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Health Care Reimbursement Newsletter

Newsletter from the Reimbursement Practice Group

2025

Contents

Steps Congress May Take To Fix Reimbursement in 2025

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In the CY 2025 Physician Fee Schedule, CMS finalized a 2.83% physician payment cut for calendar year 2025. The 118th Congress ended without lawmakers taking any action to offset the cut. Because Congress has taken no action to delay or reverse the cut, the cut went into effect on January 1, 2025. Physician groups have noted that the 2.83% cut is coupled with a 3.6% increase in medical practice cost inflation, resulting in an effective cut of over 6%. Congress did approve limited changes to Medicare policies in the final days of the last Congress, and again in March, by extending certain Medicare telehealth provisions and delaying scheduled reductions to the Medicaid Disproportionate Share Hospitals allotment until September 30, 2025.

The 119th Congress started on January 3 and lawmakers will face short and long-term challenges regarding Medicare payment programs. The short-term challenge is how to address the CY 2025 payment cuts. Congress can either provide a retrospective fix and increase all payments as of January 1 or a prospective fix that would only impact payments after the passed effective date. The retrospective fix comes with extraordinary administrative challenges for both the Medicare Administrative Contractors (MACs) and providers. In addition, the more time that passes after the new year, the harder the challenge becomes. A prospective fix, while less financially appealing to providers, is an easier administrative fix.

Assuming Congress can agree to a CY 2025 fix, will they also be willing to go further and address long-term payment reform? Early indications are that they will at least try. The new chair of the Senate Finance Committee, Sen. Mike Crapo (R-ID), recently outlined his health care policy priorities for the committee: "We must improve primary care, support chronic-care benefits in Medicare and

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provide Medicare doctors with long-term payment stability." This announcement comes after some progress was made in the House Energy & Commerce Committee during the 118th Congress to pass legislation to address long-term payment reform.

Last session, the Energy & Commerce passed the Physician Fee Schedule Updates and Improvements Act by a vote of 64-0. That legislation would reform the Medicare payment schedule budget-neutrality policies by increasing the budget neutrality from $20 million to $53 million and would allow for greater flexibility in determining pricing adjustments for services. That bill did not see further action after passing out of the Energy & Commerce Committee unanimously.

On January 31, the Medicare Patient Access and Practice Stabilization Act (H.R. 879) was introduced in the House of Representatives by Representatives Greg Murphy, MD (R-NC), Jimmy Panetta (D-CA), Mariannette Miller-Meeks, MD (R-IA), and Kim Schrier, MD (D-WA). This bipartisan bill will prospectively stop the latest round of payment cuts in full. The bill also provides physicians with a crucial two percent payment increase for 2025.

While there is bipartisan and bicameral support for passing long-term reforms, cost remains the biggest hurdle. President Trump and Congressional Republicans won control of the White House and both chambers of Congress by promising to control government spending and reduce the size of the federal government. The GOP faces the reality of having to pass much needed Medicare payment reform policies, while also promising to reduce spending. However, their cause could be bolstered by The Medicare Payment Advisory Commission's (MedPAC) June 2024 report, which voiced concern over the future of Medicare payments. MedPAC cautioned that continued cuts "could create incentives for clinicians to reduce the number of Medicare beneficiaries they treat or stop participating in Medicare entirely." The political threat of Medicare beneficiaries, and voters, left without a Medicare provider could motivate the GOP to finally pursue long-term reforms.

Six Updates to Provider Enrollment in 2024 You Need to Know

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CMS made several updates to the Medicare provider enrollment regulations and sub-regulatory guidance in 2024. Changes included revisions of enrollment forms, extension of telehealth flexibilities, well as measures to increase transparency in program integrity efforts. A summary of the major changes affecting providers and suppliers is provided directly below:

1. Telehealth Was Extended

CMS extended certain Medicare enrollment flexibilities that have been in place since the COVID-19 Public Health Emergency relating to telehealth. Namely, CMS continues to allow physicians and non-physician practitioners to render telehealth services from their homes without reporting their home address on Medicare enrollment or claims forms. Without this flexibility, practitioners providing services via telehealth would have to list their home address as a practice location on their Medicare enrollment applications, including the enrollment applications of the groups to which they reassign their Medicare billing privileges. This flexibility reduces administrative burden associated with reporting these home addresses, and confusion and limitation of services resulting from cross-state and cross-jurisdictional reassignment applications.

2. 855 Enrollment Forms Were Revised (Again)

After releasing changes to the CMS-855A in late 2023, CMS continues to roll out revised enrollment forms with the merging of the CMS-855R into the CMS-855I paper enrollment application. Physicians and non-physician practitioners can reassign their right to bill the Medicare program and receive Medicare payments for some or all the services rendered to Medicare beneficiaries, terminate a reassignment of Medicare benefits, or change their reassignment of Medicare benefit information using the CMS-855I. All data collected on CMS-855R and used to report reassignment information is now captured on the CMS-855I. Organizations/groups accepting a new reassignment of Medicare benefits, terminating an established reassignment of benefits or changing reassignment of Medicare benefit information, must also submit the 855I to report these changes.

CMS also published revisions to the 855-B enrollment form in the Federal Register on July 9, 2024, which have yet to be adopted. Through the revised form, groups can establish, terminate or change reassignments using the 855B, reflecting the phase out of the 855-R. The revisions also remove physician assistant employer relationship, adds a submittal reason for providers solely enrolling in Medicare to participate in Medicaid or another health care program, and add practice location types: Business Office for Administrative/Telehealth Use Only and Home Office for Administrative/ Telehealth Use Only.

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3. Skilled Nursing Facilities Must Now Share Additional Disclosable Parties

CMS is now requiring Skilled Nursing Facilities (SNFs) to disclose detailed information about their ownership and management and additional data regarding other parties with which the SNF is associated (known as "Additional Disclosable Parties") and the ownership structures of these parties. Although some of this data is disclosed on the 855A, some of is not and will be newly reported. The new SNF Attachment of the Form CMS-855A collects all SNF data disclosed in Sections 5 and 6 of the Form CMS-855A and additional information pertaining to Additional Disclosable Parties. The Form CMS-855A has been revised to collect the newly required SNF data and became effective on October 1, 2024. Beginning on that date, all SNFs initially enrolling, revalidating, reactivating, or undergoing a change of ownership had to submit this version of the Form CMS-855A with the SNF attachment completed. CMS also initiated off-cycle revalidations for SNFs to collect this additional information with a revised due date of August 1, 2025.

4. There Are New Requirements for a Hospice Certifying Enrollment

Starting June 3, 2024, CMS began requiring these physicians to be enrolled in or opted-out of Medicare for hospice services to be paid:

- Hospice medical director or the physician member of the hospice interdisciplinary group who certifies the patient's terminal condition (hereafter occasionally referenced as "hospice physician").
- Patient-designated attending physician who certifies their terminal condition. The attending physician must meet the definition of "physician" specified in 42 CFR § 410.20(b).

These two categories of physicians must initially certify the patient's terminal condition. For later coverage periods, only the hospice physician must certify the patient's terminal condition. Hospice claims submitted without an enrolled or opted-out physician will deny, so it is imperative for hospices to verify the enrollment status of these physicians to ensure Medicare payment. This can be completed by checking the CMS Order and Referring dataset, which lists all physicians and non-physician practitioners legally eligible to order and refer in the Medicare program and with current Medicare enrollment records.

5. Providers and Suppliers Can Now Get a Stay of Enrollment Status for Noncompliance

CMS began utilizing a "Stay of Enrollment" status as a "middle ground between a deactivation and non-action on our part," where there is non-compliance with Medicare enrollment requirements. A "stay of enrollment" is a "pause" in an existing supplier or provider's enrollment and is limited to 60 days. CMS imposes a stay of enrollment only when: (i) a provider or supplier is not compliant with at least one Title 42 enrollment requirement; and (ii) when it ascertains the non-compliance may be remedied through the provider or supplier's submission of the appropriate enrollment report.

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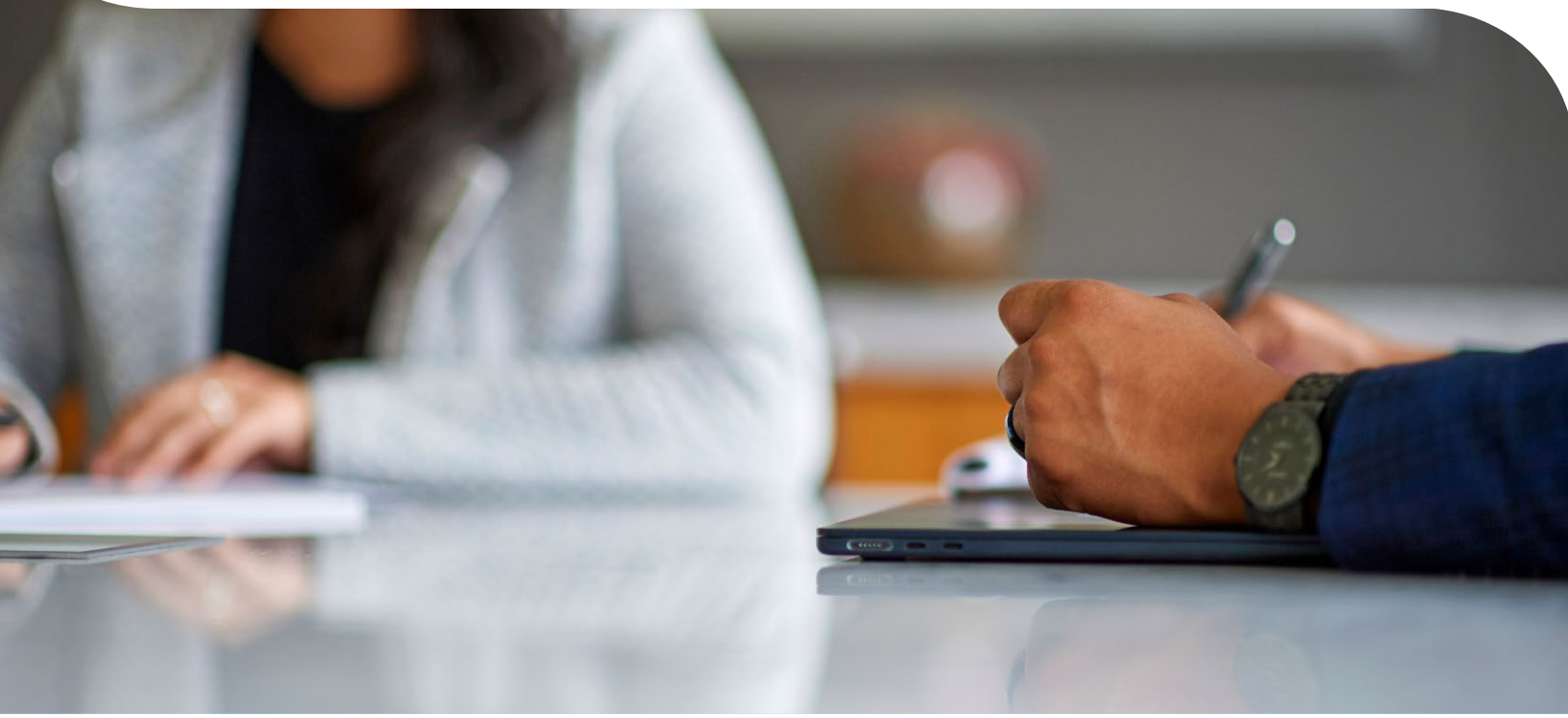
6. The Deactivation Period for Hospices Not Billing Has Been Reduced

CMS changed certain practices related to deactivations for non-billing, particularly related to the period of claims inactivity prior to when CMS will deactivate a hospice provider. In November 2023, CMS reduced the period of Medicare non-billing for which a provider or supplier can be deactivated from 12 months to six months. In March 2024, CMS began deactivating hospices after six months of non-billing if the provider has been enrolled in Medicare for at least six months, has no Medicare or Medicaid billing in the last six months, has not completed a revalidation in the last six months, and does not have a revalidation due in the next month or a revalidation in progress in the last three months. Medicare certification and provider agreements are not impacted by the deactivation, and a new survey is not required to reactivate; however, a reactivation will result in a gap in payment.

In contrast, CMS uses its discretion to only deactivate most other part A providers (e.g., HHA, SNF) if they have had no Medicare or Medicaid billing activity in the last 13 months. This change in policy related to hospice deactivations continues CMS's increased scrutiny and program integrity oversight related reducing fraud, waste, and abuse in the hospice industry.

CMS has signaled over the past few years its interest in requiring significantly greater transparency in the disclosure of ownership and control interest in Medicare providers. While it has held off implementing sweeping action, it continues to increase disclosure requirements. That said, CMS also appears open to accommodating reasonable requests, as seen by the telehealth guidance and implementation of the stay of enrollment concept.



Utilization Management Changes to Medicare Advantage

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After a scathing 2022 report from the Department of Health and Human Services' Office of Inspector General blasted Medicare Advantage (MA) plans for improperly denying coverage for medically necessary care, CMS took swift regulatory action to enact reform. Those reforms to the ways in which MA plans make their utilization management and coverage decisions took effect in 2024. CMS approached the problem from a few different angles.

First, CMS limited MA plan use of prior authorization, clarifying that an MA plan may not use prior authorization policies to delay or discourage care. Rather, a plan may only use prior authorizations to confirm the presence of diagnoses or other medical criteria to ensure that a service is medically necessary. CMS also clarified that when an MA plan provides a pre-service medical necessity determination through the prior authorization process, the plan cannot later deny coverage or payment based on medical necessity.

Second, CMS ensured that authorizations issued by an MA plan survive provider or plan transitions as well as other potential disruptions in care. These new continuity of care regulations require MA plans to approve prior authorizations that are valid for the duration of a course of treatment, in accordance with the treating provider's recommendation. They also prohibit MA plans from requiring reauthorization for new enrollees who are in an active course of treatment.

Third, CMS prohibited MA plans from relying solely on AI or other algorithmic systems to make utilization management decisions. CMS clarified that algorithms that determine coverage based on a large data set instead of the enrollee's individual medical history (including the treating physician's recommendations or clinical notes), would not be compliant with current rules requiring individualized utilization management determinations.

Finally, CMS codified longstanding CMS policy requiring MA plans to cover services to the same extent traditional Medicare does. In circumstances where Medicare statutes, regulations, or guidance create "fully established" coverage criteria for an item or service, the MA plan is required to comply with CMS' coverage criteria and is not permitted to apply additional criteria as part of its determination. When coverage criteria is not "fully established," MA plans are permitted to develop their own, but must ensure they are based on current evidence in widely used treatment guidelines or clinical literature. Any additional coverage criteria must be highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. Importantly, an MA plan's coverage criteria must be publicly available.

CMS hopes that these reforms result in fewer inappropriate authorization and coverage denials. They have only been in place for one year, so reliable data is not yet available. In our experience with MA plans in 2024, the results are very much mixed. That might

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be one reason why an increasing number of providers are dropping their participation with MA plans, despite CMS's provider and patient-friendly changes to the MA program. Providers continue to cite excessive prior authorization requirements and other administratively burdensome utilization management techniques as a reason to stop accepting MA patients. For providers that continue participation with MA plans, we are finding that the new regulations can be helpful in payment disputes when the MA plan is not in compliance.

CMS has continued its interest in MA plans' use of prior authorization techniques. Starting in 2025, MA plans are required to conduct a health-equity focused analysis of its use of prior authorization that includes metrics like the percentage of authorization requests that were approved, denied, or appealed and must post the results of the analysis on their websites. In addition, CMS also made the following changes for 2025 that might be of interest to providers:

a. New coverage for anti-obesity medication without needing an additional diagnosis, which required a change to CMS's longstanding interpretation of statutory language;

b. The out-of-pocket maximum for Part D drug cost sharing is reduced from $8,000 to $2,000, eliminating the dreaded coverage "donut hole." This reduction does not apply to Part B drugs;

c. The "cut point" measuring levels for many measures increased from 2024, making it harder to achieve or maintain high Star Ratings. For providers whose MA plan compensation is based on achievement on Star Rating quality metrics, 2025 could be a difficult year. Specific contract terms should be reviewed; and

d. Continued efforts to improve access to behavioral health services by adding network adequacy standards for "Outpatient Behavioral Health," a category that includes marriage and family therapists, mental health counselors, and a range of addiction medicine professionals. In 2024, CMS added objective network adequacy standards for clinical psychologists and clinical social workers.

The MA program continued its historic growth in 2024 and will continue to do so. Providers with thoughtful strategic approaches to their relationships with MA plans will be best positioned to be successful.

New Year, New 340B Program? Manufacturers Seek to Change the 340B Program Landscape

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2024 was an unusual year for the 340B Program and a busy one for Health Resources and Services Administration (HRSA), the agency that oversees the 340B Program. 2024 saw a significant uptick in Administrative Procedure Act (APA) cases filed against the HRSA by covered entities (CEs), manufacturers, and data vendors. The perceived statutory ambiguities present in the 340B statute, along with aggressive manufacturer policy positions, were the primary contributors to the cases being filed.

CEs spent the latter half of 2024 addressing various aggressive manufacturer policy positions, and we do not expect that to slow down in 2025. Initial action focused on inappropriate J&J audits, but as the year ended, manufacturers increased their 340B Program efforts primarily through release of controversial 340B rebate models. Manufacturer lawsuits ensued as HRSA rejected various manufacturer rebate proposals and threatened to impose sanctions on the manufacturers. The proposed rebate models may reshape the 340B Program as we know it today. Likewise, manufacturer audit activity and corresponding lawsuits will test HRSA's role and authority, and the audits could shift enforcement to manufacturers. Given the *Loper Bright* decision, the new administration, and the outcome of a slew of pending lawsuits, we expect the 340B Program to remain in focus in 2025. As the Trump Administration settles in and various bill advance through Congress, CEs must remain vigilant and should participate in key policy discussions and lawsuits. Engagement at the state level is also critical as more states pass legislation to protect the 340B Program, restore contract pharmacies, and preserve reimbursement for 340B drugs.

J&J Manufacturer Audit Activity

Last summer, J&J issued manufacturer audit requests to CE hospitals that HRSA purportedly approved. Five CEs have since filed APA actions asserting that HRSA failed to follow its own manufacturer audit guidelines, because HRSA approved J&J's audit workplans before CEs had any reasonable basis to engage in good faith discussions with J&J. The J&J audits seemed to be primarily based on drugs that were included in the first round of the Medicare Drug Negotiation Program (i.e., high dollar meds). Beyond the allegations concerning procedural flaws, CEs also asserted that the scope of the audits was overly broad and exceeded the bounds of the 340B statute (42 U.S.C. §256b(a)(5)).

Notwithstanding the five pending lawsuits, HRSA surprised the CE community when it threatened to remove the five CEs if they did not provide a date on which to start the J&J audits. In this instance, it is apparent that HRSA is poised to apply the audit provisions in the 340B statute very broadly in favor of drug manufacturers, thus the outcome could significantly change the way manufacturers and CEs interact in future good faith discussions and audits (e.g.,

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if J&J prevails, it will open the door to enhanced audit activity based purely on what many CEs would view as minor shifts in volume).

If the Trump Administration continues development of the Medicare Drug Price Negotiation Program, pay close attention to other manufacturers with products on the CY 2026 and recently proposed CY 2027 lists of drugs with negotiated pricing. We expect that those manufacturers will continue to push for more oversight of 340B as a way to recoup dollars lost under the Medicare Drug Price Negotiation Program/ IRA. Of note, the CY 2027 proposed list contains the popular products Ozempic and Wegovy. Also expect more audit activity, rebate models, and data collection activities as manufacturers address their perceived gaps between the IRA and 340B.

Proposed Rebate Models and Lawsuits

J&J, Sanofi, and several others are attempting to implement rebate models for 340B discounts (shifting from an upfront discount to an unlawful post-dispense rebate) for certain drugs, triggering HRSA to block several models and prompting a series of APA lawsuits by manufacturers against HRSA. J&J set off a potential sea change in the 340B Program on August 23, 2024, when it announced that it would only offer 340B discounts on two of its top-selling drugs through a rebate model, contingent upon collection of detailed claims data from disproportionate share hospital (DSH) CEs. HRSA responded by instructing J&J to withdraw its rebate model or face enforcement action, up to and including termination of Medicaid and Medicare coverage for all J&J drugs. HRSA took the position that the manufacturer's implementation of a rebate model without HRSA approval plainly violates the 340B statute. J&J ceased its implementation of the rebate model but on November 12, J&J sued HRSA.

Although J&J was the first manufacturer to attempt a 340B rebate model, other manufacturers have been working toward the same change. Since J&J filed suit against HRSA, several additional manufacturers have pursued a 340B rebate model, either through lawsuits or unilateral announcement. On November 15, Eli Lilly sued HRSA, seeking approval of a rebate model that would apply to all medicines and all CE types, not just DSH CEs. On November 22, Sanofi announced its rebate model, applicable to most CE hospitals and consolidated health centers (i.e. FQHCs). On November 26, Bristol-Myers Squibb (BMS) sued HRSA after receiving notice that BMS could not impose a rebate model without HRSA approval. The BMS rebate would only apply to one drug at first, leaving the door open to expand to others.

All manufacturer rebate proposals include the use of a third-party platform to collect, process, and approve a large volume of claims data from the CEs as a prerequisite for issuing the rebate payments, either Second Sight's Beacon or Kalderos' Truzo. As CEs already know from contract pharmacy restrictions, these software systems force CEs to agree to draconian terms and conditions that release the software company and manufacturers from nearly all liability. Additionally, Truzo appears to have a claims adjudication process when CEs and manufacturers disagree about 340B eligibility, which is outside the scope of the 340B statute. This would unlawfully shift 340B Program enforcement to the drug manufacturers. These data collection systems are problematic for CEs, because CEs are

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left without any recourse under the terms and conditions and without a private right of action under the 340B statute. Likewise, these systems are largely untested in being able to timely and accurately process a huge volume of CE rebate claims from thousands of CEs.

What Covered Entities Should Be Doing

In light of the significant activity by manufacturers in the last few months of 2024, CEs must watch these actions closely and be prepared to take immediate action to preserve the 340B Program in its current form.

Specifically, CEs should consider the following.

Carefully consider manufacturer good faith inquiry and audit trends when developing new programs that increase 340B utilization. While these trends may not change the decision, leadership should be aware of all legal, monetary, and reputational risks.

Be timely and strategic when responding to "good faith" inquiries from manufacturers in advance of manufacturer audits.

Utilize alternate dispute resolution (ADR) opportunities.

Monitor actions surrounding the proposed rebate data collection platforms Beacon and Kalderos and challenge problematic terms.

Tell your story! HRSA needs support in defending its position against unlawful rebate models, and manufacturers are oversimplifying the impact their rebate models will have on CEs.

Reimbursement Perspectives from the Host of The *10 Minute* HealthBizCast

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The *10 Minute* HealthBizCast is now in its eighth season and hosted by Polsinelli shareholder Bobby Guy. The podcast features interviews with executives and thought leaders in the health care and life sciences industries and focuses on the future of U.S. health care. Season eight's focus is on "rapid, incremental change."

At The *10 Minute* HealthBizCast, our tagline is "Exploring Ways to Make Healthcare Better." The HealthBizCast is a passion project that health care lawyer Jim Mathis and I started developing in 2019, and by the grace of God, it was ready to launch in the spring of 2020 – right when we all were looking for things to listen to and keep us busy.

Over the course of eight albums (we're headquartered in Nashville, so of course a season is an "album," and an episode is a "track" …), we've had the pleasure of talking to guests across numerous health care sectors, always in search of opportunities to make an inefficient system more efficient. In fact, at the HealthBizCast, we think that focusing on patient outcomes and patient experience in health care will lead to the opportunity to create and grow successful health care companies in the dynamic U.S. economy – doing well, by doing good.

Reimbursement is a recurring theme with guests in so many of interviews. For example, we've talked to numerous life sciences companies about the new diagnostics and biotech opportunities to improve health care, if only our conventional medical systems (and payor sources, including CMS) would provide more support and less resistance.

In the behavioral sector, we've talked to many thought leaders, and we believe there's a major explosion coming — potentially the health care growth opportunity of our lifetimes — to meet the needs of the U.S. population that currently has only limited access to behavioral care, because there are not enough providers. Five hundred and seventy counties in the U.S. have no psychiatric or behavioral care providers at all, and from the 1980s until now, psychiatric beds in the U.S. have dropped from about 250,000 to approximately 37,000 beds. Reimbursement complexities are a major barrier to meeting the demands of the population and we think a revolution in behavioral reimbursement is coming.

On Album 7, we talked with thought leader Paul Keckley, in a double episode, about how to use the business of health care to change the health care sector, instead of waiting for government. On Album 8, we talked to David Jarrard of national public relations firm Jarrard, about the dream of a "Manhattan Project" in health care, remaking the system and remaking reimbursement.

We've talked to a number of CEOs and thought leaders about how to navigate the wilderness of value-based care and how to adapt to the rapidly changing health care environment. We've done a full album (Album 3) on understanding U.S. health care — how we got here, where we are now, the five major trends driving health care and how to use "the Acuity Principle" as a way to predict where we're going.

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One of our favorite things on the HealthBizCast is that our last question to every guest is always “if you could snap your fingers and change one thing in health care, what would it be?” This is our search to find the biggest pain points in health care, and therefore the best potential economic opportunities to change it — we’ve also seen it as a search for potential “low hanging fruit.” For Album 6, we did a whole album recapping the answers to the “snap your fingers” question from each guest interview through that time and it reinforced our belief that many of the best ideas are so obvious that most people overlook them.

We’re excited to continue exploring these themes, and new ones that always arise, as we finish Album 8 and then launch Album 9 in the spring. And, if you know a health care or life sciences executive or thought leader that we should be interviewing, we look forward to hearing from you. We love the business and practice of health care, and we’re always looking for exciting guests to talk about new ways to change health care for the better.

The *10 Minute* HealthBizCast Guests

Paul Keckley
Keckley Report

David Jarrard
Chairman and Co-Founder of Public Relations Firm Jarrard, Inc.

The ***10 Minute*** **HealthBizCast** is available on all streaming platforms.

To sign up for the mailing list and to receive information about when we’re launching new albums, **click here**.

The Latest in Government Audits: Three Lessons for Providers

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From a monumental Supreme Court decision that could reshape the health care industry's regulatory landscape to continued scrutiny by Medicare contractors for Medicare Part A, Part B, and DMEPOS services, recent government audit activity left providers with a roadmap of the government's audit focus, yet uncertainty for how such audits may be conducted or challenged in the coming year. These are three key audit lessons and what providers can expect in the coming year.

Provider Reimbursement Disputes Go Back to 1984 Following Supreme Court's Regulatory Reset

On June 28, 2024, the United States Supreme Court issued its decision in *Loper Bright Enters. v. Raimondo* and *Relentless, Inc. v. Department of Commerce* and overruled *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, in a 6–3 decision that effectively turned back the clock 40 years to when the landmark agency deference case was first decided. The new *Loper Bright* framework poses many questions to the reimbursement landscape and is likely to result in an increase in provider challenges to agency actions.

Many Medicare overpayment determinations and refunds, including those warranted by provider self-audits, are determined by CMS's statutory interpretations and resultant rulemaking and guidance. Following *Loper Bright*, those determinations may be subject to heightened scrutiny. While the relevance and application of *Loper Bright* for many will be fact-dependent, below are some provider considerations

in key reimbursement areas given the new regulatory framework:

1. **Contractor overpayment demands.** While Medicare contractors will continue to have authority to audit providers and subject them to overpayment demands under the statutes, there may exist new opportunities for providers to limit the Medicare contractors' ability to use and rely upon, for example, statistical extrapolations to recover substantial amounts of alleged overpayments from providers. It is foreseeable that providers will seek to challenge the government's use and methods of extrapolation, as they are not based on specific statutory authority. Under *Loper Bright*, the courts may develop their own criteria for when extrapolation may be used and how it should be used.
2. **Settlement potential.** Medicare contractors may now be more willing to utilize the settlement authority conferred upon them by federal law to resolve overpayment demands rather than risk losing during the appeal process.

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3. **Overpayment appeals.** This may be where providers have the most opportunity for successful appeals. given CMS's heavy reliance upon regulations and sub-regulatory guidance to impose overpayment demands. *Loper Bright* provides a stronger basis for providers to push back on these overpayments as administrative and judicial courts no longer defer to CMS where the overpayment determination is standing on regulatory or sub-regulatory guidance alone.

UPICs Are Here to Stay

While there is little current data from CMS or HHS regarding the number of Unified Program Integrity Contractor (UPIC) audits, the government has increasingly relied upon and utilized UPICs to recover alleged overpayments, and there is little reason to doubt this trend will reverse course soon. For example, 2023 saw a significant increase in hospice-related investigations initiated through independent data analysis by UPICs. Similarly, in 2024, the OIG Work Plan included numerous areas where providers can expect increased audit activity by UPICs, including for Medicare Part B payments for skin substitutes, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), Incident-To services, and payments relating to nursing facility services, lower extremity peripheral vascular procedures, clinical laboratory services (for Medicaid reimbursement) and more.

Providers should take these audits seriously and timely respond to UPIC medical record review requests by providing complete and organized medical records. We have seen UPICs become increasingly aggressive in both the number of records requested in such a review (with UPICs often issuing multiple record requests spanning multiple years) and alleged overpayments based on their audits, which frequently include a total derived from a statistical extrapolation. However, rather than simply respond to UPIC requests, providers must proactively try to ensure that their medical record documentation comply with Medicare and Medicaid requirements, which can be accomplished through routine internal self-audits, regular updating of internal policies and procedures, maintenance of an organized mail department and by coordinating with your outside counsel to ensure you are staying informed on the latest developments to Medicare rules and regulations.

Continued Focus on DMEPOS Services

OIG announced its Durable Medical Equipment Fraud and Safeguards in Medicare report in June 2024, and in the following month announced its Followup Review of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided by Suppliers During Inpatient Stays report.

OIG notes that each year, Medicare payments for DMEPOS exceed $7 billion in traditional Medicare alone, and although CMS has several safeguards in place to prevent bad actors from billing DMEPOS in Medicare, fraudulent billing for DMEPOS continues to be a major concern. The OIG alleges that recent cases demonstrate that DMEPOS continues to be a target of fraudulent billing and that new schemes have developed. This planned review will examine the safeguards and monitoring that CMS must use to prevent fraud, waste and abuse, including looking at billing for DMEPOS in Medicare Advantage, specifically by suppliers not enrolled in Medicare fee-for-service. Such review continues a larger trend that Medicare Advantage payments

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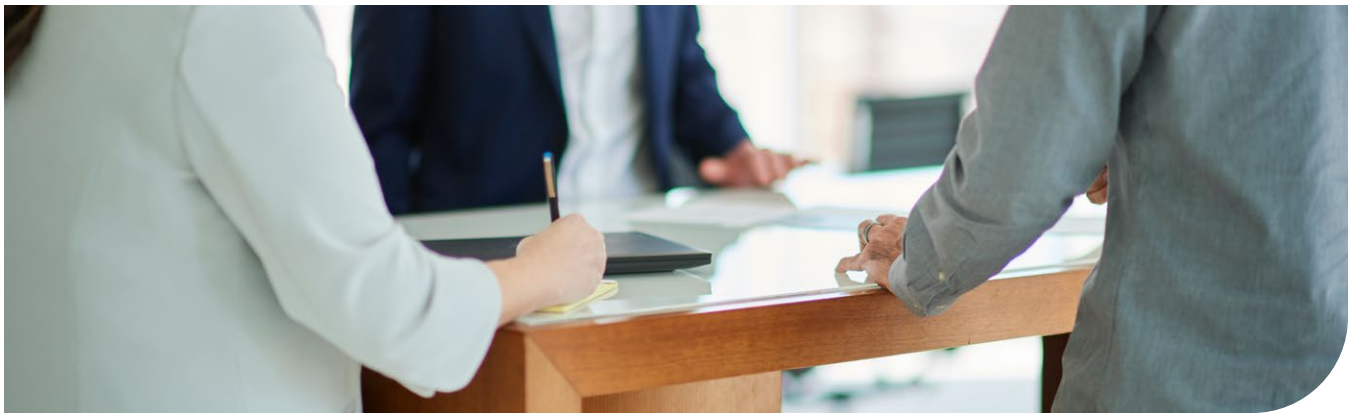
continue to be scrutinized across various federal agencies in levels not seen.

Additionally, OIG's Followup Review appears focused on "overlapping claims" that can occur during a beneficiary's inpatient hospital stay. OIG notes that overlapping claims can happen when an enrollee receives a DMEPOS item during an inpatient stay, but the item is inappropriately billed and paid separately under Medicare Part B, resulting in an overpayment. For this follow-up audit, OIG will review Medicare payments to inpatient hospitals to determine whether DMEPOS claims billed to Part B during the stay met Federal requirements. DMEPOS suppliers and providers who regularly treat patients in acute-care facilities should be prepared for increased audit activity and should perform their own internal reviews to determine whether DMEPOS items provided to patients during inpatient stays at these facilities complied with billing requirements. We encourage such providers to contact Polsinelli for assistance with conducting and managing these internal reviews and to maintain privilege over such reviews.

Finally, these reports follow an increasingly concerning pattern by the DMEPOS Medicare Administrative Contractors (DMEPOS MACs) of issuing Medicare enrollment revocations and/or denials of Medicare enrollment applications based on alleged deficiencies cited during unannounced site visits to DMEPOS supplier locations. While these revocations and denials can disrupt a supplier's operations, our success with assisting suppliers with challenging these revocations and denials demonstrates that a robust compliance program with close internal monitoring can be very effective in preventing and combating such enforcement action. But for large suppliers with numerous locations/Medicare enrollments across the country, we recognize there exists practical challenges to ensure each location always remains compliant. Conducting regular education training sessions with regional compliance leaders and site managers and performing routine internal site inspections can help reduce or eliminate the risk of a finding of noncompliance.

Concluding Thoughts

Providers should begin proactively preparing for potential audits in the areas discussed in this article by working with their internal compliance teams and legal counsel to help identify potential risks and develop strategies to navigate through audits and overpayment demands relating to the same.



Medicaid in 2025: What Stays, What Changes, and How to Prepare

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A new President and CMS Administrator brings opportunities and challenges for Medicaid providers across the country. Change in 2025 is likely to include new philosophies, priorities, and expectations for Medicaid, the largest government payor for health care in America. As we look ahead to Medicaid in 2025, here's what we're watching for:

Rearranging the Building Blocks

At a structural level, we consider what changes a new administration might promote for the overall structure of Medicaid:

1. The Affordable Care Act and Medicaid Expansion

While there is renewed discussion promoting repeal of the ACA, and with it Medicaid Expansion, we think Medicaid Expansion is unlikely to be rescinded:

a. 41 states (including D.C.) have expanded their Medicaid programs under the ACA to cover poor adults, through legislative adoption and ballot initiatives. Where Medicaid expansion has been enacted, it has decreased the number of uninsured individuals and uncompensated care.
b. The ACA has already faced (and largely overcome) numerous legal challenges and is now deeply integrated into the American health care landscape.
c. Medicaid is important and popular in States across the political spectrum.

But significant change in Medicaid financing and administration could have significant impacts on Medicaid providers and beneficiaries.

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2. Medicaid Financing

Medicaid financing could change on a state or federal level, and there are a number of proposals that would likely reduce the funds available to enroll and care for Medicaid beneficiaries.

Block Grants and Per-Capita Caps

Under a block grant structure, states would receive a fixed amount from the federal government, rather than an open-ended match. Block Grants lack flexibility for the number of enrollees or their costs of their care. States that have pursued or received approval for Medicaid block grants or similar capped funding waivers in the past include Oklahoma, Utah, Alaska, and Tennessee. Notably, Tennessee received approval for its block grant funding model — "TennCare III" — in January 2021.

Per-capita caps apply funding and limits on a per-beneficiary basis. This approach limits federal spending but maintains a link to enrollment numbers. Either approaches could threaten adequate funding for coverage and access to care, particularly during an economic downturn or public health crisis, when Medicaid enrollment typically increases. Coverage of discretionary services under Title XIX could be under threat.

Supplemental and Directed Payments

Supplemental and directed payments are specific Medicaid reimbursement programs that increase reimbursement for certain services or providers, such as nursing facilities, hospitals or physicians. These funding mechanisms are highly regulated and may face enhanced scrutiny under the new administration.

State Budget Pressure

As federal funds available during the PHE evaporate, state budget makers may be pressured to replace those federal funds with state money. Cuts to Medicaid reimbursement are effective fundraisers for state legislatures.

Same Questions – Different Approaches

A new administration will also bring different priorities, philosophies, and approaches to perennial Medicaid challenges, such as:

Access to Care Standards and Enforcement

Ensuring access to Medicaid services is challenging regardless of the state, delivery system, or provider type. Medicaid's statutory requirements for access to care haven't changed, but access to care requires funding and a new administration may decrease oversight on access, particularly in a managed care setting.

Revalidation and PHE Unwind

Medicaid revalidation after the Covid-19 PHE resulted in approximately 25 million individuals losing Medicaid coverage since April, 2023. State flexibility to promote continued eligibility and efficient eligibility revalidation may diminish or end. Challenges related to identifying Medicaid beneficiary eligibility and enrollment are likely to continue well into 2025 and will decrease the number of eligible Medicaid beneficiaries who are actually enrolled and entitled to coverage.

Waiver Services and *Olmstead*

The Supreme Court's holding in *Olmstead*, which requires beneficiary access to services in the most integrated setting appropriate to their needs, remains good law. The practical outcome of *Olmstead* is the continued importance of in-home or other community-based care (HCBS) for Medicaid

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beneficiaries needing intensive and/or long-term services. While details are not yet clear, we anticipate possible changes to funding priorities including potential modification to the 80/20 rule for the HCBS workforce.

Work Requirements?

Work requirements to maintain Medicaid eligibility may again be favored by the new administration. Between 2018 and 2022, 22 states either sought or obtained federal approval for work requirements as a condition to receiving Medicaid (Alabama, Arizona, Arkansas, Georgia, Idaho, Indiana, Kansas, Kentucky, Maine, Michigan, Mississippi, Montana, Nebraska, New Hampshire, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Utah, Virginia and Wisconsin). Expedited approvals for states seeking to impose work requirements may be granted by the new CMS Administrator.

Preparing for 2025 and Beyond

While much of the new administration's specific Medicaid policies remain unknown, there are a few steps providers can take to get ready:

1. **Stay Engaged with State Leaders.** Medicaid programmatic and policy developments will first take place at the state level as states request waivers to various federal Medicaid requirements, or state plan amendments necessary to cut reimbursement. Such waivers and reimbursement cuts may be approved by CMS without Congressional action. Early and frequent engagement may promote positive outcomes for providers and beneficiaries.
2. **Prioritize Enrollment Discipline.** Help patients navigate revalidation processes to prevent lapses in coverage and verify current enrollment. Increasing patient education and streamlining eligibility checks can prevent disenrollment.
3. **Plan for Financial Change.** Providers should plan for the impact of Medicaid financing changes including block grants or per-capita limits that could result in reduced coverage and/or reimbursement for covered services. If you receive Medicaid supplemental or directed payments, pay special attention as policy develops on those funding streams.

Our lawyers monitor Medicaid programs and advise Medicaid providers across the country. We anticipate continued change and opportunities to protect Medicaid funds and providers.

Continued Focus on the No Surprises Act and Hospital Price Transparency

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No Surprises Act

Certain aspects of the No Surprises Act (NSA), which was passed in 2020 as part of the Consolidated Appropriations Act of 2021 and ended the practice of "balance billing" by certain nonparticipating providers, has been challenged in litigation throughout 2024, (primarily the Fifth Circuit), which could lead to an eventful 2025.

On August 2, 2024, the Fifth Circuit affirmed[1] the Eastern District of Texas's opinion in *TMA II*, vacating certain rules regarding factors an independent dispute resolution (IDR) entity arbitrator of payment disputes "shall consider" in determining the rate payable. Specifically, the Fifth Circuit affirmed the lower courts vacatur of the rule requiring that the IDR entity must first consider the qualifying payment amount or "QPA"—which is, generally speaking, the health insurer's median contracted rate for the same services—before considering other statutory factors and must also explain their reasoning if they relied on factors other than the QPA. The lower court concluded that this rule impermissibly required the arbitrator to "place a thumb on the scale for the QPA" rather than considering equitable consideration of all factors.

On the other hand, on October 30, 2024, the Fifth Circuit reversed[2] the Eastern District of Texas's ruling in *TMA III*, which focused on other aspects of the rules involving QPA calculations. In *TMA III*, plaintiffs challenged the rule concerning how health insurers calculate QPAs, asserting that the rule as drafted artificially decreased QPAs. The district court held that certain rates that must be included in the QPA calculation, such as rates for services that are never performed by the provider (i.e., "ghost rates"), were invalid as arbitrary and capricious. But the Fifth Circuit reversed this holding, among a few others, upholding the Government's methodology for calculating the QPA via so-called "ghost rates." Other provisions reversed by the Fifth Circuit included the exclusion of case specific agreements, and the exclusion of bonus and incentive payments into the consideration of the QPA.

Lastly, also on the Fifth Circuit's docket is *Guardian Flight*, an appeal from the Northern District of Texas's holding[3] that the NSA does not confer private plaintiffs with an express or implied cause of action to enforce IDR awards through the courts. Notably, the Government filed an amicus brief in support of the plaintiff's position that the NSA *does* confer a private cause of action to enforce an IDR award and convert it to a final judgment. There are similar ongoing cases in federal district and state courts around the country.

1. *Tex. Med. Ass'n v. HHS*, 110 F.4th 762 (5th Cir. 2024)
2. *Tex. Med. Ass'n v. HHS*, 120 F.4th 494 (5th Cir. 2024)
3. *Guardian Flight, LLC v. Health Care Serv. Corp.*, 3:23-CV-01861-B, 2024 WL 2786913 at *5 (N.D. Tex. May 30, 2024)

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We are still waiting on a final rule governing IDR operations that could make IDR process improvements, stemming from the proposed rule titled *Federal Independent Dispute Resolution Operations*. The rule was proposed in November 2023, and the notice and comment period closed in January 2024. Other aspects of the NSA have yet to be implemented, moreover, including requirements related to transparency in plan or insurance cards, advanced explanation of benefits, provider directory accuracy and continuity of care. However, with the changing administration and many new changes coming to the heads HHS and CMS, we expect an even further delay is possible in any implementation of the NSA and of the final rule governing IDR operations.

From a litigation standpoint, we are expecting a decision in the *Guardian Flight* case discussed previously. Oral argument before the Fifth Circuit occurred on February 24, 2025. Additionally, the plaintiffs-appellees in *TMA III* filed a petition for rehearing *en banc* on December 16, 2024, which has yet to be adjudicated.

The change of administration, along with additional anticipated court decisions on various NSA challenges in 2025, particularly in light of the movement away from agency deference, suggest potential uncertainty in how questions about the NSA will develop. For example, it remains to be seen whether the incoming Trump Administration's DOJ will continue the previous administration's support for a private cause of action to enforce IDR awards.

Federal Hospital Price Transparency

In 2024, we saw deadlines for implementation of certain hospital price transparency measures, such as the requirement to post a machine-readable file (MRF) of standard charges by July 1, 2024. By January 1, 2025, all hospitals were required to amend their MRF to include additional data elements, such as an "estimated allowed amount."

On the horizon for 2025, we anticipate enforcement efforts will ramp-up on ensuring hospitals and have complied with their price transparency obligations. On October 2, 2024, the U.S. Government Accountability Office (GAO) issued a report which highlights the lack of assurance that the pricing data hospitals have published are complete and accurate.[4] In the report, the GAO recommended that HHS implement enforcement mechanisms as it deems necessary to ensure the accuracy and completeness of hospital pricing data.

The Office of the Inspector General (OIG) published a report a month later summarizing a recent survey of a set of hospitals to assess compliance with price transparency requirements.[5] The OIG found 14% of the hospitals it surveyed failed to fully comply with the requirements associated with displaying shoppable services in a consumer-friendly manner, and 34% failed to fully comply with the requirements for publishing comprehensive MRFs. Overall, the OIG estimates that almost half of all hospitals failed to fully comply the new rules.

Most recently, on February 25, 2025, President Donald Trump issued an Executive Order directing various federal agency heads to make immediate substantial efforts towards enforcement of the

4. "CMS Needs More Information on Hospital Pricing Data Completeness and Accuracy," US GAO Report No. GAO-25-106995, October 2, 2024, https://files.gao.gov/reports/GAO-25-106995/index.html
5. "Not all Selected Hospitals Complied with the Hospital Price Transparency Rule," HHS-OIG Report No. A-07-22-0618, November 5, 2024, https://oig.hhs.gov/reports/all/2024/not-all-selected-hospitals-complied-with-the-hospital-price-transparency-rule/

price transparency rules.[6] Within 90 days following this Order, we should expect to see a flurry of additional agency action pursuant to this Executive Order which may include additional proposed rulemaking, publication of additional sub-regulatory guidance, and increased enforcement actions.

6. "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information," The White House Presidential Action, February 25, 2025, https://www.whitehouse.gov/presidential-actions/2025/02/making-america-healthy-again-by-empowering-patients-with-clear-accurate-and-actionable-healthcare-pricing-information/

What to Know About Home Health & Hospice Reimbursement Updates for 2025

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As part of the CY 2025 Home Health Prospective Payment System (PPS), and the CY 2025 Hospice PPS final rules (respectively the "2025 Home Health Final Rule" and "2025 Hospice Final Rule") CMS incorporated important updates that went into effect Jan. 1, 2025, Below is what you need to know.

2025 Home Health Final Rule

Home Health Payment Updates

Overall, CMS estimated a 0.5% payment rate update for home health providers in 2025 (ca. $85M), significantly better than the anticipated rate cuts from the proposed rule. This update was derived from a payment update of 2.7%, offset by a 1.8% decrease to the national, standardized 30-day payment rate and a 0.4% decrease from the updated fixed dollar loss ratio.

With regard to PDGM and the 30-day payment unit, CMS finalized a permanent adjustment of -1.975% (half of the calculated permanent adjustment of -3.95%) to the CY 2025 home health payment rate and indicated they finalized a methodology to satisfy statutory requirements to reduce the need for future large permanent adjustments and slow temporary payment adjustments (recognizing a total adjustment of ca. 8.79% over the last three years; CY 2023 [-3.925%] and CY 2024 [-2.890%]).

These payment rate adjustments were in addition to: recalibration of PDGM case-mix weights; updates to LUPA payment adjustments, functional impairment levels, and comorbidity adjustment subgroups; adoption of recent OMB CBSA adjustments to the home health wage index (capped at no more than a 5% reduction from the prior year); add-on factors and updates to the OT, PT, SLP and skilled nursing LUPA; and updates to the fixed-dollar loss ratio for outlier payments.

New Home Health Condition of Participation (CoPs)

The 2025 Home Health Final Rule also implemented the following changes to the home health CoPs:

- CMS implemented a new standard that requires HHAs to develop, implement, and maintain an acceptance-to-

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service policy applied to each prospective patient referred for home health care. The new policy must address, the HHA's capacity to provide patient care, including the following: the anticipated needs of the prospective patient, the HHA's case load and case mix, the HHA's staffing levels, and the skills and competencies of the HHA staff. CMS indicated it selected these elements to inform an HHA's assessment of its capacity and determine its suitability to meet the anticipated needs of the prospective patient.

- CMS finalized a policy that HHAs be required to make public on at least an annual basis information about the services offered by the HHA and any limitations related to the types of specialty services, service duration, and service frequency. CMS indicated it believes these changes will facilitate a patient or family's search for an HHA to meet their needs.

Expanded Collection of Social Determinants of Health (SDOH) in OASIS

In the 2025 Home Health Final Rule CMS placed an increased emphasis on social determinants of health, acknowledging their critical role in patient outcomes, and benefits from tracking such measures. As part of that emphasis, CMS finalized the collection and submission of four new items as standardized patient assessment data elements related to social determinants of health in OASIS and modified one other (which is delayed until the CY 2027 HH QRP). The four new assessment items include the following items: living situation (housing stability), food (food security), utilities (energy security), and the modified element is related to the already existing transportation item. CMS indicated its belief that collection of this information has the potential to affect treatment preferences and goals of patients and their caregivers and may help HHAs offer assistance by connecting patients and their caregivers with social support programs, in addition to assisting in efforts to improve the quality of care provided to beneficiaries.

Additional Updates

In addition to the above updates, as part of the 2025 Home Health Final Rule CMS expanded the definition of "new provider or supplier" in connection with the 'enhanced oversight' program to include providers and suppliers that are reactivating their Medicare enrollments.

2025 Hospice Final Rule

Payment Policy Updates

Hospices enjoyed a 2.9% increase in payments for 2025 (ca. $790M), except for agencies that failed to submit the requisite quality data. Those agencies experienced -1.1% payment rate update after assessment of a 4% penalty.

The statutory aggregate cap for 2025 was set at $34,465.34 which reflects the 2.9% payment update to the 2024 aggregate cap.

In addition to these payment updates, and similar to home health, CMS finalized its policy to adopt the most recent OMB statistical area delineations revising the existing core-based statistical areas (CBSA). In finalizing this policy CMS limited the impact to agencies experiencing a change in their geographic wage index from 2024 to a maximum 5% reduction, which is consistent with the 5% cap on any decrease to the wage index from the prior year. As a result, some agencies found themselves in rural or urban CBSAs that they were not in before with no opportunity to request a reclassification (unlike hospital providers).

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Implementation

Starting October 1, 2025, CMS will implement the Hospice Outcomes and Patient Evaluation tool (HOPE Tool), replacing the Hospice Item Set (HIS). The HOPE Tool is a standardized set of assessment items that will be used to collect data on various aspects of hospice care. CMS stated its goal for the HOPE Tool was to be "more comprehensive" than HIS. Key features include:

1. Patient-Centered Focus: capturing the experiences and outcomes of hospice patients, with the goal of ensuring that care is tailored to their needs and preferences. CMS believes this will help hospices to better understand how to improve care delivery and patient satisfaction.
2. Data Collection: CMS plans to utilize this data on patient experiences and outcomes to inform quality improvement initiatives and performance measurement within the hospice setting. This includes additional data collection timepoints – providers will be required to submit data at the time of admission, up to two additional update visits following admission and at discharge.
3. Integration with Existing Quality Measures: to complement existing quality measures in hospice care and provide a more comprehensive view of the quality of care being delivered.

Additional Updates

In addition to the above updates, the following are also notable developments, among others:

- Within the 2025 Hospice Final Rule CMS reported on comments received about the potential for future implementation of enhanced payments for high intensity palliative care services (e.g., certain cancer treatments, radiation, blood transfusions, etc.) that may be considered therapeutic yet can play an important role in managing a patient's pain symptoms. CMS relayed comments received and indicated they would continue to consider development of additional payments for such services, whether through increased per diem payments, add on payments or other modalities.;
- CMS provided technical clarifications to the hospice Notice of Election and Election Statements to further aid in understanding as to how they differ;
- CMS modified its position with regards to deactivation of a hospice agencies billing privileges for non-submission of claims and reduced the window from 12 to six months;
- CMS extended the ability to use telehealth as a means to complete the hospice face-to-face evaluation.

If you have questions, comments or would like additional details in regard to these developments or others, please reach out to Ross E. Sallade or your favorite Polsinelli attorney.

CMS Updates its Interpretation of the 60-Day Overpayment Rule

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CMS finalized new overpayment updates in the CY 2025 Medicare Physician Fee Schedule (MPFS) Rule that provides the biggest changes to the so-called "60-Day Overpayment" Rule in almost ten years (since 2016). The original 60-Day Overpayment Rule implemented the statutory requirement for reporting and returning overpayment to avoid liability under the False Claims Act. While the changes may not appear significant, they may require an update to your overpayment and/or credit balance policies.

Background of 2016 60-Day Overpayment Rule

As background, the 60-Day Overpayment Rule stems from a section of the Affordable Care Act, which required providers to report and return claims-based overpayments under Medicare and Medicaid within 60-days of identifying it. Failure to return an overpayment could bring rise to False Claims Act liability.

In the 2016 rulemaking, CMS defined an overpayment as "identified" when a provider had or should have, through the exercise of "reasonable diligence," determined that it received an overpayment and quantified the amount of the overpayment. In preamble language, "credible information" supporting a belief that a provider received an overpayment triggered a duty to conduct "reasonable diligence" over a period not to exceed six months to determine whether an overpayment existed. Once the provider identified and quantified the overpayment, it had 60 days to return the overpayment.

CMS made these changes in response to court opinion in *UnitedHealthcare Insurance Co v. Azar* regarding application of the 60-Day Overpayment Rule to Medicare Part C plans, but CMS explains in the current rulemaking that the same reasoning applies across all parts of Medicare. So, to ensure consistency, CMS updated the 60-Day Overpayment Rule applicable across the board.

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What Changed in the 2025 MPFS Final Rule?

Although the changes may seem more in language than in substance, providers should nonetheless know and comply with them. The primary changes CMS made are as follows:

Replaced the "reasonable diligence" standard with the "knowing" and "knowingly" standard identified in the original ACA statute and the False Claims Act. As such, an overpayment will now be "identified" when a provider

1. Has actual knowledge of an overpayment;
2. Acts in deliberate ignorance of the truth or falsity of information regarding the overpayment; or
3. Acts in reckless disregard of the truth or falsity of information regarding the overpayment.

01

Described an overpayment as "identified," thus triggering the 60-Day clock when the provider meets the "knowing" or "knowingly" standard, even if they have not yet quantified it in its entirety.

02

Redefined the timeline for the 60-day clock. If the provider knows of an initial overpayment but believes that there may be additional related overpayments that arise from the same or similar cause or reason, the 60-day clock is suspended, and the provider has 180 days to complete a timely and good-faith investigation. At the earlier of 180 days or the date the investigation is complete, the 60-day clock recommences.

03

These changes do reflect a different way of thinking about the 60-Day Overpayment Rule for many providers. We recommend reviewing and revising policies and practices related to potential overpayments in line with this new rulemaking.

IPPS Highlights

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Changes to Payment Rates

For IPPS in FY 2025, hospitals that successfully participate in the Hospital Inpatient Quality Reporting program and are meaningful electronic health record users will receive a 2.9% increase in operating payment rates--reflecting a 3.4% market basket increase reduced by a 0.5 percentage point productivity adjustment. CMS expects Medicare payments to increase $2.9B over 2024.

For LTCH PPS, CMS is increasing the standard payment rate by 3.0% for FY 2025, with LTCH PPS payments for discharges paid the LTCH standard payment rate expected to increase by approximately 2.0% or $45 million.

Hospital Quality Reporting

The FY 2025 IPPS/LTCH PPS final rule significantly modified hospitals' existing quality measurements for the Hospital Inpatient Quality Reporting (IQR). Currently, the Hospital IQR Program requires reporting of six total electronic clinical quality measures (eCQMs): three that are selected by CMS, and three that are self-selected by each hospital. Beginning in CY 2026, hospitals will be required to report on eight total eCQMs (five selected by CMS). The number of eQCMs on which hospitals must report will steadily increase until CY 2028, when hospitals will be required to report on 11 total eCQMs, with eight selected by CMS.

First, CMS adopted seven new quality measures:

1. Hospital Harm – Falls with Injury;
2. Hospital Harm – Postoperative Respiratory Failure;
3. Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications;
4. Patient Safety Structural Measure;
5. Age Friendly Structural Measure;
6. Catheter-Associated Urinary Tract Infection Standardized Infection Ratio; and
7. Central Line-Associated Bloodstream Infection Standardized Infection.

The Patient Safety Structural Measure and Age Friendly Structural Measure will begin with the CY 2025 reporting period, the Thirty-day Risk-Standard Death Rate Measure will begin with the July 1, 2023 – June 30, 2025 reporting period, and the other Measures will begin with the CY 2026 reporting period.

Second, CMS finalized two changes to current policies related to data validation:

1. Modifications to the Global Malnutrition Composite Score eCQM which will add patients 18-64 to the current unit of patients 65 years or older; and
2. Modifications to the Hospital Consumer

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Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure, which will refine the current HCAHPS Survey.

Third, CMS removed five existing quality measures:

1. Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Acute Myocardial Infarction;
2. Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure;
3. Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia;
4. Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty; and
5. CMS PSI-04 Death Among Surgical Inpatients with Serious Treatable Complications.

Finally, CMS will continue voluntary reporting of core clinical data elements (CCDEs) after initial results of voluntary reporting demonstrated that many hospitals would not have met the reporting thresholds for CCDEs and therefore would have been subject to payment reduction.

Transforming Episode Accountability Model (TEAM)

Starting January 1, 2026 and running for five years, all acute care hospitals located within defined areas (and those that wish to voluntarily participate) will be required to participate in CMS's Transforming Episode Accountability Model (TEAM), which requires participating hospitals to coordinate care for patients undergoing certain surgical procedures or connect such patients to primary care services. TEAM will apply to all non-excluded Medicare Parts A and B items and services, beginning with either an inpatient hospitalization or outpatient procedure and ending 30 days after hospital discharge, for the following procedures furnished to Medicare FFS beneficiaries: lower extremity joint replacement, surgical hip femur fracture treatment, spinal fusion, coronary artery bypass graft, and major bowel procedure. CMS will establish preliminary target prices for TEAM participants, the TEAM participants will continue to bill Medicare-fee-for-service, and CMS will in turn determine whether there was an overpayment (because a participant spent more than the target price) or underpayment (because a participant spent less than the target price), also consider the quality measures of readmissions, patient safety and patient-reported outcomes. There are three different risk-level tracks that hospitals may choose. Additionally, CMS included a new "decarbonization and resilience" voluntary reporting aspect to the TEAM model, which likely will include reporting on greenhouse gas emissions from the hospital.

New Technology Add-on Payment (NTAP)

Under the IPPS, the New Technology Add-on Payment (NTAP) is designed to accommodate the lag in updates to the MS-DRG to reflect the increased costs of new medical services or technologies. A medical product may not be considered "new" if it is substantially similar to existing FDA approved products that have been on the market for two to three years. For FY 2025, the cutoff date for determining if a product is "new" will move from April 1 to October 1. Also for FY 2025, new products must either have FDA approval or marketing authorization at the time the NTAP application is submitted to CMS.

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Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

In an effort to combat issues related to shortages of essential medications and to increase the resilience of the nation's drug supply chain, CMS will establish a separate payment under the IPPS for the estimated additional costs of establishing and maintaining access to a six-month buffer supply of one or more of 86 essential medicines. Hospitals are eligible beginning with cost reporting periods on or after October 1, 2024. To limit demand driven shocks to the overall supply chain, the payments are limited to small, independent hospitals with 100 or fewer beds. In order to qualify for the payment, the hospital must establish the buffer supply prior to a medication experiencing a shortage. A hospital remains eligible for the payment if the supply drops below a 6-month supply if the hospital is actively using the supply to address a current shortage. The payment is designed to cover the costs associated with establishing the buffer supply, but not the costs of the medication itself.

New Graduate Medical Education Slots

The Consolidated Appropriations Act of 2023 added 200 medical residency slots, requiring that at least 100 of those slots go to psychiatry or psychiatry subspecialty training. At least 10% of all slots must be distributed to rural or rural-designated hospitals, hospitals that exceed their resident caps, hospitals with new medical schools and those hospitals in designated Health Professional Shortage Areas. Further, CMS will distribute at a maximum, only one FTE slot to each qualifying applicant hospital if there are 200 or fewer applicants and less than one FTE to each qualifying hospital if there are greater than 200 applicant hospitals. The application deadline was March 31, 2025. Qualifying recipient hospitals will be notified of any slot distributions by Jan. 31, 2026, to be effective July 1, 2026.

Changes to DSH/ Uncompensated Care

The FY 2025 Uncompensated Care pool is $5.7B, down from $5.9B in 2024. CMS believes that the uninsured percentage for Factor 2 is decreasing, suggesting that these numbers account for individuals dropped from the Medicaid rolls post-COVID because CMS believes they will have coverage from another source such as the ACA. Interim UC payments for discharge for 2025 will be two year average (remove covid year 2021) and 2026 will return to three-year average in 2025.

Wage Index

CMS adjusts the IPPS payment to account for geographic area differences in the cost of hospital labor, known as the wage index. CMS is adopting the CBSA delineations from the OMB July 21, 2023, Bulletin based on 2020 Census Bureau data. As a result, 53 counties that are currently urban will become rural, impacting 33. Additionally, 54 counties currently designated as rural are now urban, impacting 24 hospitals. This change also must be considered for hospital types that depend on a rural designation — critical access, sole community and Medicare-dependent — and will become eligible for capital DSH is they meet the 100-bed requirement. If your hospital type (CAH, SCH, MDH) requires a rural designation, that status will be lost for hospitals move to the urban classification unless the hospital applies for a rural redesignation.

Medicare Physician Fee Schedule

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The 2025 Medicare Physician Fee Schedule Final Rule included an update to the Relative Value Unit Conversion Factor, several new and updated payment policies under Medicare fee-for-service, and two significant new developments under the Medicare Shared Savings Program.

2025 RVU Conversion Factor

The 2025 RVU conversion factor will be set at $32.35, a decrease of $0.94 (or 2.83%) from the 2024 conversion factor. CMS explained that the change incorporates the 0% overall update required by law, the expiration of the temporary 2.93% increase for 2024, and a 0.02% adjustment related to changes in work relative value units for some services.

Fee for Service Payment Policy Updates

Advanced Primary Care Management

CMS has promulgated new codes and payments for Advanced Practitioner Care Management services (APCM). The new APCM codes come because of CMS' determination that primary care practitioners needed additional compensation for time spent on care management and coordination independent of patient evaluation and management visits. The new codes are for APCM services provided by clinical staff who are directed by a physician or other qualified health care professional who is responsible for all of the patient's primary care. The codes generally have the

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same basic requirements for billing, but they vary based on the patient complexity:

1. Patients with one or fewer chronic conditions (HCPCS G0556);
2. Patients with two or more chronic conditions (HCPCS G0557); and
3. Patients with two or more chronic conditions and who are Qualified Medicare Beneficiaries (HCPCS G0558).

CVD Risk Assessment

CMS provides new codes and payments for Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment and management services. The new codes will be for:

1. The administration of standardized, evidence-based ASCVD risk assessment for patients with ASCVD risk factors on the same date as an evaluation and management visit, not more often than every 12 months (HCPCS code GCDRA); and
2. ASCVD risk management services for a patient without a current ASCVD diagnosis, but with a medium or high risk for Cardiovascular Disease (CVD) as determined by a previous ASCVD risk assessment (HCPCS code GCDRM).

The proposal to add ASCVD risk management and risk assessment codes came from the CMS Innovation Center's evaluation of the Million Hearts Cardiovascular Disease Risk Reduction model. In its evaluation of the model, CMS concluded that payments for cardiovascular risk assessment and cardiovascular care management would reduce the rate of death in the disease.

Caregiver Training Services (CTS)

CMS added reimbursement for caregiver training services (CTS) related to direct care services and supports under three new HCPCS codes. Training topics for CTS could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. CMS also proposed new two new HCPCS codes for caregiver behavioral management and modification training for caregivers of individual patients. In addition, CMS allowed for CTS to be provided via telehealth in certain circumstances.

Supervision of outpatient Therapy Services in Private Practices

CMS allowed for reimbursement of general supervision—as opposed to direct supervision—of physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) by physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs). CMS commented that the direct supervision requirements had the unintended consequence of limiting access to therapy services and meant for the new general supervision standards to allow for greater flexibility in the provision of therapy services. (General supervision means that the supervising therapist must be available by telecommunication, whereas direct supervision means that the supervisor must be in the same office suite at the time the therapy services are provided.)

Certification of Therapy Plans of Treatment with a Physician or NPP Order

CMS finalized amendments meant to reduce the administrative burden on therapists requiring signed certification of treatment plans in order to obtain reimbursement for therapy services. Specifically, the amendments would allow a signed and dated order/referral form from a physician or nonphysician provider (NPP), combined with

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documentation of such order or referral in the patient's medical and evidence in the medical records that the therapy plan was transmitted or submitted to the physician or NPP, to be considered sufficient to demonstrate the physician or NPP's certification of the required conditions for provision of therapy services. CMS would effectively consider the signature on the order or referral as equivalent to a signature on the plan of treatment.

Drugs and Biologicals

Effective January 1, 2025, the following updates to drugs and biological paid under Medicare Part B went into effect:

- CMS clarified the rules requiring manufacturers of certain single-dose containers or single-use package drugs to provide refunds for discarded amounts. CMS finalized clarifications to several policies that were implemented in CY 2023 and CY 2024 with regards to section 90004 of the Infrastructure Investment and Jobs Acts such as: excluding drugs for which payment has been made under Part B for fewer than 18 months from the definition of refundable drugs, and identifying single-dose containers.

  Furthermore, the rule also

  1. Finalizes the requirement to use the JW modifier for single-dose container drugs if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process and
  2. Classifies injectable drugs with a label of 2 mL or less as single-dose containers.

  Additionally, billing and payment codes that describe products currently referred to as skin substitutes will not be counted when identifying refundable drugs for calendar quarters in 2025.
- Positive manufacturer's Average Sales Price (ASP) data are considered "available" and negative or zero manufacturer's ASP data are considered "not available" for purpose of CMS calculating a payment limit.
- With regard to the payment of radiopharmaceuticals in the physician office, payment methodologies used by a MAC prior to the MMA may continue to be used.
- In an effort to reduce the barriers for those receiving immunosuppressive therapy/drugs, CMS included certain compounded formulations of FDA-approved drugs that have approved immunosuppressive indications in the immunosuppressive drug benefit, or for use in conjunction with immunosuppressive drugs, or that have been determined by a MAC to be reasonable and necessary to prevent or treat rejection of a transplanted organ or tissue.
- Blood clotting factor treatments are covered under Medicare and blood clotting factors must be self-administered and must not be therapies that enable the body to produce clotting factors and do not directly integrate into coagulation cascade to be considered clotting factors for which the furnishing fee applies.

Evaluation and Management Service Complexity Add-On Code

CMS has updated its payment policies to permit the office/outpatient E/M complexity add-on code (G2211) to be billed even when the underlying E/M code is billed on the same day as an annual wellness visit, vaccine administration, or any other Medicare Part B preventive service. In previous years, the add-on code could not be used when the underlying E/M code was billed on the same day as any other procedure.

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Colorectal Cancer Screening

CMS has expanded Medicare coverage of colorectal screening by adding CT colonography and blood-based biomarker screening tests. At the same time, CMS removed coverage of barium enemas as a colorectal cancer screening modality as it is rarely used and no longer recommended as an evidence-based screening method.

Medicare Shared Savings Program

In addition to modifying its financial calculation methodology to account for the impact of improper payments and to exclude payment amounts for "significant, anomalous, and highly suspect" billing activity, CMS finalized two major changes to the MSSP.

Prepaid Shared Savings

ACOs that have a history of earning shared savings may apply to receive prepaid shared savings. ACOs that are accepted in the program will receive advances on earned shared savings that can be used to make investments that will aid beneficiaries, including beneficiaries in underserved communities. Those ACOs receiving advances must spend at least 50% on direct beneficiary services that would not otherwise be reimbursable under Medicare fee-for-service, and that are evidence based and medically appropriate based on clinical and social risk factors.

Health Equity Benchmark Adjustment

CMS is establishing a Health Equity Benchmark Adjustment to help encourage ACOs to serve more underserved communities, and to encourage those ACOs that serve a higher proportion of underserved communities to remain in the MSSP. For eligible ACOs, CMS will adjust the benchmark based on the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy or who are dually eligible for Medicare and Medicaid.

Skilled Nursing Facility Update

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

Enrollment Updates

On October 1, 2024, CMS published a new **Skilled Nursing Facility** (SNF) Attachment on the Form CMS-855A that seeks disclosure of an expanded array of ownership and control interests as part of the facility's enrollment records. The new attachment was immediately effective for all new enrollees, revalidations, reactivations and changes of ownership. Furthermore, in the final quarter of 2024, CMS issued off-cycle revalidation requests to all SNFs requiring the facility's submission of the newest version of the Form 855A – which includes the SNF ownership disclosure attachment.

The expanded ownership and control interests included in the SNF's enrollment record now include the following individuals and entities, as well as the facility's ownership;

- Each member of the SNF's governing body;
- Each person or entity who is an officer, director, member, partner, trustee, or managing employee (as defined in 42 C.F.R. § 424.502) of the SNF;
- Each person or entity who is an Additional Disclosable Party (ADP) of the SNF; and
- The organizational structure of the SNF and each ADP with a description of the relationship of each ADP to the facility and to one another.

An ADP is broadly defined as any person or entity who

1. Exercises operational, financial, or managerial control over the SNF or a part thereof, or provides policies or procedures for any of the SNF's operations, or provides financial or cash management services to the SNF; and/or
2. Leases or subleases real property to the SNF, or owns a whole or part interest equal to or exceeding 5% of the total value of such real property; and/or
3. Provides management or administrative services, management or clinical consulting services, or accounting or financial services to the facility.

Although CMS has published a list of examples, each SNF will need to consider who and what qualifies as an ADP. Examples include management companies, accountants, clinical consultants, lenders, financial advisors, investment managers, public relations firms, and/or marketing/ advertising firms.

Although many of the newly disclosable parties will be third parties and thus, not under the facility's control, SNFs are required to use maximum reasonable efforts to secure the required ownership information and organizational charts of these third parties.

For more information about the new Form CMS 855A SNF Attachment, please explore the frequently updated CMS guidance, here.

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FY2025 SNF PPS

On July 31, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a final rule updating Medicare payment policies and rates for skilled nursing facilities under the Skilled Nursing Facility Prospective Payment System (SNF PPS) for fiscal year (FY) 2025.

You can find the entirety of the Final Rule, here.

The final rule includes the following noteworthy updates:

- Updated SNF Payment Rates – Updated payment policies are expected to yield a 4.2% increase in Medicare Part A payments to SNFs in FY 2025, which accounts for approximately $1.4 billion in increased payments.
- Changes to Patient Driver Payment Model ICD-10 Code Mappings- CMS made several changes to the PDPM ICD-10 code mappings for providers to more accurately identify the primary diagnoses applicable to a resident's Part A SNF stay.
- Enforcement Changes - CMS expanded the type of Civil Monetary Penalties (CMPs) that can be imposed to allow for more per instance and per day CMPs to be imposed for deficiencies cited during the same survey. Previously, enforcement policies prohibited per-day and per-instance penalties from being imposed for deficiencies identified during the same survey, and per-instance penalties could not be imposed concurrently for the same deficiency. CMS has explained this change is meant to give CMS greater flexibility to impose penalties in a manner that more directly reflects the health and safety impact on residents and incentivizes permanent correction.
- Quality Reporting Changes – CMS finalized updates to the SNF Quality Reporting Program to add four new social determinants of health (SDOH) in QRP reporting, beginning with the FY 2027 SNF QRP (calculating from residents admitted on and after October 1, 2025). The stated intent of these new and amended SDOH items is to better account for adverse social conditions that negatively impact health outcomes. The changes address a resident's living situation, food, utilities, and transportation. Facilities that fail to comply with these new reporting program requirements are subject to a 2%-point reduction in the annual payment update.
- Value-Based Purchasing (VBP) Program Updates – CMS finalized its plan to adopt measure selection, retention and removal policies for the VBP program. Administrative changes were also made to allow CMS to update previously finalized VBP measures through a sub-regulatory process.

The Use of Artificial Intelligence in Reimbursement Disputes

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Guidance Governing the Use of AI in Post-Payment Reviews and Health Care

The use of generative artificial intelligence (AI) tools in post-payment reviews is increasingly being adopted by payors attracted by its promises of savings and speed. But at what cost? Claimants are exposing the lack of transparency in how some of these AI tools make determinations, denying legitimate claims without human review. The government has yet to issue guidance specifically regarding the use of AI in post-payment reviews. Normally, we would look to other guidance to find reasonable goalposts and standards, but the rapid movement by the current administration exacerbates the challenge.

On October 30, 2023, then President Biden issued an "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,"[1] (EO 114110) setting forth guiding principles and priorities for government agencies' use of AI. At the direction of EO 114110, on April 29, 2024 the Secretary of the U.S. Department of Health and Human Services (HHS) published an "AI Plan,"[2] setting forth non-mandatory recommendations for the use of AI for automated and algorithmic systems.

The Centers for Medicare and Medicaid Services (CMS) similarly issued, among other guidance, a "CMS Artificial Intelligence Playbook"[3] as well as guidance on February 4, 2024 related to the use of AI by Medicare Advantage plans in making coverage determinations and in pre-authorizations and utilization management.[4]

Across these various guidance documents, key principles included that the use of AI be: "fair and impartial; transparent and explainable; responsible and accountable; robust and reliable; private; and safe and secure."[5]

On January 23, 2025, President Trump issued an executive order revoking EO 14110, and directing the Assistant to the President for Science and Technology, the Special Advisor for AI and Crypto, and the Assistant to the President for National Security Affairs, in coordination with other heads of executive departments and agencies (collectively, the New Leadership), to develop and submit to the President a new artificial intelligence plan.

1. EO 14110; https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence
2. https://www.hhs.gov/sites/default/files/public-benefits-and-ai.pdf
3. https://ai.cms.gov/assets/CMS_AI_Playbook.pdf
4. https://www.aamc.org/media/74896/download?attachment
5. https://ai.cms.gov/

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Titled "Removing Barriers to American Leadership Artificial Intelligence"[6] EO 14179 sets forth that "it is the policy of the United States to sustain and enhance America's global AI dominance in order to promote human flourishing, economic competitiveness, and national security."

Additionally, the New Leadership have been tasked with reviewing all policies, directives, regulations, orders, and other actions taken pursuant to the revoked EO 14110 and as applicable, suspend, revise, or rescind such actions. HHS' AI Plan and CMS' Artificial Intelligence Playbook have been removed from their respective websites, with nothing currently filling that gap. The sudden change is not merely moving the goalposts. We are on high alert—claimants may have just been unceremoniously tossed into a very different game.

Case Law Challenging the Use of AI

Over the past couple of years, litigants have been increasingly challenging Medicare Advantage (MA) plans' improper use of AI in coverage determinations. Several recent cases include *Kisting-Leung v. Cigna*, Case. No. 23-at-00698 (E.D. Calif. July 24, 2023) and *Est. of Lokken, [6]et al. v. UnitedHealth Grp.,* Case No. 0:23-cv-03514 (D. Minn. Nov. 14, 2023), both of which are challenging the alleged improper denial of services solely through AI-based analytics and not based on a human evaluation. In *Est. of Lokken*, the court recently partially denied UnitedHealthcare's motion to dismiss, and has allowed Plaintiffs' breach of contract and breach of implied covenant of good faith and fair dealing claims to proceed.

Further, in the first case of its kind, *Pinnacle Medical Solutions, LLC v. La. Healthy Connections,* Case. No. 3:24-cv-00430 (M.D. La. May 31, 2024), plaintiffs have challenged a Medicaid Managed Care Organization's (MCO) improper use of AI to perform post-payment review of medical records, without sufficient human oversight that generated improper denial bases used to assert an extrapolated overpayment. Among other things, plaintiffs allege that AI hallucinated the existence of documentation never produced and denied claims based upon policies not applicable to the type of claim under review.

Many MA plan and MCO contracts have arbitration dispute resolution provisions, so other lawsuits challenging the use of AI may be in arbitration. In fact, the Pinnacle case is currently subject to arbitration due to such a provision. Nevertheless, these AI challenges implicate constitutional due process issues that are best resolved by federal courts.

Government Investigation of Providers' Use of AI

While many providers are wrestling with payors' use of AI tools to limit services or deny services provided, the Department of Justice (DOJ) is taking an active role in investigating providers' use of AI.

The current focus is on AI tools that replace activities traditionally within the scope of physicians or mid-levels (e.g., review referring physicians' medical records to gather medical history to determine current treatment) and medical coding and billing functions (e.g. AI tools that review physician notes and provide suggested codes for billing).

While many of these investigations are in early stages, there is significant concern from the government where providers are

6. "Removing Barriers to American Leadership in Artificial Intelligence," The White House Presidential Action, January 23, 2025, https://www.whitehouse.gov/presidential-actions/2025/01/removing-barriers-to-american-leadership-in-artificial-intelligence/

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dramatically increasing billing as a result of supposed efficiencies gained from AI tools that have taken over tasks that are essential the conditions of payment.

The Admissibility of AI Evidence

There is currently no case law squarely addressing the admissibility of AI evidence in federal courts. However, top scholars in this area contend the existing rules of evidence should be used and should be sufficient to handle issues regarding AI as evidence.[7] Likewise, existing case law should also be used to challenge due process and evidence-based issues.

Nonetheless, until courts have a better understanding of how to handle the evidentiary value of AI determination and resolve the issues about its validity and reliability, the admissibility of AI evidence remains in question and at courts' discretion.

Key Practical Tips

The government and other payors' use of AI is rapidly growing, expanding, and evolving. Providers using AI to assist with their coding and billing should consider annually performing an independent audit their AI assisted coding compliance as part of the providers' compliance workplan to help ensure its continued validity as compared to industry standards as they evolve.

Additionally, as providers assess new post-payment audits and reviews, they should consider whether illogical denials could be a result of the payor's improper use of AI. If so, providers should preserve and challenge this issue, as it may be a contractual violation as well as a potential constitutional due process violation. In the years ahead, providers should continue to be on the lookout for further policies and case law governing the use of AI, including in the context of post-payment reviews.

7. *See, e.g.,* https://scholarlycommons.law.northwestern.edu/njtip/vol19/iss1/2

Value-Based Care Highlights

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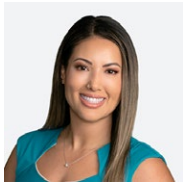

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Overview of Key Developments in 2024

Value-based care continues to make up an important part of the health care landscape. Based on data collected by the Health Care Payment Learning and Action Network (HCP-LAN), just over 44% of total health care payments were made as part of an alternative payment model or population-based payment model.[1] 28.5% of all payments involved some sharing of downside risk. The share of risk-based payments was highest for Medicare Advantage plans (just over 40%), while the share of "pure" fee-for-service payments was highest in commercial plans (about 50%).[2] The share of payments made through risk-sharing models increased in each payor category.[3]

However, there is also some policy-related uncertainty about the future of value-based care. Significantly, the Quality Payment Program's Advanced Payment Model (APM) bonus expired at the end of 2023 and was renewed on a limited basis for 2024. This program provided automatic bonuses to Medicare reimbursement for physicians (and other professionals) who participated in certain value-based models; if it expires as scheduled, participants would lose APM bonus payments starting in payment year 2026. Congress has not yet extended

1. Health Care Payment Learning and Action Network, APM Measurement: Progress of Alternative Payment Models: 2024 Methodology and Results Report, https://hcp-lan.org/wp-content/uploads/2024/11/2024-HCPLAN-Methodology-Report-11-13.pdf, p. 12.
2. Id. at p. 13.
3. Id. at pp. 12-16.

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the APM bonus as of early March 2025. Several potential legislative fixes have been proposed in Congress, each with slightly different criteria. The implementation of certain CMMI payment models also may be impacted by the change in presidential administration. For example, the prior Trump Administration ended the Obama Administration's expansion of mandatory bundled payment models, so the currently finalized TEAM Model slated to start in 2027, which involves similar mandatory models, may face a similar fate. CMS also incorporated health equity policies into several value-based payment models, and it remains to be seen whether, and how, these policies will be impacted.

At the same time, value-based care concepts continue to be incorporated into other aspects of the health care delivery system. For example, the CY 2025 Medicare Physician Fee Schedule established reimbursement for a permanent set of Advanced Primary Care Management codes that were first tested in the CMMI Primary Care First and Comprehensive Primary Care Plus models.[4] The same rule established payment for Atherosclerotic Cardiovascular Disease (ASCVD) screening and risk management, based on the CMMI Million Hearts Model.[5] CMS also finalized routine updates to the quality reporting plans for the Medicare Physician Fee Schedule and the Hospital Quality Reporting Programs for Inpatient, Outpatient, and Rural Emergency Hospitals.[6]

2024 also saw continued growth in the Medicare Advantage (MA) program in which the federal government contracts with private insurers to provide Medicare benefits to enrollees. The MA program pays insurers on a per-member per-month population health basis, so private insurers have flexibility to tailor benefits to drive value-based initiatives and provide supplemental benefit coverage for items or services not covered under traditional Medicare but valued by enrollees. The MA program now covers a majority of Medicare beneficiaries. A recent analysis estimated 54% of eligible Medicare beneficiaries are in MA plans, with nearly half concentrated in plans operated by UnitedHealthcare and Humana).[7] MA's population health-based payment model encourages plans to develop cost-efficient finance models, which often deviate from fee-for-service models. As noted above, MA plans place a higher share of payments at risk than other payor categories. Trump Administration members have been vocal proponents of significant further expansion of MA plans, and further privatization of Medicare.

CMMI encourages MA innovation through the Value-Based Insurance Design (VBID) program. This program was announced in 2017 and recently extended for a third participation period from 2025 to 2030. Important programmatic changes began on January 1, 2025. Plans operating under VBID gained additional flexibilities to address health-related social needs based on areas with demonstrated health equity need. However, the VBID hospice benefit, which allowed MA plans to offer

4. See Calendar Year (CY) 2025 Medicare Physician Fee Schedule Final Rule, CMS Fact Sheet, November 1, 2024, https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-final-rule.
5. *Id*.
6. See CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS 1809-FC), CMS Fact Sheet, November 1, 2024, https://www.cms.gov/newsroom/fact-sheets/cy-2025-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.
7. Meredith Freed et al., Medicare Advantage in 2024: Enrollment Update and Key Trends, KKF (Aug. 08, 2024) https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/.

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hospice coverage, did sunset on December 31, 2024.[8]

Key 2024 Program Model Updates

During 2024, CMMI developed or revised many models during 2024, including the Guiding an Improved Dementia Experience (GUIDE) Model, the Transforming Episode Accountability Model (TEAM) and the Innovation in Behavioral Health (IBH) Model.

Guiding an Improved Dementia Experience (GUIDE)

GUIDE is a nationwide model that aims to improve the quality of lives for people with dementia and reduce the strain on their unpaid caregivers. Health care providers eligible to be GUIDE Participants include Medicare Part B-enrolled providers and suppliers, excluding durable medical equipment (DME) and laboratory suppliers (who are eligible to bill under the Medicare Physician Fee Schedule (MPFS)). The model has one application cycle which began on November 15, 2023 and closed on January 30, 2024. The GUIDE Model launched July 1, 2024 (for established programs) and will launch July 1, 2025 (for new programs) and run for eight years. The GUIDE model seeks to improve care for patients with dementia, by providing reimbursement for Participants related to significant care coordination activities, and provision of respite care to reduce the requirements placed on those patient's caregivers.

Transforming Episode Accountability Model (TEAM)

TEAM will be a mandatory, episode-based, alternative payment model, in which participating acute care hospitals will be responsible for overseeing a patient's care from the point of hospital admission or outpatient procedure and for 30 days after the individual leaves the hospital. This oversight will include coordination and communication between providers across all care settings and with the patient and family. TEAM, in essence, will be replacing the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payments for Care Improvement (BCPI) Advanced model, which are scheduled to end in December 2024 and December 2025, respectively. While BPCI Advanced was a voluntary program, and rural and low-volume hospitals were exempted under the mandatory CJR model, that is not the case with TEAM.

The mandatory nature of TEAM is intended to create a consistent framework for evaluating the effectiveness of bundled payments.

The five different surgical procedures that will be included in TEAM are:

1. Lower extremity joint replacement;
2. Surgical hip femur fracture treatment;
3. Spinal fusion;
4. Coronary artery bypass graft; and
5. Major bowel procedure.

TEAM will be a five-year model starting in January 2026. The hospitals required to participate will be based on selected geographic regions (Core Based Statistical Areas (CBSAs)), from across the United States. In addition to those IPPS hospitals mandated to participate based on being in a selected CBSA, there is a one-time voluntary opt-in opportunity for those hospitals that participate until the last day of the last performance period in the BCPI advanced model or the last day of the last performance year of the CJR Model (December 31, 2025, and December 31, 2024, respectively). Eligible hospitals interested in voluntary opt-in will be required to submit a written participation

8. CMS.gov, Medicare Advantage Value-Based Insurance Design Model, https://www.cms.gov/priorities/innovation/innovation-models/vbid.

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election letter to CMS in a form and manner specified by CMS during the voluntary election period of January 1, 2025 to January 31, 2025. The participation election letter will serve as the participation agreement, which will bind and subject the eligible hospitals to the same terms, conditions, and requirements in TEAM as hospitals mandated to participate. This includes being required to participate for the full model performance period and being accountable for all episode categories tested in the model.

Innovation in Behavioral Health (IBH)

The IBH Model seeks to bridge the gap between behavioral and physical health. Specialty behavioral health practices under the IBH Model will screen and assess patients for select health conditions, as well as mental health conditions or Substance Use Disorders (SUD) or both. The IBH Model is a state-based model, led by state Medicaid agencies, with a goal of aligning payment between Medicaid and Medicare for integrated services. The model was expected to launch January 1, 2025. The period of performance will be for eight years consisting of a three-year pre-implementation period (January 1, 2025 – December 31, 2027) and a five-year implementation period (January 1, 2028 – December 31, 2032). The Notice of Funding Opportunity (NOFO) application period for the IBH Model closed on September 9, 2024. CMS anticipates issuing eight award notices. Additional information about eligibility to receive these payments is detailed in the NOFO.

Quality Reporting Updates

Annual updates to quality metrics across the various federal programs were made as in many past years. In addition, beginning with the 2025 performance period, to submit data on behalf of clinicians, a health IT vendor will need to meet the requirements of and self-nominate to become a qualified registry or a Qualified Clinical Data Registry (QCDR). Further, the electronic clinical quality measure (eCQMs) is a metric that will now be collected as a quality reporting measure after an initial one-year delay to calendar year (CY) 2025. Medicare Part B Claims Measure Specifications, Merit-Based Incentive Payment Systems (MIPS) clinical quality measures (CQMs) specifications/process will no longer be a quality reporting measure that will be collected in CY 2025.

APM Bonuses and Other Incentives for APM Participation

One way the government has tried to incentivize physicians to participate in advanced payment models (APMs) is by offering bonuses worth a certain percentage of the clinician's fee schedule payment (e.g., 5% from 2019-2024). There is considerable uncertainty, however, as to whether the A-APM bonus has increased participation in the A-APMs. The bonuses are set to expire in 2026 and there has been some discussion recently June 2024 about extending the bonus to incentivize clinician participation in A-APMs. Starting in 2026, MACRA will incentivize A-APM participation through higher fee schedule payment rates with clinicians in A-APMs receiving 1% higher payment rates than other clinicians in 2027 and 10.5% higher payment rates than other clinicians by 2045. While the bonus extension may provide some incentive to participate in the short term, higher fee schedule payment rates may be a more powerful and effective carrot in the long run. Further, with over one-fifth of all hospitals required to participate in TEAM starting in 2026, and CMS contemplating a mandatory

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A-APM for all specialists in ambulatory settings as early as 2026, most clinicians may soon be required to participate in an A-APM anyway, which could eliminate the need for the bonus.

The Continued Evolution of Behavioral Health Reimbursement Strategies

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Behavioral health continues to be a growing sector within the health care industry, with several recent rulemakings addressing aspects of behavioral health payment policy, including under both the Medicare Outpatient Prospective Payment System (OPPS) and the Medicare Physician Fee Schedule (MPFS). The following outlines key updates regarding Medicare and Medicaid payment for behavioral health services.

CMS Sets Rates for IOP for Federally Qualified Health Clinics and Rural Health Clinics

After a year of coverage for Intensive Outpatient Program (IOP) services in hospital outpatient departments (HOPDs), Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs), CMS made no changes to the reimbursement or APC structures for IOP services in HOPDs and CMHCs. To align reimbursement policy with HOPDs and CMHCs, however, CMS introduced a payment rate for FQHCs and RHCs furnishing IOP services with four or more services per day. The 2025 IOP payment rates for FQHCs and RHCs are $269.19 for three services per day and $408.55 for four or more services.

States Can Now Go Beyond the Four Walls for Medicaid Clinic Services

In the OPPS Final Rule, CMS allows states that implement the Medicaid clinic services benefit to cover clinic services provided outside the “four walls” of behavioral health clinics or clinics in rural areas.

New Codes for Payment of Safety Planning Interventions and Post-Discharge Telephonic Follow-Up

The CY 2025 MPFS final rule establishes a standalone code for Safety Planning Interventions (SPI) for patients at elevated risk for suicide or overdose. SPI services must be personally performed by the billing practitioner. Additionally, CMS finalized a monthly billing code for follow-up contact interventions (FCI) for patients discharged after a crisis encounter. This service includes four calls per month, each lasting 10-20 minutes, and may be provided by auxiliary personnel incident to and under the supervision of the billing practitioner.

Payment for Digital Mental Health Treatment Devices

CMS finalized payment for Digital Mental Health

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Treatment (DMHT) devices, which may be furnished incident to a billing practitioner's services as part of a behavioral health treatment plan. These devices must have FDA clearance or authorization and be prescribed by the billing practitioner, who incurs the cost of providing the device.

Interprofessional Consultations Get Payment

CMS has established new CPT codes for interprofessional consultations by Clinical Psychologists, Clinical Social Workers, Marriage and Family Therapists, and Mental Health Counselors. These codes mirror those used by practitioners eligible to bill for E/M visits, such as physicians and NPPs.

Telecommunication Flexibilities and Updated Payments for Opioid Treatment Programs (OTPs)

Effective January 1, 2025, CMS permanently extended the flexibility allowing OTPs to conduct periodic assessments using audio-only communications when video is unavailable, provided other requirements are met. CMS also permits the OTP intake add-on code to be furnished via two-way audio-video technology when methadone treatment initiation is deemed appropriate through telehealth.

Additionally, the PFS final rule includes payment updates for OTP services to align with new SAMHSA standards, including increased payments for intake activities and periodic assessments to account for social determinants of health risk assessments to identify unmet health-related social needs, or the need for harm reduction interventions and recovery support services under new SAMHSA standards. CMS also finalized, and new add-on codes for coordinated care, referral services, patient navigation, and peer recovery support services.

State Medicaid Coverage for SUD Treatment under the Consolidated Appropriations Act of 2024

The Consolidated Appropriations Act of 2024 (CAA 2024) made permanent the mandatory Medicaid benefit for medications for opioid use disorder (MOUD), which was set to expire in 2025. The Act also continues the process for states to seek an exemption based on provider shortages. CAA 2024 includes provisions for states to cover services for Medicaid beneficiaries aged 21-64 with at least one substance use disorder (SUD) diagnosis who reside in an eligible Institution for Mental Diseases (IMD). States must use evidence-based SUD placement criteria, review IMD compliance with nationally recognized standards, and assess the availability of SUD treatment at each level of care.

These updates enhance behavioral health care accessibility, ensure more accurate payment for services, and support providers in delivering quality care to individuals with behavioral health needs.

CMS Aims to Improve Payment Accuracy and Patient Access for Federally Qualified Health Centers and Rural Health Clinics

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For 2025, CMS finalized several policy and payment updates aimed at addressing concerns and priorities of Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) in their care for underserved populations. Three changes provide FQHCs and RHCs with the ability to:

1. Bill for care coordination services more accurately without losing reimbursement.
2. Extend telehealth services until the end of 2025.
3. Receive payment for vaccine administration.

CMS also clarified payment policies for dental services provided at FQHCs and RHCs.

Care Coordination

CMS implemented a new policy starting in 2025 that aligns FQHCs and RHCs with other entities offering care coordination services. From now on, FQHCs and RHCs must report individual CPT and HCPCS codes that describe care coordination services, rather than using the bundled FQHC/RHC care coordination HCPCS code, G0511. This change comes in response to requests from stakeholders who find reporting multiple codes more feasible and less burdensome than for which they were prepared in 2018, when the G0511 was adopted. To facilitate this transition, CMS provided a six-month period for updating billing systems.

Due to the phased-out G0511, there may be decreased payment for RHCs and FQHCs that primarily provide lower-cost care management services. To address this, CMS is allowing add-on codes for the time spent in care coordination services, ensuring payment accuracy and transparency for beneficiaries.

For Advanced Primary Care Management (APCM) services provided at these facilities, CMS adopted new coding and payment policies. These services are now reimbursed at national non-facility rates besides the RHC All-Inclusive Rate (AIR) or FQHC Prospective Payment System (PPS), with annual updates based on Physician Fee Schedule (PFS) amounts.

Telecommunication

Due to the widespread adoption of telehealth services during the COVID-19 pandemic, CMS is continuing to allow RHCs and FQHCs to provide and bill for telehealth services under direct supervision using interactive audio and video telecommunications until December 31, 2025. To meet the direct supervision requirements, CMS requires the supervisor to be "immediate available," which now includes availability through real-time audio and visual interactive telecommunications. HCPCS code G2025 can be used for non-behavioral health visits via telecommunication technology, including audio-only communications, through the end of 2025. Payment for these services in 2025 is calculated based on the average PFS telehealth service rates.

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Vaccines

Beginning July 1, 2025, RHCs and FQHCs can bill and receive payment for Part B preventive vaccines and their administration, including pneumococcal, influenza, hepatitis B, and COVID-19 vaccines. Payments will align with Part B preventive vaccine rates elsewhere, reconciled annually based on actual vaccine costs reported by the facilities.

Dental

CMS recognizes dental services provided at RHCs and FQHCs that are integral to other covered medical services. These services are now reimbursed under RHC AIR and FQHC PPS methodologies, respectively. The KX modifier, indicating medical necessity, must be used on claims for dental services inextricably linked to covered medical services, effective July 1, 2025. CMS clarified that dental services may be billed separately from medical visits if they are integral to the covered medical services provided on the same day.

These updates aim to streamline billing practices, enhance payment accuracy, and support continued access to essential health care services for underserved populations served by FQHCs and RHCs.

Telehealth in 2025 and Beyond: What Comes Next?

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The future of telehealth remains a pivotal topic for policy makers, health care providers, and patients alike. While historically there has been significant bi-partisan support in Congress to extend telehealth flexibilities, the ongoing uncertainty surrounding Medicare's long-term telehealth policy is an issue that Congress must address with a more permanent solution.

Six-Month Temporary Extension

As we entered 2025, the future of Medicare telehealth policy was uncertain, with key flexibilities set to expire on March 31, 2025. However, with the last-minute passage of a continuing resolution bill, Congress extended Medicare telehealth flexibilities through September 30, 2025. This six-month extension provides short-term stability for providers and patients who have relied on expanded access to telehealth services, but it leaves open the question of whether permanent policy changes will follow.

The COVID-19 Public Health Emergency (PHE) brought unprecedented changes to telehealth, including waivers of originating site and geographic restrictions, expanded audio-only services, and broader provider eligibility. Congress's most recent continuing appropriations bill extends flexibilities, which include:

- **Waiver of Geographic and Originating Restrictions:** Medicare beneficiaries can continue receiving telehealth services from their homes, regardless of location and without geographic restrictions.
- **Coverage for Audio-Only Telehealth:** Telehealth services can continue to be furnished via audio-only tele-communication technology.

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- **Expanded Provider Eligibility:** A broader range of health care providers, including physical therapists, occupational therapists, and speech-language pathologists, can continue delivering telehealth services.
- **Flexibilities for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs):** These facilities can continue to serve as distant site providers for telehealth, enabling virtual care without geographic limitations.
- **Delaying the In-Person Requirements for Mental Health Services:** Physicians and practitioners can continue to provide telehealth services, absent an in-person examination, for purposes of diagnosis, evaluation, or treatment of a mental health disorder.

With the clock now ticking toward the new September 30, 2025 deadline, major health care organizations are advocating for permanent legislative action. The American Telemedicine Association (ATA) and American Hospital Association (AHA) continue to urge Congress to cement telehealth's place in modern health care, emphasizing its role in expanding access, improving outcomes, and addressing provider shortages.

Several legislative efforts aim to make Medicare telehealth flexibilities permanent. A few notable bills include:

- **The Telehealth Modernization Act of 2024 (H.R. 7623)** which seeks to permanently extend certain telehealth flexibilities that were initially authorized during the COVID-19 public health emergency. The bill was introduced in the House on March 12, 2024, referred to the House Committee on Energy and Commerce, and as of now, it awaits further action.
- **The Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2023 (H.R. 4189; S. 2016)** is a bipartisan bill that proposes to expand coverage of telehealth services under Medicare, including permanently removing geographic restrictions and allowing patients to receive telehealth services in their homes. The bill has garnered significant support and is currently under consideration.
- **The Preserving Telehealth, Hospital, and Ambulance Access Act** which aims to extend key telehealth flexibilities through 2026, including provisions for hospital-at-home programs and ambulance services. The bill has cleared the House Energy and Commerce Committee and awaits scheduling for a full House vote.

The introduction of multiple bills aimed at making Medicare telehealth flexibilities permanent is a clear signal of strong bipartisan support for expanding telehealth access. This continued momentum signals that permanent legislative changes could be on the horizon, offering greater certainty for providers and patients who rely on telehealth services.

Telehealth Changes in the 2025 PFS Final Rule

On a similar note, the Centers for Medicare & Medicaid Services (CMS) finalized changes to telehealth as a part of the 2025 PFS Final Rule. Namely,

1. **Audio-Only Telehealth:** CMS finalized its proposal to amend the definition of "interactive telecommunications system" to include audio-only communications

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for telehealth services furnished to beneficiaries in their homes.

2. **Distant Site Practitioner Practice Location Enrollment Requirements:** Through CY 2025, CMS will continue to permit distant site practitioners to use their currently enrolled practice locations instead of their home addresses when providing telehealth services from their home.
3. **Direct Supervision via Virtual Presence:** CMS finalized its proposal to continue to allow direct supervision to be met through virtual presence — real-time audio and visual interactive telecommunications — through December 31, 2025. CMS also finalized its proposal to permanently expand the definition of direct supervision to include virtual presence for a subset of "incident to" services. For example, virtual presence may be used on a permanent basis to provide direct supervision for services described by CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional).

DEA Telemedicine Controlled Substance Prescribing

Third Temporary Extension of Controlled Substance Prescribing Flexibilities

In a separate but related policy area, the U.S. Drug Enforcement Administration (DEA) announced a third temporary extension of the telemedicine controlled substance prescribing flexibilities through December 31, 2025. These measures, originally tied to the PHE, ensure patients can continue accessing critical treatments via telemedicine. Specifically, the flexibilities continue to allow practitioners to prescribe Schedule II-V controlled substances via telemedicine without an in-person evaluation. Practitioners can also prescribe schedule III-V narcotic-controlled medications approved by the Food and Drug Administration for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine. It is important to note that this extension is not indefinite. Stakeholders widely anticipate that the DEA will release a permanent rule in 2025, clarifying policies around the prescribing of controlled substances via telemedicine. The forthcoming rule is expected to strike a balance between ensuring access to care and addressing concerns about controlled substance misuse.

Expansion of Buprenorphine Treatment via Telemedicine Encounter

Along the same lines, the DEA recently released a final rule that provides critical guidance for practitioners prescribing buprenorphine for opioid use disorder (OUD) via telemedicine. Under the new rule, practitioners may prescribe up to a six-month supply of buprenorphine via telemedicine without an in-person visit. As discussed in the final rule, generally, practitioners engaged in the practice of telemedicine must use an interactive telecommunications system that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication. However, recognizing patient access barriers, the final rule clarifies that audio-only telecommunication may be used under certain circumstances, such as for patients who are located at home, unable to use video technology, or unwilling to consent to video visits.[1]

1. DEA and HHS references the CMS definition of "interactive telecommunications system," as described in 42 CFR 410.78(a)(3), for purposes of the final rule.

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The rule also establishes requirements for continuing treatment beyond the initial six months. For patients to receive future prescriptions for buprenorphine after the initial six-month period, the practitioner must meet one of two criteria:

1. Conduct an in-person evaluation of the patient, or
2. Qualify for an exception under the Controlled Substances Act telemedicine framework.

These requirements reinforce the DEA's focus on balancing patient access with prevention of potential misuse or diversion.

On Friday, February 14, 2025, the DEA and the U.S. Department of Health and Human Services (HHS) announced that the effective date of the final rule is delayed from February 18, 2025 to at least March 21, 2025 to allow review of any question of fact, law, and/or policy raised by the rule.

Special Registrations for Telemedicine and Limited State Telemedicine Registrations

On January 15, 2025, the DEA released a proposed telemedicine special registration rule that outlines the process for practitioners to register with the DEA for telemedicine-based prescribing of controlled substances. This registration would create a long-awaited pathway for practitioners to prescribe certain controlled substances to patients without having to conduct an in-person evaluation after flexibilities expire on December 31, 2025.

The proposal introduces three type of special registrations for telemedicine:

1. **Telemedicine Prescribing Registration:** This registration authorizes qualified clinician practitioners to prescribe Schedule III-V controlled substances via telemedicine.
2. **Advanced Telemedicine Prescribing Registration:** This registration authorizes qualified, specialized clinician practitioners (e.g., psychiatrists, hospice care physicians) to prescribe Schedule II-V controlled substances via telemedicine.
3. **Telemedicine Platform Registration:** This registration authorizes covered online telemedicine platforms, in their capacity as platform practitioners, to dispense Schedule II-V controlled substances.

In addition to obtaining a special registration, practitioners would be required to maintain a DEA issued State Telemedicine Registration for every state in which they provide patient care, unless an exemption applies. Both clinician practitioners and online telemedicine platforms would be subject to this requirement. Overall, the proposed rule aims to balance expanded access to care with safeguards against the misuse of controlled substances.

It is currently unclear whether the Trump Administration will move forward with the proposal. However, stakeholders had 60 days to comment on the special registration proposed rule and are encouraged to provide their input on the time necessary to operationalize the proposed requirements.

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Looking Ahead: Policy Uncertainty and Opportunities

As we move into 2025, the future of telehealth remains at a critical juncture. While the temporary extension of PHE flexibilities for Medicare provides a short-term solution, it's clear that a more permanent regulatory framework is needed. The 2025 PFS final rule and the wave of DEA rules have shown both progress and gaps in shaping telehealth's future. While telehealth has historically enjoyed bi-partisan support, it's unclear if that momentum will continue.

This uncertainty makes it even more important for stakeholders to stay tuned to regulatory updates and be ready to adapt as changes unfold quickly. At the same time, advocating for telehealth's benefits will be crucial in ensuring its place in the future of care delivery.

2024 Rulemaking Attempts to Give Parity Requirements More Teeth

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Since its enactment in 1996, the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) has been amended multiple times and the subject of various rulemakings. Despite these efforts, however, the Departments of Health and Human Services, Treasury and Labor (the "Agencies") have found that disparities in coverage between mental health and substance use disorder benefits and medical and surgical benefits have grown and that there is insufficient compliance with the requirements of the MHPAEA. To address these insufficiencies and encourage greater compliance with the requirements of the MHPAEA, in August of 2023, the Agencies issued proposed rules to amend existing MHPAEA regulations. After receiving and reviewing 9,503 comments to those proposed rules, on September 9, 2024, the Agencies issued a final rule.

The final rule continues to implement the core principle of the MHPAEA, which is that group health plans and insurers must not limit access to care for mental health and substance abuse conditions more than they do for medical or surgical procedures. To that end, the final regulations include a meaningful access to care requirement. A group health plan or insurance product must provide "meaningful" access to care for mental health and substance abuse conditions. A plan or product will not satisfy this requirement unless it provides benefits for a "core treatment" for a mental health or substance abuse disorder in each classification in which the plan or insurance provides benefits for a core treatment for a medical condition. The final rule also includes new definitions to help ensure clarity and assist with compliance.

Many of the changes implemented by the final rule, however, are focused on requirements applicable to nonquantitative treatment limitations (NQTLs) and reflect an effort to promote equity based on a data driven analysis. Under the final rule, group health plans and insurers will be required to collect and evaluate data

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regarding NQTLs used by the plan or insurance product. In evaluating that data, employers and insurers will be required to measure the impact of NQTLs, which will include evaluating whether discriminatory information, evidence, sources, or standards are used when designing NQTLs. Where they identify a material imbalance in access, employers will be required to take remedial action.

The new rule also provides guidance regarding the NQTL comparative analysis requirement added to the MHPAEA, by the Consolidated Appropriations Act of 2021 (CAA, 2021). The rule explains that the comparative analysis must include six elements, including:

1. A description of the NQTL, including identification of benefits subject to the NQTL;
2. Identification and definition of the factors and evidentiary standards used to design or apply the NQTL;
3. A description of how factors are used in the design or application of the NQTL;
4. A demonstration of comparability and stringency, as written;
5. A demonstration of comparability and stringency, in operation, including the required data, evaluation of that data, explanation of any material differences in access, and description of reasonable actions taken to address such differences; and
6. Findings and conclusions.

In conducting the comparative analyses, group health plans and insurers must evaluate standards related to network composition, out-of-network reimbursement rates, and medical management and prior authorization NQTLs. When an ERISA group health plan is involved, a fiduciary for the plan must also certify that a prudent process was used to select the entity that will perform the comparative analysis. The Final Rule also includes certain notice requirements and allows applicable state authorities, participants, beneficiaries, or enrollees who have received an adverse benefit determination related to mental health substance abuse disorder benefits to request a copy of the comparative analysis.

The 2024 final rules have staggered effective dates. The new rules imposing additional requirements on the design of group health plans and insurance products to ensure parity in medical and surgical and mental health benefits and requiring a fiduciary certification went into effect for group health plans and insurers on January 1, 2025. Group health plans and insurers will have until January 1, 2026, to ensure compliance with the rule's provisions regarding the comparative analysis requirement, use of nondiscriminatory factors and data evaluation requirements.

While the final rules were welcomed news for behavioral health providers and patients, employer group health plans and other insurers reacted strongly, arguing that the rules go well-beyond what is required by the MHPAEA. On January 17, 2025, the ERISA Industry Committee (ERIC) filed a lawsuit in the U.S. District Court for the District of Columbia, seeking to invalidate the rulemaking. Further, on February 20, 2025, ERIC sent a letter to the new administration asking them to delay implementation pending resolution of the lawsuit. It is not yet clear what position the Trump Administration will take regarding this final rule or parity, generally.

Key Outpatient Payment Updates for Calendar Year 2025 and Beyond

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In the Calendar Year (CY) 2025 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule, CMS increased OPPS and ASC payment rates by 2.9% for hospitals and ASCs that meet quality reporting requirements.

Below we highlight several key takeaways and notable updates for providers. The full OPPS Final Rule is available here.

1. Obstetrical Services and Emergency Services Readiness CoPs

In an effort to help combat the country's maternal health crisis, CMS finalized new Conditions of Participation (CoPs) for hospitals and Critical Access Hospitals (CAHs) for obstetrical services, including new requirements for maternal quality assessment and performance improvement (QAPI), as well as baseline standards for the organization, staffing, and delivery of care within obstetrical units and staff training on evidence-based best practices every two years.

As of January 1, 2025, hospitals and CAHs that offer obstetrical services must meet nationally recognized acceptable standards of practice for physical and behavioral health care of pregnant, birthing and postpartum patients (inclusive of both mental health and substance use disorders). The new CoPs regarding organization, staffing, and delivery of services apply outside of the emergency department, although CMS reiterated Emergency Medical Treatment and Labor Act (EMTALA) obligations and affirmed commentors who hoped that the new CoPs would promote consistency in high-quality maternal care post-*Dobbs v. Jackson Women's Health Organization*.

Even if a hospital or CAH does not offer obstetric services, CMS introduced another CoP regarding "Emergency Services Readiness" that is meant to set clear expectations and improve facility readiness in caring for emergency services patients, including pregnant, birthing, and postpartum patients. This CoP applies to all hospitals and CAHs offering emergency services, whether or not a hospital/CAH offers an additional specialty service line (such as OB services).

2. Review Timeframes for the Hospital Outpatient Department (HOPD) Prior Authorization Process

For non-urgent hospital outpatient procedures that require prior authorization, CMS updated its rules so that Medicare contractors will issue decisions within seven calendar days instead of ten business days. This will align Medicare fee-for-service with timelines applicable to other payors.

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3. ASC Covered Procedures List

For CY 2025, CMS added 21 medical and dental procedures to the ASC covered procedures list (CPL) (i.e., surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD). Of the 21 procedures added to the list, 19 were dental procedures, but inclusion on the CPL does not negate the requirement that a service meet other Medicare coverage conditions (for example, dental procedures typically must be integral to other medically necessary services in order to be covered by Medicare).

4. Bundling Policy for Diagnostic Radiopharmaceuticals

CMS finalized a revision to its bundling policy for diagnostic radiopharmaceuticals, enabling separate payments for high-cost radiopharmaceuticals that exceed a specific per-day threshold. Under the new policy, radiopharmaceuticals that cost more than $630 per day will be unbundled, addressing long-standing financial barriers and improving patient access to higher-cost diagnostic radiopharmaceuticals.

5. Separate Payment for Non-Opioid Treatments

In an effort to combat the ongoing opioid crisis and in accordance with Section 4135 of the Consolidated Appropriations Act of 2023 (Access to Non-Opioid Treatments for Pain Relief), CMS finalized temporary separate payments for certain non-opioid treatment for pain relief in the HOPD and ASC settings from January 1, 2025 through December 31, 2027. The separate payments will apply to six drugs and five devices. Tables 157 and 158 in the Final Rule outline the qualifying products and applicable payment limitations.

6. Health Equity Initiatives Across Quality Programs

CMS added new health equity measures to the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) programs.

- Screen Positive Rate for Social Determinants of Health Care Measure: Voluntary reporting begins for the CY 2025 reporting period. Mandatory reporting is required by the CY 2026 reporting period/CY 2028 payment determination. This measure tracks the number of beneficiaries who test positive for each of the five specific social risk factors assessed in the screening for social determinants of health care measure.
- Screening for Social Drivers of Health Measure: Voluntary reporting begins for the CY 2025 reporting period, with mandatory reporting for the CY 2026 reporting period/ CY 2028 payment determination. This measure evaluates the number of patients screened for five specific health-related social needs, contributing to a more comprehensive understanding of factors influencing patient health outcomes.
- Hospital Commitment to Health Equity (HCHE) and Facility Commitment to Health Equity (FCHE) Measures: Starting with the CY 2025 reporting period/CY 2027 payment determination, CMS is implementing the Hospital Commitment to Health Equity (HCHE) measure for the Hospital OQR and REHQR programs, and the Facility Commitment to Health Equity (FCHE) measure for the ASCQR Program. These measures require facilities to submit annual attestations based on five key domains.

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- **The Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance (PRO-PM):** Beginning in the CY 2026 reporting period, CMS will implement voluntary reporting for the PRO-PM measure. Mandatory reporting begins in the CY 2027 reporting period/CY 2029 payment determination.

CMS also finalized several other proposals relating to quality reporting, including proposals to:

- Change the "immediate measure removal" policy to an "immediate measure suspension" policy for the measures adopted under the Hospital OQR Program;
- Mandate that electronic health record technology be certified to support the reporting of all available electronic clinical quality measures in the Hospital OQR Program; and
- Make public the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients, specifically for the Psychiatric/Mental Health Patients subgroup, on the online Care Compare tool.

7. Colorectal cancer screening test expansion

CMS finalized its proposal to expand coverage of colorectal cancer screening tests. CMS removed coverage for the barium enema procedure and added coverage for the computed tomography colonography procedure.

Polsinelli's Reimbursement Practice

Polsinelli's Reimbursement Institute was created in an effort to continuously track changes within the industry as well as analyze the implications of those changes more easily and effectively. In providing a single source of news, information and other resources, the Reimbursement Institute is intended to serve as a valuable reference to Polsinelli clients as they navigate the channels of Medicare and Medicaid reimbursement.

Understanding the nuances of Medicare and Medicaid reimbursement is one of the greatest challenges that providers face in today's quickly changing health care world. The reimbursement process can be long and arduous, and can change often, as described in this quote:

> *"There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase."*
>
> *— Rehab. Ass'n of Va. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir.1994).*

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