ROPES & GRAY

Hospital and Health Systems Reimbursement Check

June 2026

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.

Table of Contents

Focus On

PREPARING FOR MEDICARE'S NEW PROVIDER-BASED STATUS REQUIREMENTS

Executive Summary

For many hospitals, off-campus provider-based facilities have long served as a vehicle for expanding access to care, achieving operational and clinical integration of services, and supporting eligibility for programs such as the 340B drug pricing program. The Consolidated Appropriations Act of 2026 (CAA 2026), signed into law on February 3, 2026, enacts significant new requirements for off-campus outpatient provider-based departments seeking Medicare reimbursement. Beginning January 1, 2028, these facilities must obtain a separate National Provider Identifier (NPI) and submit a mandatory provider-based status attestation confirming compliance with the Medicare provider-based regulations at 42 C.F.R. § 413.65. The Centers for Medicare & Medicaid Services (CMS) has not yet proposed new regulations implementing the mandatory NPI and attestation requirements, but may do so as part of the Calendar Year (CY) 2027 Outpatient Prospective Payment System (OPPS) rule likely to be published in July. CMS has separately proposed to amend the provider-based regulation as part of the Federal Fiscal Year (FFY) 2027 Inpatient Prospective Payment System (IPPS) rule to revise one of the exceptions to the location requirements for off-campus, inpatient provider-based facilities. Specifically, CMS proposed to limit the "referral-based exception" under 42 C.F.R. § 413.65(e)(3)(iii) to outpatient provider-based departments only. Together, these developments represent the latest in a series of efforts over the past decade to curb the expansion of off-campus provider-based facilities. This article provides an overview of the current regulatory framework for provider-based status, examines the evolving legal and regulatory landscape for off-campus provider-based facilities, and offers practical guidance for hospitals preparing to comply with these upcoming changes.

Legal and Regulatory Context Surrounding Provider-Based Status

While the Medicare statute does not define the term "provider-based," the U.S. Department of Health and Human Services (HHS) issued regulations establishing requirements for "provider-based status" in 2000. *Id.* The provider-based regulations, 42 C.F.R. § 413.65, define a "provider-based entity" as a provider "either created by, or acquired by, a main provider for the purpose of furnishing health care services *of a different type* from those of the main provider under *the ownership and administrative and financial control* of the main provider, in

accordance with the provisions of this section." 42 C.F.R. § 413.65(a)(2).

Provider-based status carries important implications for hospital reimbursement and program eligibility. Under Medicare, services furnished in a hospital outpatient department generally receive higher aggregate payment than the same services performed in a freestanding physician clinic, because the hospital may bill both a facility fee (on form UB-04) and a reduced physician professional fee (on form CMS-1500), a practice known as "split billing." *See* 83 Fed. Reg. 58,818, 59,008 (Nov. 21, 2018). In addition, hospitals participating in the 340B Drug Discount Program may register provider-based outpatient departments as "child sites," thereby providing access to discounted drug pricing to patients served at those locations. *See* 59 Fed. Reg. 47,884, 47,886 (Sep. 19, 1994); *see also* Health Resources and Services Administration (HRSA) FAQs.

CMS has long recognized the need for clear criteria for provider-based status because "this designation can result in additional Medicare payments for services furnished at the provider-based facility." CMS Program Memorandum, Transmittal No. A-03-030 (April 18, 2003). All facilities seeking provider-based status must (1) operate under the same license as the main provider, unless a state requires otherwise; (2) integrate both clinical services (e.g., clinical privileges, oversight, and patient records access) and financial operations (e.g., shared income and expenses, or appropriate cost center reporting); (3) hold themselves out as part of the main provider (i.e., public awareness); and (4) fulfill obligations of hospital outpatient departments, if applicable (e.g., comply with the Emergency Medical Treatment and Labor Act (EMTALA)). 42 C.F.R. § 413.65(d).

In addition to those four requirements, for CMS to determine an *off-campus* facility has provider-based status, off-campus facilities, it must comply with three additional requirements: (i) demonstrate the facility is under the "ownership and control" of the main provider; (ii) demonstrate the facility is under "the direct supervision" of the main provider; and (iii) demonstrate that it meets one of the location requirements specified in 42 C.F.R. § 413.65(e)(3) (i.e., that the off-campus facility is either within a 35-mile radius, demonstrates a "high level of integration," or an exception applies). 42 C.F.R. § 413.65(e).

Tightening Payment and Compliance Rules for Provider-Based Facilities

The increase by hospitals in establishing provider-based facilities has drawn scrutiny from those concerned about Medicare spending. In 2014, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress "adjust[ ] the rates paid for certain services when they are provided in hospital outpatient departments (HOPDs) so they more closely align with the rates paid in freestanding physician offices." MedPAC, Report to Congress: Medicare Payment Policy, 53 (March 2014). Doing so, MedPAC argued, would "remove this distortion in the payment system" which "creates a financial incentive for hospitals to purchase freestanding physicians' offices and convert them to HOPDs without changing their location or patient mix." *Id.* Over the past decade, Congress and CMS have gradually reduced Medicare payment differentials for off-campus hospital outpatient departments through site-neutral payment policies, while largely maintaining traditional OPPS payment structures for on-campus hospital outpatient departments. While payment reductions over the last decade have focused on off-campus provider-based departments, CMS's CY 2026 OPPS final rule included a Request for Information (RFI) seeking stakeholder input on whether site-neutral policies should be extended to on-campus services in a future rulemaking. 90 Fed. Reg. 53,448, 53,821 (Nov. 25, 2025).

Bipartisan Budget Act of 2015. In 2015, for example, Congress attempted to address the incentive to convert practices into off-campus provider-based facilities through Section 603 of the Bipartisan Budget Act of 2015. Pub. L. No. 114-74, 129 Stat. 584, 597–98 (codified at 42 U.S.C. § 1395l(t)(21)). From the date of enactment, the statute prospectively excluded off-campus, outpatient provider-based facilities from payment under the OPPS, while allowing off-campus provider-based facilities that were furnishing services and billing under OPPS prior to November 2, 2015 to maintain "grandfathered" or "excepted" status, thereby continuing to receive higher payments under the OPPS.

OPPS CY 2019 and CY 2026 Final Rules. In 2018, an updated MedPAC report found a "large source of growth in spending on HOPD services appears to have been the shift of services from (lower cost) physician offices to (higher cost) HOPDs." MedPAC, Report to Congress: Medicare Payment Policy, 73 (March 2018). CMS agreed. *See* 83 Fed. Reg. at 59,005 ("we are concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, are affecting site-of-service decision-making."). To address concerns CMS had about payment differentials, including potential "unnecessary increases in the volume of covered outpatient department services," CMS cut the payment rate for outpatient clinic visits (i.e., the code for "facility charge") for the *grandfathered* sites to the same rate paid to the nonexcepted, newer sites, with a two-year phase in. 83 Fed. Reg.

58,818, 59,013–014. A series of legal challenges followed. In 2020, the American Hospital Association (AHA) and other plaintiffs lost their challenge to the site-neutral payment policy at the D.C. Circuit. *American Hospital Ass'n v. Azar*, 964 F.3d 1230 (D.C. Cir. 2020), *cert. denied*, 141 S. Ct. 2853 (2021).

In the final Medicare OPPS rule for CY 2026, CMS announced it would also lower payment for *drug administration services* at grandfathered off-campus outpatient departments to the lower rate that already applied to newer sites (i.e., the Physician Fee Schedule (PFS) rate), just 40% of the OPPS rate. The expanded site-neutral payment policy reduced Medicare reimbursement for drug administration services, including chemotherapy, immunotherapy, and related services at existing off-campus hospital outpatient departments ("excepted off-campus PBDs") to 40% of the OPPS rate. CMS estimates this provision will reduce OPPS spending by $290 million in the first year, with $220 million of the savings accruing to Medicare and $70 million saved by Medicare beneficiaries in the form of reduced coinsurance. The expansion builds on CMS's prior site-neutral efforts: in 2019, CMS began applying site-neutral rates to clinic visits in excepted off-campus Provider-Based Departments (PBDs), 83 Fed. Reg. at 58,822, and in 2024, site-neutral policies reduced payments for fee-for-service (FFS) Medicare outpatient services at hospital off-campus locations by $1.2 billion.

IPPS FFY 2027 Proposed Rule. In April, CMS released its annual proposed rule for the FFY 2027 IPPS, proposing a revision to one of the location-based exceptions for off-campus facilities to maintain provider-based status. Under the current rules, unless the provider-based facility is within 35 miles of the main provider, or another exception applies, the facility must demonstrate a "high level of integration with the main provider" by meeting either of two options: (A) at least 75% of patients served at the provider-based site reside in the same ZIP code as 75% of those served at the main provider; or (B) at least 75% of patients served by the provider-based site who required the type of care offered by the main provider actually received care from the main provider. 42 C.F.R. § 413.65(e)(3).

Under the proposed rule, however, the availability of "Option B" would be limited to outpatient departments. CMS describes this as the "original intent of the policy" (i.e., that the provider-based locations would be delivering outpatient services and referring to the main hospital for inpatient services). 91 Fed. Reg. 19671 (Apr. 14, 2026). As proposed, off-campus inpatient facilities would be required to meet "Option A." *Id.* at 19670–19671. CMS explained that this change would "eliminate[ ] the aforementioned potential for arguably unwarranted payment advantages by certain hospitals." *Id.* at 19671. CMS's stated concern was that by "allowing this referral-based exception for inpatient facilities, certain specialty and PPS)-excluded hospitals could obtain significant payment advantages for inpatient services provided at considerable distances from the main provider." *Id.* at 19671. Many hospitals and health systems operate off-campus inpatient facilities where the geographic zip-code test (Option A) may be difficult to satisfy due to the nature of the communities served, while the referral-based relationship between the main provider and the inpatient facility under Option B nevertheless demonstrates genuine integration. It is not clear why CMS's limited concern should result in the broad exemption of all off-campus inpatient provider-based facilities from what CMS calls the "referral-based exception." *See id.* If the proposal were finalized, inpatient provider-based facilities located more than 35 miles from the main provider and failing to meet any other exception under 42 C.F.R. § 413.65(e)(3), would need to demonstrate geographic overlap of patient populations with the main provider.

Consolidated Appropriations Act of 2026

Distinct from changes proposed in CMS's FY 2027 IPPS rule, Section 6225 of the CAA 2026 imposes new statutory requirements relating to off-campus provider-based departments. As previewed above, starting January 1, 2028, Medicare will reimburse off-campus outpatient departments of providers only if the provider-based location (1) obtains a separate NPI; and (2) submits an initial or updated provider-based status attestation, confirming compliance with the provider-based regulations at 42 C.F.R. § 413.65, Section 6225, CAA 2026. Congress appropriated $20 million to CMS to carry out review of attestations and issue rulemaking and required the HHS Office of Inspector General (HHS-OIG) to submit an analysis of the process and recommendations by January 2030. *Id.* CMS has not yet addressed the new statutory requirements in a rulemaking, although it is likely to do so in the near future, potentially in the CY 2027 OPPS proposed rule normally issued in July.

Advocacy and legislative history. The CAA 2026 was the culmination of a multiyear congressional effort related to off-campus provider-based departments. The provider-based provisions of the CAA 2026 had previously been introduced in 2025 in both the "Lower Costs for Everyday Americans Act" (H.R. 1768) and the "Bipartisan Health Care Act" (S. 891), and separately as the "Fair Billing Act" (S. 2497). A proposal to require separate NPIs had been introduced in 2023 in both the Site-based Invoicing and Transparency Enhancement (SITE)

Act (S. 1869) and the Facilitating Accountability in Reimbursements (FAIR) Act (H.R. 3417). Advocates supporting these measures appear to be motivated by concerns about patient affordability and price transparency, framing the legislation as a way to cut "unfair hospital facility fees[.]" Supporters of the separate NPI requirement include patient advocacy groups such as Families USA, large employer benefit organizations such as the ERISA Industry Committee, insurers like BCBSA, and health organizations, such as The Leukemia & Lymphoma Society.

Separate NPI requirement. The statute specifies that each off-campus outpatient department of a provider must obtain and bill under a separate NPI. 42 U.S.C. 1395l(t)(23)(A)(i). An NPI is used to uniquely identify a provider for purposes of health care claims, prescriptions, health plan coordination, and medical records. This change upends the current practice of off-campus outpatient departments using the NPI of their main provider, which had been done in the absence of regulation requiring otherwise. Providers may apply for an NPI either through a web-based application via the National Plan and Provider Enumeration System (NPPES), allowing an Electronic File Interchange Organization (EFIO) to file on the provider's behalf, or submitting a paper application. The AHA, in a letter to CMS, explained that requiring a separate NPI will impact hospital functions related to "electronic health records, billing platforms, payer credentialing, . . . e-prescribing and pharmacy networks, pharmacy payer agreements, pharmacy benefit manager agreements, health information exchange participation," among other registrations and enrollments. Letter from AHA to CMS, "AHA Responds to CMS Plan for Unique NPIs for Hospital Outpatient Departments" (March 24, 2026).

Mandatory attestation process. Starting on January 1, 2028, the statute requires that the provider has submitted—in the two-year period before the provision of services – a provider-based attestation. 42 U.S.C. 1395l(t)(23)(A)(ii). Since a 2003 Program Memo from CMS, the attestation process for compliance with the provider-based regulations at 42 C.F.R. § 413.65 has been voluntary. Transmittal No. A-03-030. Under the current voluntary process, providers attest to facility compliance with each of the requirements set out in the regulations and may need to submit significant documentation demonstrating compliance. *Id.* ("Sample Attestation Format"). In its attestation, a hospital currently must provide information and documentation showing that it satisfies all applicable requirements in the provider-based regulation, including financial integration, clinical integration, or public awareness. 42 C.F.R. § 413.65(b)(3); Transmittal No. A-03-030. To verify, a Medicare Administrative Contractor (MAC) might ask for, among other things, evidence of the facility's revenues and expenses on the main provider's accounts, personnel information, or photographs of outside signage. *See, e.g.,* Palmetto GBA, Documentation to Submit with Attestation. Outpatient facilities seeking provider-based status must meet additional requirements including ownership and control by the main provider; direct supervision by the main provider; and the location requirements discussed above. 42 C.F.R. § 413.65(g). Evidence of these requirements may involve submitting internal policies, the facility lease, organizational charts, reporting relationships, and other documentation. *See, e.g.,* Palmetto GBA, Documentation to Submit with Attestation.

Under the current rules, although attestation is voluntary, if CMS determines that the facility treated as provider-based did not meet the requirements, CMS can adjust future payments or recoup the difference in payments it would have made if the facility was not provider-based. 42 C.F.R. § 413.65(j). Although CMS has not yet issued a rule establishing a process for the submission of mandatory attestations, the statute signals the new process may be even more burdensome than the voluntary process of the last 23 years, referencing "site visits, remote audits, or other means" to be determined by the forthcoming rulemaking. 42 U.S.C. 1395l(t)(23)(A)(ii).

Impact of New Statutory Changes and How to Prepare

To prepare for the new attestation and NPI requirements, the following are some concrete steps hospitals should consider. Regarding the attestation requirement, hospitals should:

a. First, assess any facilities currently operating with provider-based status.

b. Determine whether each site has already completed a voluntary attestation, and whether it will require an updated attestation under the new process (i.e., any completed before January 1, 2026).

c. Establish tracking systems for attestation submission deadlines.

d. Gather any documentation either previously submitted with a prior voluntary attestation, or any relevant information demonstrating compliance with the requirements of 42 C.F.R. § 413.65.

e. Continue to monitor for the CMS rulemaking that will implement the mandatory attestation process, as well as any associated public comment opportunities. CMS may address the attestation requirements in the

upcoming CY 2027 OPPS rule, which would likely be proposed in July and finalized in November.

f. Until further guidance from CMS is available, reference provider-based requirements checklists from your MAC or the sample checklist in CMS Transmittal No. A-03-030.

g. Identify and locate any policies, records, or photographic evidence to support your compliance with each requirement at 42 C.F.R. § 413.65. Especially if your facility has not previously attested to compliance with the regulations, expect that gathering this documentation may involve significant time and resources.

Regarding the separate NPI requirement, hospitals should:

a. Conduct a comprehensive inventory of all off-campus outpatient departments to identify each location requiring a separate NPI.

b. Apply for separate NPIs for each off-campus outpatient department through the National Plan & Provider Enumeration System.

c. Update Medicare and Medicaid enrollment by submitting CMS-855A change requests to add the new NPIs.

d. Reconfigure billing platforms and Electronic Health Record (EHR) systems to associate each off-campus department with its separate NPI for claims submission.

e. Update payer credentialing and commercial insurance contracts to reflect the new NPIs.

The Health Resources and Services Administration (HRSA) has not issued specific guidance on whether the CAA 2026's separate NPI requirement would affect 340B child-site eligibility. Given this uncertainty, hospitals should monitor for further HRSA and CMS guidance on this issue but should not assume that 340B eligibility will automatically be lost solely by virtue of billing under a separate NPI. To help avoid impacts on revenue and operations, proactive preparation will be critical.

Docket Updates

1. *Challenges to Hospital IPPS Standardized Amount Set to Return to PRRB While Government Moves for Voluntary Remand in Similar Cases*

The U.S. District Court for the District of Columbia ("D.C. federal district court") continues to grant the government's motions for voluntary remand in follow-on cases after its ruling in *St. Mary's Regional Medical Center v. Kennedy*, No. 23-cv-1594 (D.D.C.). The dispute in *St. Mary's* centers on a challenge to CMS's alleged understatement of the plaintiff hospitals' FFY 2019 IPPS payments by carrying forward an error in the calculation of standardized amounts dating back to the 1983 base year. In December 2024, the D.C. federal district court held that the Medicare statute does not preclude administrative or judicial review of the challenge to the standardized amount calculation. On September 26, 2025, the D.C. federal district court granted in part the government's motion for clarification, ruling that its decision in the plaintiffs' favor was limited to confirming that their challenge to budget-neutrality adjustments was not precluded from review. Following this clarification, the government has moved for voluntary remand in several related cases, including recently in *University of Kansas Hospital Authority, et al. v. Kennedy*, No. 1:25-cv-603 (D.D.C.), which was remanded April 30, 2026.

Additionally, per recent joint status reports filed in *St. Mary's*, the CMS Administrator issued an Order dated January 23, 2026, that, *inter alia*, vacated the Provider Reimbursement Review Board's ("PRRB") jurisdictional denial of the plaintiffs' administrative appeals and ordered the PRRB to reinstate the administrative appeals and resume proceedings. On April 30, 2026, the PRRB issued an expedited judicial review determination granting expedited judicial review on the substantive claims in the appeals underlying the case.

2. *Hospital Challenges PRRB's Decision Affirming Denial of Early Effective Date for SCH Status and Rural Reclassification*

In PRRB Decision 2026-D13, the PRRB affirmed the denial of St. Charles Bend's February 2022 application for Sole Community Hospital (SCH) status and rural reclassification. St. Charles Bend, a general acute-care hospital in Bend, Oregon, and St. Charles Redmond, situated 17.8 miles apart, were both divisions of St. Charles Health System. On February 15, 2022, St. Charles Bend applied for SCH designation and rural reclassification, simultaneously submitting a Plan of Merger to combine St. Charles Redmond's provider agreement into its

own. The MAC initially recommended approval on March 17, 2022, contingent on CMS authorizing the merger.

On April 15, 2022, CMS denied the application, finding that the application was incomplete because all documentation in regard to the merger had not been submitted and that St. Charles Redmond remained a separate "like hospital" located within 35 miles. CMS instructed the Provider to resubmit its application with merger confirmation. On May 11, 2022, the Provider submitted a second application, including the State Agency's completed CMS Form 1539 certifying that St. Charles Redmond was to be a remote location of St. Charles Bend, effective February 15, 2022. On June 2, 2022, CMS approved both the rural reclassification, effective May 11, 2022, and SCH status, effective date May 12, 2022. The three-month gap between the original February application and the effective May reclassifications dates was valued by Provider at approximately $4.6 million.

The PRRB upheld CMS's denial of the February 2022 application, finding the original application was incomplete and concluding that a 2023 regulatory amendment allowing retroactive SCH effective dates for merger-dependent applications did not apply. St. Charles Health System has since filed suit challenging the PRRB's decision. *St. Charles Health Sys., Inc. v. Kennedy*, No. 6:26-cv-01141 (D. Or. June 5, 2026). The complaint alleges that CMS's requirement of prior merger approval as a condition of a "complete" SCH application is not found in any statute, regulation, or sub-regulatory guidance, and that CMS's denial violated the Medicare statute and the Administrative Procedure Act (APA). For hospitals pursuing SCH designation or rural reclassification in connection with a merger, the decision is a reminder that incomplete filings may delay the effective date and forfeit enhanced IPPS reimbursement for the intervening period.

3. *Update on Briefing on Remedy in Challenge to 2023 DSH Part C Days Rule*

On February 23, 2026, the plaintiff hospital filed its supplemental reply brief in support of its motion for summary judgment in *Montefiore Medical Center v. Kennedy*, No. 24-cv-1810 (D.D.C. 2024), the lead case challenging CMS's 2023 retroactive Medicare Disproportionate Share Hospital ("DSH") Part C days final rule. The filing of the reply brief completes the briefing on the appropriate remedy following the September 2025 ruling of the D.C. federal district court that the 2023 rule was impermissibly retroactive and arbitrary and capricious. *See* February 2026 Docket updates. The district court deferred ruling on the appropriate remedy in its summary judgment decision and ordered the parties to file supplemental briefs on that issue.

In its most recent brief, the plaintiff urged the court to vacate the 2023 rule, arguing that the government conceded that binding D.C. Circuit precedent requires universal vacatur of unlawful agency action under the APA. The plaintiff further argued that the court should issue specific remand instructions directing the agency to apply its pre-2004 policy for DSH payments and comply with the Medicare statute's anti-retroactivity provision, reasoning that the agency has exhausted every procedural avenue for changing its policy on Part C days for cost years before 2013 and that remand is futile because the agency indicated that it would attempt to readopt its policy change on the same grounds the court rejected. With briefing on remedy now complete, the case is ready for the court's decision on vacatur and specific remand instructions.

4. *Minnesota Challenges CMS Deferral of Medicaid Funding*

On March 2, 2026, the State of Minnesota filed suit in the U.S. District Court for the District of Minnesota, challenging CMS's deferral of approximately $243 million in Medicaid funding. *Minnesota v. Oz*, No. 26-cv-1701 (D. Minn. 2026). The dispute arose after CMS notified Minnesota on February 25, 2026, that it would immediately defer approximately $259 million in Medicaid funding for fourth quarter 2025 expenditures, of which approximately $243 million related to provider payments in 14 service areas CMS identified as "high-risk" for fraud and abuse. Minnesota alleges that the deferral was imposed as political punishment without due process or sufficient specificity for Minnesota to understand what additional documentation is needed to verify the allowability of the claims at issue, is unprecedented in scale, and was issued prematurely before CMS fully reviewed information the state had already provided.

The court denied Minnesota's motion for a temporary restraining order and expedited preliminary injunction on April 6, 2026, on the grounds that the agency's proceedings are not yet final and that Minnesota was unlikely to succeed on the merits. On May 7, 2026, the court granted the parties' joint motion for a stay of 120 days to allow the parties to attempt resolution of the deferrals. The court also denied without prejudice the government's motion to dismiss, with leave to refile following the lifting of the stay. The case bears watching for hospitals and health systems that depend on timely Medicaid reimbursement, as a sustained deferral of this magnitude could disrupt provider payment flows and signals a broader willingness by CMS to use funding deferrals as a compliance enforcement tool, as

demonstrated by CMS's recent deferral of $1.3 billion in California Medicaid funds.

5. *Challenge to CMS's Substance Access Beneficiary Engagement Incentive*

On March 30, 2026, the plaintiffs in *Smart Approaches to Marijuana et al. v. Kennedy et al.*, 26-cv-1081 (D.D.C. 2026), a group of cannabis legalization opponents, filed suit against HHS seeking an injunction to block CMS's Substance Access Beneficiary Engagement Incentive (BEI) program. The plaintiffs argue that the agency improperly created a federal pathway permitting cannabinoid consumer products into Medicare without following proper procedures or obtaining Food and Drug Administration (FDA) approval. The BEI program, launched on April 1, 2026, allows eligible participants to consult with beneficiaries regarding the possible use of certain hemp products and to furnish up to $500 per eligible beneficiary per year of those products. The BEI program applies to organizations participating in the Accountable Care Organizations Realizing Equity, Access, and Community Health (ACO REACH) Model, Embracing Oncology Model (EOM), and Long-term Enhanced ACO Design (LEAD) Model.

On April 13, 2026, the plaintiffs filed an amended complaint asserting that the BEI Program exceeds CMS's statutory authority, was issued without procedures, is arbitrary and capricious, and violates the Fifth Amendment's equal protection and due process requirements. The plaintiffs also filed for a preliminary injunction and a stay of agency action.

On April 20, 2026, the government moved to dismiss the action and opposed the preliminary injunction motion, arguing that the plaintiffs lack standing and a cause of action, that the plaintiffs' claims are barred by Section 1115A's judicial review preclusion, and that plaintiffs are unable to satisfy the factors required to obtain a preliminary injunction.

On May 22, the D.C. federal district court granted the defendants' motion to dismiss and denied the plaintiffs' motion for preliminary injunction as moot. In its memorandum, the court held that the plaintiffs failed to establish Article III standing to bring their claims because they had not identified any imminent, non-speculative injury under any theory, including individual, organizational, associational, competitor, or procedural standing. Accordingly, the court declined to address any of the issues on the merits. On June 8, 2026, the plaintiffs filed a notice of appeal to the D.C. Circuit.

6. *Developments in Litigation Challenging HHS Workforce Reductions*

Judicial review of the Trump administration's efforts to reduce the HHS workforce continues, with recent months bringing both new litigation and resolution of pending disputes.

Proceedings in *State of New York v. Kennedy*, No. 1:25-cv-00196 (D.R.I. 2025), remain active following the July 2025 preliminary injunction that temporarily blocked implementation of HHS Secretary Robert F. Kennedy Jr.'s March 25, 2025 "Make America Healthy Again" directive (MAHA Directive), which had ordered significant workforce reductions and the elimination of several HHS sub-agencies. *See* July 2025 Docket Updates. In October 2025, the government filed a motion to dismiss, challenging both the district court's jurisdiction and the legal sufficiency of plaintiffs' amended complaint. After briefing on the motion to dismiss concluded, the government filed Notices in February and March 2026 to inform the U.S. District Court for the District of Rhode Island of the rescission of reduction-in-force (RIF) notices issued to employees in the National Institute for Occupational Safety and Health (NIOSH), the Center for Tobacco Products, and the Office of the Assistant Secretary for Planning and Evaluation's Division of Data and Technical Analysis after the MAHA Directive. Despite these developments, the district court denied the defendants' motion to dismiss on April 7, 2026, rejecting all jurisdictional challenges and finding that plaintiffs had plausibly alleged entitlement to relief on each of the five causes of action. The court characterized the two Notices as attempts to alter the outcome of the litigation based on HHS's partial rescission of the RIFs. The parties stipulated to file a joint status report outlining their respective views on next steps in the action by June 22, 2026.

On February 13, 2026, 142 former career federal employees filed a new lawsuit in *Mullady v. Office of Management and Budget*, No. 8:26-cv-00573 (D. Md. 2026), alleging constitutional and statutory violations arising from their terminations from HHS and other federal agencies pursuant to RIFs. Plaintiffs contend that their terminations were in fact firings for cause rather than legitimate RIFs, depriving plaintiffs of protected property and liberty interests without real notice, meaningful opportunity to be heard, or the pre- and post-deprivation process required by the Constitution and federal regulations. The plaintiffs also contend that requiring them to pursue appeals first to the Merit Systems Protection Board ("MSPB"), the independent agency responsible for adjudicating personnel claims brought by federal employees, is a separate due process violation because the MSPB's statutory independence has been deliberately

undermined by the Administration, rendering appeals to the MSPB futile. The plaintiffs seek declaratory and injunctive relief, reinstatement, and damages under the Privacy Act. On April 24, 2026, plaintiffs moved for a preliminary injunction. The government filed its opposition on June 3, 2026, arguing that the plaintiffs are unlikely to succeed on the merits of their due process and APA claims, and that the plaintiffs will not suffer irreparable harm absent an injunction.

Meanwhile, one matter was resolved without further litigation. As highlighted in the February 2026 Docket Updates, the D.C. federal district court directed the parties in *National Nurses United v. Kennedy*, No. 1:25-cv-01538 (D.D.C. 2025), to submit a joint status report after HHS reinstated all previously terminated NIOSH employees. On March 23, 2026, plaintiffs filed a notice of voluntary dismissal, and the court dismissed the case without prejudice.

These recent case developments reflect incremental changes in the status of HHS workforce reduction litigation, with implications for the operation of federal programs relied upon by hospitals and health systems. The future of the HHS workforce remains uncertain, as litigation over terminations continues, while, at the same time, HHS is reportedly seeking to hire additional staff to address gaps created by last year's agency-wide layoffs.

7. Updates on Litigation Challenging Payment for Skin Substitutes

On March 12, 2026, the U.S. District Court for the Northern District of Texas ("Texas district court") dismissed a lawsuit by the Coalition Advocating for Access to Skin Substitute Technologies (CAMPs) Initiative, a Texas-based organization representing manufacturers and suppliers of skin-substitute products. *See CAMPs Initiative v. Dep't of Health and Human Servs.*, 4:26-cv-99 (N.D. Tex. 2026). The CAMPs Initiative challenged the 2026 PFS, which changed CMS's prior approach of treating skin substitutes as biologicals and reclassified such products as "incident-to" supplies, which substantially reduces the payment for skin substitute products. *See* February 2026 Docket Updates. The CAMPs Initiative filed for emergency relief, seeking a stay of the effective date of the rule under section 705 of the APA, or in the alternative, a nationwide preliminary injunction. The government opposed the motion, arguing that the Texas district court lacks jurisdiction and that the CAMPs Initiative is unlikely to succeed on the merits of its statutory claims.

The government also separately moved to dismiss the complaint, arguing that the CAMPs Initiative lacked standing, that Congress precluded judicial review of the agency determinations, and that the plaintiff failed to exhaust administrative remedies by channeling its claims to CMS. The CAMPs Initiative responded that it had standing because its members were injured by the policy change, that judicial review was not precluded because it challenged CMS's classification of skin substitutes as "incident-to" supplies rather than payment amounts or relative value units, and that the channeling requirement did not apply because, as neither a provider nor a beneficiary, it could not pursue administrative relief under the Medicare statute. The CAMPs Initiative further invoked the *Illinois Council* exception to channeling, arguing that dismissal would effectively preclude any judicial review of CMS's decision.

The Texas district court granted the motion to dismiss and denied the preliminary injunction, holding that it lacked subject matter jurisdiction because the CAMPs Initiative's claim did not satisfy the *Illinois Council* exception, which requires a "*complete* preclusion of judicial review." The court rejected the argument that the CAMPs Initiative was excused from the channeling requirement as a non-provider or beneficiary and held that providers have adequate incentive and ability to challenge CMS's reimbursement for skin substitute products, making them an adequate proxy. The Texas district court also denied leave to amend. On May 11, 2026, the plaintiff filed a notice to appeal to the Fifth Circuit.

The *CAMPs Initiative* lawsuit does not represent the only front for litigation about skin substitutes. On March 4, 2026, a group of wound care providers filed a putative class action lawsuit, also in the Texas district court, against the government related to reimbursement for skin substitute products. *See Mcgee v. Dep't of Health and Human Servs*, 4:26-cv-243 (N.D. Tex. 2026). The plaintiffs bring claims under the APA challenging what they describe as a "clawback policy," alleging the government is using audits that seek to recoup reimbursements for skin substitute products already paid for, reasoning that the use of the products was "experimental" or "investigational."

The plaintiffs filed an amended complaint on May 8, 2026. The amended complaint alleges that the defendants' adoption and enforcement of their recent alleged "clawback policy" is arbitrary and capricious because it denies coverage of claims that would have been reimbursable under previously applied Local Coverage Determinations (LCDs), without following notice and comment procedures, disclosing evidentiary support, or articulating a reasoned rationale for the change. The amended complaint further alleges that, by denying coverage and Part B payment for skin substitutes, the defendants effectively deny

access to statutorily covered medically necessary care. Finally, the plaintiffs allege that the policy amounts to a new coverage determination adopted without the required notice-and-comment procedures and in violation of the Medicare statute's bar on retroactive coverage changes. The plaintiffs moved to certify class on May 15, 2026. On May 26, 2026, the government moved to dismiss for a lack of jurisdiction, arguing that the plaintiffs had not satisfied the channeling requirement because none of the plaintiffs had presented their alleged "Clawback Policy" theory to the agency, and only six of nine plaintiffs had exhausted their administrative claims. The government also argues that venue in the Texas district court is improper because it rests solely on the residency of a plaintiff whose claims were not exhausted.

On June 9, 2026, the plaintiffs filed a motion for emergency relief seeking a nationwide stay of the enforcement of the policy. The plaintiffs argue that the alleged policy is unlawful because it adopts a coverage standard without undergoing notice-and-comment rulemaking, improperly applies that standard retroactively, and conflicts with the evidence and prior agency positions. Plaintiffs also claim they will face irreparable harm without relief.

8. Holding in District of Oregon Case Vacates the Kennedy Declaration Concerning Gender-Affirming Care

On April 18, 2026, Judge Mustafa Kasubhai of the U.S. District Court for the District of Oregon ruled in favor of the Plaintiff States in a case challenging a declaration (the "Declaration" or the "Kennedy Declaration") issued by HHS Secretary Robert F. Kennedy Jr. The Declaration purported to supersede existing state standards of medical care by asserting that what he labeled as "sex-rejecting procedures" for minors are "neither safe nor effective" and therefore "fail to meet professionally recognized standards of health care." The Declaration left hospitals and practitioners who provide gender-affirming care vulnerable to potential exclusion from participating in Medicaid and other federal health care programs that are a lifeblood for many children's hospitals that treat a high volume of Medicaid patients.

In addition to vacating the Declaration, the Court also issued a declaratory judgment that Defendants Kennedy, HHS-OIG, and HHS collectively lack the authority to unilaterally establish standards of care that supersede professionally recognized standards of care for provision of gender-affirming care (GAC) in the Plaintiff States. Finally, the Court permanently enjoined Defendants "from initiating enforcement action, enforcing, implementing, giving intent to, or relying, in whole or in part, on the Kennedy Declaration—or any materially similar policy that supersedes or purports to supersede the professionally recognized standards of care for GAC that exist in the Plaintiff States—against any provider in the Plaintiff States." Read our recent Client Alert to learn more.

Regulatory Updates

1. CMS Issues State-Directed Payments Proposed Rule

As noted in our last newsletter, CMS announced new federal payment limitations for State-Directed Payments (SDPs) in Medicaid managed care under the Working Families Tax Cut (WFTC) legislation, including limitations on grandfathering of rates under existing or pending SDPs during the phase-down period, and issued updated guidance on February 2, 2026 expanding the temporary grandfathering window. On May 21, 2026, CMS proposed a rule to formally implement these changes, along with additional proposed changes to payment limits for targeted Medicaid practitioner payments in FFS delivery systems. The proposed rule implements Section 71116 of the WFTC legislation and aligns with a Presidential Memorandum issued on June 6, 2025, directing that Medicaid payment rates not exceed Medicare rates. The agency is providing a 60-day comment period for the rule, and comments are due by July 21, 2026. Additional key provisions of the rule are as follows:

- New Payment Limits for SDPs. Currently, SDP payment rates for key services (inpatient hospital, outpatient hospital, nursing facility, and qualified practitioner services at academic medical centers) are capped at the average commercial rate ("ACR")—essentially what private insurers pay for the same services. The proposed rule would replace this benchmark with a lower, Medicare-based cap. Specifically, states that have expanded Medicaid under the Affordable Care Act ("Expansion States") would be limited to 100% of the Medicare payment rate, while states that have not expanded ("Non-Expansion States") would be limited to 110%. Where no Medicare rate exists for a Medicaid-covered service, the limit would default to 100% of the state's own approved rate. CMS proposes to extend these same limits to all services covered under SDPs, in all states, D.C., and U.S. Territories, effective with the first rating period beginning on or after January 1, 2029.

- Grandfathering and Phase-Down. SDPs submitted to CMS on or before July 4, 2025, that already exceed the new limit would not need to comply immediately. Instead, starting January 1, 2028, states must reduce these grandfathered payment amounts by at least 10 percentage points per year until they reach the applicable cap.
- Elimination of Uniform Increase SDPs. Some states currently use SDPs to add a flat dollar or percentage "uniform increase" on top of whatever a managed care plan negotiates with a provider. Beginning January 1, 2028, this type of SDP would no longer be permitted. States would instead be required to set defined minimum and/or maximum fee schedules—meaning they would specify exact rate floors or ceilings rather than layering increases on top of negotiated rates.
- Targeted Medicaid Payment Limit in FFS. Beyond the proposed changes to managed care SDP requirements, for the first time, CMS also proposes to cap Medicaid FFS payments that states direct to a select group of practitioners or providers (as opposed to payments available to all providers of a given service). The same Medicare-based caps would apply: 100% of Medicare for Expansion States and 110% for Non-Expansion States. Limited exceptions would apply where no reasonable Medicare equivalent exists or where payments are tied to actual provider costs. States with existing targeted payments above these levels would have until the start of the first state FY beginning on or after January 1, 2029 to come into compliance.
- Fiscal Impact. Because the new caps are generally lower than what many states currently pay under SDPs and targeted FFS arrangements, CMS estimates substantial reductions in provider payments over the next decade. Under CMS's primary (medium) estimate, total computable Medicaid spending would fall by approximately $774.8 billion from 2026 through 2035 (in real 2026 dollars), with the federal government paying roughly $510.1 billion less and states paying roughly $264.4 billion less. On an annualized basis discounted at 7%, these reductions equate to approximately $46.7 billion per year from the federal government and $24.2 billion per year from the states. Hospitals would bear the largest share of these reductions, followed by academic medical centers, nursing facilities, and physicians.

2. CMS Proposed Inpatient Rules

IRF Prospective Payment System Proposed Rule

On April 2, 2026, CMS issued the FFY 2027 Medicare Inpatient Rehabilitation Facility (IRF) Prospective Payment System Proposed Rule, which would update payments to IRFs starting in October 2026. CMS is proposing a 2.4% increase in payment rates (an estimated $355 million boost across the industry), while also tightening IRF day-to-day operational requirements, including mandating that all therapies begin within 36 hours of a patient's admission and that the patient's care team hold its first formal planning meeting by day four. The rule would additionally accelerate quality data reporting deadlines so that consumers can access more current information when comparing facilities. Comments on the proposed rule were due by June 1, 2026.

IPPS and LTCH Prospective Payment System Proposed Rule

On April 10, 2026, CMS also issued the FFY 2027 Medicare IPPS and Long-Term Care Hospital (LTCH) Prospective Payment System Proposed Rule, which would update Medicare payment policies and rates for inpatient and long-term care hospitals. See our recent Client Alert for more details. The rule proposes updates to Medicare payment rates and policies for acute care hospital inpatient services and long-term care hospital services effective October 1, 2026. In the aggregate, CMS estimates the proposed changes would result in aggregate payment increases of approximately $1.9 billion to acute care hospitals and $55 million to long-term care hospitals in FFY 2027 relative to FFY 2026. Below are some key features of the proposed rule:

- IPPS Payments: CMS proposes a net payment rate increase of 2.4% (after adjusting for expected productivity gains), reflecting a proposed 3.2% market basket increase reduced by a 0.8 percentage point productivity adjustment, for hospitals that (i) submit required quality data and (ii) demonstrate meaningful use of EHRs. Hospitals demonstrate "meaningful use" by meeting a performance-based scoring threshold under the Medicare Promoting Interoperability Program, measured across objectives such as electronic prescribing, health information exchange, and public health data reporting. Hospitals that fail to meet the quality reporting requirement but still use EHRs meaningfully would receive only a 1.6% increase; hospitals that meet quality reporting but fail to demonstrate meaningful EHR use would receive no

increase; and hospitals that fail both requirements would experience a 0.8% decrease.

- Provider-Based Department Policies: CMS proposes to revise requirements for off-campus provider-based departments, pursuant to which off-campus locations can qualify for "provider-based status" and bill as an extension of a main provider. Currently, under 42 C.F.R. § 413.65(e)(3)(iii), an off-campus provider that is more than 35 miles away from the main provider must, among other requirements, either demonstrate that at least 75% of patients served by the facility reside in the same ZIP code areas as at least 75% of the patients served by the main provider (the "geographic overlap") test or that at least 75% of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (the "referral-based" integration test). Under the proposal, CMS would limit the "referral-based" integration test to outpatient departments only, thereby requiring off-campus inpatient facilities that are more than 35 miles away from the main provider to satisfy the geographic overlap test. For additional discussion, see the Focus On article, above.

- Uncompensated Care and Safety Net Hospital Payments: For FFY 2027, CMS proposes to distribute approximately $7.46 billion in uncompensated care payments, which are supplemental payments to hospitals that serve a disproportionate share of low-income patients to help offset uncompensated care costs. This represents an approximately 3.3% decrease from the $7.82 billion distributed in FFY 2026, a reduction primarily driven by a reduction in the overall Medicare DSH payment pool.

- Low-Volume Hospital and MDH Program Expiration: Absent new legislation, time-limited statutory adjustments to the low-volume hospital qualifying criteria will expire effective January 1, 2027, and the qualifying criteria would revert to the significantly more restrictive pre-existing statutory thresholds, which limit eligibility to hospitals with fewer than 200 discharges and more than 25 road miles from another qualifying hospital, (for context, the expiring criteria allowed hospitals with fewer than 3,800 discharges, more than 15 road miles) that applied through December 31, 2026. Similarly, the Medicare-Dependent Hospital (MDH) program extended under § 6202 of the Consolidated Appropriations Act of 2026 expires December 31, 2026. CMS estimates approximately 80 MDHs currently paid under the blended rate would experience an overall payment decrease of approximately $110 million.

- New Technology Add-on Payments: One of the more significant components of this rule involves new technology add-on payments (NTAP), which provide additional reimbursement for cases involving costly new medical technologies that are not yet adequately reflected in standard DRG payment rates. CMS proposes to continue add-on payments for 41 previously approved technologies that remain eligible for NTAPs and estimates that such payments would total approximately $836 million in FFY 2027.

- TEAM Model Updates: CMS proposes updates to the Transforming Episode Accountability Model (TEAM), a mandatory episode-based alternative payment model that began January 1, 2026 and runs through December 31, 2030. TEAM tests five surgical episode categories, Coronary Artery Bypass Graft, Lower Extremity Joint Replacement, Major Bowel Procedure, Surgical Hip/Femur Fracture Treatment, and Spinal Fusion, to evaluate whether episode-based pricing can reduce Medicare spending while preserving or improving quality. CMS's current proposal would add Medicare Severity-Diagnosis Related Groups (MS-DRGs) 523, 524, and 525 to the spinal fusion episode, modify episode attribution rules to address overlap with the proposed Comprehensive Care for Joint Replacement Expanded Model (CJR-X), and update quality measures.

- CJR-X Model Expansion: CMS proposes to expand the CJR-X Model nationwide, beginning October 1, 2027. The expansion is based on evaluation results showing the original CJR Model achieved $112.7 million in net Medicare savings across performance years six and seven. CJR-X would be mandatory for all eligible acute care hospitals (except TEAM participants and Maryland hospitals) and would test an episode-based payment approach that would encompass a 90-day post-discharge period (as opposed to the 30-day period in TEAM. CMS projects CJR-X would generate approximately $725 million in net Medicare savings over five years.

- LTCH Payments: For LTCHs, CMS likewise proposes a net 2.4% increase to the standard federal payment rate, resulting in a proposed LTCH PPS standard Federal payment rate of $52,177.04. LTCHs that fail to submit required quality data face an additional 2.0 percentage point reduction, which would leave them with a net update of only 0.4%. CMS also proposes to remove the COVID-19 Vaccination Coverage and COVID-19 Vaccine measures from the LTCH Quality Reporting Program beginning with FFY 2028. In the aggregate, CMS estimates that LTCH payments would increase by approximately $55 million (about 2.3%) in FFY 2027. The impact varies by type of facility, ranging from an increase of 3.9% for government-owned LTCHs to 1.7% for rural LTCHs.

- Reasonable Cost Payment and Reimbursement Appeals for Independent Organ Procurement Organizations (IOPOs) and Histocompatibility Laboratories (HCLs): CMS proposes to clarify, codify, and in some cases revise Medicare reasonable cost reimbursement policies under 42 C.F.R. Part 413. CMS proposes to extend the Medicare reasonable cost reimbursement and reconciliation framework that has historically been limited to kidney acquisition to nonrenal organ acquisition costs (heart, liver, lung, pancreas) for IOPOs and HCLs, effective for cost reporting periods beginning on or after October 1, 2027. The proposal would revise 42 C.F.R. § 413.420 by changing "kidney" to "organ" throughout and adding new provisions to distinguish kidney and nonrenal organ services, while requiring IOPOs and HCLs to comply with reasonable cost principles for all organ types. CMS also proposes that Medicare contractors—rather than IOPOs themselves—would establish, adjust, and publish nonrenal organ-specific Standard Acquisition Charges (SACs) and interim rates, following the same procedures used for kidney SACs, with the stated objective of enhancing transparency, payment accuracy, and oversight of nonrenal organ costs.

- Nursing and Allied Health Education: CMS proposes to amend the nursing and allied health education (NAHE) regulations regarding the determination of "net costs" of approved programs and the procedures for allocating indirect NAHE costs. 91 Fed. Reg. at 19,519–19,521. The proposed rule would require providers with approved NAHE programs to determine "net costs" by (i) determining allowable direct costs incurred by the provider for trainee stipends and compensation of teachers employed by the provider; (2) subtracting from allowable direct costs the revenues the provider receives from students or on behalf of students enrolled in the program, such as, but not limited to, tuition, student fees, or textbooks purchased for resale; and (3) add indirect costs of the activities as determined under the Medicare cost-finding principles in 42 CFR § 413.24, but limited to indirect costs that the provider itself incurs as a consequence of operating the approved educational activities. CMS frames this as ensuring that overhead allocations proportionately reflect the benefit each department receives, while acknowledging that hospitals' operations vary, and different NAHE programs may require different forms of administrative support.

- Quality Program Updates: In addition to the measures noted above, the proposed rule includes updates to several quality programs. For the Hospital Inpatient Quality Reporting Program, CMS proposes to make the Malnutrition Care Score electronic clinical quality measure mandatory beginning with CY 2028. For the Hospital Readmissions Reduction Program, CMS proposes to adopt a Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure beginning with FFY 2029. For the Medicare Promoting Interoperability Program, CMS proposes to update the definition of certified electronic health record technology, modify the Electronic Prior Authorization measure, and add the Unique Device Identifiers for Implantable Medical Devices measure.

- Comments on the proposed rule were due by June 9, 2026.

3. Provider Reimbursement Stability Act: Bipartisan Legislation Addressing Medicare Physician Payments

On March 13, 2026, a bipartisan group of lawmakers led by Congressman Greg Murphy, M.D., introduced the Provider Reimbursement Stability Act (PRSA), legislation that its supporters say was aimed at modernizing the Medicare PFS to address longstanding payment instability for physicians. According to the American Medical Association (AMA), Medicare reimbursement for physician services has declined 33% in inflation-adjusted terms from 2001 to 2026, and certain PFS

reimbursement provisions have not been updated since the fee schedule was established in 1992. The legislation comes on the heels of the Medicare Payment Advisory Commission's March 2026 report to Congress, which recommended increasing Medicare payment rates for physicians.

The PRSA would increase the Medicare budget neutrality threshold—which mandates payment rate cuts to offset increases projected to exceed a statutory threshold—from $20 million to $54.3 million beginning in 2027, and indexing the threshold to the cumulative increase in the Medicare Economic Index (a measure of provider cost inflation) every five years thereafter, a proposal endorsed by AMA President Dr. Bobby Mukkamala. The PRSA also would (i) require corrections to budget neutrality calculations when utilization estimates for new codes prove inaccurate to reverse or reduce unwarranted offsetting cuts; (ii) mandate updates to direct costs used in practice expense relative value unit (RVU) calculations at least every five years; and (iii) cap year-to-year variance in the conversion factor— the per-RVU dollar amount established under Medicare Part B that is used to calculate the payment rate for physician services under the fee schedule—at 2.5%. These measures are intended to reduce year-to-year payment volatility, update cost inputs on a regular cycle, and address budget neutrality calculations that sponsors say have produced unintended reductions.

4. *Skilled Nursing Facility at Home: A New Frontier in Post-Acute Care Delivery*

Building on the momentum of the five-year extension of CMS's Acute Hospital Care at Home (AHCAH) program, a bipartisan legislative effort is now underway to bring skilled nursing facility (SNF) care into patients' homes. The advocacy coalition Moving Health Home is working with lawmakers to introduce a bill that would direct CMS to establish a five-year SNF at Home waiver program, enabling hospitals, SNFs, and home health agencies (HHAs) to deliver higher-acuity post-acute care in a home setting by relaxing the current 24-hour physical on-site nursing requirement. The program would serve patients who require more intensive, daily services—including therapy and assistance with activities of daily living—distinguishing it from traditional home health, which typically involves intermittent visits for more medically stable individuals. Participating hospitals and health systems would need to demonstrate their capacity to support complex patient needs, and CMS would be tasked with conducting an ongoing outcomes analysis similar to what it performs for the AHCAH program.

5. *HHS and CMS Announce Healthcare Advisory Committee Members to Improve Patient Care and Modernize the U.S. Healthcare System*

On March 26, 2026, HHS and CMS announced the membership of the Healthcare Advisory Committee (HAC), which was established as part of the Make America Healthy Again initiative. HAC members were chosen through a competitive selection process that drew more than 400 nominations from across the country. Each member will serve a two-year term, and the committee will convene on a regular basis throughout the year in meetings open to the public. HAC is charged with advising HHS Secretary Kennedy and CMS Administrator Dr. Mehmet Oz on strategies to improve the financing and delivery of care under Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. According to the announcement, the committee's recommendations will be non-binding and are intended to inform federal health care policy and program administration. Over the course of its term, HAC will concentrate on the following priorities: crafting actionable policy solutions aimed at preventing and more effectively managing chronic disease; promoting accountability for safety and outcomes while minimizing unnecessary administrative burden; leveraging real-time data to enhance care quality, accelerate claims processing, and refine quality measurement; improving care for vulnerable populations, particularly those enrolled in Medicaid; and bolstering the long-term sustainability of Medicare Advantage (MA), including through modernized approaches to risk adjustment and quality measurement. May 18, 2026, was HAC's first meeting and during its meeting, they discussed various agenda topics such as bylaws discussion, working group scope, and public comments.

6. *The Tug-of-War Over AI in Health Care Billing and Compliance Continues*

Consistent with the recent push for the incorporation of artificial intelligence (AI) in the health care industry, at the end of February, CMS issued an RFI regarding its consideration of incorporating AI tools into the MA program. CMS is seeking the use of AI to improve the accuracy of coding and hospital billing in the program. This RFI is part of the Trump administration's CRUSH initiative, which seeks to stop and prevent fraud in government health insurance programs. The focus on the MA program comes as an attempt to crack down on the prevalence of upcoding in the program. The RFI sought public comment on numerous topics, including improving accuracy and reducing "hallucinations," how recommendations should be displayed to "human reviewers," what compliance

risks should be incorporated, whether AI solutions exist to address coding issues, and how AI could be used to increase the efficiency and accuracy of hospital billing. Based on the RFI, CMS intends to employ AI to police compliance in billing and coding; however, the RFI also includes discussion of other topics including enrollment and ownership inquiries, which could be future targets for AI review. The RFI closed on March 30, 2026, and CMS has not yet issued any next steps based on the information gathered.

Just following the closure of the RFI, CMS released a notice delaying indefinitely the inclusion of certain Medicare services in the Wasteful and Inappropriate Service Reduction (WISeR) Model used for prior authorization. According to a notice from CMS on April 3, the WISeR model will no longer affect deep brain stimulation for essential tremors and Parkinson's disease as well as percutaneous image-guided lumbar decompression for spinal stenosis. Democrats, providers, and other activist groups have consistently pushed back on the model since its January 1, 2026 implementation date. Most recently, the digital rights group Electronic Frontier Foundation filed a Freedom of Information Act (FOIA) lawsuit against CMS to demand more transparency into the technology fueling the model's operations. The lawsuit comes among widespread criticism from providers and advocacy groups, despite its use in six states since its implementation. As a reminder, the WISeR model permits participating technology companies to retain 10-20% of savings generated from the prior authorization denials they issue, potentially incentivizing the denial of care in AI review models. The complaint cites that in Texas, the WISeR model approved only 62% of prior authorization requests but 84% were approved when reviewed by a human. This contrasts with the 92% prior authorization approval rate under MA plans, as cited by the complaint. As seen by the issuance of the RFI, despite pushback, the Trump administration will continue to push for the use of AI in its health care fraud and abuse enforcement agenda. We provide a more detailed description of the WISeR model in the Value-Based Care Corner, below.

7. CMS Issues MA Final Rule and Rate Announcement

On April 2, 2026, CMS finalized the MA and Part D Final Rule for Contract Year 2027, making significant changes in three areas: the Star Ratings quality measurement system, prescription drug pricing, and health equity requirements.

Under the new rule, CMS is dropping 11 quality measures that tracked administrative processes where nearly all plans already scored high, and is scrapping the Health Equity Index reward, a mechanism designed to incentivize better care for low-income, disabled, and dually eligible enrollees. Instead, CMS will keep the "historical reward factor," which rewards plans for consistent high performance across all measures. These combined Star Ratings changes are projected to cost taxpayers approximately $18.56 billion over the next decade by boosting plan ratings and the bonus payments tied to them.

On prescription drugs, the rule codifies several reforms from the Inflation Reduction Act. These include eliminating the Part D "coverage gap"—previously known as the "donut hole," where enrollees once bore the full cost of their medications—and capping annual out-of-pocket spending at $2,000. The rule also removes cost sharing once enrollees reach the catastrophic spending phase and formally establishes the Manufacturer Discount Program, which requires drug makers to provide discounts on brand-name medications, replacing the prior Coverage Gap Discount Program as of January 1, 2025.

Finally, the rule eliminates several Biden-era health equity initiatives. Previously, MA plans had to take specific steps to reduce gaps in care between different populations, and internal committees that oversee how plans approve or deny medical services were required to include a health equity expert, conduct annual equity reviews, and make those reviews public. Under the new rule, none of those requirements will remain. CMS cites Executive Order 14192, "Unleashing Prosperity Through Deregulation," as the basis for these changes.

Additionally, on April 6, 2026, CMS released its final rates for the 2027 MA and Part D programs. Overall, the final policies are projected to result in an average payment increase of 2.48%, or over $13 billion, to MA plans in 2027. When factoring in expected risk score growth from population changes and coding practices, total payments are expected to rise by about 4.98%. The effective growth rate in MA benchmarks came in at 5.33% in the final announcement, up from 4.97% in the January Advance Notice. This increase was driven mainly by CMS incorporating more recent claims data through the end of 2025. The updated rate tables have been posted on the CMS website.

AI Topics in Health Care Reimbursement

1. Rural Health Transformation Program Provides State Opportunities for Hospitals to Invest in AI

As covered in the February 2026 Newsletter, starting this year, Congress has appropriated—and CMS has awarded—$50 billion over the next five years to all 50 states through the Rural Health Transformation (RHT) Program. Pub. L. No. 119-21 § 71401, 139 Stat. 327. A central goal of the RHT Program is to invest in updated technology, including AI, to improve care delivery. In

allocating this funding, Congress encouraged states "to prioritize the use of new and emerging technologies" and approved states' use of the funds to invest in "technology-enabled solutions that improve care delivery in rural hospitals, including remote monitoring, robotics, artificial intelligence, and other advanced technologies." 42 U.S.C. §§ 1397ee(h)(2)(A), 1397ee(h)(6).

While 81% of urban hospitals used predictive AI in 2024, only 56% of rural hospitals did the same. HHS, Office of the National Coordinator for Health Information Technology, Hospital Trends in the Use, Evaluation, and Governance of Predictive AI, 2023-2024 (Table 1: Differences in non-federal acute care hospitals' use of predictive AI by hospital characteristics, 2023-2024). Most state applications for the RHT awards incorporated a proposal to use AI, according to Ropes & Gray's analysis of the applications. States' applications detailed plans to incorporate AI for various purposes, a number of which we detail below:

- Improve provider productivity with the use of AI scribes, ambient listening and documentation, and automation of administrative workflows including prior authorization, and revenue cycle management. For example, **Washington** proposed dedicating $15 million of RHT funds per year to a provider technology fund to support rural practices, and with which providers could invest in AI tools to support administrative workflows (e.g., "ambient listening, charting, appointment scheduling, note generation, claims processing, communication, and generating reports") or support financial health by "identify[ing] and recover[ing] underpayments" or "proactive contract modeling and forecasting."

- Clinical support and patient monitoring, such as AI-assisted diagnoses, treatment recommendations, remote patient monitoring, wearable sensors, as well as predictive analytics to identify high-risk patients. For example, **Indiana** proposed exploring how enabling AI technology in its Health Information Exchange Provider Portal could help providers evaluate potential drug interactions, implement natural language processing to reduce chart search burdens, assess outcomes and services to inform value-based decisions, develop treatment plans, and reduce utilization of labs and testing by using clinical decision tools. And **Nebraska** proposed utilizing AI-assisted Remote Patient Monitoring and wearable sensors to help manage chronic diseases and improve access to care.

- Consumer-facing AI engagement with health check-ins, conversational chatbots, health coaching, and patient education. For example, **Nevada** seeks to use RHT funding to support consumer-facing health technology like apps and AI chat tools for preventive health and chronic condition management. The state cautions that applicants for awards for "app-based conversational AI [which] can provide coaching, reminders, and education with a personalized experience" must comply with Health Insurance Portability and Accountability Act (HIPAA) privacy and security standards. Nevada will award at least one AI health tool grant per rural region starting in FFY 2027.

Looking ahead, hospitals should closely monitor their states' official RHT Program websites, agency updates (listservs or webinars), and grant portals and prepare materials for future funding applications. States can sub-award or contract RHT Program funds and partner with local stakeholders, including provider associations, to implement the proposed initiatives. CMS-RHT-26-001 at 8. For example, Minnesota has allocated 70% of the state's funding for Budget Period 1 to be available to 94 eligible hospitals. Currently, states vary widely in implementation progress and sub-award activity – from Iowa, which announced it was "the first state in the nation to award funding for its project initiatives" in January 2026, to Tennessee, which released its first RHT funding opportunity in May 2026, to Mississippi, which established its RHT office and website in April 2026.

If your organization has not yet engaged with potential RHT opportunities in your state, now is the time to review potential open applications. Some grant programs' initial deadlines have recently passed (e.g., Kansas' Regional Partnership Grant Program and Rural Emergency Hospital Grant applications had deadlines in late March and early April 2026). Oregon solicited project proposals through May 26, 2026 for its Catalyst Awards Request for Grant Proposals, and intends to award $50.4 million in additional funding to hospitals, health clinics, and local public health authorities by late summer. More states have announced impending grant opportunities (e.g., Arizona plans to finalize grants by this summer; Michigan's website suggests a Grant Funding Opportunity will be released soon; and Colorado held a webinar on May 26, 2026 to help stakeholders prepare in advance of the Request for Applications (RFA). Potential applicants may want to check if their stats currently have open grant applications with impending deadlines: e.g., Ohio has a list of open solicitation invitations with deadlines in mid-June, and

Tennessee will have several applications released through the summer.

For each of the five budget periods of RHT funding, states have until the end of the following FFY (September 30 each year) to spend the awarded funding, and the subsequent budget period starts October 31 of each year. Any funds *not spent* by the end of the following FFY will be redistributed in the next year. Each budget period, CMS re-calculates states' funding based on a score using data from the state's annual report, the first of which is due August 31, 2026. With states' reporting deadline only three months away, hospitals should remain alert to any developments on RHT Programs in their states and prepare to respond to any funding opportunities.

2. *Hospitals Evaluate Risks Associated with Adoption of Automatic Billing and Predictive AI*

The rapid adoption of predictive AI for hospital billing has created a need for increased governance and evaluation frameworks to ensure compliance, particularly in a climate of growing regulation and enforcement of AI use in the medical revenue cycle. According to a 2025 data brief from the Office of the Assistant Secretary for Technology Policy (ASTP), formerly the Office of the National Coordinator for Health IT (ONC), hospital use of predictive AI to simplify or automate billing procedures surged from 36% to 61% between 2023 and 2024. This growth outstripped other use cases, including scheduling facilitation and identification of high-risk outpatients. ASTP further noted that much of the growth in billing AI was driven by hospitals deploying third-party or self-developed models rather than tools furnished by their EHRs vendor, with 73% of hospitals using third-party or self-developed AI employing it for billing purposes compared to 58% of those relying on EHR-developed tools.

From a governance standpoint, the diversity of AI model sources compounds risk. As hospitals increasingly source billing AI from third-party developers and build proprietary models alongside EHR-integrated tools, accountability for evaluation of the tools for compliance is in many cases fragmented. ASTP found that 74% of hospitals reported multiple entities accountable for evaluating predictive AI, with specific AI committees (66%) and division leaders (60%) the most likely reported responsible entities. When predictive AI is being rapidly adopted, accountability is diffused throughout hospitals and health systems, resulting in risk assessments and evaluation procedures that are in many instances incomplete. For example, a 2023 study based on the 2023 AHA Annual Survey found that while approximately 65% of U.S. hospitals reported using AI-assisted predictive models, only 44% of hospitals using predictive AI models had conducted evaluations of those models for potential bias. As the use of predictive AI continues to proliferate, hospitals and health systems should evaluate their AI compliance programs for gaps in oversight that can expose them to compliance failures and take corrective action to mitigate associated risks.

Additionally, the enforcement landscape strongly suggests that AI-assisted billing will face heightened regulatory scrutiny. The DOJ-HHS False Claims Act Working Group, announced in July 2025, has identified "manipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare covered products and services" as a priority enforcement area. In its February 2026 Medicare Advantage Industry-Specific Compliance Program Guidance, HHS-OIG noted that it is increasing oversight of potential AI risks related to physician queries, provider diagnosis code reporting, and claims and prior authorization decisions. As agencies recognize the risks AI poses with relation to health care fraud laws, they are in tandem integrating AI into enforcement activities. For example, the U.S. Department of Justice (DOJ) recently established a Healthcare Fraud Data Fusion Center, which leverages cloud computing, AI, and advanced analytics to identify emerging fraud schemes. With False Claims Act (FCA) settlements and judgments involving health care exceeding $5.7 billion in FFY 2025, and AI increasingly embedded in coding and risk-adjustment workflows, hospitals, and health systems deploying automated billing tools should proactively audit their AI systems, ensure documented human review processes, and integrate AI oversight into broader compliance programs.

3. *Value-Based Payment Models and AI Tools*

Value-based payment models are emerging as a potentially more effective framework for supporting the adoption of clinical AI tools in health care, particularly as FFS reimbursement structures continue to present challenges for AI-enabled services. Under Medicare's traditional FFS payment system, AI tools often do not fit within established benefit categories, and even where billing codes exist, regional MACs typically determine pricing, creating variation across regions that limits predictability for providers and developers alike. Because FFS generally rewards volume of discrete services rather than outcomes, this framework can incentivize overuse of separately paid software tools without clear evidence of patient benefit, and simultaneously discourage investment in clinical AI tools whose value accrues over time and across workflows rather than in a single billable encounter. Value-based payment models—which

reward clinical outcomes rather than specific activities—may better support the adoption of effective AI solutions without increasing low-value spending.

In December 2025, CMS's Center for Medicare and Medicaid Innovation (CMMI) announced the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model, a voluntary, 10-year payment program designed to test Outcome-Aligned Payments (OAPs) in Original Medicare and expand access to technology-supported care, including AI-enabled solutions. Under the ACCESS Model, described in more detail in the Value-Based Care Corner section of this newsletter, participating Medicare-enrolled care hospitals and health systems receive recurring payments to manage patients' qualifying chronic conditions—including hypertension, diabetes, chronic kidney disease, obesity, depression, and musculoskeletal pain—with full payment tied to demonstrated clinical improvement or control relative to each patient's baseline. In April 2026, CMS selected 150 digital health companies and health care providers to participate in the model's launch, which is set to begin on July 5, 2026. Commercial payers representing 165 million members across MA, Medicaid, and commercial coverage have also pledged to align with the ACCESS Model's payment approach, signaling broader industry interest in outcome-aligned reimbursement for technology-supported care.

Hospitals and health systems should monitor the ACCESS Model and related value-based payment developments closely, as these models may reshape the reimbursement landscape for AI-enabled clinical tools. The ACCESS Model's design—paying for outcomes rather than defined activities—provides hospitals with greater flexibility to deploy AI, telehealth, wearables, and other digital health technologies in clinically appropriate ways without the constraints of traditional billing code requirements. That said, the payment rates CMS published for the ACCESS Model's initial period have been lower than many in the industry anticipated, raising questions about whether the rates will be sufficient to sustain high-touch, clinician-driven chronic care models and generate positive margins for participants. As policymakers and payers continue to explore how to appropriately pay for AI in clinical care, the tension between ensuring adequate reimbursement to drive adoption and guarding against low-value spending will remain a central challenge for the field.

4. CMS's WISeR Model: AI-Driven Prior Authorization Comes to Medicare and Faces Headwinds

On January 1, 2026, CMMI launched the WISeR Model, a six-year pilot program that introduces AI- and machine-learning-assisted prior authorization screening into Medicare. The model operates in six states: Arizona, New Jersey, Ohio, Oklahoma, Texas, and Washington, and targets a narrow set of Part B services deemed vulnerable to fraud, waste, and abuse, including skin and tissue substitutes, electrical nerve stimulator implants, epidural steroid injections, cervical fusion, and knee arthroscopy for osteoarthritis. Six private health technology companies serve as model participants, each assigned to a state, where they use AI-enabled tools to screen prior authorization requests and issue determinations within 72 hours. Although AI will play a significant role in the prior authorization process under this model, it preserves human involvement in the decision-making process, as all final non-payment decisions must be made by a licensed clinician, not by the algorithm alone. Participants in the model are compensated through a shared-savings structure tied to averted wasteful spending.

The WISeR Model presents several compliance and operational considerations for hospitals and providers in the six pilot states, and providers in non-pilot states should stay attuned to the implications of the model in the event that it is expanded nationally following the initial pilot stage. First, providers may either submit prior authorization requests through the model participant's electronic portal directly or through their MAC, or they may forgo prior authorization altogether; however, claims submitted without prior authorization are subject to pre-payment medical review. CMS requires that non-affirmation decisions include specific reasons grounded in Medicare coverage, coding, or payment criteria, and the agency has committed to auditing participants to prevent inappropriate denials and holding them accountable through performance metrics related to determination accuracy. Participants that fail to comply with the 72-hour turnaround requirement or that exhibit high appeal-overturn rates may face payment penalties or corrective action. CMS has also indicated it will publicly report approval and denial data and is rolling out a "gold card" exemption program beginning in mid-2026, under which providers who consistently meet a minimum affirmation threshold across at least 10 prior authorization submissions may be exempt from ongoing prior authorization and pre-payment review requirements.

Early indications of program performance remain limited, and the model has drawn scrutiny with regard to its effectiveness since its announcement. A Kaiser Family Foundation analysis published in February 2026 concluded that the model's first-year impact is likely to be modest, given that WISeR services accounted for only 5.3% of Part B spending in traditional Medicare in 2024 and that the dominant spending driver, skin

substitutes, was already being addressed by a separate, nationwide CMS payment reclassification expected to reduce skin substitute spending by nearly 90%. On the provider side, implementing physician groups and state medical associations have reported increased administrative burden and delays in care delivery since the model's launch. Moreover, legislators have focused their attention on the model: Congressional Democrats introduced legislation in the House and Senate attempting to halt the implementation of the model before it was implemented and recently filed a joint resolution seeking to disapprove the rule implementing the WISeR program. For example, Senator Maria Cantwell (D-WA) has flagged reports of significant increases in wait times in Washington State and highlighted the concerns of constituent patients and providers during a recent hearing with HHS Secretary Robert F. Kennedy, Jr. As the model progresses—and given the attention and scrutiny of lawmakers, industry actors, and patients alike—compliance teams should monitor CMS guidance updates, track their organizations' affirmation rates and exemption eligibility, and prepare internal workflows for the prior authorization and appeal processes that WISeR introduces.

5. *New AI-Specific CPT Billing Codes and Medicare Reimbursement Pathways*

The 2026 Current Procedural Terminology (CPT) code set represents a watershed moment for AI in clinical care, establishing for the first time independent reimbursement pathways for augmented intelligence clinical services. As of January 2026, there are 26 CPT codes for clinical AI solutions. Three AI solutions have received permanent Category I CPT codes: Fractional Flow Reserve derived from Computed Tomography (FFR-CT), which uses augmented software to help diagnose heart disease; a service that analyzes CT scan data to predict cardiovascular risk through quantification and characterization of coronary atherosclerotic plaque; and a tool that uses augmented imaging to detect diabetic retinopathy. The remaining AI solutions with designated CPT codes hold Category III status—temporary codes intended to collect utilization data for emerging technologies that may lack an associated payment rate and do not guarantee reimbursement. Notably, the AMA is also considering a new coding classification within the CPT code set—tentatively titled Clinically Meaningful Algorithmic Analyses (CMAA) codes—for algorithm-based services such as AI-enabled software as a service (SaaS) products, which could further standardize how AI tools are coded and billed.

Despite these coding advances, significant reimbursement challenges remain. For many AI tools billed as physician services, CMS relies on regional MACs to set payment rates on a case-by-case basis through a process known as "carrier pricing," which creates geographic variation in how and where AI is reimbursed. In the hospital outpatient setting, CMS uses New Technology Ambulatory Payment Classifications (APCs) to temporarily pay for new services, but this classification typically remains in effect for only two to three years, and CMS does not have a dedicated payment methodology for SaaS billed by hospitals in outpatient departments. To address these gaps, Senators Mike Rounds (R-SD) and Martin Heinrich (D-NM), co-chairs of the Senate Artificial Intelligence Caucus, introduced the bipartisan Health Tech Investment Act (S. 1399) in April 2025, which would assign FDA-approved algorithm-based health care services that meet Medicare coverage requirements to New Technology APCs for a minimum of five years. Under the proposed legislation, CMS would be required to determine payment rates using cost data submitted by manufacturers, including expenses such as subscription fees, invoices, clinical staffing, and overhead, and the bill would permit reimbursement for AI services even when performed concurrently with or adjunctive to other medical procedures.

Hospitals and health systems should evaluate whether current or planned AI tools qualify for standalone billing under these evolving codes and monitor the legislative trajectory of the Health Tech Investment Act. The new CPT codes transform AI from an uncompensated overhead expense into a potential direct revenue-generating service line, fundamentally altering return-on-investment calculations for hospitals and health systems considering AI acquisitions. At the same time, the overall utilization of AI-specific CPT codes remains limited—in 2023, only FFR-CT was billed at scale in the hospital outpatient setting, with 14,000 claims and $12.7 million in Medicare spending—and most AI tools continue to be billed under temporary codes without set or guaranteed payment. As CMS continues to solicit public comment on paying for SaaS in hospital outpatient departments and the AMA advances its CMAA coding framework, hospitals and health systems should stay attuned to these developments and assess how new and pending reimbursement pathways may affect their clinical AI strategies.

6. *CMS Continues to Integrate AI into Training and Agency Workflows*

Consistent with the Trump administration and CMS's Artificial Intelligence Playbook, CMS has continued its approach of

integrating AI into a number of agency workflows. At a May 20 Bipartisan Policy Center event, CMS Administrator Mehmet Oz and CMS Chief of Staff and Deputy Administrator Stephanie Carlton presented the agency's five-year strategic framework, which included several AI-oriented initiatives. Oz and Carlton explained that the agency has recruited key personnel to train agency leadership, who will in turn train other agency personnel, with the goal of enabling all 6,000 CMS employees to use AI in their day-to-day activities at the agency by the end of 2026. The move to train its staff comes at a time where the agency seeks to augment AI use cases beyond those already in place, which to date have included the prevention of high-risk payments, systematic identification and recovery of duplicate payments, and the launch of the WISeR model, among other initiatives.

During the May 20 presentation, Carlton explained that the agency is exploring the use of AI to streamline its rulemaking process. She stated that CMS has identified the public comment review phase as an especially promising application for AI as traditionally, collecting and analyzing public comments on proposed rules, clustering feedback by theme, and refining policy accordingly can take months, even with contractor support, while AI can perform this analysis in just a few hours. Carlton emphasized that the efficiency gains not only free up staff time but also prompt the agency to consider how similar efficiencies could be redirected toward improving patient care. It is unclear whether, and to what extent, CMS has begun integrating AI into the rulemaking process.

Beyond integration of AI into agency workflows, CMS is taking steps to facilitate beneficiaries' use of AI in both clinical and non-clinical contexts. Carlton, citing a study identifying AI's promise in diagnoses, expressed that the agency is committed to enhancing beneficiaries' comfort with clinical uses of AI. In the non-clinical context, Oz has previously discussed the implementation of AI-enabled solutions to assist Medicare beneficiaries with finding doctors or choosing MA plans, with the hopes of having the tools available by the end of the administration. However, agency actions to increase beneficiaries' trust of AI face an uphill climb, as a recent survey revealed that only 31% of Medicare beneficiaries trust AI to access medical records or provide personalized information and advice.

Ropes & Gray has launched the Health AI Atlas, a centralized resource for tracking state regulation of AI development and deployment by health care stakeholders, and competing de-regulatory efforts at the federal level. The Health AI Atlas offers interactive, state-by-state maps and practical regulation summaries of state AI requirements. Separate map sections provide a streamlined summary of AI-enacted state laws and common state AI requirements, in addition to a section on key federal AI developments.

Enforcement Updates

1. CMS Strengthens Its Enforcement Tool Box

As part of the CY 2026 Home Health Prospective Payment System Final Rule ("2026 HH PPS Final Rule"), effective January 1, 2026, CMS announced an expanded interpretation of its authority pursuant to 42 CFR § 424.535 to revoke a provider's or supplier's enrollment in Medicare based on engagement in problematic or otherwise non-compliant behavior. When a provider or supplier's Medicare enrollment is revoked, it is generally barred from reenrolling in Medicare for a period of one to 10 years. CMS has discretion to add three more years, if the provider or supplier attempts to circumvent its existing reenrollment bar by enrolling in Medicare under a different name, numerical identifier, or business identity. In the 2026 HH PPS Final Rule, CMS modified grounds for revoking a provider's or supplier's Medicare enrollment and expanded the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. Under the 2026 HH PPS Final Rule, CMS may now revoke a supplier's or provider's Medicare enrollment if a beneficiary attests that the items or services identified on the provider's or supplier's claim or claims were not rendered or furnished. It remains unclear whether CMS would use a threshold of beneficiary attestations or if one attestation could be used as grounds for revocation. With respect to retroactive revocation, CMS may now backdate the effective date of the revocation, which is typically effective 30 days after receipt of the notice, to the date of the action that constitutes grounds for the revocation. The 2026 HH PPS Final Rule now permits retroactive revocations for the submission of false or misleading information in the enrollment application, failure to timely report a change of ownership, or revocation of any of a provider's other enrollments. CMS now makes the list of revoked Medicare providers and suppliers publicly available, as of March 9, 2026, here. Importantly, from October 1, 2020

through September 30, 2025, CMS has issued 12,040 revocation actions, indicating CMS's willingness to use this tool for enforcement.

CMS has also recently expanded its authority under other enforcement mechanisms, including deactivation of enrollments, stays of enrollment, ownership disclosure requirements, and exclusions. CMS may now deactivate a physician's or practitioner's ability to order, certify, or refer Durable Medical Equipment Prosthetics, Orthotics, and Supplies ("DMEPOS") and Part B Medicare services and items if they have not filed a claim for such items or services in 12 consecutive months. Stays of enrollment are now an available remedy in instances where a provider fails to furnish complete information (or supporting documentation) on a revalidation or change of information application that is rejected. For proof of ownership, CMS may now require submission of any other documentation needed to validate data on an enrollment application, including, but not limited to, documentation regarding ownership or management. Finally, CMS has begun seeking exclusions for "professionally recognized standards" for the provision of gender-affirming or "sex-rejecting" procedures pursuant to Secretary Kennedy's declaration, Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents (Dec. 18, 2025). Among these updates, hospitals and health systems should especially note the implications for changes of ownership. Now, providers or suppliers can have their enrollment revoked retroactively if they fail to timely report a change of ownership; their enrollment may be stayed if they fail to provide accurate change information; and CMS may require the submission of *any* supporting documentation to validate ownership information.

2. *CMS Announces Increased Enforcement of Price Transparency Requirements*

On June 9, 2026, HHS announced on social media that the Department had begun increased enforcement of hospital price transparency requirements. In the posts, HHS stated that "THE GRACE PERIOD HAS ENDED" and that hospitals must "[c]ome into compliance immediately – or face serious consequences." The announcement coincides with a report from the Associated Press that HHS sent warnings or compliance plan requests to more than 500 hospitals that they are failing to provide the public with basic pricing information.

These increased enforcement actions reflect an apparent priority of this Administration to continue its first term actions to require hospitals to publicly report prices. In June 2019, President Trump issued an Executive Order directing CMS to implement regulations directing hospitals to disclose their actual prices for common tests and procedures. CMS' rulemaking in 2021 required hospitals to post comprehensive machine-readable files containing negotiated rates, self-pay rates and chargemaster information, and provide consumer-friendly displays of at least 300 shoppable services. CMS has continued to revise the requirements and, as described in our summary of the CY 2026 OPPS rule, hospitals must now, with few exceptions, publicly disclose the real dollar costs of their services and products, rather than estimates, in standardized, machine-readable files, and must provide the rates they negotiate with health insurance companies in those disclosures.

3. *CMS Moratorium Indicates Increased Medicare Hospice Enforcement Legislation Could Be on the Horizon*

On May 13, 2026, as part of Vice President JD Vance's Anti-Fraud Task Force, CMS announced a six-month nationwide moratorium on new Medicare enrollments for hospices and HHAs. CMS aims to spend the moratorium further investigating providers suspected of fraud, using a data-focused approach to review billing and coding data of currently enrolled providers. *Read more about the moratorium in Ropes & Gray's recent Client Alert on the topic available [here].* The moratorium is a potential preview of further aggressive enforcement action in the hospice and HHA space. On March 17, 2026, Democratic senators introduced the Hospice Care, Accountability, Reform and Enforcement (CARE) Act of 2026, sweeping hospice reform legislation that legislators state will "strengthen" the provision of hospice. The legislation was initially introduced in 2024 and has resurfaced amidst the aggressive health care enforcement environment of the Trump administration.

If enacted, this legislation would have considerable impact on all Medicare-enrolled hospice providers. Among the many measures included, the Hospice CARE Act of 2026 would start by re-examining all current Medicare enrolled hospice providers, beginning with a five-year moratorium on enrollment of new hospice providers under Medicare, though there is an exception for hospices trying to enroll in unmet geographic areas. During the enrollment moratorium, hospice providers would undergo mandatory prepayment reviews for an unspecified period of time. CMS would have discretion to terminate the prepayment review upon a determination that the provider has had a "low rate of denial," but the termination may be revoked "if determined appropriate by the Secretary." CMS would also "revalidate the enrollment" of all current hospice providers through the collection of updated enrollment information,

including ownership disclosures. Ownership information would then be published on a public website, and CMS would be tasked with publishing a report on ownership trends in the hospice space. Further changes include subjecting newly enrolled providers to more frequent surveys, conditioning payment upon the submission of quality data, requiring changes of ownership be reported at least 90 days prior to the change, and requiring HHS to send patients an explanation of benefits within 15 days of entering hospice care.

The Hospice CARE Act of 2026 aligns with the Trump administration's broader fraud and abuse identification and enforcement agenda for 2026. Hospitals and health systems that participate in hospice provision under Medicare should watch this legislation closely, as the impacts will be felt by all providers in the space.

4. Executive Order Establishing the Task Force to Eliminate Fraud

On March 16, 2026, President Trump released Executive Order 14395, Establishing the Task Force to Eliminate Fraud (the "Task Force"). Per the executive order, the purported rationale for the Task Force is that "some States have refused to institute basic fraud controls" leaving federal health care programs vulnerable to exploitation. The executive order specifically highlighted the administration's withholding of Medicaid funds from Minnesota over alleged fraudulent activity. President Trump ordered that the Task Force coordinate and accelerate a comprehensive national strategy to stop fraud, waste, and abuse within federal benefit programs, including programs administered jointly with state, local, tribal, and territorial partners. The Task Force will be chaired by the vice president and include representatives from nine cabinet agencies.

5. DOJ Establishes the National Fraud Enforcement Division

On March 24, 2026, the Senate confirmed Colin McDonald as the Assistant Attorney General for the newly created National Fraud Enforcement Division ("Fraud Division"). On April 7, 2026, Acting Attorney General Todd Blanche issued a memorandum (the "Memorandum") formally establishing the Fraud Division within the DOJ. The Memorandum and Acting Attorney General Blanche's accompanying press conference provided the first substantive insights into the Division's structure, focus, and operational framework.

The Memorandum envisions the Fraud Division as a hub for coordinated enforcement across federal, tribal, state, territorial, and local jurisdictions. Notably, the new AAG assumed operational control of three existing Criminal Division units, including the Health Care Fraud Unit. Importantly, however, the Memorandum does not direct that the Civil Division's Fraud Section—the unit responsible for the government's affirmative FCA investigations and litigation—be moved into the new Fraud Division. The Memorandum directs each of the 93 U.S. Attorney's Offices (USAO) to designate an experienced prosecutor to be detailed in place to the Fraud Division within 21 days, with that detailee responsible for administering the Division's mission in their respective district.

The Memorandum also calls for the establishment of a National Fraud Detection Center—in coordination with law enforcement agencies, agency inspectors general, and members of the Task Force created by the executive order titled "Establishing the Task Force to Eliminate Fraud"—to identify fraud across taxpayer-funded programs and generate leads. Acting Attorney General Blanche described the center as a "permanent prosecutor-led multi-agency data analytics team working to ferret out the most harmful actors defrauding federal government programs."

In addition, the Memorandum directs the Office of Legal Policy to review "relevant laws, regulations, and guidelines bearing on fraud investigations, prosecutions, and penalties" within 90 days and to "provide recommendations to the Deputy Attorney General for strengthening" them. That effort could lead to proposals for increased penalties, expanded forfeiture provisions, longer statutes of limitations, or changes to the Justice Manual that governs how the DOJ exercises its prosecutorial discretion. Read our recent Client Alert to learn more about the new Fraud Division.

6. CMS Announces Nationwide Moratorium on Medicare Enrollment of DMEPOS Suppliers and HHAs

On February 27, 2026, CMS announced a six-month nationwide moratorium on the Medicare enrollment of DMEPOS supplier medical supply companies in efforts to mitigate fraud, waste, and abuse among such providers. The moratorium prohibits new Medicare enrollments by any entity seeking to enroll as one of seven medical supply company types. Subsequently, on May 13, 2026, CMS announced a similar six-month moratorium on the Medicare enrollment of new HHAs, citing similar concerns regarding rapid growth in enrollments, improper ownership transfers, and alleged fraudulent billing activity. Both sets of moratoria have the effect of prohibiting both: (1) prospective entities seeking to newly enroll in Medicare; and (2) currently enrolled medical entities that need to submit a new initial enrollment application, such as when opening a new practice

location or following certain changes in majority ownership. Per CMS regulations, CMS has the authority to extend these moratoria in six-month increments if CMS deems it necessary.

7. CMS Announces Medicaid Verification Requirements for States

On April 21, 2026, CMS Administrator Dr. Oz announced that all states would be required to submit a plan within 30 days on how they would revalidate Medicaid providers. On April 23, CMS sent letters to each state governor and state Medicaid director formally requesting that they develop and submit a comprehensive two-year provider revalidation strategy. In the letter, Oz warned that "failure to carry out swift revalidation will be considered as we evaluate the likelihood of fraud in each state moving forward." The strategy contemplated by the letter must include a proposed methodology and timeline for conducting off-cycle provider revalidation, with a focus on "high-risk providers," which is left to each state to define. In addition, the strategy must indicate the metrics the state will use to measure its efficacy and progress, the state's approach to verifying the accuracy of provider information, how the state will ensure consistency and accuracy of provider data across FFS and managed care delivery systems, and how the state will coordinate with relevant law enforcement partners.

8. CMS Announces Withholding of More than $1.3 Billion in Medicaid Funds from California

On May 13, 2026, the Trump administration announced that CMS would withhold roughly $1.3 billion in Medicaid funding from California, alleging that state officials have "not taken fraud very seriously." According to CMS, this is the largest deferral ever made by the agency and is the first time it has targeted payments to the state. The purported goal of the withholding is to force state officials to account for how certain outlier payments were generated by demonstrating that eligible patients actually received services. This announcement follows CMS's decision earlier this year that it would be withholding more than $300 million in Medicaid reimbursements to Minnesota based on similar allegations of fraudulent billing, which Minnesota has challenged in court.

9. HHS OCR Announces Civil Enforcement Program for Confidentiality of Substance Use Disorder Patient Records

On February 13, 2026, the HHS Office for Civil Rights (OCR) announced its civil enforcement program to implement the updates to the Substance Use Disorder (SUD) confidentiality provisions of the regulation at 42 CFR Part 2 (Part 2).[1] The new enforcement program became effective February 16, 2026, in accordance with the deadline set by the 2024 Final Rule modifying Part 2 (2024 Final Rule). See our recent Client Alert for more details.

10. Notable Enforcement Actions since early 2026

- On March 3, 2026, DOJ announced that Tri-City, a Phoenix-area physician group, and three individual physicians agreed to pay $4.75 million to settle allegations that they violated the FCA by carrying out medically unnecessary vein ablation procedures. According to the government, Tri-City and the physicians recorded inaccurate information in patient medical records, such as diameter of veins or duration of outward blood flow, which created the false impression that the ablation procedures were medically justified and consistent with accepted standards of care.
- On March 5, 2026, the USAO for the Eastern District of Wisconsin announced that Kinex, a durable medical equipment (DME) distributor, agreed to pay $6.9 million to resolve allegations that it provided medically unnecessary medical braces to patients and billed government programs for the braces in violation of the FCA. To encourage patients to take the braces, Kinex allegedly waived co-pays and provided other equipment at no cost.
- On March 11, 2026, the USAO for the Eastern District of Pennsylvania announced that Aetna, Inc. will pay a combined $117.7 million in connection with two settlements to resolve allegations that it violated the FCA by submitting and failing to correct inaccurate diagnosis codes for MA enrollees. The first settlement, which totaled $106.2 million, relates to a "chart review" that Aetna allegedly completed in payment year 2015 in which it reviewed records to identify potential additional diagnosis codes. During that review, Aetna allegedly identified both codes that could be added to records as well as codes that had previously been submitted to the government that were not supported by underlying documentation. According to the government, Aetna submitted the newly identified diagnosis codes for further reimbursement but failed to alert the government to the existence of the unsupported diagnosis codes. The remaining $11.5 million settlement resolves separate allegations that, between 2018 and 2023, Aetna submitted obesity-related diagnosis codes for individuals who did not

meet the clinical definition of obesity. This settlement highlights the DOJ's recent focus on high-value MA cases.

- On April 10, 2026, the DOJ announced that a federal contractor agreed to pay $17 million to resolve FCA allegations arising from allegedly discriminatory employment practices tied to its diversity, equity, and inclusion (DEI) programs. For more detail, see the "Updates on Litigation Related to Federal Funding Certifications" in the Federal Awards and Grants Updates, below.
- On May 1, 2026, the DOJ announced that an Orange County-based provider of medical scans agreed to pay $8.3 million to resolve FCA allegations that it violated federal law by paying referring cardiologists excessive fees to supervise positron emission tomography (PET) scans. The government alleges that the provider paid above fair market value fees for cardiologists to supervise PET scans for the patients they referred to the medical scan provider.

Value-Based Care Corner

1. Mandatory and Permanent Comprehensive Care for Joint Replacement Program

In its FFY 2027 Hospital IPPS Proposed Rule, discussed in detail in the Regulatory Updates section, CMS also announced the expansion of the Comprehensive Care for Joint Replacement Model. Comprehensive Care for Joint Replacement Expanded (CJR-X) is a retrospective episode-based bundled payment program focused on Lower Extremity Joint Replacement (LEJR) procedures—primarily hip and knee replacements—that holds participating hospitals accountable for the cost and quality of care from the initial procedure through 90 days post-discharge. This is a mandatory expansion model that would begin on October 1, 2027.

The original CJR Model ran from April 1, 2016, through December 31, 2024, and was tested in selected Metropolitan Statistical Areas (MSA). Evaluation results showed it produced $112.7 million in net savings to Medicare across Performance Years six and seven while maintaining quality. Based on those results, the Secretary determined expansion was warranted and would produce additional Medicare savings.

If finalized as proposed, CJR–X would extend mandatory episode-based accountability for LEJR procedures to all eligible acute care hospitals nationwide beginning in FFY 2028. CMS projects the model would generate approximately $725 million in net Medicare savings over its first five years.

Key changes from CJR to CJR–X include the geographic scope and participation requirements. Under the original CJR Model, participation was mandatory for hospitals within selected MSAs. Under CJR–X, participation would be mandatory for all acute care hospitals paid under both the IPPS and OPPS nationwide, with limited exclusions. Whereas the CJR Model offered certain rural and low-volume hospitals a one-time option to opt out of participation, the only exclusions under CJR–X are for TEAM participants and acute care hospitals in Maryland. TEAM participants are excluded because, while LEJR episodes exist under both models, CJR–X would continue testing 90-day episodes—which demonstrated savings in the CJR Model—whereas TEAM tests 30-day episodes. Keeping the two separate allows CMS to compare the impacts of 30- and 90-day episode lengths on savings and quality of care, while maintaining a consistent methodology across all five TEAM episodes. Maryland hospitals are excluded because of the state's unique rate-setting authority; CMS does not believe the regional pricing methodology used in CJR–X would accurately reflect episode spending for Maryland hospitals.

2. TEAM Updates

TEAM is a five-year, mandatory, episode-based payment model that went live on January 1, 2026, and will end on December 31, 2030. In TEAM, select acute care hospitals coordinate care from surgery through 30 days post-hospitalization for people with Original Medicare undergoing one of the five surgical episode categories—coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion—across selected Core Based Statistical Areas.

In CMS's IPPS proposed rule, CMS proposes several modifications to TEAM's episodes, quality measure assessment, and pricing methodology. A few of these modifications are provided below:

- First, CMS would expand the types of spinal fusion surgeries covered by the model by adding three new diagnosis-related group codes (MS-DRGs 523, 524, and 525), starting October 1, 2026. These codes were recently created to better distinguish among complex spinal fusion cases, and including them in TEAM keeps the model up to date with how Medicare classifies and pays for these procedures.

- Second, CMS is proposing to update the way it sets quality benchmarks under TEAM by using a rolling baseline rather than a fixed one. In practice, this means the quality standards hospitals are measured against would refresh each year based on the most recent data, rather than staying locked to a single point in time — helping ensure the benchmarks reflect current performance trends. CMS would also adjust the timing of certain baseline periods to better align with other Medicare quality reporting programs.
- Lastly, CMS is proposing to build two new adjustment factors into how it sets spending targets for each episode: one that accounts for annual changes in outpatient payment rates and another that accounts for changes in inpatient payment classifications. Together, these adjustments would help ensure that the cost target hospitals are measured against keep pace with the payment rates Medicare actually uses during the performance period.

3. ACO Expansion Advocacy Efforts

As Accountable Care Organizations (ACOs) continue to expand, stakeholders are actively seeking expansion and revision to CMS's ACO programs. Moves from industry leaders, Congress, and CMS officials indicate a strong push to expand participation in ACOs and move away from FFS Medicare. Most significantly, on March 26, a bipartisan pair of lawmakers introduced legislation to establish a permanent, full-risk ACO program within traditional Medicare. Since the formal creation of ACOs in the Affordable Care Act, CMMI models have shown the success of ACOs in delivering improved care and reducing Medicare expenditures. If passed, the HHS secretary would be required to establish a "Full Risk ACO Program" by June 30, 2026. Under the program, providers would take on 100% of the savings and losses for their aligned beneficiaries, subject to a CMS-set discount and risk corridors. Providers would have the option of two risk tracks, a standard population option, and a "complex care" track for higher acuity beneficiaries. Further, providers would qualify as advanced alternative payment model participants under the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) and be exempt from the Merit-Based Incentive Payment System (MIPS).

ACOs are advocating for solutions to the issue of physician pay reform in response to a recent RFI on reforming the MACRA on March 6. An overwhelming initial response to the RFI indicates that stakeholders broadly dislike MIPS across the board. Discussions on needed reform have been focused on stabilizing physician payment updates and strengthening incentives for clinicians to move into alternative payment models and other value-based care arrangements.

Separately, the Coalition for Accountable Care Access sent a letter to CMS on March 10 advocating for reform in the Medicare Shared Savings Program (MSSP). The group is pushing CMS to incorporate the voluntary alignment framework used in the ACO REACH model into the MSSP, stating the move could connect more than half a million additional seniors to coordinated care and generate more than $100 million in annual Medicare savings. The letter further notes that less than one in 400 seniors in MSSP choose to voluntarily align with an ACO because of the tedious current Medicare.gov-based process. Voluntary alignment would remove that step from the process, permitting beneficiaries to simply connect with a primary physician and their coordinated care team.

This activity comes amidst claims from Chris Klomp, Director of the Center for Medicare, that CMS is considering the possibility of automatically enrolling beneficiaries into ACOs, likely based on the concept of geographic alignment considered by prior administrations.

4. CMS Releases Additional Details on LEAD Model

The application period for CMS's LEAD model for ACOs has come and gone, opening on March 31, 2026 and closing on May 17, 2026. CMS quickly released an RFA for participation in the model on April 15, 2026. The voluntary ACO model uses a longer performance window, 10 years, and redesigns benchmarking for the different two-sided risk payment tracks: a professional option with 50% shared savings and losses, as well as a global option with 100% risk. CMS hopes the model will attract small and rural practices that do not typically participate in CMMI models due to administrative and cost barriers. In addition to the features mentioned above, other elements of LEAD that are new to ACOs, including incentives for healthy behaviors, reduced Part B cost-sharing, and the eventual ability to buy down Part D premiums, mirror those historically only present in the MA program. This is an intentional move by CMS and aligns with its goals to move beneficiaries away from traditional Medicare and into more value-based systems like ACOs and MA.

The model leverages interoperability requirements, technology integration, and expanded telehealth benefits to reach more Medicare beneficiaries, especially high-needs and dual-eligible beneficiaries. The technological element of the model supports

CMS's push toward AI and wearables integration into health care programs. Participating ACOs must require providers to use certified EHR technology for the sharing of medical records to ensure interoperability. The most significant inclusion in the model is the flexible telehealth benefit that waives the originating site requirements for telehealth services, which require a patient to travel to a health care facility to qualify for covered telehealth services. Under LEAD, a beneficiary's home can qualify as an originating site. The originating site fee would be waived when the beneficiary's home serves as the originating site for services. Further, LEAD waives the interactive requirement for asynchronous telehealth services for dermatology and ophthalmology, as these typically rely on images to inform diagnoses. Finally, the model includes an optional Tech Enabler that will allow participants to use certain AI and technology applications identified by CMS to improve health outcomes.

While ACOs have praised the model, there is a concern that the rollback of equity measures included in prior ACO models will negatively impact the performance of the small and rural providers the model targets. Without risk adjustments for social determinants of health, shared savings and incentives may not be enough to encourage participation. CMS expects to release additional details on the benchmark methodologies later this Summer.

5. ACCESS Model Gets Mixed Reviews Prior to Implementation

Concern over low reimbursement rates clouds the upcoming launch of the ACCESS model in July 2026. CMS states the 10-year voluntary model is intended to leverage new technology in the health care space, including the use of wearables, to manage the care of beneficiaries with common chronic conditions. The program will also permit greater use of telehealth, including asynchronous benefits to expand accessibility of care options.

ACCESS will use OAPs, which will be recurring payments for managing patients' qualifying conditions, with full payment tied to achieving measurable health outcomes. The payment rates for these new codes, announced by CMS in early March, are significantly lower than expected and likely would result in reimbursement lower than traditional FFS. The rates range from $90 to $420 per beneficiary per year (i.e., $7.50 to $35 per month). While the use of technology and AI-assisted tools should improve efficiency and lower costs, the initial low reimbursement rates may do little to entice buy-in and initial participation from technology companies, which is essential for the success of the model. Additionally, providers billing these codes are prevented from billing other Medicare claims.

Currently, the model has four different common condition tracks that group conditions that are commonly treated using similar types and levels of care. CMS has indicated that it would add tracks for other conditions based on the success of the model. Participating organizations will then be responsible for managing all qualifying conditions in a track to promote coordination of patient care. Each track accordingly includes a set of condition-specific measures and outcome targets informed by clinical guidelines. Outcomes will be measured by clinical improvement or control of a condition based on each person's starting point. For performance year 2026, full payment is conditioned upon at least 50% of aligned beneficiaries meeting all required outcome targets. By rewarding outcomes rather than defined activities, CMS hopes ACCESS will give clinicians greater flexibility to incorporate emerging technology into their practices more readily. Companies had until May 15 to apply for ACCESS to participate in the first cohort launching in July. Later applicants will be slated for participation beginning January 1, 2027.

6. CMS Releases Details about the New ASPIRE Model

On March 25, 2026, CMS announced the new Accelerating State Pediatric Innovation Readiness and Effectiveness (ASPIRE) Model. The voluntary model aims to increase care coordination for children and young adults enrolled in Medicaid and CHIP who either have or are at risk of developing complex medical and/or behavioral needs. Specifically, the model will target behavioral health conditions, substance use disorders, chronic conditions, and certain physical, intellectual, and developmental disabilities for intervention. CMS seeks participation from up to five states and will release a Notice of Funding Opportunity (NOFO) in 2026 to solicit participation from state Medicaid agencies (SMAs). These SMAs must partner with managed care plans or ACOs for the administration of ASPIRE.

ASPIRE will use total cost of care payments to incentivize providers to (1) improve the delivery of coordinated services for physical and behavioral health needs, (2) provide resources to help empower families and caregivers with information regarding their children's care, and (3) encourage long-term planning to support health, productivity, and economic stability to this population during the transition to adulthood. A core element of ASPIRE is a unified care plan accessible and shared by pediatricians, behavioral health specialists, and school-based providers to ensure alignment and cooperation between involved parties. Similar to other recently developed models, ASPIRE has a technological component at its heart. The model prioritizes integrated care coordination platforms, telehealth

services, and EHRs to improve interoperability and connect health providers, schools, social workers, and families. Interested providers and plans should review the model and consider engaging their state and its Medicaid agency to encourage application once the NOFO is released.

7. ACO REACH Financial Settlement Reopening Guidance

On March 31, CMS announced a new policy that allows ACOs participating in the ACO Realizing Equity, Access, and Community Health (REACH) model to request a reopening of financial settlement calculations to review for potentially improper claims that can skew ACOs' performance (Reopening Policy). The financial settlement calculation determines whether an ACO must pay CMS shared losses or receive shared savings from CMS. This policy issuance comes in the wake of numerous bad-actor DME "pop-up" vendors that bill Medicare for supplies that have neither been prescribed (there is no referring provider or office visit) nor provided (the patients have not received wound care services). The DME companies typically shut down before CMS can respond and reopen as a new entity.

The Reopening Policy seemingly gives CMS broad discretion over the approval of reopening requests and subsequently performing the claim reviews, while further restricting administrative or judicial review that ACOs could seek for inclusion of such improper claims. Notably, while the Reopening Policy offers the option for ACOs to seek reopening and recalculation of their financial settlement based on removed improper claims, it does not specify any thresholds or factors that CMS considers when approving or denying a reopening request. Further, the Reopening Policy specifically notes that reopening may result in either a positive or negative financial outcome, including the possibility of repayment to CMS, so ACOs should closely review eligible financial settlements before seeking reopening.

ACOs may seek reopening of a financial settlement within two years of the final financial settlement for the applicable performance year. CMS will then review submitted requests and provide its initial findings before permitting ACOs to proceed with the reopening or defer. If the ACO defers, it may wait within the two-year window for additional improper payment determinations to be finalized and later reinitiate the process, though it must wait at least six months between reinitiation requests and generally cannot add new providers to the original list. If an ACO proceeds with reopening, CMS's review must meet an undefined "internal threshold" for CMS to recalculate the financial settlement. If the threshold is not met, CMS denies the request and the ACO forfeits its reopening opportunity for that performance year with no right of appeal.

Federal Awards and Grants Updates

1. OMB Publishes Proposed Rule to Overhaul the Uniform Guidance

On May 29, 2026, the Office of Management and Budget (OMB), joined by federal award-making agencies, published a proposed rule in the Federal Register that would substantially revise 2 C.F.R. Part 200, commonly referred to as the "Uniform Guidance"—the government-wide framework governing the management of federal grants, cooperative agreements, and other forms of federal financial assistance. If finalized, the proposed rule would represent a significant overhaul of federal award management requirements. The proposed changes codify into regulation a series of executive orders issued beginning in January 2025—most notably Executive Order 14332, "Improving Oversight of Federal Grantmaking," as well as several other orders addressing DEI programs, gender ideology, merit-based opportunity, and foreign collaborations—and would shift the Uniform Guidance from guidance to regulation, including via a proposed name change (the "Uniform Grants Regulation"). Comments are due July 13, 2026, with a proposed effective date of October 1, 2026.

For further detail about these proposed changes and how they would affect funding recipients if finalized, see our client alert, "OMB Proposed Revisions to the Uniform Guidance: Key Takeaways for Award Recipient Organizations." In addition to summarizing the proposed changes, the alert provides helpful reference materials, including a redline comparison of the proposed revisions against the current Uniform Guidance and a summary chart comparing key provisions.

2. Updates on Litigation Related to Federal Funding Certifications

Litigation challenging the January 2025 Executive Orders targeting DEI in federal awards continues to evolve.

As background, Executive Order 14173 (EO 14173), "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," orders federal funding agencies to include in award terms a requirement that contractors and grant recipients under such awards certify that they do not—and will not during the award term—operate any programs promoting DEI that violate any applicable federal antidiscrimination laws (the "Certification Provision"). In January 2025, the Trump administration issued another executive order targeting DEI in federal awards.

Specifically, Executive Order 14151, "Ending Radical and Wasteful Government DEI Programs and Preferencing," requires federal agencies, departments, and commission heads to terminate all "equity-related" grants or contracts. A wave of lawsuits challenge the constitutionality of this funding condition as implemented by numerous federal funding agencies, including the Department of Homeland Security, Department of Education, Department of Transportation, DOJ, Department of Housing and Urban Development, Department of Labor, Department of the Interior, and the Federal Emergency Management Agency.

For the most part, plaintiffs have been successful in district court challenges. To date, only two of these challenges have been heard by federal appellate courts. In one such case, the U.S. Court of Appeals for the Fourth Circuit vacated a nationwide preliminary injunction that had blocked application of the Certification Provision. *National Association of Diversity Officers in Higher Education v. Trump*, 167 F.4th 86 (4th Cir. 2026). The Fourth Circuit held that the plaintiffs—the National Association of Diversity Officers in Higher Education, the American Association of University Professors, and the mayor and city council of Baltimore, Maryland—were unlikely to succeed on their First Amendment facial challenge to EO 14173's Certification Provision.

In the Fourth Circuit's view, requiring recipients to certify compliance with existing federal antidiscrimination laws does not, on its face, suppress protected speech. The Fourth Circuit found that the provision is not facial viewpoint discriminatory because it targets illegality, not a particular viewpoint. The Fourth Circuit's panel was unpersuaded that it should consider the administration's interpretation of antidiscrimination law rather than the text of the Certification Provision. As the Fourth Circuit explained: "What plaintiffs are really asking us to do is read subtext into the Provision's text. And what they're really challenging is how the Administration and its agency actors interpret antidiscrimination law in relation to plaintiffs' DEI programming. Neither is fertile ground for a facial attack against the Certification Provision." Notably, the Fourth Circuit panel repeatedly signaled that if agencies misinterpret or misapply antidiscrimination laws to lawful DEI activity, recipients may bring as-applied challenges. The case was remanded for further proceedings, which have yet to occur. For further detail, see our client alert, "Fourth Circuit Ruling and GSA SAM Proposal Address Antidiscrimination Certifications."

The only other challenge that has been considered at the appellate level is *Chicago Women in Trades v. Trump*, No. 25-2144 (7th Cir. 2026). In that case, the plaintiff, a nonprofit organization dedicated to promoting DEI within the skilled trades industry, challenged the DEI Certification as implemented in its Department of Labor awards. The district court found that plaintiffs were likely to succeed on the merits of a First Amendment challenge and issued a preliminary injunction enjoining the Department of Labor, the OMB, and the DOJ from pausing, terminating, or modifying the terms of the plaintiff's grants in accordance with the challenged provision. The case was argued before the U.S. Court of Appeals for the Seventh Circuit on January 30, 2026, and a decision is forthcoming. Early press coverage suggests that the Seventh Circuit's panel appeared frustrated with the government's failure to define what constitutes "illegal DEI" and receptive to at least some of the challenger's arguments, raising the possibility of a circuit split and continuing legal uncertainty for federal award recipients. "The reality of these [executive orders] are that programs that have been seen as combating historical discrimination were suddenly characterized as violating antidiscrimination laws, with no definition as to how and when DEI programs will fall on the illegal side of the analysis," Judge Rovner said. "The district court complained that the government emphasized that the certification provision implicates only illegal DEI programs, but according to the district court, neither in briefing nor oral arguments, did the government provide any definition to what is now considered illegal."

In a separate but related development, federal agencies are also beginning to implement Executive Order 14398 (EO 14398), "Addressing DEI Discrimination by Federal Contractors," which President Trump issued on March 26, 2026. EO 14398 directs agencies to incorporate a new clause prohibiting "racially discriminatory DEI activities" into contracts that are subject to the Federal Acquisition Regulation (the FAR). On its face, it does not appear applicable to grants or cooperative agreements, or to certain types of government contracts (e.g., payor participation agreements) that are not otherwise subject to the FAR. While the certification language must flow down to subcontracts, this obligation may be limited where subcontracts flow from federal non-contract prime awards—such awards typically are governed not by the FAR but rather by 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), which references only specific provisions that must be included in contracts issued under federal non-contract prime awards. Our clients have begun to receive this certification language in their contracts with federal

agencies, through agencies' amendments to existing contracts as well as new contracts. EO 14398 is being challenged in *National Association of Diversity Officers in Higher Education v. Trump*, No. 8:26-cv-01532 (D. Md. Apr. 2, 2026). The same coalition that challenged the DEI Certification in the above-referenced case now seeks to enjoin EO 14398, arguing that it violates the First Amendment, unlawfully treats DEI activity as racial discrimination, and exceeds the president's procurement authority.

Most recently, on April 10, 2026, the DOJ announced that a federal contractor agreed to pay $17 million to resolve FCA allegations arising from allegedly discriminatory employment practices tied to its DEI programs. The government alleges that IBM certified compliance with antidiscrimination requirements incorporated in its federal contracts while knowingly maintaining employment practices that the United States contends unlawfully discriminated against employees and applicants for employment because of race, color, national origin, or sex (collectively, "protected demographic characteristics"). The alleged discriminatory practices included taking protected demographic characteristics into account as part of hiring and promotion decisions, developing race- and sex-based demographic goals for business units, and tying managers' bonus compensation to achieving demographic targets in employment decisions. This settlement represents the first public resolution under the DOJ's Civil Rights Fraud Initiative and signals that the administration's FCA-based enforcement of antidiscrimination certifications is now an operational reality that recipients of federal funds must take seriously. Read our recent Client Alert to learn more.

Notwithstanding ongoing litigation, federal agencies have continued to implement these and other related executive orders through revised certification requirements, contract clauses, and compliance obligations, including OMB's proposed revisions to the Uniform Guidance that would codify in regulation these executive orders and other antidiscrimination-related writings of the current administration (described in the prior section) and the General Services Administration's (GSA) proposed revisions to the System for Award Management (SAM) certification requirements described in the following section. Future litigation likely will turn on concrete disputes about how agencies interpret and apply federal antidiscrimination law in connection with particular funding decisions, certifications, contract clauses, and enforcement actions. In the meantime, recipients of federal funds should continue to review and comply with all applicable award terms and conditions, keep abreast of applicable litigation updates, and carefully evaluate DEI-related programs in light of the administration's revised interpretation of applicable federal antidiscrimination laws.

3. GSA Proposes DEI Certifications for Applicants and Recipients of Federal Awards

The GSA administers SAM, a federal procurement database that serves as a central hub for entities that seek or receive federal financial assistance. Save certain limited exceptions, SAM registration and profile maintenance are required for prime recipients of federal financial assistance, whether grants, contracts, cooperative agreements, scholarships, or other forms of federal financial assistance.

In a January 28, 2026 notice requesting public comment, GSA proposed amending SAM's Financial Assistance General Representations and Certifications to align with executive guidance, including EO 14173, "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," and the DOJ's Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination (the DOJ Memo), a July 29, 2025, memo from the Attorney General instructing federal funding recipients to eliminate "discriminatory" practices (e.g., race-based preferential treatment, use of non-protected characteristics as proxies for protected characteristics), regardless of DEI labels. GSA's SAM notice is part of a larger trend of conditioning award funding on recipients' agreement not to engage in unlawful DEI-related discrimination, as discussed in our February 2026 newsletter.

On February 18, 2026, GSA published draft certification language which, among other revisions to the existing certification language, requires compliance with all federal laws and "relevant" executive orders that prohibit "unlawful discrimination on the basis of race or color in the administration of federally funded programs[.]" The supporting statement gives examples of practices that "may" violate federal antidiscrimination laws, such as (1) preferential treatment based on race or color in granting scholarships or hiring or in imposing "cultural competence" requirements, and (2) retaliation against individuals for engaging in protected activities that oppose DEI practices that they reasonably believe violate federal antidiscrimination laws. The statement also flags additional prohibited practices that were not addressed in GSA's original notice, including (a) harboring or hiring an "illegal alien" and (b) funding, subsidizing, or facilitating "violence, terrorism, or other illegal activities that threaten public safety or national security."

While institutions already certify to compliance with federal laws (including federal antidiscrimination laws) in SAM at the point of

application and renewal, GSA's proposed inclusion of specific reference to EO 14173 and the DOJ Memo could, depending upon the ultimate certification phrasing adopted, force awardees to attest to compliance with the executive's own interpretation of what constitutes illegal discrimination, even if such interpretation is not reflected in legislation or the courts. Although the draft certification provides examples of potentially unlawful practices and suggests that EO 14173 and the DOJ Memo may be instructive, multiple courts have enjoined implementation and enforcement of provisions of EO 14173 or have remanded litigation on the merits to the district court level, and the DOJ Memo is framed as "non-binding suggestions" that "are not mandatory requirements but rather practical recommendations to minimize the risk of violations." As a result, it is unclear where exactly the line between permitted and discriminatory practices lies. Similarly, the contours of the provision regarding "activities that threaten public safety or national security" are left vague. The draft certification provides no statutory authority—and therefore, no explanatory context or limiting principles—for this provision, which could be read to encompass a wide range of lawful activities, such as classroom instruction or research activities related to terrorism and extremism. Given this lack of clarity, to mitigate risks of regulatory scrutiny, some institutions ultimately may take conservative, risk-averse approaches to compliance, curtailing programs and initiatives that, historically, have been considered to be lawful.

GSA's SAM notice signals a move toward a single, government-wide certification of compliance with anti-discrimination law as a condition of award eligibility and funding, in addition to certifications included within contracts and other agreements for federal financial assistance such as the DEI Certification described above. Consistent with this broader trend, the proposed revisions to the Uniform Guidance (discussed above) would, among other things, prohibit the use of "disparate-impact liability" based on protected characteristics, discriminatory event services, DEI and gender-related programs, and discrimination against faith-based organizations. Together, these developments reflect a shift away from agency-by-agency implementation of antidiscrimination certifications to a uniform certification that would reach most institutions receiving federal financial assistance. Agency reliance on a single SAM certification would reduce—or potentially eliminate—the need for agency-specific implementation and would centralize institutional compliance risk, including potential FCA exposure, at the point of SAM certification.

Notably, GSA's current proposed language does not include an express reference to the certification being "material" for FCA purposes, and specifically states that unlawful discrimination is prohibited "in the administration of federally funded programs," which is more limited than EO 14173's broader language requiring recipients "to certify that it does not operate any programs promoting DEI that violate any applicable Federal antidiscrimination laws." Nevertheless, the notice suggests that the threat of FCA liability will remain part of grant and contract requirements for the foreseeable future, including with respect to DEI programming and related practices that the Trump administration considers to be potentially discriminatory.

The comment period for the SAM notice closed on March 30, 2026. As of the date of publication, GSA has not published final certification language. For further detail, see our February 20, 2026, client alert, "Fourth Circuit Ruling and GSA SAM Proposal Address Antidiscrimination Certifications."

4. Appropriation and Spending of NIH Funds

Researchers who hold or are seeking National Institutes of Health (NIH) funding should be aware of significant and ongoing disruptions to the federal research funding pipeline. Although Congress restored billions of dollars in funding for 2026, the Trump administration has signaled that it may pursue alternative strategies that effectively limit the availability of those appropriated funds.

OMB Director Russell Vought testified in April 2026 that the Trump administration will not commit to spending all congressionally appropriated NIH dollars, stating that it will rely on its own legal interpretations rather than those of the Government Accountability Office (GAO). In an August 2025 report, the GAO found that the Trump administration's earlier funding withholdings violated the Impoundment Control Act.

In practice, watchdog analyses indicate that NIH is now issuing far fewer new grant awards—approximately half the number issued at the same point in the prior year—by restructuring grants to distribute larger amounts over longer periods. Researchers often rely on forecast records that provide insight into anticipated notices of funding opportunity. More than 200 NIH funding opportunity forecasts have passed their promised posting dates without any full announcement being published, creating uncertainty for investigators who relied on those forecasts to plan applications. These developments have already resulted in delayed peer review timelines, research programs ending prematurely due to a lack of funds, and staff lay-offs at affected institutions. Researchers currently awaiting award

decisions, preparing applications in response to posted forecasts, or managing active awards should carefully assess the reliability of anticipated federal funding, plan for potential delays or reductions, seek other avenues of funding (i.e., private funding), and consult with their institutions' offices of sponsored programs regarding contingency measures and compliance obligations that may arise from interrupted or restructured awards.

5. NIH FY2027 Budget Proposal, Restructuring, and Emerging Operational Impacts

The Trump administration proposed a $5 billion reduction to NIH funding in its FY2027 budget. The proposal also calls for restructuring the agency in a manner that would eliminate or consolidate several NIH institutes and centers. The budget frames these changes as part of a broader effort to refocus NIH on measurable public health outcomes. Priority areas include nutrition, chronic disease research, aging and disease biomarkers, and human-centric systems as an alternative to traditional animal testing.

Specifically, the budget proposes to eliminate the National Institute on Minority Health and Health Disparities, the Fogarty International Center, and the National Center for Complementary and Integrative Health. Congress declined a similar proposal for FFY 2026. The budget also proposes to consolidate the National Institute on Drug Abuse with the National Institute on Alcohol Abuse and Alcoholism. The proposal would cap indirect cost (IDC) rates at 15%, though it is unclear how NIH intends to impose such a cap given judicial decisions and recent appropriations bills purporting to prohibit NIH from imposing such a cap. The proposal introduces structural and funding changes aimed at increasing oversight of NIH-funded research.

Congress is unlikely to adopt the budget cuts given the broad benefits of NIH funding across the political aisle. Although the budget proposal remains subject to congressional action, it arrives at a time when NIH is already experiencing significant operational strain. Award recipients have reported delays in the issuance of new awards, slower processing of renewals, and increased use of incremental funding (i.e., partial funding of awards).

6. Publication of Revised NIH GPS

In March 2026, NIH published a revised version of its Grants Policy Statement (the 2026 NIH GPS) reflecting several converging policy priorities. First, it substantially overhauls the structure for international research collaborations by eliminating foreign subawards and requiring all funded international collaborations to proceed through a new dedicated award mechanism, enhancing NIH's direct oversight of funds flowing to foreign organizations. Second, it codifies recent research security obligations under the CHIPS and Science Act of 2022, including a bar on individuals participating in Malign Foreign Talent Recruitment Programs serving as senior/key personnel and mandatory Research Security Training certification for all Senior/Key Personnel that must be completed within one year of application submission. Third, it establishes new biosecurity provisions. For example, it prohibits the distribution of NIH-funded human biospecimens of U.S. persons to institutions or parties located in countries of concern and requires institutions to procure synthetic nucleic acids and related equipment only from vendors compliant with the 2024 White House Office of Science and Technology Policy Framework for Nucleic Acid Synthesis Screening, among other compliance obligations.

As for updates relevant to clinical research, basic experimental studies with humans (BESH) are no longer characterized as clinical trials and therefore will not be subject to NIH clinical trial requirements, such as ClinicalTrials.gov registration and reporting requirements. This change meaningfully reduces the administrative burden for BESH, though all other applicable clinical research laws and policies, such as those related to human subjects protections, still apply. As announced in January 2026, NIH has also imposed a complete prohibition on the use of funds for research involving human fetal tissue from elective abortions. For further information, see our January 27, 2026 client alert "NIH Prohibits Use of Federal Funds for Research Involving Human Fetal Tissue from Elective Abortions."

On the administrative side, NIH has developed new AI integrity provisions warning that applications substantially developed by AI will not be treated as original work and may trigger referrals to the HHS Office of Research Integrity. With regard to mandatory disclosures by applicants, recipients, and subrecipients, the 2026 NIH GPS broadens the scope to cover conflict of interest and civil FCA violations, the latter echoing the Trump administration's heightened focus on FCA enforcement. The 2026 NIH GPS also introduces a new "Defend the Spend" requirement, whereby award recipients must include a detailed justification at each fund drawdown; the justification is then subject to NIH review and approval. And as discussed in a prior newsletter, by July 2025, NIH had terminated over $2 billion in award funding, with termination notices often stating that the research projects "no longer effectuate[ ] program goals and agency priorities." Many

affected institutions submitted administrative appeals challenging agencies' adverse determinations, in part arguing against the basis that projects no longer aligned with agency priorities. In response to this wave of activity, in the 2026 NIH GPS, the agency reserves the right to terminate awards if an award no longer effectuates program goals and agency priorities and states that such terminations are not eligible for appeal under the relevant provisions of the Uniform Guidance or HHS regulations.

Finally, the 2026 NIH GPS systematically revises inclusion-related terminology, using broad, neutral phrasing in lieu of express references to protected classes. For example, in the prior iteration of the GPS, the Kirschstein National Research Service Award was described as a program "to help ensure that a diverse and highly trained workforce is available . . ." The 2026 GPS now states that the purpose of the program "is to help ensure that a highly trained workforce is available"; the "diversity" reference has been removed. Similarly, in the discussion of eligibility for career development awards, the 2026 NIH GPS replaced language stating that "[i]ndividuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are always encouraged to apply for NIH programs" with a sentence stating that "[i]ndividuals from all backgrounds are always encouraged to apply for NIH programs."

Together, these changes reflect converging priorities around national security, research integrity, fiscal accountability, and a recalibration of inclusion and civil rights language. Grant recipients should assess their operations against these newly established requirements to ensure compliance, as the GPS is incorporated into the terms and conditions of NIH awards, as these revised provisions of the 2026 NIH GPS may serve as a basis for prospective audits or enforcement actions.

7. *The Litigation-Based Fight over IDC Rate Caps Has Slowed (For Now)*

As reported in the July 2025 and October 2025 newsletters, in the early days of the second Trump administration, several federal funding agencies announced caps limiting rates for facilities and administrative (F&A) costs, sometimes referred to as IDCs. Courts blocked each agency's attempt to impose such a cap, and the government appealed each decision. As further reported in our January 8, 2026, client alert and February 2026 newsletter, on January 5, 2026, in *Massachusetts v. NIH*, 164 F.4th 1 (1st Cir. 2026), the U.S. Court of Appeals for the First Circuit upheld a district court judgment preventing NIH from implementing a policy that adopted a uniform 15% cap on the IDC rate of federally funded research institutions.

NIH did not appeal the First Circuit's order to the Supreme Court prior to the statutory deadline. As a result, the First Circuit's judgment is no longer subject to appeal, and the district court judgment is final. By law, a litigant seeking Supreme Court review of a circuit court decision must apply for a writ of certiorari within 90 days after entry of judgment. *See* 28 U.S.C. § 2101(c). As such, any appeal to the Supreme Court of the First Circuit's judgment could have been filed no later than April 6, 2026.

Massachusetts v. NIH was the last remaining case in active litigation regarding IDC rate caps, as the government had voluntarily dismissed its appeals of decisions blocking IDC rate caps imposed by the Department of Energy, the National Science Foundation (NSF), and the Department of Defense.

Recently enacted appropriations bills have further limited the Trump administration's ability to limit IDC rates through other means. The Commerce, Justice, Science; Energy and Water Development; and Interior and Environment Appropriations Act, 2026 (H.R. 6938), enacted on January 23, 2026, requires each of the Department of Commerce, National Aeronautics and Space Administration, NSF, and Department of Energy to continue to apply negotiated IDC rates. Similarly, the CAA 2026 requires the Department of Defense and HHS to continue to apply negotiated IDC rates

Notably, however, NIH has interpreted CAA 2026's provision requiring NIH to apply the IDC provisions in 45 C.F.R. Part 75 "to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017" as requiring the agency to rescind certain flexibilities adopted by NIH for new and competing renewal awards issued on or after October 1, 2024. On April 20, 2026, NIH issued a notice reverting to the "old" *de minimis* rate of 10% as set forth in the now rescinded HHS regulations at 45 C.F.R. Part 75. The *de minimis* IDC rate is a simplified methodology for calculating indirect costs available to entities that do not have a negotiated IDC rate. Under this methodology, indirect costs are calculated as a fixed percentage of the modified total direct costs (MTDC). Through the April 20, 2026 notice, NIH also reduced from $50,000 to $25,000 the portion of each subaward that may be included in the MTDC base for purposes of calculating indirect costs. The lower MTDC threshold reflects the indirect cost provisions in place prior to the April 2024 revisions to the Uniform Guidance and HHS's subsequent implementation of corresponding changes, with agency-specific modifications, at 45 C.F.R. Part 75. As

described in our October 2025 newsletter, effective October 1, 2025, HHS adopted the Uniform Guidance in full and rescinded 45 C.F.R. Part 75, such that NIH's April 20, 2026 notice applies IDC provisions set forth in regulations that no longer exist, despite the current Uniform Guidance provision at 2 C.F.R. § 200.414(f) that establishes a 15% *de minimis* IDC rate.

This NIH action demonstrates that while federal efforts to create across-the-board IDC rate caps may have stalled, agencies may reduce or constrain IDC reimbursement through other avenues. Another example comes from OMB's proposed revisions to the Uniform Guidance (described above). If adopted as proposed, federal agency reviewers of discretionary award applications would be directed to give preference to institutions with lower indirect cost rates, which could negatively affect the competitiveness of applications submitted by research institutions with higher negotiated indirect cost rates and essentially operate as a cap on indirect costs.

Transaction Trends

1. Early 2026 Brings Accelerated M&A Activity and Continued Portfolio Rationalization

The number of hospital transactions has surged in early 2026, but the deals look different than they did a year ago. Large systems are selling hospitals in markets where they lack scale, with more than two-thirds of the 22 transactions announced in Q1 2026 being divestitures. At least six additional deals were announced in early Q2. In 2025, financially distressed sales accounted for 43.5% of all hospital transactions. By Q1 2026, that figure dropped to 18%, and only one of the six deals announced in early Q2 involved a distressed seller. The divestitures now driving deal volume are not all sales in distressed situations. Instead, many of these transactions represent deliberate decisions by health systems to walk away from markets where they have been unable to achieve the scale needed to fund capital investment, pursue digital transformation, or compete effectively.

On the other side of the table, regional systems and academic medical centers are acquiring these assets as a platform for geographic growth. For example, in April UConn Health announced letters of intent with Day Kimball Hospital and Bristol Hospital, independent hospitals that have been struggling financially, to extend the academic medical center's reach into underserved communities.

As we noted in our February 2026 newsletter, hospital and health system transaction activity has been building since the second half of 2025, and the first four months of 2026 have confirmed that trajectory. Meanwhile, the anticipated health care spending reductions under the One Big Beautiful Bill Act, which could begin impacting Medicaid reimbursement as early as 2027, are compressing the timeline for independent systems weighing their options. Systems that are financially stable today but lack the reserves to weather a sustained reimbursement cut are choosing to partner now, while they still have leverage, rather than risk finding themselves in a distressed situation later.

2. AI Due Diligence in Hospital Transactions

The scope of AI adoption in the hospital sector is accelerating rapidly as health systems deploy AI solutions in a variety of ways, including reducing documentation burdens, implementing AI-driven revenue cycle automation, and incorporating clinical decision support tools across diagnostics and treatment pathways. As hospitals deploy AI across a variety of functions, acquirers, and hospitals and health systems invest in or partner with AI platforms, they should conduct careful diligence that intersects health care regulatory, data privacy, and intellectual property law.

Potential acquirers evaluating targets that deploy AI should assess whether the target maintains a formal AI governance framework, review the target's inventory of all AI tools and models in use, confirm whether clinical AI tools carry appropriate FDA clearance for their intended use, and confirm whether AI systems processing protected health information comply with HIPAA's Security Rule through appropriate administrative, physical, and technical safeguards. Acquirers should also conduct careful examination of contracts with AI vendors. Key provisions to evaluate include data ownership and use rights, performance warranties, and liability allocation. Similar considerations should be taken into account before investing in or partnering with AI companies.

The regulatory landscape adds an additional layer of complexity. In December 2025, President Trump signed an executive order directing federal agencies to challenge state AI laws deemed inconsistent with a "minimally burdensome national standard" for AI, and the Trump administration released a formal legislative framework in March 2026 recommending that Congress preempt state laws that "impose undue burdens," but no comprehensive federal legislation has followed. State legislatures, however, have continued to advance AI-specific regulation. In Texas, the Texas Responsible Artificial Intelligence Governance Act (HB 149), effective January 1, 2026, requires health care providers to inform patients whenever AI is used in any health care service or treatment, with disclosures that are "clear and conspicuous" and written in "plain language."

Colorado's AI Act (SB 26-189), was passed on May 9, 2026 and was signed by the governor on May 14, 2026. The law focuses on automated decision-making technology that processes personal data used to "materially influence" a "consequential decision," including generating predictions or recommendations. These laws represent only the beginning of a rapidly expanding patchwork of state-level AI regulation, requiring an acquirer to evaluate a target's AI compliance on a jurisdiction-by-jurisdiction basis.

For further detail on current AI activity, please see the "AI Topics in Health Care Reimbursement" section, above.

Latest on 340B

1. *HRSA Issues Request for Information on 340B Rebate Model*

As discussed in our prior newsletter, on February 5, 2026, HRSA ended the 340B Rebate Model Pilot Program, which would have allowed pharmaceutical companies to apply rebates to certain 340B-eligible medications rather than provide upfront discounts. The termination came in response to a lawsuit filed in the U.S. District Court for the District of Maine by the AHA and health systems seeking to enjoin the pilot program as unlawful under the APA. On appeal, the federal government stated in a filing that the agency planned to address the procedural deficiencies described in the district court's decision. The case was voluntarily dismissed on January 20, 2026. As a result, manufacturers already approved for participation in the pilot program are expected to continue to offer covered outpatient drugs at the 340B ceiling price as an upfront discount.

On February 17, 2026, HRSA published an RFI in the Federal Register to gather input on the potential use of rebates in the 340B Program, including standards and procedures governing manufacturer rebate model approval and stakeholder impacts. The RFI sought comments on costs to covered entities, payment timing and cash-flow impacts, rebate denials, data collection, program integrity, and manufacturer reporting to avoid duplicate discounts. HRSA stated that the agency is undertaking a "methodical and deliberate approach" to assess whether a rebate model is consistent with its statutory authority. Comments were due by March 19, 2026, and over 2,400 comments were submitted.

The RFI represents the next step in HRSA's reconsideration of the rebate approach. Hospitals and health systems should closely monitor HRSA's next steps as the agency reviews the comments received and determines whether to proceed with a revised rebate model.

2. *Federal Court Vacates HRSA's Child Site Registration Requirement*

On March 3, 2026, in response to a summary judgment request in litigation filed by more than 40 covered entity plaintiffs, the U.S. District Court for the District of Columbia vacated HRSA's requirement that hospital "child sites" – off-campus facilities operated by a covered entity – must be included on the hospital's Medicare cost report and register with the Office of Pharmacy Affairs Information System (OPAIS) *before* accessing 340B drug pricing.

In 1994, HRSA published guidance stating that a hospital's off-site outpatient facility was "an integral part" of the hospital and therefore eligible for 340B drug discounts if and when included on the hospital's Medicare cost report. Because a facility had to be listed on a filed hospital cost report and then included in the OPAIS covered-entities database in order to access 340B drug pricing, child sites could not access 340B pricing immediately upon beginning operations. In 2020, amid the COVID-19 pandemic, HRSA published guidance waiving the registration requirement. In October 2023, HRSA published a notice in the Federal Register ending the pandemic-era waiver. Shortly after the notice was published, plaintiffs filed suit challenging the registration requirement under the APA.

The district court held that the registration requirement constituted an eligibility condition not authorized by the 340B statute and that HRSA lacked general rulemaking authority to impose such conditions. The district court concluded that Congress specified that a covered entity (i) cannot claim a Medicaid rebate and a 340B discount on the same drug unit or transfer 340B drugs to non-patients and (ii) must permit audits by the HHS Secretary or manufacturers as the only conditions for 340B participation. As a result, the court vacated the 2023 notice. On April 28, 2026, HRSA appealed the decision to the U.S. Court of Appeals for the District of Columbia Circuit, where the case remains pending.

3. *Federal Court Vacates HRSA's Longtime Group Purchasing Organization Prohibition for 340B Hospitals*

On March 31, 2026, the U.S. District Court for the District of Columbia vacated HRSA's 2013 policy barring DSH hospitals from using a replenishment model. Under this model, the hospital purchases all drug inventory through a group purchasing organization (GPO) and, after dispensing the drugs, determines which prescriptions were filled for 340B-eligible patients and then places a replenishment order at the 340B price (not through the GPO). The court granted summary judgment to the GPO

plaintiff, Premier, Inc. (Premier), and denied the government's cross-motion for summary judgment.

In a 2013 policy, HRSA's Office of Pharmacy Affairs declared that the replenishment model violated the 340B statute, which bars DSHs from buying covered outpatient drugs through GPOs. The 2013 policy stated that any DSH using a GPO would be removed from the 340B Program and could be subject to repayment to manufacturers.

The district court held that HRSA offered "almost no reasoning" in the 2013 policy. According to the court, HRSA failed to explain why the statute prohibited the replenishment model, which does not explicitly address it. The court also found it significant that HRSA appeared to permit the replenishment model prior to 2013. Despite vacating the 2013 policy, the court stated that HRSA may, after properly assessing the replenishment model under the APA, adopt the same view that replenishment models violate the 340B statute.

4. *Ninth Circuit Holds FCA Claims Are Not Barred by Section 340B's Lack of a Private Right of Action*

On March 17, 2026, a panel of the U.S. Court of Appeals for the Ninth Circuit reversed and remanded the dismissal of a *qui tam* complaint brought by a covered entity, Adventist Health System of West (Adventist), under the FCA and state law analogues against multiple drug manufacturers, holding that the absence of a private right of action under the 340B statute did not bar FCA claims. Defendants sought rehearing *en banc* and the petition was denied on May 27, 2026.

Adventist alleged that the manufacturers charged inflated drug prices that did not reflect the statutorily required discount. Defendants moved to dismiss, arguing that *Astra USA, Inc. v. Santa Clara County* barred Adventist's claims. In *Astra*, the Supreme Court held that there was no private right of action under the 340B statute for covered entities to sue manufacturers for overcharging or to seek repayment.

The district court granted the motion, holding that Adventist's claims were "in essence" claims to enforce the 340B statute. The Ninth Circuit reversed the district court's dismissal, holding that Adventist sued as a relator on behalf of the government, not to enforce the 340B statute for its own behalf, making the FCA an independent vehicle for relief.

5. *AbbVie Challenges HRSA's 1996 Patient Definition as Overly Broad*

On April 8, 2026, AbbVie Inc. filed a complaint for declaratory and injunctive relief in the U.S. District Court for the District of Columbia against HRSA, challenging the agency's 1996 interpretation of the term "patient" under the 340B statute's anti-diversion provision. AbbVie alleges that HRSA's interpretation facilitates widespread program abuse by enabling covered entities to claim 340B discounts based on superficial encounters, including brief telehealth visits and referrals to non-covered entity providers.

The 340B statute prohibits a covered entity from transferring a 340B-discounted drug to a non-"patient." In 1996, HRSA issued guidance providing that an individual is a "patient" of a covered entity if: (i) the covered entity has established a relationship with the individual, such that the covered entity maintains health records of the individual's health care; (ii) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and (iii) the individual receives health care services from the covered entity consistent with the services for which grant funding or Federally Qualified Health Center (FQHC) look-alike status has been provided to the entity. DSHs are excluded from the final requirement.

AbbVie contends that HRSA's 1996 "patient" definition is not the best reading of the term under *Loper Bright* and that the definition undermines Congress's intent to ensure that manufacturers are obligated to provide steep discounts only in limited situations. AbbVie argues that "patient" requires: (i) the drug to be prescribed as a direct result of an encounter with a provider acting under an employment or contractual agreement with the covered entity; (ii) substantive medical care, meaning a health care encounter sufficient to meet clinical practice standards for diagnosing and treating the condition for which the drug is prescribed; (iii) the service to take place within 12 months of dispensing or administering the drug; (iv) the service to be consistent with grant funding or FQHC look-alike status, unless the entity is a DSH; and (v) direct provider oversight of the individual's care, meaning the health care professional is responsible for diagnosing and managing the patient's condition for which the drug is prescribed and the covered entity maintains primary responsibility for the patient's condition for which the drug is prescribed.

The lawsuit represents a direct challenge by a manufacturer to the definition that covered entities have relied upon for 30 years to determine 340B patient eligibility. If AbbVie succeeds in obtaining a narrower judicial interpretation of "patient," covered

entities could face a more restrictive standard for determining which prescriptions qualify for 340B pricing.

6. *Circuit Split Emerges on State Contract Pharmacy Litigation*

As discussed in our prior newsletters, states have enacted legislation requiring manufacturers to offer 340B pricing on products purchased for dispensing at contract pharmacies. Several stakeholders have challenged these laws in courts across the country.

Recent activity includes three circuit court decisions in two federal circuits.

- On February 9, 2026, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's grant of summary judgment for Louisiana, rejecting claims that Act 358 was preempted or unconstitutional. The court found it was bound by *AbbVie Inc. et al. v. Fitch*, which established that "Mississippi's materially indistinguishable law" regulated drug distribution—an area of traditional state police power—rather than drug pricing, costs, eligibility, or compliance, which are governed by the 340B statute. Therefore, the court held that Act 358 "regulates the distribution of drugs to patients and the role of pharmacies in this distribution—areas left free under the 340B Program for state supplementation." The court also rejected (i) the Takings Clause argument, finding that Act 358 imposes a non-interference obligation rather than a compelled property transfer; (ii) the Contracts Clause challenge, finding the 340B Pharmaceutical Pricing Agreements silent on delivery logistics and thus that the law does not alter the terms, rights, or obligations under the agreement; and (iii) the vagueness challenge, finding the term "interfere" in the statutory text sufficiently clear in statutory context. The case is pending two petitions for rehearing: a petition for panel rehearing filed February 23, 2026, and a petition for rehearing *en banc* filed March 25, 2026, respectively.
- On April 9, 2026, the Fifth Circuit also affirmed two additional rulings rejecting challenges from stakeholders to Mississippi's 340B contract pharmacy law. In both opinions, the court again held that it was bound by *AbbVie v. Fitch*. Accordingly, the court concluded that Mississippi's law was not preempted. On April 22, 2026, the manufacturer filed a petition for rehearing *en banc*, which the appellate court denied on May 5, 2026. In the second case, on April 15, 2026, the stakeholder filed an unopposed motion to extend the time to file a petition for rehearing. On April 16, 2026, the court granted the motion, extending the rehearing deadline for 14 days from the date the petition for rehearing is ruled on in the Fifth Circuit's case *AbbVie et al. v. Murrill*, discussed previously.
- On March 31, 2026, the U.S. Court of Appeals for the Fourth Circuit upheld a preliminary injunction against enforcement of West Virginia's S.B. 325. West Virginia's S.B. 325 barred manufacturers from interfering with the delivery of 340B drugs to pharmacies under contract with a 340B entity and prevented manufacturers from requiring covered entities to submit claims or utilization data. Manufacturers sued to enjoin the law, and the district court granted a preliminary injunction.

  The Fourth Circuit affirmed the preliminary injunction. The court described the 340B Program as a contractual bargain, pursuant to which Congress allows manufacturers to access the Medicaid market if they offer discounted drugs to safety-net providers. According to the court, West Virginia's law attempted to interfere with the federal bargain and would likely be preempted. The court added that Congress made HHS the sole enforcer of the 340B Program and that S.B. 325 granted the state attorney general and courts certain 340B-enforcement authority to determine whether there has been "any offer" under the 340B statute. Finally, the court determined that the state law frustrated manufacturer audits and the HHS-administered dispute resolution process, which rely on claims and utilization data. On April 14, 2026, the West Virginia Attorney General and other defendant-appellants filed a petition for rehearing *en banc*. On April 17, 2026, AHA and other nonprofit organizations representing covered entities filed an amicus brief in support of the request for an *en banc* review. The petition was granted on May 28, 2026.

With these latest circuit court decisions, a split in the circuits has emerged. The Fourth Circuit decision conflicts with decisions in the Fifth Circuit and Eighth Circuit (discussed in our previous newsletter), all of which considered similar laws, raising the prospect of Supreme Court review.

Relatedly, district courts also continue to grapple with the permissibility of these laws.

- Hawaii: On February 23, 2026, a federal district court denied AstraZeneca's request for a preliminary injunction against Hawaii's contract pharmacy law. The U.S. District Court for the District of Hawaii found that the law regulated drug delivery conditions, not pricing, so it did not conflict with federal law. The court noted that the presumption against preemption applied because the law addressed traditional state public health concerns. The court also rejected the manufacturer's patent preemption argument, reasoning that patent law protects the right to exclude competitors, not a right to maximize revenue in regulated markets. AstraZeneca has appealed this decision to the Ninth Circuit, where the case is ongoing. At the district court level, the case is proceeding on the merits.

- Washington: On March 25, 2026, Washington Governor Ferguson signed S.B. 5981, prohibiting manufacturers from restricting 340B pricing to contract pharmacies or conditioning access on claims data submission. In a lawsuit filed challenging the law, plaintiffs argued that the law is preempted because it regulates manufacturers' obligations under the 340B statute and frustrates Congress's intent by outlawing conduct allowed under federal law. They added that the law discriminates against manufacturers and regulates out-of-state transactions. On April 27, the DOJ filed a statement of interest arguing the law is preempted by federal law. DOJ argued that the law imposed additional burdens on manufacturers participating in the 340B Program, while nonparticipants remain unregulated, creating an incentive for manufacturers to withdraw from the 340B Program, Medicare, and Medicaid. On June 9, 2026, a federal district court denied the manufacturers' requests for a preliminary injunction against the Washington law. The U.S. District Court for the Western District of Washington found that the statute does not impose any additional obligations on manufacturers and that, instead, the statute just mandates that manufacturers deliver drugs to any pharmacy under contract with a covered entity without affirmatively imposing a change in the number of 340B transactions that are occurring with each covered entity. The court also found that the statute does not obstruct 340B audits; invite conflicting adjudications between state and federal law; impose novel penalties for the same conduct; or regulate out-of-state conduct. The manufacturers filed notices indicating that they will appeal the decision to the Ninth Circuit.

- North Dakota: On April 27, 2026, a federal district court entered summary judgment in favor of the stakeholders, finding that North Dakota's H.B. 1473 illegally interfered with the federal 340B drug-pricing regime. Specifically, the U.S. District Court for the District of North Dakota held that H.B. 1473 was not limited to drug delivery. Rather, it altered the conditions imposed on manufacturers under the 340B statute and imposed penalties that impermissibly interfered with the government-manufacturer relationship. The court added that the law impermissibly regulated out-of-state transactions between manufacturers and wholesalers. The case is on appeal to the Eighth Circuit.

7. *Drug Manufacturers Expand Claims-Level Data Requirements to In-House Pharmacies; AHA Urges HRSA Enforcement Action*

Lilly and Novo Nordisk have separately announced policies requiring covered entities to submit claims-level data for all 340B drug dispenses, including those through in-house pharmacies. Previously, such policies were limited to contract pharmacy arrangements. In response to these policies, AHA is urging HRSA to take enforcement action against the manufacturers.

- On January 15, 2026, Lilly announced its revised policy. Lilly stated that the policy was intended to ensure 340B prices were not "exploited by hospitals and their for-profit partners." Effective February 1, 2026, Lilly's policy dictates that data must be submitted within 45 days of product dispensing for most products, or within 60 days for certain specified products.

- On January 26, 2026, AHA urged HRSA to take immediate action to stop Lilly's policy from taking effect, including by assessing civil monetary penalties. Specifically, AHA argued that the policy would "vastly increase the costs and burdens on 340B hospitals" because, unlike contract pharmacy data, data for in-house dispenses are often spread across multiple recordkeeping systems, and hospitals do not currently submit medical claims data to any 340B vendor.

- On January 27, 2026, Lilly wrote a letter to HRSA, in response to AHA's letter, arguing that its policy does

not impose any new burdens on covered entities and is consistent with the 340B statute.

- Separately, on March 2, 2026, Novo Nordisk announced a similar policy, effective April 1, 2026. Under the new Novo Nordisk policy, failure to submit claims-level data within 45 days of the date of dispensing may result in suspension of access to 340B pricing.
- On March 3, 2026, following Novo Nordisk's announcement, AHA again wrote to HRSA, calling on the agency to take "immediate enforcement action, including the use of civil monetary penalties, against both Lilly and Novo."
- On April 27, 2026, the AHA urged HRSA once more to take enforcement action against these policies, stating that manufacturers were blocking access to "statutorily owed" 340B pricing. The AHA provided a copy of a letter from Lilly to covered entities, warning providers of the imminent loss of 340B pricing for Lilly's products unless hospitals complied with Lilly's new policy.
- On May 13, 2026, AHA wrote directly to Lilly, urging the company to drop its January 2026 claims-data policy and proposing a neutral, third-party clearinghouse as an alternative.

The dispute remains ongoing and the disputed policies remain in effect.

8. Sagebrush 340B Eligibility Litigation Continues

Litigation involving the 340B Program eligibility of certain clinics continues. On April 27, 2026, the U.S. District Court for the District of Columbia sided with HRSA on all issues raised by Sagebrush Health Services (Sagebrush). As discussed in our prior newsletters, HRSA investigated Sagebrush, an operator of 340B-enrolled clinics, and determined that Sagebrush's clinics were not 340B-eligible. HRSA disenrolled the clinics between annual recertifications and directed Sagebrush to repay manufacturers for improperly received discounts. Sagebrush sued, challenging HRSA's statutory authority and procedures.

In the recent decision, the district court held that HRSA had statutory authority to remove ineligible clinics between annual recertifications, stating that, when Congress authorizes an agency to make a decision, the legislature implicitly authorizes the agency to reconsider that decision. According to the court, reconsidering a prior certification is not a new recertification subject to the annual-frequency limitation because the reconsideration looks backward at eligibility at the time of the original decision. Next, the court found that HRSA adequately explained its differential treatment of Sagebrush's clinics. HRSA contended that it asked Sagebrush to provide documentation proving its clinics' eligibility, and Sagebrush provided sufficient documentation for its eligible clinic, but insufficient documentation for the clinics that HRSA found ineligible. The court stated that HRSA's differential treatment was based on the difference in documentation. Finally, the court declined to vacate HRSA's repayment statements because they did not impose binding legal consequences, as HRSA later reenrolled clinics without requiring payment.

Separately, as discussed in the prior newsletter, Sagebrush filed a complaint against Amgen in California state court for cutting off 340B sales to its Nevada clinics and clawing back more than $7 million in 340B discounts Sagebrush had realized through wholesalers. Amgen removed the action to federal court on January 16, 2026. On April 15, 2026, the federal court dismissed Sagebrush's lawsuit, holding its state law claims were barred under *Astra*. The court reasoned that although Sagebrush's claims were styled as California state law causes of action, they were an attempt to enforce Sagebrush's right to purchase drugs at the 340B price. The case is pending appeal before the Ninth Circuit.

Relatedly, as also mentioned in our prior newsletter, Amgen, Eli Lilly, and UCB sued HRSA for failure to oversee the 340B Program by allowing ineligible Sagebrush clinics to participate. Community Care Resources of Florida, a certified 340B clinic, joined as an intervenor on HRSA's side. On March 20, 2026, the plaintiffs filed for summary judgment, arguing that HRSA unlawfully certified and recertified Sagebrush clinics as 340B-eligible STD grantees and never developed the statutorily mandated certification process or published criteria for manufacturers. On April 24, 2026, HRSA filed a cross-motion for summary judgment, arguing that HRSA has established certification procedures since 1993. Community Care Resources of Florida filed a cross-motion the same day, arguing, in part, that the manufacturers' claims were time-barred and that the plaintiffs failed to exhaust mandatory administrative remedies. The case remains ongoing.

9. Program Efficiency and Integrity Information Collection Request Update

As discussed in our prior newsletter, on August 7, 2025, HRSA published a notice in the Federal Register announcing its intent to submit to the OMB a revised Information Collection Request

(ICR) for the 340B Program. HRSA's proposed changes included clearer address fields, documentation requirements for Sexually Transmitted Disease /Tuberculosis (STD/TB) grantees, time-period data for Family Planning entities, collection of Tribal Agreement numbers for certain entities, and alignment of hospital fields with CMS terminology.

On January 8, 2026, HRSA published a notice summarizing the public comments received and opening a 30-day window for further input. In the public comments, covered entities disagreed that shipping addresses required additional clarification, small and community-based STD clinics expressed concern that the proposed documentation requirements would strain administrative staff and funding, and other commenters argued that the modified trial balance requirements could lead to inappropriate termination of 340B Program registrations.

On January 12, 2026, HRSA submitted the revised ICR to OMB's Office of Information and Regulatory Affairs (OIRA), where the comment period on OIRA's review has closed. The revised ICR remains pending OMB/OIRA review. The current OMB approval is set to expire on May 31, 2026.

LOOKING AHEAD

On Tuesday, June 30, Ropes & Gray will host a networking reception during the AHLA 2026 Annual Meeting. For more information on the event, please contact Marnine.Wilensky@ropesgray.com.

Ropes & Gray attorneys will speak at the National Association of College & University Attorneys (NACUA) Annual Conference, June 29 through July 2. For registration information, visit the NACUA website.

- Stephen Sencer will present on Title VI Compliance
- Leslie Thornton will present on Federal Research Funding

Ropes & Gray is sponsoring the IPMI Healthcare Law & Compliance Institute, October 4 through 6. For registration information, visit the IPMI website.

- Torrey McClary and Jane Willis will present "Navigating State Health Care Transaction Approvals, Federal Antitrust Enforcement, and Community Engagement Processes"
- Leslie Thornton will present "Navigating the New Realities of Federal Research Funding and its Evolving Compliance Landscape"

Ropes & Gray is sponsoring the Consero Healthcare General Counsel Fall Forum, October 11 through 13, 2026. For registration information, visit the Consero website.

- Christina Bergeron will present "Navigating the Regulatory Maze: Managing Successful Healthcare Transactions"

WHAT HAVE OUR HOSPITAL & HEALTH SYSTEM LAWYERS BEEN UP TO?

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

Publications

- FFY 2027 IPPS and LTCH Proposed Rules
- CMS Home Health and Hospice Moratoria Update: Emerging Guidance and Enforcement Update
- Connecticut Enacts Sweeping AI Law Covering Employment, Healthcare, and Online Safety
- OMB Proposed Revisions to the Uniform Guidance: Key Takeaways for Award Recipient Organizations
- Colorado Scales Back AI Law, with Targeted Implications for Health Care
- CMS Announces Nationwide Moratoria on Hospice and Home Health Agency Medicare Enrollments - Key FAQs for Hospice Providers and Home Health Agencies
- The White House Legislative Recommendations: National Policy Framework for Artificial Intelligence and Federal Preemption of State AI Laws
- Examining the Landscape and Limitations of the Federal Push to Override State AI Regulation
- Navigating Healthcare M&A in 2026: Advancing Deal Execution Through Regulatory Strategy
- Paging Dr. Algorithm: Navigating the Regulatory Landscape for Agentic AI in the Healthcare Industry
- The HHS Office of Inspector General Speaks: Direct-to-Consumer Discount Drug Programs under the Federal Anti-Kickback Statute

Podcasts

- AHLA "Speaking of Health Law" - Agentic AI in Health Care: Regulatory Uncertainty, Federal Preemption, and Governance Strategies

Trending Videos

- Medicaid Cuts and 2026 Healthcare Market Effects

Webinars and Speaking Engagements

- Brett Friedman presented "How AI Technology Can Improve Health Care Outcomes and Affordability" (FirstMark Venture Capital Presentation | June 5, 2026)
- Mark Barnes, Stephen Sencer, and Leslie Thornton presented "OMB's Proposed Overhaul of the Uniform Guidance: What Federal Award Recipients Need to Know" (Ropes & Gray Webinar | June 2, 2026)
- Brett Friedman presented "Examining Payor-Provider Risks and Opportunities – from Coding and Care Management to Documentation and Prior Authorization" (ACI Healthcare AI Summit Presentation | February 27, 2026)
- Christine Moundas presented "From Design to Deployment: Cybersecurity Best Practices for Healthcare AI" (ACI Healthcare AI Summit Presentation | February 26, 2026)

Website on Health Care Transaction Regulatory Developments

Ropes & Gray continues to track real-time updates on state health care transaction laws related to competition, quality, access, cost and more, through its RG HealthTrax tool.

The Providers Deploying AI Atlas includes examples and requirements for health care professionals, hospitals, health systems, clinics, managed service organizations and telehealth providers creating AI solutions.

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