ROPES & GRAY

Hospital and Health Systems Reimbursement Check

February 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.

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Focus On

$50 BILLION TO BECOME AVAILABLE FOR RURAL HEALTH TRANSFORMATION

Executive Summary

In 2026, each state will receive a federal award through the Rural Health Transformation ("RHT") Program, a five-year program authorized by Congress in 2025. To receive federal awards, states late last year applied to the Centers for Medicare & Medicaid Services ("CMS") with proposed initiatives across 11 different categories including provider payments, workforce recruiting in rural communities, information technology ("IT") advances, and innovative models of care. On December 29, 2025, CMS announced states' awards for fiscal year 2026, which range from $147 million for New Jersey to $281 million for Texas. To determine what state-level funding opportunities are available for providers, hospitals and health systems should begin by reviewing their state's application to CMS to understand the proposed initiatives and eligibility requirements, then monitor for official requests for proposals, consider joining or forming regional collaboratives, and prepare tailored application materials.

The Rural Health Transformation Program

The 50 states will be awarded a total of $50 billion to strengthen rural health through the RHT Program, as statutorily authorized by the "One Big Beautiful Bill Act" ("OBBBA") in July 2025. Pub. L. No. 119-21 § 71401, 139 Stat. 327. Through the OBBBA, Congress appropriated $50 billion to CMS to fund the RHT Program over the next five years ($10 billion per year), starting in Federal Fiscal Year ("FFY") 2026. 42 U.S.C. § 1397ee(h)(1)(A).

As part of the states' applications for an RHT Program award, they were required to submit rural health transformation plans to CMS by November 5, 2025. The statute required that states detail in their plans how they intended to improve access to hospitals and health care for rural residents, prioritize new technology and data solutions, forge regional strategic partnerships between rural hospitals and other health care providers, enhance recruitment of health care workers, and manage rural hospitals' financial solvency. *See* 42 U.S.C. § 1397ee(h)(2)(A). Full state applications are available through the states' websites, but CMS also summarized each application's key initiatives. While only states were eligible as primary recipients of the awards, states can now "sub-award or contract RHT Program funds" to "partners like universities, local health departments, community-based organizations, and provider associations in designing and implementing the planned activities proposed in your application[.]" CMS-RHT-26-001 at 8.

Although Congress did not define "rural" in the statute as it applies to allowable uses of the funds, the term "rural health facility" was defined in the statute for purposes of allocating funding among the states. 42 U.S.C. § 1397ee(h)(3)(D). To determine state allotments, CMS was required to consider "the proportion of rural health facilities . . . in the State relative to the number of rural health facilities nationwide[.]" 42 U.S.C. § 1397ee(h)(3)(C)(ii). For this purpose, the statute defines a "rural health facility" to include, among other things, an acute care hospital that is "located in a rural area" or that is "treated as being located in a rural area" following a reclassification from urban to rural under section 1886(d)(8)(E) of the Social Security Act. 42 U.S.C. § 1397ee(h)(3)(D)(i).

While the statute did not dictate precise eligibility rules for subawards of RHT funds, Congress required that states use RHT funds for at least three of the health-related activities listed in the statute, including, e.g., "[p]roviding payments to health care providers for the provision of health care items or services," "[p]roviding training and technical assistance for the development and adoption of technology-enabled solutions that improve care delivery in rural hospitals," and "[r]ecruiting and retaining clinical workforce talent to rural areas[.]" 42 U.S.C. § 1397ee(h)(6). In its Notice of Funding Opportunity ("NOFO") posted September 15, 2025, CMS specified two additional uses for which states could spend RHT Program funding: (1) "[i]nvesting in existing rural health care facility buildings and infrastructure," and (2) "strengthening local and regional strategic partnerships between rural facilities and other health care providers[.]" CMS-RHT-26-001 at 12. As a requirement for award approval, states' applications needed to "reflect that [the state] will use awarded funds to invest in at least three of these permissible uses[.]" CMS-RHT-26-001 at 11. In the NOFO, CMS details certain unallowable costs under the RHT program, including funding for provider payments for the provision of health care items or services that exceed 15% of total funds, or funding to replace an electronic medical record system that exceeds 5% of total funds, among other limitations. CMS-RHT-26-001 at 19–20.

State Allocations

On December 29, 2025, CMS announced the awards for fiscal year 2026, averaging $200 million. To allocate the appropriated funding ($10 billion for 2026) among the states, as required by the statute, first, CMS split half the funding ($5 billion) equally among all states as "Baseline funding." CMS-RHT-26-001 at 13. CMS will distribute the remaining $5 billion, or "Workload funding," based on state rural population data. For example, CMS considered data such as the percentile ranking of the size of a state's rural population, the proportion of rural health facilities in the state, the percentage of uncompensated care in the state, the percentage of hospitals in a state that receive Medicaid Disproportionate Share Hospital ("DSH") payments, and the percentage of the state's population located in a rural area. In addition to this data, CMS also scored states based on qualitative assessments of the proposed initiatives, and any existing or proposed state policies that CMS believes would enhance program-related initiatives. *Id.* For example, CMS would award more points if the state participates in licensure compacts (like the Interstate Medical Licensure Compact) (which "increase the supply of accessible rural health providers."); or if the state had a Restriction Waiver in place "prohibiting the purchase of non-nutritious items in SNAP" (which CMS claims "can help improve dietary intake and clinical indicators associated with long-term disease in rural populations."). CMS-RHT-26-001 at 76–77, 83–87. States submitted a one-time application for an RHT Program award, but CMS will recalculate individual states' funding amounts annually, based on data provided through annual reporting. CMS-RHT-26-001 at 14.

To the extent states had already selected specific subrecipients or types of potential subrecipients of their awards, those were included in one-page project summaries. CMS-RHT-26-001 at 27. Some states expressed that subrecipients would be determined through competitive procurement processes. Other states shared they expect subrecipients to include health care providers, hospitals, rural hospitals, clinics, Federally Qualified Health Centers ("FQHCs"), and local community organizations. Finally, a few states specified named subrecipients (e.g., Delaware named several health systems as known partner organizations, and some hospital associations have been named subrecipients, including the Hospital Association of Rhode Island, Nebraska Hospital Association, and Washington State Hospital Association).

States are currently in the early stages of communicating how they will allocate funding to carry out initiatives. For example, in Illinois, [s]taff planning and implementation are underway[,]" and in Michigan, "a [Grant Funding Opportunity] will soon be released to support RHT efforts. Details about eligibility, timelines, and application requirements will be shared once the GFO is published." Some states may have more information available – such as Georgia, where the Department of Community Health provides a list of the value-based care model eligible hospitals. If the state's awarded funding from CMS differs from the state's requested funding amounts, states may

also need to make adjustments at this time – for instance, Washington State's next step is "to revise the budget to account for the difference" between the award received and the funding requested.

While the federal statute does not limit funding to only providers that are located in rural areas, some states have proposed conditioning subaward funding on being located in a "rural area" as they define it, and other states may impose similar conditions as more details are released about eligibility for potential funding. Notable examples of states that propose to condition funding on being located in a "rural area" include Virginia, for which subrecipients "should be located in rural counties as defined by [the Federal Office of Rural Health Policy (FORHP)], or they must demonstrate that the project being funded will effectively target residents of rural counties." Virginia's Project Narrative at 9. In Indiana, each proposed initiative specifies the impacted communities. Some initiatives will impact all counties, some will prioritize rural counties, and for one Indiana initiative, "[a]ll funded activities must be implemented in rural areas as defined by FORHP/[Health Resources and Services Administration ("HRSA")] rural designation criteria." Indiana's Project Narrative at 9–42.

Next Steps

As an initial step, hospitals and health systems should review their state's applications (also called "project narratives") for details about proposed initiatives, eligibility for potential funding opportunities, and states' implementation plans and timelines. The Rural Health Information Hub contains a resource list of all the states' applications to CMS or state websites relevant to the RHT Program. Hospitals should remain apprised of any updates from relevant agencies and grant websites in their states regarding requests for applications or proposals for subawards to providers. Michigan and Minnesota offer listservs providing news about the RHT Program. And Arkansas's application advises that "[f]unding opportunities will be announced through state and local channels to ensure that all eligible entities are informed[.]"

Many states' applications to CMS lay out proposed implementation timelines. For example, Florida's application proposes a timeline (discussed below) for submitting applications for subawards . Texas's application details target completions by fiscal year quarters for each initiative and explains that applicants will be assessed "based on a pre-determined scoring process." Indiana's application provides a regional grant application timeline (with March 2026 set as the target date for a RFA to be released to the public).

Washington's application indicates the state plans to post requests for proposal in Q1 2026, while other states provide more high-level sequencing with forthcoming updates expected, and all are subject to change as states finalize procurements. Hospitals should monitor their state's website for requests for proposals or applications, which will likely provide details on application requirements and deadlines, as well as potential procedures for requesting deadline extensions or contesting subaward determinations.

While states are still in the early stages of determining subawards, hospitals and health systems might consider taking the following steps now:

1. First, join or form the right consortium. Several states will prefer awards to hospital-anchored or regional collaboratives (i.e., formal groups of rural providers, such as hospitals, FQHCs, Rural Health Clinics ("RHCs"), practitioners, EMS, and community organizations that pool resources, coordinate planning, and submit a single unified proposal on behalf of their region). As examples, Florida will only accept applications from regional collaboratives within four "Super Regions[,]" Florida's Project Narrative, Budget Narrative at 2. New York will use provider-led partnership networks with a rolling application process after finalizing eligibility criteria, New York's Project Narrative at 45, and Texas will run multiple competitive procurements that award at least one applicant per rural county and may require oral presentations when counties have multiple applicants, Texas's Project Narrative at 40–41.

2. Second, consider framing subaward funding requests around value-based payment models. Florida explicitly links investments to enabling rural providers to participate in value-based Medicaid models and integrated Medicare-Medicaid arrangements, Florida's Project Narrative at 15. New York will support practices with care-coordination tools (such as Patient-Centered Medical Home certification and artificial intelligence ("AI") support), fund regional provider networks, and distribute savings from reduced hospitalizations among network partners, New York's Project Narrative at 15. Rhode Island will pay hospitals and primary care practices incentive payments for alternative payment model ("APM") reporting and then performance, aligned with approved advanced APMs, Rhode Island's Project Narrative at 37. Massachusetts ties investments to expanding rural provider participation in MassHealth Accountable Care Organization ("ACO") and managed care arrangements, with payment incentives and technical

assistance to support the transition, Massachusetts's Project Narrative at 21.

3. Third, prepare and tailor an application "core kit". Such a kit should include a needs assessment, initiative alignment, staffing, sustainability, and data/reporting, tailored to each target state's subaward process and published guidelines. For example, Florida has proposed an RFA calendar, with a scheduled release date of January 28, 2026, and applications due March 20, (which will require detailed plans, attestations, and budgets from regional collaboratives) with awards scheduled, tentatively, to be posted April 21, Florida's Project Narrative at 49. Texas lays out separate five-stage implementation timelines for each of its initiatives (such as technology and workforce), with competitive procurement processes and scoring criteria for each. And technology-focused awards will go to provider networks where at least 60% of members are rural, while workforce awards use county-level competitions, Texas's Project Narrative at 22–54. New York's provider-anchored partnership networks will finalize eligibility, launch rolling applications, and select Round 1 awards in FFY 26, so hospitals should consider assembling partner rosters and priority service lines now, New York's Project Narrative at 18–19, 45.

Conclusion

The RHT Program represents a historic federal investment in rural health infrastructure, and with the announcement of funding awards to the states at the end of last year, the window for hospitals and health systems to position themselves for subaward funding is now open. With $10 billion allocated for each of the next five years, states are now actively developing their procurement and distribution processes. Providers that act promptly—by reviewing state project narratives, establishing or joining regional collaboratives, and preparing tailored application materials—will be best positioned to secure funding. As implementation timelines vary significantly across states and are subject to change, close monitoring of state agency communications and official grant announcements will be essential. Providers with questions about RHT Program eligibility, application strategy, or subaward compliance should consult with experienced health care regulatory counsel.

Docket Updates

1. Briefing on Remedy in Challenge to 2023 DSH Part C Days Rule

In *Montefiore Medical Center v. Kennedy*, No. 24-cv-1810 (D.D.C. 2024), the parties recently filed their opening briefs on the issue of the appropriate remedy in light of the district court's grant of plaintiff hospital's motion for summary judgment. *Montefiore* is the lead case challenging CMS's 2023 retroactive Medicare DSH Part C days final rule. On September 30, 2025, the U.S. District Court for the District of Columbia ("D.C. district court) ruled in favor of the plaintiff, holding that the 2023 rule was impermissibly retroactive and arbitrary and capricious. *See* October 2025 Docket Updates. The court deferred ruling on the appropriate remedy for these legal violations and ordered the parties to file supplemental briefs on that issue.

The opening supplemental brief, filed on December 22, 2025, argues that then D.C. district court should vacate (i.e., set aside) the unlawful 2023 rule as to all hospitals and specifically instruct the agency to recalculate the Medicare DSH payment with interest. Vacatur is the ordinary remedy for unlawful action under the Administrative Procedure Act ("APA"), and plaintiff argues it is warranted in this case due to the seriousness of the challenged rule's flaws and the lack of disruption that would be caused by vacatur, as evidenced by the vacatur of past actions in cases challenging prior attempts by the agency to enact its Part C days policy. The plaintiff further argues that the agency's decades of obfuscation on the Part C days issue justify the extraordinary remedy of specific instructions on how the agency should move forward.

In its supplemental brief, the government argues that the court should not vacate the unlawful rule or issue specific instructions. Although the government concedes the availability of vacatur under existing precedent, it argues that the APA does not authorize courts to vacate rules at all. It further argues that the case does not present the type of extraordinary circumstances required for specific instructions because the agency has followed past court orders and may have alternative means for counting Part C days in the DSH fraction on remand without further rulemaking.

Briefing is currently scheduled to conclude with Plaintiff's supplemental reply brief, which is due February 23, 2026.

2. Fifth Circuit Finds No Jurisdiction over Challenge to 2024 Rule Excluding Uncompensated Care Pool Waiver Days from DSH Calculation

On December 9, 2025, in a significant jurisdictional ruling, the United States Court of Appeals for the Fifth Circuit ("Fifth Circuit") decided *Baylor All Saints Medical Center v. Kennedy*, 161 F.4th 298 (5th Cir. 2025), reversing and remanding the judgment of the U.S. District Court for the Northern District of Texas ("Northern District of Texas") that had vacated provisions of the FY 2024 Inpatient Prospective Payment System ("IPPS")

final rule governing the exclusion of hospital days for patients whose care is provided through uncompensated care pools under a section 1115 waiver from the count of Medicaid-eligible days used to determine DSH payments. *See* March 2025 Docket Updates for further details. This case reached the Fifth Circuit on appeal after the Northern District of Texas reached the merits of the case, granted summary judgment, and vacated the rule in question.

In its opinion, the Fifth Circuit held that it did not have jurisdiction to hear the case under 42 U.S.C. § 1395oo(a)(1)(A)(ii) because the plaintiff hospitals did not properly present their claims before the agency. Although the plaintiff hospitals had appealed the lawfulness of the regulation to the Provider Reimbursement Review Board ("PRRB"), the PRRB dismissed the appeal on jurisdictional grounds, reasoning that the rule did not constitute a final determination on a hospital's payment amount that is appealable to the PRRB. In its ruling, the Fifth Circuit reversed the district court and agreed with the PRRB's jurisdictional ruling, holding that the plaintiffs had not satisfied the Medicare statute's presentment requirement, which in the court's view, cannot occur until "a hospital submits its cost report" to a Medicare contractor. The Fifth Circuit rejected the plaintiffs' alternative argument that the Medicare channeling requirement was "inapplicable" because the claim arose under the Public Health Services Act as opposed to the Medicare statute, reasoning that the Medicare Act provided both the standing and substantive basis for the claims. It also rejected the argument that the exception to Medicare channeling recognized in *Shalala v. Illinois Council on Long Term Care, Inc.* (529 U.S. 1 (2000) applies because the hospitals were not completely precluded from challenging the rule after presenting a claim and exhausting the administrative process. The Fifth Circuit did not address the merits of the plaintiffs' challenge.

The Fifth Circuit's decision in *Baylor* relies upon *Battle Creek Health System v. Kennedy,* 151 F.4th 464, 465 (D.C. Cir. 2025), in which the U.S. Court of Appeals for the D.C. Circuit ("D.C. Circuit") held that the PRRB properly dismissed for a lack of jurisdiction a challenge brought directly to the DSH Supplemental Security Income fractions for FFY 2007. *See* October 2025 Docket Updates for more on the *Battle Creek* decision. Though focused on a direct challenge to published DSH fractions rather than a direct challenge to a regulation, the D.C. Circuit in *Battle Creek* endorsed a similar rationale as the Fifth Circuit in *Baylor*. In *Battle Creek*, the D.C. Circuit found that, for retrospective adjustments such as DSH payments, a final determination does not occur until the contractor issues a Notice of Program Reimbursement ("NPR") and thus, hospitals must wait until issuance of an NPR to challenge the amount of a DSH payment.

The Fifth Circuit's mandate in *Baylor*, issued on January 30, 2026, has the effect of reinstating the previously vacated rule. As no court has yet addressed the merits of the agency's exclusion of section 1115 uncompensated care pool days, there will be continued litigation on this issue. Indeed, a hospital recently filed a substantively similar challenge as in *Baylor* in the Northern District of Texas, in a case that does not involve the same jurisdictional issues because it reached the court on a grant of expedited judicial review from the PRRB after the contractor's failure to issue an NPR within a year of the cost report's filing. *Covenant Medical Center v. Kennedy*, 4:26-cv-77 (N.D. Tex. 2026).

3. Emergency Litigation Filed against Change to Payment for Skin Substitutes under the Physician Fee Schedule

The CAMPs Initiative, a Texas-based organization that represents manufacturers and suppliers of advanced skin substitute products, recently filed suit in the Northern District of Texas (Fort Worth Division) to challenge the portion of the 2026 Physician Fee Schedule ("PFS") that caps payments for those products. *The CAMPs Initiative v. Dep't of Health and Human Servs.*, 4:26-cv-99 (N.D. Tex. 2026). The PFS changes CMS's longstanding approach of treating skin substitutes as biologicals and paying for them based on the Average Sales Price ("ASP") by reclassifying such products as "incident-to" supplies, which according to the CAMPs Initiative, will result in a 90% reduction in payments for these products. The CAMPs Initiative argues that the reclassification of skin substitutes violates the Medicare statute because these products satisfy the statutory definition of biologicals and thus must be paid for based on the ASP. Plaintiff further argues that the move violates the statute's budget neutrality requirement because CMS has not yet made cuts to other payments to account for the increased payments that result from adding skin substitutes under the PFS and that the move is otherwise arbitrary and capricious.

The CAMPs Initiative seeks an immediate nationwide stay of the effective date of the Rule under section 705 of the APA or, in the alternative, a nationwide preliminary injunction. The case is currently pending before Judge Reed O'Connor, who has set a briefing schedule under which the parties will complete briefing on the plaintiff's pending motion for a stay or preliminary injunction by February 24, 2026. Defendants have indicated they will also move to dismiss the complaint for lack of subject matter jurisdiction.

4. Challenges to IPPS Standardized Amount Set to Return to PRRB While Government Motions for Voluntary Remand in Similar Cases

Following clarification from the D.C. district court that its decision in the plaintiffs' favor was limited to confirming that their challenge to budget-neutrality adjustments was not precluded from review, the 50 hospitals and health systems in *St. Mary's Regional Medical Center v. Kennedy*, No. 23-cv-1594 (D.D.C.) are moving closer toward a remand of the dispute to the PRRB. The dispute in *St. Mary's* centers on a challenge to CMS's alleged understatement of the 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 district court held that the Medicare statute does not preclude administrative or judicial review of the challenge to the standardized amount calculation. *See* March 2025 Docket Updates.

In January 2025, the government filed a motion asking the court to clarify or reconsider its decision. In particular, the government sought confirmation that the court ruled only on the specific jurisdictional issue relating to the preclusion of judicial or administrative review for budget-neutrality adjustments—not any other jurisdictional issues or the merits of the claims, which would be at issue in future proceedings. In September 2025, the district court granted the motion to clarify, explaining that the ruling only reached the issue of jurisdiction and discussion implicating other issues "should be understood only as dicta." On January 26, 2025, the Office of the Attorney Advisor for the CMS Administrator issued an order that vacated the PRRB's jurisdictional denial of plaintiffs' administrative appeals and ordered the PRRB to reinstate the administrative appeals and resume proceedings in accordance with the district court's rulings. Although the government did not appeal the jurisdictional decision in *St. Mary's*, its motion for clarification suggests that, upon remand, the government may seek a jurisdictional dismissal on other grounds or contest the merits of the hospitals' claims.

Following the clarification order in *St. Mary's*, the D.C. district court has granted the government's motions for voluntary remand in two related cases that were stayed pending further proceedings in *St. Mary's*: *Adena Regional Medical Center v. Becerra*, No. 1:24-cv-03336 (D.D.C. 2024) and *New York City Health and Hospitals Corp. v. Becerra*, No. 1:24-cv-01302 (D.D.C. 2024). Because *Adena* and *New York City Health* raise similar issues to *St. Mary's*, it is possible that the government may pursue jurisdictional and merits arguments upon remand in these cases, too. Thus, the battle of over alleged carried-forward errors in the 1983 IPPS rule looks poised to continue before the PRRB.

5. PRRB Continues Applying "Fixed-Fixed" Methodology for Recalculations of Volume Decrease Adjustment Payments in the Wake of Lake Region

The PRRB continues to actively issue decisions in appeals requesting recalculation of volume decrease adjustment ("VDA") payments. VDAs are payment adjustments designed to compensate for large decreases in patient admissions, which often affect small and rural health care facilities. In November 2025, the PRRB remanded four appeals to Medicare Administrative Contractors ("MACs") to recalculate providers' VDA payments using the "fixed-fixed" methodology, which looks to the difference between fixed costs for treating Medicare patients and an estimate of the portion of diagnosis-related group ("DRG") payments that compensate for those fixed costs. The remands relied on the D.C. Circuit's September 2024 decision in *Lake Region Healthcare Corp. v. Becerra*, No. 22-cv-5318. In that case, the D.C. Circuit held that the agency's use of a "fixed-total" approach, which looks to the difference between the fixed costs and total DRG payments, "overstates the amount of a hospital's reimbursed fixed costs and thus understates the amount of its unreimbursed fixed costs, shortchanging the hospitals." Since the *Lake Region* decision, the PRRB has continued to issue VDA decisions applying the Board's 'fixed-fixed' methodology for cost reporting periods before October 1, 2017. *See* July 2025 Docket Updates.

6. Further Developments on HHS Workforce Reductions

Federal courts continue to consider challenges to the Trump Administration's efforts to significantly reduce the HHS workforce. Recent court rulings and agency policy actions further clarified the limits of these efforts, even as related litigation remains pending in multiple jurisdictions.

On September 13, 2025, the U.S. District Court for the Northern District of California issued a permanent injunction in *AFSCME, AFL-CIO v. OMB*, No. 3:25-cv-1780 (N.D. Cal. 2025), blocking terminations of thousands of probationary employees from HHS and several other agencies. The government defendants did not appeal the judgment.

Further, recent agency action has altered the course of litigation challenging reductions-in-force ("RIFs") at the National Institute for Occupational Safety and Health ("NIOSH"). In January 2026, courts in both *National Nurses United v. Kennedy*, No. 1:25-cv-1538 (D.D.C. 2025) and *Wiley v. Kennedy*, 2:25-cv-227 (S.D.W. Va. 2025) granted motions to hold the cases in abeyance

following HHS's reinstatement of all previously terminated NIOSH employees. In each case, the district court directed the parties to submit a joint status report in March 2026 addressing the status of the NIOSH workforce and proposing a path toward resolution.

Other challenges to HHS restructuring efforts remain ongoing. In *New York v. Kennedy*, No. 1:25-cv-196 (D.R.I. 2025), litigation continues over HHS's planned RIFs and restructuring, with a preliminary injunction discussed in the July 2025 Docket Updates still in place. In *Jackson v. Kennedy*, No. 1:25-cv-1750 (D.D.C. 2025), the D.C. district court has allowed former HHS employees to continue pursuing claims that several agencies acted unlawfully in initiating RIFs in April 2025, but dismissed duplicative claims against individual officials.

These developments reflect continued judicial scrutiny of HHS workforce reductions. As litigation proceeds, substantial changes to HHS's workforce and organizational structure could affect the operation and oversight of federal programs on which hospitals and health systems depend.

7. 340B Litigation Heats Up: Appeal on Rebate Pilot Terminated, Split Contract Pharmacy Rulings, and Continuing Sagebrush Dispute

340B litigation is accelerating on a number of fronts. As detailed below in the 340B Updates section of this newsletter, the Health Resources and Services Administration ("HRSA") has ended its appeal in the lawsuit challenging its rebate pilot; manufacturers and HRSA are testing the limits of rebate authority on appeal, and states' contract pharmacy mandates are producing conflicting federal rulings—while an eligibility fight carries on.

Regulatory Updates

1. CMS Tightens Medicaid Provider Tax Rules

CMS issued a final rule, slated to take effect April 3, 2026, to close a purported long-criticized loophole in Medicaid provider tax waivers by adding a new "generally redistributive" requirement to 42 C.F.R. § 433.68. The published version was issued February 2, 2026. Over the next two years, states that currently have Medicaid provider tax waivers will be forced to comply with the new requirement, which potentially could reduce tax revenues available to those states to finance Medicaid expenditures.

The rule states that it aims to conform the regulatory framework governing health care-related taxes — taxes levied by states to finance the non-federal share of Medicaid expenditures — with the requirements set forth in Section 1903(w) of the Social Security Act, which allow states to obtain waivers of the statutory requirements that a health care-related tax be "broad-based" and "uniform" provided that the net impact of a tax is "generally redistributive." According to the rule, under pre-existing regulations, it was possible for states to design taxes on managed care organizations that imposed higher tax rates on Medicaid lines of business that nonetheless would qualify for waivers because the taxes satisfied the requirements of existing statistical tests meant to assess whether or not a tax was "generally redistributive."

Under the final rule, in addition to satisfying the existing statistical tests, states seeking a waiver must also meet a new "generally redistributive" standard. This new standard prohibits states from (i) explicitly taxing Medicaid business at higher rates, (ii) imposing higher tax rates for taxpayers or tax rate groups on the basis of higher rates of Medicaid utilization, or (iii) imposing lower tax rates on taxpayers or tax rate groups defined by characteristics that are effectively a proxy for Medicaid utilization. While CMS has not confirmed which states will be impacted, it confirms that seven states will be affected by the changes. Third-party sources indicate that the likely impacted states are California, Illinois, Massachusetts, Michigan, New York, Ohio, and West Virginia.

The final rule also establishes staggered deadlines for affected states to comply with the new requirements. Waivers for Medicaid Managed Care Organization ("MCO") taxes approved within two years before April 3, 2026, must come into compliance by January 1, 2027. Older MCO tax waivers must comply by the first state fiscal year that begins at least one year after April 3, 2026. All non-MCO tax waivers must comply by the end of the state fiscal year that ends in 2028 (no later than September 30, 2028). After the transition period, CMS may deduct impermissible tax revenue from medical assistance expenditures before calculating federal matching funds. Penalties will apply prospectively to collections after the deadlines.

As the effective date of these changes approaches, providers in states with active Medicaid tax waivers should monitor how those states revise their provider taxes to comply with these new requirements, which potentially could result in a reduced tax burden for Medicaid providers, but also lower funding for state Medicaid programs.

2. HHS Moves to Deregulate Nursing Home Staffing Standards

On December 3, 2025, the Trump Administration issued an interim final rule (RIN 0938-AV25) withdrawing Biden-era staffing standards for nursing homes under Medicare and Medicaid. The withdrawn policies, issued May 10, 2024, established minimum staffing thresholds for long-term care facilities with a stated aim of improving care in nursing homes in response to concerns raised by the Federal Trade Commission ("FTC"), the Department of Justice ("DOJ") Antitrust Division, and the HHS about the quality of patient care and safety due to limited staffing and other cuts (see FTC, DOJ, and HHS joint press release; see also National Bureau of Economic Research report and Private Equity Stakeholder Project report). These requirements included 3.48 hours per resident day ("HPRD") of total nurse staffing, which mandated at least 0.55 HPRD of direct registered nurse ("RN") care and 2.45 HPRD of direct nurse aide care.

The decision to withdraw the rule comes in the wake of persistent industry and legal pushback, including the passage of H.R. 1 in July 2025, which delayed implementation of the rule for 10 years, and two district court decisions vacating the rule, finding it arbitrary and capricious (*American Health Care Association, et al. v. Robert F. Kennedy, Jr., et al.* (N.D. Tex. 2025); *State of Kansas, et al. v. Robert F. Kennedy, Jr., et al.* (N.D. Iowa 2025). CMS had estimated that implementing the staffing rule would cost the industry $40.6 billion over 10 years. The withdrawal was welcomed by industry leaders that saw the standards as unrealistic and burdensome, especially to rural and Medicaid-dependent facilities that can't afford to hire more staff. The interim rule went into effect on February 2, 2026.

3. Rural Health Funding Program

As discussed in detail in this issue's Focus On section, CMS announced $50 billion in awards to strengthen rural health in all 50 states. The program provides funding for states and rural providers to implement evidence-based, measurable interventions that improve prevention and chronic disease management while directly funding health care services. As a result, this may lead to increased transaction activity in rural markets.

4. Update on Application of State Directed Payments

As noted in our last newsletter, on September 9, 2025, CMS announced new federal payment limitations for State Directed Payments ("SDP") in Medicaid-managed care under the OBBBA, including limitations on "grandfathering" of rates under existing or pending SDPs during the "phase-down" period. On February 2, 2026, CMS rescinded the September 9, 2025 guidance and issued updated guidance, expanding the temporary grandfathering window to 180 business days before or after July 4, 2025 (rather than 180 calendar days) and adding calendar year ("CY") 2024 and CY 2026 to the examples of eligible rating periods. The current guidance also adds a provision prohibiting states from revising SDP preprint rating periods to circumvent the grandfathering criteria. Provisions unaffected by the updated CMS guidance include the phase-down of "grandfathered" SDPs by 10 percentage points per year, beginning January 1, 2028, until they reach 100% of Medicare rates in the 40 Medicaid expansion states and 110% of Medicare in the 10 non-expansion states.

In practical terms, this guidance places a ceiling on SDP-driven managed care payments that are explicitly tied to Medicare. For example, in a Medicaid expansion state—one that has adopted the Affordable Care Act ("ACA") option to cover nearly all adults under age 65 with incomes up to 138% of the Federal Poverty Level — if Medicare would pay $100 for a service, the SDP-affected payment cannot exceed $100; in a non-expansion state, the maximum would be $110. Recent CMS approval letters indicate that many state proposals "likely qualify for the temporary grandfathering period," allowing states to maintain—but not increase—their approved SDP levels until the phase-down takes effect.

5. CMS Releases Final Outpatient Prospective Payment System and Ambulatory Surgical Center Rule for CY 2026

On November 21, 2025, the CMS issued the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center ("ASC") Payment System Final Rule for CY 2026 ("OPPS Final Rule") (CMS-1834-FC). The OPPS Final Rule includes updates to Medicare payment policies and rates for hospital outpatient and ASC services, including increasing OPPS payment rates for hospitals and ASCs that meet applicable quality reporting requirements by 2.6%. These updates are based on the hospital market basket percentage increase of 3.3%, reduced by a 0.7 percentage point productivity adjustment. The productivity adjustment accounts for process and technological advancements that increase hospitals' efficiency in treating patients.

CMS also finalized its proposal to phase out the so-called "Inpatient Only List" over a three-year period, beginning with the removal of 285 mostly musculoskeletal procedures for CY 2026. The Inpatient Only List includes procedures that are only

reimbursed when performed in a hospital setting due to their complexity, risk, or need for extensive recovery. This change will allow patients to obtain certain musculoskeletal procedures in outpatient settings and institutions to receive reimbursement for the delivery of such services. Additionally, CMS added 271 of the codes that were removed from the Inpatient Only List to the ASC covered procedures list ("CPL") and added 289 other procedures to the ASC CPL.

The OPPS Final Rule also included updates to the pricing of skin substitute products in hospital outpatient departments and physician office settings. CMS is aligning payment rates with the Food and Drug Administration ("FDA") regulatory status for skin substitute products: Pre-Market Approvals and 510(k)s. For CY 2026, CMS will use a single payment rate for the three categories to initially ensure rates sufficiently cover the resources involved with furnishing such services. CMS indicated that it intends to propose future payment rates differentiating between the three FDA regulatory categories.

Among other updates, the OPPS Final Rule finalized CMS's proposal to apply the PFS payment rate, rather than the OPPS rate, for certain drug administration services when provided at an excepted off-campus provider-based department. For CY 2026, CMS estimates that this change alone will reduce OPPS spending by $290 million, with $220 million of the savings accruing to Medicare, and $70 million saved by Medicare beneficiaries in the form of reduced beneficiary coinsurance. For more details, please refer to our full summary of the rule.

6. CMS Finalizes Medicare PFS Rule for Cost Year 2026

On November 5, 2025, CMS issued the CY 2026 Medicare PFS final rule (the "PFS Rule"), finalizing policy proposals impacting telehealth, behavioral health, dental services, skin substitutes, the Shared Savings Program ("SSP"), the Ambulatory Specialty Model ("ASM"), the Medicare Diabetes Prevention Program, the Part B drug inflation rebate program, and the Quality Payment Program ("QPP"). The PFS Rule became effective January 1, 2026, with CMS invoking "good cause" to waive the 60-day delayed effective date to ensure Medicare PFS policies and budget neutrality apply at the start of the calendar year.

Major updates also include:

- Telehealth and Behavioral Health: CMS permanently adopted a definition of "direct supervision" that allows a supervising practitioner to be immediately available via real-time audio/video communications technology (excluding audio-only), applicable to all RHCs and FQHCs. CMS will continue paying RHCs and FQHCs for non-behavioral health visits furnished via telecommunication technology at rates aligned with the PFS while it evaluates longer-term options. CMS also finalized a policy allowing multiple-family group psychotherapy to be delivered by telehealth. Separate from telehealth, the Marriage and Family Therapists and Mental Health Counselors may furnish Community Health Integration and Principal Illness Navigation services under general supervision, or they may bill directly when personally performing those services within their benefit categories.
- Skin Substitutes: Beginning January 1, 2026, CMS began paying for certain skin substitute products used in covered application procedures in the non-facility setting (such as physician offices) as "incident-to" supplies under the PFS. Products are grouped into payment categories based in part on their FDA pathway. For 2026, all products paid under the new incident-to policy will be reimbursed at the same rate while CMS evaluates further adjustments to the payment categories and the related reimbursement rates. The finalized policy announced on December 24, 2025, comes as CMS and its MACs withdrew Local Coverage Determinations that would have significantly reduced coverage for many skin substitute products. Separately, on Thursday, January 29, 2026, and as described in the Docket Updates section, above, a coalition of skin substitute manufacturers filed suit against the Trump Administration challenging the new policy.
- Medicare Shared Savings Program: CMS finalized a policy capping at five years the time an ACO can remain in upside-only tracks during its initial agreement period, a change from seven performance years. This change applies to agreement periods beginning on or after January 1, 2027, and will push more ACOs into two-sided risk. CMS also finalized changes to program eligibility and financial reconciliation requirements with respect to the requirement that ACOs have at least 5,000 assigned Medicare fee-for-service beneficiaries. The revisions provide flexibility regarding the minimum number of assigned beneficiaries required in benchmark years by allowing ACOs to meet the 5,000-beneficiary minimum in benchmark year 3, even if they were below 5,000 in benchmark years 1 and/or 2. To protect the Medicare Trust Fund and ACOs from normal variation in expenditures, CMS implemented safeguards, including capping shared savings and losses at lower amounts if an ACO has fewer than 5,000 assigned beneficiaries in any

benchmark year and barring ACOs that fall below 5,000 in any benchmark year from using policies that give certain low-revenue BASIC track ACOs extra opportunities to share in savings. These revised policies apply to ACOs in agreement periods beginning on or after January 1, 2027. CMS also modified the quality of performance standard and other quality reporting requirements, including removing the health equity adjustment applied to an ACO's quality score beginning in performance year 2026 and revising terminology used to describe the adjustment and related terms in the SSP regulations for performance years 2023 through 2025.

- Ambulatory Specialty Model: As discussed in detail in this issue's Value-Based Care Corner, CMS finalized a mandatory payment model for specialists treating beneficiaries with heart failure and lower back pain. Performance is evaluated across four categories—quality, cost, improvement activities, and Promoting Interoperability—with the final score based 50/50 on quality and cost and with potential negative adjustments if minimum expectations are not met for the other two categories.
- Part B Drug Inflation Rebate: CMS finalized "clarifications" to the Part B Drug Inflation Program explaining that it will review current and historical ASP submissions, and as applicable, manufacturer-identifying information in other CMS systems (including the Medicaid Drug Rebate Program system) and other public sources to ensure accurate and timely identification of the "responsible manufacturer" for Part B inflation rebates. CMS also finalized methods for establishing the payment-amount benchmark when data are missing: CMS will first use the published payment limit for the applicable benchmark quarter; if none is available, CMS will calculate the benchmark using positive ASP or positive Wholesale Acquisition Cost ("WAC") reported to the ASP Data Collection System; and if neither is available there, CMS will obtain WAC from other public sources—an approach intended to prevent distorted rebates, especially for drugs with zero or negative sales in the benchmark quarter. Skin substitutes remain excluded from Part B inflation rebates under existing regulations, and CMS reiterates that Medicare Advantage ("MA") units are not counted for Part B rebate purposes.

For more details, please refer to our full summary of the rule.

7. Increase in Medicare Dialysis Reimbursement across Settings

On November 20, 2025, CMS issued a final rule updating the End-Stage Renal Disease ("ESRD") Prospective Payment System, increasing Medicare payments to hospital-based dialysis centers by 1.5% and standalone clinics by 2.2%, effective January 1, 2026. The final rule (RIN 0938-AV52) allocates $6 billion to approximately 7,600 ESRD facilities in 2026. Under the rule, CMS estimates that Medicare payments to ESRD facilities will increase by approximately $180 million in CY 2026 as compared with CY 2025 (~$140 million paid by the government; ~$40 million paid by beneficiaries via co-insurance increases). Through the rule, CMS also removed three health equity-related quality measures: (1) Facility Commitment to Health Equity, (2) Screening for Social Drivers of Health, and (3) Screening for Positive Rate for Social Drivers of Health.

The revised quality measurements follow the Trump Administration's move away from equity-based regulations. Finally, CMS formally terminated the ESRD Treatment Choices Model in the final rule, following its March 12, 2025 announcement of the intention to terminate the model, stating the model was "not showing the quality results around home dialysis and transplant waitlisting or the expenditure savings that were initially projected."

Enforcement Updates

1. Executive Order Establishing New DOJ Division for National Fraud Enforcement

On January 8, 2026, the Trump Administration announced the creation of a new DOJ Division for National Fraud Enforcement, marking a significant development in federal efforts to combat fraud targeting government programs. The new division will be led by a Senate-confirmed Assistant Attorney General with nationwide authority to investigate and prosecute fraud affecting federal government programs, federally funded benefits, businesses, nonprofits, and private citizens.

The creation of this new division stems from heightened attention to fraud allegations in Minnesota's state-administered social services programs. Those allegations sprang in part from the Feeding Our Future case, an alleged COVID-era scheme involving a nonprofit that purported to distribute meals to children but instead submitted fraudulent meal count sheets to receive over $250 million in federal funds. Federal investigators subsequently uncovered what prosecutors describe as "schemes stacked upon schemes," including fraud in Minnesota's Housing Stabilization Services Program (a Medicaid-funded safety net to

help people with disabilities find housing), the Early Intensive Developmental and Behavioral Intervention program (providing autism therapy for children), and numerous other Medicaid programs. As of January 2026, the DOJ has charged 98 defendants in Minnesota fraud-related cases, while issuing over 1,750 subpoenas and executing over 130 search warrants.

The Administration has now mobilized a broad response extending beyond DOJ, and the newly announced division is reportedly designed to centralize and coordinate these efforts nationwide. CMS Administrator Dr. Mehmet Oz notified Minnesota that the state's Medicaid agency was operating in "substantial noncompliance" with federal requirements, and CMS has announced plans to withhold over $2 billion annually in federal Medicaid matching funds until compliance is achieved—the first time in the 60-year history of the Medicaid program that CMS has employed such measures against a state. Additional agencies involved in the response include the FBI (deploying forensic accountants and data analytics teams), DHS (which has sent roughly 2,000 agents to Minnesota for targeted investigations), HHS, the Small Business Administration (which suspended 6,900 borrowers due to approximately $400 million in suspected fraudulent activity), HUD, the Department of Labor, and the Department of Agriculture.

Given this interagency enforcement posture, entities receiving federal funds or operating in sectors that receive federal funding should expect heightened scrutiny. The aggressive, multiagency tactics currently deployed in Minnesota are expected to expand, particularly in the area of health care benefits. Organizations should consider revisiting their compliance programs around federal benefits, preparing for increased federal oversight, and ensuring executives and boards are updated on compliance matters in light of these evolving enforcement priorities.

2. *Recent Oral Argument Highlights Threat to FCA Qui Tam Provision*

The Eleventh Circuit recently heard oral argument in *United States ex rel. Zafirov v. Florida Medical Associates*, a significant case challenging the constitutionality of the False Claims Act's ("FCA") *qui tam* provisions. The appeal follows a September 2024 district court ruling that held that relators—private whistleblowers who pursue FCA claims on behalf of the government—are effectively "officers" exercising significant executive power without proper appointment, in violation of Article II's Appointments Clause. This marks the first appellate review of this constitutional question since several Supreme Court Justices suggested in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023) that *qui tam* provisions may be "inconsistent" with Article II.

In *Zafirov*, the defendants argue that *qui tam* relators impermissibly wield core executive authority without appointment or presidential control. The relator and DOJ counter that historical practice, statutory safeguards, and the government's retained oversight powers—including the ability to intervene, dismiss, or settle cases—are sufficient to satisfy Article II requirements.

The Eleventh Circuit's decision could have immediate and far-reaching consequences for FCA enforcement. If the court affirms the district court's approach, relators would be unable to pursue government-declined cases in Alabama, Florida, and Georgia, potentially reducing the number of *qui tam* filings and prompting relators to seek other forums. Regardless of the outcome, this case may be destined for Supreme Court review.

3. *Record-Breaking FCA Settlements in 2025*

DOJ recently announced that FCA settlements and judgments exceeded $6.8 billion in fiscal year 2025, marking the highest annual recovery in the history of the statute. This record-breaking figure underscores the government's continued aggressive enforcement posture, particularly in the health care sector, which accounted for over $5.7 billion of the total recoveries. Whistleblower activity also reached unprecedented levels, with relators filing 1,297 *qui tam* lawsuits—the highest number recorded in a single year—breaking the prior record of 980 set in fiscal year 2024. *Qui tam* actions generated more than $5.3 billion in recoveries, representing approximately 78% of all FCA recoveries for the year.

The health care industry remains squarely in DOJ's crosshairs, with MA fraud continuing to be a significant enforcement priority. On January 14, 2026, Kaiser Permanente affiliates agreed to pay $556 million to resolve allegations that they violated the FCA by submitting invalid diagnosis codes for their MA plan enrollees to obtain higher payments from the government. The government alleged that Kaiser engaged in a scheme from 2009 to 2018 in which it systematically pressured physicians to alter medical records after patient visits to add diagnoses that were not considered or addressed at those visits, in violation of CMS rules. This represents the largest FCA settlement involving allegations of MA risk adjustment fraud to date.

Given these developments, organizations should carefully evaluate their compliance programs, particularly those operating in health care. The record-breaking number of *qui tam* filings

signals that whistleblower risk remains high, and companies should ensure robust internal reporting mechanisms and respond meaningfully to compliance concerns. DOJ continues to emphasize that timely self-disclosure, meaningful cooperation, and concrete remediation measures can yield credits in the form of reduced penalties or damage multiples. Companies facing potential FCA exposure should proactively involve counsel to evaluate strategic options, including the benefits of self-disclosure and cooperation.

4. DOJ Increases Wound Care Enforcement

DOJ has significantly intensified its enforcement focus on fraud involving wound care products and skin substitutes. In November 2025, DOJ announced a $45 million settlement with Vohra Wound Physicians Management LLC, one of the nation's largest wound care providers for nursing home patients. The settlement resolves allegations that Vohra overbilled Medicare for medically unnecessary surgeries and programmed its electronic health record and billing software to ensure higher-reimbursed procedures were always billed while creating false medical record documentation to support the scheme.

In December 2025, DOJ announced what it described as "the first [criminal] prosecution of its kind" involving wound care fraud, which resulted in the husband and wife owners of wound graft companies in Arizona being sentenced to over 14 years imprisonment for causing over $1.2 billion in false claims to be submitted to Medicare Part B and other federal health care programs for medically unnecessary wound grafts. The defendants were ordered to pay more than $1.2 billion in restitution and also agreed to pay over $309 million to resolve civil FCA liability arising from whistleblower lawsuits. According to DOJ, the scheme involved medically untrained sales representatives locating elderly Medicare beneficiaries—many of whom were in hospice care—with any type of wound, then ordering only the largest sizes of expensive bioengineered skin substitutes regardless of wound size to maximize reimbursement. The scheme resulted in "large grafts applied to small wounds, several grafts applied to single wounds, grafts applied to non-existent wounds and grafts applied to terminally ill patients receiving palliative care."

According to CMS, Medicare spending on skin substitutes rose from $256 million in 2019 to over $10 billion in 2024. Effective January 1, 2026, CMS implemented significant reimbursement changes that shifted most skin substitutes from a higher ASP methodology to a standardized flat rate, which CMS predicts will reduce Medicare spending on skin substitutes by approximately 90%. Given this enforcement environment and the extended statute of limitations for health care fraud (up to 10 years for FCA violations), providers in the wound care space should carefully review their billing practices, clinical documentation, and internal compliance controls.

5. CMS Issues Letter to States Regarding Tax and Health Care Fraud

On November 25, 2025, CMS issued a letter to all 50 states inviting state governments to partner with the agency to pursue providers and suppliers involved in both Medicare fraud and related state tax evasion. Per CMS, health care providers who bill fraudulent insurance claims often fail to report the associated income on their tax returns, creating a dual-layered crime that drains both federal and state tax systems. Accordingly, the initiative seeks to leverage state criminal tax actions, which can move faster than traditional health care fraud prosecutions, to enable CMS to swiftly revoke Medicare billing privileges following convictions. CMS highlights prior joint efforts that identified and prosecuted 12 providers, and a recent state review that found 32 providers with more than $2 million each in unreported earnings, underscoring the increased enforcement risk when claims and tax data are combined.

For Medicare providers and their partners, CMS's letter signals a desire for a more integrated federal-state approach that may expand investigative touchpoints and shorten the timeline from allegation to administrative action, making proactive compliance and tax-reporting hygiene even more critical. CMS outlines a straightforward participation model for states, designating a point of contact, prioritizing targets with CMS-supplied claims/financial data, and establishing ongoing information-sharing procedures, suggesting that more states are likely to join and intensify scrutiny of high-risk billing patterns. Providers should anticipate greater cross-referencing of claims data with tax filings and be prepared to respond quickly to inquiries or audits that may now arrive through either a health care or tax enforcement channel.

6. Administration Takes Further Enforcement Actions Relating to Gender-Affirming Care

The administration has taken several actions on gender-affirming care in late 2025. These actions follow the White House's issuance of the executive order concerning gender-affirming care in early 2025, as well as the Supreme Court's June 2025 decision in *United States v. Skrmetti*, 605 U.S. 495 (2025) upholding a state law restricting certain interventions for minors under rational basis review. These actions demonstrate the administration's continued focus on gender-affirming care issues and the risk of enforcement actions against providers.

On December 19, 2025, CMS issued a proposed rule to prohibit the use of federal Medicaid funds for "sex-rejecting procedures" for individuals under 18 and to prohibit federal CHIP funding for those under 19. Under the proposed rule, for which comments must be received by February 17, 2026, mental health services would remain eligible for federal funding, and states could still use state-only funds outside Medicaid/CHIP to cover these procedures if they choose. In a companion move, HHS announced that CMS will propose Medicare/Medicaid Conditions of Participation to bar hospitals that participate in those programs from performing "sex-rejecting procedures" on minors. HHS also highlighted related marketplace coverage changes: beginning with Plan Year 2026, issuers subject to the ACA's essential health benefits may not treat specified sex-trait modification procedures as essential health benefits, and the U.S. Office of Personnel Management has directed that Federal Employee Health Benefits and Postal Service Health Benefits plans exclude chemical and surgical sex-trait modification services (including "gender transition" services) for Plan Year 2026. HHS proposes aligning CHIP financing restrictions with these changes. CMS has also sent oversight letters to hospitals seeking information on informed consent protocols for minors, evidence and adverse events, and financial data for pediatric procedures paid partly or wholly with federal funds.

Beyond CMS, HHS's Office for Civil Rights has proposed to revise Section 504 regulations to clarify that "gender dysphoria not resulting from a physical impairment" is excluded from the definition of "disability," responding to litigation and confusion stemming from the 2024 rule's preamble. Further, FDA issued warning letters to 12 manufacturers and retailers over alleged illegal marketing of breast binders to children for treatment of gender dysphoria, warning of potential enforcement actions including import alerts, seizures, and injunctions if violations continue.

Finally, the HHS Secretary issued a declaration, asserting that procedures the administration describes as "sex-rejecting" for minors do not meet professionally recognized standards of care, and that practitioners who perform them on minors would be out of compliance with those standards under HHS programs. In tandem with that declaration, the Assistant Secretary for Health released a public health message to providers, families, and policymakers stating that current evidence does not support puberty blockers, cross-sex hormones, and surgeries as safe and effective treatments for pediatric gender dysphoria.

7. OIG Releases Remote Patient Monitoring Reports

On August 25, 2028, the HHS Office of Inspector General ("OIG") released a new data snapshot on billing for remote patient monitoring ("RPM") in Medicare for CY 2024, highlighting rapid growth and emerging program integrity risks. OIG reports that RPM usage continued to expand, with Medicare payments exceeding $500 million in 2024 and nearly 1 million beneficiaries receiving RPM services, reflecting a 31% year-over-year increase and continued upward trend since broader coverage began in 2019. OIG frames RPM as a technology-enabled service that transmits physiologic data from connected devices to providers for ongoing management, especially for chronic conditions such as hypertension.

While most medical practices appear to bill within expected patterns, OIG identifies outlier behaviors that warrant further scrutiny and targeted oversight. Examples include large, sudden spikes in new RPM enrollees at certain practices; billing where a practice lacks a prior medical relationship with a high proportion of patients despite CMS's requirement for an established relationship; high rates of patients who never receive monthly treatment management; frequent billing for the same enrollee by multiple practices; and repeated billing for more than one device per month per enrollee, which Medicare generally does not allow. OIG emphasizes that monitoring for these patterns can help CMS and Medicare Advantage Organizations ("MAOs") safeguard program integrity while ensuring beneficiaries receive appropriate RPM benefits, and it reiterates prior recommendations for CMS to strengthen RPM oversight.

For health plans and provider organizations, immediate business takeaways include validating that RPM enrollment reflects established patient relationships, that treatment management time is consistently documented and billed when furnished, and that device billing aligns with one-device-per-month parameters in Original Medicare, recognizing that repeated exceptions trigger scrutiny signals in OIG's framework. Given the growth trajectory and OIG's focus, aligning internal analytics with these measures—spikes in new enrollees, prior-relationship gaps, absence of treatment management, multi-practice billing for the same enrollee, and multiple devices per month—can reduce fraud, waste, and abuse risk while supporting compliant RPM expansion.

Federal Awards and Grants Updates

1. First Circuit Win in IDC Rate Litigation

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 indirect costs ("IDC"). Courts blocked each agency's attempt to impose such a cap, and the government appealed each decision.

On January 5, 2026, the U.S. Court of Appeals for the First Circuit upheld a district court judgment preventing the National Institutes of Health ("NIH") from implementing a policy that adopted a uniform 15% cap on the IDC rate of federally funded research institutions.

With respect to subject matter jurisdiction, the First Circuit relied on two recent emergency orders from the Supreme Court and, in particular, Justice Barrett's concurrence in *NIH v. American Public Health Association (APHA)*, No. 25A103 (U.S. Aug. 21, 2025), to distinguish between challenges to the withholding of funds under individual grants—which, per that opinion, must be raised in the U.S. Court of Federal Claims—and challenges to agency-wide funding policies—which, per that opinion, must be raised in a federal district court. The First Circuit reasoned that, because the plaintiffs "challenge[d] only the agency-wide guidance announcing that NIH will reimburse IDCs at a 15% rate going forward," the First Circuit ruled that the district court had subject matter jurisdiction to address the plaintiffs' claims.

On the merits, the First Circuit agreed with the district court that NIH's guidance violated the relevant appropriations rider and federal regulations. Based on the language of the appropriation rider, the First Circuit carefully parsed the appropriation rider's language to conclude that Congress had expressly prohibited NIH from deviating from the relevant regulations and the existing institution-specific framework for negotiating F&A reimbursement rates.

The First Circuit's decision is a significant victory for research institutions, which have relied for decades on carefully negotiated, institution-specific IDC rates to secure funding to support those research costs that cannot be assigned to a specific research project. The decision also clarifies that litigants can continue to challenge agency-wide policies in federal district courts under the APA, and courts will continue to hold agencies to their implementing regulations and enforce Congress's appropriations directives.

For further detail, see our January 8, 2026 client alert, "First Circuit Affirms a Lower Court Decision Prohibiting NIH from Capping Reimbursements for Facilities & Administrative (or 'Indirect') Costs."

2. Recent Updates on Federal Funding Litigation

APHA v. NIH. As noted in the July 2025 and October 2025 newsletters, the *APHA v. NIH* litigation challenged NIH's termination of already awarded research grants pursuant to agency directives disfavoring topics such as "diversity," "transgender issues," and "vaccine hesitancy" (the "Challenged Directives"). In May 2025, the U.S. District Court for the District of Massachusetts held the Challenged Directives unlawful and vacated the resulting terminations. *APHA v. NIH*, No. 1:25-cv-10787 (D. Mass. 2025), appeal docketed No. 25-1611 (1st Cir., June 24, 2025) ("*APHA*"). In August 2025, the U.S. Supreme Court ruled that the district court likely lacked jurisdiction to review NIH's termination of research grants but declined to stay the district court's conclusion that the Challenged Directives violated the APA. *See NIH v. APHA*, No. 25A103 (U.S. Aug. 21, 2025). The U.S. Court of Appeals for the First Circuit heard oral argument on the jurisdictional issue on January 6, 2026, and a decision is pending.

The *APHA* litigation also alleged that NIH unlawfully refused to review, delayed action on, or failed to decide *pending* grant applications submitted in 2025 because of the Challenged Directives. These claims concerned grant applications that had not resulted in funded awards and, therefore, were not subject to termination. On December 29, 2025, NIH entered into two joint stipulations to resolve these application review-related claims (the "Joint Stipulations"). The Joint Stipulations address grant applications that were denied or left undecided in 2025 ("Impacted Grant Applications"); they do not cover grants terminated pursuant to challenged agency directives, which, per above, are pending review in the First Circuit. One Joint Stipulation, led by 16 state attorneys general, covers more than 5,000 grants; the other Joint Stipulation, led by the APHA, covers approximately 400 grants. In neither agreement did NIH concede any legal violation in declining to review or delaying decisions on affected applications.

The Impacted Grant Applications include (i) those for which NIH has not yet decided to withdraw, deny, or award; (ii) those administratively withdrawn or denied

after the withdrawal of a NOFO; and (iii) those NIH considered but declined to fund pursuant to the Challenged Directives.

Under the Joint Stipulations, NIH agrees to make "good faith" decisions without applying the Challenged Directives. The Joint Stipulations further confirm that the close of FFY 2025 will not prevent NIH from reviewing or awarding any Impacted Grant Applications submitted in FFY 2025. The Joint Stipulations also provide that NIH will not decline to review or award an Impacted Grant Application solely because a NOFO was withdrawn pursuant to the Challenged Directives, and that it will complete its reviews according to the timelines specified in the Joint Stipulations. As reported by *Inside Higher Ed*, by the first such deadline, NIH had approved at least 634 of 674 re-reviewed Impacted Grant Applications. Additional reviews will continue through July 31, 2026.

American Academy of Pediatrics v. HHS. On January 11, 2026, the U.S. District Court for the District of Columbia issued a preliminary injunction blocking the Centers for Disease Control and Prevention ("CDC") and HRSA—both components of the HHS—from giving effect to the termination of seven federal grants awarded to the American Academy of Pediatrics ("AAP").

As discussed in our January 29, 2026 client alert, "U.S. District Court Grants Preliminary Injunction Restoring Seven Federal Grants to the American Academy of Pediatrics, Citing Retaliation for Constitutionally Protected Activity," CDC and HRSA reasoned in their termination notices that the awards no longer effectuated agency or HHS priorities pursuant to 2 C.F.R. § 200.340(a)(4). However, in its complaint filed on December 24, 2025, AAP alleged that the terminations violated the First Amendment by retaliating against protected speech and discriminating based on viewpoint, among other claims. AAP argued that HHS used its power to terminate grants in a retaliatory manner, designed to chill AAP's speech on topics for which AAP's views differ from those of current HHS leadership.

Judge Beryl A. Howell granted preliminary relief, enjoining defendants from enforcing or giving effect to the award terminations, including the enforcement of closeout obligations, and from re-obligating funds used to support the affected AAP awards, as well as requiring defendants to ensure that CDC and HRSA disburse award funds "in the customary manner and in customary timeframes." The court found that AAP is likely to succeed on its First Amendment retaliation claim, emphasizing "substantial and undisputed" evidence that statements and actions by HHS leadership reflected a retaliatory motive tied to AAP's protected advocacy on childhood vaccination and gender-affirming care. The court further found that HHS's stated rationale—realignment with agency priorities—was not plausible, particularly given that the terminated grants were unrelated to the contested policy issues and similarly situated grantees were not subject to comparable terminations.

3. NIH Issues Updated Instructions to Grant Application Reviewers

On December 12, 2025, NIH issued updated staff guidance on reviewing grant applications in accordance with the Trump administration's priorities, superseding staff guidance issued in March 2025. The updated guidance, titled "Reviewing Grants for Priority Alignment," appears designed to address recent court decisions finding certain federal award terminations unlawful where (i) agencies had relied on priorities that had not been announced publicly and (ii) terminations were implemented without individualized review. In August 2025, NIH Director Jay Bhattacharya issued a statement articulating NIH's priorities, aimed at resolving concerns about providing adequate notice of agency priorities to current and potential funding recipients.

The December guidance focuses on the process for conducting individualized award reviews to confirm alignment with agency priorities. Program officers are directed to evaluate both existing and prospective awards using a computational text analysis tool to flag terminology that suggests potential misalignment with current priorities. If the tool identifies concerning language, staff must conduct a manual review to confirm whether such language reflects misalignment with agency priorities and, if so, whether the award can be brought into alignment or should be terminated. Awards that "pass" this review then undergo a secondary scan to confirm alignment.

Some categories of research may be reconciled with agency priorities through reframing and scope adjustments. For example, it is possible for a health equity research project to be aligned with agency priorities if the project examines and attempts to mitigate specific, measurable health disparities, is scientifically justified, and its proposed interventions focus on areas that can be directly influenced by health care or biomedical science. Per the guidance, interventions that target broad

areas—such as poverty, employment, or immigration—are couched as not being capable of direct influence by health care or biomedical science; however, factors like poverty may be taken into account as demographic indicators that influence specific health outcomes. Although some reframing may appear semantic, the guidance stresses that renegotiation typically requires substantive modification of project components, not "just changing words."

If misalignment cannot be resolved, program officers must identify the specific aspects of the project that conflict with NIH priorities, explain why renegotiation is not viable, and evaluate reliance and other countervailing considerations. The Office of Policy for Extramural Research Administration, which provides oversight of grants management policy and compliance for NIH extramural research staff, prepares a draft decision memorandum analyzing the proposed termination. That memorandum is subject to approval by the relevant NIH Institute or Center (*e.g.*, the National Cancer Institute) and subsequently is submitted to the NIH Director for final approval before any termination is effected.

4. SAMHSA Terminates and Reinstates $2 Billion in Federal Awards

On January 14, 2026, the Substance Abuse and Mental Health Services Administration ("SAMHSA") abruptly terminated thousands of federal awards, effective immediately, via a form termination notice sent to awardees. Following backlash from providers, advocacy groups, legislators, and members of the public, SAMHSA rescinded the award terminations the following day. Neither SAMHSA nor the HHS has issued an official statement regarding the terminations.

According to media reports, SAMHSA terminated between 2,500 and 2,900 awards, totaling approximately $2 billion in award funding. Impacted areas included training programs for doctors, social workers, nurses, and law enforcement personnel; programs intended to prevent suicide, programs preventing HIV infections and helping pregnant and postpartum women diagnosed with substance use disorders; and programs designed to reduce underage drinking and cannabis use. Terminations did not appear to impact substance use prevention, treatment, and recovery services block grants, community mental health services block grants, state opioid response grants and funding for Certified Community Behavioral Health Clinics, and the 988 crisis line.

Termination notices sent to award recipients stated that such awards were terminated pursuant to SAMHSA's authority to terminate an award "to the extent authorized by law, if an award no longer effectuates program goals or agency priorities[.]" (Note: As discussed in the July 2025 and October 2025 newsletters, award terminations issued by other federal agencies, including the NIH, the National Science Foundation, the Department of Education, and the Department of Defense ("DOD"), often have cited "program goals and agency priorities" as the basis for terminations.) The termination notices cited SAMHSA's current strategic priorities (*e.g.*, preventing substance misuse, abuse, and addiction; addressing serious mental illness; and expanding crisis intervention care and services), but did not provide individualized analyses explaining why the terminated awards were not in line with SAMHSA's priorities.

Although rescinded, these terminations may nevertheless prove to be a harbinger of added uncertainty and increased financial pressures for entities operating in the substance abuse and mental health treatment spaces. This uncertainty persists notwithstanding HHS's February 2, 2026 announcement of $100 million in new or expanded behavioral health and substance use investments administered through SAMHSA, which appear to reflect a reorientation of funding priorities. Providers may continue to face volatility as SAMHSA evaluates existing programs and reallocates funding consistent with evolving agency priorities. Additionally, Medicaid funding cuts and other changes to the Medicaid program enacted as part of the OBBBA may result in reduced reimbursement to substance use and mental health providers.

5. Alternative IDC Models

The National Defense Authorization Act for Fiscal Year 2026 ("NDAA"), in part, sets forth the policies and authorities for DOD programs and activities. Section 230 of the NDAA entitled "Prohibition on Modification of Indirect Cost Rates for Institutions of Higher Education and Non-Profit Organization" prohibits DOD from modifying IDC rates applicable to DOD grants and contracts awarded to institutions of higher education and nonprofit organizations until DOD develops an alternative IDC model in consultation with members of the extramural research community.

The alternative IDC model must fulfill two criteria: (1) it must reduce the IDC rates for all covered institutions, as compared to the FFY 2025 IDC rates; and (2) it must optimize payment of "legitimate and essential" IDC incurred in DOD-funded research in a manner that promotes "transparency and efficiency." Once developed, the DOD must also create an

implementation plan that allows "adequate transition time" for the affected organizations to adjust to the changes.

Although an alternative IDC model has not been adopted by the DOD, a joint association of extramural members of the research community has proposed an alternative approach to Congress and the Executive Branch. The Fiscal Accountability in Research ("FAIR") model would modernize the existing research reimbursement framework by introducing three cost categories: (i) research performance costs, which are attributable to project-specific research activities; (ii) essential research performance support costs, which are necessary for research operations but cannot be assigned to a particular project; and (iii) general research operation costs, which relate to institution-wide infrastructure required to conduct research.

Under the FAIR model, institutions could choose one of two budgeting structures that integrate these cost categories. Under the first option, award recipients would directly charge all essential research performance support costs to individual research budgets. Under the second option, recipients would allocate a fixed percentage of a project's total budget to certain essential research performance support costs (*i.e.*, information and data services, facilities, and operations), and apply direct charges to other essential research performance support costs (*i.e.*, regulatory compliance and award management, oversight, and reporting costs).

To date, neither Congress nor the Executive Branch has adopted the FAIR model or issued a public response to the proposal.

6. FEMA Public Assistance Program Funding

Severe winter storms have prompted multiple emergency declarations across the country, with additional declarations likely as wintry conditions persist. At the same time, uncertainty surrounding Federal Emergency Management Agency ("FEMA") leadership, staffing, and funding has increased scrutiny of Public Assistance ("PA") eligibility and cost reasonableness. Hospitals and other private nonprofit providers should anticipate tighter enforcement of PA requirements than in recent years and should reassess FEMA-related policies and grant management practices that may not have been updated since the COVID-19 public health emergency.

Hospitals responding to winter storm events and planning to seek FEMA PA funding should consider the following actions:

- Track declaration-specific requirements closely and not assume reimbursement for response activities absent alignment with FEMA guidance or a government request. PA eligibility is limited to the incident period, geographic areas, and categories of work expressly approved in each emergency declaration. Performing necessary work alone does not guarantee eligibility.
- Maintain contemporaneous documentation of any mission-tasked or government-requested support to state or local governments.
- Confirm that hospital response activities are consistent with internal emergency and disaster response policies applicable to federally declared events.
- Preserve detailed records of damage, work performed, costs, insurance recoveries, and procurement actions to support eligibility and cost reasonableness.
- Include required federal clauses, and document exigency and price reasonableness, in procurement contracts.
- Clearly identify and separate non-PA-eligible items (*e.g.*, standard business interruption losses) in insurance claims and settlements to avoid FEMA offsets.

In a more constrained PA funding environment, hospitals should treat FEMA reimbursement as a compliance-driven process and align response, documentation, and procurement practices accordingly.

7. Federal Funding Restrictions Continue in 2026, Reflecting Areas of New or Renewed Interest for the Trump Administration

On January 23, 2026, the Trump Administration announced three rules that impose specific limitations on recipients of grants and cooperative agreements issued under Title III Bilateral Economic Assistance, the primary funding source for U.S. government humanitarian and international development programs. Collectively denominated the Promoting Human Flourishing in Foreign Assistance Policy (the "PHFFA Policy"), these rules mark an expansion of previous iterations of the Mexico City Policy, which conditions eligibility for U.S. assistance on a foreign NGO's agreement not to perform or actively promote abortion as a method of family planning. The PHFFA Policy also imposes "DEI [diversity, equity, and inclusion]" and "gender ideology" conditions on foreign assistance funds. For further detail, see our January 30, 2026 client alert, "State Department Issues New Foreign Assistance Rules, Expanding the Mexico City Policy."

Separately, on January 27, 2026, the NIH issued NOT-OD-26-028, which prohibits the use of NIH funds for research

involving human fetal tissue obtained from elective abortions. The notice signals forthcoming agency actions related to human embryonic stem cells. 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." These actions were foreshadowed by and promoted in Project 2025, which sought to "[e]nd intramural research projects using tissue from aborted children within the NIH" and "ensure that abortion and embryo-destructive related research, cell lines, and other testing methods become both fully obsolete and ethically unthinkable."

Value-Based Care Corner

1. CMS Announces Multiple Value-Based Care Models

CMS recently announced a range of new value-based care models that will launch in 2026 and 2027. These include the Make America Healthy Again ("MAHA") Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence ("Elevate") Model, Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Model, Global Benchmark for Efficient Drug Pricing ("GLOBE") Model, Better Approaches to Lifestyle and Nutrition for Comprehensive Health ("BALANCE") Model, and Advancing Chronic Care with Effective Scalable Solutions ("ACCESS") Model. According to CMS, these models collectively aim to reform the U.S. health system, reduce out-of-pocket drug costs for Medicare beneficiaries, and expand access to technology-enabled care to improve health.

- MAHA Elevate Model. The MAHA Elevate Model seeks to combat chronic disease by funding up to 30 three-year projects (about $100 million total) that promote evidence-based, whole-person care—including lifestyle and functional medicine—for Original Medicare beneficiaries. These services, not currently covered by Medicare, are intended by CMS to augment existing medical care while generating new cost and quality data to guide future policy and reduce Medicare spending. Proposals should focus on services not presently covered by Original Medicare and be backed by documented evidence of effectiveness. Cooperative agreements will prioritize organizations with proven experience integrating such approaches into care and rigorously evaluating their impact, with scientifically demonstrated improvements in health. Awardees will work with CMS to develop a comprehensive plan for data collection and quality assurance, outcome measurement, participant recruitment, and cost containment. All proposals must include a nutrition or physical activity component, and three awards will be reserved for interventions addressing dementia. A NOFO is expected in early 2026, with the voluntary model launching September 1, 2026. The second cohort will launch in 2027.

- GUARD Model. As one of two new drug payment models, CMS issued a Notice of Proposed Rulemaking ("NPRM") proposing the mandatory GUARD Model, which would require manufacturers to pay rebates on certain Medicare Part D drugs when the Medicare net price exceeds an international benchmark, with the stated goal of lowering beneficiaries' out-of-pocket costs and overall Medicare spending, while preserving or enhancing quality of care. The model would test replacing the current Part D inflation rebate calculation for select sole-source drugs—that are in the following specific therapeutic categories: Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents, —with an international pricing benchmark derived from economically comparable countries. If finalized, GUARD would have a five-year performance period from January 1, 2027, through December 31, 2031, with invoicing and reconciliation continuing into 2033, and would operate in randomly selected areas covering 25% of Part D enrollees. Rebates would flow to the Medicare Supplementary Medical Insurance Trust Fund ("MSMITF"). Public comments on the NPRM are due by February 23, 2026.

- GLOBE Model. As mentioned in a previous client alert, the other new drug payment model, the GLOBE Model, is a proposed mandatory initiative that would assess rebates on certain Medicare Part B drugs when U.S. prices exceed those paid in economically comparable countries. CMS anticipates that GLOBE would lower out-of-pocket costs for people with Medicare and generate savings for the program. The model targets drugs administered in clinical settings, such as oncology treatments and therapies for autoimmune diseases and arthritis. Under GLOBE, CMS would test an alternative method for calculating manufacturer rebates under the Medicare Part B Inflation Rebate Program, using an international benchmark

derived from pricing in economically comparable countries rather than the current domestic benchmark. The benchmark would rely on manufacturer-reported international pricing or other pricing information available to CMS. Manufacturers would continue to remit rebate payments directly to the MSMITF. For beneficiaries receiving GLOBE Model Drugs, out-of-pocket costs would be tied to the international benchmark, reducing costs for people covered under Medicare Part B. As outlined in the NPRM, GLOBE would operate for five years, launching on October 1, 2026, and run through 2031, with rebate invoicing and reconciliation continuing through 2033. Public comments on the proposed rule must be submitted by February 23, 2026.

- BALANCE Model. The BALANCE Model is a voluntary initiative to expand access to select glucagon-like peptide-1 ("GLP-1") medications alongside healthy lifestyle interventions, helping people with Medicare and Medicaid improve their health. Access to GLP-1s would be expanded by securing lower prices through direct negotiations with eligible manufacturers. Under BALANCE, CMS will conduct negotiations on behalf of state Medicaid agencies and Medicare Part D plans with GLP-1 manufacturers, and the agreements also address patient eligibility criteria. The model also offers beneficiaries access to structured lifestyle support programs that help them adopt a reduced-calorie diet and increase physical activity. This design aligns with FDA labeling, which recommends that GLP-1s be used alongside appropriate lifestyle modifications when prescribed for obesity or weight management. State Medicaid agencies may join beginning in May 2026, and Part D plans beginning in January 2027. Model testing will conclude in December 2031.

- ACCESS Model. In December 2025, CMS introduced a voluntary payment model that will reimburse providers for using telehealth, wearables and other digital health technologies. The ACCESS Model will reward providers for improving outcomes for traditional Medicare beneficiaries with chronic conditions. Participants will receive recurring payments for managing patients' qualifying conditions—such as high blood pressure, chronic kidney disease, cardiovascular disease, chronic musculoskeletal pain, depression, and anxiety— with full payment contingent on achieving clear measurable health outcomes. Participants must offer tech-enabled care that may include coaching, behavioral support, patient education, medication management, ordering and interpreting diagnostic tests and imaging, use or monitoring of FDA authorized devices, and other services that help manage chronic conditions. They also can use remote patient monitoring devices and wearables to monitor patients. Providers must apply by April 1, 2026, to be considered for the model's first performance period, which will begin July 1, 2026. Applications received after this date will be considered for a January 1, 2027 start. The ACCESS Model is set to run for 10 years. While hospitals and health systems stand to benefit from the enhanced payment structures, participants will need to navigate a "fee-for-service" exclusion that limits the participating organization from billing for any Medicare claims other than the codes created by – and covered under – the model.

2. The Wasteful and Inappropriate Service Reduction ("WISeR") Model Continues to Receive Pushback

As mentioned in our last newsletter, the WISeR Model was designed to reduce the use of low-value services—those with little or no evidence-based clinical benefit—among Original Medicare beneficiaries. Although voluntary and launched on January 1, 2026, the WISeR Model has drawn significant Congressional pushback. On January 8, 2026, the House Energy & Commerce Health Subcommittee advanced legislation to bar CMS from implementing the model. Proponents emphasize that WISeR does not change Medicare coverage policy; rather, it seeks to ensure that, for a defined set of non-emergency services, beneficiaries receive safe, effective, and appropriate care. Opponents contend that Medicare could use AI to fast-track care denials instead of limiting the technology to streamlining administrative tasks such as billing and paperwork. Additionally, providers are struggling to comply with program requirements as coverage data transmission and coverage review have been slow to date. Providers remain concerned that, as implemented, patients are seeing delays in timely receipt of necessary care. The WISeR Model runs for six performance years through December 31, 2031, in six states: New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington.

3. Finalized Mandatory Ambulatory Specialty Model

The Medicare PFS Rule for CY 2026, released on November 5, 2025, includes a new mandatory ASM (see the final rule here). ASM aims to promote greater coordination between specialists and primary care providers, including those in ACOs. Under ASM, specialists within selected geographic areas who frequently treat people with Medicare for low back pain or heart failure in

outpatient settings will be financially responsible for patient outcomes through a two-sided risk model. Participant performance will be measured across four categories: (1) quality, (2) cost, (3) improvement of clinical processes and patient engagement, particularly regarding health-related social needs, and (4) interoperability advances. The performance measures will be tailored to the provider and treatment of the specific conditions.

This framework may look familiar, as CMS modeled ASM after the Merit-based Incentive Payment System Value Pathways program. ASM's performance measures, however, will be transparent to other participants, as well as CMS, to encourage shared improvements between physicians of the same specialty in the same geographic region. As a two-sided risk model, participants will receive a higher rate (positive payment adjustment), the standard rate (neutral payment adjustment), or a lower rate (negative payment adjustment) on their future Medicare Part B claims for covered services, based on performance relative to their geographic peers. CMS has stated that it intends to permit ASM participants the ability to request enhanced performance data related to episode-based costs, utilization, and quality, enabling physicians to gain deeper insight into their patient population's care patterns and care needs. Specialty providers of heart failure or low back episodes in the mandatory geographic regions should take advantage of the data offerings CMS may offer during the program. ASM will begin on January 1, 2027 and run for five performance years through December 31, 2031.

4. Medicare Advantage Shake-Up

CMS is considering numerous updates to the MA program, including a proposal to align benefits for people with both Medicare and Medicaid that could shift the MA market further toward large health insurance companies that already do business with both programs. Under the CY 2027 MA and Part D Proposed Rule available here, issued November 25, 2025, CMS issued three requests for information ("RFIs") regarding improvements to MA for which the comment period closed on January 26, 2026.

Most significantly, the first RFI considers a requirement that health insurance companies selling MA Chronic Condition Special Needs Plans ("C-SNPs") also be Medicaid managed care contractors. More MA members signed up for C-SNPs than for any other kind of policy in 2025, and enrollment spiked 67.5% to 1.1 million. If CMS moves forward with this proposal, insurers that are already active in Medicaid and Medicare stand to benefit. It could, however, also limit competition in the market for C-SNPs. Smaller plans and states, however, may decide that C-SNPs are not worth offering, due to the increase in administrative requirements on both the plan side and state side.

The second RFI solicits input on risk adjustment and quality bonus payment changes to promote competition among MA providers. The current risk adjustment system favors more well-established providers that have the resources to prioritize investment in coding activities, while newer, smaller, plans struggle to keep up with coding requirements. To diminish this deficit, CMS is exploring solutions to modernize risk adjustment, including leveraging AI and alternative data sources, to streamline the quality measurement timeline and reduce the current two-year lag between measurement and payment that further disadvantages smaller MA plans.

Shifting away from technical MA requirements, the final RFI focuses on well-being and nutrition policy changes. Specifically, the RFI seeks comments on tools and policies that would improve MA beneficiary overall health, happiness, and satisfaction, including aspects of emotional well-being, social connection, purpose, and fulfillment. The other element of the RFI focuses on nutritional improvements in MA, aligning with the Trump Administration's focus on nutrition as a key factor of health care and reducing chronic illness. For example, the proposed rule references incentives for MAOs to support beneficiaries seeking to improve their nutrition.

Together, these RFIs signal CMS's recognition of the recent industry shift away from MA and its efforts to remedy elements that have influenced the exodus from the program. Further, these opportunities for MA program updates align with the Administration's goals to incorporate AI into reimbursement, and reinvigorate the promotion of nutrition in health care.

5. Physician-Focused Payment Model Technical Advisory Committee ("PTAC")

PTAC, an independent federal advisory committee that makes recommendations to HHS on physician-focused payment models, is considering implementation of the Transcript-Cited GenAI Payment Model for Care Coordination, for which the comment period ended on January 30, 2026. The model uses generative artificial intelligence ("GenAI") to capture complete transcripts of patient interactions, and generate structured documentation such as care plan updates, quality measure reporting, risk adjustment coding, and social determinants of health capture. The model reimburses providers when GenAI-supported documentation is (1) cited back to a transcript; (2)

used to update care plans, report quality measures, or capture risk adjustment conditions; and (3) reviewed and approved by the provider or clinical staff member. While there is much criticism around the use of AI in Medicare reimbursement, the model is specifically aimed to promote integrity in billing through the required citations to the patient interaction and clinical review by staff, to ensure GenAI documentation is accurate.

To account for the use of GenAI, the model also introduces new add-on CPT or G-codes or PMPM modifiers for the use of transcript-cited documentation. To further induce provider participation, there is an optional opportunity for providers to participate in shared savings for improved care gap closure and risk adjustment accuracy. If approved, implementation of the model will begin within 30 days of approval. The proposal of the model under consideration is available here. Interested providers should review the proposal in anticipation of the decision on the model.

Transaction Trends

1. Anticipated Increase in Hospital Transactions in 2026

After a slow first half of 2025, driven primarily by policy and reimbursement uncertainty, hospital and health system transactions rebounded in the latter half of the year, entering this year with more momentum and setting the stage for a more active 2026. The early 2025 slowdown has generally been attributed to uncertainty created by federal policy moves affecting reimbursement and the regulatory environment, including the passage of the OBBBA that resulted in Medicaid cuts. The momentum from the end of 2025 is continuing into 2026, as the impacts of the OBBBA become clearer for hospitals and health systems. 2025 saw a high share (43.5%) of deals involving distressed parties, signaling that operating pressure remains a core driver heading into 2026. Not-for-profit acquirers led most transactions in 2025, while only one transaction involved a for-profit acquirer, signaling the financial challenges facing hospitals in the current environment and a shift in for-profit entities' investments to other health care services sub-sectors or an exit in general.

Looking ahead to 2026, strategy is increasingly oriented toward outpatient growth and operating leverage in lower-acuity settings. Experts expect deal value and volume to grow in 2026 as health systems sell high-quality, cash-generating assets and investors prioritize sectors with clearer and more consistent reimbursement, favoring consolidation of smaller hospitals into larger regional systems seeking scale and capacity relief, as well as carve-outs, over riskier transactions. Further, ambulatory and post-acute platforms, behavioral health, and physician networks are anticipated to command interest, as well as continued divestitures and distress-led transactions.

As health systems plan for 2026, emphasis remains on transactions with clear paths to growth and disciplined capital deployment, particularly where outpatient capabilities, physician networks, and value-based models improve access, experience, and total cost of care.

2. Evolving State Role in Transactions

States have increasingly stepped beyond traditional oversight in recent years, acting as facilitators, funders, or policy enablers to stabilize distressed providers, preserve access, and avoid abrupt closures. Massachusetts's role in brokering sales of Steward Health Care facilities following the system's bankruptcy exemplifies the shift from pure regulation to hands-on transaction enablement in crisis contexts. Connecticut likewise enacted an emergency certificate of need pathway to expedite transfers when hospitals enter bankruptcy, a mechanism used to advance Hartford HealthCare's acquisition of two Prospect Medical facilities. Separately, legislators approved UConn Health's investment to stabilize Waterbury Hospital amid Prospect's restructuring, illustrating the breadth of state involvement from process acceleration to public capital commitments.

New York broadened the model with its October 2025 announcement to fund transformational partnerships involving six safety net hospitals and other health care organizations through the Health Care Safety Net Transformation Program, committing more than $2.6 billion. The program aims to improve quality, stabilize operations, and ensure sustainable access, and includes health system affiliations, electronic health records investments, facility modernizations, network expansions, and other types of partnerships and collaborations.

This new role for states comes during a time of increased oversight into health care transactions and indicates that states may take a bifurcated approach to this oversight power by both implementing new and expanded oversight regimes in the form of pre-merger review and notification statutes and heightened scrutiny of discretionary consolidation and separately proactive facilitation where community access is at risk. As discussed in the Focus On section, states also have the opportunity to partner with hospitals and health systems to leverage RHT Program dollars to support strategic partnerships, test new value-based care models, expand workforce training and access to health care

in rural settings, and promote regional collaboration. Notably, the funding may not be used for rate enhancements, and, instead, must be used for specific projects, investments, and initiatives.

3. Hospital Investment in and Partnerships with AI Companies

Health systems are increasingly investing in and partnering with AI companies to target measurable returns in administrative operations, revenue cycle, and clinical documentation, which are areas where adoption can improve access, reduce administrative burden, and drive operating margin. Mass General Brigham, for example, has invested $30 million in an Artificial Intelligence and Digital Innovation Fund to invest in venture stage companies whose offerings further the health system's strategic initiatives.

Priority areas for health systems include automating claims, coding, prior authorization, and denial management; streamlining documentation and coding documentation improvement; and enhancing patient access and engagement. These are capabilities that convert unstructured data into actionable information and reduce manual intervention across the revenue cycle. Point of care solutions, including scribing and imaging-supported workflows are also gaining traction, with an increased share of physicians adopting documentation support solutions and large systems publicly reporting that AI is being deployed to ease clinician burden. As providers pursue both internal buildouts and external partnerships, leaders are focused on investments that deliver clear returns on investment while supporting access, quality, and efficiency goals.

340B Updates

1. 340B Rebate Pricing: Proposals and Challenges

Proposals to shift 340B pricing from point-of-sale discounts to post-sale rebates, including a government-proposed pilot program and manufacturer-initiated models, are driving significant regulatory and litigation activity. As discussed in our prior newsletter, on July 31, 2025, the HRSA announced a 340B Rebate Model Pilot Program, permitting certain manufacturers to offer 340B pricing through post-purchase rebates, rather than through traditional point-of-sale discounts. As described in the Federal Register, HRSA would permit manufacturers selected for the pilot program to provide rebates to covered entities equal to the WAC *less* the statutory 340B ceiling price. The pilot program has been subject to legal challenge in the courts and the subject of public calls for government action. Litigation challenging manufacturer-initiated rebate models is also subject to ongoing litigation.

- *HRSA's 340B Rebate Model*

  In the fall, HRSA took action to implement the pilot program, announcing the first set of selected drugs and approved rebate plans, including rebate model plans from nine manufacturers. HRSA's Office of Pharmacy Affairs approved the following drugs for participation in the rebate pilot program: Eliquis, Enbrel, Farxiga, Imbruvica, Januvia, Jardiance, Novolog/Fiasp, Stelara, Xarelto, and Entresto. The pilot program was set to go into effect on January 1, 2026. Prior to implementation, the pilot program was challenged by the American Hospital Association ("AHA") and multiple hospitals.

- *Litigation over HRSA's 340B Rebate Model Results in Model's Termination*

  On February 5, 2026, HRSA ended the 340B Rebate Model, which would have allowed pharmaceutical companies to apply rebates to a set of 340B-eligible medications, rather than provide upfront discounts. The termination comes in response to a lawsuit filed in the U.S. District Court for the District of Maine by the AHA and multiple health systems in December seeking to enjoin the pilot model, arguing that the pilot program was unlawful under the APA. A joint motion filed by the parties asked the court to vacate the litigation and send the model back to the agency. Should the agency decide to revive the model, it would do so in revised form through notice-and-comment rulemaking.

  The court had previously granted plaintiffs a preliminary injunction, halting HRSA's implementation of the pilot program. The court determined that the agency failed to consider the reliance interests created by decades of upfront discounts to safety-net providers, as well as the costs of compliance and of paying wholesale prices pending rebates. HRSA appealed the decision to the First Circuit Court of Appeals (Please see our client alert for additional details.).

  After the First Circuit denied HRSA's request for a stay pending appeal and then denied the federal government's motion for an emergency stay of the preliminary injunction blocking the pilot program, HRSA paused the implementation of the pilot program, and the federal government notified the court that HRSA was considering returning the pilot program back to the agency for reconsideration. On January 16, 2026, the federal government dismissed its appeal, stating in a filing

that the agency planned to address the procedural deficiencies described in the district court's decision.

HRSA subsequently indicated that manufacturers approved for participation in the pilot program should continue to offer their covered outpatient drugs to covered entities at the 340B ceiling price as an upfront discount.

- *Hospital Association Argues Rebate Models Are Anti-competitive*

  On September 8, 2025, the AHA published an open letter to the FTC and the DOJ's Antitrust Division, urging the agencies to investigate drug manufacturers' alleged "coordinated" shift from upfront discounts to post-sale rebate models in the 340B Program. The letter contended that the shift would negatively affect safety-net hospitals, potentially creating significant cash-flow strain and curtailing health care services. The AHA pointed to manufacturers' closely timed rebate-model announcements, analogizing the rebate trend to the alleged facts at issue in a case from the Second Circuit, in which the court of appeals permitted antitrust claims to proceed based on manufacturers' parallel restrictions on contract pharmacy 340B pricing. The AHA concluded the letter by requesting antitrust enforcement.

- *Update on J&J, Eli Lilly Rebate Litigation*

  As discussed in previous newsletters, pharmaceutical manufacturers have challenged HRSA's rejection of manufacturer-initiated rebate models. The manufacturers contended that the 340B statute permits rebate models at a manufacturer's discretion. HRSA rejected this argument, stating that the statute requires the HHS Secretary to approve any rebate pricing mechanism and that unapproved implementation would violate the statute's "must offer" mandate. The U.S. District Court for the District of Columbia sided with HRSA, concluding that rebate models required prior approval from the agency. The district court's decision is now on appeal. Oral arguments for the now consolidated lawsuit were held on November 17, 2025. The court has not issued any decisions since our last newsletter.

2. *Manufacturer Disputes Relating to State Contract Pharmacy Mandates Lead to Intra-Circuit Split*

As described in previous newsletters, drug manufacturers are continuing to challenge, with varying success, state laws requiring manufacturers to offer 340B drug prices on products purchased for dispensing at contract pharmacies; however, the courts have been divided on whether these state laws are permissible. Litigation has been ongoing since our last newsletter.

On October 31, 2025, the U.S. District Court for the Western District of Oklahoma granted in part and denied in part manufacturers' motions for preliminary injunction, ultimately enjoining the Oklahoma Attorney General from enforcing an Oklahoma state law that would prohibit interference with the acquisition of a 340B drug by a covered entity or a contract pharmacy while the case remains pending. The court stated that the Oklahoma law was preempted by and conflicted with the federal 340B Program and that the law constituted an uncompensated taking. On the preemption point, the court concluded that the Oklahoma law operated as a pricing mandate by compelling manufacturers to deliver drugs at 340B discounted prices to an unlimited number of contract pharmacies. The court further found a direct conflict with the federal 340B scheme because the state law barred manufacturers from conditioning discounts on the provision of certain claims data. Separately, the court reasoned that Oklahoma could not raise the cost of access to federally created markets by forcing sales at "confiscatory" prices without compensation, particularly where the resulting windfalls flow to private actors without any requirement to put those profits toward a public good. On November 12, 2025, the state of Oklahoma appealed the court's decision to the Tenth Circuit, where briefing remains ongoing. The Oklahoma Attorney General's opening brief is due February 19, 2026.

On October 31, 2025, the U.S. District Court for the District of Colorado denied a large pharmaceutical company's motion for a preliminary injunction against a Colorado law that would prohibit restrictions on the acquisition of a 340B drug by a covered entity or a contract pharmacy. Unlike the federal court in Oklahoma, the court here rejected the manufacturer's contention that the Colorado law regulated pricing, stating that the law did not compel sales to non-covered entities. The court also found that the state law did not conflict with the federal 340B enforcement scheme. Finally, the court further diverged from the Oklahoma federal court in concluding that conditions tied to participation in the voluntary 340B Program did not constitute a *per se* taking. On November 19, 2025, the pharmaceutical company appealed the decision to the Tenth Circuit, where the case remains pending.

On December 17, 2025, the same court in Colorado denied a similar motion for preliminary injunction by AstraZeneca. The

district court echoed much of the rationale from its October 31 decision, but also stated that the Colorado law complemented federal objectives by facilitating access for low-income patients to drugs at 340B prices via contract pharmacies.

3. HHS Proceeds with Medicare OPPS Drugs Acquisition Cost Survey

In its CY 2026 Hospital OPPS Final Rule, CMS confirmed that the agency would conduct a Medicare OPPS Drugs Acquisition Cost Survey to collect hospital acquisition costs for *all* separately payable covered outpatient drugs reimbursed under OPPS for use in setting the payment rates for such drugs. In doing so, CMS referenced Executive Order 14273, "*Lowering Drug Prices by Once Again Putting Americans First*," signed by President Trump on April 18, 2025, which directed the HHS Secretary to conduct a survey to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. According to the agency, the survey will apply to about 700 HCPCS codes. As part of the survey, CMS would gather data at the National Drug Code ("NDC") level for purchases from July 1, 2024 to June 30, 2025, requesting total units and total net acquisition cost, inclusive of all rebates and discounts, for each NDC. CMS indicated that the submission window would run from January 1 through March 31, 2026, with survey results informing payment policymaking beginning with the CY 2027 OPPS Proposed Rule, expected in July 2026.

CMS stated that all hospitals paid under the OPPS "are required to respond to the survey," but the agency acknowledged that the authorizing statute does not prescribe specific consequences for no response. The AHA has stressed to hospitals that the "burdensome" survey is optional, but that a failure to respond could factor into any future rate reduction, potentially leading to lower reimbursement rates. CMS has also stated that the agency may consider nonresponses when setting future payment policies. As noted in our prior newsletter, the survey is a potential precursor to a proposal to reduce or otherwise modify payment for drugs in the hospital outpatient setting.

4. CMS Does Not Finalize Plan to Accelerate Claw Back of Additional OPPS Payments Following Litigation Invalidating Rule on 340B Drugs

In the CY 2026 Hospital OPPS Final Rule, CMS also announced the agency will apply a 0.5% reduction (instead of the 2% reduction initially proposed) to the OPPS conversion factor. In reducing the conversion factor, CMS states that it seeks to claw back gains from hospitals that received increased payments from 2018 to 2022 when Medicare paid less for 340B-acquired drugs. As discussed in our prior newsletter, the Supreme Court in *AHA v. Becerra* concluded that such reductions were unlawful and hospitals must receive additional payments to correct the underpayment for drugs. Thus, CMS was required to "claw back" the increases in other products and services to preserve the required budget neutrality. The 0.5% reduction applies prospectively. Hospitals that enrolled in Medicare after January 1, 2018, are excluded from the offset. CMS estimates that the CY 2026 0.5% reduction will decrease payments to approximately 3,229 affected providers by $275 million.

For now, CMS will not implement the proposed 2% reduction for 2026 mentioned in the prior newsletter. According to CMS, this delay will provide hospitals additional time to prepare for the new payment rate. CMS currently anticipates delaying the adjustment for just one year, stating that hospitals should expect that the agency will implement a larger adjustment (such as 2% or another adjustment greater than 0.5%) beginning in CY 2027.

5. CMS Excludes 340B Drugs from Medicare Part D Inflation Rebate Calculation

On November 5, 2025, CMS published the CY 2026 PFS Rule, which excludes drugs purchased under the 340B Program from the Medicare Part D Drug Inflation Rebate calculations, effective January 1, 2026. To effectuate the exclusion, CMS finalized a claims-based Prescriber-Pharmacy Methodology that identifies potentially 340B-eligible Prescription Drug Event records by linking prescribers affiliated with covered entities and contract pharmacies. Based on a preliminary analysis, CMS expects this methodology to remove 10% to 35% of units for "most" Part D rebate-eligible drugs. This exclusion could result in additional administrative burdens to hospitals, which must flag 340B units in Part D claims, including those dispensed by contract pharmacies.

According to CMS, to improve accuracy and to avoid duplicate discounts, the agency will launch a voluntary Medicare Part D Claims Data 340B Repository (expected to be available in fall 2026) to accept retrospective submissions directly from covered entities (or their third-party administrators) of certain data elements for claims with dates of service on or after January 1, 2026, allowing CMS to remove those claims from the Part D rebate calculation. In the proposed rule, CMS estimated that 6,500 covered entities would submit data to the voluntary repository, with about eight hours spent per submission. CMS acknowledged that, to foster robust data reporting, covered entities will need time to develop a process for data collection and to prepare the data in the form and manner prescribed by the agency, with CMS providing no additional funding for system upgrades.

6. *HRSA Seeks Further Information Related to 340B Program Efficiency and Integrity*

On August 7, 2025, HRSA published a notice in the Federal Register, announcing its intent to submit to OMB a revised Information Collection Request ("ICR") for the 340B Program. According to HRSA, the agency's changes to the ICR are limited to modifying certain forms to increase program efficiency and integrity. Changes include clearer shipping and street address fields to distinguish pharmacies and sites; documentation requirements for STD/TB grantees; time-period data for Family Planning entities; collection of Tribal Agreement numbers for Urban Indian and Tribal 638 FQHC entities; and alignment of hospital fields with CMS terminology, plus clarified Worksheet S and trial balance instructions.

On January 8, 2026, HRSA published a notice in the Federal Register summarizing the 14 comments the agency had 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 limited administrative staff and funding, and other commenters argued that the modified trial balance requirements could lead to inappropriate termination of 340B Program registrations. In its January notice, HRSA specifically asked for comments, by February 9, 2026, on (i) the need and utility of the proposed information collection for HRSA's performance of its functions, (ii) the accuracy of the estimated burden, (iii) ways to enhance the quality and clarity of the information to be collected, and (iv) the use of automated collection techniques and other forms of IT to minimize the information collection burden.

7. *Sagebrush 340B Eligibility Fight Broadens: Cross-Motions with HRSA, Manufacturers' Suit Proceeds, and New California Case against Amgen*

As discussed in our prior newsletter, Sagebrush Health Services ("Sagebrush") challenged its clinics' termination from the 340B Program. According to HRSA, the agency terminated the clinics because Sagebrush failed to provide adequate documentation proving that the clinics were eligible for the 340B Program as STD grantees. On October 15, 2025, Sagebrush filed a motion for summary judgment. Sagebrush argued that HRSA lacked statutory authority to remove sites from the 340B Program midway through their certification year because Congress only permitted termination after an audit finding "systematic and egregious" diversion that is "knowing and intentional." Sagebrush contended that the termination violated the 340B statute's annual recertification process and occurred without any audit or diversion finding.

The government defendants filed a cross-motion for summary judgment on December 15, 2025. In its motion, HRSA argued that Sagebrush failed to provide timely documentation verifying the clinics' 340B eligibility. Specifically, despite requests from HRSA, Sagebrush allegedly did not prove that its clinics received requisite "section 318" funding from a state or local government for the treatment of STDs. HRSA asserted that the agency had broad statutory authority to administer certifications and an inherent authority to verify provider eligibility and correct erroneous prior certifications. HRSA countered Sagebrush's arguments, contending that the 340B statute did not guarantee a one-year certification period and that the clinic terminations were for failure to meet threshold eligibility requirements, not for diversion or duplicate discounting. Briefing is ongoing.

A group of manufacturers' related lawsuit also remains open. As discussed in our prior newsletter, Amgen, Eli Lilly and Company, and UCB, Inc. sued HRSA as co-plaintiffs for the agency's alleged failure to fulfill its obligations to oversee the 340B Program by permitting ineligible Sagebrush clinics to participate in the program. On August 4, 2025, the U.S. District Court for the District of Columbia denied HRSA's motion to dismiss parts of the manufacturers' complaint. On November 25, 2025, the court finalized the briefing schedule, with plaintiffs' motion for summary judgment due by February 20, 2026. On January 27, 2026, the court granted Community Care Resources of Florida's ("CCRF") motion to intervene, finding that CCRF, a certified STD clinic participating in the 340B Program, shared common legal questions and sought the same relief as the government defendants. Specifically, the court stated that CCRF sought to uphold HRSA's 340B certification process.

As the latest development in this litigation, on December 30, 2025, Sagebrush also filed a complaint against Amgen in California state court, accusing Amgen, among other things, of (i) unlawfully cutting off 340B sales to its Nevada clinics and (ii) improperly clawing back at least $7,000,000 in past discounts, allegedly disrupting care for low-income and uninsured patients. Sagebrush's causes of action include (i) conversion, (ii) intentional interference with contract, (iii) intentional interference with prospective economic advantage, (iv) California Penal Code violations, and (v) California Business and Professions Code violations. Amgen filed a notice to remove to Federal District Court on January 16, 2026.

Looking Ahead

On Wednesday, March 18, Ropes & Gray will host a networking reception at The Bygone during the AHLA Institute on Medicare and Medicaid Payment Issues. For more information on the event, please contact Marnine.Wilensky@ropesgray.com.

Ropes & Gray is sponsoring the ACI Inaugural Healthcare AI Summit on February 26 and 27. For registration information, visit the ACI website.

- Christine Moundas is presenting on Cybersecurity Best Practices for Healthcare AI
- Brett Friedman is presenting on Payor-Provider Risks and Opportunities
- Jamie Darch is presenting on Data Privacy for AI MedTech and Digital Tools

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

Ropes & Gray has released a 2026 Healthcare Market Outlook video, overviewing the key market trends and regulatory developments shaping the industry forecast. Please contact our health care team at HealthcareLifeSciences@ropesgray.com for a complimentary briefing on our 2026 health care market outlook and/or specific trends.

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

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 deregulatory efforts at the federal level. The Health AI Atlas includes examples and requirements for health care professionals, hospitals, health systems, clinics, managed service organizations, and telehealth providers creating AI solutions. The Atlas also 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.

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

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

Publications

- U.S. District Court Grants Preliminary Injunction Restoring Seven Federal Grants to the American Academy of Pediatrics, Citing Retaliation for Constitutionally Protected Activity
- NIH Prohibits Use of Federal Funds for Research Involving Human Fetal Tissue from Elective Abortions
- False Claims Act Insights: Key Takeaways from DOJ's Fiscal Year 2025 Cases & Recoveries
- Rhode Island Adopts Final Rule Requiring Notice of Medical-Practice Group Transactions
- DOJ's *Done Global* Telehealth Prosecution Signals Expanded Criminal Risk for Telehealth Platforms, MSOs, and Investors
- First Circuit Affirms a Lower Court Decision Prohibiting NIH from Capping Reimbursements for Facilities & Administrative (or "Indirect") Costs
- Is International Pricing Coming Onshore for Testing? CMS Proposes Models Tying Medicare Part B and Part D Drug Rebates to International Pricing
- Federal District Court Enjoins HRSA's 340B Rebate Model Pilot Program
- Trump Attempts to Preempt State AI Regulation Through Executive Order

Podcasts

- Five Things Developers Should Remember about New State AI Laws in Health Care

Trending Videos

- Digital Health, Data, and AI
- Healthcare M&A Regulatory Strategy
- 2026 Drug Pricing Outlook

Webinars

- Navigating Healthcare M&A in 2026: Advancing Deal Execution Through Regulatory Strategy
- Pharma's Foreign Fault Lines: Most Favored Nation Pricing, BIOSECURE Act, and a New Era of Populist Pricing Proposals and National Security Safeguards

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