of information to other entities that follow the framework (or CMS Aligned Networks).

As of October 2025, at least 30 companies, including 11 health systems, have pledged to promote real health outcomes with technology over the coming months. A full list of companies who have currently pledged their support for CMS' Health Tech Ecosystem initiative can be found here. Provider and health system participants are expected to commit to ensuring patients have access to their health data readily and to "kill the clipboard" through efforts to make patient forms accessible through links or QR codes. CMS states it is looking for "early adopters" to pledge to meet the five objectives of the Interoperability Framework by the first quarter of 2026. The five objectives include (1) patient access and empowerment, (2) provider access and delegation, (3) data availability and standards compliance, (4) network connectivity and transparency, and (5) identity, security, and trust. These objectives aim to facilitate more seamless sharing of health information between participants to increase patient access and interaction with their own health data. CMS cites the May 2025 request for information issued by CMS and the Assistant Secretary for Technology Policy, which solicited suggestions from stakeholders on ways to modernize the nation's digital health ecosystem, as a main driver of the initiative. While the initiative is currently voluntary, if deemed successful, broader implementation could follow. Information for interested EHR companies, health systems and providers, payers, and digital health product companies in becoming an "early adopter" can be found here.

### 4. *Medicaid State Directed Payment Guidance*

On September 9, 2025, CMS issued preliminary guidance to states regarding the implementation of new federal payment limits set in the OBBB for State Directed Payments ("SDPs") in Medicaid-managed care (the "SDP Letter"). The OBBB requires CMS to reduce the total payment rate for SDPs in four service areas: (1) inpatient hospital services, (2) outpatient hospital services, (3) nursing facility services, and (4) qualified practitioner services at an academic medical center. The new required safeguards go into effect for rating periods beginning on or after July 4, 2025, at which point, total payment rates will be limited to 100 percent of Medicare rates (or 110% of Medicare rates for states that haven't expanded Medicaid).

Certain SDPs, however, will qualify for a grandfathering period during which existing rates will be maintained. To qualify, an SDP's rating period must occur 180 days before or after July 4, 2025 and meet one of the five criteria set out in the OBBB, which include: (1) SDPs (other than for rural hospitals) for which written prior approval was made by CMS before May 1, 2025, (2) SDPs (other than for rural hospitals) for which a good faith effort to receive CMS approval was made before May 1, 2025, (3) SDPs for rural hospitals for which written prior approval was made by CMS before July 4, 2025, (4) SDPs for rural hospitals for which a good faith effort to receive CMS approval was made before July 4, 2025, and (5) SDPs for which a completed pre-approval application (or "preprint") was submitted to CMS prior to July 4, 2025.

Until the phase down for grandfathered SDPs on January 1, 2028, the total dollar amount of a grandfathered SDP cannot increase, and a state cannot increase this amount under any change or revision to the grandfathered SDP, including a revision to the preprint, amendment SDP, or renewal SDP. States may, however, choose to decrease this amount at any time. The SDP Letter further indicates that CMS is preparing a notice of proposed rulemaking to revise the regulation governing SDPs, 42 CFR part 438, as required by the OBBB. It is unclear

when this proposed rule will be released. Hospitals and health systems participating in Medicaid-managed care in states with applicable SDPs should check the approval dates to check whether current rates will be grandfathered in through January 1, 2028.

### 5. *Implementation of the Rural Health Fund*

On September 26, 2025, CMS released guidance on the Rural Health Transformation ("RHT") Program, funded by the Rural Health Fund included in the OBBB. The RHT guidance explains the five goals of the program: (1) innovations focused on disease prevention, (2) sustainable access to care, (3) workforce development, (4) innovative care to improve coordination, and (5) using technologies to promote efficient care. The RHT Program is funded for $50 billion over five fiscal years to be allocated to approved states, beginning in FFY 2026 and ending in FFY 2030. $25 billion will be distributed equally amongst all approved states, while the other $25 billion will be allocated by CMS based on a variety of factors. These factors include rural population, the proportion of rural health facilities in the state, the situation of certain hospitals in the state, and other factors to be specified by CMS. Applications for the RHT opened in mid-September, and the submission deadline is November 5, 2025, a date that as of now has not been delayed as a result of the ongoing government shutdown. Award decisions will be released on December 31, 2025. Providers in impacted states should seek opportunities to participate in funding opportunities. However, should the shutdown continue, CMS may be forced to delay the implementation of the program.

### 6. *CMS Proposes Medicare Physician Fee Schedule Rule for CY 2026*

On July 16, 2025, CMS issued its proposed Calendar Year ("CY") 2026 Physician Fee Schedule, Medicare Shared Savings Progrm ("MSSP") and Medicare Prescription Drug Inflation Rebate Program proposed rule. Key proposals include a shift in practice expense ("PE") methodology between facility and non-facility settings, reducing the portion of indirect PE allocated to facility-based services. The proposed rule also would add a negative 2.5% efficiency adjustment for codes not based on time, including those describing procedures, radiology services, and diagnostic tests. For the first time, CMS also proposed two separate conversion factor ("CF") calculations: one for qualifying Alternative Payment Model ("APM") participants and one for non-qualifying participants. The CF update would incorporate a one-time 2.5% payment increase required under the OBBB, resulting in an increased conversion factor of $33.59 APM participants and $33.42 for non-participants. The proposed rule would also extend telehealth flexibilities for 2026.

For a more detailed overview of the proposed rule, see our full summary.

### 7. *CMS Proposes Outpatient Prospective Payment System and Ambulatory Surgical Center Rule for CY 2026*

On July 15, 2025, CMS issued a proposed rule that proposes updates to the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center ("ASC") payment system for Calendar Year ("CY") 2026. In accordance with Medicare laws, CMS proposes increasing OPPS base rates by about 2.4% and applying a prospective 2% reduction to non-drug OPPS items and services at affected hospitals to accelerate recovery of the 340B drug discount program remedy overpayments, which are estimated through CY 2031. For ASCs, CMS proposes to extend use of the hospital market basket update through CY 2026 and increase ASC payment rates by approximately 2.4% for ASCs meeting ASCQR requirements, with a proposed conversion factor of $56.207 (and $55.109 for ASCs that do not meet ASC Quality Reporting ("ASCQR") requirements) and estimates total ASC payments of roughly $9.2 billion in CY 2026.

The proposed rule advances OPPS site neutrality by proposing physician fee schedule–equivalent payment for drug administration services furnished in excepted off campus provider-based departments, with an exemption for rural Sole Community Hospitals, and requests input on broader alignment where services are predominantly performed in lower cost settings. CMS also addresses the interaction of this OPPS policy with ASC payments by proposing not to pass through the OPPS 2% prospective offset when setting ASC rates for device intensive procedures, to avoid understating device portions and potential access issues in the ASC setting. CMS also proposes to begin a three-year elimination of the Inpatient Only list starting in 2026—removing 285 mostly musculoskeletal procedures—and to assign newly outpatient eligible services to appropriate Ambulatory Payment Classifications ("APCs"), with continued protections against patient status medical review during the transition. In parallel, CMS proposes to significantly expand the ASC Covered Procedures List ("CPL") by revising 42 CFR 416.166 to modify the general standards and eliminate five general exclusion criteria (reframed as nonbinding physician safety considerations), and to add approximately 276 procedures to the ASC CPL, along with an additional 271 codes corresponding to procedures proposed for removal from the IPO list.

Service specific OPPS proposals include separately payable skin substitute products organized into three new APCs by FDA pathway with a common initial rate, updated packaging

thresholds and pathways (Average Sales Price/Wholesale Acquisition Cost/Average Wholesale Price) for drugs and diagnostic radiopharmaceuticals, and maintenance of the OPPS outlier target at 1.0% with routine wage index updates. Quality and transparency proposals emphasize adjustments to Hospital Star Ratings to weight Safety of Care more heavily and strengthened hospital price transparency standards, including standardized machine-readable files, encoding, and attestation enhancements.

Finally, as described in the 340B Updates section, below, CMS proposed it would conduct a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS by early CY 2026. The proposal is a key component of CMS's goal to reduce reimbursement for hospital outpatient drugs, which the Trump administration first sought to do for hospital outpatient drugs purchased at 340B prices in the president's first term.

For a more detailed overview of the proposed OPPS rule, see our full summary.

### 8. *CMS Finalizes Hospice Wage Index Payment Rate*

On August 1, 2025, CMS issued a final rule that updates Medicare hospice payment rates and the aggregate cap amount. The FFY 2026 Hospice Wage Index and Payment Final Rule gives hospices a modest payment increase of 2.6% starting October 1, 2025, which is about $750 million in aggregate additional payments across the sector. In addition, CMS finalized the FFY 2026 aggregate cap at $35,361.44 and confirmed continued use of the hospice floor and the 5% cap methodology at the county level. The rule also adopts several policy changes: a physician member of the hospice interdisciplinary group may recommend admission; the face to face encounter attestation must include the practitioner's signature and date, and a signed, dated clinical note documenting the encounter will satisfy this requirement; and telehealth could be used for face to face recertification encounters through September 30, 2025. Finally, CMS reiterated that the Hospice Outcomes and Patient Evaluation (HOPE) tool and the transition to the internet Quality Improvement and Evaluation System ("iQIES") submission system will begin October 1, 2025, with public reporting of HOPE-based measures no earlier than FFY 2028.

## Enforcement Updates

### 1. *Increased DOJ Focus on Criminal Healthcare Fraud Enforcement*

DOJ has increased its focus on criminal enforcement of health care fraud in recent months, and specifically through the Criminal Division's Health Care Fraud Unit. On June 30, 2025, DOJ announced that through its National Healthcare Fraud Takedown (the "Takedown"), it is pursuing criminal charges against 324 defendants, including 96 doctors, nurse practitioners, pharmacists, and other licensed medical professionals, for their alleged participation in various health care fraud schemes involving over $14.6 billion in losses to the government. DOJ also announced civil charges against 20 defendants for $14.2 million in alleged fraud in addition to civil settlements with 106 defendants totaling $34.4 million. Prominent enforcement actions relate to alleged fraudulent claims for wound care, illegal diversion of opioids and other controlled substances, and telemarketing of genetic testing, among others. This record-breaking "takedown" on health care fraud is aligned with the Trump administration's stated goal to stamp out waste, fraud and abuse in government health care programs.

The Takedown was followed by the first two corporate resolutions by the DOJ's Health Care Fraud Unit in nearly a decade. On August 20, 2025, Troy Health, Inc. entered into a Non-Prosecution Agreement ("NPA"), through which it admitted to fraudulently enrolling Medicare beneficiaries and agreed to pay a $1.4 million criminal penalty. The company admitted that it enrolled beneficiaries in Troy's Medicare Advantage plans without their knowledge or consent, including by providing beneficiaries with false information regarding the plans. On August 28, Kimberly-Clark Corporation entered into a more severe Deferred Prosecution Agreement ("DPA") and agreed to pay $40.4 million to resolve criminal charges related to the company's sale of surgical gowns. As part of the DPA, Kimberly-Clark admitted to preparing test samples for surgical gowns that did not meet testing requirements to avoid filing a 510(k) pre-market notification with the FDA. In comments at the Global Investigations Review annual meeting on September 19, the Head of the DOJ's Criminal Division stated that he expects to see more health care fraud-related corporate resolutions in the coming months.

### 2. *DOJ Increases FCA Enforcement Involving Cybersecurity Vulnerabilities*

On July 30, 2025, DOJ announced that biotechnology company Illumina, Inc. agreed to pay $9.8 million to settle allegations that the company misrepresented compliance with federal cybersecurity requirements for medical device software. The complaint alleged that, from January 2016 through April 2023, Illumina did not implement adequate cybersecurity measures into the design, development, installation and marketing of certain products used for research and clinical purposes. The complaint was filed by a qui tam relator, who also alleged that during the period at issue, Illumina failed to maintain adequate

product security programs, correct known cybersecurity vulnerabilities that created vulnerabilities, or provide sufficient support for personnel and systems tasked with product security.

This settlement is the first to focus on alleged failures to meet cybersecurity requirements for medical devices and, notably, did not involve allegations of a cybersecurity breach. Illumina allegedly certified to the FDA that its products complied with applicable cybersecurity requirements. The DOJ's theory of liability turned on those false representations of compliance and inadequate internal controls to detect cybersecurity vulnerabilities.

DOJ has increasingly demonstrated this approach in False Claims Act ("FCA") prosecutions involving alleged cybersecurity-related compliance violations, even when, as here, no actual breach occurred. For example, DOJ announced on March 26, 2025 that Department of Defense ("DOD") contractor MORSECORP, Inc. agreed to pay $4.6 million to resolve allegations that it failed to comply with cybersecurity requirements in its contracts with the Departments of the Army and Air Force. Health Net Federal Services, Inc., another DOD contractor, and its parent Centene Corporation settled similar allegations with DOJ in February 2025. Given this recent DOJ focus, providers should ensure their cybersecurity protocols and practices comply with federal guidelines.

### 3. *HHS OIG Issues Audit Report on the Provider Relief Fund and Hospital Compliance with the Balance Billing Requirement*

On September 19, 2025, the Department of Health and Human Services, Office of Inspector General ("HHS OIG") issued a report finding that 17 of 25 audited hospitals did not comply – or may not have complied – with the Provider Relief Fund ("PRF") balance billing requirement for out of network COVID-19 inpatients, which prohibits collection of out-of-pocket payments from presumptive or actual COVID-19 patients in excess of what the patients otherwise would have been required to pay if the care had been provided by in-network providers.

Common issues included (i) billing despite health plan COVID 19 cost sharing waivers, (ii) applying out of network rather than in network cost sharing amounts, and (iii) charging above the Affordable Care Act ("ACA") Marketplace annual out of pocket maximum when an in-network amount could not be reasonably determined. The report also provides additional clarification on the methodology HHS OIG and the Health Resources and Services Administration ("HRSA") expected for compliance.

Based on HHS OIG's recommendations, HRSA confirmed that it will verify that audit identified patients received refunds or that collection activity ceased for such patients, and that it will conduct additional post payment reviews—including at the hospitals HHS-OIG identified as potentially noncompliant—to assess adherence with the balance billing requirement based on the methodology outlined in the report. For further detail, see our client alert, "HHS-OIG Audit of Provider Relief Fund Balance Billing Compliance: Findings, Methodology, and Planned HRSA Follow-Up."

### 4. *DOJ Increases Enforcement Regarding Gender-Affirming Care and Revised Interpretations of the FDCA's Application to Off-Label Administration*

DOJ has taken several recent steps to increase enforcement against gender-affirming care in the wake of Executive Order 14187, entitled "Protecting Children from Chemical and Surgical Mutilation." Following directives in the order, DOJ issued a memorandum on April 22, 2025, entitled "Preventing the Mutilation of American Children," which instructed DOJ to open investigations into suspected cases of female genital mutilation and violations of the FCA and Food, Drug and Cosmetics Act ("FDCA"). Following directives in the executive order, DOJ transmitted a legislative proposal to Congress on September 3, 2025, which would prohibit healthcare professionals from providing children with gender-affirming care and create a private right of action for children and parents whose "healthy body parts have been damaged by medical professionals practicing chemical and surgical mutilation." Further, CMS has issued specific guidance for whistleblowers of issues related to the executive order. That guidance aims to allay potential whistleblower concerns by explaining: (1) "that HIPAA does not prohibit the disclosure of information related to the chemical and surgical mutilation of children, provided certain conditions are met"; and (2) "the law provides robust anti-retaliation protections for individuals who make a report in order to ensure compliance with the Executive Order."

On July 9, 2025, DOJ announced that it had subpoenaed over 20 "doctors and clinics involved in performing transgender medical procedures on children" to investigate "healthcare fraud, false statements, and more." Receiving parties are currently responding to or contesting those subpoenas. On September 9, 2025, Judge Myong J. Joun of the District of Massachusetts granted the motion of Boston Children's Hospital to quash one of those subpoenas, holding that the subpoena was issued in "bad faith" and without a legitimate purpose because it sought to end the provision of gender-affirming care that was lawful under state law and was not tied to any legitimate investigation of potential criminal conduct.

In September 2025, several child patients and their parents filed a motion to quash certain requests in a subpoena issued to the University of Pittsburgh Medical Center ("UPMC") seeking the medical records of UPMC patients who had received gender-affirming care. In re: 2025 UPMC Subpoena, No. 2:25-mc-01069 (W. D. Pa. filed Sep. 24, 2025). On October 2, 2025, DOJ filed a response brief in which it argued that providers' off-label administration of drugs may be a criminal violation of the FDCA; a supporting declaration by Lisa K. Hsiao, acting Director of the Consumer Protection Branch within DOJ, was attached to the brief. This argument represents a dramatic expansion of the government's interpretation of the FDCA.

In the declaration, Director Hsiao argues that under the FDCA, if a doctor does anything more than simply sign a prescription (such as giving instructions on how to administer a drug for an off-label use), the doctor is engaged in "distribution" and the doctor's instructions become "labeling" for the drug. The declaration states that this labeling misbrands the drug, because it is not consistent with the FDA-approved label and gives rise to an intended use other than the one FDA has approved. Furthermore, Director Hsiao argued that hospital executives could be strictly liable for a misdemeanor criminal violation of the FDCA if this violation takes place within the hospital, even without their direct participation. The declaration also states that "fraud" and "deception" such as mis-coding or misrepresenting the dangers to the patient can be evidence of intent that could support a felony FDCA violation.

On October 27, 2025, in another suit challenging a similar subpoena in the Western District of Washington, the court granted a motion to quash the subpoena concluding the subpoena had not been issued for a legitimate investigative purpose.

These subpoenas and the government's arguments in support of them represent unique challenges to providers. Providers should continue to monitor developments in these cases and review their policies regarding the provision of gender-affirming care.

## Federal Awards and Grants Updates

### 1. *Federal Grantmaking EO (EO 14332)*

On August 7, 2025, the Trump administration issued Executive Order 14223 (published in the Federal Register on August 12, 2025) ("EO 14332"), "Improving Oversight of Federal Grantmaking." As discussed in Ropes & Gray's August 2025 webinar, the order seeks to overhaul existing federal grantmaking infrastructure.

The stated purpose of EO 14332 is to "strengthen oversight and coordination of . . . agency grantmaking" to address certain "problems" enumerated within the order. Per EO 14332, these problems include: (i) the use of federal funds in ways that do not "improve American lives or advance American interests," such as funding "drag shows in Ecuador," training in critical race theory, transgender-sexual-education programs, and other "anti-American ideologies"; (ii) too many federal research funds going to university facilities and administrative costs; and (iii) an ineffective federal grant review process that rewards those institutions that can navigate the complex grantmaking process, rather than those with the best proposals. These assertions by the Trump administration are not new, following several other executive orders since the president's inauguration that address the Trump administration's stated concerns with diversity, equity, and inclusion ("DEI") programs and scientific research ("Ending Radical and Wasteful Government DEI Programs and Preferencing," Executive Order, January 20, 2025; "Ending Illegal Discrimination and Restoring Merit Based Opportunity," Executive Order, January 21, 2025; "Restoring Gold Standard Science," Executive Order, May 23, 2025).

One of the most notable requirements of the order is the insertion of political appointees, referred to as "senior appointees," into the grantmaking process, who are to use their "independent judgment" to review and approve Funding Opportunity Announcements and related discretionary awards to "ensure that they are consistent with agency priorities and the national interest." See EO 14332, §§ 2(h), 3(a), (4)(a). Because discretionary awards must demonstrably advance the president's political priorities, agency heads must designate senior appointees to review discretionary awards annually for "consistency with agency priorities and substantial progress." See EO 14332, § 3(b). To this end, the order includes an express prohibition on awards being used "to fund, promote, encourage, subsidize, or facilitate: racial preferences or other forms of racial discrimination," including activities where race or proxies for race are used as selection criteria for participation, "denial . . . of the sex binary in humans or the notion that sex is a chosen or mutable characteristic, illegal immigration, or any other initiatives that compromise public safety or promote anti-American values." See id. at § 4(b)(ii). The order also instructs agency heads to create "an accountability mechanism for officials responsible for selection and granting of the awards" to further encourage those officials to ensure that awards align with agency priorities. See EO 14332, § 3(b). EO 14332 goes on to instruct the Office of Management and Budget ("OMB") Director to revise OMB's uniform grants guidance ("Uniform Guidance") "to further clarify and require all discretionary grants to permit termination for convenience, including when the award no longer advances agency priorities or the national interest. . . ."

Id. at § 5(a). By making awards terminable by convenience, the proposed Uniform Guidance alteration would create a termination mechanism that is more akin to those seen in federal contracts.

EO 14332 also addresses indirect costs ("IDCs") (also referred to as facilities and administration costs). The OMB Director is instructed to revise the Uniform Guidance to "appropriately limit the use of discretionary award funds for costs related to facilities and administration." See id. at § 5(b). While the precise manner of implementation is unclear, this suggests that the administration intends to decrease IDC funds, which aligns with the administration's ongoing efforts to cap federal agencies' IDC rates, as discussed in our July 2025 newsletter. The order also encourages agencies to give preference to applicants with lower IDC rates. Large research institutions are more likely to have higher negotiated IDC than smaller institutions. The EO 14332 Fact Sheet emphasizes that grants should be awarded based on "merit" and that "[f]ederal grant money should be awarded based on a grantee's ability to produce results, not based on its ability to hire lawyers and grant-writing experts."

The new grantmaking framework presents several challenges to federal awardees. Procedurally, agencies may pause or slow their existing grantmaking processes while newly mandated processes are established; reviews could take longer as new accountability and reporting layers are added; and the order's requirement that recipients seek an agency's "affirmative authorization" prior to funds draw down could slow administration processes even for existing awards. See EO 14332, § 6(c)(i). In addition, established research institutions that historically have had a high number of awards, high-value awards, and/or high IDC rates could be disadvantaged in their new award applications in comparison with smaller research institutions and/or those with relatively low IDC rates.

### 2. *Recent Updates on Federal Funding Termination Litigation*

We continue to follow closely the Trump administration's actions relating to federal awards and proposed changes to established law, regulation, and guidance governing federally funded research programs, including federal agency terminations of awards that allegedly focus on or promote certain topics that are disfavored by the Trump administration (e.g., DEI, health equity, vaccine preparedness) and federal agency efforts to cap IDC rates.

As described in our previous newsletter, in two consolidated cases, plaintiffs (the American Public Health Association, in one case, and a coalition of states in another) brought claims against HHS and the National Institutes of Health ("NIH") in the U.S. District Court for the District of Massachusetts alleging that the Trump administration unlawfully cancelled federal awards funding and medical and scientific achievements, 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. *American Public Health Association v. NIH.*, No. 1:25-cv-10787 (D. Mass. 2025), appeal docketed No. 25-1611 (1st Cir., June 24, 2025) ("APHA").

On June 16, 2025, after a bench trial, Judge Young ruled that both internal HHS and NIH guidance directing agency personnel to terminate certain categories of awards as well as the award terminations pursuant to the agency guidance, are arbitrary and capricious. *American Public Health Association v. National Institutes of Health*, No. 1:25-cv-10787, slip op. at 14 (D. Mass. July 2, 2025). The Trump administration appealed the decision to the U.S. Court of Appeals for the First Circuit and filed an application to the Supreme Court to stay the judgments of the district court pending the disposition of the appeal to the First Circuit.

On August 21, 2025, in a fractured ruling, the Supreme Court stayed, pending appeal, the portion of the court's order vacating the award terminations; however, the Supreme Court did not stay the portion of Judge Young's order vacating the HHS and NIH guidance on which the terminations were based. *See NIH v. American Public Health Association*, No. 25A103 (U.S. Aug. 21, 2025) (hereinafter "*APHA*"). The crux of the Justices' disagreements is the question of whether plaintiffs' claims are "founded . . . upon any express or implied contract with the United States," which, under the Tucker Act, must be brought in the Court of Federal Claims as claims for money damages. 28 U.S.C. § 1491(a)(1); *Department of Education v. California*, 604 U.S. 650, 651 (2025).

The Supreme Court's emergency order is not a decision on the merits. However, the decision has significant practical implications for plaintiffs. As a general rule, "the Court of [Federal] Claims has no power to grant equitable relief" such as injunctions or declaratory judgment. *Richardson v. Morris*, 409 U.S. 464, 465 (1973). Under the Court's reasoning, a plaintiff seeking relief for grant terminations based on an agency policy must file suit in federal district court to challenge the policy and in the Court of Federal Claims to challenge the resulting grant terminations. Moreover, as Justice Barrett notes in her concurrence, plaintiffs may be required to "proceed sequentially rather than simultaneously," because the Court of Federal Claims is barred from hearing claims arising from "substantially the same operative facts" as claims pending in other courts.

The First Circuit appeal is ongoing. The government filed its

appellants' brief on October 10, arguing that (i) the district court lacked jurisdiction to vacate the challenged award terminations; (ii) challenges to agency guidance are moot due to updated guidance; (iii) plaintiffs lack standing to challenge the agency guidance because plaintiffs' alleged injuries arise from the award terminations, not from the agency guidance; and (iv) the agency guidance is not reviewable under the Administrative Procedure Act ("APA") because such guidance does not constitute final agency action and is under agency discretion by law. Plaintiff-appellees' brief is due November 12, 2025, and the reply brief is due December 3, 2025. The First Circuit has not yet stated whether it will hold oral argument.

### 3. *Recent Updates to IDC Rate Litigation*

As discussed in the July 2025 newsletter, in the early days of the second Trump administration, several federal funding agencies -- specifically, NIH, National Science Foundation ("NSF"), DOD, and Department of Education ("DOE") -- each announced caps limiting IDC rates to 15%. Courts blocked each agency's attempts to impose the rate caps, and the government appealed each decision to the U.S. Court of Appeals for the First Circuit. As described in more detail below, the government's appeals regarding the NIH, DOD, and DOE caps are ongoing, however, the government moved to voluntarily dismiss its appeal of the decision blocking NSF's rate cap.

- NIH**.** After the U.S. District Court for the District of Massachusetts granted a permanent injunction blocking implementation of the IDC rate cap, the government appealed to the First Circuit on April 8, challenging the permanent injunction. In the appellants' brief, filed on May 9, the government argument challenges both the merits of the district court's decision as well as the district court's jurisdiction over plaintiffs' challenges to the IDC rate change for existing awards. Citing the Supreme Court's emergency order in *Department of Education v. California*, 604 U.S. 650 (2025), the government asserts that plaintiffs' claims are "in essence contractual and so governed by the Tucker Act," and therefore the Court of Federal Claims has exclusive jurisdiction. The government also argues that the First Circuit should overturn the district court's judgment because the IDC rate change was lawfully issued pursuant to express regulatory authority, reasonable, reasonably explained, and not impermissibly retroactive. Oral arguments are scheduled for November 5, 2025.

- DOE**.** After Judge Allison D. Burroughs of the U.S. District Court for the District of Massachusetts entered a final judgment vacating the DOE cap on June 30, 2025, the government appealed to the First Circuit on July 31. The government's brief, filed on September 26, 2025, makes substantially the same arguments as those described above in connection with the government's appeal of the judgment enjoining NIH's IDC rate change. The plaintiff-appellees' brief was originally due on October 24, 2025 but the court has been indefinitely stayed the briefing schedule as a result of the ongoing government shutdown. As of the date of this publication, the First Circuit has not scheduled oral argument.

- NSF. On June 20, 2025, 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; the government appealed this decision to the First Circuit on August 15. However, on September 26, prior to filing an appellants' brief, the government instead moved to voluntarily dismiss its appeal, and the First Circuit dismissed the case on September 30, 2025.

- DOD. On June 17, 2025, 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. Following oral arguments held on September 4, the district court issued an order vacating DOD's IDC rate cap and declaring the cap invalid, arbitrary and capricious, and contrary to law. However, the district court declined to issue a permanent injunction prohibiting DOD from implementing the rate cap policy, reasoning that declaring unlawful and vacating the policy would fully resolve the dispute and prevent injury to plaintiffs, and that "[a]n injunction would have no additional, meaningful practical effect[.]" *Association of American Universities v. Department of Defense*, No. 1:25-cv-11740, slip op. at 58 (D. Mass. Oct. 10, 2025) (internal quotation marks omitted). As of the date of this publication, the government has not appealed the decision.

### 4. *GAO Report on Impoundment Control Act*

In an August 5, 2025 report, the U.S. Government Accountability Office ("GAO") found that the Trump administration violated the Impoundment Control Act ("ICA") through NIH's cancelation of existing awards and decline in NIH funds awarded from February to June 2025 as compared to prior years. According to the report, NIH's actions show that the agency intended to withhold funds that had been budgeted

by Congress to federal research from obligation and expenditure, without regard to ICA processes. Pursuant to the ICA, "executive branch officials must take care to ensure that they prudently obligate appropriations during their period of availability" unless Congress has enacted a law that allows an agency to forego the obligation of funds. Although the ICA allows the president to withhold funds from obligations, the president is only allowed to do so under strictly limited circumstances and, in a manner, consistent with the ICA. For example, the president may seek to withhold funds temporarily by proposing a "deferral" or may seek the permanent cancellation of funds for fiscal policy or other reasons by proposing a "rescission." In these instances, however, the president is required by the ICA to transmit a special message to Congress outlining the restricted amount of funds and the purpose for the restriction. Ultimately, the executive branch must justify withholding of budget authority, and to date, the president has not provided the required justification to GAO to explain NIH's cancelation of existing awards and decline in NIH funds awarded.

### 5. *HHS Adoption of the Uniform Guidance*

Effective October 1, 2025, HHS adopted in full the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards as set forth at 2 C.F.R. Part 200 (the "Uniform Guidance"), with additional HHS-specific provisions codified at 2 C.F.R. Part 300. The change was announced in an interim final rule published on October 2, 2024. The Uniform Guidance, which OMB first established in 2013, sets forth administrative requirements for federal awards—including requirements applicable to federal agencies' award-making processes and management of federal financial assistance programs and requirements that agencies may impose on recipients and subrecipients throughout the lifecycle of a federal award—as well as principles for determining allowable costs and audit standards.

Prior to adopting the Uniform Guidance in full, HHS had codified the Uniform Guidance in its own separate set of regulations, with agency-specific modifications, at 45 C.F.R. Part 75. Explaining the agency's decision to adopt the Uniform Guidance in full, HHS states in the interim final rule that many of its prior modifications are no longer necessary. Specifically, HHS states that nearly all modifications adopted by HHS to implement and adapt the 2013 Uniform Guidance have been formally adopted by OMB in the most recent Uniform Guidance, while other HHS-specific modifications "merely cite to other existing regulations or statutes," such that removing the citations from the HHS regulations for federal awards "has no effect on the other regulations, nor on their applicability to the regulated community." 89 Fed. Reg. 80055, 80056 (Oct. 2, 2024). HHS states that certain other provisions—such as forms for HHS financial assistance (previously 45 C.F.R. § 75.206) and HHS policy on property (previously at 45 C.F.R. § 75.316)—articulate HHS policy that is "better suited to sub-regulatory guidance" and as such will address such topics through the HHS Grants Policy Statement.

Notably, HHS's adoption in full of the latest iteration Uniform Guidance also resolves certain ambiguity regarding HHS's rights to terminate awards. Although OMB revised 2 C.F.R. § 200.340 in 2020 to permit agencies to terminate awards "to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities[,]" HHS never updated its regulations to reflect this change. As a result, prior to October 1, 2025, HHS regulations addressing termination of awards permitted terminations only (i) for non-compliance, (ii) for cause, or (iii) with the consent of the awardee. *See* 45 C.F.R. § 75.372(a). As such, although HHS has in award termination notices asserted authority under the Uniform Guidance to terminate awards on the basis of program goals or agency priorities, HHS had not yet adopted through regulation the provision permitting termination for this reason. With HHS's full adoption of the current Uniform Guidance, HHS regulations now permit termination "to the extent authorized by law, if an award no longer effectuates program goals or agency priorities."

Nevertheless, award recipients whose federal awards have been terminated by a federal agency on this "program goals or agency priorities" basis may have reasonable arguments against such termination. Specifically, a federal agency should not have the authority to terminate based on its unilateral, post-award change in priorities; the precise language—"no longer effectuates"—indicates that the relevant change is a change in the award's ability to meet the program goals or agency priorities and not a change in the agency's goals or priorities. Also, as the qualifier "to the extent authorized by law" suggests, the adoption of this provision does not give HHS *carte blanche* to terminate awards at will. For example, in the 2020 final rule, OMB frames this termination provision in terms of "additional evidence," explaining that an award might be terminated on the basis of agency priorities if "additional evidence reveals that a specific award objective is ineffective at achieving program goals . . . [or] caus[es] the Federal awarding agency to significantly question the feasibility of the intended objective of the award[.]" 85 Fed. Reg. 49506, 49507–08 (Aug. 13, 2020). Furthermore, a termination on the basis of agency priorities must reflect the reasonable exercise of discretion and rational decision making, based on consideration of the relevant factors. As such, termination on the basis of agency priorities is available only where HHS

appropriately interprets a change in agency priorities and articulates a satisfactory explanation for the termination, including a rational connection between the facts found and the choice made.

### 6. *HHS Departmental Appeals Board Processes*

Under the direction of the Trump administration, federal funding agencies, including HHS, have terminated awards *en masse*. In addition to litigation, many federal award recipients have appealed terminations directly to the agencies. If an initial appeal to an HHS agency like NIH is unsuccessful, an awardee generally has two paths: (1) appeal to the HHS Departmental Appeals Board ("DAB"); or (2) treat the agency denial as final agency action and potentially file suit in federal court.

The DAB reviews certain disputes involving HHS agencies, including the Centers for Disease Control and Prevention ("CDC"), CMS, the FDA, and NIH. To accept an appeal, the dispute must arise under a program that uses the DAB for dispute resolution and meet any special conditions established for that program. 45 C.F.R. § 16.3(a). Additionally, the appellant must exhaust any preliminary appeal process required by regulation. 45 C.F.R. § 16.3(c). Following the preliminary review or appeal, an appeal to the DAB must be filed within 30 days after receiving the final decision from the funding agency. 45 C.F.R. § 16.3(b); 45 C.F.R. § 16.7(a).

Whether an appeal meets the necessary conditions for DAB review is determined by the DAB Chair. 45 C.F.R. § 16.7(b). If there is a question, the DAB may request the issuing agency's written opinion. Appeals to the DAB thus far have resulted in such jurisdictional inquiries.

The DAB has jurisdiction to hear disputes regarding, among other issues, "a disallowance or other determination denying payment of an amount claimed under an award, or requiring return or set-off of funds already received" but not including disposition of unobligated balances and "a termination for failure to comply with the terms of an award." 45 C.F.R. Part 16, Appendix A. A termination of an award due to a change in agency priorities could constitute a "termination for failure to comply with the terms of an award" insofar as the funding agency believes compliance with new agency priorities is a necessary term or condition of the award. Alternatively, a termination could constitute a denial of payment, to the extent that the balance has been obligated.

### 7. *DOJ Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination*

For many years, institutions that receive federal funding have had to attest that they will comply with federal antidiscrimination laws (e.g., Title VI, Title VII, and Title IX of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act, the Age Discrimination Act, and Section 1557 of the Affordable Care Act, collectively, "Civil Rights Laws") as a condition of such funding, whether receiving federal grants, cooperative agreements, or contracts. While Civil Rights Laws themselves have not changed in 2025, the interpretation of those laws has changed in the Trump administration, and there has been a coordinated, federal-wide effort to more closely tie acceptance of federal funds, Civil Rights Laws, and the FCA.

On July 29, 2025, DOJ published a memorandum entitled, "Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination." This guidance reiterates the Trump administration's policy position regarding DEI programs and interpretations of Civil Rights Laws. It emphasizes that federal funds may not support programs that discriminate based on protected characteristics and notes that race- and sex-based policies are subject to heightened level of judicial scrutiny. The memorandum echoes previous statements and actions of the administration such as the issuance of several executive orders opposing so-called DEI programs and widespread agency cancellations of federally funded research projects labeled as DEI-related.

The publication follows prior steps taken by the DOJ in this area. In May 2025, the DOJ published a memorandum on its Civil Rights Fraud Initiative, which asserts that "[o]ne of the most effective ways" to enforce "federal civil rights laws and ensur[e] equal protection under the law" is through "vigorous enforcement of the False Claims Act." *See* DOJ, Civil Rights Fraud Initiative Memorandum (May 19, 2025). To this end, the memorandum states that the FCA "is implicated when a federal contractor or recipient of federal funds knowingly violates civil rights laws—including but not limited to Title IV, Title VI, and Title IX of the Civil Rights Act of 1964—and falsely certifies compliance with such laws." *Id.*

Note: In May 2025, Ropes & Gray attorneys hosted a webinar on FCA risks flowing from agency certifications.

## Value-Based Care Corner

### 1. *Changes to the AHEAD Model*

On September 2, 2025, CMS announced significant changes to the Achieving Healthcare Efficiency through Accountable Design ("AHEAD") Model, including extending its end date to December 31, 2025, for all cohorts. As discussed in a previous client alert, AHEAD Model is a voluntary, state-based total cost of care ("TCOC") model designed to help states transform their healthcare systems to improve population health, promote

healthier living, and curb health care cost growth, with a particular emphasis on increasing investment in primary care to deliver value-based care for Medicare and Medicaid beneficiaries. Participating states include Maryland (Cohort 1); Connecticut, Hawaii, and Vermont (Cohort 2); and Rhode Island and sub-state regions in New York (Cohort 3, commencing in 2028).

Key changes to the AHEAD Model include a requirement that participating states implement at least two policies to promote choice and competition in their health care markets during the implementation period. In addition, states with existing hospital rate-setting authority will no longer be permitted to design their own hospital global budget methodologies for Medicare fee-for-service; instead, CMS will standardize that methodology. Further, beginning in 2028, CMS will introduce a new framework in AHEAD Model regions that uses geographic attribution for beneficiaries not otherwise attributed to a CMS accountable care organization program, thereby expanding TCOC accountability. The framework will give risk-bearing Geographic Entities more tools and flexibility to improve care and lower costs, using two-sided risk arrangements that share savings and losses. Patients, in turn, may receive extra incentives while keeping all existing protections under Original Medicare. Lastly, the model will replace Health Equity Plans with Population Health Accountability Plans, with a focus on preventive care, including chronic disease prevention.

### 2. *Proposed Mandatory Ambulatory Specialty Model*

In its proposed Physician Fee Schedule rule for CY 2026, CMS proposed the mandatory Ambulatory Specialty Model ("ASM"), which is a new five-year payment model that would begin January 1, 2027 and end December 31, 2031. ASM focuses on ambulatory specialty care for Medicare beneficiaries with heart failure and low back pain, requiring clinicians to report measures relevant to their specialty and condition. By evaluating individual clinicians and comparing peers within the same condition cohort, ASM aims to drive competition, reduce low-value services, and improve coordination with primary care.

The new model would blend elements of the Merit-based Incentive Payment System ("MIPS") and MIPS Value Pathways ("MVPs") into a new Alternative Payment Model ("APM"). Participation is mandatory for selected specialists in designated geographies who meet episode-volume thresholds based on MIPS episode-based cost measures. ASM keeps traditional fee-for-service billing but applies scaled positive, neutral, or negative Part B payment adjustments two years after each performance year based on peer comparisons within each condition cohort, funded by an incentive pool with maximum risk levels starting at 9% and rising to 12%, and it waives MIPS reporting in years clinicians are eligible under the model. CMS is seeking comments for ASM, including, the definition of ASM, the proposed test period of seven years, and CMS's proposal on requiring mandatory participation.

### 3. *Medicare Shared Savings Program Results*

On September 29, 2025, CMS shared the latest MSSP results, which showed a strong performance year in 2024. Three out of four ACOs earned shared savings, covering roughly 80% of the program's 10.3 million beneficiaries. In total, participating Accountable Care Organizations ("ACOs") earned $4.1 billion in shared savings payments, with $2.5 billion in net savings for Medicare, both the highest levels since the program began. Savings per patient rose, led by physician-driven, primary care-focused ACOs, which also used fewer costly services like hospital stays and skilled nursing. Only 16 ACOs (out of almost 500 MSSP ACOs) recorded losses, totaling about $20 million. On quality, ACOs improved blood pressure control, diabetes management, and depression screening, and continued to outperform comparable physician groups on quality and patient experience.

Looking ahead, CMS is proposing changes to keep the momentum while reducing administrative burden. These include limiting time in one-sided risk for Basic track ACOs to five years, providing more flexibility around the 5,000-beneficiary minimum during benchmarking, streamlining and aligning quality reporting, and extending extreme and uncontrollable circumstance policies—such as cyber attacks—to affected ACOs. Overall, the program continues to demonstrate how coordinated primary care-led models can improve outcomes at a lower total cost of care.

### 4. *AI in Value Based Care*

CMS continues to focus on broader use of AI to drive higher value care, including through the following recent agency actions:

- *CMMI Releases FAQ on WISeR Model*

  On August 12, CMMI released an FAQ on the Wasteful and Inappropriate Service Reduction ("WISeR") Model. The WISeR model 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. The FAQ clarifies details regarding key elements of the model to combat concerns regarding claim denials under the model. First, it clarifies that the model will not change any Medicare coverage policies

or provider or supplier payment for covered services. Rather, the model aims to improve the accuracy and efficiency of the coverage review process. CMS explains that response time under the model will be within 72 hours. Second, to combat inappropriate denials (non-affirmations), denials under the model require the review of human clinicians for validation. Third, CMS will audit participants to ensure that determinations are consistent with Medicare coverage criteria. Fourth, for non-affirmed prior authorization requests, providers will have unlimited opportunities to resubmit requests, and providers retain the same administrative appeal rights with the MACs, as those providers not participating in the model. CMS includes such safeguards to prevent improper denials, while helping patients avoid unnecessary, inappropriate procedures. Providers in participating MAC jurisdictions or regions should anticipate engaging in increased MAC appeals as the model is implemented.

- *CMS "Chili Cook-Off" Challenge Solicits AI Solutions to Tackle Medicare Fraud*

  On August 19, CMS announced a market-based research challenge that intends to harness machine learning ("ML") models to detect anomalies and trends in Medicare claims data that can be translated into novel indicators of fraud, including the types of fraud continually impacting ACOs. CMS has named the program the "Crushing Fraud Chili Cook-Off Competition" (the "Competition"). The Competition will run in two phases. Phase 1, which began on August 19, 2025, is comprised of proposal submission and participant selection on October 20, 2025. Phase 2 begins October 30, 2025, when chosen participants will get access to the Competition data. Final submissions for the Competition are due on December 1, 2025, and CMS will announce the winner on December 15, 2025. CMS will publicly recognize the 10 finalists and the winner on CMS social media channels. Participants will then have the opportunity to leverage these innovations for any future contract bids that CMS announces. CMS aims to use submissions to identify investment opportunities that can be addressed through innovative technologies and approaches. Hospitals and health systems should follow the results of the Competition for insights on future CMS AI initiatives and opportunities to incorporate new technologies into existing systems.

## Transaction Trends

### 1. *Hospital Transactions Trends: Increased Focus on Outpatient Care*

Hospitals and health systems continue to seek opportunities to expand outpatient networks, including through outpatient-focused transactions, such as ASCs, expansion and creation of regional provider networks and deepening physician partnerships to strengthen care coordination; joint ventures; and other expansions of outpatient sites. This ongoing strategic shift reflects converging pressures and opportunities: the migration of surgical volume to lower-cost outpatient settings, in particular as more complex and higher acuity cases have shifted to ASCs; persistent margin compression from labor, supply, and pharmaceutical costs; payer steerage toward site-of-care optimization, especially for diagnostic imaging and infusion services; and the continued rise of risk-bearing and value-based arrangements.

One notable example of such expansion in this space is Ascension Health's pending $3.9 billion acquisition of AMSURG, an ambulatory surgery management services company, which was announced in June 2025. Further, HonorHealth, an Arizona-based health system which Arizona-based HonorHealth operates including nine acute care hospitals, a medical group, outpatient surgery centers and a cancer care network, agreed to acquire Evernorth Care Group in September. Evernorth Care Group, formerly Cigna Medical Group, is a subsidiary of The Cigna Group and provides primary care to nearly 80,000 patients.

By expanding ASC footprints and aligning with physician groups, health systems can capture outmigration, enhance network adequacy, reduce total cost of care, and improve patient access and experience. Further, by entering into joint venture arrangements for outpatient services, hospitals and health systems can explore opportunities to expand and diversify services without relinquishing control of a service line, but with less risk and commitment and often an infusion of cash that can serve to support other initiatives.

### 2. *OBBBA Uncertainties Stymie Potential Hospital Transactions*

Despite economic uncertainty due to shifts in federal reimbursement, thirteen hospital transactions were announced in the first half of 2025 and seven have been announced since July. At the same time, parties to at least two transactions that had

been in announced decided to step away from those plans, citing uncertainty arising from the OBBBA and reimbursement challenges stemming from the recently passed legislation.

- On August 13, 2025, the San Benito Health Care District ("District") and Hazel Hawkins Memorial Hospital ("Hawkins") announced that Insight Medical ("Insight") was withdrawing from the proposed lease and purchase of agreement with Hawkins, following ongoing negotiations and an approved ballot measure that authorized the District to lease certain real property assets and sell substantially all other assets to Insight. The District and Hawkins cited unprecedented uncertainty stemming from the OBBBA, and noted particularly the $137 billion in reductions projected to directly impact rural healthcare as a result of the OBBBA.
- On September 23, 2025, FHN announced its decision to withdraw from a previously announced partnership with Beloit Health System to formally propose a new 10-bed micro-hospital on the campus of NorthPointe Health in Roscoe, IL. FHN noted that reimbursement reductions from the OBBBA would present further financial challenges that required the Illinois-based health system to prioritize local needs. Beloit Health System indicated it will continue to pursue the project.

Hospitals across the country could see an aggregate decrease of up to $25 billion in net revenue annually as a result of reimbursement changes, with each system potentially losing between $1 million and $4 million in net revenue annually. These reductions are likely to hit systems unevenly, based on size and payer mix. Health system operators may consider how to prepare for cost reductions, or increase payer reimbursement elsewhere to offset the revenue declines, including through strategic partnerships.

### 3. *Rise in Medical School Expansion*

Hospitals have long identified physician shortages in the areas of primary care as a pervasive problem. In 2024, the Association of American Medical Colleges projected a physician shortage of up to 86,000 by 2036, citing growing health care needs and the impending retirement of physicians. Hospitals have increasingly sought to address these concerns through partnerships to develop schools of medicine, with at least nine medical schools formed through collaborations involving health systems and higher education institutions opening since 2010. Establishing a training pipeline provides hospitals with a source of well-trained physicians for their workforce, and can work to increase access in underserved communities. Hospitals may also seek to leverage research and clinical trial opportunities for their medical schools through their collaboration with another institution. Through these medical school collaborations, hospitals can meet rising demand and physician shortages, deepen research, and close critical access gaps.

Note: 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. *Updates on Prior Proposals by the Trump Administration*

As discussed in our prior newsletter, the Trump administration has announced a number of proposals related to the 340B drug discount program ("340B Program"). Recent government actions attempt to advance those proposals.

First, President Trump had signed an executive order that included two initiatives that could impact the 340B Program. With respect to the first initiative, related to insulin and injectable epinephrine pricing at health centers receiving funding from HRSA under the federal health center program, HRSA announced on June 24, 2025 that the agency had issued updated award terms requiring the health centers to provide insulin and injectable epinephrine to low-income patients at or below the price paid by the health center through the 340B Program. With respect to the second initiative, related to hospital acquisition costs, on July 15, 2025, CMS issued the CY 2026 Medicare OPPS proposed rule, which announced that it would conduct a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS by early CY 2026. Such a survey is a prerequisite to reducing reimbursement for hospital outpatient drugs (which CMS sought to do for hospital outpatient drugs purchased at 340B prices under the first Trump administration).

Secondly, President Trump had issued a budget proposal for FFY 2026 that would reorganize HRSA and other agencies into a new agency, the administration for a Healthy America. The proposal would also shift responsibility for the 340B Program from HRSA to CMS. To date, the Trump administration has not taken any action to implement this proposal.

Lastly, CMS had announced in its CY 2026 Medicare OPPS proposed rule that it would accelerate the recapture of funds from hospitals that experienced a purported "windfall" following

*AHA v. Becerra*. Specifically, CMS proposed to revise the annual reduction to the OPPS conversion factor used to determine the payment amounts for non-drug items and services from 0.5 percent to 2 percent, allowing the agency to recapture all funds in approximately six years. CMS said that recapturing funds too slowly would interfere with the agency's efforts to restore hospitals to as close as possible to the approximate financial position that they would have been in had the 340B Payment Policy never been implemented. According to CMS, extending the adjustments too far from 2018 through 2022 would make it less likely that the relative hospital utilization of non-drug items and services will correlate to the relative hospital utilization of non-drug items and services from 2018 through 2022. The calendar year 2026 Medicare OPPS final rule has not yet been published, and therefore, there are no updates on this initiative.

### 2. *Hospitals and Manufacturers Fight over HRSA's 340B Rebate Model Pilot Program*

On July 31, 2025, HRSA announced a voluntary pilot program, summarized in our client alert, allowing qualifying manufacturers to offer 340B pricing through post-purchase rebates, rather than point-of-sale discounts that traditionally have been extended on 340B drug purchases. As described in Federal Register commentary, under a rebate model, a covered entity would pay a higher upfront price and then later receive a rebate equal to the difference between that price and the 340B price. HRSA Administrator Tom Engels stated that the pilot program creates "a measured approach to the process of approving manufacturer rebate models under the 340B Program."

This pilot program is limited to the universe of drugs included in the Inflation Reduction Act ("IRA") Medicare drug price negotiation program, with the first round of the pilot program limited to drugs subject to negotiated pricing in 2026: Eliquis, Enbrel, Entresto, Farxiga, Imbruvica, Januvia, Jardiance, NovoLog (and similar rapid-acting insulin products from Novo Nordisk), Stelara, and Xarelto.

HRSA encouraged manufacturers to submit participation plans by September 15, 2025. Approvals were set to be issued on October 15, 2025 (although nothing has been publicly announced to date), for a January 1, 2026 start, with later submissions receiving delayed effective dates. Manufacturers must notify covered entities of rebate model details at least 60 days before implementation. HRSA's Office of Pharmacy Affairs may expand the rebate model to other 340B drugs following its evaluation of the pilot.

After HRSA announced its 340B Rebate Model Pilot Program, more than one thousand public comments were submitted, including from hospitals and drug manufacturers. Hospitals generally warned that the rebate model could strain providers' cash flow and disrupt operations. Manufacturers generally supported the rebate model, stating that it would ensure drug discounts went to eligible patients. And some manufacturers suggested that the eligible drug list should be expanded beyond the drugs chosen for the Medicare drug price negotiation program.

On September 8, 2025, a bipartisan group of legislators sent an open letter to Secretary Kennedy, urging HHS to abandon the pilot or impose stronger guardrails, maintaining that a rebate model would require 340B providers to float significant cash to manufacturers in the hope of receiving a rebate. In their letter, the lawmakers argued that the pilot would threaten providers' ability to remain open.

### 3. *District Court Upholds HRSA's Authority over 340B Rebate Models in Johnson & Johnson Lawsuit.*

As discussed in previous newsletters, Johnson & Johnson ("J&J") and other pharmaceutical manufacturers have separately filed lawsuits against HRSA, arguing that HRSA violated the APA by rejecting the manufacturers' proposed 340B rebate models because the 340B statute permits rebate models at a manufacturer's discretion. HRSA has contended that the statute requires approval from the HHS Secretary for any rebate-based pricing (i.e., where drugs are offered to covered entities at the list/commercial price and 340B discounts are later made available to covered entities, upon submission of claims data, through rebates) and that unapproved implementation would violate the statute's "must offer" provision. Briefing has been ongoing since November 2024.

On June 27, 2025, the U.S. District Court for the District of Columbia upheld HRSA's authority to require prior approval for rebate models under the 340B Program. The court found that the 340B statute grants the HHS Secretary discretion to determine whether to permit rebate models and HRSA's refusal to approve J&J's rebate model was not arbitrary or capricious. The court also expressly clarified that a rebate model would be lawful if a manufacturer received prior approval for such model from HRSA.

On June 30, 2025, J&J appealed the district court's decision to the U.S. Court of Appeals for the District of Columbia Circuit. The case has been consolidated with similar appeals by other manufacturers and oral argument has been scheduled for November 17, 2025.

### 4. *Litigation over Nevada Clinic's Participation in the 340B Program Continues*

As discussed in our prior newsletter, Sagebrush Health Services

("Sagebrush"), a Nevada-based STD clinic, challenged HRSA's refusal to reinstate certain Sagebrush sites into the 340B Program and the termination of other sites. Sagebrush argued that HRSA exceeded its authority, acted arbitrarily, and improperly demanded repayment of manufacturer discounts. On June 27, 2025, the U.S. District Court for the District of Columbia denied Sagebrush's motion for a preliminary injunction, finding that HRSA's decision to terminate the sites from the 340B Program was reasonable based on the information available to the agency at the time of its decision. The court stated that, at the time the sites were terminated from the 340B Program, Sagebrush had not provided documentation sufficient to prove the clinics were receiving the requisite government funding for STD services. The litigation remains pending.

Amgen's lawsuit related to the Sagebrush dispute remains ongoing. As discussed in our prior newsletter, Amgen sued HRSA, alleging that the agency failed to fulfill its obligations to oversee the 340B Program by permitting ineligible Sagebrush clinics to participate in the program. On August 4, 2025, the U.S. District Court for the District of Columbia denied HRSA's motion to dismiss parts of Amgen's complaint, holding that Amgen did not need to exhaust the administrative remedies available to the manufacturer prior to suing HRSA because the APA allows immediate judicial review of a final agency action unless another statute or regulation clearly requires exhaustion. Here, the court determined that no applicable law required exhaustion. The court also found that the case was not moot despite the decertification of certain clinics because Amgen challenged HRSA's general certification process, not the certification of any particular clinic, and the possibility of future recertification remained. As such, the court said that effective relief was still available. This case remains pending.

### 5. *Fifth Circuit Upholds Mississippi's 340B Contract Pharmacy Protections Against Manufacturers' Challenge*

A number of states have enacted legislation requiring manufacturers to offer 340B drug prices on products purchased for dispensing at contract pharmacies, including Colorado, Hawaii, Nebraska, South Dakota. These laws have been subject to challenge in multiple lawsuits filed by pharmaceutical manufacturers and their industry association, including a June 2025 AstraZeneca suit in Nebraska and a July 2025 suit in Hawaii brought by the Pharmaceutical Research and Manufacturers of America ("PhRMA"). AstraZeneca challenges the Nebraska statute arguing that it (i) is preempted by federal patent law under the Supremacy Clause, (ii) is preempted by the federal 340B statute (42 U.S.C. § 256b) with respect to the data collection restriction, (iii) violates the Contracts Clause, and (iv) violates the Takings Clause. PhRMA challenges the Hawaii statute arguing that the statute is preempted by the federal 340B statute under the Supremacy Clause.

Recently, on September 12, 2025, the U.S. Court of Appeals for the Fifth Circuit affirmed the denial of a preliminary injunction sought by AbbVie and other drug manufacturers against Mississippi's H.B. 728, aligning with a similar decision previously issued by the Eighth Circuit in 2024 and summarized in our November 2024 newsletter.

H.B. 728 prohibits manufacturers from restricting the distribution of discounted 340B drugs through contract pharmacies that serve low-income patients. Manufacturers argued that the state law constituted an unlawful taking of property and was preempted by federal law. The Fifth Circuit found that H.B. 728 does not compel manufacturers to transfer property, sell their drugs to any other party, or sell discounted drugs in quantities beyond what the federal 340B statute requires. The Fifth Circuit also concluded that the federal 340B statute neither occupies the field of drug distribution nor exclusively governs the role of pharmacies in distribution. AbbVie must file any petition to the Supreme Court for a writ of certiorari by December 11, 2025.

### 6. *340B Program Legislation Introduced in the U.S. Congress*

In the midst of an evolving 340B Program landscape at both the state and federal level, members of the U.S. House of Representatives and Senate have introduced legislation aimed at reforming the 340B Program. Currently pending legislation includes:

- H.R. 4581 (340B PATIENTS Act of 2025) – The bill was introduced by Democratic members in the House on July 22, 2025, but the bill has not otherwise progressed through Congress. The bill would, among other things, clarify manufacturers' obligation to provide 340B discounted pricing to covered entities regardless of the manner or location in which the drug is dispensed, such as in-house, through contract pharmacies, by mail order, or by specialty pharmacies. The companion Senate bill is S.2372.

- H.R. 5256 (340B ACCESS Act) – The bill was introduced by Republican members in the House on September 10, 2025, but the bill has not otherwise progressed through Congress. The bill would narrow eligibility criteria for patients and covered entities, increase reporting, auditing and public disclosure

requirements for covered entities, institute mandatory sliding fee scales and out-of-pocket caps, restrict contract pharmacy arrangements and strengthen federal oversight of the 340B Program, including increased audit powers and penalties for noncompliance.

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

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

**Publications**

- National Institutes of Health Announces New Restrictions on the Sharing of Human Biospecimens with China and other "Countries of Concern"
- Financial Support for Organizations Investing in Rural Health: Congress Establishes $50 Billion Rural Health Transformation Program
- HHS Announces New and Renewed Efforts to Promote Health Information Sharing and Interoperability
- HHS OCR Empowered to Administer and Enforce Federal Substance Abuse Privacy Part 2 Regulations
- HRSA Announces 340B Rebate Model Pilot Program
- Closeout Requirements During Appeals of Terminations of NIH Research Grants
- U.S. District Court Ruling Vacates HIPAA Final Rule that Strengthened Privacy Protections for Reproductive Health Information
- California's Office of Health Care Affordability ("OHCA") Initiates First Cost and Market Impact Review ("CMIR")
- New Health AI Guidance Features a Provider-Centric Approach
- Maintaining the Integrity of the Biomedical Research Record Through Timely, Appropriate Corrective Action
- How States Are Regulating Health Insurers' AI Usage

**Podcasts**

- Health Care Data Breach Preparedness and Response Best Practices

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