

Hospital & Health System Reimbursement Check

October 2026

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

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Medicaid Services (CMS) estimates these regulatory changes would together reduce federal Medicaid spending by approximately \$775 billion (state-directed payment changes) and \$246 billion (provider tax changes) over the next decade. Third, a recent Provider Reimbursement Review Board (PRRB) decision (Decision 2026-D21, July 9, 2026) highlights CMS's restrictive treatment of the provider taxes a hospital has paid on its Medicare cost report. Hospitals should consider the potential financial impact to their organizations of each policy and determine whether CMS's policy is consistent with the provider's own understanding of HR 1 and the Medicare statute, such as whether CMS exceeded its statutory authority by creating or eliminating regulatory provisions on which HR 1 was silent. Hospitals that will be financially impacted and seek to dispute one or more of those policies should begin formulating their policy and legal strategies for addressing those rules now to be prepared if CMS ultimately finalizes either of the proposed rules.

[Provider Taxes and the Hold Harmless Prohibition](#)

1. Provider Taxes

Provider taxes are health care-related taxes that states assess on hospitals, nursing homes, managed care organizations, and other providers. State legislatures sometimes call them provider "assessments" or "quality assurance assessments," see, e.g., 91 Fed. Reg. 46562, 46564–65 (July 23, 2026). States typically use the revenue from those taxes to finance the state's share of Medicaid expenditures, as authorized under the Medicaid statute at 42 U.S.C. § 1396b(w). The federal government matches state Medicaid contributions under the Federal Medical Assistance Percentage set forth in 42 U.S.C. § 1396d(b), at a rate that varies by state based on per capita income; this federal share is called federal financial participation. Over the years, provider taxes have become an increasingly popular tool for states seeking to make supplemental Medicaid payments to certain providers. In

Focus On

PREPARING FOR MEDICARE'S NEW PROVIDER-BASED STATUS REQUIREMENTS

[Executive Summary](#)

First, a proposed rule (91 Fed. Reg. 30400, May 22, 2026) arising from the One Big Beautiful Bill Act (HR 1), Pub. L. No. 119-21, § 71116, 139 Stat. 72, 303–04 (2025), would cap state-directed Medicaid managed care payments. Second, a separate proposed rule (91 Fed. Reg. 46562, July 23, 2026) would lower the threshold for finding an impermissible indirect hold-harmless arrangement—one in which the overall structure of the tax and payment scheme, rather than an explicit state guarantee, effectively ensures that tax-paying providers are reimbursed for some or all of their tax costs through enhanced Medicaid payments. See HR 1 § 71115. The Centers for Medicare &

2026, provider taxes produced almost \$100 billion in incremental federal Medicaid expenditures, more than a quarter of the total non-federal share of Medicaid, with taxes on hospitals (\$61 billion) and managed care organizations (\$28 billion) accounting for 90% of all state provider taxes.

2. The Hold-Harmless Prohibition

For a provider tax to be permissible under Medicaid, it must be broad-based (all providers in a class are taxed) and uniform (same rate for all). CMS may, however, waive one or both requirements at a state's request, provided the net impact of the tax and subsequent Medicaid payments is generally redistributive and the amount of the tax is not tied to the amount of Medicaid payments the provider receives. *See* 42 U.S.C. § 1396b(w)(1); 42 C.F.R. § 433.68(b)–(e); *see also* 91 Fed. Reg. at 46563. Critically, the tax may not include a “hold harmless” provision—an arrangement where the state “provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax.” 42 U.S.C. § 1396b(w)(4)(C)(i); 42 C.F.R. § 433.68(f). In a “direct” hold-harmless arrangement, the state explicitly guarantees to repay taxpaying providers for all or part of the taxes they paid, regardless of the number of Medicaid enrollees a particular provider serves. In an “indirect” hold-harmless arrangement, even absent an explicit guarantee, the overall structure of the tax and payment scheme effectively ensures that taxpayers are reimbursed for their costs. CMS cannot waive the prohibition on hold-harmless arrangements. *See* 42 U.S.C. § 1396b(w)(3)(E); 91 Fed. Reg. at 46567. According to CMS, these restrictions are necessary to ensure states contribute their share of any increased Medicaid payments; if every provider is paid back for its tax obligations, any resulting increased Medicaid payments would consist solely of federal funds. *See* Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality 89 Fed. Reg. 41002, 41073 (May 10, 2024) (final rule).

CMS's regulations establish two tests for determining whether an indirect hold harmless arrangement exists. First, a provider tax exceeding 6% of the taxed providers' net patient revenue triggers a rebuttable presumption of an impermissible hold harmless arrangement. This 6% threshold was established by regulation in 1993 and codified by the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, Pub. L. No. 102-234. *See* 42 U.S.C. § 1396b(w)(4)(C)(ii); 42 C.F.R. § 433.68(f)(3)(i). Second, even if a tax exceeds the 6% threshold, the state may still receive federal financial participation based on that tax if fewer than 75% of taxpaying providers receive 75% or

more of their tax costs back through enhanced Medicaid or other state payments. *See* 42 C.F.R. § 433.68(f)(3)(ii). This test is commonly referred to as the “75/75 test.” As discussed below, the proposed rule would eliminate the 75/75 test altogether and substantially modify the 6% threshold.

In recent years, CMS became concerned about possible private arrangements in which taxpaying providers pool and redistribute the increased Medicaid payments financed by the tax so that all taxpaying providers are reimbursed for their tax payments. *See* 89 Fed. Reg. at 41073. In February 2023, CMS issued an [Informational Bulletin](#) stating that such private redistribution arrangements could violate the hold-harmless rule if they create a “reasonable expectation” that taxpayers would be held harmless. In May 2024, CMS codified related provisions in the Medicaid and CHIP Managed Care Access, Finance, and Quality Final Rule at 42 C.F.R. §§ 438.6(c)(2)(ii)(G), 438.6(c)(2)(ii)(H), and 430.3(e), taking the position that those private redistribution arrangements constitute prohibited direct hold-harmless arrangements under 42 U.S.C. § 1396b(w)(4)(C)(i). 89 Fed. Reg. at 41076. Two recent court decisions, however, have reached different conclusions about whether CMS can regulate these arrangements.

In [*Texas v. Brooks-LaSure*](#), No. 6:23-cv-161-JDK (E.D. Tex. Sept. 24, 2025), a federal court granted summary judgment in favor of Texas, vacating CMS's 2023 and 2024 guidance and the challenged regulatory provisions (42 C.F.R. §§ 438.6(c)(2)(ii)(G), 438.6(c)(2)(ii)(H), and 430.3(e)), and permanently enjoining CMS from enforcing its interpretation of the statutory hold harmless provision. The court held that private redistribution arrangements among providers do not constitute a direct hold-harmless arrangement; such an arrangement can exist only if the state expressly guarantees to hold taxpaying providers harmless. CMS has appealed to the Fifth Circuit, No. 25-40766, where briefing is underway with multiple amicus briefs filed in support of Texas.

In [*Florida Agency for Health Care Administration v. Administrator for the Centers for Medicare & Medicaid Services*](#), No. 24-10875 (11th Cir. Dec. 5, 2025), the Eleventh Circuit Court of Appeals reached the opposite conclusion, holding that the best reading of the statute includes private redistribution arrangements among hospitals in its prohibition against hold-harmless arrangements. The court rejected Florida's argument that the statute requires the state itself to guarantee to repay taxpaying providers.

[CMS Proposed Rule on State-Directed Payments \(CMS-2449-P\)](#)

One way that states have used revenues from provider taxes to

finance increased Medicaid payments to providers is through state-directed payments (SDPs). Most states contract with managed care organizations to administer Medicaid benefits for at least some of the state's enrollees. *See* [42 C.F.R. § 438.6](#). In doing so, states are generally prohibited from directing Medicaid managed care plans' expenditures, instead permitting the plans to negotiate payment rates directly with providers. *See* [42 U.S.C. § 1396b\(m\)\(2\)\(A\)\(iii\)](#) (limiting managed care contracts between states and managed care organizations to payments for services and associated administrative costs that are actuarially sound); 42 C.F.R. § 438.6(c) (generally prohibiting states from contractually directing managed care organizations' expenditures unless an enumerated exception applies).

In its 2016 Medicaid managed care final rule, *see* 81 Fed. Reg. 27498 (May 6, 2016) (codified at 42 C.F.R. § 438.6), CMS created an exception to that general rule allowing states to require managed care organizations to make certain directed payments in certain circumstances and with prior written approval from CMS. Under that exception, the state may instruct or "direct" managed care plans administering Medicaid benefits to provide supplemental payments to identified categories of health care providers. These supplemental payments are made in addition to the plan's contracted rates for a particular claim and intended to allow the state to further certain goals or objectives, such as through minimum fee schedules or rate "add-ons." In doing so, the agency said it sought to modernize the Medicaid managed care rules to align with the commercial and Medicare markets, improve quality of care, and promote efficiency in care delivery. States often use provider taxes to finance the non-federal share of increased Medicaid managed care payments for services furnished by specified categories of providers that are designed to incentivize delivery system reforms or implement performance improvement initiatives. 91 Fed. Reg. at 30403. Under existing CMS policy, SDPs have generally been subject to caps that limit any rate add-on to the "average commercial rate" (ACR)—the average rate that private commercial insurers pay for the same services (sometimes calculated on a provider-class or regional basis). States must submit annual preprint forms demonstrating compliance with this cap. *Id.* at 30402. SDPs have become a major Medicaid revenue source for hospitals since their introduction in 2016. CMS's Office of the Actuary estimated total Medicaid SDP spending to be \$97.8 billion in fiscal year 2024, and projected that number to increase to \$124.3 billion in 2025 and \$144.6 billion in 2026. *Id.* at 30404.

Congress stated that it sought to reduce states' use of SDPs as a mechanism to increase providers' Medicaid compensation as part of HR 1. Pub. L. No. 119-21, § 71116, 139 Stat. 72, 303–04.

Under section 71116 of that statute, Congress instructed CMS to amend the regulation governing SDPs, 42 C.F.R.

§ 438.6(c)(2)(iii), to replace the ACR benchmark with Medicare-based caps. Pub. L. No. 119-21, § 71116(a). CMS's proposed rule (CMS-2449-P, 91 Fed. Reg. 30400, May 22, 2026) would implement that statutory mandate. Under the proposal, expansion states would be limited to 100% of the total published Medicare payment rate; non-expansion states would be limited to 110% of Medicare. *Id.* at 30433. Where no Medicare rate exists, payments would be capped at 100% of the applicable Medicaid state plan rate. *Id.* at 30416. The caps apply at the individual claim or service level and incorporate applicable Medicare payment adjustments (geographic adjustments, add-ons, modifiers). *Id.* at 30413–14.

Previously approved SDPs that exceed the new caps would be temporarily grandfathered but must phase down by at least 10 percentage points per year beginning January 1, 2028, until they reach the applicable cap. *Id.* at 30420. Additionally, some states currently use SDPs to add a flat percentage "uniform increase" on top of whatever rate a managed care plan negotiates with a provider. Beginning January 1, 2028, this type of SDP would no longer be permitted. *Id.* at 30427. The proposed rule would extend these Medicare-based limits to all SDPs beginning January 1, 2029. *Id.*

CMS estimates that this rule would reduce total Medicaid spending (federal and state combined) by approximately \$775 billion over the next decade (2026–2035). *Id.* at 30451.

According to CMS, hospitals would bear the largest share of these reductions. *Id.* at 30447. The comment period closed on July 21, 2026. As of this publication, CMS has not yet issued a final rule.

What This Means for Hospitals. The SDP-proposed rule would substantially reduce Medicaid payments to hospitals in states where current SDP payments exceed the proposed Medicare-based caps. Hospitals that have relied on SDP-funded supplemental payments to support their operations should model the financial impact of a transition to Medicare-based caps. This includes providers in [37 states](#) that are expected to see cuts to their SDP programs as a result of HR 1. Grandfathered SDPs would phase down by at least 10 percentage points annually beginning in January 2028, so hospitals should work to understand the timeline and advocate for state- and federal-level solutions to preserve Medicaid funding.

[CMS Proposed Rule on Hold-Harmless Arrangements \(CMS-2452-P\)](#)

1. What has changed: The One Big Beautiful Bill Act (July 2025)

[Section 71115](#) of the One Big Beautiful Bill Act significantly limited the amount of provider taxes that states may use to finance the non-federal share of their Medicaid payments. Pub. L. No. 119-21, § 71115, 139 Stat. 72, 301–02 (2025) (codified as amended at 42 U.S.C. § 1396b(w)(4)). Congress replaced the prior 6% threshold with new state-specific and provider-class-specific thresholds. *Id.* § 71115(a)(2), 139 Stat. at 301 (codified at 42 U.S.C. § 1396b(w)(4)(D)(i)(I)). The new thresholds are set at each state’s actual tax levels for the relevant provider class as of July 4, 2025; for example, a state with a 4% hospital tax in place on that date would have a 4% threshold—not the former 6% ceiling. *Id.* This effectively freezes existing taxes and precludes states from creating new provider taxes or increasing existing ones. Any tax that was not “enacted and imposed” as of that date has a threshold of 0%, meaning that new provider taxes are prohibited. *Id.*

States that expanded Medicaid under the [Affordable Care Act](#), commonly called “expansion states,” face an additional reduction. Beginning in federal fiscal year (FFY) 2028 (which starts October 1, 2027), the maximum possible threshold drops to 5.5% and then decreases by 0.5% each year until it reaches 3.5% in FFY 2032. *Id.* § 71115(a)(2), 139 Stat. at 301–02 (codified at 42 U.S.C. § 1396b(w)(4)(D)(i)(II)). Taxes on nursing facilities and intermediate care facilities are exempt from this phase-down.

2. CMS’s Proposed Rule

CMS published a proposed rule ([CMS-2452-P](#), 91 Fed. Reg. 46562) on July 23, 2026, to implement these statutory changes. The proposed rule explains that CMS considers a tax to have been in effect as of July 4, 2025 if taxpayers were subject to a legally enforceable obligation to pay the tax as of that date, even if the state has not taken any action to collect. 91 Fed. Reg. at 56571. If the tax involves a waiver of the broad-based or uniformity requirements, described in Section II.B above, the waiver must have been approved with an effective date of July 4, 2025, or earlier. *Id.* CMS also clarified that the tax need not have been actively collected as of that date, departing from preliminary guidance issued in November 2025. *Id.* at 46572; *see also* CMS, Section 71115 and 71117 of Working Families Tax Cuts Legislation on Provider Taxes (2025).

The proposed rule would also eliminate the 75/75 test for

federal fiscal years beginning on or after October 1, 2026. 91 Fed. Reg. at 46581–82. CMS asserts that, although HR 1 § 71115 does not expressly eliminate that test, doing so is consistent with congressional intent to freeze provider taxes at their July 4, 2025 levels, so eliminating the 75/75 test would ensure that the statutory limit sets the permissible level for provider taxes. *See id.* at 46581. The agency also pointed to a 2018 U.S. Department of Health and Human Services Office of Inspector General report as further support. *Id.* That [report](#) recommended that CMS reevaluate the test after finding that hospital tax programs in several states complied with hold-harmless requirements but the tax burden on hospitals was “significantly mitigated” through offsetting Medicaid payments and recommended that CMS reevaluate the test. Office of the Inspector General, U.S. Dep’t of Health & Human Servs., *Although Hospital Tax Programs in Seven States Complied with Hold-Harmless Requirements, the Tax Burden on Hospitals Was Significantly Mitigated* (2018).

The proposed rule also seeks to establish new state reporting requirements. 91 Fed. Reg. at 46583–86. If finalized, the rule would require states to submit one-time interim reports by December 31, 2026, using “the best available” tax and other data. CMS says that it needs these reports to determine whether a particular state’s provider tax had been “enacted and imposed” on a particular class of providers as of the July 4, 2025 statutory deadline for determining each state’s newly applicable hold-harmless thresholds, as discussed above. *Id.* at 46583. Final reports are due June 30, 2028. CMS expects to announce final thresholds by September 30, 2028. The comment period closed on September 21, 2026.

3. What This Means for Hospitals

These statutory and regulatory changes freeze states’ provider taxes at July 4, 2025 levels. Consequently, moving forward, states would be unable to finance the state’s share of any new supplemental Medicaid payments to providers using provider taxes. In some states, existing Medicaid payments to hospitals may decline if the state cannot maintain its current supplemental payment levels without exceeding the new tax thresholds. Indeed, CMS [estimates](#) the provider tax changes will save the federal government \$246 billion over the next decade (2026–2035). *See* 91 Fed. Reg. at 46591. Expansion states face the greatest risk: 40 states and DC have expanded Medicaid and would face a phase-down of the threshold from their current rate (up to 6%) to 3.5% by FFY 2032. KFF, *Status of State Medicaid Expansion Decisions* (Aug. 21, 2026), <https://www.kff.org/medicaid/status-of-state-medicaid->

[expansion-decisions](#); see also 91 Fed. Reg. at 46576–77. This estimate is separate from, and in addition to, the \$775 billion in total savings CMS projected from the SDP changes discussed in Section III. Together, these proposed rules represent a significant tightening of Medicaid financing for hospitals and other providers.

Moving forward, states seeking to increase Medicaid payments for certain classes of providers will need to identify alternative sources for the state’s share of those payments. Those alternative sources could come from the state’s general tax revenue, fees, or other funding sources.

[PRRB Decision 2026-D21: Provider Taxes on Medicare Cost Reports](#)

While states are unlikely to increase provider taxes to cover the state’s share of future Medicaid supplemental payments for the reasons discussed above, states can continue to impose the ones that existed before HR 1 became law. Providers who are reimbursed by Medicare in whole or in part on a reasonable cost basis (e.g., critical access hospitals or hospitals paid under the inpatient prospective payment system who have, for example, organ acquisition or nursing and allied health education costs) may be able to recoup some of the costs of those taxes through increased Medicare payments by claiming the costs of the taxes in their year-end cost reports. A recently issued decision of the PRRB indicates that whether and how much of a provider tax qualifies as reasonable costs depends largely on how state law has structured those taxes and highlights the types of documentation providers can use to show whether and how much of those taxes they can include in their cost reports. Accordingly, providers seeking to claim those costs on their cost reports should carefully review the applicable state law and retain adequate provider-specific documentation to verify the total tax expenses.

Some Medicare providers may be able to claim the “net tax expense” of provider taxes as costs on their year-end cost reports. Under the Medicare reasonable cost reimbursement principles ([42 C.F.R. Part 413](#)), allowable costs must be “related to patient care” and actually incurred. CMS has not codified rules expressly permitting providers to include the cost of provider taxes in calculating their reasonable costs. But the agency announced its policy in its fiscal year 2011 Inpatient Prospective Payment System final rule that providers may only claim the “net tax expense” as an allowable Medicare cost. See 75 Fed. Reg. 50042, 50363 (Aug. 16, 2010). The agency defined the net tax expense as the amount of taxes the provider paid less any payments received that are “associated with the assessed

tax.” *Id.* CMS subsequently added that instruction for how to calculate net tax costs in Section 2122.7 of the Provider Reimbursement Manual (PRM). Courts have generally upheld CMS’s “net tax expense” policy. See [Breckinridge Health, Inc. v. Price](#), 869 F.3d 422 (6th Cir. 2017) (upholding CMS’s offset of tax reimbursement by Medicaid payments), *cert. denied* 586 U.S. 815 (2018); [Dana-Farber Cancer Institute v. Hargan](#), 878 F.3d 336 (D.C. Cir. 2017) (reversing district court and holding that the Board’s net-cost interpretation was reasonable); [Abraham Lincoln Memorial Hospital v. Sebelius](#), 698 F.3d 536 (7th Cir. 2012) (same); [Kindred Hospitals East, LLC v. Sebelius](#), 694 F.3d 924 (8th Cir. 2012) (upholding CMS’s policy).

A recent PRRB decision applied this policy and provides some insight into what payments CMS considers to be “associated with” a provider tax. In PRRB Decision 2026-D21, issued July 9, 2026, the Board ruled against a critical access hospital in Michigan. The hospital paid a Michigan provider tax called the Quality Assurance Assessment Program (QAAP) and claimed a portion of those tax payments as reimbursable costs on its Medicare cost report. The state law imposing the QAAP tax provided that a portion of the QAAP taxes the state collects is used as the state’s share of certain supplemental Medicaid payments to providers. The state keeps the remainder, called the state retention amount, to offset general fund revenue used for hospital services and therapy. The hospital accordingly included the state retention amount, about 34 or 35% of the QAAP tax fund, as reasonable costs in its 2017, 2018, and 2019 cost reports. It asserted that this “retention amount” was a reasonable cost incurred and that it did not receive any payments “associated with” that amount because those funds were used to offset general state budget costs, not to fund the supplemental Medicaid payments hospitals received.

The Medicare Administrative Contractor (MAC) disallowed those costs, and the PRRB affirmed for two reasons. First, the Board rejected the hospital’s argument that the state retention amount of the QAAP tax is essentially a separate tax. Because the retention amount of the tax goes to the state’s general fund, it argued that portion of the QAAP tax was not used to finance the supplemental payments, so those retention amounts were therefore not “associated with” the amount the state retained. In doing so, the Board declined to distinguish between the portion of the QAAP tax used to finance supplemental Medicaid payments from the portion the state retained. Because the hospital ultimately received a net gain from the combined state and federal share of the resulting supplemental Medicaid payments compared to the total QAAP tax it paid, the Board held there was no net tax expense. The Board based its decision

in part on its interpretation of the Michigan law governing the QAAP tax. That law provides that, “[a]ny portion of the quality assurance assessment collected from a hospital that is not eligible for federal matching funds must be returned to the hospital.” The Board noted that the retention amount had not been returned to the providers, so it must have been used to draw down federal dollars, making the entire tax “associated with” the supplemental payments.

Second, the Board found the hospital did not provide sufficient documentation demonstrating the amount of QAAP taxes it actually paid or the revenues it received from supplemental Medicaid payments to properly calculate its net tax expense. The Board faulted St. Francis for failing to provide invoices from the state, records of payments received, or other provider-specific documentation that would allow the MAC to verify its net tax expense. St. Francis relied instead on documentation showing the total QAAP taxes it paid and a letter from the state saying the retention amount for 2019 was 34.7 percent, extrapolating from that information that the net tax expense attributable to the retention amount was 34.7 percent of its total QAAP payments. The Board concluded that such general information did not satisfy the requirement that Medicare providers must provide data that is accurate and provides sufficient detail to show its net tax expenses. The hospital did not challenge the Board’s decision.

Practical Takeaways for Hospitals. The decision comports with CMS’s view stated in the 2011 IPPS final rule, 75 Fed. Reg. at 50363, and the PRM at 2122.7 that net-of-payments reporting is required. Hospitals seeking to claim provider taxes as reimbursable costs on their Medicare cost reports should carefully review state law governing provider taxes to determine what portion of those taxes are used to finance payments to providers, including but not limited to supplemental Medicaid payments. For statutory schemes similar to the Michigan QAAP tax at issue in St. Francis, where only a portion of the provider tax is used to finance payments to the provider and the rest goes to the state’s general fund, providers should consider working with state officials to restructure the law to separate the portions of the tax that are associated with payments from those that are not.

Hospitals should also maintain detailed records of both tax payments (invoices, quarterly bills) and related Medicaid receipts. While HR 1 and CMS’s proposed changes to the hold-harmless threshold limit states’ reliance on provider taxes moving forward, states can continue to impose those that existed as of July 4, 2025. So, providers reimbursed in whole or in part on a

reasonable cost basis should still take steps to retain adequate documentation of the provider taxes they pay to successfully claim any net tax expenses on their cost reports. As the recent PRRB decision demonstrates, aggregate data at a state level may not suffice if the Medicare contractor disputes the hospital’s inclusion of provider taxes at audit. If a provider wants to distinguish between portions of a provider tax that are “associated with” payments and those that are not, the provider must ensure it has sufficient data to clearly identify and separate the components of the tax.

Conclusion: What Hospitals Should Do Now

Monitor the regulatory landscape. Neither the provider tax hold-harmless rule nor the directed payment rule has been finalized as of this publication. Hospitals should watch for publication of the final rules, which will establish the framework going forward. In the meantime, providers should assess the expected financial impact of the new restrictions on provider taxes and work with their states to find alternative financing and payment mechanisms that would permit states to implement future supplemental Medicaid payments. While CMS indicates that both of the regulations discussed above are intended to implement statutory changes to SDPs and the hold-harmless threshold, providers should review the proposed rules to identify any potential legal vulnerabilities or impermissible deviations from the statute. For example, CMS’s proposed hold-harmless rule would eliminate the 75/75 test under which provider taxes that exceed the indirect hold-harmless threshold are nevertheless permissible, but HR 1 § 71115 does not by its terms eliminate that test. It therefore remains an open question whether CMS has the statutory authority to do so. Providers negatively impacted by one or both of these rules, which includes providers in the [37 states](#) that will see reduced SDPs as a result of the SDP rule, will have the opportunity to challenge these policies once CMS issues its final rules.

Review Medicare cost report treatment. In light of PRRB Decision 2026-D21, hospitals should review state laws and regulations governing provider taxes to determine whether any portion of those tax payments may qualify as reimbursable costs and, if so, providers must carefully document the differential treatment to satisfy the Board’s documentation requirements.

Reimbursement Docket Updates

COURT LITIGATION UPDATES

1. *D.C. District Court Vacates 2023 Retroactive DSH Part C Days Rule*

On August 28, 2026, the U.S. District Court for the District of Columbia ruled in *Montefiore Medical Center v. Kennedy*, No. 24-cv-1810 (D.D.C. 2024), the lead case challenging the CMS's 2023 retroactive rule on Part C days in the Medicare Disproportionate Share Hospital (DSH) payment, that the proper remedy for the impermissibly retroactive rule was vacatur of the rule. The parties have filed cross-appeals to the D.C. Circuit.

The court previously granted the plaintiff's motion for summary judgment in September 2025, holding that CMS's 2023 rule was impermissibly retroactive and arbitrary and capricious in violation of the Medicare statute and the Administrative Procedure Act (APA). See [October 2025 Docket Updates](#). In that earlier decision, the court deferred ruling on the appropriate remedy and required supplemental briefs on remedy. In its most recent decision, the court vacated the rule but declined to specifically order CMS on remand to recalculate the DSH payment adjustment using its pre-2004 policy. On October 26, 2026, the government appealed the now final judgment in the case, and the following day, the plaintiff filed a cross-appeal.

2. *Texas District Court Again Vacates Section 1115 Waiver Day Exclusion Rule in Covenant Medical Center v. Kennedy*

On July 27, 2026, the U.S. District Court for the Northern District of Texas vacated the provision of the FFY 2024 Inpatient Prospective Payment System (IPPS) rule that excluded 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 (the "Exclusion Rule"). *Covenant Medical Center v. Kennedy*, 2026 WL 2149486 (N.D. Tex. Jul. 27, 2026). The inclusion of Section 1115 uncompensated care pool days in the count of Medicaid-eligible days would provide a significant boost to certain hospitals' Medicaid fractions of the DSH payment adjustment, potentially enhancing hospital qualification for the 340B Drug Pricing Program and for DSH payments and the size of DSH payment adjustments.

As reported in the [February 2026 Docket Updates](#), the Texas district court previously vacated the Exclusion Rule in a case brought by 14 Texas hospitals. However, in December 2025, the U.S. Court of Appeals for the Fifth Circuit reversed that

decision on jurisdictional grounds, holding that the hospitals had not completed the Medicare administrative channeling process before filing suit. See *Baylor All Saints Med. Ctr. v. Kennedy*, 161 F.4th 298 (5th Cir. 2025). Under that process, a hospital may challenge a DSH payment rule in court only after the rule has been applied in its Medicare cost report, the Medicare contractor has issued a final payment determination, and the hospital has appealed that determination to the Provider Reimbursement Review Board. Covenant Medical Center cured the jurisdictional defect by exhausting the administrative appeals process before filing in federal court on January 21, 2026.

As it had originally held in the *Baylor All Saints* case, the district court in the second case again held that binding Fifth Circuit precedent in *Forrest General Hospital v. Azar*, 926 F.3d 221 (5th Cir. 2019), requires patient days covered under a state's Section 1115 demonstration project to be included in the Medicaid fraction of the DSH calculation under 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II), and that the Exclusion Rule therefore contradicts the statute's plain text. The government argued that the text of the statute, which provides that "the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days" of patients receiving benefits under a demonstration project, grants the Secretary ongoing discretion not only to authorize a state's demonstration project but also to determine which categories of patient days within an approved project count toward the Medicaid fraction. The district court rejected that argument, reading *Forrest General* as holding that the Secretary's discretion extended only to the decision whether to approve the demonstration project and not to the decision to exclude categories of patient days from an approved demonstration project. As in *Baylor All Saints*, the district court ordered vacatur under of the rule 5 U.S.C. § 706 but did not grant a permanent injunction.

The government filed a notice of appeal to the Fifth Circuit on September 24, 2026. See *Covenant Medical Center v. Kennedy*, No. 26-10897 (5th Cir. 2026). This decision has important consequences for hospitals in states such as Texas, Tennessee, and Florida, which used Section 1115 demonstrations to fund uncompensated care pools. Based on this decision, these hospitals may be able to count these days on their cost reports, increasing their DSH payments and potentially helping them establish or maintain 340B eligibility.

3. *D.C. Circuit Hears Oral Arguments in Baptist Healthcare of Oklahoma, LLC v. Kennedy, No. 25-5358 (D.C. Cir. 2026)*

On September 24, 2026, the U.S. Court of Appeals for the D.C.

Circuit heard oral argument in an appeal challenging CMS's exclusion of patient days associated with the plaintiff hospitals' inpatient psychiatric units from their DSH payment calculation.

The PRRB excluded patient days from two Oklahoma hospitals with inpatient psychiatric units furnishing care to adolescent Medicaid recipients. The PRRB relied on a CMS regulation defining the statutory term "hospital's patient days" for purposes of the DSH payment to include only patient days attributable to hospital units providing services that would be generally payable under the IPPS. CMS found that the hospitals' inpatient psychiatric units did not provide services that would be generally payable under the IPPS because Oklahoma's Medicaid program classified the majority of the inpatient units' services as "residential," as opposed to "acute" care. The plaintiffs challenge the PRRB's decision as inconsistent with the statutory language of the DSH calculation, arguing that the statute requires inclusion of all patient days within non-IPPS exempt units of subsection (d) hospitals. In addition, the plaintiffs argue that the Board's decision was arbitrary and capricious because the Board incorrectly concluded that the hospitals' units did not provide acute services that would be generally payable under the IPPS by placing undue weight on Oklahoma's payment classifications and the average length-of-stay for patients in those units.

The parties are now awaiting a decision from the D.C. Circuit. A favorable ruling for the hospitals could assist other DSH hospitals seeking to include similar patient days in non-distinct-parts psychiatric units in the Medicaid fraction of the DSH calculation now excluded under the existing regulation. In addition, this case represents a significant test of how the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* to overturn the Chevron doctrine will apply in Medicare reimbursement disputes.

4. Skin Substitute Litigation Shifts to Wyoming Following Procedural Dismissals in Texas District Court

On September 26, 2026, the legal dispute over CMS reimbursement policies for skin substitute products moved to a new jurisdiction with the filing of *Wyoming Medical Associates LLC v. Kennedy*, No. 2:26-cv-275 (D. Wyo. 2026). This lawsuit marks a strategic attempt by industry stakeholders to obtain a substantive ruling after a series of procedural dismissals in Texas federal court.

The litigation centers on significant changes to CMS payment and coding policies for skin substitutes. CMS had long reimbursed all covered skin substitutes under Medicare Part B

based on their Average Sales Price (ASP). Effective January 1, 2026, however, CMS limited ASP-based reimbursement to skin substitutes licensed as biologicals under Section 351 of the Public Health Services Act and began reimbursing other skin substitute products at a flat national rate as "incident-to" supplies. The agency's changed policy has resulted in a drastic reduction in payments for skin substitutes.

Efforts to challenge these CMS policies have repeatedly stalled in the U.S. District Court for the Northern District of Texas due to procedural barriers. As detailed in the [June 2026 Docket Updates](#), the CAMPs Initiative, a coalition of skin substitute manufacturers, filed a lawsuit challenging CMS's payment reduction. On March 12, 2026, the court dismissed the case for failure to satisfy the Medicare statute's channeling requirement because the CAMPs Initiative had not presented claims for reimbursement to the agency. *See Order, CAMPs Initiative v. U.S. Dep't of Health & Human Servs.*, No. 4:26-cv-99 (N.D. Tex. Mar. 12, 2026), ECF No. 44. In response to that dismissal, the CAMPs Initiative filed a new lawsuit along with two physician co-plaintiffs, who had submitted claims for reimbursement to the agency but filed suit after an initial reimbursement determination from the contractor and without completing all four levels of administrative review for Part B reimbursement claims. *See CAMPs Initiative v. U.S. Dep't of Health and Human Servs.*, 4:26-cv-769 (N.D. Tex. 2026). On August 26, 2026, the court dismissed this second lawsuit for lack of subject matter jurisdiction as well, concluding that although the physician plaintiffs had properly presented their claims to CMS, they still had not satisfied the channeling requirement because they failed to exhaust their administrative remedies. *See CAMPs Initiative v. U.S. Dep't of Health & Human Servs.*, 2026 WL 2517671 (N.D. Tex. Aug. 26, 2026).

That same day, the Texas district court also dismissed a putative provider class action alleging that CMS unlawfully implemented a "clawback policy" through audits and claim denials, retroactively denying coverage for skin substitutes derived from donated human amniotic tissue. *McGee v. Kennedy*, 2026 WL 2517672 (N.D. Tex. 2026). The plaintiffs argued that CMS labeled these products "experimental" or "investigational" without following notice-and-comment procedures or offering a reasoned explanation for departing from previously applied Local Coverage Determinations. The court granted the government's motion to dismiss for lack of subject matter jurisdiction over six of the nine plaintiffs, finding that they had not exhausted their administrative remedies and that none of the exceptions to the exhaustion requirement applied. The court rejected the plaintiffs' argument that exhaustion was futile

because CMS's alleged clawback policy predetermined the denial of their claim, reasoning that the plaintiffs' belief that an appeal would fail did not excuse their failure to pursue the administrative process. The remaining claims were dismissed for improper venue. In both cases, plaintiffs have until October 26, 2026, to file a notice of appeal.

In response to these setbacks, nine skin substitute providers from across the country filed a new complaint in the U.S. District Court for the District of Wyoming. *See Wyo. Med. Assocs. v. Kennedy*, No. 2:26-cv-275 (D. Wyo. 2026). Several of these providers were also parties in the *McGee* case, and the new case largely follows the framework of *McGee*, similarly challenging the alleged clawback policy on behalf of a putative class of providers. The new complaint alleges that three plaintiffs have fully exhausted administrative remedies, including a plaintiff that anchors venue in the district. The government has not responded to the complaint as of the date of publication.

5. Coalition of 25 States and the District of Columbia Challenge Medicaid Work Requirements Interim Final Rule

On June 29, 2026, a coalition of 25 states and the District of Columbia filed suit in the U.S. District Court for the District of Massachusetts challenging CMS's interpretation of the statutory exclusion of "medically frail" individuals from the Medicaid work requirements reflected in the agency's June 3, 2026, interim final rule (IFR). *Massachusetts v. O'Leary*, No. 1:26-cv-12962 (D. Mass. 2026). Under the 2025 One Big Beautiful Bill Act, beginning January 1, 2027, states must require adult Medicaid enrollees ages 18–64 who are covered under the expanded eligibility group created in the Affordable Care Act to provide documentation demonstrating that they work or volunteer at least 80 hours per month as a condition of coverage. Congress excepted "medically frail" individuals from the new community engagement requirement, specifying a list of conditions that are to be included in the medically frail category. The statute also instructed CMS to promulgate an IFR to implement the community engagement requirement. In its IFR, CMS provided that enrollees seeking a medical frailty exception must show both that they have at least one of the conditions listed in the statute and that the condition significantly impairs the enrollee's ability to work or volunteer at least 80 hours per month.

The plaintiffs allege that CMS's interpretation of the "medically frail" exclusion is contrary to law and arbitrary and capricious under the APA. They argue that CMS's approach conflicts with Congress's intent to categorically exclude from the community engagement requirement individuals with one of the qualifying

health conditions identified in the statute because the IFR requires individuals to demonstrate not only that they have a qualifying health condition but also that the condition significantly impairs their ability to work. The plaintiffs further argue that the rule is arbitrary and capricious because it ignores the weight of the evidence showing that imposing a significant impairment requirement is likely to cause substantial coverage losses and harm to medically vulnerable individuals. The court denied the plaintiffs' motion for a preliminary injunction on July 29, 2026, leaving the IFR in effect while the litigation proceeds. The parties have filed cross-motions for summary judgment, culminating in a motions hearing scheduled for October 22, 2026.

The case has attracted support from numerous stakeholders, including an amicus brief filed by the American Medical Association, a coalition of public health organizations and 161 deans and public health scholars, and multiple medical specialty and mental health organizations. Moreover, on September 18, 2026, a second lawsuit challenging CMS's approach to the medical frailty exclusion was filed in the U.S. District Court for the District of Maryland by a group of Medicaid enrollees from five states, several provider organizations, and the City of Columbus, Ohio. On October 14, 2026, the court set a briefing schedule for cross-motions for summary judgment, under which the motions will be fully briefed by December 2, 2026. *See Taylor v. Kennedy*, No. 1:26-cv-3705 (D. Md. 2026).

6. HHS Announces Additional Medicaid Funding Deferrals as Minnesota's Challenge Remains Pending

On July 21, 2026, the U.S. Department of Health and Human Services (HHS) [announced](#) an additional \$1.06 billion in Medicaid funding deferrals affecting California and Minnesota, pausing federal reimbursements for state-incurred spending pending the review of additional documentation proving compliance. In Minnesota, CMS deferred roughly \$199 million after reviewing claims in 14 "high-risk" areas, including expenditures tied to providers flagged through program integrity reviews as well as other claims with potential eligibility or billing concerns. For California, CMS deferred approximately \$867.5 million in payments after examining claims for in-home care programs, citing spending growth that outpaces national trends and documentation issues.

Neither state has filed suit specifically challenging these latest deferrals, but Minnesota's challenge to a previous deferral remains pending in the U.S. District Court for the District of Minnesota. Minnesota contested CMS's February 2026 deferral of about \$243 million in Medicaid funding in *Minnesota v. O'Leary*

0:26-cv-1701 (D. Minn. 2026). See [June 2026 Docket Updates](#). Minnesota argued that the deferral was imposed as political punishment, without due process or sufficient clarity regarding the documentation needed to verify the claims. On April 6, 2026, the court denied Minnesota's request for a temporary restraining order and expedited preliminary injunction, concluding that the agency's deferral was not final agency action and that Minnesota was therefore unlikely to prevail on the merits. The court subsequently granted a 120-day stay on May 7, 2026, which was later extended through January 4, 2027.

The Trump administration is now withholding more than \$2.76 billion in federal Medicaid matching funds from California and Minnesota. In its press release, HHS characterized these actions as part of the Trump administration's broader efforts to "combat fraud, waste, and abuse in Medicaid," and indicated that HHS will continue to use exclusion authorities to remove "bad actors" from Medicare and Medicaid programs.

7. *States Challenge HHS Rule That Would Prohibit Reimbursement for Gender-Affirming Care for Minors*

On September 2, 2026, a coalition of 21 state attorneys general and one governor filed a complaint in the U.S. District Court for the District of Massachusetts challenging an HHS final rule (the "GAC Rule") that would prohibit federal reimbursement for gender-affirming care for minors in Medicaid and the CHIP program. *Illinois v. Dep't of Health & Human Servs.*, 1:26-cv-14051 (D. Mass. 2026).

The GAC Rule, published by CMS on August 13, 2026, would bar states from using federal funds to cover puberty-suppressing medications, hormone therapy, and surgical procedures for individuals under 18 in Medicaid and under 19 in CHIP, when used to treat gender dysphoria.

In their complaint, the plaintiffs allege that the GAC Rule is unconstitutional and violates the APA, seeking a court order to block its implementation. Specifically, they raise the following legal theories:

- **Statutory Authority.** CMS lacks statutory authority to categorically prohibit federal funding for medically necessary services included in state Medicaid and CHIP programs and already approved by CMS as part of a State Plan.
- **State Authority/Conflict with Federal Law.** The rule exceeds HHS's legal authority, infringes on states' authority to regulate the practice of medicine, and conflicts with federal laws and regulations, including

the Affordable Care Act and statutes governing Medicaid and CHIP.

- **Spending Clause.** The rule violates the Spending Clause by altering fundamental conditions attached to Medicaid funding without notice or Congressional authorization.
- **Arbitrary and Capricious.** The rule is arbitrary and capricious under the APA, in light of a lack of reasoned decision-making, selective reliance on evidence, and failure to consider the health benefits of gender-affirming care.

The plaintiffs assert that the GAC Rule would cause immediate and significant harm to states, including fiscal losses from the withdrawal of federal funding for required health care services, increased operational costs for state Medicaid agencies, and infringement on states' authority to administer their Medicaid and CHIP programs according to state law and established standards of care.

The GAC Rule went into effect on October 13, 2026. As of the date of publication, defendants have not responded to the complaint.

8. *Federal Employee Unions Secure Settlement Restricting Shutdown RIFs at HHS and Other Agencies*

On September 28, 2026, the U.S. District Court for the Northern District of California granted a joint motion to hold *American Federation of State, County and Municipal Employees, AFL-CIO (AFSCME) v. Office of Mgmt. & Budget*, a challenge to the Trump administration's reductions in force (RIFs) at HHS and other federal agencies during the 2025 government shutdown, in abeyance after the parties reached a settlement. See Order, *AFSCME*, No. 3:25-cv-08302 (N.D. Cal. Sept. 28, 2026), ECF No. 199.

The lawsuit was filed on September 30, 2025, on the eve of the 2025 government shutdown. The court previously issued a preliminary injunction on October 28, 2025, blocking the administration from issuing or enforcing RIF notices at agencies represented by the unions. See [October 2025 Docket Updates](#). On November 12, 2025, President Trump signed a continuing resolution that ended the shutdown, paused layoffs through January 30, 2026, and required reinstatement of employees terminated during the shutdown. After several agencies failed to comply with the continuing resolution, the district court issued an additional injunction on December 17, 2025, directing agencies to follow the requirements of the continuing resolution.

Litigation continued until the parties reached a settlement, which was finalized on September 23, 2026. Under the settlement, the government agreed to rescind all shutdown-related RIF guidance and directives, notify agencies that all remaining shutdown-related RIF plans are abandoned, and require agencies to remove any references to such RIFs from their websites and shutdown contingency plans within 30 days. Additionally, the settlement requires agencies to remove, within 30 days, any language from contingency plans operative through December 31, 2026, that allows RIFs or related work during a lapse in appropriations, unless specifically authorized by statute. If agencies seek to reintroduce such language, they must provide 30 days' advance notice to plaintiffs and publish the proposed change. The abeyance will last until December 31, 2026, or until fiscal year 2027 appropriations are enacted for all defendant agencies, whichever occurs first.

While the *AFSCME* settlement is a significant victory for federal employees affected by the 2025 shutdown-related RIFs, it is limited to that context and does not resolve other ongoing challenges to restructuring at HHS and other agencies under the Trump administration. See e.g., *New York v. Kennedy*, No. 1:25-cv-0196 (D.R.I. 2025), and *Mullady v. Office of Management and Budget*, No. 8:26-cv-573 (D. Md. 2026). These and other challenges remain pending in federal district courts even as HHS announced plans in April 2026 to hire 12,000 additional employees to rebuild its workforce after the 2025 staffing cuts. See [June 2026 Docket Updates](#).

ADMINISTRATIVE LITIGATION UPDATES

1. PRRB Upholds Bad Debt Disallowance over Missing Contemporaneous Financial Assistance Policy

On June 4, 2026, the PRRB upheld a MAC decision to disallow a portion of indigent bad debt reimbursement in Fiscal Year (FY) 2014 for a nonprofit hospital in Florida. [Decision 2026-D18](#). For purposes of determining patient indigence, the Provider's financial assistance policy reviewed a patient's income, but not their assets. 2026-D18 at 3. The MAC argued that the Provider did not properly document patient indigence because (1) it "should take all resources into account" under Medicare's bad debt requirements and (2) the Provider had not adequately shown that it was following its own indigence policies. 2026-D18 at 9, 10.

First, citing an earlier district court decision in *Baptist Healthcare System v. Sebelius*, 646 F. Supp. 2d 28 (D.D.C., 2009), the Board found that the word "should" in PRM 15-1 § 312(B) did not necessarily require asset testing. In 2020, CMS amended the bad

debt regulation for determining whether a patient qualifies as an indigent non-dual eligible beneficiary at [42 C.F.R. § 413.89\(c\)\(2\)](#), to require that the provider "[m]ust take into account the analysis of both the beneficiary's assets . . . and income[.]" [85 Fed. Reg. 58432](#), 59024 (Sep. 18, 2020) (*italics added*). See 2026-D18 at 12–13 (citing [85 Fed. Reg. 58432](#), 58997 (Sep. 18, 2020)). However, because this regulatory change only applied prospectively, the Board found the requirement did not exist for the 2014 year at issue. See 2026-D18 at 13.

However, the Board nonetheless ruled against the hospital, finding that it had not demonstrated a written financial assistance policy in effect during the period at issue. The Board noted that it had previously interpreted the requirement that a hospital engage in "*reasonable and customary* attempts to collect[.]" (*italics added*) to require that a provider have a written debt collection policy and that the provider follow that policy. 2026-D18 at 11. The Board found that this requirement extends to indigent patient policies, as "part of a provider's overall debt collection policy[.]" *Id.* Because the Provider submitted a financial assistance policy with an effective date in 2015 and a financial assistance application with a footer indicating a revision date of 2017, it could not demonstrate a written policy in place in 2014 or how the Provider decided patient indigence status that earlier year.

This decision underscores the importance of regularly maintaining contemporaneous policy documentation with effective dates and revision dates.

2. PRRB Upholds CMS Authority to Exclude Outlier Hospital Wage Data from Tulsa Wage Index

On August 5, 2026, the Board held that CMS had the authority to exclude the wage data of a particularly high-wage hospital from calculation of the wage index in Tulsa, Oklahoma for FFYs 2015 through 2018. [Decision 2026-D24](#).

In this case, nine other hospitals in the Tulsa area ("the Providers") argued, among other points, that CMS had improperly excluded "properly documented" wage data of one hospital from the wage index. 2026-D24 at 10. The parties stipulated that CMS stated in both the IPPS final rules for FY 2015 and FY 2016 that the hospital's "wage data were properly documented," but that its "average hourly wage is extremely and unusually high, significantly higher than the next highest average hourly wage in that CBSA and in the surrounding areas." [80 Fed. Reg. 49326, 49491 \(Aug. 17, 2015\)](#); see [79 Fed. Reg. 49854, 49965 \(Aug. 22, 2014\)](#) (using similar language); see also 2026-D24 at 10.

The Board found that the single hospital's data "was not 'typical' of the Tulsa CBSA" because it exceeded the average hourly wage of the Tulsa CBSA by 36% to 63% from 2015 to 2018. 2026-D24 at 17–18. The Board concluded that the data exclusion aligned with statutory requirements because "its inclusion in the Tulsa CBSA wage index would not ensure that the Tulsa CBSA wage index reflects 'the relative hospital wage level in the geographic area of the hospital as compared to the national average hospital wage level' as required by Section 1886(d)(3)(E) of the Social Security Act." 2026-D24 at 19 (quoting 42 U.S.C. § 1395ww(d)(3)(E)(i)) (internal footnote omitted). Further, the Board added that CMS annually "uses its discretion to remove the wage data of hospitals with unusually high and unusually low average hourly wages[.]" 2026-D24 at 19. This decision suggests that the Board is receptive to CMS's view that the agency can exclude properly documented, outlier data from the wage index calculation.

3. *PRRB Denies GME and IME Payments Lacking FTE Cap Under New Provider Number*

On September 8, 2026, the Board agreed with a MAC's determination that a psychiatric hospital in North Carolina did not qualify for direct graduate medical education (GME) or indirect medical education (IME) payments for the fiscal year ending (FYE) June 30, 2013. 2026-D26 at 1–2. Prior to September 1, 2008, under its previous Provider Number, the hospital had been eligible for reimbursement as a teaching hospital. 2026-D26 at 2, 7–9. However, as of September 1, 2008, Cherry Hospital, under a different provider number, had "closed." 2026-D26 at 7. In July 2009, the hospital was certified with new Provider Number, 2026-D26 at 7, and described itself as a "teaching site" for a local School of Medicine. 2026-D26 at 8 (emphasis removed). The PRRB upheld the MAC's denial of the hospital's eligibility for GME and IME payments and for the reasonable cost reimbursement for physician medical and surgical services. 2026-D26 at 15.

Under its new provider number, the hospital no longer had an established FTE resident cap or per resident amount (PRA); as a result, the Board concluded it could not receive Medicare Part A GME payments per 42 C.F.R. § 413.76. Without the FTE count, the Board similarly found the hospital could not receive IME payments per 42 C.F.R. § 412.105. 2026-D26 at 15. This decision highlights that "[t]here is no automatic carry-forward or transfer of a previous hospital's FTEs to a new provider number, even if it overlaps with the same campus or programs as the prior hospital." 2026-D26 at 9.

Second, the Board rejected the Provider's argument it was owed

"payment on a reasonable cost basis for direct medical and surgical services of physicians," finding the hospital did not notify the MAC in writing, as required by 42 C.F.R. § 415.160(b)(1). 2026-D26 at 12, 13, 15. The Board found that the regulation "requires the hospital to submit an affirmative, written notice of election outside of the cost report to the Medicare Contractor." 2026-D26 at 13. Because the Board concluded the hospital failed to do so, the Board found it was not entitled to reasonable cost reimbursement for physician medical and surgical services. 2026-D26 at 15. The decision also highlights that providers must notify the MAC separately from the cost report, *in writing*, of the intention to be paid on a reasonable cost basis for physician services as a teaching hospital, and this should happen before or at the start of the fiscal year. See 2026-D26 at 8, 13–14.

Regulatory Updates

1. *FY 2027 IPPS and LTCH Final Rule*

On July 31, 2026, CMS published the FY 2027 final [rule](#) updating Medicare payment policies for IPPS and Long-Term Care Hospital (LTCH) prospective payment system (PPS), effective October 1, 2026. Below is a summary of notable provisions, including updates related to payment rates and program quality measures. See our recent [Client Alert](#) published on August 6, 2026 for more details.

Payment Rate Updates

- **Payment Rate Update.** CMS finalized a net 2.3% increase to IPPS payment rates for FY 2027. This increase reflects a 3.2% market basket update, offset by a 0.9 percentage point reduction for the statutory multifactor productivity adjustment. Overall, the rule is expected to increase aggregate hospital payments by approximately \$2.9 billion in FY 2027 compared to FY 2026. In addition, DSH and uncompensated care payments are projected to increase by approximately \$228 million.
- **LTCH PPS Update.** CMS finalized a 2.3% annual update to the LTCH standard federal payment rate. As a result, LTCH PPS payments are expected to increase by approximately \$54 million in FY 2027.
- **New Medical Technology Payments.** Additional payments for inpatient cases involving qualifying new medical technologies are projected to increase by approximately \$779 million in FY 2027. These add-on payments are designed to support hospital adoption of

innovative treatments and devices during the period before costs are fully captured in the DRG rate-setting process.

- Low-Volume and Medicare-Dependent Hospitals. Under current law, additional payments for Medicare-Dependent Hospitals and the temporary low-volume hospital payment adjustment are set to expire on December 31, 2026. Absent congressional action to extend these provisions, CMS estimates that such hospitals would receive \$300 million less.

GME Requirements and Criteria

- Definition of a New Program for GME Reimbursement. CMS revised the definition of a “new” medical residency training program codified at 42 C.F.R. § 413.79(l). That definition is used to determine whether a hospital qualifies for permanent increases to its FTE resident caps for GME and IME payments. Under the amended regulation, in addition to receiving initial accreditation, at least 90 percent of the individual residents (counted by person, not by FTE) who enter the program during its five-year cap-building period must have no prior training in another program in the same specialty. CMS also eliminated the requirement that the program director and faculty also be new, allowing programs to hire experienced staff. Programs accredited for 16 or fewer positions do not have to meet the 90 percent test at all. The new definition covers programs still within their five-year cap-building period as of October 1, 2026, and programs that start training on or after that date.

Provider-Based Department Rules

- Provider-Based Rules. CMS finalized its proposal to limit the “referral-based” test for meeting the “same patient population” criterion to outpatient departments, which means remote off-campus inpatient departments can no longer rely on it to qualify for provider-based status. Under the current rules, an off-campus facility located more than 35 miles from the main provider, and not covered by another exception, must show a high level of integration with the main provider in one of two ways. It can show that at least 75% of its patients live in the same ZIP codes as 75% of the main provider’s patients, or that at least 75% of its patients who needed the type of care the main provider offers actually received that care from the main provider. The

amended regulation at 42 C.F.R. § 413.65(e)(3)(iii)(B) now applies the second option only to “an *outpatient* facility or organization.” CMS noted that although the referral test has been in place for over 20 years, it could not find any case that relied on it, and it declined to exempt existing locations because it does not believe any higher payments those facilities receive are justified or equitable.

Revisions to Rules Governing Organ Acquisition Cost

- Organ Acquisition Cost Policies. The final rule codifies Medicare’s reconciliation of organ acquisition costs for non-renal organs processed by Independent Organ Procurement Organizations (IOPOs) and Histocompatibility Laboratories. Notably, CMS adopted a two-year delayed implementation timeline, meaning these provisions will take effect for cost reporting periods beginning on or after October 1, 2028. This delay is intended to provide IOPOs and affected laboratories sufficient time to align their reporting practices with the new requirements.

Program and Quality Measure Updates

- Hospital Readmissions Reduction Program. CMS adopted a new readmission measure to track readmissions following sepsis hospitalization, expanding the set of conditions tracked under the Hospital Readmissions Reduction Program. Hospitals will first receive confidential early-look reports on this measure during FY 2028 and FY 2029, providing an opportunity to review performance data before it affects reimbursement. Payment reduction calculations incorporating the sepsis readmission measure will begin with the FY 2030 payment determination.
- Hospital Inpatient Quality Reporting (IQR) Program. CMS finalized the inclusion of Medicare Advantage beneficiaries in three “Excess Days in Acute Care” (EDAC) measures within the Hospital IQR Program, beginning with the FY 2028 payment determination. The three measures apply to patients hospitalized for acute myocardial infarction, heart failure, and pneumonia. CMS also finalized a change to shorten the performance period for these measures from three years to two years, which is intended to make the data more current and actionable for quality improvement purposes.

- Medicare Promoting Interoperability Program. CMS designated the Electronic Prior Authorization measure as an optional bonus measure for CY 2027 reporting, transitioning to a mandatory measure beginning with CY 2028.

Other Notable Provisions

- TEAM Updates. The Transforming Episode Accountability Model (TEAM) is a five-year mandatory episode-based alternative payment model, running from January 1, 2026 through December 31, 2030. Covering five surgical episodes, the model tests whether quality-based payment at selected acute care hospitals can reduce Medicare spending without lowering care quality. CMS also finalized three new spinal fusion categories to better account for patient severity and resource use. See Value-Based Care Corner Section for more details.
- Comprehensive Care for Joint Replacement Expanded (CJR-X) Model. CMS finalized a nationwide Phase II expansion of the Comprehensive Care for Joint Replacement (CJR) model, slated to begin on January 1, 2028. The expansion seeks to build upon the success of the CJR model, which CMS states generated \$112.7 million in net Medicare savings in Performance Years 6 and 7 with no loss in quality. Subject to limited exceptions, participation is mandatory for eligible acute care hospitals nationwide, including D.C. and the U.S. Territories, that start lower extremity joint replacements and are paid under both IPPS and Outpatient Prospective Payment System (OPPS). See Value-Based Care Corner Section for more details.

2. CY 2027 OPPS/ASC Proposed Rule

On July 7, 2026, CMS issued a proposed [rule](#) updating Medicare payment policies and rates for hospital outpatient and Ambulatory Surgical Center (ASC) services under the Hospital OPPS and the ASC Payment System for Calendar Year (CY) 2027. The comment period for this proposed rule closed on August 31, 2026. Below is a summary of the key proposals. See our recent [Client Alert](#), published on July 30, 2026, for more details.

Payment Updates

- OPPS and ASC Payment Update. CMS proposed a 2.4% update to both OPPS and ASC payment rates for CY 2027. The proposed increase is based on a 3.2%

market basket update, reduced by 0.8 percentage points to account for the statutory multifactor productivity adjustment. This update is intended to reflect changes in the prices of goods and services used by hospitals and ASCs in furnishing care to Medicare beneficiaries.

- 340B Drug Payment Reduction. Drawing on the results of a drug acquisition cost survey, CMS proposed reducing payment for 340B-acquired drugs from the current rate of ASP plus 6% to ASP minus 33.4%. CMS estimates that this change would result in an approximately \$4.55 billion reduction in Original Medicare drug payments and approximately \$1.15 billion in savings in the first year for beneficiaries through reduced cost-sharing. The proposal would be implemented on a budget-neutral basis, meaning that the OPPS conversion factor for non-drug services would increase to offset the reduction in drug payments. See the [Latest on 340B Section](#) for more details.
- 340B Recoupment Acceleration. CMS proposed increasing the annual 340B recoupment offset from 0.5% to 3% of OPPS payments. The offset stems from the Supreme Court's 2022 decision in *American Hospital Association v. Becerra*, in which the Court held that CMS unlawfully cut OPPS payment rates for drugs purchased by 340B hospitals in CYs 2018 and 2019 because it did not first survey hospitals' drug acquisition costs. In response to this decision, in 2023 CMS issued a remedy rule providing lump sum payments to 340B hospitals, which CMS then offset to ensure budget neutrality by establishing a prospective reduction to OPPS payments for non-drug items and services first taking effect in CY 2026. The reduction recoups the higher non-drug payments hospitals received while the 340B drug payment cuts were in effect. Under this accelerated schedule, the recoupment process — which addresses overpayments identified under the prior 340B payment methodology — would be completed by CY 2029, significantly earlier than the previously projected completion date of CY 2041. See the [Latest on 340B Section](#) or more details.

Site-Neutral and Procedure List Changes

- Site-Neutral Expansion to Imaging. CMS proposed extending site-neutral payment policies to imaging services furnished without contrast in excepted off-

campus provider-based departments. Under this proposal, payment for these services would be reduced to the Physician Fee Schedule (PFS) equivalent rate, aligning reimbursement with the amount paid when the same services are furnished in a physician's office. CMS estimates that this expansion would reduce Medicare Part B expenditures by approximately \$260 million in the first year of implementation.

- **Continued Inpatient-Only List Phase-Out.** CMS proposed removing 637 additional procedures from the Inpatient-Only list as part of the second year of a planned three-year phase-out of the list. In conjunction with this change, CMS proposed expanding the ASC Covered Procedures List by 618 procedures, allowing a broader set of surgical services to be performed and paid for in the ambulatory surgical setting.

Other Notable Proposals

- **Prior Authorization Expansion.** CMS proposed requiring prior authorization for eight additional botulinum toxin injection codes, citing concerns regarding overutilization of these services.
- **Provider-Based Attestations.** The Consolidated Appropriations Act (CAA), 2026 enacted new requirements for off-campus outpatient provider-based departments to receive Medicare reimbursement, effective January 1, 2028. From that date, Medicare will not pay for services at an off-campus department unless (1) the department bills under its own National Provider Identifier (NPI) and (2) the hospital has submitted an attestation confirming the department meets the provider-based requirements. For departments already operating, CMS proposes that hospitals submit attestations between January 1, 2026, and December 31, 2027. New departments would have to attest within two years before they bill for services. Hospitals would then re-attest at least every five years. Before attesting, hospitals would need to get a separate NPI for each off-campus department and update their PECOS enrollment records. CMS plans to screen every attestation automatically. If CMS finds a department does not qualify, it can recover the extra payments made since the attestation date.
- **Software as a Medical Service Payment.** CMS proposes renaming AI-driven and other clinical decision software

from Software as a Service (SaaS) to Software as a Medical Service (SaMS). For CY 2027, CMS would also designate 36 codes as SaMS assigned to New Technology Ambulatory Payment Classifications under a new "O1" status indicator that allows separate payment, keep rates close to CY 2026 levels so that thin claims data does not cause sharp payment drops, and move 10 software-only laboratory codes from the Clinical Laboratory Fee Schedule into the OPPS. See the [AI Topics in Health Care Reimbursement Section](#) for more details.

- **Hospital Price Transparency Request for Information.** CMS issued a Request for Information (RFI) seeking public input on ways to strengthen hospital price transparency, with a particular focus on improving data standardization and comparability across hospitals.

3. *CY 2027 Medicare Physician Fee Schedule Proposed Rule*

On July 16, 2026, CMS released the CY 2027 Medicare PFS proposed [rule](#), which includes proposals to restructure clinician quality reporting under the QPP and significant changes to the Medicare Shared Savings Program (MSSP). The comment period for this proposed rule closed on September 14, 2026. Below is a summary of the key proposals. See our recent [Client Alert](#) published on July 30, 2026, for more details and the [Value-Based Care Corner Section](#) for more details on MSSP.

- **Sunsetting Traditional Merit-based Incentive Payment System (MIPS) Reporting.** CMS proposed to sunset the traditional MIPS reporting framework effective 2029, transitioning clinicians to specialty-focused MIPS Value Pathways (MVPs). Under the proposal, clinicians who are eligible for MIPS would have until the end of 2028 to transition to an MVP, unless they participate in a MIPS alternative payment model (APM) and report through the APM Performance Pathway. This proposal reflects CMS's longstanding goal of moving away from the broad, one-size-fits-all MIPS framework towards more specialty-specific quality measurements.
- **Three New MVPs for CY 2027.** CMS proposed the introduction of three new MVPs for CY 2027, focused on diabetes, hypertension, and hospital-based care. If these MVPs are finalized, CMS estimates that the MVP inventory would provide a reporting option for approximately 98% of clinical specialties, substantially

closing the gap that has left some specialties without a tailored reporting pathway.

- **Revised APM Incentive Payment Methodology.** CMS proposed revising the methodology for paying APM incentive payments, shifting from payment at the individual NPI level to payment at the taxpayer identification number/national provider identifier (TIN/NPI) level. According to CMS, this approach would prevent approximately \$2.4 billion from flowing to clinicians who are not actively participating in an APM, thereby better targeting incentive payments to those clinicians who are meaningfully engaged in value-based care arrangements.
- **Telehealth Updates.** The CAA 2026 extended key COVID-era Medicare telehealth flexibilities into late 2027 and early 2028, including (1) no geographic limits on where patients can be located, (2) audio-only visits, and (3) a delay of the in-person visit requirement for mental health telehealth. CMS proposes to update its regulations to reflect these extensions. CMS also proposes to (1) add advance care planning, group medical visits, pediatric speech therapy, and vaccine reaction evaluations to the list of services Medicare covers by telehealth; (2) create new billing modifiers, starting January 1, 2027, for services provided through virtual telehealth platforms; (3) switch critical care telehealth consultation codes to time-based billing; (4) give teaching physicians more flexibility by allowing them to bill for services involving residents when either the teaching physician or resident is in the same physical location as the beneficiary, rather than requiring all three parties to be in different locations; and (5) increase the telehealth originating site facility fee by 2.5%, to \$32.65.
- **RFI.** CMS sought public comments, which were due on September 14, 2026, on how to change primary care payment under the PFS. CMS states that primary care payments are inadequate and wants to shift the system toward prevention. The request asks about potential restructuring of primary care visit and care management codes, paying for technology and AI in primary care, and establishing a prospective primary care payment permanently in MSSP. See the [AI Topics in Health Care Reimbursement Section](#) for more details on the RFI on Redesigning Primary Care to Make America Healthy Again.

4. **Advancement of Prior Authorization & Transparency Medicare Bills.**

The House Ways & Means Committee advanced a package of Medicare and Medicare Advantage (MA) bills on July 15, 2026. The Improving Seniors' Timely Access to Care Act (H.R. 3514) aims to modernize the MA prior authorization process. The bill would require electronic prior authorization to increase transparency around plan decisions and standardize administrative requirements. The bill's goal is to reduce delays in medically necessary care that have long been attributed to the prior authorization process. This bill has been introduced repeatedly in prior years without passage.

Lawmakers also advanced the Healthcare Price Certainty for All Americans Act (H.R. 9645), a transparency package requiring hospitals and health plans to publicly disclose prices. H.R. 9645 would codify and significantly expand existing price transparency requirements. Among other things, the stated goals of the bill are:

- **Expand covered entities:** extend disclosure obligations beyond hospitals to clinical laboratories, imaging providers, and ambulatory surgical centers;
- **Strengthen enforcement:** impose tiered civil monetary penalties scaled by facility size (with additional penalties of up to \$10 million for persistent noncompliance);
- **Require executive attestations:** require senior executive attestations certifying the accuracy of disclosed pricing data;
- **Mandate MA ownership reporting:** mandate that health plans publish more granular rate, payment, and drug pricing information on a quarterly basis through standardized machine-readable files. The bill would also require MA organizations to report ownership interests in providers and pharmacies and direct the Medicare Payment Advisory Commission (MedPAC) to study the growing role of vertical integration in the health care system.

The Ways & Means Committee also advanced (i) the Medicare Advantage Medical Loss Ratio (MLR) Transparency Act (H.R. 9644), which would require MA plans to report more detailed medical loss ratio information beginning in 2029; (ii) the Rural Patient Monitoring Act (H.R. 3108), which would establish Medicare payment requirements for remote patient monitoring services; (iii) the Essential Caregivers Act of 2026 (H.R. 9641), which would guarantee access to essential caregivers during

future public health emergencies; (iv) the Medicare Access To Rural Anesthesiology Act (H.R. 9642), which would increase Medicare reimbursement for rural anesthesiology services; and (v) the Saving Today's Acute Care Resources (STAR) Act (H.R. 9468), which addresses site-neutral payment policies for long-term care hospitals.

This package of bills advances the government's priority to reduce MA spending and root out potential areas of fraud in the program. Participating hospitals and health systems should accordingly track the advancement of these bills.

AI Topics in Health Care Reimbursement

1. CMS Proposes Separate Payment for Clinical Diagnostic Software Under New "Software as a Medical Service" Category

In July, CMS introduced its proposed rule for CY 2027 OPPS, including a proposed separate payment for Artificial Intelligence ("AI") technology. As reimbursement pathways for AI-enabled clinical tools continue to evolve, CMS's proposal represents a step toward establishing a more tailored payment framework for these technologies. In recent years, software technologies with advanced capabilities, such as AI, have become increasingly important in supporting clinical decision-making in outpatient and physician office settings. CMS introduced a new interim payment framework for these technologies, now referred to as SaMS. CMS defines SaMS as "software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality."

Under its proposal, CMS would designate thirty-six Healthcare Common Procedure Coding System (HCPCS) codes as SaMS services, and assign them to New Technology Ambulatory Payment Classifications (APCs), creating a new OPPS payment status indicator—"O1" (Software as a Medical Service, Paid under OPPS; separate APC payment) to distinguish these technologies from other services in the New Technology APC series. CMS proposes to reassign SaMS technologies currently assigned to clinical APCs to New Technology APCs, with payment rates that approximate their current CY 2026 levels. CMS proposes to maintain existing assignments for SaMS already in New Technology APCs.

CMS frames this as an interim step, explaining that the existing clinical APC structure "does not adequately accommodate SaMS" and that the new approach would allow CMS to take "the first step towards standardization and applying a consistent payment methodology across these services." CMS would also reassign ten HCPCS codes describing algorithmic analyses

currently paid under the Clinical Laboratory Fee Schedule (CLFS) to New Technology APCs under the OPPS, reasoning that these stand-alone algorithmic analyses are "substantively similar to other SaMS technologies" and should be treated consistently regardless of whether the underlying data originated from imaging or laboratory tests.

Separately, CMS [included](#) parallel SaMS proposals in its proposed rule for the CY 2027 PFS, proposing to adopt the same SaMS terminology for services paid under the PFS. It also proposes to move ten HCPCS codes for SaMS analyses performed on laboratory tests from the CLFS to the PFS, where they would be contractor priced. As a result, payment would be available under the PFS for these SaMS analyses.

Hospitals and health systems using or evaluating AI-enabled diagnostic tools should review [Table 61](#) of the proposed rule for the full list of affected technologies. The comment period for the CY 2027 OPPS Proposed Rule closed on August 31, 2026. Hospitals and health systems should continue to monitor CMS's development of the SaMS payment framework and assess how it may affect the reimbursement of their AI-enabled diagnostic tools.

2. CMS Seeks Input on Reimbursing AI Technologies in Primary Care

CMS [issued](#) an RFI on "Redesigning Primary Care To Make America Healthy Again" as part of its CY 2027 PFS proposed rule. The RFI seeks input on how technology and clinical AI are reshaping primary care delivery and what payment approaches may best support technology-enabled care. CMS acknowledges that these technological developments were not anticipated when defining the relative value units and the time and intensity of services delivered by physicians, and notes that tools focused on reducing clinician documentation burden (e.g., AI scribes) alone have reached an estimated 25% adoption rate among U.S. physicians. The RFI seeks comment across three areas:

1. **Reconsidering primary care valuation**, including whether CMS should adopt a "two-track" approach to care management, with one track focused on technology-enabled care;
2. **Payment implications of technology-enablement of primary care**, including how clinical AI is impacting the time and intensity of services, whether technology-enabled Annual Wellness Visits can improve outcomes, and how CMS should value these services; and

3. **Prospective primary care payment** in the Medicare Shared Savings Program.

CMS poses pointed questions, including: “If we were to approach paying for technology-enabled primary care differently, how should we consider the relative valuation, in terms of time and intensity of services? How else could these services be valued? How should we consider evidence of the impact or outcome of technology-enabled services in primary care?”

The comment period for the CY 2027 PFS Proposed Rule closed on September 14, 2026. While the RFI does not propose specific rule changes, hospitals and health systems should monitor CMS’s approach and assess how future rulemaking may affect the valuation and payment of technology-enabled primary care under the PFS.

3. **State-Level AI Healthcare Laws: Guardrails on AI in Claims Processing and Prior Authorization**

States continue to lead regulation of AI in health care, with jurisdictions enacting laws that impose guardrails on insurers’ and providers’ use of AI in claims processing and prior authorization. Here are two examples:

1. **Indiana HB 1271.** Effective July 1, 2026, Indiana’s [HB 1271](#) addresses AI on both sides of the claims process. On the insurer side, the law prohibits an insurer from using an automated process, system, or tool, including AI, as the sole basis to downcode a claim based on medical necessity without review of the covered individual’s medical record by an employee or contractor of the insurer. In addition, insurers must disclose “in an easily accessible and readable manner” when AI is used to make an adverse determination on a prior authorization request or to downcode a claim. On the provider side, the law prohibits a provider from using an automated process, system, or tool, including AI, to submit a health benefits claim without review by a provider or other person involved in the development of the claim. The law also separately restricts downcoding practices more broadly, prohibits downcoding based solely on diagnosis codes, and establishes a 180-day appeal window for downcoded claims.
2. **Washington SB 5395.** Effective June 11, 2026, Washington’s [SB 5395](#) takes a comprehensive approach to restricting AI in prior authorization. The law provides that only a licensed physician or a licensed health professional working within their scope of

practice may deny a prior authorization request based on medical necessity. AI “shall not be the sole means used to deny, delay, or modify health care services,” and “[a]lgorithms may be used to process and approve prior authorization requests, but may not be used without human review to deny care based on a determination of medical necessity.” Where a carrier does use AI in prior authorization, the law requires that the AI base its determination on the enrollee’s individual medical history and clinical circumstances, not solely on a group data set, and that the AI’s performance must be periodically reviewed for accuracy and reliability. The law also requires carriers to report to the insurance commissioner the percentage of total prior authorization denials that were aided by AI. While the law is generally effective June 11, 2026, certain provisions, including requirements related to interoperable electronic prior authorization systems for prescription drugs and reporting requirements, have later implementation or effective dates extending into 2027.

Hospitals, health systems, and payors should evaluate their AI-enabled billing, coding, and utilization management tools for compliance with these new requirements. Organizations operating across multiple states should monitor the growing patchwork of state-level AI regulations and assess whether their current compliance programs address the varying disclosure, human-review, and reporting obligations. To keep pace with these evolving requirements, organizations should also maintain effective AI governance programs, including documented policies for human oversight, disclosure protocols, and periodic audits of AI-enabled workflows, to support ongoing compliance as additional states enact similar legislation.

4. **The Joint Commission’s New Voluntary “Responsible Use of AI in Healthcare” Certification**

On June 1, 2026, the Joint Commission [launched](#) its new Responsible Use of AI in Healthcare (RUAIH) certification, a first-of-its-kind voluntary program designed to recognize U.S. healthcare organizations that “demonstrate they have the governance, safeguards, monitoring processes, and education in place to use AI responsibly in healthcare settings.” The certification follows initial Joint Commission guidance [issued](#) in 2025 and was developed after the Joint Commission convened more than 20 coalitions and groups with expertise in health care and technology. As Joint Commission president and CEO Jonathan B. Perlin, M.D., Ph.D., stated, “[w]ith more than 80%

of physicians currently using AI in professional settings, there is a fast-growing need for universal standards for implementing this transformational technology in responsible ways.”

The RUAH certification standards are organized around five areas: (1) governance; (2) effective data management; (3) risk and bias reduction; (4) monitoring, evaluating, and validating safety performance, effectiveness, and responsible use; and (5) transparency, education, and training. Notably, the certification is focused on the organization’s framework for deploying AI responsibly and it does not validate or certify individual AI products or tools. Healthcare organizations do not need to be accredited by the Joint Commission to apply for the certification. The Coalition for Health AI (CHAI) has endorsed the program, noting that it is “tightly aligned” with CHAI’s recently published governance playbooks.

Although the RUAH certification is voluntary and does not directly affect reimbursement, hospitals and health systems may consider evaluating the program as part of their broader AI governance strategies. As AI becomes increasingly embedded in clinical, operational, and billing workflows, demonstrating adherence to recognized governance standards may become vital to payer contracting, regulatory compliance, and risk management. Organizations interested in pursuing the certification can learn more at the Joint Commission’s RUAH certification page. The certification also reflects a broader industry trend toward increasing expectations for formal AI governance, oversight, and accountability.

Enforcement Updates

1. Notable Recent Enforcement Actions

- a. Medicare Advantage Risk Adjustment and Coding Enforcement
 - i. On August 3, 2026, Department of Justice (DOJ) announced that Complete Health Partners Holdings, a Florida-based management services organization (MSO), agreed to pay \$14.1 million to resolve allegations that it had violated the False Claims Act (FCA) by causing the submission of false diagnosis codes in order to increase payments received from the Medicare Advantage program. The fraud claims were initially brought under the *qui tam* provisions of the FCA by a former employee at VIVA Health, who will receive approximately \$2.5 million as their share of the federal recovery. DOJ alleged that Complete Health disseminated incorrect coding

guidance to its coders and physicians regarding diagnosis codes for certain behavioral health conditions. DOJ further alleged that the codes were not substantiated or clinically justified and resulted in increased payments from CMS to the Medicare Advantage plans in which Complete Health’s patients were enrolled.

- ii. On August 26, 2026, DOJ announced that Villages Health System LLC (“Villages”), a Florida-based health care provider, agreed to pay \$541.5 million to settle allegations that it violated the FCA by causing the submission of false diagnosis codes to increase payments it received from Medicare Advantage. Villages made a submission pursuant to the HHS Office of the Inspector General’s (OIG’s) Self-Disclosure Protocol disclosing that from 2020-2024, it had submitted invalid diagnosis codes to multiple Medicare Advantage Organizations (MAOs), increasing the capitated payments the MAOs received from the CMS.
- b. CMS Program Integrity and Payment Exclusion Actions
 - i. On September 8, 2026, CMS announced that it had identified and barred 11 durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) companies from receiving future Medicare Advantage payments due to more than \$3.4 billion in suspected fraudulent billings in 2025 and 2026. These companies were targeted because they had not submitted any claims prior to 2025, used improper billing practices, and billed for equipment to beneficiaries who never requested it or who were already deceased. Four of the companies had already been revoked from Original Medicare and billed Medicare Advantage plans instead. One of the companies had allegedly submitted approximately \$18.4 million in catheter claims over two consecutive days for over 1,000 beneficiaries who were deceased. Another provider billed Medicare Advantage for 38 separate encounters in which the beneficiary was already deceased.
- c. Criminal Health Care Fraud Takedowns and Other Initiatives

- i. On June 23, 2026, the DOJ announced the 2026 National Healthcare Fraud Takedown, which resulted in charges against 455 defendants for their alleged participation in health care fraud and opioid abuse schemes involving over \$6.5 billion in false claims. The Takedown involved prosecutions in 56 federal districts and 45 U.S. states and territories, with 50 state Medicaid Fraud Control Units participating. As part of the takedown, DOJ secured over \$73 million in Civil Monetary Penalty settlements and revoked billing privileges for more than 1,400 providers. Major targets of the Takedown included fraudulent amniotic wound allograft schemes, with 11 defendants charged for over \$2 billion in questionable billings and kickbacks.
- ii. On August 4, 2026, the National Fraud Enforcement Division (“Fraud Division”) announced criminal charges against 19 defendants, including owners and employees of home care companies, for their alleged participation in various fraud schemes involving over \$4 million in claims to Medicare and Medicaid. The charges were announced in connection with the Fraud Division’s expansion to Philadelphia of the Strike Force model, an enforcement initiative that has led to the prosecution of over 6,200 defendants who collectively billed federal health care programs and insurers more than \$45 billion. The Fraud Division also expanded its Strike Force program earlier this year on the West Coast with a focus on prosecutions of fraudulent wound care schemes.

2. Eleventh Circuit Upholds Constitutionality of FCA’s Qui Tam Provisions

On September 1, 2026, the U.S. Court of Appeals for the Eleventh Circuit reversed the first and only federal court ruling to strike down the FCA’s *qui tam* mechanism. In *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, the Court held that private relators who bring fraud claims on behalf of the United States are not “officers of the United States” subject to Article II’s Appointments Clause because they do not occupy a “continuing position established by law.” The Eleventh Circuit remanded the case for further proceedings before the District Court for the Middle District of Florida, which will likely

consider other arguments not addressed in the District Court’s earlier decision that the *qui tam* provisions are unconstitutional. Although parallel challenges are advancing in other circuits, and multiple Supreme Court justices have signaled interest in the Article II implications of *qui tam* enforcement, the Eleventh Circuit’s long-anticipated ruling—which avoids creation of a circuit split and leaves the *qui tam* mechanism presently intact—is likely to delay a Supreme Court ruling on the mechanism’s constitutionality.

3. Trump Administration Refers Providers and Pharmacy Benefit Managers to DOJ over Youth Gender-Affirming Care Billing

On August 12, 2026, HHS Secretary Robert F. Kennedy sent a letter to OIG referring hundreds of health care organizations for investigation of insurance claims they filed related to gender-affirming care services for minors. The list of referrals targeted health systems, pediatric hospitals, physician groups, pharmacy benefit managers, and specialty pharmacies. These referrals stem from a report commissioned by HHS that identified coding practices that its authors alleged allowed providers to financially benefit from gender-affirming care. HHS is seeking review of what it has called “anomalous billing practices,” including claims for puberty blockers.

4. DOJ Establishes the National Fraud Detection Center

On August 24, 2026, DOJ announced the launch of the National Fraud Detection Center (NFDC), a prosecutor-led, multi-agency team designed to investigate fraud across federal programs. The NFDC is made up of leaders across the federal government, including the FBI and Offices of Inspector General across several agencies, and includes several state officials. Attorney General Todd Blanche had called for the establishment of the NFDC in a March 2026 memorandum establishing the National Fraud Enforcement Division, a hub for coordinated enforcement across jurisdictions. Blanche described the center as a “permanent prosecutor-led multi-agency data analytics team working to ferret out the most harmful actors defrauding federal government programs.” Acting Assistant Director Amanda Riedel of the Executive Office for U.S. Attorneys and Acting Chief Cody Matthew Herche of the Global Trade & Commerce Enforcement Section will lead the NFDC.

5. DOJ Declines Charges Against Optometry Group Under New Corporate Enforcement Policy

On July 29, 2026, DOJ’s National Fraud Enforcement Division announced that it would not pursue criminal charges against Campus Eye Management Holdings LLC and its subsidiary

Campus Eye Management LLC (collectively, “Campus Eye”) pursuant to its Corporate Enforcement and Voluntary Self-Disclosure Policy (the “Corporate Enforcement Policy”). The Division declined to prosecute Campus Eye for health care fraud, illegal kickbacks and bribes after it voluntarily self-disclosed the misconduct and agreed to pay back \$1 million to victims. This is the first time DOJ has declined prosecution of health care fraud charges under the Corporate Enforcement Policy, released March 10, 2026. In issuing the declination, DOJ cited the organization’s “timely and voluntary self-disclosure of the misconduct,” its “full and proactive cooperation,” and its “timely and appropriate remediation” efforts. Campus Eye’s founder, E. Bruce DiDonato, has been indicted on conspiracy, health care fraud, and kickback charges, demonstrating that under the Corporate Enforcement Policy, declination for the organization does not shield the responsible executives from criminal charges.

6. DOJ Revises Select Policies Concerning False Claims Act Enforcement

On September 18, 2026, DOJ issued a press release announcing two revisions to the Justice Manual—which publicly sets forth internal DOJ policies and procedures—concerning FCA enforcement. The revisions address sections of the Manual related to (1) the limits on the use of sub-regulatory guidance in cases brought by the Department, and (2) when the Department will seek dismissal of *qui tam* actions that do not serve the interests of the United States under 31 U.S.C. § 3730(c)(2)(A). The first change marks a reinstatement of the [2018 Brand Memo’s](#) prohibition on relying on nonbinding agency guidance to establish liability, but the Justice Manual permits the use of such guidance to help establish that a party had the requisite knowledge of a legal requirement (i.e., the scienter requirement). The second change signals modest updates to the previously codified factors DOJ will consider when evaluating dismissal of *qui tam* actions and provides more specificity about when DOJ will evaluate dismissal.

7. CMS Moratorium on Medicare Enrollments of DMEPOS Suppliers Expired

On August 27, 2026, CMS announced the expiration of its six-month moratorium on the Medicare enrollment of DMEPOS suppliers. Accordingly, the National Provider Enrollment Contractors are once again accepting initial enrollment applications from such providers. CMS announced this enrollment moratorium on February 27, 2026 in an effort to mitigate fraud, waste, and abuse among DMEPOS suppliers. CMS also imposed a six-month moratorium on the Medicare

enrollment of hospices and home health agencies on May 13, 2026, which is currently set to expire on November 13, 2026, unless CMS decides to extend it by an additional six months.

Value-Based Care Corner

1. TEAM Model Updates (Finalized)

The FY 2027 IPPS Final Rule finalized several updates to the TEAM, the mandatory five-year bundled payment model that launched January 1, 2026. TEAM tests whether financial accountability for five high-cost, common surgical episode categories reduces Medicare expenditures while preserving or enhancing care quality. The model operates at approximately 750 hospitals across 188 selected Core-Based Statistical Areas.

- Episode Trigger and Pricing Updates.** The FY 2027 rule finalized updates affecting episode category triggers, quality measure assessment, and target price construction. The target price serves as a pre-established spending benchmark for each surgical episode, against which a participating hospital’s actual Medicare fee-for-service (FFS) spending is measured to determine whether the hospital earns a reconciliation payment or owes a repayment to CMS. TEAM episodes include a 30-day post-discharge period and incorporate more comprehensive risk adjustment factors than the original CJR model. Target prices are calculated regionally and include provisions protecting safety net hospitals and low-volume hospitals from disproportionate financial risk.
- Quality Measure Updates.** CMS finalized quality measures for TEAM including the Information Transfer Patient-Reported Outcome-Based Performance Measure (PRO-PM) for lower extremity joint replacement and Spinal Fusion episodes, with a calendar year 2029 composite quality score baseline period. The Composite Quality Score (CQS) reconciliation process, which consolidates a hospital’s performance on selected quality measures into a single score that is used to adjust the reconciliation amount, accounts for Medicare Severity Diagnosis Related Group mapping changes for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year, ensuring target prices reflect current Medicare payment policies.
- Request for Information on Physician-Owned Hospitals.** CMS included an RFI soliciting comments

on whether to provide a voluntary opt-in opportunity for physician-owned hospitals (POHs) to participate in TEAM. Comments and CMS policy intent will inform future rulemaking on POH participation.

- **Transition to CJR-X.** TEAM will expire in 2030, and TEAM participant hospitals will transition to CJR-X in 2031. CMS expects TEAM participants will not reduce episode spending when they enter CJR-X because their savings are already part of the CJR-X baseline.

TEAM participants should prepare for quality measure reporting aligned with the CY 2029 CQS baseline period, and plan for the 2031 transition to CJR-X, recognizing that CJR-X extends episode accountability from 30 days to 90 days post-discharge. Health systems with hospitals in both TEAM and non-TEAM markets should coordinate episode management strategies across their networks.

2. *Nationwide Expansion of CJR-X Bundled Payments (Finalized)*

As part of the FY 2027 IPPS Final Rule, CMS finalized the mandatory CJR-X model, a nationwide expansion of the CJR model. Like TEAM, CJR-X is a mandatory bundled payment model. It will hold hospitals accountable for cost and quality across lower-extremity joint replacement episodes (hip, knee, and ankle) performed in both inpatient and outpatient settings, and it extends the episode through 90 days after discharge or the outpatient procedure (compared to the 30-day post-discharge period under TEAM). This model serves as an expansion of the already active TEAM program. The decision to expand the program was based on CJR model evaluation results showing \$112.7 million in net savings to Medicare across Performance Years 6 and 7 while maintaining quality of care. Although the CJR-X model applies only to episodes of care rendered to Medicare FFS beneficiaries, not Medicare Advantage beneficiaries, CMS will permit hospitals to participate concurrently in accountable care organization (ACO) models.

- **Overview of Mandatory Model.** CMS finalized a January 1, 2028 start date (delayed from the originally proposed October 1, 2027). Performance years will align with calendar years rather than fiscal years, providing a 17-month implementation period for hospitals to prepare. Hospital participation is mandatory except for (1) hospitals participating in TEAM until TEAM ends in 2030; (2) Maryland hospitals under the Total Cost of Care Model; and (3) Critical Access Hospitals. Hospitals currently

participating in TEAM will transition to CJR-X in 2031 following TEAM's expiration. CMS will calculate target prices using three years of regional baseline episode spending data, weighted at 17%, 33%, and 50% across the three years from oldest to most recent year, respectively. This is the same methodology as TEAM, with high-cost outlier episodes capped at the 99th percentile. CMS has not yet published a specific year over year baseline schedule, but based on the TEAM precedent, it will likely use years 2024 through 2026 as the 2028 baseline years. Target prices are risk-adjusted for beneficiary age, clinical complexity (determined by the number of Condition Categories associated with the episode), economic risk, prior post-acute care use, disability status, and recent medical history, as well as facility bed-size and safety net status.

- **Quality Measures and Composite Quality Score.** CJR-X includes five quality measures: (1) Hospital-Level Risk-Standardized Complication Rate following elective primary Total Hip Arthroplasty and/or Total Knee Arthroplasty; (2) Hospital Visits within 7 days of Hospital Outpatient Department Surgery; (3) Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey; (4) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey; and (5) Hospital-Level Total Hip and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure. Quality performance affects both reconciliation payment eligibility and the effective discount factor, with "Good" performance qualifying for a reduced 1.0% discount and "Excellent" performance qualifying for a 0.0% discount.
- **Financial Safeguards.** CJR-X includes two-sided risk from Performance Year 1, meaning hospitals face both upside opportunity and downside repayment obligations. CMS declined requests for an upside-only first performance year, stating that downside risk encourages participants to implement care redesign processes from the outset. Stop-loss and stop-gain limits protect against disproportionate financial exposure. CMS estimates the model will generate Medicare savings of approximately 1% of episode spending annually.

Hospitals should prepare for quality measure reporting and CQS calculation, which affects discount factor adjustments; and

evaluate the interaction between CJR-X and any existing ACO or Medicare Advantage arrangements in which they participate.

3. *CY 2027 PFS Proposed Rule: Key Changes to MSSP, ACO Participation, and Value-Based Care*

As mentioned in the Regulatory Updates section, CMS issued the CY 2027 Medicare PFS proposed [rule](#), which also includes significant proposed changes to the MSSP that CMS states are designed to strengthen financial incentives, expand ACO participation, and advance value-based care within traditional fee-for-service Medicare. Key provisions are summarized below. See our recent [Client Alert](#) for more details.

Financial Methodology and Risk Track Incentives. CMS proposes a coordinated set of changes to the MSSP financial methodology that CMS says are intended to rebalance incentives across risk tracks and encourage both continued participation and new entry into the program. Under current rules, ACOs in BASIC track Level E receive a maximum 50% sharing rate, while ACOs in the ENHANCED track receive 75%. CMS proposes to increase the BASIC track Level E sharing rate from 50% to 60% for agreement periods beginning on or after January 1, 2027, with the stated goal of narrowing the incentive gap between the two tracks and reducing pressure on less-experienced ACOs to advance prematurely to the ENHANCED track. At the same time, CMS proposes to reduce the maximum positive regional-adjustment weight for lower-spending ENHANCED track ACOs from 50% to 35%, citing concerns that the current structure may allow some ACOs to earn shared savings based on favorable benchmark positioning rather than genuine operational efficiency. CMS's analysis of performance year 2024 financial reconciliation data indicates that lower-spending ENHANCED ACOs received an average positive regional adjustment of approximately \$304 per beneficiary, compared to \$166 for BASIC Level E ACOs.

Quality Measurement Changes. Under Medicare's Quality Payment Program, MSSP ACOs report quality data on behalf of their participating clinicians through MIPS using Clinical Quality Measures (CQMs)—standardized tools for measuring the quality of health care services. An ACO's quality performance score under MIPS directly determines whether the ACO meets the MSSP's quality performance standard, which in turn affects its eligibility for maximum shared savings and its exposure to shared losses. CMS proposes several changes to reduce quality reporting burden for ACOs during the ongoing transition to digital quality measurement, including extending the availability of certain reporting pathways (MIPS CQMs and flat benchmarks for Medicare CQMs) and introducing a new "Medicare eCQMs"

collection type that would allow ACOs to report only on their assigned Medicare beneficiary population rather than the broader all-payer population.

Beneficiary Engagement and Part B Cost Sharing. To expand the tools available to ACOs for beneficiary engagement, CMS proposes to allow eligible MSSP ACOs—upon submission and approval of a Part B cost sharing support application—to reduce or eliminate Part B cost sharing for eligible beneficiaries. CMS anticipates collecting initial applications in early 2027, with a target approval date in the second quarter of 2027 and a possible effective date of April 1, 2027. Separately, CMS proposes to discontinue the prepaid shared-savings payment option, citing limited uptake—only four ACOs are currently participating. One final cohort would be accepted during the performance year 2027 application cycle, and prepaid shared-savings payments would cease after December 31, 2027.

Specialty Care and Future Directions. In addition to the proposals summarized above, CMS issued an RFI on integrating specialty care into the MSSP, recognizing that specialists account for roughly 80% of Medicare Part B physician spending but currently have limited direct accountability for total cost and quality under the program's primary-care-centered assignment model. CMS seeks input on specialty-specific assignment approaches, shared accountability structures, condition-specific benchmarks, quality measures, and regulatory flexibilities that could better support specialist engagement. CMS also solicited comments on primary-care-focused capitated payment arrangements within the MSSP, including hybrid capitation and full primary-care capitation models. Comments were due on September 14, 2026. These RFIs signal CMS's interest in extending accountability beyond primary care while preserving ACO-level quality and cost safeguards, and hospitals and health systems participating in or considering the MSSP should closely monitor future rulemaking in this area.

4. *ACCESS Model Updates.*

CMS is continuing to develop its Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model, which launched in July 2026 and reimburses organizations for providing tech-enabled care aimed at improving Medicare beneficiaries' health outcomes. As of August 17, 2026, more than 150 leading health care organizations have been accepted to participate in the launch of the ACCESS model. CMS continues to review applications on a rolling basis, and applications received after May 15, 2026 will be considered for a January 1, 2027 start date. CMS has also announced plans to add new clinical tracks to the model beginning next spring, including heart failure, chronic

obstructive pulmonary disease, substance use disorders, tobacco cessation, and expanded support for bone, joint, and mobility conditions. These additions build on ACCESS's existing tracks covering early and late cardiometabolic and kidney conditions, musculoskeletal conditions, and behavioral health conditions. CMS Administrator Dr. Mehmet Oz has indicated that the agency is exploring whether the ACCESS framework could eventually be adopted by Medicare Advantage and Medicaid.

Federal Awards and Grants Updates

1. *Uniform Guidance Revisions: Proposed Rule Comment Period Closed, Final Rule Potentially Delayed by Congressional Action*

As detailed in our [June newsletter](#), on May 29, 2026, the Office of Management and Budget (OMB), joined by federal award-making agencies, [published a proposed rule in the Federal Register](#) that would substantially revise 2 C.F.R. Part 200, commonly referred to as the "Uniform Guidance"—the government-wide framework governing the management of federal grants, cooperative agreements, and other forms of federal financial assistance. The proposed changes would codify into regulation a series of executive orders issued beginning in January 2025—most notably Executive Order 14332, "Improving Oversight of Federal Grantmaking," as well as several other orders addressing diversity, equity, and inclusion (DEI) programs, gender ideology, merit-based opportunity, and foreign collaborations. The proposed rule also would convert the Uniform Guidance from guidance (separately codified into agency-specific regulations) into binding regulation. For further detail about these proposed changes and how they would affect funding recipients if finalized, see our client alert, "[OMB Proposed Revisions to the Uniform Guidance: Key Takeaways for Award Recipient Organizations](#)" and the corresponding [webinar slides](#).

The comment period closed on July 13, 2026, with 496,606 comments, a volume that underscores the breadth of regulatory, compliance, operational, and scientific concerns raised by the proposed rule.

However, Congress has since passed a bipartisan [continuing resolution](#) (CR) that bars issuance or finalization of a final rule through December 11, 2026, and states that if such rule is issued or finalized, it will not take effect through December 11, 2026. The CR's practical effect is to delay the effective date of a final rule, which OMB anticipated would be October 1, 2026. As a result, the OMB proposed rule is effectively on hold until at least December 11, 2026, and its future will depend on whether

Congress extends, changes, or lets these restrictions expire after that date.

2. *Pending Executive Order to Insert Political Review into NIH Review Process*

Multiple news outlets have reported that, during an Oval Office meeting on September 18, 2026, President Trump directed OMB Director Russell Vought to draft an executive order establishing an external board with final authority over National Institutes of Health (NIH) grant awards. The proposed board reportedly would include both Vought and NIH Director Jay Bhattacharya and would require unanimous decisions on which grants NIH should fund.

Currently, NIH grant applications undergo a well-established, internal review process: independent scientific peer review panels evaluate proposals on their merit, advisory councils issue recommendations, and the directors of NIH's 27 institutes and centers—most of whom are career scientists, not political appointees—make final funding decisions. The proposed board would insert a political checkpoint into this process, effectively placing oversight of NIH's research portfolio into the hands of administration officials. This initiative follows a broader pattern of executive action aimed at controlling and redirecting federal research spending, including OMB's proposed rule revising the Uniform Guidance (summarized above), which would similarly embed political-appointee review in the award process across all federal awarding agencies.

Institutions that rely on NIH funding should closely monitor these developments. If enacted, the executive order could inject new uncertainty into grant timelines, shift funding priorities away from scientific consensus, and reshape the competitive landscape for federally funded research.

3. *Litigation Related to Grant Terminations*

Litigation challenging the mass federal grant terminations carried out by the administration, beginning in spring 2025, continues to evolve.

On May 26, 2026, the Ninth Circuit affirmed in part and reversed in part a district court preliminary injunction ordering federal agencies to reinstate University of California (UC) research grants that were terminated en masse pursuant to various executive orders. [Thakur v. Trump](#), No. 25-4249 (9th Cir. May 26, 2026). The court addressed two provisionally certified classes of UC researchers:

- As to researchers whose grants were terminated by form letter without any award-specific explanation, the

Ninth Circuit reversed the injunction, holding that under *NIH v. American Public Health Association*, 145 S. Ct. 2658 (2025), the Tucker Act likely bars district court jurisdiction over what is essentially a contract-based APA claim seeking to enforce an obligation to pay money pursuant to research-related grants.

- As to researchers whose grants were terminated pursuant to executive orders targeting DEI programs, the Ninth Circuit affirmed the injunction. The court concluded that the agencies selected particular grants for termination regardless of the programs through which they were funded, and made the decision to terminate based solely on the recipients' perceived expression of DEI or environmental justice viewpoints. Because the terminations were aimed at the suppression of viewpoints with which the government disagrees, they likely constitute unconstitutional viewpoint discrimination in violation of the First Amendment.

On July 17, 2026, in *New Jersey v. OMB*, the District Court for the District of Massachusetts found that the Uniform Guidance's federal award termination provision at 2 C.F.R. § 200.340 does not permit the termination of federal awards based on program goals or agency priorities identified after an award was granted. No. 1:25-cv-11816-IT, 2026 WL 2069832 (D. Mass. July 17, 2026). The court's analysis noted that the Uniform Guidance requires agencies to establish and disclose program goals and priorities before announcing a funding opportunity and to monitor grantee performance against those goals and priorities. Permitting termination based on undisclosed post-award priorities would "obviate any need to notify parties of program goals and priorities" and undermine the scheme's coherence. The court also identified a constitutional concern: if the goals and priorities against which a grant is measured can shift after the award, states would lack the clear notice of funding conditions required by the Spending Clause. Thus, the court concluded that the Uniform Guidance permits termination on the basis of agency priorities only where the grantee's performance no longer carries out the goals and priorities identified by the agency when the award was made.

Separately, the court addressed a threshold jurisdictional question. The court acknowledged that the Tucker Act would bar a suit seeking money damages for the termination of a federal award but concluded that the plaintiffs were bringing a permissible "pre-enforcement" challenge. Plaintiffs sought only a forward-looking declaration of the parties' rights and

obligations and not monetary damages or retroactive relief arising from past terminations. The court's jurisdiction over such pre-enforcement challenges is consistent with Justice Barrett's concurrence in *NIH v. American Public Health Association*, No. 25A103 (U.S. Aug. 21, 2025) which recognized that district courts retain jurisdiction over agency guidance whereas challenges of grant terminations themselves must proceed in the Court of Federal Claims.

Taken together, *Thakur v. Trump* and *New Jersey v. OMB* demonstrate that while the Supreme Court's decision in *NIH v. American Public Health Association* significantly narrowed the path for district court challenges to federal grant terminations—particularly where plaintiffs seek reinstatement of funding through contract-based APA claims—lower courts continue to identify viable grounds for relief. These decisions suggest that plaintiffs who frame their claims around constitutional violations or prospective declaratory relief—rather than retroactive enforcement of contractual payment obligations—may continue to find avenues for judicial review outside the Court of Federal Claims, notwithstanding the jurisdictional constraints imposed by the Supreme Court.

4. Priority Research Areas for FY2028

On July 21, 2026, the White House Office of Science and Technology Policy (OSTP) released a [report](#) outlining a broad vision for restructuring the federal research and development (R&D) enterprise. An accompanying joint OSTP-OMB memorandum (starting on page 103 of the report) sets out the administration's R&D budget priorities for FY 2028.

Consistent with the administration's broader promotion of the hard sciences—reflected in agency budgets and executive orders—the memorandum directs agencies to prioritize the physical sciences, chemistry and materials science, mathematics and computer science, and engineering sciences.

The report and memorandum call for several structural shifts in how federal research dollars are allocated. Agencies are directed to award more long-duration grants of five years or more, fully funded at award start. Though the report frames multiyear grants as awarding researchers greater autonomy and reducing administrative burdens, some argue that the practice [harms early-career researchers](#). The memorandum also encourages the use of "fast grants" with simplified applications and brief review timelines of under one month, experimental mechanisms such as "golden tickets" that allow individual reviewers to champion unconventional proposals outside of consensus-driven peer review, and prize mechanisms that pay researchers for results or

outcome-based goals rather than for time, equipment, and supplies. The memorandum envisions other reward mechanisms as well, including fast-tracking regulatory review, for desirable performance such as leveraging private over federal investment at a specific ratio (3:1).

The administration also directs agencies to fund a broader range of recipients beyond traditional universities, including new institutional models like the NSF's X-Labs program, which provides operational funding to independent research teams outside of academia. The memorandum encourages agencies to direct funding to individual researchers with portability across institutions, modeled on NSF's Graduate Research Fellowship Program, so that programs "distribute funding directly to students and researchers" rather than to institutions.

The report calls on agencies to "rein in indirect cost recovery that supports administrative bloat," though it does not prescribe a specific mechanism. The report does not direct agencies to move specific dollar amounts away from universities, but it consistently frames the traditional university grant model as insufficient and emphasizes the need to support research in new settings, including independent research organizations, industry labs, and public-private partnerships.

Within 90 days (approximately October 19, 2026), the head of each agency with \$3 billion or more in FY 2026 R&D budget authority must submit an action plan to OSTP and OMB, identifying specific implementation actions, timelines, and responsible offices. Budget formulation priorities are to be reflected in agency FY 2028 budget submissions.

5. *AHRQ Issues Notices of Non-Award, Effectively Terminating Millions in Federal Funding*

Since early 2025, the federal government has undertaken an unprecedented wave of research award terminations across multiple agencies. The Agency for Healthcare Research and Quality (AHRQ) has followed this broader pattern with actions notable for both their scale and their process. On July 15, 2026, AHRQ-funded researchers received [non-award notices](#) terminating future funding installments for ongoing grants, affecting approximately 150 grants totaling roughly \$94 million. The letters offered no grant-specific justifications, instead stating that the agency was "adjusting its discretionary health services research award portfolio in order to better prioritize agency resources" toward areas including patient safety, antibiotic resistance, digital health tools, AI, long COVID, nutrition, and autism research. Grants focused on training the next generation of health services researchers were among those discontinued,

despite training being among AHRQ's own stated priorities. The notices came after months of uncertainty, during which investigators had been waiting for notices of award granting funding for the current budget year.

These developments unfold against a backdrop of significant institutional erosion at AHRQ, which has experienced sharp staff reductions, a decline in grantmaking activity, and the impoundment of approximately \$80 million in FY 2025 funding. Taken together, these factors raise serious questions about the agency's capacity to spend down the remaining tens of millions of dollars in [appropriated AHRQ research funding](#), which expired on September 30, 2026. Democratic members of the Senate Appropriations Committee have demanded that HHS release information about its spending plans for those funds, noting that HHS informed the senators it plans to award just 90 grants through AHRQ this year—hundreds fewer grants than in previous years—and intends to transfer \$100 million in AHRQ-appropriated funding to other agencies through inter-agency agreements. These developments coincide with reports that NIH has [diverted funds to the Department of War](#), a precedent that may foreshadow a similar redirection of the remaining AHRQ appropriations. On September 25, 2026—just days before the funds' expiration—the president transmitted a [Special Message to Congress](#) proposing the rescission of \$810 million in appropriated funds, including \$27.7 million from AHRQ's appropriation.

In October 2026, the U.S. Government Accountability Office (GAO) issued a decision concluding that AHRQ violated the Impoundment Control Act by failing to obligate or expend the funds for a permissible purpose. GAO acknowledged that AHRQ's appropriation gave the agency broad discretion over which grants to fund, but held that this discretion does not allow an agency to withhold funds altogether. Congressionally allocated funds not spent on one program must still be prudently obligated for other permissible purposes and AHRQ failed to carry out this requirement.

6. *Executive Order to Establish NIH Women's Health Division*

On October 19, 2026, President Trump signed an [executive order](#), "Advancing Women's Health to Improve Outcomes in All Phases of Life," directing HHS, acting through the NIH Director, to establish a new Women's Health Division within NIH within 90 days. In coordination with the NIH Office of Research on Women's Health, the division will expand scientific review of understudied women's health conditions (e.g., cancer, infertility, menopause), strengthen grant recipients'

accountability for adhering to NIH's policy requiring research to account for sex as a biological variable, and accelerate the translation of research into clinical care. The order also establishes a White House Women's Health Task Force, co-chaired by the HHS Secretary and the White House Chief of Staff, to coordinate federal efforts to improve women's health. The order revokes two Biden-era actions on women's health research: Executive Order 14120, "Advancing Women's Health Research and Innovation," and the November 13, 2023 Presidential Memorandum on the White House Initiative on Women's Health Research. NIH award recipients should anticipate closer scrutiny of their compliance with [requirements related to sex as a biological variable](#).

Transaction Trends

1. Hospital M&A Continues to Rebound in 2026

Hospital merger and acquisition (M&A) activity has rebounded sharply in 2026 after reaching a 15-year low of just 46 transactions in 2025. Forty deals were announced in the first half of 2026 alone, and at least 30 have already been finalized.

Mega-mergers, defined as transactions involving an acquired organization with more than \$1 billion in annual revenue, are a defining feature of the 2026 landscape. For example, the proposed combination of Sutter Health and Allina Health would create a 39-hospital, \$26 billion nonprofit system spanning California, Minnesota, and Wisconsin. In North Carolina, WakeMed, a financially healthy community health system, has agreed to combine with Atrium Health, North Carolina's largest health provider, in a deal that would give Atrium access to the Research Triangle, a major metropolitan and research hub anchored by the cities of Raleigh and Durham and the town of Chapel Hill, while WakeMed benefits from Atrium's \$2 billion capital commitment to fund infrastructure expansion. Sanford Health and North Memorial Health closed a deal in September 2026 under an oversight agreement with the Minnesota Attorney General that imposes conditions on the combined system, including commitments to maintain services, preserve access, and explore expanding behavioral health in underserved areas of the state.

Additionally, outpatient growth strategies continue to accelerate in 2026. Ascension's acquisition of AMSURG established the system as the nation's third-largest ambulatory surgery center platform, reflecting a broader industry pivot toward lower-acuity, higher-margin care delivery. For-profit operators are increasingly acting as sellers, shedding non-core assets to refocus on markets where they can maintain scale. The pattern is

consistent with trends we have seen this year: health systems are moving decisively, whether through large-scale strategic combinations, outpatient platform acquisitions, or portfolio rationalization, to position themselves ahead of anticipated reimbursement pressure.

2. Reimbursement Pressure Continues to Drive Hospital Transactions

The widening gap between operating costs and government payer rates continues to pressure hospital operators toward transactions, and state governments have emerged as key enablers, deploying billions in safety-net transformation funding to facilitate deals and stabilize community access to care. This evolving state role builds on the pattern we identified in our February 2026 newsletter as states are moving beyond traditional regulatory oversight to function as active facilitators, funders, and policy enablers and are intervening directly to stabilize distressed providers, preserve access, and avoid abrupt closures.

The proposed acquisition of Maimonides Health by the NYC Health + Hospitals system is a leading example. New York State has offered the systems up to \$2.245 billion through the State's Safety Net Transformation Program in connection with this transaction. This transaction follows New York's broader commitment under the Health Care Safety Net Transformation Program, which in October 2025 announced more than \$2.6 billion in funding for transformational partnerships involving six safety net hospitals and other health care organizations, including health system affiliations, electronic health records investments, facility modernizations, and network expansions. WMCHHealth assumed full ownership of three Bon Secours Charity Health System hospitals and one HealthAlliance hospital in the Hudson Valley with \$100 million in state support through the Safety Net Transformation Program to fund the integration and preserve access in the region, and Montefiore Health System received approval from the New York State Public Health and Health Planning Council at its September 17, 2026 meeting to acquire St. John's Riverside Hospital in a transaction also supported by State Safety Net Transformation Program dollars.

In Oregon, the Oregon Health Authority fast tracked Salem Health's affiliation with Santiam Hospital in Oregon through an emergency exemption after the smaller hospital withdrew from the standard regulatory review process to avoid insolvency. The Salem Health transaction echoes earlier state-facilitated deals, such as Connecticut's enactment of 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.

These transactions illustrate a recurring dynamic: financially distressed hospitals, especially those serving high proportions of Medicaid patients, are increasingly seeking the scale, capital, and payer leverage that larger systems can provide. This new role for states, acting simultaneously as transaction facilitators and as regulators implementing pre-transaction review requirements, reflects a split approach to healthcare consolidation oversight that is likely to continue shaping deal structures and timelines.

3. *FTC Enforcement Against Hospital Mergers Under Second Trump Administration*

In September 2026, the Federal Trade Commission (the FTC) issued a statement supporting Adena Health's acquisition of Fairfield Medical Center, after the agency had investigated Fairfield's proposed sale to the larger OhioHealth system. The investigation raised concerns regarding the risk of raising costs and reduced quality of care for patients, as well as questions regarding the thoroughness of Fairfield's process to identify potential buyers. The FTC coordinated with the Ohio Attorney General's Office throughout the investigation.

In a statement, FTC Chairman Ferguson noted that "financial distress is not a blank check for mergers" and outlined the agency's expectations for a good-faith shop process under the failing-firm defense. The statement makes clear that the FTC views the failing-firm defense as a narrow exception, not a presumptive safe harbor, and that the agency will look beyond the identity of the proposed acquirer to evaluate whether the selling hospital conducted a meaningful search for less anticompetitive alternatives. The statement emphasizes that the antitrust laws permit an anticompetitive merger as an alternative to hospital closure only if no alternative transaction would preserve competition or present fewer or less severe competition concerns. The Fairfield outcome is particularly notable given rising hospital transaction volume in 2026 and the increased number of deals involving distressed hospitals (with or without additional State support as reflected above). As deal activity accelerates and more hospitals, including financially distressed operators, enter the market, the FTC's willingness to intervene in a single community hospital sale signals that enforcement resources remain focused on hospital consolidation.

The Fairfield matter further illustrates that the FTC will continue to scrutinize hospital transactions even when the target is in financial distress, and that the current administration's generally more permissive posture toward M&A does not extend to hospital deals in concentrated markets. The agency's statement also carries broader implications for the significant number of distressed hospital transactions still in the pipeline. Hospitals in

financial distress considering a sale that may be viewed by the FTC as anticompetitive should endeavor to ensure their shop process is well-documented, broadly solicited, and structured to withstand FTC scrutiny. This process would include evidence of outreach to a meaningful number of potential partners, clear documentation of why alternatives were not viable, and a record demonstrating that the ultimate transaction was the least anticompetitive option reasonably available.

4. *Behavioral Health Transaction Activity Continues to Accelerate in 2026*

Behavioral health continued to be among the most active deal categories through the summer of 2026, with 47 behavioral health care deals reported through late July 2026. Counseling and psychiatric care (18 deals) and autism spectrum disorder treatment (11 deals) were the most active specialties. The pace is consistent with what industry analysts predicted at the start of the year: behavioral health, along with tech-enabled care and physician specialty platforms, was expected to command significant deal interest in 2026 as acquirers pursue growth in areas with clearer and more consistent reimbursement.

The headline transaction was a large behavioral health provider's acquisition of a virtual mental health platform, completed in 2026, which the acquirer described as creating a full continuum of behavioral health care spanning inpatient, outpatient, and virtual settings. The deal reflects the growing recognition that behavioral health delivery must extend beyond traditional brick-and-mortar settings to meet patient demand at scale. There was also a notable divestiture in the behavioral healthcare space. A large national health system sold one of its behavioral health facilities in the Mid-Atlantic region to a regional health care provider in 2026, marking the buyer's entrance into the behavioral health market. Taken together, these transactions illustrate a market that is attracting both large health systems looking to build full-continuum platforms and new entrants seeking footholds in a high-demand specialty.

State regulators are also beginning to treat behavioral health access as a condition of merger approval. A state attorney general's oversight agreement governing a recent combination specifically requires the combined system to maintain and explore expanding behavioral health services in underserved areas of the state. This is an emerging trend that parallels the broader pattern of states acting as both transaction facilitators and regulators. As deal activity in this space accelerates and regulators increasingly tie behavioral health commitments to transaction approval, health systems should evaluate how behavioral health fits into their broader transaction and growth

strategies, whether as a standalone acquisition target, an integrated component of a larger platform strategy, or a condition that must be addressed to secure regulatory clearance for other transactions.

Latest on 340B

1. HRSA 340B Rebate Model Pilot Program

a. HRSA Announces Revised 340B Rebate Model Pilot Program 2.0

On July 31, 2026, the Health Resources and Services Administration (HRSA) [announced](#) a revised 340B Rebate Model Pilot Program (the “Revised Pilot”), which will provide qualifying drug manufacturers with a voluntary pathway to offer the 340B ceiling price to covered entities through post-purchase rebates, rather than upfront discounts, for a limited set of covered outpatient drugs. The Revised Pilot expands the scope of the prior pilot program to 25 drugs — up from the 10 drugs approved under the original pilot. Eligible manufacturers seeking to participate were required to submit rebate plans to HRSA by August 24, 2026, with approved plans taking effect on January 1, 2027.

The Revised Pilot follows a Request for Information [issued](#) in the Federal Register on February 17, 2026, in which HRSA sought input on the potential use of rebates in the 340B Program, including standards and procedures governing manufacturer rebate model approval and stakeholder impacts. The RFI generated more than 2,400 public comments from hospitals, health centers, manufacturers, pharmacies, patient advocates, and other stakeholders.

The Revised Pilot also follows the termination of the original 340B Rebate Model Pilot Program. As discussed in previous [newsletters](#), HRSA ended the original pilot program on February 5, 2026, in response to a lawsuit filed in the U.S. District Court for the District of Maine by the American Hospital Association (AHA) and multiple health systems. *AHA v. Kennedy*, 820 F. Supp. 3d 30 (D. Me. 2025). The district court granted plaintiffs a [preliminary injunction](#) in December 2025, concluding that HRSA 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. After the First Circuit [denied HRSA’s request](#) for a stay pending appeal, the federal government dismissed its appeal and HRSA withdrew the original pilot program, stating that the agency planned to address the procedural deficiencies identified in the district court’s decision. The Revised Pilot represents the agency’s comeback.

b. First Circuit Update on Manufacturer Intervention Appeal

Litigation on the original pilot program proposed by HRSA remains active despite the federal government dismissing its appeal and HRSA withdrew the original pilot program. As discussed in our [prior newsletter](#), manufacturers had previously sought to intervene in the original pilot program litigation, but the U.S. District Court for the District of Maine found that their interests were sufficiently represented by the government. The manufacturers have filed a separate appeal to the First Circuit contesting the denial of intervention. On September 15, 2026, a First Circuit panel heard oral arguments in the appeal and [raised](#) mootness concerns. The panel acknowledged that a new round of litigation over the Revised Pilot will almost certainly follow, with one judge noting that the manufacturers could seek review in future proceedings if denied intervention in those future cases. Counsel for the manufacturers argued that the dispute was “the type of dispute that evades review,” contending there may not be time for the First Circuit to hear an appeal before the manufacturers’ statutory obligations would begin on January 1, 2027. Counsel for the hospitals countered that the case is moot, stating, “[t]his court does not have jurisdiction . . . [t]his case is moot. It ended seven months ago.” A decision from the First Circuit remains pending.

c. D.C. Circuit Rules Manufacturers Cannot Unilaterally Implement 340B Rebate Models

On July 21, 2026, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the district court’s [decision](#) in the consolidated appeal *Novartis Pharmaceuticals Corp. v. Kennedy*, holding that Section 340B of the Public Health Service Act 42 U.S.C. § 256b(a)(1), requires the HHS Secretary to approve a rebate mechanism before manufacturers may implement one.

As discussed in our prior [newsletters](#), in 2024, Novartis, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, and Kalderos, Inc., each proposed switching from the prevailing upfront discount purchase model to a post-purchase rebate model, under which covered entities would purchase drugs at full price and then submit claims for a cash refund equal to the difference between that price and the 340B ceiling price. HRSA responded that the Secretary had not provided for such a model and that unilateral implementation would be inconsistent with the 340B statute. The manufacturers sued under the APA, and the district court entered [summary judgment](#) for HRSA.

First, the court rejected the argument that Section 340B prohibits all rebate models, holding that the statute explicitly

envisions that the “amount required to be paid” may “tak[e] into account” a “rebate.” [42 U.S.C. § 256b\(a\)\(1\)](#). The court cited legislative history confirming that Congress “does not specify” whether covered entities would receive favorable prices “through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism.” [H.R. Rep. No. 102-384, pt. 2, at 16](#).

Second, on the central question, the court held that the phrase “as provided by the Secretary” in Section 340B(a)(1) establishes a preapproval requirement: manufacturers may not unilaterally impose a rebate mechanism unless the Secretary has “provided” for it. The court reasoned that the contrary reading would “counterintuitively let manufacturers . . . take the lead in administering the 340B Program,” citing the Supreme Court’s recognition of the Secretary’s control over the program in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 114 (2011).

Finally, the court rejected the manufacturers’ argument that any restriction on rebate models must appear in the pharmaceutical pricing agreements (PPAs) that manufacturers sign to participate in the 340B Program, noting that the PPAs are “form agreements, composed by HHS” that “contain no negotiable terms,” directly quoting *Astra*, 563 U.S. at 113, 118. The court also rejected the manufacturers’ arbitrary-and-capricious claims, reasoning that the statute does not delegate discretionary authority to the agency in this respect, and held that the manufacturers’ remaining challenges were unripe because the Secretary’s consideration of the proposals remains ongoing.

Notably, the court observed in a footnote that, in [June 2026](#), HRSA announced its intent to introduce a revised 340B Rebate Model Pilot Program (which, as noted above, HRSA subsequently published in July 2026).

2. **CY 2027 OPPS Proposed Rule: Proposed 340B Reimbursement Reduction**

In its CY 2027 OPPS [proposed rule](#), published in July 2026, CMS proposes to substantially reduce Medicare reimbursement for separately payable drugs acquired under the 340B Program by non-exempt hospitals paid under the OPPS. As discussed in a [prior newsletter](#), the Medicare OPPS Drugs Acquisition Cost Survey collected hospital drug acquisition cost data at the National Drug Code (NDC) level for the period from July 1, 2024 through June 30, 2025. Drawing on the results of the survey, CMS proposes to cut reimbursement from the current rate of ASP plus 6% to ASP minus 33.4%, an effective reduction of approximately 37%. CMS estimates that the proposed reduction would decrease Medicare drug payments by nearly

\$4.85 billion and reduce beneficiary cost-sharing by approximately \$1.2 billion in CY 2027. As required by the OPPS budget-neutrality framework, the agency would offset the drug payment reduction with an estimated 8.44% increase in non-drug outpatient service payments.

The proposed rule would also accelerate CMS’s recoupment of estimated increased payments previously made to hospitals for non-drug services. In the wake of the Supreme Court’s decision in *AHA v. Becerra*, which held that CMS reductions to 340B drug reimbursement rates in effect from 2018 through 2022 were unlawful, CMS made hospitals whole for the prior drug underpayments. Due to statutory budget neutrality requirements, CMS also had to offset the drug repayments by clawing back increased non-drug payments the hospitals had received during the same period. In the CY 2026 OPPS [Final Rule](#), CMS applied a 0.5% reduction to the OPPS conversion factor to do so. The proposed rule would increase that annual reduction from 0.5% to 3% through CY 2029 — a significant acceleration from the prior pace, which would have extended through 2035 — in order to recoup approximately \$7.8 billion in outstanding amounts. CMS estimates that the accelerated recoupment would reduce payments to affected providers by an additional \$2.3 billion in CY 2027. Notably, children’s hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals are excluded from the proposed reduction.

3. **Medicare Drug Price Negotiation Program Proposed Rule**

On June 16, 2026, CMS published a [proposed rule](#) (CMS-4215-P) that would codify the Inflation Reduction Act’s Medicare Drug Price Negotiation Program into federal regulation (42 C.F.R. Part 429) to replace the administrative guidance that has governed the program to date. The rule would address Maximum Fair Price (MFP) implementation, manufacturer compliance requirements, and civil monetary penalties. The comment period closed August 17, 2026.

- **Retrospective Rebate Option.** The proposed rule would allow manufacturers the option to satisfy MFP obligations through retrospective rebates rather than point-of-sale discounts. The proposed approach would require tracking and retrospective reconciliation of purchases and rebates and thus could introduce additional complexity for pharmaceutical supply chain participants, as well as increase administrative costs and the likelihood of disputes regarding eligibility and claim matching. For hospitals operating outpatient pharmacies or 340B programs, this also could

complicate acquisition cost tracking and program compliance.

- **Selected Drug Expansion.** If the rule is finalized, the first year of negotiated prices under this rule would go into effect in 2028. This would represent the third cycle of drugs with negotiated prices since the initiation of the Medicare Drug Price Negotiation Program. For 2028, CMS will select up to 15 additional high expenditure, single-source drugs payable under Part B and/or covered under Part D and an additional 20 for 2029. CMS will also renegotiate MFPs for drugs selected in earlier cycles, if applicable. Negotiated MFPs went into effect beginning January 1, 2026 for the first cohort of 10 selected drugs.
- **Civil Monetary Penalties.** The proposed rule would establish a comprehensive enforcement framework with significant civil monetary penalties for manufacturer noncompliance. The first key penalty provision imposes penalties of up to \$1 million per day for violation of a Negotiation Program Agreement requirement. The second imposes penalties of \$100 million per item of false information provided in connection with (a) requesting a “biosimilar delay,” which is a mechanism that allows CMS to delay selecting a biologic for price negotiation if a competing biosimilar is highly likely to reach the market soon, or (b) eligibility for a small biotech exception. The third imposes penalties equal to ten times the rebate amount owed for failure to pay a biosimilar delay rebate (which is the rebate that manufacturers who receive a biosimilar delay must pay if no competitor product enters the market). Manufacturers would have 60 days to pay penalties after notice, with appeal rights through administrative procedures established under 42 CFR Part 423, Subpart T.

As this rule moves to finalization, hospitals and health systems should monitor: (1) the retrospective rebate mechanism, which may complicate 340B Program compliance and acquisition cost tracking; (2) Medicare Transaction Facilitator participation requirements for hospital-based pharmacies and other dispensing entities; and (3) the expanding list of selected drugs, which may affect formulary decisions and drug cost projections.

4. Ninth Circuit 340B Qui Tam Litigation Update: Defendants Raise Public Disclosure Bar on Remand

As discussed in our prior [newsletter](#), on March 17, 2026, a panel

of the U.S. Court of Appeals for the Ninth Circuit [held](#) that the absence of a private right of action under the 340B statute did not bar FCA claims, reversing the dismissal of a *qui tam* complaint brought by a covered entity under the FCA and state law analogues against multiple drug manufacturers. The case was ultimately remanded back to the district court.

On remand, on July 1, 2026, defendants filed a renewed [motion](#) to dismiss arguing that plaintiff’s claims are barred by the FCA’s public disclosure bar at 31 U.S.C. § 3730(e)(4)(A). Defendants contend that the material elements of the alleged fraud, *i.e.*, that manufacturers overcharged 340B covered entities by failing to follow penny pricing (HRSA’s policy requiring manufacturers to charge covered entities \$0.01 per unit when the ceiling price calculation equals zero or less), were publicly disclosed through multiple channels well before plaintiff filed suit, including: (i) a prior *qui tam* action, *United States ex rel. Joyce v. AstraZeneca Pharmaceuticals LP*, which alleged substantially similar overcharges involving several of the same defendants and products; (ii) federal reports and congressional testimony dating back to 2003 from the HHS Office of Inspector General and the Government Accountability Office documenting 340B overcharges; and (iii) extensive news media coverage. Defendants further argue that Adventist does not qualify as an “original source” of the information underlying its claims for purposes of the “original source” exception to the public disclosure bar (permitting a *qui tam* action, notwithstanding the public disclosure bar, where the relator has knowledge independent of the publicly disclosed allegations and voluntarily provided that information to the federal government) because the pricing data on which it relies was available to every covered entity. Adventist filed an opposition brief on August 19, 2026. After defendants filed replies on September 16, 2026, the court took the motion under submission without a hearing on October 1, 2026. That same day, 24 states, Puerto Rico, and the District of Columbia notified the court that they oppose dismissal of their state FCA claims on public disclosure grounds. Defendants responded on October 6, 2026 that the states’ October 1 filing does not affect the federal FCA claim or the claims of Florida and Michigan, which did not join, and that the court should decline supplemental jurisdiction over the remaining state-law claims if the federal claim is dismissed. A decision remains pending.

5. AbbVie 340B Patient Definition Litigation Update

As discussed in our prior [newsletter](#), on April 8, 2026, AbbVie Inc. [filed](#) a complaint for declaratory and injunctive relief in the U.S. District Court for the District of Columbia against HRSA, challenging the agency’s 1996 interpretation of the term

“patient” under the 340B statute’s anti-diversion provision. 42 U.S.C. § 256b(a)(5)(B). AbbVie contends that HRSA’s 1996 [Guidelines](#) define “patient” too broadly and facilitate program abuse by enabling covered entities to claim 340B discounts based on superficial encounters, including brief telehealth visits and referrals to non-covered-entity providers. AbbVie argues that, under *Loper Bright*, the 1996 Guidelines are not entitled to deference and do not reflect the best reading of the statute.

On June 16, 2026, HHS filed a [motion to dismiss](#) AbbVie’s complaint, arguing that the manufacturer’s claims are not ripe for judicial review and that it lacks standing. On July 28, 2026, AbbVie filed its opposition to the [motion to dismiss](#). AbbVie argues that HRSA’s refusal to approve its audit workplans constitutes final agency action because the agency categorically declared that it would not “enforce corrective actions for any findings resulting from AbbVie’s application of a patient definition that exceeds the 1996 Guidelines.” AbbVie contends that this determination consummated the agency’s decision-making process. AbbVie also argues that its claims present a purely legal question, *i.e.*, the correct statutory meaning of “patient,” that is ripe for review and not committed to agency discretion. On August 31, HHS filed a reply brief in support of the [motion to dismiss](#).

Separately, multiple covered entity groups sought to intervene. On June 23, 2026, 340B Health, UMass Memorial Medical Center, and Genesis Healthcare System filed a motion to intervene as [defendants](#), and on July 6, 2026, the National Association of Community Health Centers, Inc. and Ryan White Clinics for 340B Access filed a joint motion to intervene as [defendants](#). On August 24, 2026, the court granted both [motions to intervene](#). The American Hospital Association, America’s Essential Hospitals, and other healthcare provider associations also filed an amicus brief on July 14, 2026, in support of the [motion to dismiss](#). On September 8, 2026, the National Association of Community Health Centers and Ryan White Clinics filed a [reply brief](#) arguing that the court lacks jurisdiction over AbbVie’s claims because AbbVie failed to follow the mandatory administrative process for diversion disputes before filing suit. On September 10, 2026, AbbVie filed a motion to strike that portion of the reply brief, or in the alternative, for leave to file a sur-reply. AbbVie argued that the intervenors raised an “entirely new theory” that should not be considered because it was introduced for the first time in a reply brief and, in any event, because there is no statute or rule requiring plaintiffs to exhaust the administrative process under Section 340B before filing suit under the Administrative Procedure Act. According to AbbVie, the federal government

took no position on the motion, while the advocacy groups opposed the request. On September 15, 2026, the motion was granted in part and denied in part. The court declined to strike any portions of the reply brief but granted AbbVie leave to file a sur-reply. AbbVie filed its sur-reply on September 29, 2026, arguing that the court had jurisdiction over its claims. On September 30, 2026, two intervenor-defendants filed a joint motion for leave to file a sur-reply in support of the motion to dismiss.

The motion to dismiss filed on June 16, 2026 remains pending.

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

As discussed in our prior [newsletters](#), states have enacted legislation requiring manufacturers to offer 340B pricing on products purchased for dispensing at contract pharmacies, and several stakeholders have challenged these laws in courts across the country with split decisions. Since our last newsletter, circuit court and district court activity has continued to widen the split.

- Fifth Circuit (Louisiana):** As discussed in our prior [newsletter](#), the Fifth Circuit had previously affirmed a district court decision rejecting claims that [Louisiana’s Act 358](#), which prohibits manufacturers from interfering with the delivery of 340B drugs to contract pharmacies and bars discriminatory reimbursement by payors, was preempted or unconstitutional. On July 6, 2026, the Fifth Circuit granted intervenor Louisiana Primary Care Association’s petition for panel rehearing and issued a new opinion again affirming [summary judgment](#) for Louisiana. The new opinion reaffirmed that Louisiana’s Act 358 “regulates the distribution of drugs to patients and the role of pharmacies in this distribution—areas left free under the 340B Program for state supplementation.”
- Fourth Circuit (West Virginia):** As discussed in our prior [newsletter](#), the Fourth Circuit [upheld](#) a preliminary injunction blocking West Virginia’s [S.B. 325](#) on March 31, 2026. The Fourth Circuit concluded that the West Virginia law, which barred manufacturers from interfering with the delivery of 340B drugs to pharmacies under contract with a 340B covered entity and prevented manufacturers from requiring covered entities to submit claims or utilization data, likely interfered with the 340B statute. On June 2, 2026, the Fourth Circuit [granted](#) rehearing *en banc*. Supplemental

briefing was completed by July 31, 2026, and oral argument is scheduled for October 27, 2026.

- **North Dakota:** On July 7, 2026, North Dakota filed a motion to stay the district court’s April 27, 2026 summary judgment and permanent injunction invalidating [H.B. 1473](#), which prohibits manufacturers from restricting contract pharmacy access to 340B drugs or conditioning access on claims data submission, citing intervening developments including the Eighth Circuit’s decision upholding a similar Missouri law in *Novartis v. Hanaway*, the vacatur of the Fourth Circuit opinion pending *en banc* review, and the Fifth Circuit’s substituted opinion in *AbbVie v. Murrill*. On July 27, 2026, the district court denied the motion, finding that stark differences between North Dakota’s law—which imposes criminal penalties classified as a class B misdemeanor—and the Missouri statute analyzed in *Hanaway* undermined North Dakota’s likelihood of success on the [merits](#).
- **Washington:** Following the June 9, 2026 denial of manufacturers’ requests for a preliminary injunction against [S.B. 5981](#), which prohibits manufacturers from restricting contract pharmacy access to 340B drugs or requiring claims data as a condition of sale, Washington’s law took effect on June 11, 2026. Multiple manufacturers and PhRMA have [appealed](#) to the Ninth Circuit, *AbbVie Inc., et al. v. Brown, et al.*, Docket Nos. 26-3709, 26-3712, 26-3714 (9th Cir. Jun 09, 2026), where briefing is ongoing.

7. Lilly’s 340B Claims-Data Policy Sparks Litigation and Competing Reform Proposals

As discussed in our prior [newsletter](#), in January 2026, Lilly announced a policy requiring covered entities to submit claims-level data for all 340B in-house pharmacy dispenses within 45 days, or 60 days for specified products. The dispute has since escalated, with Lilly enforcing the policy and two hospitals filing lawsuits.

On June 1, 2026, Lilly sent a [letter](#) to HRSA Administrator Thomas Engels stating that approximately 70 percent of covered entities purchasing Lilly products (roughly 2,350 entities) had complied with the data submission requirement. Lilly announced the manufacturer would give noncompliant entities five business days to submit claims data before instructing its wholesalers to cut off 340B pricing.

Lilly followed through on its warnings, cutting off 340B pricing for two hospitals in June and July, 2026, respectively. Both hospitals have since filed suit.

- On July 2, 2026, a hospital filed a complaint against Lilly in the U.S. District Court for the Middle District of Florida, Tampa Division, alleging violations of the Florida Deceptive and Unfair Trade Practices Act, [Fla. Stat. § 501.204 et seq.](#) The hospital estimates annual losses of approximately \$24.7 million.
- On July 27, 2026, another hospital filed a complaint and motion for preliminary injunction against Lilly in the U.S. District Court for the District of New Hampshire. The hospital alleges a *per se* violation of Vermont law ([18 Vt. Stat. Ann. § 4682](#)), which prohibits manufacturers from conditioning 340B pricing on claims data submission, and additionally asserts claims under New Hampshire’s Consumer Protection Act (RSA chapter 358-A), breach of contract, breach of the implied covenant of good faith and fair dealing, and unjust enrichment. The hospital alleges annualized excess costs of at least \$4.7 million.

Both hospitals allege that Lilly possesses existing statutory audit rights under [42 U.S.C. § 256b\(a\)\(5\)\(C\)](#) and [61 Fed. Reg. 65,406 \(Dec. 12, 1996\)](#) to address compliance concerns, and that the data requirements impose significant operational, privacy, and financial burdens on covered entities. Both cases remain in early stages of litigation.

On June 29, 2026, more than 70 members of Congress signed a [letter](#) to HRSA, calling on the agency to take action against Lilly’s pricing cutoffs, stating that “Congress did not authorize manufacturers to unilaterally impose additional reporting mandates or data-sharing requirements as a prerequisite for obtaining those discounts.”

More broadly, at least [12 leading manufacturers](#), including [Sanofi](#), [Novartis](#), and [AstraZeneca](#), have implemented or announced policies requiring covered entities to submit claims-level data for in-house pharmacy dispenses. [Johnson & Johnson](#) is the latest manufacturer to announce a claims data submission policy, and unlike other manufacturer policies to date, the manufacturer is the first to [extend](#) the policy’s reach to community health centers as well as hospitals. HRSA has not yet taken a public stance on the permissibility of these data-submission requirements. The AHA sent letters to HRSA in [January](#) and [April](#) 2026 urging the agency to take action, including assessing civil monetary penalties, and criticized the

agency's inaction as raising "serious questions within the regulated community about whether HRSA has now tacitly blessed these unilateral claims-data policies."

8. *Hospital Challenges HRSA's Registration System and DSH Eligibility Determinations under the 340B Program*

On September 3, 2026, a nonprofit teaching hospital in Michigan filed a complaint in the U.S. District Court for the District of Columbia challenging HRSA's administration of the 340B Program's registration and eligibility processes.

The hospital stated that the hospital has participated in the 340B Program since 2019 and has qualified as a DSH since 2024. According to the hospital, in early 2026, preliminary projections from the hospital's cost reporting team suggested that its disproportionate share adjustment could potentially drop below the 11.75% DSH threshold on its upcoming Medicare Cost Report. Because HRSA permits covered entities to register under only a single 340B eligibility category and requires entities to immediately report any change in eligibility status, the hospital stated that it submitted an application during the January 2026 registration window to register as a Rural Referral Center (RRC), which carries a lower 8% threshold. According to the hospital, HRSA approved the RRC registration on February 4, 2026, effective April 1, 2026.

By HRSA's next registration window in April 2026, the hospital stated that it confirmed that its preliminary projections were incorrect and that it maintained a 12.39% disproportionate share adjustment during FY 2025, satisfying the 11.75% DSH threshold. According to Beaumont Hospital, it filed a new registration application on or about April 15, 2026 to reinstate its DSH status, but HRSA rejected the application on the ground that the hospital did not submit an attestation by its "Authorizing Official" within a five-day response window. HRSA denied reconsideration on June 11, 2026, directing Beaumont Hospital to reapply during the July registration window, with any approved reinstatement effective no earlier than October 1, 2026. As a result, Beaumont Hospital alleges it has been unable to purchase Orphan Drugs at 340B pricing as a DSH for the six-month period beginning April 1, 2026, despite meeting the 11.75 percent DSH threshold throughout the period.

Beaumont Hospital brings claims under the APA, contending that HRSA exceeded its statutory authority by conditioning 340B participation on agency-created registration requirements and filing deadlines that do not appear in the 340B statute.

Beaumont Hospital seeks declaratory relief, as well as injunctive

relief ordering HRSA to retroactively reinstate the hospital's DSH status as of April 1, 2026. The hospital also filed a sealed motion for preliminary injunction. The case is in its early stages and remains pending.

9. *Congressional 340B Reform Proposals: The SUSTAIN 340B Act and the Senate HELP Committee Discussion Draft*

Two separate legislative proposals advancing 340B reform are under consideration in the Senate. The bipartisan [SUSTAIN 340B Act](#) and a [discussion draft](#) circulated to the Senate Committee on Health, Education, Labor, and Pensions on June 29, 2026 titled the "340B Drug Pricing Integrity and Affordability for Patients Act," each address potential changes to covered entity eligibility requirements, program integrity measures, and manufacturer obligations. The proposals reflect growing congressional interest in reshaping the 340B Program amid ongoing litigation and continued program expansion.

- Claims Data and Pricing Mechanisms.** The two proposals diverge on how covered entities should access 340B ceiling prices. The discussion draft authorizes manufacturers to elect among three mechanisms: (1) a point-of-sale discount with segregated inventory, (2) a retrospective rebate, or (3) a discount processed through a Secretary-operated claims repository. In a [letter](#) to Senator Cassidy dated August 25, 2026, the AHA warned that the discussion draft would shift control of the 340B Program to manufacturers and undermine patients' access to pharmacies and outpatient clinics. By contrast, the SUSTAIN 340B Act would preserve point-of-sale discounts and sunset the HRSA 340B Rebate Model Pilot Program within one year, transitioning to a "340B Drug Discount Program Data Clearinghouse" — a third-party entity contracted by the Secretary.
- Statutory "Patient" Definition.** Both proposals codify a statutory "patient" definition for 340B purposes, providing that an individual would qualify as an eligible "patient" only if the individual (i) has received an outpatient health care service at the covered entity within the preceding two years, (ii) has a relationship with the entity such that the entity creates and maintains an auditable medical record, and (iii) has received the prescription as a result of a covered-entity encounter or referral. The SUSTAIN 340B Act additionally excludes from the "patient" definition

individuals whose only outpatient service consisted of drug administration, dispensing, or infusion.

- **Contract Pharmacies.** Both proposals codify covered entities' right to enter into contract pharmacy arrangements and impose new compliance obligations related to written agreements, registration requirements, and audit provisions. The discussion draft additionally requires that contract pharmacies be located within the covered entity's service area, caps contract pharmacies at five for certain hospital covered entities (excluding mail order pharmacies), and imposes escalating civil monetary penalties, up to \$3,000 per claim, and potential removal from the program for a minimum of two years for non-compliance with the program-integrity obligations, including compliance-procedure violations, duplicate discounts, and diversion. The SUSTAIN 340B Act requires covered entities to cancel contracts with pharmacies that have not dispensed 340B drugs in the most recent 12-month period and requires manufacturers to offer ceiling prices regardless of whether the drug is dispensed by the covered entity or a contract pharmacy.
- **Transparency.** Both proposals impose new transparency obligations on covered entities. The SUSTAIN 340B Act requires annual reporting on charity care, patient demographics, payer mix, use of 340B savings, and an executive-officer attestation that 340B savings received benefit patients and communities. The discussion draft similarly requires annual reporting on 340B drug margins, patient populations served, and charity care expenditures, and requires publication of that information on the HHS website in a searchable format.
- **Patient Affordability and Program Integrity.** The discussion draft requires hospital covered entities to establish sliding fee scales capping out-of-pocket costs for 340B drugs based on income. The SUSTAIN 340B Act requires that each covered entity maintain a transparent financial assistance policy, including a sliding fee scale, that is publicly reported and applied uniformly across child sites and contract pharmacies. On program integrity, the SUSTAIN 340B Act authorizes enhanced audits and establishes new HHS enforcement mechanisms, including corrective action plans, civil monetary penalties, and potential disenrollment from the program for up to three years.

10. Sagebrush 340B Eligibility Litigation Updates

Litigation involving the 340B Program eligibility of certain clinics affiliated with Sagebrush Health Services ("Sagebrush") continues to develop on multiple fronts.

a. *Sagebrush v. Amgen (Ninth Circuit)*

As discussed in our prior [newsletter](#), a federal court dismissed Sagebrush's lawsuit against Amgen on April 15, 2026, holding that its state law claims were barred under the Supreme Court's [decision](#) in *Astra*. Sagebrush had claimed that Amgen cut off 340B sales to its Nevada clinics and clawed back more than \$7 million in 340B discounts that Sagebrush had realized through wholesalers. The court reasoned that, although Sagebrush styled its claims as California state law causes of action, they constituted an attempt to enforce Sagebrush's right to purchase drugs at 340B prices.

On August 7, 2026, Sagebrush filed its opening brief in the U.S. Court of Appeals for the Ninth Circuit. In its brief, Sagebrush argues that *Astra* is limited to barring claims that seek to enforce 340B's ceiling price obligations and does not preclude state law claims arising from independent substantive obligations under California law. Sagebrush contends that its claims address Amgen's unilateral, post-transaction claw back of more than \$6 million (the lower figure used in its appellate brief, versus more than \$7 million alleged at the district court level) in 340B savings from third-party wholesalers, rather than seeking to enforce 340B pricing. Sagebrush's brief also argues that its claims are not preempted, asserting that the 340B statute does not occupy the field of manufacturers' post-transaction conduct and that the claims complement, rather than conflict with, the 340B Program's objectives. Amgen's answering brief is due October 8, 2026.

b. *Amgen v. Becerra (D.D.C.)*

In the related manufacturers' action, Amgen, Eli Lilly, and UCB challenged HRSA's certification of Sagebrush clinics as 340B-eligible covered entities. The manufacturers filed for summary judgment on March 20, 2026, and HRSA and intervenor Community Care Resources of Florida filed cross-motions for summary judgment on April 24, 2026.

On August 14, 2026, the U.S. District Court for the District of Columbia granted the manufacturers' motion for summary judgment in part. The court concluded that the clinics received their qualifying STD-grant funding through Sagebrush — a private entity — rather than through "a State or unit of local government" as required by 42 U.S.C. § 256b(a)(4)(K). The court found that Sagebrush was the named grant subrecipient,

that a Sagebrush official signed the grant award, and that the clinics were in fact separate organizations contracting with Sagebrush for its qualifying state-grant funding, rather than organizational subdivisions of Sagebrush. The court ordered that the clinics' present and prior certifications be set aside and that the Government not recertify the clinics based on funds received through Sagebrush or another private entity.

11. Potential Transfer of 340B Oversight from HRSA to CMS

Various sources, including the [340B Report](#), have reported that the Trump administration is expected to transfer 340B Program oversight from HRSA to CMS later in September 2026. The Trump administration's FFY 2027 budget [proposal](#) seeks to move 340B Program oversight from HRSA, where the program has been housed since it was established in 1992, to CMS, while significantly increasing its funding. No further public updates have been made by the Trump administration to date.

Looking Ahead

The Hospital & Health Systems Reimbursement Check Newsletter team is now planning a series of podcasts on the kinds of developments we present here in the newsletter. Stay tuned!

[Leslie Thornton](#) will present "What in the World Is Going On? Navigating Global Changes in Research Policy and Ethics" at the PRIM&R Annual Conference on November 16, 2026. For registration information, visit the [PRIM&R website](#).

[Christine Moundas](#) will present "Hot Topics in Health Data Privacy & Security" at the Privacy + Security Forum on November 5, 2026. For registration information, visit the [Privacy + Security Academy website](#).

[Tim McCrystal](#), [Brett Friedman](#), and [Sarah Blumenthal](#) will present "Under Pressure: Market Trends, Medicaid and Regulatory Changes, and Deal Structures for Distressed Hospitals Transactions", a Ropes & Gray Webinar on November 4, 2026. Registration information will be sent via email.

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

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

Publications

- [OHCA Continues Expansion of Health Care Transaction Review Authority: Updated Regulations, Post-Transaction Monitoring, and Legal Challenges](#)
- [Illinois Enacts Legislation Enhancing Oversight of Private Equity Investments in Health Care](#)
- [FFY 2027 IPPS and LTCH Final Rule](#)
- [New York State Department of Health Imposes Six-Month Medicaid Provider Enrollment Moratorium](#)
- [CMS Issues Proposed Calendar Year 2027 Payment Rules: Outpatient Prospective Payment System/Ambulatory Surgical Center and Physician Fee Schedule](#)
- [A New Regulatory Environment For PE In Calif. Healthcare](#)
- [HHS "Operation TrialBlazer" and the Future of U.S. Clinical Trial Access, Payment, and Infrastructure Reform](#)
- [Vermont Enacts New Restrictions on Private Equity and Hedge Fund Involvement in Health Care: Key Takeaways for Investors, MSOs, and Providers](#)

Webinars and Speaking Engagements

- [Christina Bergeron](#) moderated "Navigating the Regulatory Maze: Managing Successful Healthcare Transactions" (Consero Healthcare General Counsel Forum | October 11, 2026)
- [Jamie Darch](#), [Michael Lampert](#), and [Christine Moundas](#) presented "AI in Healthcare: Emerging Legal, Regulatory & Commercial Issues" (Ropes & Gray Webinar | September 10, 2026)

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