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Health Care Reimbursement Newsletter

Newsletter from the Reimbursement Practice Group

2026

2026 Health Care Reimbursement Outlook

Key payment rules, enforcement trends, and policy shifts shaping the year ahead

- 2025 Wrap-Up: Key CMS Enrollment Changes and Disclosure Developments
- What Hospitals & ASCs Need to Know About the 2026 Outpatient Prospective Payment and ASC Final Rule
- Durable Medical Equipment Update
- 2026 Medicare Physician Fee Schedule Final Rule Highlights
- Forecasting Medicaid Challenges for Providers in 2026
- Rural Health Providers Face a Tough Financial Road in 2026 – Will the Rural Health Transformation Program Save Them?
- Medicare Advantage Reimbursement Implications from the 2027 Proposed Rule
- Looking Ahead to 2026: CMS Finalizes Significant Hospice & Home Health Updates
- Challenges to Health Plans' Use of AI in Claims Determinations
- Year-End Reflections for 340B Covered Entities Navigating Change: Key Developments Shaping the 340B Program in 2025
- Looking Forward: Key Highlights of the Skilled Nursing Facility Payment Rule
- No Surprises, Real Consequences: NSA Litigation And Provider Payment In 2026
- The Latest in Government Audits: Lessons from 2025 and Looking Ahead to 2026
- Top 5 Reimbursement Highlights for Behavioral Health Care Providers in 2026
- DC Update: The Uncertain Future of ACA Subsidies
- Key Highlights from the FY 2026 Inpatient Prospective Payment Final Rule
- Telehealth at a Crossroads in 2025

2025 Wrap-Up: Key CMS Enrollment Changes and Disclosure Developments

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As 2025 draws to a close, the Centers for Medicare and Medicaid Services (CMS) has enacted Medicare enrollment and disclosure changes, including heightened enforcement activity, expanded revocation and deactivation authority, updates to the Program Integrity Manual (PIM) and unexpected provider-based department site designations in the Medicare Provider Enrollment, Chain and Ownership System (PECOS). These developments have introduced operational challenges for providers while expanding the compliance landscape in ways that will continue to shape enrollment strategy well into 2026. This year-end summary reviews four major developments: (1) increased CMS enforcement related to affiliates and disclosable events; (2) significant revocation and deactivation updates finalized in the Home Health Rule; (3) clarifications to the revocation and re-enrollment bar process in the PIM; and (4) the new provider-based department site designations added in PECOS. Each of these changes underscores the growing importance of accurate enrollment data and proactive compliance oversight.

CMS Uptick in Enforcement Related to Affiliates and Disclosable Events

This year, we saw increased activity from CMS in relation to enforcement and revocations, and notably an increase in revocations by CMS in reliance upon 42 C.F.R. §424.535(a)(19) ("affiliation that poses an undue risk"). More specifically, these revocations draw support from the "Disclosure of Affiliations" regulation at 42 CFR §424.519(i), which enables CMS to unilaterally revoke providers where a "disclosable affiliation" poses an undue risk of fraud, waste or abuse, even though the provider or supplier is not yet required to report that affiliation directly. In particular, CMS seems to be most interested in affiliations with unpaid debts to the Medicare program (especially those referred to the U.S. Treasury Department) and affiliations with revocations based on various billing errors. Should a provider or supplier receive a revocation notice — based on a finding by CMS that it has an affiliation that poses an undue risk of fraud, waste or abuse to the Medicare program — it's extremely important to act on such notices immediately, as there can be the possibility to seek reversal of the revocation if the business relationship with the affiliate is terminated within 15 days of receipt of the revocation notice. Further, appeals of revocation actions must be filed within 65 days of receipt of the revocation notice. If providers miss these deadlines, they waive all appeal rights, and the re-enrollment bar will go into effect. Re-enrollment bars can vary in length from one year to 10 years, depending on the severity of the revocation reason — but re-enrollment bars based on an affiliation posing an undue risk of fraud, waste or abuse are 10 years.

CONTINUED FROM PAGE 3

CMS Expansion of its Revocation, Deactivation and Stay of Enrollment Authority

In the CY 2026 Home Health Prospective Payment System Rate Update, published at the end of November, CMS included major enrollment updates related to revocations, deactivations and stay of enrollment. Although these changes are in the Home Health Final Rule, they apply to all providers and suppliers. Below is a high-level list of the changes.

- Revising the language regarding revocations based on "Authority to Prescribe Drugs," "Pattern or Practice of Prescribing" and "Abuse of Billing Privileges" to clarify their meaning or expand their scope;
- Adding seven new reasons to retroactively revoke a provider or supplier's Medicare billing privileges with a retroactive effective date, based on: (i) lapse in an IDTF's comprehensive liability insurance; (ii) submission of false or misleading information on an 855 Form; (iii) failure to timely report a change in information, adverse legal action, or change, addition or deletion of a practice location; (iv) surrender of a DEA certificate or registration in response to a show cause order; (v) state suspension or revocation of a practitioner's ability to prescribe drugs; (vi) revocation of a provider or supplier's other enrollments; and (vii) a DMPOS suppliers non-compliance with a condition or standard under 42 C.F.R. §424.57(b), (c).;
- Expanding the reasons for which CMS can apply a stay of enrollment, specifically to include change of information or revalidation applications that were rejected under 424.525(a)(1) or (2) (failure to submit information within 30 days);
- Requiring providers and suppliers to report any adverse legal actions imposed against them, their owners, their managers, etc. within 30 days, instead of the current 90 days;
- Deactivate physicians and practitioners who have not ordered or certified services for 12 consecutive months; and
- Revoking providers' or suppliers' enrollment when beneficiaries attest that a provider or supplier did not furnish them the service(s) claimed.

CMS states that these actions will further strengthen its oversight to reduce improper Medicare payments and protect beneficiaries. However, some of these changes increase the administrative burden on providers and detract resources from patient care, so providers need to stay informed. CMS's expansion of its authority to issue revocations and deactivations will ultimately lead to more of these notices being issued to providers.

Medicare Program Integrity Manual Updates

In late September, CMS provided some needed clarification on the revocation and re-enrollment bar process through updates to the Medicare Program Integrity Manual. While CMS emphasized its continued ability to revoke the Medicare enrollments of not only the Medicare provider at issue, but other Medicare providers owned by that legal entity, for a variety of reasons related to non-compliance, it identified certain circumstances when it may limit the re-enrollment bar to the specific provider in certain situations. Of the seven revocation reasons they identified from 42 C.F.R. §424.535(a) that would receive favorable treatment, it was particularly notable that CMS included non-compliance with reporting accurate information. This inclusion appears to show that CMS is less focused on

CONTINUED ON PAGE 5

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punishment for enrollment information updates and would prefer to use other methods to get providers to update this information, like the revalidation process.

Provider-Based Designations Added in PECOS

In July 2025, CMS introduced new "Provider-Based Department Site" designations in PECOS for hospital provider-based departments. These labels previously appeared only on the CMS-855A paper application, not in PECOS. Since the rollout, CMS appears to have auto-assigned site type designations across current hospital records, and early review suggests that some assignments are inaccurate. For instance, long-standing on-campus hospital locations may be marked in PECOS as "off campus of the main provider," despite no enrollment changes in years. CMS has not released guidance explaining the update or how the designations were applied to existing enrollments. Although the changes were applied automatically and potentially inaccurately to existing enrollments, providers ultimately bear responsibility for ensuring the accuracy of these designations.

These unexpected changes raise concerns about potential billing edits and whether CMS or the MACs may treat the auto-assigned designations as validated information. Because PECOS does not offer a mechanism to confirm or dispute the assignments, the only corrective pathway is to submit Change of Information applications for affected enrollments so the records reflect accurate provider-based status.

Questions have also arisen regarding the MACs' guidance to hospitals that provider-based outpatient departments offering PT, OT or SLP services identify the site in Sect. 4.A of the 855A as an "Outpatient Physical Therapy Extension Site." Specifically, MACs have recently issued guidance directing providers to use this label for provider-based outpatient departments offering only PT, OT and SLP services. While the terminology appears in the CMS-855A Medicare Enrollment Application, it historically refers to a rehabilitation agency site under 42 C.F.R. §485.703, not a provider-based outpatient department. Though it appears contrary to the appropriate designation, the current MAC guidance is clear that the "Outpatient Physical Therapy Extension Site" designation should be used for PT, OT and SLP for provider-based hospital outpatient departments offering these services.

Until CMS provides more guidance on this change, we recommend providers evaluate their PECOS enrollments and update the "Provider-Based Department Site" designations if necessary.

Takeaways

Taken together, the 2025 enforcement trends, expanded revocation authority, PIM clarifications and new PECOS provider-based designations reflect a continued shift toward heightened transparency, more granular data reporting, and closer alignment between enrollment records and program integrity objectives. Although CMS has offered limited formal guidance on several of this year's changes, providers should anticipate increased scrutiny of enrollment accuracy, organizational disclosures and location-level designations in the months ahead. Strengthening internal controls, reviewing enrollment data for accuracy, and proactively responding to CMS notices will be essential steps as these reforms take effect in 2026.

What Hospitals & ASCs Need to Know About the 2026 Outpatient Prospective Payment and ASC Final Rule

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The Calendar Year 2026 Outpatient Prospective Payment System (OPPS) Final Rule, released on Nov. 21, 2025, brings a 2.6% increase to rates under the OPPS and Ambulatory Surgical Center (ASC) Payment System and several important changes to hospital outpatient and ASC reimbursement policy. We hit on several key updates below, and the full OPPS Final Rule is available here.

Adieu to the Inpatient Only List

CMS has finalized a consequential structural change to Medicare surgical payment, beginning a three-year phase-out of the Inpatient Only (IPO) list, with complete elimination by Jan. 1, 2029. For CY 2026, CMS removed 285 procedures — primarily musculoskeletal but also cardiovascular, digestive, gynecologic and endovascular services — from the IPO list. This set includes many of the same code categories that have been the subject of repeated removal-and-restoration cycles over the past several rulemaking years.

Importantly, CMS reiterated that removal from the IPO list does not require outpatient treatment. Physicians may continue to admit patients for inpatient care when clinically appropriate, and Medicare Part A payment remains available for inpatient admissions that satisfy the statutory criteria. Services that remain on the IPO list continue to be treated as inpatient-only, and removal simply permits — but does not mandate — OPPS payment when furnished in the outpatient setting.

To support a smooth transition, CMS will continue exempting procedures

CONTINUED ON PAGE 7

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removed from the IPO list from certain "two-midnight" medical review activities, minimizing the risk of denials tied solely to site-of-service during the initial years of IPO list elimination. Claims may still be denied if the service itself is not reasonable or necessary, but not solely due to site-of-service after IPO removal. This exemption will remain in place until CMS determines a given procedure is commonly performed on an outpatient basis.

Expansions to Ambulatory Surgical Center Covered Procedures List (ASC CPL)

In addition to IPO list elimination, CMS expanded the list of procedures that can be covered in an ASC setting. For CY 2026, CMS revised the regulatory criteria under 42 C.F.R. § 416.166 by removing five longstanding exclusion criteria (blood loss, body cavity invasion, major vessels, emergent nature and the need for thrombolytics) and relocated them into a new section as nonbinding physician considerations. This policy shift broadens the scope of procedures eligible for ASC performance while maintaining the expectation that physicians evaluate patient-specific safety. CMS retained only three binding exclusions: procedures that remain inpatient-only; those described by unlisted CPT codes; and procedures otherwise statutorily excluded.

In total, 547 procedures will newly qualify for ASC payment beginning Jan. 1, 2026, marking one of the largest expansions of the ASC CPL to date. CMS emphasizes that this broadened framework will support ongoing additions in future rulemaking cycles, and external parties may continue to submit procedure recommendations through the pre-proposed rule recommendation process or during the public comment period. Once a service is added, physicians will determine — based on medical judgment — whether the procedure is appropriate for a given patient in an ASC setting.

CMS will also maintain the policy that IPO-designated procedures cannot be added to the ASC CPL; however, once a procedure is removed from the IPO list, the exclusion no longer applies, and the procedure may be evaluated for ASC placement under the revised criteria.

Site Neutrality for Hospital Outpatient Drug Administration

For several years, Congress and CMS have pushed to neutralize payments for hospital outpatient services as compared to services furnished in freestanding clinic settings. Most notably, CMS implemented Section 603 of the 2015 Bipartisan Budget Act by creating site-neutral payments for off-campus hospital outpatient settings established on or after Nov. 2, 2025. Expanding site neutrality further, in 2019 CMS established a policy of site neutral payments for off-campus hospital clinic visits even if the clinic was operating prior to Nov. 2, 2025. Since that time, Congress and CMS have continued to explore ways to further neutralize hospital outpatient payments.

With the OPPS Final Rule, CMS will extend site neutral payments to drug administration services (i.e., services assigned to drug administration ambulatory payment classifications, or "APCs") furnished in off-campus hospital clinics. CMS is exempting rural sole community hospitals from this wave of site neutrality.

Hospitals should continue to closely monitor this space, as MedPAC and others continue to push for more extensive site neutrality reforms.

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Payment Overhaul for Skin Substitutes

In the OPPS Final Rule, CMS finalized a major restructuring of Medicare payment for skin substitute products, marking the most significant overhaul of this category in more than a decade. Beginning Jan. 1, 2026, CMS will unpackage skin substitute products from the application procedure and instead provide separate OPPS payment for these products as incident-to supplies. To establish a more consistent and clinically aligned structure, CMS is creating three new APC groups based on FDA regulatory pathway — PMA (APC 6000), 510(k) (APC 6001) and 361 HCT/P (APC 6002) — and has added unlisted codes (Q4431–Q4433) for newly approved products without assigned HCPCS codes. These new APC groups are intended to align with updated skin substitute pricing under the MPFS.

CMS has set a single national payment rate of $127.14 per cm^2 for all three APC categories for CY 2026, calculated using volume-weighted ASP data supplemented by MUC, WAC or AWP when ASP is unavailable. Despite strong stakeholder requests, CMS declined to incorporate physician-office utilization data into initial rate setting, citing distorted non-facility utilization patterns and finalizing its proposal to rely solely on OPPS hospital outpatient claims data. CMS also declined to extend separate payment to non-sheet products such as gels, liquids, and particulates, which will continue to be packaged with procedures under the OPPS in 2026. These policy changes have significant operational and financial implications for hospitals, ASCs, physicians and manufacturers. Stakeholders should begin preparing now to adjust coding workflows, evaluate product utilization strategies, and assess reimbursement impacts.

Price Transparency Changes

The OPPS Final Rule introduces significant new requirements intended to strengthen the Hospital Price Transparency (HPT) framework, improve the comparability of pricing information across hospitals, and address longstanding concerns from patients, employers and regulators regarding the usability of published machine-readable files (MRFs). These changes are effective Jan. 1, 2026, but CMS is delaying enforcement until April 1, 2026.

Building on rulemaking from 2020, 2022 and 2024, CMS is requiring hospitals to report four new data elements whenever a payer-specific negotiated charge is calculated using a percentage or algorithm: the median allowed amount, 10th percentile allowed amount, 90th percentile allowed amount, and the count of allowed amounts used to calculate those values. These additions replace the previously required "estimated allowed amount" and are designed to provide a clearer, data-driven picture of contracted reimbursement patterns. CMS clarified that hospitals may rely on EDI 835 ERA remittance data or an equivalent source and finalized a 12–15-month lookback period to calculate these values. CMS also finalized new attestation requirements, requiring inclusion of the name of the hospital's CEO, president, or other senior official who attests to the completeness and accuracy of the data encoded within the MRF. In addition, hospitals must include their National Provider Identifier (NPI) in the MRF to facilitate improved alignment with Transparency in Coverage (TiC) files and other federal data sources. These steps directly reflect the Biden and Trump administrations'

CONTINUED ON PAGE 9

CONTINUED FROM PAGE 8

shared policy priority of enabling consumers, employers and innovators to use hospital pricing data for meaningful comparison and decision-making.

CMS also significantly revised the burden estimates associated with compliance, acknowledging extensive stakeholder feedback that earlier projections dramatically underestimated the labor and cost required to prepare and maintain compliant MRFs. Hospitals noted vendor fees as high as $250,000 annually and staffing demands ranging from multiple FTEs to substantial executive oversight. In response, CMS revised its estimates upward for both one-time implementation and ongoing annual compliance, now projecting 12 hours of one-time labor per hospital and 56 hours per year for ongoing maintenance, for an estimated national annual cost of more than $40 million. CMS emphasized that these requirements — and the accompanying enforcement posture — are consistent with the February 2025 Executive Order directing agencies to ensure disclosure of "clear, accurate, and actionable" pricing information. CMS also reiterated that while public visibility of charges alone cannot transform the healthcare marketplace, these updates are intended to support a more competitive, affordable, and high-value system. Hospitals should expect continued audits, targeted enforcement, and heightened scrutiny of data quality throughout 2026 and beyond as CMS accelerates its transparency agenda.

Outpatient Quality Reporting Updates

The OPPS Final Rule included several notable updates to the Hospital Outpatient Quality Reporting (OQR) Program, reflecting CMS's continued emphasis on modernizing quality measurement and reducing provider burden.

CMS finalized targeted measure removals intended to streamline the OQR measure set. Beginning with the CY 2024 reporting period/CY 2026 payment determination, the agency removed the COVID-19 Vaccination Coverage Among Healthcare Personnel measure. Additional social-risk–related measures — including the Hospital Commitment to Health Equity, Screening for Social Drivers of Health (SDOH), and Screen Positive Rate for SDOH — were removed beginning with the CY 2025 reporting period. CMS has stated that these changes aligned reporting requirements across the OQR, Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) programs and were intended to reduce redundancy while supporting more outcome-focused measurement.

One major addition to the OQR program was CMS's adoption of the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM). The measure was finalized to be voluntary for the CY 2027 reporting period, transitioning to mandatory reporting for CY 2028/CY 2030 payment determination. CMS also finalized the removal of two ED throughput measures — Median Time from ED Arrival to Departure for Discharged Patients and Left Without Being Seen — beginning with the CY 2028 reporting period, contingent on implementation of the new eCQM.

Durable Medical Equipment Update

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The Centers for Medicare and Medicaid Services' (CMS) CY 2026 Home Health Prospective Payment System Final Rule (CMS-1828-F) (Final Rule) includes several significant policy changes affecting suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), with a strong emphasis on program integrity and supplier performance. These changes reshape key operational areas such as provider enrollment, accreditation, prior authorization and competitive bidding. DMEPOS suppliers should begin preparing now, as the rule materially increases compliance expectations and accelerates CMS oversight.

Supplier Enrollment

The Final Rule expands CMS's ability to apply retroactive revocations of DMEPOS suppliers' Medicare enrollment for more types of non-compliance. In these instances, the enrollment may be revoked retroactive to the date noncompliance began rather than 30 days after CMS provides notice of the revocation, thereby allowing CMS to recoup Medicare payments made in the interim. This expansion of revocation retroactivity poses significant financial risk to DMEPOS suppliers, as there is often a substantial lapse in time between when CMS alleges the noncompliance giving rise to the revocation and when it notifies suppliers that their enrollment has been revoked retroactively.

CMS also reiterates its existing authority to revoke a supplier's billing privileges if a beneficiary attests they did not receive the items or services billed.

These changes underscore that DMEPOS suppliers are subject to the same heightened program integrity rules as other Medicare providers and suppliers, meaning compliance with enrollment and billing for DMEPOS suppliers will be more tightly enforced going forward.

Annual DMEPOS Accreditation

Driven by concerns over longstanding vulnerabilities in the accreditation process, CMS finalized significant updates, including annual surveys and reaccreditation requirements, to the accreditation process for DMEPOS suppliers. Previously, CMS required that DMEPOS suppliers be resurveyed and reaccredited every three years. Under the new rule, surveys and reaccreditation will occur every year. This change appears driven by an increased focus on program integrity, as CMS aims to reduce fraud, waste, and abuse by closing gaps that may have made it easier for noncompliant suppliers to continue billing Medicare.

Finalized Exemption Process for Prior Authorization of Certain DMEPOS Items

The Final Rule formalizes a performance-based exemption process from prior authorization for certain DMEPOS items, giving high-performing suppliers relief from prior authorization burden. Specifically, the CMS Required Prior Authorization List currently contains

CONTINUED ON PAGE 11

CONTINUED FROM PAGE 10

67 Healthcare Common Procedure Coding System (HCPCS) items, including 46 power mobility devices (PMDs), five pressure reducing support surfaces (PRSSs), six lower limb prosthetics (LLPs), and ten orthoses. Prior authorization of these HCPCS is required as a condition of payment nationwide.

Suppliers that achieve a 90% or higher prior authorization request approval rate become eligible for exemption from required prior authorization for the applicable DMEPOS items. To maintain the exemption, the supplier must undergo periodic post-payment medical review sampling by the applicable DME Medicare Administrative Contractor (MAC) and continue to meet the 90% claim-approval rate. Suppliers who do not meet the 90% threshold must revert to submitting prior authorization requests as usual. In either instance, the DME MACs must give suppliers at least 60 days' notice before granting or withdrawing an exemption.

This change makes the prior authorization exemption a carrot for compliance: suppliers that consistently submit accurate, supportable claims may reduce their administrative burden, but they must maintain high performance or risk losing the exemption.

DMEPOS Competitive Bidding Program

The Final Rule finalizes important updates to the DMEPOS Competitive Bidding Program (CBP), paving the way for a new bidding round under revised rules. For example, CMS states that it intends to soon announce the product categories for the next round of bidding and the specific timeframe, meaning the Final Rule tees up a potential new regulatory framework rather than locking in the competition details. More concretely, the Final Rule provides for the future furnishing of certain items, including class II continuous glucose monitors (CGMs) and insulin infusion pumps, under the CBP. Once these items are under the CBP, CMS will pay all CGMs and insulin pumps on a monthly rental basis to promote access to current, supported technology consistent with evolving industry standards. CMS indicates that use of the CBP should help protect the Medicare Trust Fund and potentially lower copays for beneficiaries via competition.

Although the Final Rule does not yet specify the next-round timing, CBP product list, or exact payment amounts, these provisions signal future material developments for DMEPOS suppliers, especially those who provide CGMs and insulin pumps.

Expansion of 36-Month Rule

Similar to home health and hospice agencies before them, CMS took the opportunity this year to add new restrictions to the purchase and sale of DMEPOS suppliers, often referred to as the "36-month rule." Specifically, the Final Rule provides that a supplier's Medicare billing privileges will not transfer to a new owner if the transaction results in a "change in majority ownership" of the company within 36 months after the supplier's initial Medicare enrollment effective date or within 36 months after the supplier's most recent change in majority ownership, unless an exception is met. A "change in majority ownership" is defined to include instances where an individual or organization acquires more than a 50% of a **direct** ownership interest in a DMEPOS supplier (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires a majority ownership directly in a DMEPOS supplier through sequential transactions with a cumulative effect. The exceptions to the rule track

CONTINUED ON PAGE 12

CONTINUED FROM PAGE 11

those already in existence for home health and hospice agencies and include internal corporate restructuring of the supplier's parent company, a change in corporate structure (e.g., from an LLC to a corporation or vice-versa), and the death of an individual owner; **indirect** ownership acquisitions are also excluded. Absent application of an exception, a supplier undergoing a change in majority ownership that triggers the 36-month rule will have to enroll as a new supplier and receive a new Medicare provider number, similar to the result that already exists for an asset transaction.

Final Takeaways

The 2026 Final Rule marks a significant tightening of CMS oversight over DMEPOS, from enrollment and accreditation to prior authorization and bidding. Suppliers must maintain rigorous compliance efforts (quality standards, accurate claims, active accreditation) to avoid risk of retroactive revocation or loss of prior-authorization exemptions. At the same time, high-performing suppliers may benefit through eased prior-authorization burden and potential access to new product markets (e.g., CGMs/insulin pumps under CBP). Key takeaways for DMEPOS suppliers include:

- To help mitigate the risk of retroactive revocations, DMEPOS suppliers should ensure that enrollment information (ownership, locations, accreditation status) and all related documentation is accurate, current, and fully aligned across all CMS systems.
- With CMS now requiring yearly accreditation surveys (instead of every three years), suppliers should shift to continuous survey readiness, updating policies, quality standards, and documentation on an ongoing basis.
- DMEPOS suppliers seeking exemption from prior authorization should focus on implementing internal tracking tools and improving documentation supporting medical necessity to achieve the requisite 90% approval request rate.
- Finally, with CGMs, insulin pumps, and potentially other DMEPOS moving under the CBP and a monthly rental payment structure, suppliers should assess operational, financial and inventory impacts now and monitor CMS announcements for the next CBP bidding round.

2026 Medicare Physician Fee Schedule Final Rule Highlights

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The 2026 Medicare Physician Fee Schedule (MPFS) signals another consequential year for physicians and other practitioners billing Medicare Part B. The final rule addresses payment rates, evaluation and management refinements, quality reporting, and compliance obligations, with meaningful operational and financial implications.

Rate Setting and Conversion Factor

Medicare payment for physician (and many other) services is calculated by multiplying the applicable Relative Value Units (RVUs) by an annually updated conversion factor. This year, as required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS adopted two conversation factors: one for "Qualifying Participants" in a Medicare Alternative Payment Models (APMs) and a lower factor for all other clinicians. After applying budget neutrality adjustments and a one-time 2.5% increase, the two conversion factors are $33.57 for qualifying APM participants and $33.40 for all others.

CMS also finalized a significant reduction to the practice expense RVUs (PE RVUs) for facility-based services by cutting the indirect practice expenses (such as practice administrative expenses) by 50% for facility-based services. Although CMS did not provide supporting analysis for this reduction, it invited public comment and may revisit the policy. The change could significantly affect specialties that primarily furnish services in facility settings.

Efficiency Adjustment

Based on CMS' suspicions that technology and physician experience have led to a reduction in service times as compared to survey data, CMS applied a 2.5% efficiency reduction to the time component for all non-time-based services, excluding telehealth services and services that have just been added to the 2026 MPFS. CMS stated that the 2.5% efficiency reduction will be applied every three years to reflect the continuing efficiency gains with each service. While the impact of these changes is modest this year, it is likely that the work RVU value of procedures and diagnostic tests will diminish over time as compared to time-based services like evaluation and management codes. CMS again invited interested parties to comment if there are particular codes that have been disproportionately affected by the changes.

Skin Substitutes

CMS finalized a rule that fundamentally changes Medicare payment methodology for a broad range of skin-substitute products used in wound care. Beginning in Jan, 2026, most skin-substitute products

CONTINUED ON PAGE 14

CONTINUED FROM PAGE 13

will shift from average sales price (ASP)-based payments to a flat, standardized rate. For 2026, that rate is $127.28/cm^2 — likely reflecting a significant payment cut for most products and for the providers who administer them. This payment change, which CMS also implemented for skin substitutes used in hospital outpatient departments, follows regulatory and enforcement scrutiny surrounding these products, which, according to CMS, have seen a nearly 40-fold increase in Medicare spending since 2019.

Drugs and Biological Products Paid Under Medicare Part B

CMS refused to increase the applicable percentage above which manufacturers of two drugs must refund Medicare for discarded amounts of single-dose container or single-use package drugs under Part B. With respect to the calculation of a manufacturer's average sales price (ASP), CMS: (1) defined the term "bundled arrangement" and clarified how to account for bundled price concessions when calculating ASP; (2) required that manufacturers provide reasonable assumption in quarterly ASP data submissions to CMS, including documentation of the methodology used to determine fair market value of bona fide service fees; and (3) clarified that units of selected drugs sold at the maximum fair price (MFP) must be included in ASP calculations. CMS will continue to bundle the costs of cell or tissue procurement and processing in the payment for CAR T-cell therapies and extend this policy to autologous cell-based immunotherapy and gene therapy.

Medicare Prescription Drug Inflation Rebate Program

CMS formalized the Medicare Prescription Drug Inflation Rebate Program based on policy structure from its prior Part B and Part D guidance documents. The rule applied these regulatory provisions back to the start of the applicable inflation rebate periods — Oct. 1, 2022 for Part D drugs and Jan. 1, 2023 for Part B drugs — and spelled out a clearer framework for how inflation rebates will be computed, reconciled, adjusted for certain circumstances (like shortages) and enforced.

CMS further clarified how the inflation rebate program will operate under both Medicare Parts B and D. For Part B, CMS explained how it will compare quarterly payment amounts to inflation-adjusted benchmarks to determine when beneficiary coinsurance must be reduced, refined benchmarks for certain delayed-market FDA approvals, extended the exclusion of certain 340B units, established a formal reconciliation process (including discarded-drug refunds), and outlined civil money penalties for manufacturers that fail to pay rebates accurately or on time. For Part D, CMS addressed how benchmark periods will be determined when pricing data are unavailable, adopted a staged reconciliation process at 12 and 36 months, and established parallel penalty authority. CMS also described how rebates may be reduced during drug shortages and confirmed that, beginning in 2026, it will rely on claims-based data and potential 340B reporting tools—rather than estimates—to implement statutory 340B exclusions.

Quality Payment Program Changes

In 2015, MACRA created the Quality Payment Program (QPP) to use the MPFS to drive value-based care principles. As discussed above, in 2026, CMS will implement a bifurcated conversion factor. "Qualified Participants" (QPs) in an APM will be entitled

CONTINUED ON PAGE 15

CONTINUED FROM PAGE 14

to a slightly higher wRVU conversion factor. CMS implemented several new rules around becoming a QP, including clarification that it would assess QP status at the individual level (not at the level of a practice or APM entity level) and assess both primary care/evaluation and management services and by all covered professional services.

CMS also established important technical rules for 2026 MIPS participation. As a sampling, it finalized six new MIPS Value Pathways (MVPs) and modified the 21 existing MVPs and clarified that specialty groups can self-attest to their specialty makeup for purposes of reporting MVPs. It also confirmed that the performance threshold (i.e., the score above which a provider may be eligible to earn a bonus) will remain at 75 points through CY 2028. CMS also added several new Improvement Activities and modified Promoting Interoperability measures.

Medicare Shared Savings Program Changes

CMS made several technical changes to the Medicare Shared Savings Program. These include:

- For new ACOs starting in 2027, waiving the requirement that an ACO must have at least 5,000 attributed beneficiaries in each of the three years preceding the start of the ACO's participation. The ACO must still have 5,000 attributed lives in the year immediately preceding the start of the ACO's participation and throughout the participation period.
- Requiring ACOs to report certain Medicare changes of ownership (CHOWs) involving ACO participants and affiliated SNFs. Under this policy, an ACO participant undergoing a CHOW to a new TIN could continue to participate in the program.
- Reducing the amount of time in which an ACO can stay in upside-only risk from seven year to five years (for new ACOs starting Jan. 1, 2027).
- Establishing a new Extreme and Uncontrollable Circumstances (EUC) policy for cyberattacks. Unlike prior EUCs, this EUC would not be automatically applied by CMS. Instead, the ACO must apply for the policy and potentially submit additional evidence.

Ambulatory Specialty Model

The proposed Ambulatory Specialty Model (ASM) is intended to improve the prevention and early management of chronic conditions, with the goal of reducing avoidable hospitalizations and unnecessary procedures. The model would require certain specialists who provide outpatient care to Original Medicare patients for heart failure or low back pain to participate in selected regions. ASM is planned to start on Jan. 1, 2027 and will run for five performance years, ending on Dec. 31, 2031.

Poor outcomes for people with or at risk of chronic disease are often caused by delayed diagnosis, financial incentives that promote unnecessary procedures, and limited coordination between specialists and primary care providers. These issues can lead to ineffective disease management.

ASM seeks to address these challenges by encouraging preventive care and stronger coordination with primary care providers. Specialists would be rewarded for improving patient outcomes and managing chronic diseases more effectively.

CONTINUED ON PAGE 16

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Improving Global Surgery Payment Accuracy

CMS continues to tinker with the methodology for bundling procedure costs with pre- and post-op care for approximately 5,500 surgical procedures, referred to as "global surgical packages." CMS is addressing, in part, concerns that fewer post-op visits occur than the global surgical packages assume, and since 2015, CMS has explored different avenues for improving payment accuracy. In the CY2026 proposed rule, CMS sought comments on several aspects of the global surgery payment methodology. The final rule makes no changes but states that CMS will take public comments into account for possible future rulemaking.

Forecasting Medicaid Challenges for Providers in 2026

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Medicaid providers will face new challenges in 2026, including changes to Medicaid financing, new administrative requirements impacting enrollment and enhanced government enforcement efforts. As we look ahead to Medicaid in 2026, here is what we are monitoring:

House Resolution 1 (a/k/a One Big Beautiful Bill Act)

House Resolution 1 (H.R. 1), signed July 4, 2025, contains several provisions that impact Medicaid financing, reimbursement and beneficiary eligibility and enrollment. Although much of H.R. 1 does not take effect until 2027 or later, states and providers are anticipating implementation and bracing for impact.

Medicaid Financing and Reimbursement

Medicaid is financed jointly by states and the federal government. H.R. 1 made several changes to Medicaid financing mechanisms used to support state-share funding of Medicaid programs, which will result in diminished supplemental payments to providers and enrollee benefits.

Provider Fees and Taxes

Provider fees and taxes are a mechanism for states to fund the state share of Medicaid spending. As of July 4, 2025, there is a moratorium on new provider taxes, effectively freezing this tool to raise state-share funding to help cover increased costs or new programs. Beginning FY 2028, states that have expanded Medicaid eligibility to poor adults under the Affordable Care Act relying on "safe harbor" protection will be required to incrementally reduce provider taxes (except provider taxes on nursing facilities and intermediate care facilities) from 6% of net patient revenue to no more than 3.5% by FY 2032. These new restrictions will either require increased general fund expenditures or decreased state contribution to Medicaid funding — forcing states to make difficult budget decisions including

CONTINUED ON PAGE 17

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potential reimbursement cuts for providers and limitations on covered benefits.

State Directed Payments

State directed payments (SDPs) are a tool used by states to require Medicaid Managed Care Organizations (MCOs) to direct specific reimbursement for certain services or providers. Historically, states could mandate MCOs make supplemental payments up to average commercial rates for hospitals and other providers to enhance the quality and access to care. H.R. 1 caps Medicaid SDPs at 100% of published Medicare rates for expansion states and 110% of published Medicare rates for non-expansion states. Certain grandfathered programs can maintain their current upper payment limit (UPL) rate potential until Jan. 1, 2028, at which time they must incrementally phase down 10% per year until they reach 100% or 110% of published Medicare rates. Lowering the UPL will decrease reimbursement to Medicaid providers, further pressuring budgets, especially for higher-acuity services and providers that historically received commercial-rate equivalents.

Medicaid Beneficiary Enrollment

H.R. 1 adds new qualifications for Medicaid beneficiaries seeking and maintaining enrollment, which will decrease Medicaid enrollment and increase the number of uninsured people. Although some administrative requirements do not take effect until 2027, providers should anticipate and plan for a change in payor mix and increased uncompensated care.

Work Requirements

Beginning Jan. 1, 2027, certain nonpregnant, nondisabled adult Medicaid beneficiaries will be required to work 80 hours per month to be eligible for Medicaid benefits. The Congressional Budget Office (CBO) estimates Medicaid work requirements will drive the largest share of Medicaid savings and cause an increase in the number of people without health insurance coverage. States will manage compliance with the requirement, but providers will be significantly impacted, as adults who cannot verify compliance with the work requirements will not maintain Medicaid coverage.

Eligibility Redeterminations

Beginning Jan. 1, 2027, states must redetermine eligibility of the Medicaid expansion population every six months. States will continue to redetermine eligibility annually for other beneficiaries. More frequent redetermination is likely to result in decreased Medicaid coverage due to procedural burdens. Providers can expect increased enrollment and eligibility errors and need for patient financial services arising from increased Medicaid eligibility churn and coverage losses. Ultimately, increased administrative requirements will impact providers through additional bad debt and uncompensated care.

Additional Hurdles

H.R. 1 contains additional administrative hurdles, including Medicaid enrollee verification requirements, new limits on retroactive coverage, and a required quarterly review of enrollment records to ensure deceased enrollees and providers do not remain in Medicaid. We anticipate providers will see lower revenue from Medicaid due to the cumulative impact of these provisions as the total number of enrolled Medicaid beneficiaries decreases.

Enhanced Government Enforcement and Immigration Policies

Fraud, Waste and Abuse

CMS has reiterated its commitment to addressing fraud, waste and abuse in

CONTINUED ON PAGE 18

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federal health care programs such as Medicare and Medicaid. Providers should anticipate CMS, DOJ and OIG, as well as their state counterparts, will ramp up audits and investigations with a focus on eliminating fraud, abuse, improper payments and patient abuse or neglect. Areas of focus continue to include DME suppliers, home health agencies, and more recently, autism therapy providers. Providers should also implement preventive measures in anticipation of increased provider enrollment scrutiny and reimbursement audits in the future.

Immigration Policies

Recent Trump Administration policy changes are likely to further reduce Medicaid enrollment numbers. In November, CMS published a notice that it will share data it receives from states, including citizenship and immigration status, location, and phone numbers, with the Department of Homeland Security (DHS) and Immigration and Customs Enforcement (ICE). That same month, DHS also published a proposed rule that would allow immigration officers to consider whether an individual uses a noncash program, such as Medicaid and other health and support programs, when determining whether that individual is likely to become a "public charge" who is primarily dependent on the federal government when considering applications for legal status. These policy changes may lead to increased Medicaid disenrollment, higher levels of uncompensated care and overall reductions in health care coverage and accessibility.

Budget Crunch

Over the next 10 years, the Congressional Budget Office predicts federal spending on Medicaid will decrease by approximately $900 billion. States are already working to address the anticipated shortfalls, calling special legislative sessions or announcing plans to help mitigate the impacts of federal Medicaid funding cuts. Providers can anticipate state cuts to optional benefits, such as dental and behavioral health as states prepare for their growing budget crunch.

Preparing for 2026 and Beyond

While the true impact of recent legislation and enhanced enforcement efforts remains to be seen, there are a few steps providers can take to get ready:

Be Proactive, Stay Engaged

Many of the Medicaid programmatic changes will be implemented at both the federal and state levels, and both state and federal agencies will be releasing a meaningful amount of guidance over the coming months. Early and frequent engagement with government entities enables providers to help steer policy developments and advocate for enhanced reimbursement opportunities. Advocacy at the state level can also help to guide state budget decisions or administrative implementation mechanisms to reduce the potential impact of these changes.

Remember: Each state implements its Medicaid program differently. If you operate in more than one state, you need to pay attention to all of them to make sure you are best positioned for the coming months.

Prepare Your Systems Now

Providers will face new administrative burdens to verify Medicaid beneficiary eligibility and enrollment as states implement the work requirements, exceptions and new eligibility screening. While we wait for state guidance, providers should evaluate their current

CONTINUED ON PAGE 19

CONTINUED FROM PAGE 18

processes to determine where potential vulnerabilities may exist and what additional steps can be included to bolster prospective compliance in light of these pending requirements.

Educate Patients about Administrative Pitfalls

Educate patients about recent changes to the Medicaid enrollment process. Provide information regarding new work requirements, re-eligibility determinations and verification requirements. Taking proactive steps to ensure patients are aware of the upcoming requirements may prevent disenrollment. Where possible, explore what level of assistance your organization may be able to provide to individuals seeking to maintain their Medicaid eligibility and enrollment.

Plan for Budget Crunch

Providers should evaluate their exposure to and plan for the impact of Medicaid financing changes, including limitations on provider taxes and state directed payments, higher levels of uninsured or underinsured patients and the potential for higher emergency department utilization. Explore alternate funding sources while proactively planning for projected budget impacts.

Our lawyers monitor Medicaid programs and advise Medicaid providers across the country. We anticipate continued changes throughout 2026 and additional opportunities to assist providers navigating the evolving Medicaid framework.

Rural Health Providers Face a Tough Financial Road in 2026 – Will the Rural Health Transformation Program Save Them?

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Rural health care providers enter 2026 facing a complex legal and financial landscape, which will require a close eye on federal and state policies over the coming year and strategic operational decisions to maintain viability in the years to come. While rural health providers had some modest successes in Medicare's annual payment rules and some short-term and still temporary, relief for ongoing telehealth services, the headline continues to be how rural health will fare in light of the Medicaid cuts and significant increase the uninsured populations expected from the July 4, 2025 passage of House Resolution 1 (HR 1) (a/k/a the One Big Beautiful Bill Act).

In response to concerns raised about the impact of HR 1 on rural health care providers in particular, Congress established opportunities for states and health care providers to improve rural health care delivery systems through the Rural Health Transformation Program (RHTP). RHTP will infuse $10 billion annually into state budgets to help transform rural health care delivery systems by investing in innovation, infrastructure, partnerships and workforce development. This investment, however, only offsets about 37% of the estimated $137 billion in cuts to federal Medicaid spending in rural areas over the next ten years. The net result is that rural communities will undoubtedly continue to struggle with access to care and quality of care concerns as federal Medicaid spending declines and the uninsured population soars.

HR 1 appropriated $50 billion to CMS to be distributed to the states over a five-year period ($10 billion per fiscal year, from FY2026 to FY2030). States were required to submit an application that aligns with program requirements by Nov. 5, 2025, to be eligible to receive funds. All fifty states submitted applications. CMS will decide which applications are approved by Dec. 31, 2025. If a state receives funding under RHTP, it will receive funding for all five years.

Many questions remain regarding the distribution of RHTP funds. The first $25 billion from RHTP must be split evenly among states with an approved application, regardless of the number of rural providers in the state. The second $25 billion will be split at CMS's discretion among the states, subject to certain restrictions. CMS maintains broad discretion under the RHTP to distribute the amount of the allotment for each state, subject to certain guidelines, and "any other factors that the [CMS] Administrator determines are appropriate." A state is not required to provide any matching funds as a condition for receiving payment. However, the state plan must contain a certification that none of the allotted funds will be used by the state to finance the non-federal share of Medicaid payments.

While many of the logistical details surrounding implementation of the RHTP are still unclear, the RHTP offers a strategic opportunity for certain rural health care providers, including health systems, to advocate for and secure

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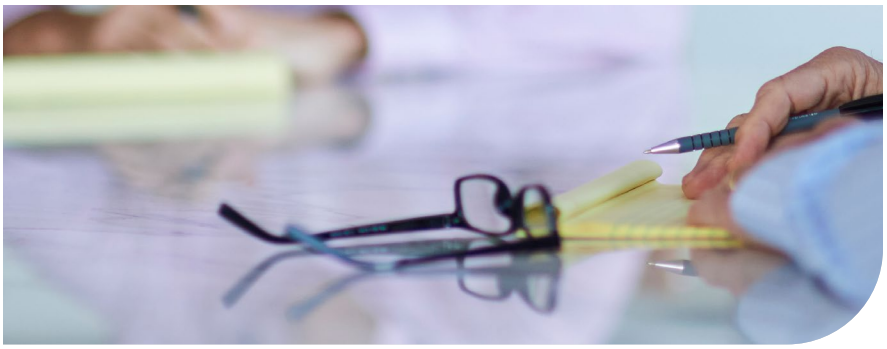
funding for transformative projects. Health care providers should collaborate with state agencies early and often as engaged stakeholders to help steer the ongoing implementation of approved initiatives.



Medicare Advantage Reimbursement Implications from the 2027 Proposed Rule

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On Nov. 25, 2025, the Centers for Medicare and Medicaid Services (CMS) released its 2027 proposed rule for the Medicare Advantage program (MA Proposed Rule).[1] In the last year, several members of the Trump administration made comments about significant changes needed in the MA program. For example, Dr. Mehmet Oz, the CMS administrator, characterized the MA program as "upside down" at his confirmation hearing, referring to the fact that a program intended to save CMS money has resulted in CMS paying more for MA patients than for traditional Medicare patients. The MA Proposed Rule represents the administration's first effort at implementing some of those changes. Comments to the MA Proposed Rule are due by Jan. 26, 2026.

The MA Proposed Rule reflects the agency's focus on clinical outcomes, patient experience, continuity of care and greater plan accountability. Understanding these regulatory shifts could be critical for anticipating changes in rate negotiations, utilization expectations and value-based program participation. Specifically, these priorities, combined with structural changes to quality measurement, enrollment rules and risk adjustment oversight, could influence how providers are paid, how contracts are structured and how plans manage utilization.

Proposed Recalibration of the Star Ratings System

CMS proposes to remove 12 Star Rating quality measures (mostly focused on administrative aspects); add a new depression screening measure; and simplify and streamline the measures to focus on clinical care, outcomes and patient experience. CMS also proposes to drop the Health Equity Index reward, which was designed to reward high measure-level scores for the subset of enrollees with specified social risk factors. CMS projects that these changes will redistribute approximately $13.18 billion in payments to MA plans for contract years 2027 through

1. *2027 MA Proposed Rule*, 90 Fed. Reg. 54894 (Nov. 25, 2025). Available: https://www.govinfo.gov/content/pkg/FR-2025-11-28/pdf/2025-21456.pdf

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2036. CMS's simulations suggest that while most MA plans will maintain their Star Rating, 38% will see rating shifts upward or downward by at least one-half star as a result of these changes.

As performance measures become more outcome-driven and more closely tied to patient experience, providers may face increasing expectations to deliver measurable and coordinated results that directly impact plan reimbursement. Providers participating in value-based arrangements with MA plans will be even more directly impacted.

Changes to the Provider Terminations Special Enrollment Period (SEP)

CMS is proposing to allow enrollees to switch plans any time their provider is terminated from an MA network. Under current rules, an SEP is available only when CMS determines that a change in the provider network is "significant." The Proposed Rule eliminates this prerequisite and instead provides that any enrollee who has received care from a terminated provider within the past three months is eligible for an SEP, allowing them to switch plans or return to traditional Medicare. While this policy shift strengthens beneficiary protections, it also could increase the risk of membership churn for plans when they terminate provider contracts.

This new approach to the SEP could give providers, particularly those with substantial attribution or those caring for high-need populations, greater leverage in contract negotiations because plans must now anticipate the possibility of member attrition whenever a provider agreement is terminated. The changes to the SEP may discourage plans from severing relationships with providers; however, it could also prompt MA organizations to be more selective during the contracting phase, favoring lower-cost or higher-performing providers to minimize the risk of enrollee disruption.

Risk Adjustment Request for Information

In addition to the enrollment and network changes, CMS also signals forthcoming changes to MA risk adjustment. The MA Proposed Rule includes a broad Request for Information (RFI) requesting input for how the MA risk adjustment methodology might be changed, including "entirely new approaches for risk adjustment… that do not rely on collection of diagnosis data and, instead, incorporate alternative factors to infer a patient's health risk…"

Earlier this year, CMS announced a significant expansion of its Risk Adjustment Data Validation (RADV) auditing efforts.[2] Among other changes, CMS

2. *CMS Rolls Out Aggressive Strategy to Enhance and Accelerate Medicare Advantage Audits* (May 21, 2025), CMS Newsroom. Available: https://www.cms.gov/newsroom/press-releases/cms-rolls-out-aggressive-strategy-enhance-and-accelerate-medicare-advantage-audits

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intends to immediately begin using artificial intelligence to review medical records, increase RADV audit volume by reviewing all MAOs instead of just a handful, and increasing its medical coding staff to 2,000 individuals. This earlier announcement, along with the RFI in the MA Proposed Rule, signals that RADV audit scrutiny will increase and significant risk adjustment reforms are likely in future rulemaking cycles. In the short term, providers should expect an increase in documentation requests and audits and elevated scrutiny of coding accuracy. In the medium term, providers should closely monitor any changes to the risk adjustment program, as modifications could affect MA plan revenue and provider reimbursement.

Conclusion

Overall, the MA Proposed Rule highlights the increasing importance of clinical documentation, quality outcomes, and strategic positioning within MA networks. Proactive planning is recommended to secure favorable reimbursement and maintaining operational stability in a shifting MA environment. Providers should proactively assess their contractual language, quality reporting infrastructure, risk-adjustment workflows and negotiation strategy to ensure alignment with the future direction of the MA program.

Providers who wish to submit comments on the Proposed Rule must do so by Jan. 26, 2026.

Looking Ahead to 2026: CMS Finalizes Significant Hospice & Home Health Updates

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CMS's 2026 hospice and home health final rules continue the agency's trend of expanding regulatory oversight and imposing new operational expectations on post-acute care providers. The rules introduce payment updates, wage index adjustments, and refinements to quality reporting requirements that will require providers to reassess budgets, documentation practices, and compliance infrastructure—often without corresponding increases in resources or reimbursement. Hospice providers will face regionally uneven reimbursement shifts and added administrative pressure under the Hospice Quality Reporting Program (HQRP), while home health agencies (HHAs) must contend with yet another recalibration of the Patient-Driven Groupings Model (PDGM), additional reporting measures, and heightened scrutiny of program compliance. Taken together, the 2026 rules represent a continued shift toward tighter controls and more complex reporting obligations, placing additional strain on providers already navigating workforce shortages, rising costs, and increasing audit exposure.

Fiscal Year 2026 Payment and Policy Updates for Hospices

The Fiscal Year 2026 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Program final rule (the Hospice Final Rule) took effect on October 1, 2025, bringing reimbursement adjustments that will certainly influence hospice financial planning throughout 2026. Along with the routine statutory payment update (2.6%) and adjusted aggregate cap amount ($35,361.44), CMS finalized several changes to the wage index methodology—continuing the use of hospital wage data and retaining a permanent 5% cap on wage index declines. While these adjustments are framed as promoting stability, they could still create uneven financial impacts across markets, with some hospices seeing modest rate increases and others absorbing reductions that may not reflect their actual cost pressures. These dynamics require executive teams to reassess budget assumptions, model localized reimbursement risk, and evaluate labor strategies at a time when wage inflation and staffing shortages continue to challenge the industry.

New regulatory clarifications were also incorporated in the Hospice Final Rule related to admissions and face-to-face (F2F) encounter attestations, areas that have historically driven significant audit and denial activity. It expands who may recommend and certify patients for admission to hospice under § 418.24(a) and (b) to the physician member of the interdisciplinary group. The Hospice Final Rule also adds detail to § 418.22(b)(4) for F2F attestations, confirming that the performing practitioner's

CONTINUED ON PAGE 25

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signature and date thereof are required content elements, and that attestations may also be documented in a clinical note. Although framed as clarifications, these changes effectively raise the bar for compliance and increase the risk of technical denials, even where patients are clinically eligible. Hospices must strengthen internal oversight, eligibility review processes, and clinician documentation practices to avoid reimbursement losses tied to minor procedural lapses.

Finally, the Hospice Final Rule also addresses HQRP reporting obligations and the implementation of the Hospice Outcomes and Patient Evaluation (HOPE) tool. CMS confirmed the HOPE tool would replace the Hospice Item Set (HIS) as planned on October 1, 2025, and several existing quality measures have been retained, although new quality measures based off HOPE data will likely be added in coming years. Although CMS believes the HOPE tool and related updates (e.g., QIES vs. iQIES) to be quality-improvement initiatives, they introduce additional administrative and documentation burdens without corresponding increases in reimbursement to support implementation. The ongoing 4% payment reduction for failure to meet the timeliness threshold of 90% for HQRP requirements heightens financial exposure, particularly for providers already strained by resource shortages or high reliance on contracted or part-time staff. As reporting expectations grow more complex, hospices must invest in upgraded data systems, internal auditing, and staff training simply to avoid penalties—efforts that may divert limited resources away from direct patient care.

Calendar Year 2026 Payment and Policy Updates for HHAs

The Calendar Year (CY) 2026 Home Health Prospective Payment System Final Rule (the Home Health Final Rule) implements an estimated 1.3% decrease in overall payments compared to CY 2025, which is a welcomed relief from the 6.4% decrease CMS initially proposed in June. This is calculated by a 2.4% increase offset by an estimated decrease in final permanent adjustment to the base payment rate of 0.9% and another estimated decrease of 2.7% stemming from a temporary adjustment to the base payment rate. Notably, these estimated decreases to the base payment rate differ from the finalized behavior adjustments to the base payment rate of -1.023% (permanent) and -3.0% (temporary) because the estimated figures reflect all payments and the finalized figures are to the national standardized 30-day payment rate alone. CMS estimates that Medicare payments to HHAs in CY 2026 will decrease in the aggregate by an estimated $220 million. In addition, CMS is finalizing recalibrated PDGM case-mix weights; updated low-utilization payment adjustment (LUPA) thresholds using CY 2024 claims data, updated functional impairment levels as determined by responses to certain OASIS items associated with activities of daily living and risk of hospitalization, and comorbidity adjustment subgroups for CY 2026.

A significant regulatory change in the Home Health Final Rule affects the requirement for the F2F encounter for home health eligibility. The Home Health Final Rule expands what types of certifying practitioners can conduct F2F encounters to include nurse practitioners, clinical nurse specialists, physician assistants, and certified nurse-midwives. The F2F documentation must sufficiently demonstrate that the encounter was related to the primary reason that home health services were needed.

CONTINUED ON PAGE 26

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The Home Health Final Rule also brings updates for the Home Health Quality Reporting Program (HH QRP). The rule amends applicable provisions to streamline how certain patient assessments are triggered and to clarify data submission expectations, permitting HHAs to request extensions to file reconsideration requests in case of emergencies. In addition, CMS has updated its policy and process for reconsideration requests when a HHA is found non-compliant with QRP data requirements, signaling that data accuracy and timeliness will remain priorities going forward.

Beginning with CY 2026, the Home Health Final Rule enhances requirements for all-payer data submission via the standardized patient assessment instrument used in home health (known as OASIS). HHAs now must provide a comprehensive patient assessment for all patients no later than five calendar days after the start of care, incorporating the most current versions of the OASIS data items. The amendments to the Conditions of Participation (COPs) at §§ 484.45(a) and 484.55(d)(1)(i) reflect these changes to enable better risk adjustment, outcome tracking, and comparative performance analysis.

CMS has also updated its approach to the Home Health Value-Based Purchasing Program (HHVBP) to account for these changes to the COPs. Historically, HHAs were required to report OASIS data only for Medicare and Medicaid patients due to statutory limitations, but the IMPACT Act mandated movement toward a unified, cross-setting assessment system. With CMS now fully implementing all-payer OASIS reporting, the Home Health Final Rule will replace references in the COPs from "beneficiary" to "patient," clarifying that OASIS requirements apply to all HHA patients receiving skilled services. CMS emphasized that no new OASIS data items or EMR system changes are required, and agencies will continue using existing submission processes. Patient exemptions remain unchanged (patients under 18, maternity services, and non-skilled personal care or chore services), and the requirement does not apply to Part B outpatient therapy patients. These updates harmonize regulatory language with the all-payer policy and reinforce agencies' obligation to complete and submit comprehensive OASIS assessments for all skilled patients regardless of payor.

Challenges to Health Plans' Use of AI in Claims Determinations

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Riding the modern American wave of artificial intelligence infatuation, managed care entities have integrated AI into their claim evaluation practices. While adoption will only expand over time, the current use of AI poses significant challenges for both payors and providers. Two ongoing federal cases illustrate these challenges in particularly sharp relief. In *The Estate of Gene B. Lokken et al. v. UnitedHealth Group, Inc.*, several estates of Medicare Advantage enrollees allege that United improperly denied post-acute care, contributing to declining health and even death. Central to the complaint is United's alleged reliance on the nH Predict AI Model, a tool that estimates necessary lengths of stay by comparing patients to historical cohorts. Plaintiffs argue that United used the model to predetermine coverage outcomes, overriding treating physicians' assessments, while United denies that the tool influenced its determinations. The court permitted the plaintiffs' breach of contract and good-faith claims to proceed because United had expressly promised that decisions would be made by clinicians, although it dismissed statutory and equitable claims under Medicare Advantage's preemption rules.

A parallel class action against Cigna in the Eastern District of California, *Kristing-Leung et al. v. Cigna Corp.*, centers on allegations that Cigna relied on its PxDx algorithm to deny claims in massive batches without meaningful physician review. Plaintiffs, citing a ProPublica investigation, assert that Cigna physicians denied over 300,000 claims in two months while spending roughly 1.2 seconds per claim—far too little time to conduct any individualized assessment. Although the court dismissed the wrongful-denial claim, it allowed the breach of fiduciary duty claim and request for injunctive relief to proceed, underscoring that algorithmic decision-making may expose payors to heightened ERISA scrutiny when medical necessity determinations are effectively delegated to automated systems.

These lawsuits shed light on broader effects of AI on claims adjudication, particularly the increased rate and scale of denials. AI tools designed to detect patterns of low-value or historically non-payable services may flag claims for denial en masse, and health plans may use algorithmic outputs to accelerate throughput even when doing so undermines individualized clinical review. Because many of these tools rely on historical data, they risk replicating outdated or flawed denial patterns—creating the perception that claims are rejected automatically. This trend creates tension between AI-generated recommendations and treating physicians' judgment, especially where health plans have represented that decisions will be made by clinical personnel. Courts are beginning to scrutinize these representations and examine whether payors have met contractual and fiduciary obligations when AI informs or replaces human review.

The increasing use of AI in claims processing also raises compliance concerns under state unfair claims settlement laws, ERISA fiduciary duties, Medicare Advantage regulations requiring

CONTINUED ON PAGE 28

CONTINUED FROM PAGE 27

physician involvement, and emerging state AI transparency statutes. Regulators, including CMS and state insurance departments, have expressed growing interest in how AI tools are deployed, and CMS has warned that Medicare Advantage plans may not rely on AI tools in ways that conflict with individualized coverage determinations required under traditional Medicare rules. As litigation progresses, health plans may face difficult discovery questions regarding the transparency, methodology, and explainability of algorithmic tools—issues likely to influence both litigation strategy and regulatory policy development.

For health care providers, the effects of algorithmic adjudication are substantial. Automated denials impose higher administrative burdens and disrupt revenue cycles, especially for post-acute care and other service lines with complex medical necessity criteria. Providers often face unpredictable reimbursement patterns when automated tools do not align with clinical realities, and opaque AI models complicate appeals, as clinicians may not know why a claim was flagged. Cigna's paused E/M downcoding policy—which relied on automated logic to reduce evaluation and management codes based on perceived documentation discrepancies—further illustrates how automated tools, whether formally classified as AI or not, can materially affect reimbursement and provoke resistance from health care providers.

Taken together, these developments emphasize the need for robust clinical review, careful documentation, and vigilant monitoring of denial patterns that may indicate algorithmic screening. They also signal that courts and regulators are increasingly willing to scrutinize AI-assisted claims practices, particularly when they appear to override clinical judgment or contradict promises made to enrollees. As AI continues to reshape managed care, both payors and providers must navigate the legal, regulatory, and operational complexities associated with automated claims adjudication.

Year-End Reflections for 340B Covered Entities Navigating Change: Key Developments Shaping the 340B Program in 2025

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2025 has set the stage for transformative changes in the 340B program, with congressional scrutiny toward how Covered Entities (CEs) use their 340B revenue, state law impacting contract pharmacy networks, and the Centers for Medicare and Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) announcing plans and programs that will affect CEs beginning in 2026. Under these new programs, CEs are required to provide voluminous data to regulators and third-party aggregators. Now more than ever, CEs must be well-informed and prepared to respond to regulatory, legislative and market shifts impacting 340B operations. Given these and other enforcement developments, compliance must remain a key CE priority.

CEs need to understand the big changes coming and how to prepare, including staying informed of the fast-paced changes to the 340B program; understanding the complex requirements of various programs and initiatives; and ensuring their internal 340B programs are keeping up with the shifting landscape. Polsinelli regularly publishes news alerts to keep our CE clients informed of major developments and their significance, and we are available to support CEs with every element of 340B compliance. By staying informed, staying engaged and working collaboratively, we can preserve and safeguard the mission of the 340B program to support providers and their patients.

OPPS Drug Acquisition Cost Survey

Under the CY 2026 OPPS Final Rule published in November, CMS will conduct a Drug Acquisition Cost Survey to collect NDC-level pricing data on separately payable 340B and non-340B drugs from all hospitals except critical access hospitals. CMS will launch a portal on Jan. 1, 2026 that hospitals must use to upload drug acquisition cost data from July 1, 2024 to June 30, 2025. Hospitals should begin validating their ability to extract 340B vs non340B acquisition detail at the NDC level using the Draft Survey Template published by CMS. Early review of the Draft Survey Template is essential, as hospitals will need to extract data for more than 2,300 NDCs and account for varied discount structures that are generally not captured in a single, uniform manner.

Though CMS does not explicitly require participation with an enforcement mechanism, participation is effectively mandatory according to CMS. Hospitals that do not report their drug acquisition costs may be viewed as lacking meaningful additional, marginal costs related to their acquisition of the drugs, and CMS may determine the drugs costs should not be paid separately but should be packaged. This would be a detrimental outcome for a CE. On a broader scale, if CMS takes this “packaging” approach based on broader industry-wide responses or lack

CONTINUED ON PAGE 30

CONTINUED FROM PAGE 29

thereof, the reimbursement landscape could be in flux for some time. Many would argue that CMS lacks statutory authority to engage in such discriminatory rate setting, and that was all but confirmed by the Supreme Court's June 2022 decision that deemed CMS's prior 340B rate cut unlawful. However, CMS is back at the drawing board and hopes to conduct a valid survey that will support varying rates by hospital group. Therefore, hospitals should carefully consider the risks when considering how to respond to the survey. In any event, preparation is key.

HRSA 340B Rebate Model Pilot Program

In July, HRSA announced a 340B Rebate Model Pilot Program (340 Rebate Pilot) that will change how the 340B program has been operating since its inception. The 340B Rebate Pilot will require CEs to front the costs of 340B drugs at wholesale acquisition cost (WAC) and submit data via a manufacturer-selected third-party portal to request a post-purchase rebate, rather than being afforded the discounted 340B pricing at the time of purchase. HRSA has approved nine drugs to participate in the 340B Rebate Pilot, which is slated to begin on Jan. 1, 2026 (Novartis' Ernesto will begin on April 1, 2026); however, on Dec. 1, 2025, two hospital groups and four major health systems have sued to block the Department of Health and Human Services from implementing the 340B Rebate Pilot. At the time of publication of this article, it's possible that the District Court has issued or denied a temporary restraining order.

The 340B Rebate Pilot raises several concerns for CEs including operational, compliance, financial and privacy concerns. Manufacturers had the option to participate in the 340B Rebate Pilot by submitting plans for HRSA's consideration, but HRSA did not provide an opportunity for CEs to opt out, despite CEs being primarily impacted by the announcement. The 340B Rebate Pilot requires manufacturers to pay rebates within 10 days of CE data submission; however, there are no clear and immediate penalties for manufacturers who withhold rebates, and there is no recourse for CEs except Administrative Dispute Resolution (ADR), which could take months or years to resolve, delaying the rebate payment. HRSA's current ADR process simply is not designed to handle the sheer volume of claims that are potentially at issue.

Manufacturer Audits and Ongoing Manufacturer Good Faith Inquiries

In June, several CEs across the nation received notices that J&J received HRSA approval to audit the CEs' 340B Programs. This began a snowball effect as several other manufacturers such as Sanofi, Exelixis, Genentech, Boehringer Ingelheim and BMS reaching out to CEs under the guise of conducting a "good faith" inquiry to obtain data from CEs. Manufacturers are taking the approach that CEs must provide all detailed dispensing data elements requested, or they will seek HRSA's approval to conduct a manufacturer audit. Given the uptick in manufacturer audit activity, CEs who receive communications from manufacturers need to be cautious when responding and ensure that appropriate team members such as legal and finance are looped in from the start given the likelihood of a manufacturer audit. Polsinelli is actively representing numerous CEs who are undergoing manufacturer audits, and based on our experience, the landscape and manufacturer approaches have changed drastically in this space. Likewise, HRSA has taken a more hands-off approach to audit approvals, so we expect audit activity to increase.

CONTINUED ON PAGE 31

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Congressional Inquiries and Reports

In April, the HELP Committee released a comprehensive majority-staff report on the 340B Drug Pricing Program (the 2025 Report), concluding that "Congress must act to bring needed reforms to the 340B Program." The 2025 Report followed a multi-year inquiry launched in 2023 seeking detailed information from hospitals, federally qualified health centers (FQHCs), contract pharmacies and manufacturers. The 2025 Report quantified 340B-related revenues at certain hospitals and FQHCs between 2018 and 2023. The 2025 Report also expressed concern about the role of contract pharmacies and third party administrators, including complex fee structures and increasing retention of 340B savings by intermediaries rather than CEs.

In contributing to the underlying inquiry, Polsinelli's team saw firsthand the importance of CEs being able to efficiently and effectively convey how 340B savings are used and what the underlying regulatory and compliance costs are under the current regulatory regimen. CEs should evaluate their data-tracking capabilities, contract pharmacy strategies, and use of refund dollars in anticipation of further inquiries and proposed reform.

State 340B-Related Legislation

Over the past several years, many states have introduced and/or enacted legislation in attempt to protect CEs' 340B programs and the integrity of the 340B Program overall, including legislation preserving CEs' use of contract pharmacies. These state laws have been challenged by multiple manufacturers in various courts, who are overwhelmingly ruling in favor of CEs. Given the litigation outcome, we expect this trend of states passing 340B legislation to continue in 2026. CEs should stay informed of state laws (e.g. 340B non-discrimination, PBM reform, 340B reporting, any-willing-pharmacy, etc.). These laws can also be a very helpful payor/PBM contracting tool as CEs and their pharmacies consider expanding.

Looking Forward: Key Highlights of the Skilled Nursing Facility Payment Rule

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Skilled Nursing Facilities and other certified long term care providers will continue to see substantial enrollment, reimbursement, and enforcement changes in 2026.

FY2026 SNF PPS

On July 31, 2025, the Centers for Medicare & Medicaid Services (CMS) issued a final rule for updates to Medicare payment policies and rates for skilled nursing facilities under the Skilled Nursing Facility Prospective Payment System (SNF PPS) for fiscal year (FY) 2026. Some key changes found in the rule include:

- Increasing SNF PPS payments by 3.2%, for an estimated overall increase in payments totaling $1.16 billion;
- Finalizing changes to the ICD-10 code mappings used in the Patient-Driven Payment Model (PDPM);
- Removing four social determinants of health data elements related to living situation, food, and utilities from the SNF Quality Reporting Program for residents admitted on or after October 1, 2025;
- Removing the Health Equity Adjustment in the SNF Value-Based Purchasing Program; and
- Updating the Extraordinary Circumstance Exception (ECE) policy to allow CMS to grant discretionary extensions when providers can provide proof that extraordinary events impacted the SNF's ability to meet reporting requirements.

Revalidation Deadline Indefinitely Suspended

CMS issued updated sub-regulatory guidance announcing that the previously established January 1, 2026 deadline for SNFs to submit the new SNF Attachment to the Form CMS-855A has been **indefinitely suspended** and as such, there is no submission deadline until further notice. This deadline suspension applies to all SNFs, including those that: received a revalidation notice in October, November or December 2024; and had an initial, revalidation, reactivation or change-of-ownership (CHOW) application pending as of October 1, 2024, and were instructed to complete the new SNF Attachment.

Although the mandatory deadline has been paused, CMS emphasizes that for SNFs that had initial, reactivation, revalidation or CHOW applications pending as of October 1, 2024, the applications will continue to process while awaiting the SNF Attachment submission, but final approval of any currently pending enrollment action will not occur until the SNF Attachment is submitted.

Although the submission deadline is now uncertain, the requirement to submit the extensive ownership, managerial and Additional Disclosable Party (ADP) information remains a requirement, so SNFs should continue to work towards the goal of updating their enrollment records appropriately.

CONTINUED ON PAGE 33

CONTINUED FROM PAGE 32

HHS Repeals Staffing Rule

Earlier this year, the U.S. District Court for the Northern District of Iowa vacated the provisions of the CMS staffing mandate requiring 24/7 RN staffing and the fixed hours-per-resident mandate, ruling that CMS lacked statutory authority to impose such rigid nationwide requirements. As a result of the ruling, the U.S. Department of Health and Human Services (HHS) formally repealed portions of the staffing mandate. This repeal is a win for long-term care providers, especially in light of staffing related issues that facilities continue to struggle with post-pandemic.

Changes to Star Rating Calculations and Publishing of Data/Guidance

Beginning in July 2025, CMS made changes to its Star Rating Calculations and the information publicly available on its Nursing Home Care Compare website (Website). Revisions include:

- Publishing performance information, including 5-star ratings, health inspections, staffing, and quality measures for each chain or affiliated entity on CMS' Nursing Home Care Compare website.
- Star Ratings for Health Inspections will be based on the two most recent standard surveys - eliminating the third, oldest cycle - with the most recent survey being weighed at 75% and the older survey being weighed at 25%. The three-year lookback for complaint and infection control inspections will still impact rating calculations.
- CMS will stop displaying COVID-19 vaccination data for residents and staff on each nursing home's main page on the Website.
- CMS will enhance the calculation of antipsychotic use percentages by adding Medicare and Medicaid claims data, and Medicare Advantage encounter data, alongside MDS data. This change aims to capture prescriptions missed in the MDS 7-day look-back window.
- CMS may now release CMS-2567 forms immediately. This replaces the previous holding period of 90-days after survey completion or until the approval of the Plan of Correction (POC) or Allegation of Compliance (AOC) by the Survey Agency or CMS.

CMS also published revised guidance for nursing home surveyors, available in the State Operations Manual and ASPEN system in November 2024. These revisions include revising the F-tags (adding, deleting, and consolidating tags) and clarifying guidance on a variety of topics such as: Admissions, Transfers and Discharges; MDS Accuracy & Certification; QAPI & Health Equity; Chemical Restraints and Psychotropic Medications; CPR; and Infection Control.

No Surprises, Real Consequences: NSA Litigation And Provider Payment In 2026

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The No Surprises Act (NSA) did what Congress promised: it pulled most patients out of the middle of surprise billing disputes and put the payment fight where it belongs between providers and plans. Providers have adapted to that model and, broadly speaking, welcome it.

Now the question for providers is different: how do you turn the NSA into a reliable, strategic payment tool in a world of opaque qualifying payment amounts (QPAs), aggressive plan interpretations, and uneven enforcement of independent dispute resolution (IDR) awards.

The answer is not to wait for agencies[1] or courts to "fix" it. It is to understand how litigation and rulemaking are reshaping the landscape and use that to your advantage.

IDR Reality Check: Arbitrators Are Not Treating QPA As Market Rate

If you listened only to plan talking points, you might think QPA equals "market rate" and IDR should be a rarely used backstop. The data say otherwise.

Providers have filed the overwhelming majority of IDR disputes and prevailed in the vast majority determinations. Analyses of public IDR data show provider win rates roughly in the low-80s percent range, with median prevailing provider offers several hundred percent of the QPA for many services.[2] That is hard to reconcile with the notion that the QPA is a neutral benchmark. What it shows is that when neutral decision makers see both offers, they frequently conclude that plan-calculated QPAs are too low.

CMS's own reports confirm that IDR is now a central payment forum, not a sideshow. Filing volumes have been many times higher than the Departments predicted, and only recently have certified IDR entities begun closing more disputes than they receive in a given month.[3]

For providers, the message is encouraging: when you get into IDR with a strong record, arbitrators often agree with you. The challenge is getting there efficiently and making sure favorable awards actually translate into payment.

TMA And LifeNet: Courts Pull The System Back Toward The Statute

On the regulatory front, providers have already won several major rounds that yanked the thumb off the QPA scale.

1. *References in this article to the "agencies" or "Departments" are to the U.S. Department of Health and Human Services, the U.S. Department of Labor, and the U.S. Department of the Treasury, which jointly implement and enforce the No Surprises Act for most commercial coverage.*
2. See Jack Hoadley, Kennah Watts & Zachary Baron, *Independent Dispute Resolution Process 2024 Data: High Volume, More Provider Wins* (Ctr. on Health Ins. Reforms, July 1, 2025).
3. See Ctrs. for Medicare & Medicaid Servs., *Fact Sheet: Clearing the Independent Dispute Resolution Backlog* (Sept. 19, 2025); U.S. Gov't Accountability Office, GAO-24-106335, *Private Health Insurance: Roll Out of Independent Dispute Resolution Process for Out-of-Network Claims Has Been Challenging* (2023).

CONTINUED ON PAGE 35

CONTINUED FROM PAGE 34

In TMA I, the Eastern District of Texas vacated the original rule that told IDR entities to presume the QPA was the correct payment amount and deviate only when other factors clearly outweighed it, holding that the presumption conflicted with the NSA and violated the Administrative Procedure Act.[4]

In TMA II, the court, later affirmed by the Fifth Circuit, struck down the "double-counting" rule that tried to prevent IDR entities from considering information if the agencies believed it was already "accounted for" in the QPA.[5] The message was clear: Congress wrote a list of factors and told arbitrators to weigh them all; agencies cannot quietly reinstall a QPA presumption by limiting what arbitrators can see.

TMA III and IV pushed further. In decisions grouped under those labels, the Eastern District of Texas invalidated steep IDR administrative fee increases, restrictive batching rules, and parts of the QPA methodology regulations.[6] A Fifth Circuit panel later reversed much of the QPA-methodology ruling in TMA III.[7] That panel opinion has been vacated, and the case is now before the full Fifth Circuit en banc.[8]

Bottom line: the formal QPA presumption is gone, the double-counting restriction is gone, and the most aggressive fee and batching rules are under significant pressure. Provider-led litigation has already reshaped the rules and will continue to do so.

QPA Audits: Only CMS Gets To Look Under The Hood

A persistent frustration is that providers cannot audit QPAs themselves. The Departments have also said that arbitrators are not supposed to "recalculate" QPAs in IDR; they are to assume the number provided is the plan's QPA and weigh the statutory factors around it.[9]

That makes QPA audits, conducted by CMS, the only formal check on how plans are actually doing the math.

To date, CMS has publicly released only one detailed QPA audit report, and it validates many provider concerns. In a 2024 federal QPA audit of Aetna Health Inc. in Texas, CMS found that Aetna miscalculated QPAs for certain air ambulance services by using paid claim amounts instead of contracted rates and by counting identical claims as separate contracted rates. CMS also found that Aetna failed to provide required NSA disclosures to providers, including QPA information and notice of IDR deadlines.[10]

In other words, the one time regulators have lifted the hood in a public, detailed way, they found real problems with both QPA calculations and disclosures.

Providers cannot trigger these audits on demand, and they cannot subpoena plan contracting data in IDR. What they can do is build a record: track unusual QPAs, capture deficient remittances, and feed that information into IDR submissions and, when appropriate, complaints to regulators. That is exactly the type of documentation that makes it easier for

4. *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* (TMA I), 587 F. Supp. 3d 528 (E.D. Tex. 2022). Air ambulance providers secured similar relief under the air ambulance provisions in *LifeNet, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 587 F. Supp. 3d 547 (E.D. Tex. 2022).
5. *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* (TMA II), 654 F. Supp. 3d 575 (E.D. Tex. 2022), aff'd, 110 F.4th 762 (5th Cir. 2024).
6. *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:23-cv-59, 2023 WL 4977746 (E.D. Tex. Aug. 3, 2023); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:22-cv-450, 2023 WL 5489028 (E.D. Tex. Aug. 24, 2023).
7. 120 F.4th 494 (5th Cir. 2024).
8. *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 138 F.4th 961 (5th Cir. 2024) (order granting rehearing en banc).
9. *See Requirements Related to Surprise Billing*, 88 Fed. Reg. 88,494, 88,505 (Dec. 21, 2023).
10. Ctrs. for Medicare & Medicaid Servs., *Final Report: Federal Qualifying Payment Amount Audit of Aetna Health Inc. (Aetna-TX) (May 29, 2024).*

CONTINUED ON PAGE 36

CONTINUED FROM PAGE 35

agencies and courts to see patterns of underpayment.

IDR Conduct Litigation: When Strategy Gets Called "Abuse"

IDR is supposed to be a neutral backstop. Increasingly, it is also a source of "conduct" litigation, with parties accusing others of misusing the process.

Payors have alleged that providers and intermediaries are abusing IDR by submitting ineligible claims, improperly batching disputes, mischaracterizing services as NSA-covered, or "gaming" information that feeds into QPA. Some complaints even frame IDR behavior as fraud or part of a broader scheme.

For providers, the takeaway is not to be timid about IDR. It is to run your IDR program like a compliance program: clear eligibility screening, defensible batching, accurate coding, consistent documentation, and a written rationale for why each dispute qualifies under the statute. That approach both improves your odds in front of an IDR entity and puts you in a strong position if a payor ever tries to rebrand legitimate NSA use as "abuse" in court.

Must Payors Actually Pay IDR Awards And What Comes Next

The next big question is what happens after you win in IDR. Most plans pay. Some do not. The resulting enforcement fights are producing some of the most important NSA case law to date and are driving legislative proposals.

In *Guardian Flight, L.L.C. v. Health Care Serv. Corp.,* air ambulance providers sued after HCSC failed to pay multiple "binding" IDR awards within the statutory 30-day window.[11] They asserted claims under the NSA and ERISA. The Fifth Circuit held that the NSA does not create a private right of action for providers to enforce IDR awards and that the providers, as assignees, lacked Article III standing on their ERISA claims because the patients themselves had not suffered out-of-pocket harm.

The United States filed an amicus brief supporting the providers and arguing that NSA rights, including the obligation to pay IDR awards, must be enforceable in court and that providers with assignments should have standing to sue under ERISA.[12] The Fifth Circuit disagreed.

The Guardian Flight providers have now asked the U.S. Supreme Court to step in, seeking review of both the standing analysis and the enforcement question.[13] District courts in several other circuits have begun citing and following Guardian Flight's core conclusion on the lack of a provider cause of action under the NSA, often in relatively brief opinions that adopt the Fifth Circuit's reasoning at a high level.

But the story is not one-way. In *Guardian Flight LLC v. Aetna Life Ins. Co.*, the District of Connecticut held that the NSA does allow providers to enforce IDR awards in court and allowed ERISA and state-law claims based on nonpayment to proceed.[14] In GPS of *N.J. M.D., P.C. v. Horizon Blue Cross & Blue Shield,* the District of New Jersey confirmed an NSA IDR award under the Federal Arbitration Act, effectively treating the IDR decision like an arbitration award that can be turned into a judgment.[15]

Congress has taken notice. "No Surprises Act

11. 140 F.4th 271 (5th Cir. 2025)
12. Brief for the United States as Amicus Curiae in Support of Plaintiffs-Appellants, *Guardian Flight, L.L.C. v. Health Care Serv. Corp.*, No. 24-10561 (5th Cir. Oct. 4, 2024).
13. Petition for Writ of *Certiorari, Guardian Flight, L.L.C. v. Health Care Serv. Corp.*, No. 25-441 (U.S. filed Oct. 10, 2025).
14. 789 F. Supp. 3d 214 (D. Conn. 2025)
15. 2023 WL 5815821 (D.N.J. Sept. 7, 2023)

CONTINUED ON PAGE 37

CONTINUED FROM PAGE 36

Enforcement Act" proposals, including H.R. 4710 and S. 2420 in the 119th Congress, would increase penalties for noncompliant plans, clarify enforcement tools, and require more transparency around payment and IDR outcomes. Sponsors have been explicit that the goal is to give regulators and providers stronger leverage when plans ignore statutory deadlines and IDR determinations.

For providers, enforcement strategy now matters as much as IDR strategy. High-value cases deserve an enforcement plan from day one. Tracking nonpayment and chronic delay is essential, both for individual enforcement efforts and to inform future legislative and regulatory pushes.

What Might Be In Store In 2026

Most NSA implementation still rests on 2021 interim final rules and a 2022 final rule, now operating in the shadow of TMA, Guardian Flight, QPA audits, and the first wave of IDR-related conduct litigation.[16]

In November 2023, the Departments issued a proposed rule on Federal IDR operations that would tighten timelines, refine batching rules, adjust fee structures, and codify many operational policies.[17] All stakeholders are waiting to see how that proposal will be finalized.

That might sound chaotic. For providers, it is also an opportunity. The NSA is not a fixed obstacle course; it is a statute that can be a powerful payment tool for those who know how to use it.

Heading into 2026, providers who want to be in the strongest position should consider:

- Treating NSA and IDR as core revenue-cycle functions, not occasional emergencies.
- Designing IDR submissions around the statutory factors and real market data so that arbitrators have a clear, compelling path to your number.
- Systematically tracking QPAs, payment deadlines, and IDR awards to spot patterns and support both regulatory complaints and enforcement efforts.

The patient side of the NSA is largely settled: patients are protected from most surprise bills. The provider side is where the action is. With the right strategy, the NSA can become a central tool to protect the value of your services in 2026 and beyond.

16. *See* Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,872 (July 13, 2021); Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55,980 (Oct. 7, 2021); Requirements Related to Surprise Billing, 87 Fed. Reg. 52,618 (Aug. 26, 2022).
17. Federal Independent Dispute Resolution Operations, 88 Fed. Reg. 75,744 (Nov. 3, 2023) (proposed rule).

The Latest in Government Audits: Lessons from 2025 and Looking Ahead to 2026

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As 2025 draws to a close, the year has revealed a significant shift in the federal audit and reimbursement landscape. These changes have been marked by the deployment of more sophisticated tools to identify program-integrity risks across provider types and benefit categories. Providers in all care settings have faced more aggressive documentation demands, deeper analytic review of utilization patterns, and expanding expectations for proactive compliance, making 2025 one of the most consequential audit years in recent memory and signaling continued regulatory intensity in 2026.

Front End, Enrollment-Based Enforcement in 2025: Site Visits, Revocations, and Supplier Scrutiny

Federal oversight models in 2025 reflected a broad and systemic focus on provider and supplier enrollment as a mechanism for safeguarding the integrity of the Medicare and Medicaid programs. CMS and OIG have signaled that enrollment verification, site validation, and categorical risk-based screening will continue to serve as central program-integrity tools, particularly for high-risk entities such as durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. Department of Health and Human Services, Office of Inspector General. (2024). *Durable Medical Equipment Fraud and Safeguards in Medicare* (OEI-02-24-00310).

The 2025 OIG Work Plan reflected increased attention on the Medicare enrollment process, particularly for DMEPOS suppliers. CMS's used National Provider Enrollment (NPE) contractors to oversee enrollment and screening, and CMS continues to evaluate the program's effectiveness in reducing fraudulent billing schemes. NPE investigators frequently conduct unannounced site visits, and identified administrative deficiencies may result in payment suspension. Proactive compliance training and routine internal site reviews remain key mitigation strategies.

Finally, a new Work Plan item in 2025 indicates that CMS is revisiting the use of surety bonds to recover DME supplier overpayments and deter fraud. A prior OIG report found that CMS recovered only $263,000 from surety bonds tied to approximately $50 million in identified overpayments. Department of Health and Human Services, Office of Inspector General. (2013). *Surety Bonds Remain an Underutilized Tool To Protect Medicare From Supplier Overpayments* (OEI-03-11-00350). A renewed federal interest suggests continued scrutiny of bonding requirements and their role in future audit and collection activity.

Skin Substitutes: Continued Oversight and Significant Payment and Enforcement Developments

Skin substitutes remained under heightened federal scrutiny throughout 2025 due to rapid spending growth, coding complexity, and reporting variability.

CONTINUED ON PAGE 39

CONTINUED FROM PAGE 38

CMS reported that Medicare Part B spending increased from approximately $250 million in 2019 to more than $10 billion in 2024.

Enforcement activity focused on utilization and ordering practices, including allegations of medically unnecessary applications and improper financial arrangements. DOJ actions emphasized concerns with product sizing and selection driven by reimbursement incentives rather than clinical need. See, Department of Health and Human Services, Office of Inspector General. (2013). *Medicare Part B Payment Trends for Skin Substitutes Raise Major Concerns About Fraud, Waste, and Abuse* (OEI-BL-24-00420); Benjamin Wallfisch & Gulnara Anzarova, *CMS Finalizes Sweeping Reforms to Skin Substitute Payments Amid Rising Costs and Enforcement Activity,* Polsinelli Publications, Nov. 10, 2025, https://polsinelli.gjassets.com/content/uploads/pdf/cms-finalizes-reforms-skin-substitute-payments-rising-costs-enforcement-activity.pdf.

A major development for this category came late in 2025, when CMS finalized a policy shifting most skin substitute products from average sales price (ASP) based reimbursement to a standardized flat-rate payment of $127.28 per cm^2, effective January 1, 2026. Under this reform, CMS will maintain ASP-based reimbursement only for biological products licensed under Section 351 of the Public Health Service Act, while products regulated as PMA devices, 510(k) devices, or HCT/Ps under Section 361 will be paid as "incident to" supplies at the new rate. Put simply, the reform preserves ASP-based reimbursement for true biologics but moves the bulk of skin substitute products into a single, uniform payment category. CMS also indicated its intent to retain existing HCPCS codes for nearly all products and signaled that future payment rates may diverge by regulatory category based on additional data collection. The reform reflects an effort to establish a more consistent payment framework across clinical settings and respond to concerns that wide variability in pricing and reporting created incentives that contributed to the rapid growth in spending.

Clinical Laboratory Oversight: Medicaid–Medicare Alignment and UPIC Targeting

Laboratory services continued to be viewed as high-risk for improper payments in 2025. CMS and OIG audits focused on reimbursement under both Medicare and Medicaid, emphasizing coverage compliance and fee-schedule alignment. Furthermore, the OIG Work Plan's laboratory-related initiatives indicate that oversight bodies continue to view this sector as a significant area of program-integrity attention for 2026.

Oversight activity in 2025 reflected sustaineet'd scrutiny of laboratory services historically associated with perceived elevated improper-payment risk. Categories such as genetic testing, toxicology, and other high-volume test clusters have been recurring priorities for federal program-integrity review due to documented concerns regarding medical necessity, ordering practices, and billing accuracy. This focus reflects federal interest in examining entities that routinely submit higher-risk claims or exhibit utilization patterns that may require closer analysis. These themes suggest that the federal oversight approach continues to target categories in which

CONTINUED ON PAGE 40

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complex coverage criteria and rapid test expansion can create vulnerabilities.

In practice, this type of scrutiny is frequently observed through the use of Unified Program Integrity Contractors (UPICs), whose reviews are designed to evaluate laboratory billing across both Medicare and Medicaid, using multi-year, data-driven methodologies. UPIC investigations typically compare utilization patterns against established norms and assess whether ordering and documentation practices align with applicable coverage standards. Their role in examining trends, rather than isolated claims, makes UPICs a primary mechanism through which high-risk laboratory categories receive federal attention.

Taken together, the developments of 2025 reflect a program integrity focus on data-driven analysis, cross-program coordination, and high-risk areas of reimbursement. CMS, OIG, and their audit partners have emphasized front-end controls, longitudinal review methodologies, and targeted scrutiny of services and products associated with elevated improper-payment risk. As 2026 begins, providers should expect continued reliance on sophisticated analytics and multi-year review frameworks from auditors, reinforcing the importance of strong compliance infrastructure and self-audit program, as well as proactive monitoring across all aspects of billing and reimbursement.

Top 5 Reimbursement Highlights for Behavioral Health Care Providers in 2026

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Behavioral-health reimbursement continues to evolve rapidly as the federal and state governments prioritize mental-health access, parity and integration across care settings, while balancing the increasing costs and tightening budgets for behavioral health care. The 2026 Medicare regulatory cycle, including the 2026 Medicare Physician Fee Schedule (PFS) and Outpatient Prospective Payment System (OPPS) rules, reflects continued expansion of behavioral-health coverage, refined payment methodologies and heightened operational and compliance expectations for providers beginning Jan. 1, 2026. Unfortunately, however, the outlook for Medicaid payments of behavioral health care is not so good.

Five Updates Providers Should Know

Continued Movement Toward Integrated Care

CMS finalized new add-on codes for Advanced Primary Care Management (APCM) services for providers furnishing Behavioral Health Integration (BHI) or psychiatric Collaborative Care Model (CoCM) services. The codes are meant to pay rates directly comparable to existing CoCM and BHI codes, but unlike the existing codes, the new APCM add-on codes do not require time capture.

Updates to IOP and PHP Payment

Medicare will continue to cover Intensive Outpatient (IOP) services furnished for at least nine hours per week, and Partial Hospitalization Program (PHP) services furnished for at least 20 hours per week, when furnished by a hospital outpatient department, CMHC, RHC, FQHC or OTP. As before, Medicare payment will depend on whether the IOP/PHP services are based on three service days or four-plus service days.

The most significant update related to the calculation of the CMHC, IOP and PHP rates. For 2026, CMS will not use CMHC costs data to set pricing but rather will apply a 40% relativity adjustment to the hospital PHP/IOP geometric mean cost. This change will resolve a cost inversion in CMHC cost data that resulted in higher geometric mean costs for three service days than for four service days. CMS intends these revisions to provide more predictable rates while maintaining a methodology that reflects a broader set of cost data.

Short-Term Updates to Telehealth Services for Behavioral Health

Behavioral health providers received welcome, albeit short-term, relief from the expiration of several telehealth flexibilities that have been in place since the COVID-19 pandemic. As part of the legislation reopening the government after the lengthy shut down, Congress extended the waiver of in-person visit requirements for mental health providers until Dec. 31, 2026. Without Congressional action, providers will need to ensure that they see telehealth patients in-person within six

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months of an initial telehealth visit and annually thereafter beginning Dec. 30, 2026.

Expanded Access to Digital Mental Health Treatment (DMHT)

In 2025, CMS adopted payment provisions for DMHT devices approved by the FDA under 21 C.F.R. § 882.5801 (Computerized behavioral therapy device for psychiatric disorders). To seek payment, the billing practitioner must diagnose the patient with a mental health condition, order the use of DMHT, incur the cost of the device and furnish it incident to ongoing behavioral health treatment. Further, the DMHT device must be used in accordance with the FDA-classified indications.

In 2026, CMS expanded coverage to devices approved by the FDA under 21 C.F.R. § 882.5803 (Digital therapy device for ADHD). All the previous guidance and the relevant codes remain the same. CMS declined to extend coverage to non-FDA approved digital tools.

Medicare will continue to pay for the initial supply of the device and patient education under HCPCS G0552. Although commenters raised concerns regarding inconsistent pricing across MAC jurisdictions, CMS responded that national pricing was not yet feasible due to the limited claims data and the rapidly evolving technology. As such, devices will continue to be contractor priced in 2026.

Medicaid Budget Issue may Thwart Goals of Expanded Behavioral Health

We anticipate that 2026 will see state governments and Medicaid agencies grappling with their stated plans to expand access and reimbursement for behavioral health care and the budget realities prompted by the July 4, 2025 adoption of House Resolution 1 (HR1) (a/k/a the One Big Beautiful Bill Act). HR 1 is expected to significantly limit states' options for financing Medicaid. We anticipate that states will continue to move toward broader adoption of integrated care and value-based care as they plan for the cuts. We are monitoring state action related to HR 1.

DC Update: The Uncertain Future of ACA Subsidies

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As 2025 draws to a close, one of the most significant unresolved issues on Capitol Hill is the fate of the enhanced subsidies under the Affordable Care Act (ACA). What began as a temporary relief measure has morphed into a protracted political stalemate — and unless Congress acts soon, millions of Americans may face higher premiums in 2026. Below we provide a concise overview of where things stand, how we got here, and what to expect in the coming weeks.

Background: What Are the ACA Subsidies and Why Do They Matter?

When the ACA was enacted in 2010, it created a system of premium tax credits and cost-sharing reductions to help lower- and moderate-income Americans afford health coverage purchased through ACA marketplaces. The original credits were modest, reflecting early assumptions about health premiums and income distributions. Over time, as costs rose and coverage gaps remained, the need for enhanced financial help became more urgent.

In 2021 and 2022, in response to economic disruption caused by the COVID-19 pandemic, Congress temporarily expanded the subsidies. The enhanced subsidies increased premium tax credits, lowered cost-sharing and made coverage more affordable for a broader swath of Americans — including many middle-income households who had previously been ineligible for assistance. The expanded federal subsidies dramatically reduced premiums for beneficiaries and increased marketplace enrollment, giving many Americans access to coverage that would otherwise have been unaffordable.

Those temporary enhancements, however, were set to expire at the end of 2025. Unless Congress acts before the end of the year, subsidies will revert to their original, lower levels — potentially causing substantial premium increases for many enrollees.

What's Happening Now and Why It Matters

The end-of-year 2025 budget environment has created a high-stakes showdown over the fate of the enhanced ACA subsidies. With much of the federal budget already addressed through a short-term continuing resolution (CR), negotiations over health coverage relief have become intertwined with broader fiscal and funding battles. Complicating matters, Democrats tried to leverage a recent government shutdown to extract concessions, linking the short-term funding bill or debt negotiations to an extension of the ACA subsidies. That strategy, however, failed to yield agreement, illustrating the political and procedural difficulty of coupling healthcare policy to appropriations fights.

In the House and Senate, lawmakers are currently debating competing proposals. On one side, a group of Senate Democrats has circulated a plan to extend the enhanced subsidies for three years, arguing that the relief remains crucial for affordability and continuity of coverage. On the other, some Senate Republicans have floated alternative proposals — including narrower, means-tested subsidies or scaled-back versions of the credits — reflecting concerns over long-term federal

CONTINUED ON PAGE 44

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spending. Across the Capitol, a bipartisan group of House members is proposing a solution that would extend the subsidies, but include new caps on eligibility. And some House Republicans are calling for the adoption of policies that promote increased competition in the health insurance marketplace to reduce the cost of coverage.

Additionally, President Trump is calling for Congress to amend the ACA to ensure that the federal health coverage subsidies are paid directly to individual Americans instead of to insurance companies.

As of now, no bipartisan consensus has emerged. Scheduled votes are being eyed in both chambers, but timing remains uncertain. Because lawmakers are prioritizing passage of the continuing resolution (CR) that funds most federal government operations — which will expire on Jan. 30, 2026 — many Capitol Hill observers believe real negotiations over the subsidies may not resume until after the CR is settled.

Looking Ahead to 2026

Given the current impasse, our view is that the enhanced ACA subsidies are likely to expire at the end of this year, reverting premium tax credits to their original, lower levels. That outcome seems probable unless one of two things occurs: (1) a Congressional agreement before Jan. 1, 2026, or (2) an extension via another legislative vehicle early in 2026.

Assuming expiration, the consequences could be significant:

- Premiums for many marketplace enrollees could rise sharply, particularly for middle-income households that benefited most from the enhanced credits.
- Marketplace enrollment may drop as individuals reassess affordability.
- Pressure may mount on lawmakers to act under public and political pressure, potentially making the subsidies a central issue in the next Congress and the midterm elections.

Once the CR is resolved — presumably by the end of January 2026 — we expect Congress to turn its full attention back to healthcare negotiations. At that point, a real attempt may be made to either restore the enhanced subsidies (perhaps with revised eligibility or cost controls) or to implement more limited, compromise-based relief.

Bottom Line

At present, the future of the ACA's enhanced subsidies remains murky. While many Members of Congress continue to push for an extension, political divides and broader fiscal fights leave the odds of a pre-January resolution uncertain. For now, stakeholders across the healthcare ecosystem should prepare for a likely reversion to 2010–era subsidy levels. That outcome could ripple across enrollment, premiums, and access to coverage — making 2026 a potentially turbulent year in the ACA landscape.

Key Highlights from the FY 2026 Inpatient Prospective Payment Final Rule

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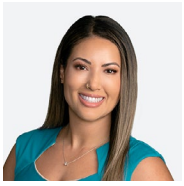

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CMS published the FY 2025 IPPS final rule on Aug. 4, 2025. For FY 2026, hospitals that successfully participate in the Hospital Inpatient Quality Reporting Program (IQR) and are meaningful electronic health record uses will receive a 2.6% operating payment rate increase. This increase reflects a 3.3% market basket offset by a 0.7 point productivity adjustment. CMS estimates roughly $5 billion in additional IPPS operating and capital payments compared with FY 2025, before hospitalspecific impacts (case mix, wage index, VBP/HRRP/HAC, etc.).

Wage Index

CMS will discontinue the low wage index adjustment policy in FY 2026, following a court decision in 2024[1] that vacated the original 2020 policy to increase the wage index adjustment for the hospitals in the bottom 25th percentile of wage index values.

1. *Bridgeport Hosp. v. Becerra*, 108 F.4th 882 (D.C. Cir. 2024).

CONTINUED ON PAGE 45

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Hospital Quality Reporting

Under the Hospital IQR Program, hospitals are required to report data on selected measures to receive the full annual percentage increase to their IPPS payment. The final rule makes several changes to the IQR set by adding four new reporting measures; shortening the reporting period from three to two years; and removing four existing reporting measures. Removed reporting measures include COVID-19 vaccination of health care workers; the commitment to health equity; screening for social drivers of health; and the "screened positive rate" for social drivers of health. The changes become effective for the reporting periods listed below, impacting the stated payment determination years.

Reporting Measures Added

Measure	Reporting Period	Payment Determination Year
Hospital-Level, Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty	April 1, 2023 – March 30, 2025	2027
Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity	July 1, 2023 –June 30, 2025	2027
Hybrid Hospital-Wide Readmission	July 1, 2025 – June 30, 2026	2028
Hybrid Hospital-Wide All-Cause Risk Standardized Mortality	July 1, 2025 – June 30, 2026	2028

Similarly, CMS is removing the same four social determinants of health-related measures from the LTCH Continuity Assessment Record and Evaluation Data Set.

Health Data, Technology and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization (HTI-4)

The final rules included a bonus final rule, HTI-4, which creates standards and certification criteria that encompass all of the aspects of HTI-4: electronic prescribing, electronic prior authorizations and electronic (real-time) data regarding a prescription benefit plan. Like the many EMR, electronic billing and HIPAA standard transactions before it, the purpose of HTI-4 is to promote and optimize the workflow associated with prescribing, prior authorizations and determining benefits. HTI-4 also includes criteria for application programming interface (API) functionality.

Transforming Episode Accountability Model (TEAM)

As previously outlined in the FY 2025 IPPS, CMS has been preparing to roll out the TEAM beginning Jan. 1, 2026. TEAM is a five-year, episode-based, bundled payment model that will run from Jan. 1, 2026, to Dec. 31, 2030 and is mandatory for selected acute care hospitals. Hospitals required to participate in the

CONTINUED ON PAGE 47

CONTINUED FROM PAGE 46

model will coordinate care from surgery through 30 days post-hospitalization for people with original Medicare undergoing one of five selected surgical procedures.

Although TEAM was largely described in the prior rulemaking, certain policies and issues were not fully addressed or resolved. Thus, in the FY 2026 final rule, CMS has finalized updates to the soon-to-be-effective model. These updates include a limited participation deferment period for newly opened hospitals or hospitals that newly meet the TEAM participant definition; refined quality reporting requirements; and broadening the three-day Skilled Nursing Facility Rule waiver for TEAM beneficiaries discharged to hospitals providing post-acute care under swing bed arrangements.

Additional information and a list of TEAM participating hospitals may be found on the model webpage.

New Technology Add-on Payment (NTAP)

Under the IPPS, the NTAP provides supplemental payment for eligible new medical services and technologies whose costs are not yet fully reflected in the MSDRGs, subject to CMS's "newness" cost and substantial clinical improvement criteria. For FY 2026, CMS continues to cap NTAP at the lesser of 65% of the cost of the technology or 65% of the amount by which case costs exceed the MSDRG payment (increased to 75% for certain infectious disease products), and it projects roughly $192 million in additional NTAP-related payments.

Beginning with application for FY 2027, all resubmissions will require a letter from the FDA stating that the FDA review has restarted and is active. Data available to the public regarding NTAP applications will also be expanded in 2027.

Reasonable Cost Payment for Nursing and Allied Health Education Programs

Although restrictions and obstacles have increased in recent years, Medicare has historically paid providers on a pass-through basis for Medicare's share of the costs that providers incur in connection with approved educational activities for nursing and allied health (NAH) education programs.

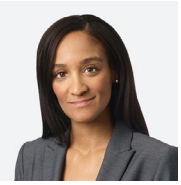
In a 2017 transmittal, CMS updated cost reporting instructions to direct the order of operations for hospitals determining allowable costs under the NAH regulations, resulting in significant reimbursement reductions for hospitals. Five hospitals sued, and in 2024, the U.S. District Court for the District of Columbia found that CMS's new interpretation did not comport with the text of the regulations. *Mercy Health-St. Vincent Med. Ctr. LLC v. Becerra,* 717 F. Supp. 3d 33 (D.D.C. 2024).

CMS disagreed with the *Mercy Health-St. Vincent Med. Ctr.* decision, and in the FY 2026 IPPS proposed rule, set out to amend the regulations. In the face of significant negative feedback, however, CMS is not currently moving forward with this proposal. CMS did state that it intends to revisit this issue in the future. Accordingly, hospital providers should continue to stay up-to-date on NAH proposals and requests for information and should be prepared to provide feedback.

DSH/Uncompensated Care

CMS finalized a $2 billion increase in Medicare disproportionate share/uncompensated care payments, with ongoing reliance on S10 and other data. This is an increase over 2025 and the amount from the proposed rule.

Telehealth at a Crossroads in 2025



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The year 2025 has been one of the most dynamic periods for telehealth since the early phases of the COVID-19 Public Health Emergency (PHE). Providers, plans and technology-enabled care organizations have navigated shifting statutory deadlines, a federal government shutdown, evolving supervision standards and renewed attention to digital health oversight. As the year concludes, Medicare telehealth policy stands at a significant inflection point. The discussion below summarizes key developments throughout 2025 and highlights what stakeholders should anticipate as the industry moves into 2026.

Medicare Telehealth Flexibilities in 2025

- **Early 2025 Extensions.** At the start of 2025, Congress relied on a series of short-term funding measures to maintain pandemic era Medicare telehealth flexibilities. These measures postponed the expiration of expanded originating site rules, broadened practitioner eligibility, audio only coverage, and authority for FQHCs and RHCs to serve as distant site providers. The initial extensions carried the program into the spring and were followed by additional legislation that extended these authorities through Sept. 30, 2025.
- **The September 30 Expiration and Industry Disruption.** When Congress did not enact a longer-term solution by Sept. 30, 2025, the U.S. entered a federal government shutdown and the statutory Medicare telehealth flexibilities expired. As of Oct. 1, 2025, Medicare telehealth services again became subject to the statutory coverage criteria that existed prior to the public health emergency. This

CONTINUED ON PAGE 49

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shift created immediate operational and clinical challenges for providers who had relied on the expanded flexibilities for more than four years.

Once the flexibilities lapsed, Medicare telehealth coverage narrowed significantly. Providers had to ensure that telehealth services met the following pre-pandemic statutory requirements:

- **Originating site geographic limitations.** Patients were required to be located in a rural area, including Health Professional Shortage Areas, outside a Metropolitan Statistical Area, or in a telehealth demonstration project area.
- **Originating site facility requirements.** Most telehealth services had to be furnished at an approved originating site, such as a physician office or hospital. Patient homes no longer qualified as a telehealth site except for limited exceptions such as end stage renal disease, mobile stroke units and certain behavioral health services.
- **Distant site provider restrictions.** Federally Qualified Health Centers and Rural Health Clinics no longer qualified as distant site providers for telehealth services.
- **Eligible practitioner limitations.** Physical therapists, occupational therapists, speech language pathologists and audiologists were no longer eligible to furnish Medicare covered telehealth services.
- **Mental health in person requirements.** Certain mental health telehealth services again required an in person visit within six months of initiating telehealth and annually thereafter.

These expirations led to significant uncertainty across the industry. Claims were delayed or held, and many organizations had to rapidly adjust their telehealth programs to remain compliant during the lapse period. This period represented a significant interruption to the virtual care landscape since the start of the PHE. Although the flexibilities were later reinstated and extended, the temporary expiration underscored the fragility of telehealth policy under short-term statutory extensions.

- **Retroactive Restoration Through Jan. 30, 2026.** On Nov. 12, 2025, President Trump signed a short-term federal spending bill that restored the key Medicare telehealth flexibilities and the Acute Hospital Care at Home program through Jan. 30, 2026. The extension applied retroactively to Oct. 1, which helped stabilize the significant operational and reimbursement disruptions that occurred following the lapse of these flexibilities on Sept. 30. Although the action provided immediate relief to providers and beneficiaries, it was temporary and set the stage for renewed uncertainty as the next expiration date approaches.

Because the flexibilities were reinstated retroactively, providers were advised to expect further operational guidance from CMS. This guidance is anticipated to address several practical issues, including the reprocessing of previously held or denied claims, updates to place of service reporting, and confirmation of documentation expectations for services furnished during the retroactive period.

To date, CMS has only addressed the status of telehealth claims during the shutdown in a public FAQ. In response to questions regarding services furnished between Oct. 1 and Nov. 12, CMS stated that it would continue to pay telehealth claims in the same manner

CONTINUED ON PAGE 50

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as before Oct. 1. The agency clarified that the restored telehealth flexibilities would apply retroactively as though no lapse had occurred, and that this retroactive application would continue through Jan. 30, 2026.

The retroactive restoration eased many of the immediate administrative burdens that providers faced, but it also underscored the challenges created by short term extensions.

Virtual Supervision and Incident-To Services

In 2025, CMS finalized substantial changes to Medicare's direct supervision requirements, marking one of the most significant updates to the incident-to framework in recent years. These changes, which take effect in 2026, reflect CMS's effort to modernize supervision standards and acknowledge the operational realities of contemporary clinical practice.

Under longstanding Medicare rules, services furnished incident to a physician or non-physician practitioner require direct supervision, meaning the supervising practitioner must be immediately available to furnish assistance. Historically, CMS interpreted immediate availability to require the practitioner's physical presence within the office suite. During the PHE, however, CMS temporarily allowed direct supervision to be satisfied through real time, two way audiovisual technology. This flexibility enabled supervising practitioners to be immediately available without being physically present and supported care delivery during periods of staffing strain and high patient demand. The temporary flexibility was extended several times and was scheduled to expire on Dec. 31, 2025.

As CMS evaluated the role of virtual supervision after the end of the PHE, it initially adopted a narrow permanent policy in the CY 2025 Physician Fee Schedule Final Rule. That policy preserved virtual supervision only for a limited subset of incident to services beginning Jan. 1, 2026, including services with a PC or TC indicator of 5 and services described by CPT code 99211. CMS indicated at the time that it was continuing to study whether a broader modernization was appropriate.

Following continued stakeholder feedback, CMS finalized a far more comprehensive approach in the CY 2026 PFS rulemaking cycle. Beginning in 2026, practitioners may meet the direct supervision requirement through real time audiovisual technology for nearly all services that may be billed incident to, as well as for cardiac, pulmonary, and intensive cardiac rehabilitation services. The only exception applies to procedures with a 10-day or 90-day global surgery period, which CMS determined still require physical presence due to the clinical complexity of perioperative care.

Although the new policy allows for broad use of virtual supervision, CMS emphasized that supervising practitioners must continue to use their professional judgment in determining whether virtual presence is clinically appropriate in each situation. State scope of practice laws and licensure requirements also continue to govern delegation and supervision.

If implemented thoughtfully, the finalized policy has the potential to significantly reshape outpatient operations. Practices may benefit from improved staffing efficiency, expanded access to supervision across locations, and greater flexibility in structuring clinical teams. At the same time, providers should review their supervision protocols, documentation practices

CONTINUED ON PAGE 51

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and telehealth technology standards to ensure they align with the new requirements.

Telehealth Services List and Technology-Enabled Care

Updates to the Medicare Telehealth Services List. For 2025, CMS added new services to the Medicare Telehealth Services List and maintained its two tier structure for permanent and provisional telehealth codes. Notable additions for the year include caregiver training services, certain behavioral health and crisis intervention services and counseling related to pre-exposure prophylaxis for HIV prevention. CMS has indicated that it will conduct a comprehensive review of provisional codes at a future date.

Audio-Only Telehealth in the Home. A significant regulatory change took effect on Jan. 1, 2025. CMS revised the definition of interactive telecommunications system to include audio-only technology for any telehealth service furnished to a beneficiary in the home, provided that the practitioner has the ability to use audio-video technology and the beneficiary is unable or unwilling to use such technology. This rule gives audio-only a more durable regulatory basis that operates independently of the temporary statutory flexibilities.

Facility-Based Telehealth. CMS also advanced policies for hospital outpatient departments and other facility-based settings. These efforts aim to harmonize coverage for telehealth and remote services furnished by hospital staff to beneficiaries located in their homes, and they provide greater alignment between the Physician Fee Schedule and the Outpatient Prospective Payment System in this area.

Telemedicine and Controlled-Substance Prescribing

Federal policy surrounding controlled-substance prescribing via telemedicine continued to evolve in 2025, and the year closed with an important development that will affect virtual care providers throughout 2026.

The Drug Enforcement Administration (DEA) has signaled that it will again extend the temporary telemedicine prescribing flexibilities that allow DEA-registered clinicians to prescribe Schedules II through V controlled substances via telehealth without an initial in-person examination. These flexibilities were first implemented during the PHE and have been renewed multiple times over the past several years. They are currently scheduled to expire on Dec. 31, 2025.

On Nov. 11, the DEA posted notice of a forthcoming rule titled the Fourth Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications. Although the agency has not yet released the text, industry sources indicate that the extension is expected to be a clean, one-year continuation of the existing framework. If finalized as anticipated, the extension would allow telehealth prescribers to continue operating under the current flexibilities well into 2026, while the DEA and the Department of Health and Human Services work toward establishing a permanent regulatory structure governing telemedicine prescribing of controlled medications.

This forthcoming action would provide near term stability for virtual prescribing programs, but organizations should continue to monitor DEA rulemaking closely. The agency has repeatedly signaled its intent to create a long awaited permanent framework, and additional regulatory changes may

CONTINUED ON PAGE 52

CONTINUED FROM PAGE 51

follow once the temporary extension is issued.

Broader Digital Health Trends in 2025

Beyond Medicare rulemaking, the digital health sector experienced intensified scrutiny in several areas. Online weight management programs using GLP-1 medications faced regulatory, legal and supply chain challenges. State health data privacy laws continued to expand and impose new compliance requirements for telehealth platforms, particularly with respect to tracking technologies and consumer health data. Reproductive health telemedicine raised complex interstate legal questions as states tested the boundaries of shield laws and extraterritorial enforcement.

These trends highlight the growing importance of incorporating privacy, licensure, and risk management considerations into telehealth program development.

What To Expect in 2026

With the current statutory telehealth flexibilities scheduled to expire on Jan. 30, 2026, stakeholders again face the possibility of a significant regulatory shift. Several bipartisan bills seek to extend or make permanent key components of the Medicare telehealth landscape. Until Congress enacts a longer-term solution, providers should prepare for multiple operational scenarios and maintain flexibility in planning and documentation practices.

The year 2025 marked a pivotal period in the evolution of telehealth policy. Despite considerable uncertainty, the retroactive restoration and extension of Medicare telehealth flexibilities, the development of permanent virtual supervision rules, and the continued maturation of digital health regulation illustrate the federal government's ongoing commitment to supporting virtual care. As stakeholders move into 2026, close attention to federal rulemaking, legislative activity and state level trends will be essential to ensuring compliance and sustaining high-quality, patient-centered telehealth programs.

Polsinelli's Reimbursement Practice

Understanding and complying with the nuances of Health Care reimbursement is one of the greatest challenges that providers face in today's quickly changing health care world. Polsinelli boasts one of the largest health care reimbursement groups in the country with extensive experience in all areas of health care reimbursement, including coverage and payment under Medicare, Medicaid, VA, TriCare and commercial payors.

Polsinelli's deep bench of reimbursement attorneys brings in-depth, strategic and pragmatic guidance related to government and commercial health care reimbursement across the health care spectrum. We partner with health care providers of all types to meet and exceed their revenue, clinical and compliance goals.

We regularly advise the following types of health care providers:

- Hospitals and Health Systems
- Nursing Homes
- Physician Groups
- Home Health and Hospice
- Dialysis Providers
- Behavioral Health and Community Mental Health Care Providers
- FQHCs and Rural Health Clinics
- Safety Net and Rural Hospitals
- Ambulatory Surgery Centers
- Rehabilitation agencies and CORFs
- Pharmacies
- Laboratories
- Diagnostic Testing Facilities
- Ambulance Suppliers
- MedSpas

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- Colorado Health Care Regulatory Update – Thursday, Jan 29th (Denver)
- Polsinelli's Healthcare Dealmakers Conference – May 13th and 14th (Dallas)

Reimbursement Summit Returns in 2026

We're pleased to announce the return of the Reimbursement Summit. Join us on **April 16 in Nashville** for a focused program featuring insights and updates on key reimbursement issues and developments.

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