

Vizient Office of Public Policy and Government Relations

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

July 28, 2025

Background & Summary

On July 15, the Centers for Medicare & Medicaid Services (CMS) issued the <u>annual proposed rule</u> to update the Calendar Year (CY) 2026 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS) (Proposed Rule). The Proposed Rule includes changes to payment policies, payment rates and quality provisions for Medicare patients who receive care at hospital outpatient departments (OPDs) or receive care at ambulatory surgical centers (ASCs). Among other changes, the agency's proposals would expand certain site neutral payment policy related to drug administration services, modify the previously finalized 340B remedy offset and modify the Overall Hospital Quality Star Ratings methodology. This summary focuses primarily on policies related to hospital OPDs.

The Proposed Rule also updates the Hospital Outpatient Quality Reporting (OQR) Program, including the removal of two chart-abstracted measures, and includes Requests for Information (RFIs) on well-being and nutrition, expanding methods to control for unnecessary increases in the volume of covered OPD services (i.e., additional site neutral payment policy) to on-campus clinic visits, adjustment of payment under the OPPS for services predominantly performed in the ASC or physician office setting and software as a service (SaaS). Additionally, CMS proposes updates to hospital price transparency (HPT) regulations.

Comments are due **September 15, 2025**, and the final rule is expected to be released by early November. Most provisions will go into effect January 1, 2026. Vizient looks forward to working with members to help inform our letter to the agency.

OPPS Payment Update

For CY 2026, CMS proposes to apply an OPD fee schedule increase factor of 2.4 percent, except for those hospitals not meeting certain quality reporting requirements, which would be subject to a 2 percent reduction resulting in a fee schedule increase factor of 0.4 percent. The proposed increase factor of 2.4 percent is based on the proposed hospital inpatient market basket percentage increase of 3.2 percent for inpatient services paid under the hospital Inpatient Prospective Payment System (IPPS), minus the proposed productivity adjustment of 0.8 percentage points.

Based on this update, CMS estimates that all total payments to OPPS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for CY 2026 will be approximately \$100 billion, an increase of approximately \$8.1 billion compared to estimated CY 2025 OPPS payments. CMS proposes a CY 2026 conversion factor (CF) of \$91.75 for hospitals that meet the Hospital Outpatient Quality Reporting (OQR) Program requirements.

CMS also proposes a 340B remedy offset which would reduce hospital payment by 2 percentage points (approximately \$1.1 billion) for hospitals subject to the offset, as further detailed <u>below</u>.

As highlighted in Table 1, CMS estimates that, for CY 2026, the cumulative effect of all proposed changes will increase Medicare OPPS payments by 1.9 percent for all providers and 2.0 percent for all hospitals.

Table 1. Estimated Impact of the Proposed CY 2026 Changes for the Hospital OPPS

rabio 1. E	# of Hospitals	Proposed Ambulatory Payment Classification	New Wage Index and Provider	All budget neutral changes (combined cols 2-3)	Proposed Payment Adjustment for Drug Admin. At	All Proposed Changes	Reduction for Providers Subject to the 340B
	(1)	Recalibration Changes (2)	Adjustments (3)**	with Market Basket Update (4)***	Off Campus PBDs (5)****	with Outlier (6)^	Remedy Offset (7)
All providers	3496	0.0	0.1	2.5	-0.3	1.9	-1.9
All hospitals*	3398	0.1	0.1	2.6	-0.3	2.0	-1.9
Urban hospitals	2710	0.1	0.1	2.6	-0.3	2.0	-1.9
Rural hospitals	688	-0.4	0.4	2.5	-0.1	2.0	-1.9
Non- teaching status hospitals	2051	0.0	0.2	2.6	-0.1	2.2	-1.9
Minor teaching status hospitals	896	0.2	0.2	2.8	-0.2	2.2	-1.9
Major teaching status hospitals	451	-0.1	0.0	2.3	-0.4	1.7	-1.9

^{*}Excludes hospitals held harmless and Community Mental Health Centers (CMHCs)

CY 2026 Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy

From January 1, 2018 through September 27, 2022, under the OPPS, CMS reimbursed for certain separately payable drugs acquired through the 340B Program at average sales price (ASP) minus 22.5 percent, in a budget neutral manner by providing increased payments to all hospitals for non-

^{**} Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2026 hospital inpatient wage index. The rural SCH adjustment proposes to continue our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the proposed CY 2026 target payment-to-cost ratio is the same as the CY 2025 PCR target

^{***}Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.4 percent OPD fee schedule update factor (3.2 percent reduced by 0.8 percentage points for the productivity adjustment).

^{****}Column (5) shows the separate impact of the proposed payment adjustment for drug administration services furnished at excepted off campus providers.

[^]Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments.

^{^^}Column (7), CMS estimates that 3,270 providers would be subject to the reduction to payments that result from the 340B remedy offset.

drug items and services.¹ The results of this policy meant that hospitals received an estimated \$10.6 billion less in 340B drug payments, including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments, than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B payment policy not been implemented.

Also, this 340B payment policy was the subject of extensive litigation resulting in a June 2022 Supreme Court ruling² that found that CMS could not implement different payment rates for 340B drugs without first conducting a survey of hospitals' acquisition costs. This invalidated the 340B payment cuts implemented from CY 2018 onward. In the CY 2023 OPPS Final Rule³, CMS finalized a policy reversing the 340B payment policy, so that going forward CMS would pay for 340B acquired drugs no differently the agency paid for drugs that are not acquired through the 340B program. To address the reduced drug payment amounts in effect for CY 2018 through September 27, 2022, CMS made one-time lump sum payments to affected 340B covered entity hospitals as outlined in separate rulemaking.⁴

Due to budget neutrality concerns from CMS and to ease the financial impact on providers, in the CY 2024 OPPS Final Rule on the Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022⁵, CMS finalized a plan to prospectively offset the estimated \$7.8 billion in increased payments for non-drug items and services made from CY 2018–2022 due to the ASP minus 22.5 percent payment policy. The remedy was to reduce the conversion factor for non-drug items and services to all OPPS providers, except any hospital that enrolled in Medicare after January 1, 2018, by 0.5 percent each year until the total offset was reached. CMS estimated the offset would be reached in about 16 years.

In the Proposed Rule, CMS reconsiders whether the remedy is the best method to restore hospitals to as close to the financial position they would have been in had the 340B payment policy never been implemented. For example, CMS indicates that a hospital's utilization of non-drug items and services is likely going to diverge more from CY 2018 utilization in CY 2041 than it would in CY 2031 or CY 2026. CMS also notes that the more a hospital's utilization of non-drug items and services diverge, the less hospitals would be restored to as close as possible to the approximate financial position as they would have been in had the 340B payment policy never been implemented.

Accordingly, for CY 2026, CMS proposes to revise the annual reduction to the OPPS conversion factor used to determine the payment amounts for non-drug items and services from 0.5 percent to 2 percent. Under this revised rate, it is expected to take approximately 6 years to reach the total offset of \$7.8 billion. In Addendum R of the Proposed Rule, CMS lists the providers that would be subject to proposed payment reduction and welcomes comments from these providers regarding this proposal. CMS also includes an alternative policy option with an annual reduction of 5 percent, which would reach the total offset of \$7.8 billion in approximately 3 years.

Additionally, related to 340B, CMS indicates that it intends to conduct a drug acquisition cost survey. Information regarding this update is noted below.

¹ https://www.govinfo.gov/content/pkg/FR-2017-11-13/pdf/2017-23932.pdf

² Am. Hosp. Ass'n v. Becerra, 142 S. Ct. 1896, 1906, https://supreme.justia.com/cases/federal/us/596/20-1114/

³ https://www.govinfo.gov/content/pkg/FR-2022-11-23/pdf/2022-23918.pdf

⁴ https://www.federalregister.gov/documents/2023/11/08/2023-24407/medicare-program-hospital-outpatient-prospective-payment-system-remedy-for-the-340b-acquired-drug

https://www.govinfo.gov/content/pkg/FR-2023-11-08/pdf/2023-24407.pdf

Site Neutral Payment Policies

Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs): Drug Administration Services

In recent years, CMS has found that there has been an increase in volume of services, including many drug administration services, that have shifted from freestanding physician offices to the OPD setting.⁶ CMS also indicates that higher OPPS payment rates for drug administration services, compared to physician fee service (PFS) rates, have created financial incentives that led to unnecessary growth in OPD utilization. Therefore, for the CY 2026 OPPS, CMS proposes to use its statutory authority⁷ to apply a PFS relativity adjuster of 40 percent for any HPCPCs codes assigned to the drug administration services APCs (APCs 5691-5694, Levels 1-4 Drug Administration), when provided at an excepted off-campus PBD.⁸ For CY 2026, CMS estimates this provision reduces OPPS spending by \$280 million, with \$210 million of the savings accruing to Medicare, and \$70 million saved by Medicare beneficiaries in the form of reduced beneficiary coinsurance.

CMS proposes to exempt Rural Sole Community Hospitals (SCHs) because CMS reviewed utilization data for drug administration services at rural SCHs and did not find strong evidence that drug administration services are being utilized at an unnecessary volume at excepted off-campus PBDs of rural SCHs⁹. **CMS invites comments on the proposed exemption for rural SCHs from the method to control unnecessary volume of drug administration services**.

CMS also solicits comments on other potential opportunities to expand site neutral payment policy.¹⁰

Continuation of Payment Policy for Radiation Therapy Services Furnished at Non-Excepted Off-Campus Provider Based Departments (PBDs)

Section 603 of the Bipartisan Budget Act of 2015 resulted in lowered Medicare payment rates for services furnished by non-excepted off-campus PBDs. Effective January 1, 2017, services provided by non-excepted off-campus PBDs were paid at PFS-equivalent rates.

CMS established HCPCS Level II G-codes to describe radiation treatment delivery services when furnished in the physician office setting¹¹ but these codes are not recognized under the OPPS.

⁶ For example, CMS looked at the growth in volume at the HCPCS code level and found that some HCPCS codes within the drug administration APCs have experienced significant growth. HCPCS code 96413 – which describes chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug – is the most frequently billed HCPCS code within any of the drug administration APCs at excepted PBDs. This code has seen an almost 70 percent increase in volume from 2011 to 2023.

Tection 1833(t)(2)(F) of the Social Security Act https://www.ssa.gov/OP Home/ssact/title18/1833.htm

⁸ In the Proposed Rule, CMS says this proposal aligns with President Trump's Executive Order (E.O.) 14273, "Lowering Drug Prices by Once Again Putting Americans First." Section 11 of the E.O., "Reducing Costly Care for Seniors," directs the Secretary to "evaluate and, if appropriate and consistent with applicable law, propose regulations to ensure that payment within the Medicare program is not encouraging a shift in drug administration volume away from less costly physician office settings to more expensive hospital outpatient departments."

⁹ CMS notes that rural areas often experience lower availability of health care professionals and hospitals than urban areas and hospital closures in rural communities are associated with lower access to health care and worse health outcomes.

¹⁰ "Are there other services for which CMS should develop a method to control unnecessary increases in the volume of covered OPD services by paying a PFS-equivalent rate for services provided at excepted off-campus PBDs? Of particular concern for us are the services within the imaging without contrast APCs (APCs 5521-5524). Imaging without contrast services are some the most costly and frequently provided services at excepted PBDs. We believe that there is a high likelihood that there has been unnecessary growth in this space and that a volume control method would be appropriate to apply here in the future. Would it be appropriate to apply this method to the Imaging Without Contrast APCs?"

¹¹ https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/34652_13/L34652_RAD014_BCG.pdf

Instead, CPT codes are used to describe these services when furnished in the OPD. As discussed in the CY 2026 PFS <u>Proposed Rule</u>, CMS plans to delete radiation therapy G-codes (G6001 – G6017) that describe imaging guidance for radiation treatment (G6001, G6002, G6017) and radiation treatment delivery (G6003-G6015) because CPT codes 77402, 77407, and 77412 have been revised and may be used to report these services instead.

For CY 2026, CMS proposes to maintain its current payment policy for radiation therapy services furnished by non-excepted off-campus PBDs by transitioning from HCPCS G-codes to revised CPT codes effective January 1, 2026. With the planned deletion of G-codes G6001–G6017, CMS will adopt revised CPT codes 77402, 77407, and 77412 to continue paying the technical component rate under the PFS. Non-excepted off-campus PBDs must continue using modifier "PN" to identify these services, and CMS emphasizes this is a continuation of existing policy, adjusting for the newly revised CPT codes and the corresponding deletion of the G codes.

RFI: Expanding the Method to Control for Unnecessary Increases in the Volume of Covered OPD Services to On-Campus Clinic Visits

In the Proposed Rule, CMS recognizes that clinic visits are still the most utilized service across the OPPS, with over 60 percent of clinic visits furnished on-campus. CMS is requesting information on the potential impact of a policy to pay the PFS-equivalent rate for clinic visit services furnished in on-campus OPDs and intends to use the responses to this request to inform future rulemaking. In the Proposed Rule (pg. 497-498), CMS provides list of specific questions for this RFI.

RFI: Adjusting Payment under the OPPS for Services Predominately Performed in the Ambulatory Surgical Center or Physician Office Settings

CMS requests feedback for future rulemaking on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital OPD setting based on financial incentives rather than medical necessity and adjusting payments accordingly. A list of questions can be found in the <u>Proposed Rule</u> (pg. 504-506).

Proposed Wage Index Changes

By law, CMS must determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. This wage adjustment must be done in a budget neutral manner, and this portion of the OPPS payment rate is called the labor-related share. CMS proposes to continue setting the OPPS labor-related share at 60 percent of the national OPPS payment, meaning that for hospitals, approximately 60 percent of the costs of services paid under the OPPS are attributable to wage costs. CMS also proposes to continue using the wage index established under the Inpatient Prospective Payment System (IPPS). CMS estimates that the update of the wage index, based on the fiscal year (FY) 2026 IPPS proposed rule wage index, will result in a 0.1 percent increase for urban hospitals under the OPPS and a 0.4 percent increase for rural hospitals.

Additionally, for CY 2026, CMS proposes to continue implementing various provisions affecting the wage index, such as reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment) and the permanent 5 percent cap on any decrease to a hospital's wage index from its wage index in a prior FY.

After considering the July 2024 D.C. Circuit court's decision in *Bridgeport Hosp. v. Becerra*, ¹² in the FY 2026 IPPS Proposed Rule, CMS proposed to discontinue the low wage index hospital policy. In *Bridgeport* the court ruled that the Department of Health and Human Services (HHS) lacked authority to implement the low wage index hospital policy and vacated both the policy and the related budget neutrality adjustment. To align the IPPS and OPPS wage index values for CY 2026, CMS proposes eliminating the low wage index hospital policy under the OPPS and using the IPPS wage index in CY 2026 and subsequent years.

To fully align OPPS and IPPS wage index values in CY 2026, CMS proposes basing the 5 percent cap on wage index decreases on the FY 2025 IPPS wage index, rather than the CY 2025 OPPS wage index. This shift may result in wage index reductions greater than 5 percent for some hospitals, so CMS proposes a transitional payment exception under the OPPS for CY 2026 to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Specifically, CMS would provide additional payment to hospitals whose CY 2026 wage index drops more than 9.75 percent compared to CY 2024, effectively setting their wage index at 90.25 percent of the CY 2024 value. This adjustment would be applied after the standard 5 percent cap and implemented in a budget-neutral manner.

Proposed Hospital Outpatient Outlier Payments

OPPS provides outlier payments (added to the Ambulatory Payment Classification (APC) amount) to help mitigate financial risks associated with high-cost and complex procedures that could present a hospital with significant financial loss. For CY 2026, CMS estimates a \$6,450 fixed-dollar amount threshold plus the APC payment amount. The CY 2026 multiplier threshold would remain at 1.75 times the APC payment amount. When the cost of a hospital outpatient service is above these thresholds (i.e., 1.75 is multiplied by the total line-item APC payment to decide eligibility for outlier payments and the estimated cost of a service must be greater than the APC payment amount plus the fixed-dollar amount threshold), the hospital would receive an outlier payment.

Proposed Updates Affecting OPPS Payments

Recalibration of APC Relative Payment Weights

At least once annually, CMS must revise the relative payment weights for APCs to consider changes in medical practice, changes in technology, the addition of new services, new cost data and other relevant information and factors. Consistent with CY 2025, for CY 2026, CMS proposes to recalibrate the APC relative payment weights for each APC based on claims and cost report data for hospital OPD services to construct a database for calculating APC group weights. For CY 2026 APC recalibration, CMS proposes to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios to convert charges to estimated costs through the application of a revenue code-to-cost center crosswalk¹³. The CY 2026 recalibration will use CY 2024 claims data.

Proposed Calculation of Single Procedure APC Criteria-Based Costs: Brachytherapy Sources

CMS has consistently made separate payments for certain products, such as brachytherapy

¹² https://cases.justia.com/federal/appellate-courts/cadc/22-5249/22-5249-2024-07-23.pdf?ts=1721746878

¹³ https://www.cms.gov/files/document/2026-nprm-opps-claims-accounting.pdf

sources¹⁴, through APCs rather than packaging payment for them into payment for procedures in which they are administered. For CY 2026 and subsequent years, CMS proposes to pay for HCPCS codes C2698 and C2699, representing stranded and non-stranded brachytherapy sources, at the lowest applicable prospective payment rate for each type, calculated on a per-source basis rather than per unit of radioactivity (e.g., per mCi). CMS also proposes to designate six brachytherapy APCs and five clinical APCs as low volume APCs¹⁵ under the OPPS based on their alignment with established criteria for low utilization. **CMS invites recommendations for new codes to describe new brachytherapy sources which CMS may add on a quarterly basis.**

Comprehensive APCs (C-APCs) for CY 2026

CMS defines a C-APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. For CY 2026, the number of C-APCs would remain stable at 72 C-APCs.

Complexity Adjustments

CMS applies complexity adjustments to increase payment when a claim includes paired "J1" services or add-on codes that reflect a more complex or more costly form or version of the primary service. These qualifying combinations are promoted from the originating C-APC to a higher-paying C-APC within the same clinical family after CMS assesses the claim for eligible code pairings. Once the primary service is identified, CMS evaluates its combination with other "J1" services, or applicable add-on codes, on the claim to determine whether any pairings meet the complexity adjustment criteria. For CY 2026, there is no change to policy, but CMS is requesting comments on potential refinements to its C-APC complexity adjustment criteria for CY 2026. Specifically, the agency is considering expanding the types of code combinations, including service pairings and clusters, that may qualify for complexity adjustments when they represent clinically appropriate, high-cost subsets of a primary "J1" service. CMS seeks feedback on how to define these combinations, establish cost and frequency thresholds and identify clinically integral services that warrant additional payment. The agency is also requesting comments on how granular coding practices may impact the effectiveness and accuracy of complexity adjustments in hospital outpatient settings.

Proposed Changes to Packaged Items and Services

The OPPS packages payments for multiple interrelated items and services into a single payment that is designed to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. CMS does not propose changes to the overall packaging policy but does provide proposals related to diagnostic radiopharmaceuticals and non-opioid treatments for pain relief.

Proposed Payment for Diagnostic Radiopharmaceuticals

CMS notes that under the OPPS it packages several categories of non-pass-through drugs, biologicals and radiopharmaceuticals, regardless of the cost of the products. A diagnostic product

¹⁴ Statute requires CMS to create additional groups of covered OPD services that classify devices of brachytherapy – cancer treatment through solid source radioactive implants – consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services.

¹⁵ See Table 39 on Page 206 of the Proposed Rule for a list of APCs designated as a low volume APC for CY 2026

(e.g., contrast agents, stress agents and other products) is a type of product where the cost is "policy packaged" for purposes of determining the costs of the associated procedures in the APC. For CY 2026, CMS proposes a technical refinement to the current policy of paying separately for diagnostic radiopharmaceuticals with per-day costs exceeding a designated threshold, initially set at \$630 and updated annually using the Producer Price Index (PPI), for prescription pharmaceuticals. Based on updated methodology for updating the \$630 threshold, 16 the updated threshold is \$655 per day for CY 2026. CMS also proposes assigning HCPCS codes for diagnostic radiopharmaceuticals with per-day costs above the \$655 packaging threshold to status indicator "K". signifying separate payment based on the code's arithmetic Mean Unit Cost (MUC). HCPCS codes for radiopharmaceuticals at or below the threshold would retain status indicator "N", meaning their payment remains packaged with the associated service. The proposed list of diagnostic radiopharmaceuticals that were calculated as having per day costs that exceed \$655 and their proposed status indicators can be found in Table 4 (pg. 81) of the Proposed Rule, CMS is seeking comment from interested parties on how CMS can ensure more consistent, validated, and universal reporting for ASP¹⁷ to be a viable payment methodology utilized in future rulemaking.

Proposed Payment for Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 provides temporary additional payments for non-opioid treatments for pain relief furnished between January 1, 2025 and January 1, 2028. For CY 2026, CMS proposes to continue the CY 2025 policy of providing temporary separate payment for qualifying non-opioid treatments for pain relief under OPPS. **CMS is also seeking public comments on proposed qualifying products for CY 2026**.

Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services and items are generally based on medical billing codes, specifically HCPCS codes, that are reported on hospital OPD claims. HCPCS codes are used to report surgical procedures, medical services, items and supplies under the hospital OPPS and are updated and changed throughout the year. In the April 2025 OPPS update, CMS established 104 new HCPCS codes effective April 1, 2025, and introduced 110 new HCPCS codes effective July 1, 2025. A full list of the April updated codes can be found in Table 9 (pg. 132-135) and the July updated codes are listed in Table 10 (pg. 136-140) of the Proposed Rule. Furthermore, the codes for these updates are designated with comment indicator "NP" in Addendum B. CMS seeks comments on these proposed APC and status indicator assignments.

Application of the 2 Times Rule

CMS notes that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to resource use if the highest cost for an item or service in the group is more than two times greater than the lowest cost for an item or service within the same

¹⁶ CMS plans to use the most recently available forecast for the four-quarter moving average Produced Price Index (PPI) levels for Pharmaceutical for Human Use, Prescription from the third quarter of 2025 to the third quarter of 2026, and to round the resulting dollar amount to the nearest \$5 increment.

¹⁷ While CMS proposes to continue to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2026, CMS reiterates that manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2026, ASP reporting is voluntary for diagnostic radiopharmaceuticals paid under the OPPS.

groups (known as the "2 Times Rule"). However, CMS may provide exceptions to the 2 Times Rule in unusual cases (e.g., low-volume items and services). For CY 2026, CMS proposes to grant exceptions to 26 APCs that exceed the limits of the 2 Times Rule; Table 12 of the Proposed Rule (pg. 148) lists proposed exception codes.

RFI: Software as a Service (SaaS)

CMS has concerns that available claims may not accurately reflect the true cost of evolving SaaS technologies and has issued an RFI seeking feedback on alternative and consistent payment methods for SaaS under the OPPS to consider for future rulemaking. Specifically, CMS is evaluating the development of a consistent, cross-setting payment policy for SaaS technologies, including AI tools used in outpatient care. In recent years, CMS has paid separately for SaaS under the OPPS through New Technology APCs but lacks a dedicated methodology. Since SaaS continues to evolve, CMS seeks comments on how best to reflect the value of these technologies in Medicare payment, ensure fiscal responsibility and good stewardship by promoting high-value, cost-effective care and navigate challenges such as unverifiable costs, lack of comparators and limited claims data. Specific questions on this RFI can be found in the Proposed Rule (pg. 215). CMS issued a similar comment solicitation on a payment policy for SaaS under the CY 2026 Physician Fee Schedule (PFS) Proposed Rule.

Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

Notice of Intent to Conduct Medicare OPPS Drugs Acquisition Cost Survey

In the Proposed Rule, CMS provides notice of the agency's intent to conduct a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including specified covered outpatient drugs (SCODs) and drugs and biologicals CMS has historically treated as SCODs. CMS intends to conduct this survey from January 1, 2026 through March 31, 2026. An Information Collection Request (ICR) for this survey is included in the Proposed Rule (pg. 822-826).

CMS states that the survey is designed to impose the least amount of burden on hospitals as possible. CMS plans to survey hospitals only about drugs that are separately paid under the OPPS and will ask hospitals to report the total acquisition cost, net of all rebates and discounts, of each drug by National Drug Code (NDC) purchased during the 1-year timeframe of July 1, 2024, through June 30, 2025. There are approximately 700 drug HCPCS codes that will be subject to the survey, with most HCPCS codes having multiple NDCs per HCPCS code. CMS will publish a draft list of the NDCs that CMS intends to include in the survey and plans to ask hospitals to separately list their acquisition costs for drug NDCs acquired through the 340B program and those drug NDCs acquired outside of the 340B program. CMS intends to use the survey to inform CY 2027 payment policy.

CMS seeks comment on survey design, response requirements and methodologies, particularly whether the survey should be a mandatory requirement of all hospitals paid under the OPPS and how CMS should approach payment to hospitals for drugs usually paid under the OPPS absent a hospital's response to the survey as non-responses may suggest minimal or strategically withheld acquisition cost data. To estimate costs for hospitals that do not respond to the survey, CMS may use the lowest reported cost among similar respondents or rely on external benchmarks like Federal Supply Schedule pricing, 340B ceiling prices or ASP-based rates. CMS will evaluate whether non-responses should influence packaging decisions—potentially treating drug costs as ancillary and bundling them into associated service payments.

Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals and Radiopharmaceuticals

Current statute provides for temporary additional payments, "transitional pass-through payments," for certain drugs and biologicals. ¹⁸ Under the OPPS, CMS primarily uses the manufacturer-reported ASP as the basis of reimbursement but may use alternative data (e.g., wholesale acquisition cost (WAC), average wholesale price (AWP)) in certain circumstances, such as if ASP data is not available. Transitional pass-through payments for a drug or biological can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2026 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to this Proposed Rule.

CMS lists 28 drugs and biologicals for which pass-through payment status expires by December 31, 2025 in <u>Table 57</u> (pgs. 317-318) and proposes to end pass-through payment status in CY 2026 for 52 drugs and biologicals, listed in <u>Table 58</u> (pgs. 321-324).

CMS proposes to continue pass-through payment status in CY 2026 for 41 drugs and biologicals which had pass-through payment status begin between April 1, 2024 – April 1, 2025 and these drugs and biologicals are listed in Table 59 of the Proposed Rule (pgs. 327-329).

Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status: Proposed Packaging Threshold

For CY 2026, CMS proposes updating the packaging thresholds for drugs and diagnostic radiopharmaceuticals using the four-quarter moving average of the PPI for Pharmaceuticals for Human Use (Prescription), consistent with the methodology finalized in CY 2007. CMS also proposes a technical refinement to ensure the threshold is trended from the third quarter of the prior year to the third quarter of the payment year. If more recent PPI data becomes available before finalization, CMS may revise these thresholds accordingly. As a result, for CY 2026, CMS proposes a packaging threshold of \$140 for drugs, biologicals and therapeutic radiopharmaceuticals.

For diagnostic radiopharmaceuticals, CMS proposes to package those items with a per day cost less than or equal to \$655 and identify items with a per day cost greater than \$655 as separately payable.

Medicare Part B Drugs without a Medicaid National Drug Rebate Agreement (NDRA)

CMS is notifying stakeholders that certain single-source drugs, biologicals and radiopharmaceuticals, identified in Table 66 in the Proposed Rule, currently lack a Medicaid National Drug Rebate Agreement (NDRA). Manufacturers must have an active NDRA for their covered outpatient drugs to remain eligible for Medicare Part B payment. If these manufacturers or

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¹⁸ As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. "Current" refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented. Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as a hospital OPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs."

labelers do not promptly enter into such agreements, CMS will designate the associated HCPCS codes with OPPS status indicator E1 and ASC payment indicator B5, rendering them non-payable under Medicare in outpatient settings.

Add-on Payment for Technetium-99m (Tc-99m) Derived from Domestically Produced Molybdenum-99 (Mo-99)

To support domestic Mo-99 production, CMS initially provided a \$10 add-on payment for Tc-99m derived from non-HEU sources but finalized its phase-out by the end of CY 2025. CMS raised concerns that once U.S. companies initiate Mo-99 production, the difference in pricing models will likely create a payment inequity, as hospitals purchasing Tc-99m derived from domestically produced Mo-99 would likely pay higher prices than those purchasing Tc-99m derived from imported Mo-99. To address this possible payment inequity, CMS established a new add-on payment of \$10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026, in the CY 2025 Final Rule.

In the Proposed Rule, to help implement the previously finalized add-on payment, CMS proposes to establish a new HCPCS C-code C917X (Tc-99m from domestically produced non-HEU Mo-99, [minimum 50 percent], full cost recovery add-on, per study dose). Hospitals can bill this add-on code if the hospital can certify that at least 50 percent of the Mo-99 in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99. In the Proposed Rule, CMS indicates that it expects hospitals requesting additional payment to perform standard due diligence to ensure their claims are supported by internal records (e.g., supplier invoice, label, contract) and provides that this proposal is similar to the existing non-HEU add-on payment and certification requirement. CMS also notes its intent to establish documentation requirements in future rulemaking to ensure providers can access the add-on payment once domestic production begins. Additionally, CMS invites comments on targeted questions designed to help refine its approach to recognizing the per-dose cost of Tc-99m, including additional steps CMS can take to reduce administrative burden for purposes of this add-on payment. A list of questions is in the Proposed Rule (pgs. 412-413).

Payment for Skin Substitutes

CMS indicates that several emerging industry practices have been contributing to significant growth in the number of available skin substitute products, including shifts in their sales and distribution strategies and rapid turnover in manufacturer ownership. To address this growth, CMS proposes, starting January 1, 2026, to separately pay for the provision of certain groups of skin substitute products as incident-to supplies when they are used during a covered application procedure paid under the PFS in the non-facility setting or under the OPPS. This proposal does not apply to biological products licensed under section 351 of the Public Health Service Act (PHSA), which will continue to be paid as biologicals under the ASP methodology.

¹⁹ In the Proposed Rule, CMS makes several proposals related to domestically produced Tc-99m that are consistent with the Department of Energy, National Nuclear Security Administration's (DOE/NNSA's) recommendations. CMS also reiterates that the DOE/NNSA would establish criteria to certify whether the Tc-99m radiopharmaceutical dose is derived from domestically produced Mo-99 and eligible for the add-on payment.

CMS also proposes grouping skin substitute products that are not drugs or biologicals into three payment categories based on FDA regulatory classifications (PMAs²⁰, 510(k)s²¹, and 361 HCT/Ps²²). CMS proposes to establish three APCs and initial payment rates for the three FDA regulatory categories based on the volume-weighted average ASP for skin substitute products in each category as submitted by manufacturers, when available. This policy is proposed to be implemented in a site neutral manner across both the non-facility setting under the PFS and OPD settings under OPPS. For CY 2026, CMS proposes to establish the same initial APC payment rate for each group of skin substitutes, including the three FDA classification groups. **CMS requests comment on the proposal to group skin substitutes into three FDA approval categories, PMA, 510(k) and 361 HCT/P, to set payment rates and the proposal to group any skin substitutes authorized through the De Novo pathway with those cleared under 510(k)s for payment purposes.**

As device pass-through payment status would still be available to new skin substitutes that meet the pass-through payment criteria in the OPD setting, CMS proposes to continue offering device pass-through payment status for new skin substitutes that meet eligibility criteria in the hospital outpatient setting. Skin substitutes approved under device pass-through would be paid in alignment with other devices in that pathway, rather than being categorized by cost.

CMS also proposes creating a new status indicator "S1" under the OPPS for CY 2026 and beyond to designate that skin substitute products are paid separately from associated procedure codes. CMS proposes assigning all existing HCPCS codes describing skin substitute products to status indicator "S1" for CY 2026, signaling their standalone payment status under OPPS. The complete list of proposed CY 2026 payment status indicators and their definitions is displayed in Addendum D1 to the Proposed Rule.

Proposed OPPS Payment for Devices

Proposed OPPS Pass-Through Payment for Devices

Transitional device pass-through payment facilitates access for beneficiaries to new and innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate. Under the OPPS, a category of devices may be eligible for transitional pass-through payments for a minimum of two years, but not to exceed three years. Table 46 (pgs. 222-224) of the Proposed Rule lists the devices with pass-through status expiring in 2025, 2026, or 2027. CMS received 8 complete applications by the March 3, 2025, quarterly deadline which is the last quarterly deadline for applications to be included in the Proposed Rule. CMS received 4 alternative pathway device pass-through applications (i.e., devices that received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation). More information regarding the applications is available in the Proposed Rule (pgs. 229-299). CMS welcomes comments on these applications.

²⁰ PMA-approved wound care products generally are intended to go beyond a simple wound cover to provide some type of direct treatment effect.

²¹ 510(k)-cleared devices are dressings intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap. Also, CMS proposes to group any skin substitutes authorized through the De Novo pathway with those cleared under 510(k)s.

²² Registered 361 HCT/Ps generally are dressings intended only to cover and protect a wound and are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap.

<u>Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients</u>

In the CY 2026 PFS Proposed Rule, CMS proposed to make permanent the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS, except for services that have a global surgery indicator of 010²³ or 090²⁴. As a result, CMS proposes the same policy in the Proposed Rule to make the availability of the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) permanent, except for diagnostic services that have a global surgery indicator of 010 or 090.

Proposed Services That Will Be Paid Only as Inpatient Services

The inpatient only (IPO) list identifies services for which Medicare will only make payments when the services are furnished in the inpatient hospital setting because of the nature of the procedure, the underlying physical condition of the patient or the need for at least 24 hours of postoperative recovery time or monitoring period before discharge. Currently, there are approximately 1,731 services on the IPO list and CMS annually reviews the IPO list to identify any services that should be removed from, or added to, the list, based on the most recent data and medical evidence available. CMS uses five specific criteria for assessing procedures for removal from the IPO list.²⁵

CMS initially finalized two IPO payment policies in the CY 2021 OPPS Final Rule. The first was to entirely remove the IPO list and the second was that procedures removed from the IPO list would be indefinitely exempted from certain medical review activities related to the two-midnight policy. These policies were subsequently reversed. For CY 2026 and subsequent years, CMS again proposes to eliminate the IPO list through a 3-year transition, completing the elimination by January 1, 2029, to allow providers time to prepare to furnish newly removed procedures on an outpatient basis, update their billing systems and gain experience with newly removed procedures eligible to be paid under either the IPPS or OPPS.

For CY 2026, CMS recommends the removal of 285 mostly musculoskeletal services as the first group of services removed from the IPO list because of the development of new technologies and advances in surgical care protocols, expedited rehabilitation protocols, improved infection control practices and significant enhancements to postoperative processes. A list of the 285 musculoskeletal services proposed for removal of the IPO list can be found on Table 69 (pg. 465-478) of the Proposed Rule.

Proposed Changes to the Ambulatory Surgical Center (ASC)-Covered Procedures List (CPL)

²³ "Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable"

²⁴ 090 "Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount"
²⁵ The five criteria CMS uses are: 1. Most outpatient departments are equipped to provide the services to the Medicare population. 2. The simplest procedure described by the code may be furnished in most outpatient departments. 3. The procedure is related to codes that we have already removed from the IPO list. 4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis. 5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

²⁶ https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf

For CY 2026, CMS proposes adding 276 surgery codes to the ASC-CPL that are not on the CY 2025 IPO list and adding 271 surgery codes to the CPL that are currently on the IPO list, if the proposal to remove these services from the IPO list is finalized for CY 2026. These codes are listed in Tables 80 and 81 (pgs. 568-589) of the Proposed Rule.

Also, CMS proposes revising the general standard criteria for adding procedures to the ASC-CPL starting in CY 2026 and proposes two additional methods for adding procedures to the ASC-CPL. CMS notes that once procedures are added, physicians would use patient-specific clinical judgment to determine whether the procedure can be safely performed in an ASC setting.

Quality Program Updates

<u>Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs</u>

Proposed Measure Changes

For the Hospital OQR and ASCQR Programs, CMS proposes to remove the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/CY 2026 payment determination)²⁷. If this proposal is finalized, hospitals and ASCs that do not report their CY 2024 reporting period data for this measure would not be considered noncompliant with the measure for their CY 2026 payment determination and not be penalized for CY 2026 payments due to this measure. **CMS invites comments on this proposal.**

Also, for the Hospital OQR, REHQR and ASCQR Programs, CMS proposes to remove the Hospital Commitment to Health Equity (HCHE) and Facility Commitment to Health Equity (FCHE) measures beginning with the CY 2025 reporting period/CY 2027 payment or program determination. ²⁸ If this proposal is finalized, hospitals, REHs and ASCs that do not report their CY 2025 reporting period data for the HCHE or FHCE measure to CMS would not be considered noncompliant with the measure for purposes of their CY 2027 payment or program determination. **CMS requests comment on this proposal.**

In addition, CMS proposes to remove the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health process measures from the Hospital OQR, REHQR and ASCQR Programs beginning with the CY 2025 reporting period²⁹. **CMS asks for comment on these proposals.**

Proposed Updates to the Extraordinary Circumstances Exception (ECE) Policy

²⁷ CMS estimates the burden of collecting this information annually across all 3,200 hospitals in the Hospital OQR Program is between \$1,446,400 and \$1,687,680. Across the 4,590 ASCs in the ASCQR Program, the estimated annual burden is between \$2,074,680 and \$2,420,766.

²⁸ CMS estimates removal of these measures would alleviate an estimated annual burden of approximately 533 hours, at a cost of \$22,518, across all participating hospitals; 6 hours, at a cost of \$332, across all participating REHs; and 746 hours, at a cost of \$41,313 across all participating ASCs.

²⁹ CMS estimates a total annual burden of 6,878,055 hours at a cost of \$168,460,032 in the Hospital OQR Program (89 FR 94523 and 94524), 12,984 hours at a cost of \$318,163 in the REHQR Program (89 FR 94530 and 94531), and 711,479 hours at a cost of \$17,447,164 in the ASCQR Program (89 FR 94534 and 94535), to screen all admitted patients in accordance with measure specifications for Screening for Social Drivers of Health and report the measure data. For Screen Positive Rate for Social Drivers of Health, we estimated a total annual burden of 533 hours at a cost of \$29,518 in the Hospital OQR Program (89 FR 94524), 6 hours at a cost of \$332 in the REHQR Program (89 FR 94531 and 94532), and 746 hours at a cost of \$41,313 in the ASCQR Program (89 FR 94535), to report the measure data.

Under the current ECE regulations³⁰, CMS grants exceptions to data submission deadlines and requirements for the Hospital OQR, REHQR and ASCQR Programs in the event of extraordinary circumstances beyond the control of a hospital, rural emergency hospital (REH), or ASC. CMS proposes to shorten the ECE request window from 90 to 30 calendar days after the event's occurrence, aligning with implementation timelines across CMS quality reporting programs. The request must be made in writing.

CMS also proposes that the agency may grant an ECE to one or more hospitals, REHs or ASCs that have not requested an ECE if CMS determines that a systemic problem with a CMS data collection system directly impacted the ability to comply with a quality data reporting requirement or that an extraordinary circumstance has affected an entire region. **CMS welcomes comment on these proposals.**

Measure Concepts under Consideration for Future Years in the Hospital OQR, REHQR, and ASCQR Programs— RFI: Well-Being and Nutrition

CMS is seeking public input on well-being and nutrition measures for potential inclusion in the Hospital OQR, REHQR and ASCQR Programs. Specifically, CMS invites comments on tools that evaluate overall health, emotional wellness, social connection, life satisfaction, and fulfillment. CMS also welcomes feedback on measures that support complementary and integrative health, skill building, self-care, optimal nutrition, and preventive care across these quality reporting programs. Assessments for nutritional status may include strategies, guidelines, and practices that promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. Such assessments may also include aspects of health that support or mediate nutritional status, such as physical activity and sleep.

Hospital Outpatient Quality Reporting Program

The Hospital OQR Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency and ensure accountability of hospital OPDs. Certain hospitals³¹ that do not submit data required for measures selected with respect to such a year will incur a 2.0 percentage point reduction to their annual OPD fee schedule increase factor.

Proposed Changes to the Hospital OQR Program Measure Set

Proposed Adoption of the Emergency Care Access & Timeliness eCQM Beginning With Voluntary Reporting for the CY 2027 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2028 Reporting Period/CY 2030 Payment Determination

Due to growing concerns about the quality and timeliness of care in the hospital emergency department (ED), CMS proposes adoption of the Emergency Care Access & Timeliness eCQM.³² If the proposal to adopt this measure is finalized, CMS will monitor the burden on patients and

³⁰ (42 CFR 419.46(e); 419.95(g); 416.310(d), respectively).

³¹ Subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act)

³² This measure specified for the hospital setting and calculates the proportion of four outcome metrics that quantify access to and timeliness of care in an ED setting against specified thresholds, including: (1) patient wait time – 1 hour; (2) whether the patient left the ED without being evaluated; (3) patient boarding time in the ED; (as defined by a Decision to Admit (order) to ED departure for admitted patients) – 4 hours; and (4) patient ED LOS (time from ED arrival to ED physical departure, as defined by the ED departure timestamp) – 8 hours.

providers and identify areas where challenges may persist as part of the standard measure maintenance.

Additionally, for the CY 2027 reporting period, CMS proposes that hospitals that voluntarily submit Emergency Care Access and Timeliness eCQM data could submit data for any quarter(s) up to all four quarters of data. Beginning with the CY 2028 reporting period/CY 2030 payment determination, CMS proposes to require that hospitals report all four calendar quarters (one calendar year) of data and for this measure to be submitted by May 15 in the year prior to the affected payment determination year. For example, for the CY 2028 reporting period/CY 2030 payment determination, hospitals would be required to submit eCQM data by May 15, 2029.

A full description of the proposed measure calculation, including information on the numerator and denominator, is found on pgs. 638-641 of the <u>Proposed Rule</u>. **CMS requests comments on these proposals**.

Proposed Removals of the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) Measure and the Left Without Being Seen Measure Beginning With the CY 2028 Reporting Period/CY 2030 Payment Determination

CMS notes that the numerator components³³ of the proposed Emergency Care Access & Timeliness eCQM measure overlap with the patient population and measure specifications of the Median Time for Discharged ED Patients measure³⁴ and the Left Without Being Seen measure³⁵. CMS notes that if the Emergency Care Access & Timeliness eCQM is finalized as proposed, it would serve as a replacement for these two existing chart-abstracted measures in the Hospital OQR. **CMS requests comments on this proposal.**

Modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) Measure (Excessive Radiation eCQM) from Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination to Continue Voluntary Reporting in the CY 2027 Reporting Period and Subsequent Years

In the CY 2024 OPPS Final Rule³⁶, CMS adopted the Excessive Radiation eCQM with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, one year later than originally proposed. The delay was in response to stakeholder concerns regarding the burden associated with implementing the eCQM. CMS proposes to modify the reporting requirements for this measure by maintaining voluntary reporting of this measure instead of mandatory reporting, continuing with the CY 2027 reporting period. CMS plans to continue to consider feedback regarding this measure and may propose additional changes in future rulemaking. **CMS invites comment on this proposal**.

³³ Numerator component (2) overlaps with the Left Without Being Seen patient population, and numerator component (4) overlaps with the Median Time for Discharged ED Patients measure. In addition to capturing the same data elements as the Median Time for Discharged ED Patients and Left Without Being Seen measures, the Emergency Care Access & Timeliness eCQM measures boarding time in the ED, numerator component (3), and time from arrival to placement in a treatment room, numerator component (1), which are not currently captured by any other measure currently in the Hospital OQR Program measure set.

³⁴ The Median Time for Discharged ED Patients measure assesses the time patients spent in the ED before being sent home, also known as ED throughput.

³⁵ The Left Without Being Seen measure assesses the percentage of patients who leave the ED without being evaluated by a physician/advanced practice nurse/physician's assistant (physician/APN/PA).

³⁶ https://www.govinfo.gov/content/pkg/FR-2023-11-22/pdf/2023-24293.pdf

Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Summary

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS's hospital quality measurement programs, by assigning hospitals between one and five stars. Measures reported on the provider comparison tool on Medicare.gov³⁷ that meet the criteria for inclusion in the Overall Hospital Quality Star Rating are organized into five measure groups: Safety of Care, Mortality, Readmission, Patient Experience (all of which include outcome measures) and Timely and Effective Care (which includes a selection of process measures). To receive an Overall Hospital Quality Star Rating, hospitals must have at least three measures in at least three measure groups, one of which must be Mortality or Safety of Care. These two groups are weighted most heavily at 22 percent each. Once a hospital qualifies for a rating, all groups with any scored measures are included. Even if a hospital has only one or two Safety of Care measures, it still receives a score for that group. CMS now proposes a two-stage update to give greater emphasis to the Safety of Care group.

In the first stage, CMS proposes to limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of 4 stars out of 5 so that any hospital that is assigned 5 stars but has a lowest quartile Safety of Care score (based on at least three Safety of Care measures) would be reassigned to 4 stars in the CY 2026 Overall Hospital Quality Star Rating.³⁸ For the second stage of the methodology update, CMS proposes to reduce the Overall Hospital Quality Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measure scores) by 1 star, to a minimum 1-star rating for the 2027 Overall Hospital Quality Star Rating and later years.³⁹ CMS provides hospitals the opportunity to preview their Overall Hospital Quality Star Rating prior to publication. Hospitals have at least 30 days to preview their results, and if necessary, can reach out to CMS with questions. **CMS invites comments on these proposals**.

Proposed Market-Based Medicare Severity-Diagnosis Related Groups (MS-DRG) Relative Weight Data Collection and Change in Methodology for Calculating MS-DRG Relative Weights under the Inpatient Prospective Payment System

CMS is revisiting a policy that was reversed in the FY 2022 IPPS Final Rule related to data used for MS-DRG rate setting. ⁴⁰ In the Proposed Rule, CMS proposes a similar policy to use market-based data to calculate MS-DRG relative weights. Specifically, CMS proposes that hospitals report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage Organization (MAO) payers, by MS-DRG, effective for cost reporting periods ending on or after January 1, 2026, and to use this data in a new market-based MS-DRG relative weight methodology, beginning in FY 2029.

If this proposal is finalized, this data would be used in a market-based MS-DRG relative weight methodology, starting with relative weights calculated for FY 2029. As related to the IPPS relative weight methodology, CMS indicates that the use of the median payer-specific negotiated charges

³⁷ https://www.medicare.gov/care-compare/

³⁸ CMS estimates that using 2024 Overall Hospital Quality Star Rating data, implementing a cap of 4 stars in the lowest quartile of Safety of Care with at least three safety measures would result in 14 hospitals, out of 2,847 hospitals, receiving a lower Overall Hospital Quality Star Rating.

³⁹ CMS estimates that using 2024 Overall Hospital Quality Star Rating data, applying a 1-star reduction for all hospitals in the lowest quartile of Safety of Care with at least three safety measures would result in 459 hospitals, out of 2,847 hospitals, receiving a lower Overall Hospital Quality Star Rating beginning in CY 2027 and for later years.

⁴⁰ https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf

would replace the current use of gross charges that are reflected in a hospital's chargemaster and cost information from Medicare cost reports for the development of the IPPS MS-DRG relative weights.

CMS anticipates that hospital price transparency information may be relevant for purposes of reporting the proposed median payer-specific negotiated charge by MS-DRG for MAOs. As noted below, CMS proposes additional hospital price transparency requirements.

In the <u>Proposed Rule</u> (pgs. 771-779), CMS provides instruction on how hospitals would calculate the median of the payer-specific negotiated charges for an MS-DRG using data from the machine-readable file (MRF) that hospitals are required to disclose under the hospital price transparency regulations. **CMS asks for comment on all elements of this proposed market-based data** collection for cost reporting periods ending on or after January 1, 2026, and market-based methodology for estimating the MS-DRG relative weights beginning in FY 2029. CMS also asks for comment on potential unintended consequences of this proposal, if any, including if special considerations are needed to mitigate those potential consequences for certain hospitals and how these or other market-based strategies could be utilized in additional Medicare FFS payment systems and the benefits of these market-based approaches.

<u>Price Transparency: Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges</u>

The CY 2020 OPPS Final Rule⁴¹ adopted requirements for hospitals to make public their standard charges through a comprehensive MRF and in a consumer-friendly format. In subsequent regulatory action, CMS strengthened both the <u>Hospital Price Transparency</u> (HPT) enforcement process and revised several HPT requirements to improve access to, and the usability of, hospital standard charge information; standardize the way hospital charges are presented; align certain HPT requirements and processes with requirements in the <u>Transparency in Coverage (TiC) initiative</u>; and strengthen and streamline monitoring and enforcement capabilities. Consistent with a recent Executive Order⁴² and to better attain the goals articulated in previous HPT rulemaking, CMS proposes several modifications to current HPT requirements.

New Data Elements and Definitions

In response to stakeholder feedback on the usability of data and the agency's observations through audits, CMS proposes to require hospitals to report four new data elements when a standard charge is based on a percentage or algorithm.⁴³ These include the median allowed amount (which would replace the estimated allowed amount data element), the 10th percentile and 90th percentile allowed amounts and the count of allowed amounts used to calculate the median, 10th, and 90th percentile allowed amounts. To align with this proposal, the agency proposes to add definitions for

⁴¹ https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf

⁴² "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information, https://www.presidency.ucsb.edu/documents/executive-order-14221-making-america-healthy-again-empowering-patients-with-clear-accurate

accurate

43 CMS estimates that hospitals will incur an additional one-time cost to update their processes and systems to (1) identify and collect new data elements and (2) encode the standard charge information for the newly proposed elements in the CMS standard template. This one-time burden estimate, as demonstrated in section "XXII. Collection of Information" of this proposed rule is 37,080 hours for all hospitals (5 hours x 7,416 hospitals) at a cost of \$3,545,441.28 (7,416 hospitals x [(\$87.52 x 4 hours) + (\$128.00 x 1 hour)]).

three new data elements, the "median allowed amount⁴⁴," the "tenth (10th) percentile allowed amount⁴⁵," and the "ninetieth (90th) percentile allowed amount⁴⁶."

Updates to Reporting Requirements

Under current regulations, hospitals must disclose the percentage or algorithm used to calculate payer-specific negotiated charges when those charges are not expressed as fixed dollar amounts. They must also calculate and encode an estimated allowed amount in dollars for each item or service. CMS proposes revising the regulations to require hospitals, beginning January 1, 2026, to report the median allowed amount, instead of the estimated amount, when a payer-specific negotiated charge is based on a percentage or algorithm. The median allowed amount would reflect the midpoint of actual payments received from third-party payers over the prior 12 months, calculated using electronic remittance advice data. If the median falls between two values, hospitals must report the next highest observed amount. **CMS requests comments on this proposal**.

CMS also proposes to amend regulations to require that, beginning January 1, 2026, if a payer-specific negotiated charge is based on a percentage or algorithm, the hospital must calculate and encode a 10th and a 90th percentile allowed amount in dollars for that item or service in MRFs. CMS proposes to require that hospitals only use EDI 835 ERA transaction data⁴⁷ to calculate and encode the allowed amounts, excluding zero-dollar claims to avoid skewed results. Hospitals with no historical data may encode "0" and provide explanatory notes, such as "new or recently revised payer contract." Additionally, CMS proposes that hospitals base the median allowed amount, the 10th and 90th percentile allowed amounts and the count of allowed amounts on EDI 835 ERA transaction data from a lookback period of no longer than 12 months prior to posting the MRF to ensure consistency and comparability across hospitals. **CMS requests comments on these proposals.**

Proposal to Modify the MRF Affirmation Statement

CMS proposes replacing the current MRF affirmation statement requirement with a more detailed attestation statement within the MRFs, effective January 1, 2026. Under this proposal, hospitals would be required to attest that all applicable standard charge information is included and is true, accurate, and complete as of the file's date; all payer-specific negotiated charges that can be expressed in dollars are encoded; and for charges based on a percentage, algorithm, or formula, hospitals must confirm that such methodology precludes the provision of a fixed dollar amount and that all necessary information has been provided to allow the public to derive the dollar amount. Additionally, hospitals must encode the name of the CEO, president, or senior official responsible

received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 10th percentile allowed amount is the next highest observed value.

^{44 &}quot;Median allowed amount" would be defined as the median of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated median fall between two observed allowed amounts, the median allowed amount is the next highest observed value.
45 "Tenth (10th) percentile allowed amount" would be defined as the 10th percentile of the total allowed amounts the hospital has historically

⁴⁶ Ninetieth (90th) percentile allowed amount" would be defined as the 90th percentile of total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount is the next highest observed value.

⁴⁷ EDI 835 ERA transaction data is electronic transaction data that provides claim payment information that hospitals use to track and analyze their claims and reimbursement patterns, including any adjustments made to the claim such as denials, reductions, or increases to the amount charged, and expected patient co-pays, coinsurance or secondary coverage, would meet the requirement to calculate an allowed amount.

for overseeing the accuracy and completeness of the data. CMS requests comment on this proposal.

Proposal to Report Hospital National Provider Identifier (NPI) Information in the MRF

Stakeholders have reported that current requirements are inadequate to facilitate comparing hospital MRF data with other datasets that include hospital-related information and that a standard identifier would bolster these efforts. Therefore, CMS proposes to update regulations to require hospitals, beginning January 1, 2026, to report a unique identifier, specifically their NPI(s), in their MRFs. Specifically, CMS proposes to require that hospitals report, in a newly created general data element in the MRF, any Type 2 NPI(s)⁴⁸ that has a primary taxonomy code starting with '28' (indicating hospital) or '27' (indicating hospital unit) and that is active as of the date of the most recent update to the standard charge information. CMS plans to include additional technical instructions in the CMS data dictionary and JSON schema in the Hospital Price Transparency – Data Dictionary GitHub Repository. 49 CMS requests feedback on this proposal and any additional taxonomy codes that would be necessary or helpful to consider.

Proposal to Improve and Enhance Enforcement

CMS enforces HPT requirements through an established process⁵⁰, including issuance of civil monetary penalties (CMPs) when a noncompliant hospital fails to respond to a request to submit a corrective action plan (CAP) or comply with the requirements of the CAP. Current HPT regulations include the criteria used to determine the CMP amount⁵¹ and permit hospitals to appeal a CMP within 30 days of issuance of the notice to an administrative law judge (ALJ). CMS notes that other CMS enforcement programs offer entities subject to CMPs the ability to waive appeal rights in exchange for a 35 percent discount on the amount of the CMP owed.⁵² Therefore, CMS proposes an update to the HPT regulations offering the amount of a CMP to be reduced by 35 percent should a hospital submit to CMS a written notice requesting to waive its right to a hearing within 30 calendar days of the date of the notice of imposition of the CMP. If a hospital waives its right to appeal a CMP and receives a 35 percent reduction, the hospital: (1) would not be eligible to receive a 35 percent reduction on any CMPs that result from the same instance(s) of noncompliance (that is, continuing violations); and (2) would waive its right to appeal CMPs for any such continuing violations. A hospital that meets the criteria to receive a reduction to the civil monetary penalty that had been imposed upon it must pay the CMP within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS.

CMS proposes to restrict CMP reduction opportunities in two key scenarios where hospitals fail to meet essential HPT requirements. In such cases, hospitals would forfeit eligibility for penalty mitigation and be required to pay the full CMP amount. Hospitals that do not waive their right to a hearing within 30 days of a CMP notice, or that fail to post required pricing information, would lose eligibility for reduced penalties and must pay the full amount. CMS asks for comment on these proposals.

⁴⁸ Healthcare providers who are individuals are assigned a Type 1 NPI and healthcare providers that are organizations are assigned a Type 2 NPI.

⁴⁹ Available at https://github.com/CMSgov/hospital-price-transparency

^{50 § 180.90(}a), https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-E/part-180/subpart-C/section-180.90 (§ 180.90(c)), https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-E/part-180/subpart-C/section-180.90

⁵² For example, with the CMP reduction pertaining to LTC facilities from CYs 2016 and 2022, around 80 percent of LTC facilities submitted waivers, with the figure rising to 91 percent in CY 2021 but retreating to 81 percent in CY 2022, while also a considerable percentage of the remaining facilities did not submit a waiver but also not did not contest the penalty and its basis. Most significantly, throughout the period only between 2 to 6 percent of facilities availed themselves of the full hearing process.

Graduate Medical Education Accreditation

A recent Executive Order⁵³ directs the Attorney General, in consultation with the HHS Secretary, to investigate and act against medical schools and graduate medical education entities that enforce diversity, equity and inclusion (DEI) based accreditation standards, particularly those advanced by the Liaison Committee on Medical Education (LCME⁵⁴) and the Accreditation Council for Graduate Medical Education (ACGME⁵⁵). CMS remarks that many DEI programs unlawfully discriminate against Americans based on race, justifying this statement with a 2023 Supreme Court ruling⁵⁶ that race-based admissions policies, even when focused on the goal of diversity, violate the Equal Protection Clause of the Fourteenth Amendment unless they satisfy strict scrutiny.

CMS proposes that accreditors may not require as part of accreditation, or encourage institutions to put in place, DEI programs that encourage unlawful discrimination based on race or other violations of Federal law beginning on January 1, 2026. Additionally, CMS notes that the HHS Secretary may recognize other organizations that meet or exceed Medicare's requirements as accreditors to increase the potential for competition in the accreditation space and improve the quality of the accreditation process. **CMS welcomes feedback on this proposal.**

What's Next?

The OPPS tables for the Proposed Rule are available on the <u>CMS website</u>. CMS is anticipated to publish the final OPPS regulation in early November, and the changes are effective at the beginning of the calendar year (January 1, 2026). The comment period closes on September 15, 2025.

Vizient's Office of Public Policy and Government Relations looks forward to hearing member feedback on this Proposed Rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to <u>Jenna Stern</u>, Vice President, Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.

⁵³ "Reforming Accreditation to Strengthen Higher Education, https://www.whitehouse.gov/presidential-actions/2025/04/reforming-accreditation-to-strengthen-higher-education/

⁵⁴ The Liaison Committee on Medical Education (LCME) is an accrediting body for medical education programs leading to the MD degree.
⁵⁵ The Accreditation Council for Graduate Medical Education (ACGME) is the primary organization in the United States that currently conducts accreditation for Graduate Medical Education ('GME') Programs. While ACGME accreditation is a voluntary process, programs.
⁵⁶ Students for Fair Admissions v. President and Fellows of Harvard College, https://www.supremecourt.gov/opinions/22pdf/20-1199 hgdj.pdf. While the ruling applies specifically to admissions decisions at institutions of higher education, its broader reasoning—especially the requirement that any use of race be narrowly tailored to a compelling interest—strongly suggests that race-conscious elements in Diversity, Equity, and Inclusion (DEI) initiatives in federally funded education programs are generally impermissible.