



## SUMMARY OF PROPOSED RULE – AUGUST 2025

### CY 2026 Outpatient Prospective Payment System

#### Overview

In the July 17 *Federal Register* (FR), the Centers for Medicare & Medicaid Services (CMS) published a [proposed rule](#) providing updates and policy changes to the Medicare Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2026. The policy and payment provisions are generally effective for CY 2026 services, beginning January 1, 2026, unless otherwise noted.

The following is a comprehensive summary of the rule's hospital outpatient provisions. In addition to annual payment and quality updates, the summary details policies related to the inpatient-only (IPO) list, price transparency requirements, and payment for separately payable drugs acquired under the 340B Drug Pricing Program. The proposed rule also includes provisions for ambulatory surgical centers (ASCs).

The proposed rule and other resources related to the OPPS are available on the [CMS website](#).

Comments are due to CMS by **September 15, 2025**, and can be [submitted electronically](#).

#### For Additional Information

With questions about this summary, or for a detailed summary of the ASC provisions, contact Michelle Millerick, vice president, policy at [mmillerick@calhospital.org](mailto:mmillerick@calhospital.org) or Megan Howard, vice president, policy, at [mhoward@calhospital.org](mailto:mhoward@calhospital.org). Facility-specific CHA DataSuite analyses were sent under separate cover. Questions about CHA DataSuite should be directed to Alenie Reth, data analytics coordinator, at [areth@calhospital.org](mailto:areth@calhospital.org).

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## Summary of Key Provisions

The proposed rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates, as well as regulations that implement new policies. CMS proposes to:

- Increase the market basket by net 2.4%
- Further reduce payments for non-drug OPPS services from a planned 0.5% to 2% as part of a scheduled recoupment resulting from adverse litigation against the Health and Human Services Secretary for 340B-acquired drugs
- Conduct a survey of hospital acquisition cost for Medicare Part B drugs in early 2026
- Reduce payments for drug administration services furnished in off-campus provider-based departments (PBDs)
- Phase out the IPO list over three years
- Modify hospital price transparency reporting and attestation requirements
- Make health and safety requirements to perform surgical procedures in an ASC non-binding, while expanding the list of procedures Medicare would pay for in an ASC
- Revise Medicare payments for skin substitutes in hospital outpatient departments
- Adopt a policy to make the relative weights under the Inpatient Prospective Payment System (IPPS) using hospital-reported data on negotiated charges with Medicare Advantage organizations (MAOs)

CMS also issued several requests for information (RFIs) in the 2026 OPPS proposed rule — including several on site-neutral payment, described below.

The increase in spending due solely to changes in the 2026 OPPS proposed rule is estimated to be approximately \$1.61 billion. Considering estimated changes in enrollment, utilization, and case mix for 2026, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, would be approximately \$100 billion, approximately \$8.1 billion higher than estimated expenditures in 2025. These figures do not account for the proposed reduction to the OPPS payment update to accelerate recoupment of additional spending for 340B-acquired drugs resulting from adverse litigation against CMS. CMS estimates a 2% reduction to payments for non-drug OPPS services for most hospitals would reduce OPPS payment by \$1.1 billion relative to the reduction not being applied.

## CY 2026 OPPS Payment Update

CMS typically uses the most up-to-date claims data and cost report data (cost report data that is one year behind claims data) to set OPPS rates for the upcoming year. For CY 2026 OPPS rate setting, CMS proposes to use CY 2024 claims data and CY 2023 Healthcare Cost Report Information System (HCRIS) data.

CMS estimates that the update to the conversion factor net of the productivity will increase payments by 2.4% in 2026, which reflects a market basket update of 3.2% minus a 0.8 percentage point (PPT) productivity adjustment. After including changes to outlier payments and pass-through payments, as well as applying the frontier state wage adjustment, CMS estimates a 1.9% increase in payments between 2025 and 2026.

However, this increase is before application of a 2% reduction in payment for non-drug OPPS services for recoupment of past additional spending for 340B-acquired drugs. Accounting for this adjustment would make the average increase across all facilities paid under the OPPS 0.1% across all services (non-drug and drug).

Hospitals that satisfactorily report quality data will qualify for the full update, while hospitals that do not would be subject to a 2 percentage point reduction in the applicable update.

The table below shows the final CY 2025 conversion factor compared to the proposed CY 2026 conversion factor.

	Final CY 2025	Proposed CY 2026	Percent Change
OPPS Conversion Factor	\$89.169	\$91.747	+2.89%
OPPS Conversion Factor with 340B Remedy Offset	\$89.169	\$89.958	+0.88%

The following table provides details of the proposed annual updates to the CY 2026 update factor.

Proposed CY 2026 Update Factor Component	Change to OPPS Conversion Factor
Market Basket Update	+3.2%
Affordable Care Act (ACA)-Mandated Market Basket Productivity Adjustment	-0.8 PPT
Wage Index Budget Neutrality (BN) Adjustment	+1.16%
Wage Index 5% Stop Loss and Transitional Exception BN	-0.45%
Pass-through Spending	-0.22%
Cancer Hospital BN Adjustment	0.00%
Outlier BN Adjustment	0.00%
Overall Proposed Rate Update	+2.89%
340B Remedy Offset	-1.95%
Overall Proposed Rate Update with 340B Remedy Offset	+0.88%

Although CMS projects an estimated increase of less than 0.1% for all facilities, the rule's impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location, and other factors. Impacts for selected categories of hospitals are shown in the following table.

Facility Type	2026 Impact
All Hospitals	0.1
All Facilities (including community mental health centers and cancer and children's hospitals)	0.0
Urban	0.1
Large Urban	0.0
Other Urban	0.3

Facility Type	2026 Impact
Rural	0.1
Beds	
0-99 (Urban)	0.5
0-49 (Rural)	0.0
500+ (Urban)	-0.1
200+ (Rural)	0.3
Major Teaching	-0.2
Type of ownership	
Voluntary	-0.1
Proprietary	0.7
Government	0.1

California's estimated impacts, provided by CHA DataSuite, are noted in the table below; impacts will vary by hospital.



## OPPS CY 2026 Proposed Rule Analysis

CY 2026 Proposed Rule Compared to CY 2025 Final Rule

### California

Impact Analysis	Dollar Impact	% Change
<i>Estimated CY 2025 OPPTS Payments</i>	<i>\$7,365,925,400</i>	
Market Basket Update	\$179,745,800	2.44%
ACA-Mandated Productivity Adjustment	(\$44,936,500)	-0.61%
340B Remedy Offset	(\$112,234,900)	-1.52%
Budget Neutrality Adjustments	\$46,427,600	0.63%
Wage Index (Removal of Previous Bottom Quartile and Stop Loss (including rural floor))	(\$5,906,900)	-0.08%
Wage Index (Removal of Previous Rural Floor BN)	\$90,680,600	1.23%
Wage Index (Removal of Previous Rural Floor Wage Index)	(\$369,178,500)	-5.01%
Wage Index (Change due to WI and LS prior to rural floor)	(\$92,961,700)	-1.26%
Wage Index (Current Rural Floor Wage Index Added)	\$354,718,000	4.82%
Wage Index (Current Rural Floor Budget Neutrality Added)	(\$55,238,900)	-0.75%
Wage Index 5% Stop Loss	\$1,642,800	0.02%
Change in Rural Add-On	\$0	0.00%
APC Factor/Updates	\$23,416,500	0.32%
SN PBD OPPTS Drug Admin	(\$18,834,700)	-0.26%
<i>Estimated CY 2026 OPPTS Payments</i>	<i>\$7,363,264,600</i>	
<b>Total Estimated Change From CY 2025 to CY 2026</b>	<b>(\$2,660,800)</b>	<b>-0.04%</b>

Source: CHA DataSuite Analysis, August 2025

## Site-Neutral Payment Reduction for Drug Administration Services at Certain Off-Campus Hospital Outpatient Departments

### Background

In the 2019 OPPTS rule, CMS adopted a policy to reduce payment for a clinic visit (Healthcare Common Procedure Coding System [HCPCS] code G0463) when furnished in an off-campus PBD. The policy was adopted without applying budget neutrality. CMS cited its authority under section 1833(t)(2)(F)

of the Social Security Act to “develop a method for controlling unnecessary increases in the volume of covered OPD [outpatient department] services” to adopt this policy.

The American Hospital Association challenged CMS’ use of section 1833(t)(2)(F) to adopt the payment reduction for a clinic visit, but CMS’ policy was upheld by the U.S. Court of Appeals for the District of Columbia Circuit. The court concluded that “a service-specific, non-budget-neutral rate reduction falls comfortably within the plain text of subparagraph (2)(F).”<sup>1</sup>

### **Expanding the “Method” to Other Services**

CMS expresses concern about the increasing share of chemotherapy administration services being performed in hospital outpatient departments. In a June 2023 report to Congress, the Medicare Payment Advisory Commission (MedPAC) stated that the share of chemotherapy services furnished in OPDs has grown from 35.2% in 2012 to 51.9% in 2021. HCPCS code 96413 — which describes chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug — pays \$119 under the physician fee schedule (PFS) and \$341 under the OPPTS, a difference of 186%. CMS further indicates that between 2012 and 2021, the OPD share of nuclear cardiography services grew from 33.9% to 47.6%, and its share of echocardiography services grew from 31.6% to 43.1%.<sup>2</sup>

According to the proposed rule, it is naturally inferred that these changes are the result of financial incentives, and therefore are unnecessary increases in the volume of OPD services. CMS believes that this problem is pervasive and exists across service families. For 2026, CMS proposes to address drug administration services provided in off-campus PBDs. In future years, CMS plans to examine other ambulatory payment classification (APC) families of services, such as imaging without contrast, and other settings, specifically on-campus outpatient clinic visits.

### **Utilization of Drug Administration Services**

CMS indicates that the high volume of drug administration services and the magnitude of rate differences between the physician office and OPD settings make it a family of services likely to migrate to a higher paying setting of care. The proposed rule further indicates that drug administration can be performed in either physician offices or OPDs — claiming that 68% of these services are performed in physician offices, despite the increasing share being performed in hospital outpatient departments<sup>3</sup> — and the resource costs are not meaningfully different between the sites.

This section of the proposed rule reiterates similar statistics as the prior section on overall growth of drug administration services and the increasing share of these services performed in PBDs. CMS notes that the number of beneficiaries enrolled in fee-for-service (FFS) Medicare decreased by more than 14% between 2018 and 2024<sup>4</sup>; however, CMS analysis of claims data and Medicare FFS enrollment shows an increase in the volume of drug administration services provided in OPDs utilized per beneficiary. CMS concludes from these statistics that the increase in off-campus hospital outpatient department volume over a 10-year period was at least partially driven by the payment differential between the physician office and OPD setting.

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<sup>1</sup> 964 F.3d 1230, 1245 (D.C. Cir. 2020)

<sup>2</sup> [https://www.medpac.gov/wp-content/uploads/2023/06/Jun23\\_Ch8\\_MedPAC\\_Report\\_To\\_Congress\\_SEC.pdf](https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf).

<sup>3</sup> <https://craftmediabucket.s3.amazonaws.com/uploads/Drug-Admin-Off-Campus-Site-Neutrality-2023.10.18.pdf>.

<sup>4</sup> <https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicare-reports/medicare-monthly-enrollment>

CMS further expresses concern about beneficiaries with higher cost-sharing requirements because of the payment incentives driving them to OPDs (a small portion of the population with high utilization). One study found that:

In 2021, approximately 74,000 Medicare FFS chemotherapy patients utilized excepted off-campus OPDs and would have had cost sharing expenses that were \$292 lower per patient had site neutrality applied. For the highest utilizing 5,000 patients who received chemotherapy most frequently at excepted off-campus OPDs, cost sharing would have been \$1,055 lower per patient if payments had been site neutral.<sup>5</sup>

MedPAC found that it would be reasonable to align the OPPTS payment rates with the PFS payment rates for all four of the drug administration APCs, as these services have a higher volume in freestanding facilities than in OPDs — indicating that these services can be safely provided to beneficiaries in a lower cost care setting.

### **Payment for Drug Administration Services at Provider-Based Departments**

Under the Balanced Budget Act of 2015, off-campus PBDs within hospitals that first began billing Medicare under the OPPTS after November 2, 2015, are paid at a site-neutral rate equal to 40% of the OPPTS rate and bill Medicare with a “PN” modifier on the claim. Other off-campus PBDs bill Medicare with a “PO” on the claim.

CMS examined the top 20 most frequently billed HCPCS codes in the drug administration APC family billed with a “PN” and “PO” modifier and found that they are the same with slight variations in the order based on volume. CMS asserts that this finding indicates the site-neutral payment rate is sufficient to support the provision of these services in an off-campus PBD currently paid at the OPPTS rate.

### **Patient Severity and Cost of Care**

CMS reports that comments in prior rules on this issue have indicated that the higher payments for services in hospital outpatient settings are justified by the level of care patients need, the higher costs of providing care in hospitals, and the costs of maintaining emergency care and standby capacity. CMS summarizes that MedPAC found that, on average, OPD patients have higher risk scores but the difference in patient severity between settings is small and not statistically significant as the services, like drug administration, are generally of low complexity.<sup>6</sup>

### **Impact of ‘Unnecessary Increases’ in Volume on the OPPTS**

CMS expresses that its concern with “unnecessary increases” in the volume of drug administration services is ultimately tied to the OPPTS’ long-term health and sustainability. Originally designed to manage Medicare spending growth by replacing a cost-based system with a prospective payment system, the OPPTS is now one of the fastest-growing Medicare payment sectors for Parts A and B services.<sup>7</sup> CMS believes that paying for drug administration services provided at excepted off-campus departments at the PFS-equivalent rate would effectively control the volume of these unnecessary services because the payment differential it believes is driving the site-of-service decision would be removed.

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<sup>5</sup> <https://craftmediabucket.s3.amazonaws.com/uploads/Drug-Admin-Off-Campus-Site-Neutrality-2023.10.18.pdf>

<sup>6</sup> [https://www.medpac.gov/wp-content/uploads/2023/06/Jun23\\_Ch8\\_MedPAC\\_Report\\_To\\_Congress\\_SEC.pdf](https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf)

<sup>7</sup> <https://www.govinfo.gov/content/pkg/FR-2018-11-21/pdf/2018-24243.pdf>



The proposed policy would apply to APCs 5691-5694. While Social Security Act section 1833(t)(9)(B) requires that certain “adjustments” made under the OPPS be made in a budget-neutral manner, While section 1833(t)(9)(B) of the act requires that certain “adjustments” made under the OPPS be budget neutral, CMS does not consider its proposed volume control method to be an “adjustment” subject to budget neutrality. Section 1833(t)(2)(F) of the act refers to a “method” for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Further, CMS states that implementing a volume control method in a budget-neutral manner would not appropriately reduce unnecessary spending — it would just redistribute the spending to other services.

CMS estimates savings from the proposed policy at \$280 million, with \$210 million of the savings accruing to Medicare and \$70 million saved by Medicare beneficiaries. **The proposed rule further requests comment on other services, such as imaging without contrast, for which CMS should pay a PFS-equivalent rate at off-campus locations; these are noted below.**

### Exemptions for Rural Sole Community Hospitals

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051), CMS finalized an exemption to its clinic visit volume control method to instead pay the full OPPS payment rate, rather than the PFS-equivalent rate, in rural sole community hospitals (SCHs). Rural SCHs have historically received special payment treatment to account for their higher costs and the disproportionately harmful impact reduced payments would cause.

CMS indicates that many rural providers — and rural SCHs in particular — are often the only source of care in their communities,<sup>8</sup> which means beneficiaries and providers are not choosing between a higher-paying off-campus PBD of a hospital and a lower-paying physicians’ office. CMS has reviewed utilization data for drug administration services at rural SCHs and has not found strong evidence that drug administration services are being utilized at an unnecessary volume at off-campus PBDs of rural SCHs. For this reason, CMS is proposing to exempt drug administration services from site-neutral payment at rural SCHs. Lost savings from exempting rural SCHs from the drug administration site-neutrality policy would be \$16 million for 2026.

### Impact of Drug Administration Payment Reductions

The proposed CY 2026 OPPS full payment rates for drug administration APCs 5691, 5692, 5693, and 5694 are shown in the table below. The proposed rule indicates that the site-neutral payments are determined by applying the 40% relativity adjuster<sup>9</sup> to the full OPPS payment rates.

APC	Full OPPS Payment	OPPS Payment x 40% Relativity Adjuster
5691	\$47.83	\$19.13
5692	\$74.57	\$29.83
5693	\$216.49	\$86.60
5694	\$341.52	\$136.61

<sup>8</sup> [https://www.shepscenter.unc.edu/wp-content/uploads/dlm\\_uploads/2017/11/SCHs\\_Differences\\_in\\_Community\\_Characteristics.pdf](https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf)

<sup>9</sup> Earlier in this discussion, CMS indicates that the volume control “method” is not an “adjustment” subject to budget neutrality yet in this discussion indicates that the site neutral payment is determined by applying an “adjuster” to full OPPS payment.

CMS estimates that this policy will result in a 10-year savings to Medicare of \$8.150 billion, as well as \$2.770 billion in savings for Medicare beneficiaries due to reduced coinsurance.

### **RFI: Expanding the Site-Neutral Policy to On-Campus Clinic Visits**

The clinic visit (G0463) is still the most utilized service across the OPPS; more than 60% of clinic visits furnished under the OPPS are furnished on campus. **CMS is requesting information on whether it would be appropriate to address unnecessary increases in the volume of covered OPD services by expanding the method to control unnecessary increases in volume to on-campus clinic visits, and poses five specific questions in the proposed rule.**

### **RFI: Reducing OPPS Payment for Services Performed in ASCs and Physician Offices**

CMS is seeking feedback for future rulemaking on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity. The proposed rule seeks public comment on 11 categories of questions:

- Items and services paid under the OPPS that may have experienced unnecessary increases in volume
- Limiting payment based on the site where the service is most frequently performed
- Whether to use the most recent data or older data to make policy (based on a concern that new data may already reflect utilization shifts based on payment)
- How to account for variances in the availability of OPDs, ASCs, and physician offices when determining the setting in which a service is most frequently performed
- How to address different packaging and bundling policies across ambulatory payment systems
- Whether to exempt emergent care, trauma-related care, or other care where the hospital is the most appropriate setting, regardless of whether the item or service is typically furnished in a different setting
- Whether to apply OPPS site-neutral policies more broadly to all hospital OPDs or limit it only to only certain hospital OPDs, such as off-campus hospital PBDs
- Whether to exempt rural hospitals like SCHs, Medicare Dependent Hospitals, or Rural Emergency Hospitals
- Other methods, beyond changes to payment rates, that may be warranted to control unnecessary increases in the volume of outpatient services
- The impact of the proposed ambulatory payment adjustment on beneficiaries and health care innovations

### **Notice of Intent to Conduct Medicare OPPS Drugs Acquisition Cost Survey**

Under Social Security Act section 1833(t)(14)(A)(iii), CMS may either set payment rates for Part B drugs furnished in hospital OPDs based on a survey of hospital acquisition costs, or, if hospital acquisition costs are not available, default to the amount otherwise paid under various provisions of statute (generally section 1847A of the act and average sales price [ASP]). Under section 1833(t)(14)(D)(ii) of the act, CMS will be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS from January 1, 2026, through March 31, 2026. CMS intends to propose Part B drug payment policies based on this survey when setting 2027 OPPS rates.

The proposed rule indicates that hospitals have an obligation to respond to the survey. Despite this statement, CMS asks whether it should make survey response mandatory for all hospitals paid under the OPPTS.

CMS is also requesting comment on options for addressing hospitals that fail to respond, including:

- Using the lowest acquisition cost reported among otherwise similar responding hospitals as a proxy for the non-respondent's cost
- Using supplemental data sources, such as the Federal Supply Schedule, as the non-respondent's cost
- Assuming an ASP add-on percentage (0%, 6%, or some other percent) as the hospital's cost
- Assuming that a non-respondent has insignificant drug costs and always package and never pay separately for the non-respondent's drug costs

The survey will ask only about drugs that are separately paid under the OPPTS. Hospitals will be asked to report the total acquisition cost, net of all rebates and discounts, of each drug by National Drug Code (NDC) from July 1, 2024, through June 30, 2025. The survey will also ask hospitals to distinguish drugs and discounts acquired under the 340B program from other drugs and discounts.

Approximately 700 drug HCPCS codes will be subject to the survey, with most HCPCS codes having multiple NDCs per HCPCS code. Only the total cost and the total units of the drug acquired need to be reported.

This survey will apply to all hospitals paid under the OPPTS (approximately 3,500 hospitals). CMS estimates each hospital will require 73.5 hours to complete the survey, including time required to review instructions, gather data (potentially from hospital wholesalers), perform basic addition, and enter data.

### 340B-Acquired Drugs Recoupment Adjustment

CMS provides the regulatory and litigation history of its policy to pay for drugs acquired under the 340B program at ASP minus 22.5% rather than ASP plus 6% (its otherwise applicable default methodology). In summary:

- Beginning in 2018, CMS adopted a policy to pay for drugs acquired under the 340B program at ASP minus 22.5% to approximate a minimum average discount for 340B drugs based on findings from the Government Accountability Office and MedPAC that hospitals acquire drugs at a significant discount under the 340B program. CMS made this reduction budget neutral by increasing payments for non-drug OPPTS services by 3.19% (approximately \$1.6 billion). This adjustment remained on the rates paid for non-drug OPPTS services through September 27, 2022, and was not updated for changes to utilization of 340B drugs.
- On December 27, 2018, the U.S District Court for the District of Columbia concluded that the Health and Human Services secretary lacked authority to bring the default rate in line with average acquisition cost.<sup>10</sup> While the initial decision applied only to CMS' 2018 policy, the district court later made the same finding for CMS' 2019 policy.<sup>11</sup> The policy continued while CMS pursued its appeal.

<sup>10</sup> American Hospital Association v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018)

<sup>11</sup> Am. Hosp. Ass'n v. Azar, 385 F. Supp. 3d 1 (D.D.C. 2019)

- On June 15, 2022, the U.S. Supreme Court held that the secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs.<sup>12</sup>
- On September 28, 2022, the district court vacated CMS' 340B reimbursement rate for the remainder of 2022 without requiring any offset for budget neutrality.<sup>13</sup> In response to this order, CMS changed its payment systems to make payment at ASP plus 6% for claims received shortly after the district court's order with a date of service after September 27, 2022. Some of CMS' contractors allowed for reprocessing of **all** 2022 claims at the revised ASP plus 6% rate.
- On January 10, 2023, the district court issued a remand to CMS giving it the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for 2018 through 2022.<sup>14</sup>

Effective January 1, 2023, CMS is paying for all 340B-acquired drugs at ASP plus 6%. CMS made this policy budget neutral by applying a negative 3.09% adjustment to all non-drug OPPS rates.<sup>15</sup>

From January 1, 2018, through September 27, 2022, hospitals received \$10.6 billion less in payment for 340B-acquired drugs using ASP minus 22.5% (relative to payment based on ASP plus 6%). CMS increased payments from January 1, 2018, through December 31, 2022, for non-drug OPPS services by an aggregate \$7.8 billion. While the increase in non-drug OPPS services was intended as a budget-neutral offset to the reduction in payment in 340B-acquired drugs, it was a lesser amount because CMS did not update the budget neutrality adjustment after 2018 for increases in the utilization of 340B-acquired drugs — despite repeated public comments asking CMS to do so. The two periods of time do not correspond because the district court vacated CMS' reduction to payment for 340B-acquired drugs on September 27, 2022, but CMS could not accomplish rulemaking to adjust rates downward by 3.09% for non-drug OPPS services until January 1, 2023.

On November 8, 2023, CMS published a final rule<sup>16</sup> announcing its plan for applying a remedy to address the policy the U.S. Supreme Court found to be out of compliance with applicable law. In summary, CMS adopted policies to:

- Repay 340B hospitals for money owed from January 1, 2018, through September 27, 2022, through a lump sum payment minus amounts already paid through claims reprocessing that occurred for services furnished between January 1, 2022, through September 27, 2022; these one-time lump sum payments were issued in early 2024
- Provide the repayment amount to hospitals inclusive of any additional beneficiary coinsurance and not allow hospitals to collect additional coinsurance
- Maintain budget neutrality for these additional payments to 340B hospitals through a negative 0.5 PPT adjustment to the annual OPPS payment rate update that applies to non-drug OPPS services beginning January 1, 2026, and continuing until the full amount of the additional payment is recouped (estimated to be 16 years).

<sup>12</sup> 142 S. Ct. 1896 (2022)

<sup>13</sup> See *Am. Hosp. Ass'n v. Becerra*, 18-cv-2084 (RC), 2022 WL 4534617

<sup>14</sup> *Am. Hospital Ass'n v. Becerra*, 18-cv-2084 (RC), 2023 WL 143337

<sup>15</sup> See 87 FR 71975. The original adjustment multiplied the OPPS conversion factor by 1.0319 (3.19 percent) so reversing the adjustment requires dividing the OPPS conversion factor by 1.0319 or 1/1.0319 or 0.9691 which equals a reduction of 3.09 percent.

<sup>16</sup> 88 FR 77150

Hospitals that enrolled in Medicare after January 1, 2018, and did not receive the benefit of the increase in payments for non-drug OPPTS services are exempted from the 0.5 PPT reduction to the OPPTS update scheduled to begin in 2026.

CMS is reconsidering whether a 0.5 PPT annual reduction for approximately 16 years restores hospitals to as close to the financial position they would have been in had the 340B drug policy never been implemented. With a shorter recoupment period, CMS believes relative hospital utilization of non-drug items and services will more closely correlate to service utilization from 2018 through 2022. However, the more a hospital's utilization of non-drug items and services diverge, the further it would be from being made whole.

By beginning the decrease to non-drug item and service payments in 2026, there is already an eight-year delay between the first year of the OPPTS 340B payment policy and the first year of the prospective offset. In addition, some hospitals that received the benefit of the 3.19% increase for non-drug OPPTS services may leave the market, increasing the repayment burden on other hospitals. Further, CMS notes that \$7.8 billion being recouped includes neither interest costs nor an adjustment for inflation.

Accordingly, effective January 1, 2026, CMS proposes to revise the annual reduction to the OPPTS update used to determine the payment amounts for non-drug items and services from 0.5% to 2% beginning in 2026. With this revision to the recoupment schedule, CMS estimates the total offset of \$7.8 billion would occur over six years rather than 16 years. CMS also presents an alternative in which the annual reduction to the update would be 5% beginning in 2026, with recoupment occurring over three years.

The proposed rule indicates that revisions to the OPPTS conversion factor can have an indirect impact on the ASC payment system. The device-related portion of a device-intensive APC paid under the ASC system is a pass-through to the OPPTS before adding the non-device-related portion, which will be a percentage of the OPPTS payment. If the OPPTS conversion factor is reduced, the device-related portion passed through to the ASC payment system would be decreased. However, the system is budget neutral, meaning the non-device-related portion would increase. Payment would be redistributed from device-intensive procedures to non-device intensive procedures under the ASC payment system.

CMS proposes not to apply the 2% reduction to the OPPTS conversion factor when determining ASC payments to avoid this payment redistribution. The reduction to the OPPTS payment rate is intended to place hospitals as close as possible to the financial position they would have been in had the 340B drug payment policy never been implemented. By contrast, CMS is not under any statutory requirement to pass through the reduction to the OPPTS conversion factor to ASCs. Even though such a reduction would be budget neutral under the ASC payment system, CMS does not believe any policy purpose would be served by redistributing payment from device-intensive services to other services resulting from an issue that has nothing to do with ASC payment.

## Changes to Hospital Price Transparency (HPT) Requirements

CMS proposes a variety of new requirements and policy changes affecting hospitals subject to the HPT requirements, including:

- Requiring hospitals to encode in the machine-readable file (MRF) the 10th percentile, median, and 90th percentile allowed amounts when the payer-specific negotiated charges are based on percentages or algorithms; CMS proposes definitions for these new terms and would also require hospitals to display, for each payer and plan, the count of the allowed amounts used for these calculations
- Requiring hospitals to use electronic data interchange (EDI) 835 electronic remittance advice (ERA) transaction data to calculate and encode the 10th percentile, median, and 90th percentile allowed amounts, using a specific methodology and lookback period
- Replacing the currently required “good faith effort” and affirmation statement in the MRF with a new and expanded attestation
- Requiring hospitals to encode additional hospital information in the MRF including: the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate, and complete data; and the hospital’s organizational National Provider Identifier(s) (NPIs)
- Reducing penalties issued to hospitals it determines are noncompliant by 35%, under certain conditions, when a hospital waives its right to appeal

Each of these proposals is described in greater detail on the following pages.

## **Proposal to Replace the Estimated Allowed Amount with the Allowed Amounts Data Elements and the Count of Allowed Amounts Data Element**

### **Background and Clarification on Encoding Payer-Specific Negotiated Charges as Dollar Amounts**

CMS expects that, for most contracting scenarios, a hospital’s payer-specific negotiated charges can be expressed as a dollar amount. Therefore, if a dollar amount can be derived from a hospital’s payer-specific negotiated charge, it must be encoded as a dollar value in the MRF. Specifically, for items and services encoded in the MRF with a “standard charge methodology” of “case rate,” “per diem,” or a known “fee schedule,” CMS expects that hospitals will be able to encode a “payer-specific negotiated charge: dollar amount.”

CMS notes that there may be situations where the payer-specific negotiated charge is a percentage of a fee schedule that is not available to the hospital. In such instances, under CMS’ existing policies, the hospital must encode a “payer-specific negotiated charge: percentage” and an estimated allowed amount (which would be replaced with the median allowed amount should CMS’ proposal, discussed below, be finalized) and may indicate in the additional notes data element the type of fee schedule. Hospitals encoding a case rate or per diem as the standard charge methodology must encode the dollar amount for the service package base rate, which may be coupled with a “payer-specific negotiated charge: algorithm” and an estimated allowed amount (which would be replaced with the median allowed amount should CMS’ proposal, discussed below, be finalized) if necessary. CMS encourages readers to review the scenarios and examples on the CMS Hospital Price Transparency – Data Dictionary GitHub Repository [website](https://github.com/CMSgov/hospital-price-transparency/tree/master/examples) for examples of how to encode standard charge data.<sup>17</sup>

### **Replacing the Estimated Allowed Amount with the Median Allowed Amount**

Currently, the regulation requires that if the payer-specific negotiated charge is based on a percentage or algorithm, the MRF must also describe the percentage or algorithm that determines the dollar amount for the item or service and calculate and encode an estimated allowed amount in dollars for

<sup>17</sup> CMS, (2024, June), Hospital-Price-Transparency Examples, Hospital Price Transparency, GitHub.  
<https://github.com/CMSgov/hospital-price-transparency/tree/master/examples>

that item or service.<sup>18</sup> The regulation defines “estimated allowed amount” as the average dollar amount that the hospital has historically received from a third-party payer for an item or service.

CMS continues to believe that having a contextual data element displayed in dollars would improve users’ ability to make price comparisons across hospitals and would support a better understanding of the costs of care, especially given the complexities of hospital contractual arrangements with third-party payers. However — in light of feedback from stakeholders as well as [Executive Order 14221](#), which aims to strengthen accurate and actionable health care pricing information — **CMS proposes to require hospitals to encode, beginning January 1, 2026, the “median allowed amount,” rather than the estimated allowed amount, if a payer-specific negotiated charge is based on an algorithm or percentage.** Under this proposal, the “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 period no longer than the 12 months prior to posting the MRF. CMS would further require that if the calculated median falls between two observed allowed amounts, the median allowed amount is the next highest observed value. CMS states that requiring the median rather than the average is consistent with generally accepted statistical principles for assessing the central point of a distribution when there are outliers and ensures an actual dollar value is identified, rather than an average of two amounts.

#### **Proposal to Add the 10th and 90th Percentile Allowed Amounts**

CMS believes that requiring only the median allowed amount may not be sufficient to provide innovators, researchers, and other MRF users with enough of a basis to understand a consumer’s potential financial obligations. Thus, in addition to calculating and displaying the median allowed amount, **CMS proposes to require, beginning January 1, 2026, hospitals to calculate and encode a 10th and a 90th percentile allowed amount in dollars for any items or services that have payer-specific charges based on a percentage or algorithm.**

CMS proposes to define “tenth (10th) percentile allowed amount” as the 10th percentile of the total allowed amounts the hospital has historically received from a third-party payer for an item or service for a period no longer than the 12 months prior to posting the MRF. If the calculated percentile falls between two observed allowed amounts, the 10th percentile allowed amount would be the next highest observed value.

CMS proposes to define “ninetieth (90th) percentile allowed amount” 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 period no longer than the 12 months prior to posting the MRF. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount would be the next highest observed value.

CMS explains that research demonstrates that prices for a health care service can vary widely, even within one insurer, and they are not uniformly distributed. However, requiring a hospital to post every possible value and the frequency of those values would be highly burdensome and would produce unmanageably large data files that are difficult to access and interpret. CMS believes that encoding 10th and 90th percentile allowed amounts, if a payer-specific negotiated charge is based on a percentage or algorithm, would provide MRF users with useful information about the distribution of allowed amounts as simply and directly as possible. Likewise, researchers, innovators, policy officials, employers, and others MRF users would be able to use the information to improve data analysis and develop more

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<sup>18</sup> §180.50(b)(2)(ii)(C)



accurate predictive models, better and more precisely model health care costs and cost estimation algorithms, provide insights into health care pricing dynamics, and gain a deeper understanding of price dispersion across contracts that might provide a basis for negotiation and advocacy to more effectively bargain with health care providers and payers to yield more competitive pricing.

CMS considered requiring hospitals to remove outlier allowed amounts to provide MRF users a range of expected allowed amounts that are not distorted by unusually low or high claims, which are common in health care data. However, CMS believes that the 10th and 90th percentiles, along with the median (the 50th percentile), will convey sufficient information about the allowed amounts that the hospital has actually received for an item or service as, by definition, 80 percent of observations fall between the 10th and 90th percentile values. CMS notes that the 10th and 90th percentiles are commonly used in research studies and claim and cost analyses.

CMS also considered a recommendation received from stakeholders in prior rulemaking to require hospitals to display a maximum allowed amount. CMS had previously elected not to adopt this suggestion because this could be skewed to the point where it would not present useful information to consumers or the public. As opposed to the maximum allowed amount, CMS believes that the 90th percentile of the total allowed amounts for an item or service would be more representative of the dollar amount the individual might be responsible for paying, less subject to extreme outliers, and would provide an additional data point to contextualize the dollar value when the payer-specific negotiated charge for an item or service is a percentage or algorithm. Similarly, CMS discusses its concerns related to display of a minimum allowed amount and believes that the 10th percentile would be a better representation of the data.

CMS notes that in many cases, the 10th percentile allowed amount, median allowed amount, and 90th percentile allowed amount could fall between two actual prices; in other words, where the total count of data points would be an even number. In such instances, **CMS proposes** the hospital should identify and display the next highest value. CMS provides an example of this in Table 90 in the proposed rule preamble.

## Calculation of Allowed Amounts

### (1) Determining the “Total Allowed Amount”

As discussed above, CMS proposes new definitions for “median allowed amount,” “10th percentile allowed amount,” and “90th percentile allowed amount.” These definitions would require hospitals to identify allowed amounts from the “total allowed amounts” that the hospital has historically received for an item or service. Under this proposal, **a “total allowed amount” dollar figure would be derived from the gross charge minus contractual adjustments and consist of the portion billed to a payer for a particular plan and the portion, if any, billed to the patient.** As discussed in the next section, hospitals would determine the “total allowed amount” from EDI 835 ERA transaction data, which includes information about what the hospital was reimbursed by the plan, any secondary or other payer payment, and the patient’s cost-sharing responsibility for an item or service.

### (2) Data Source for Calculating the Allowed Amounts

Currently, hospitals have flexibility, in the interest of reducing burden, to determine the best data source(s) for calculating the estimated allowed amount data element. In the CY2024 OPPTS/ASC final rule, CMS agreed with commenters that using information from EDI 835 ERA transaction data would appear to be an appropriate data source for the required calculation. To enhance the consistency of hospital standard charge information and the comparability of the median allowed amount, and the



10th percentile and the 90th percentile allowed amounts, and in accord with what commenters had earlier suggested, **CMS proposes to require that hospitals only use EDI 835 ERA transaction data to calculate and encode the allowed amounts.** CMS states that EDI 835 ERA transaction data, the 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, co-insurance or secondary coverage, would meet the requirement to calculate an allowed amount.

**CMS seeks comment** on this proposal and whether there are instances where a hospital would not have access to EDI 835 ERA transaction data. CMS also seeks comment on whether there are alternative data sources it should consider for calculating the allowed amounts and count of allowed amounts.

### **(3) Lookback Period for Calculating the Allowed Amounts**

Currently, CMS does not specify a lookback period for hospitals when calculating the estimated allowed amount. This flexibility was intended to reflect the variations in frequency and timing with which hospitals negotiate contracts with payers. However, CMS now believes that if hospitals use substantially different lookback periods, particularly across multiple years, it could distort the allowed amounts, because of — for example — pricing changes over time such as inflation, efficiencies, or the introduction of new products or services. Additionally, hospitals using varied lookback periods reduces comparability across MRFs.

To help ensure that all hospitals calculate the allowed amount data elements consistently, based on the most recent reimbursements, **CMS proposes that:**

- Hospitals would be required to base the median allowed amount, the 10th and 90th percentile allowed amounts, and the count of allowed amounts (discussed below) on EDI 835 ERA transaction data from no longer than 12 months prior to posting the MRF.
- If the negotiated percentage or algorithm associated with the allowed amounts was only used for a portion of the 12-month time period prior to posting the MRF, the hospital would be required to encode the median allowed amount (and 10th and 90th percentile allowed amounts, and count of allowed amounts) from the EDI 835 ERA transaction data for the portion of time that the percentage or algorithm was used.
- If the negotiated percentage or algorithm associated with the allowed amounts was used for the entire 12-month period prior to posting the MRF, the hospital would encode the median allowed amount (and 10th and 90th percentile allowed amounts, and count of allowed amounts) from the EDI 835 ERA transaction data for the entire 12-month period prior to posting the MRF.

CMS notes that under this proposal, a hospital may need to use different lookback periods to calculate the allowed amounts for each payer, depending on when a contract was negotiated. Additionally, CMS clarifies that the allowed amounts would be based on the EDI 835 ERA transaction data available at the time the hospital updates its MRF, recognizing there may be situations where the EDI 835 ERA transaction data is not yet final or may change after the allowed amounts are encoded in the MRF due to additional adjustments being applied to a claim(s).

CMS discusses various alternative lookback periods it considered, but are not proposing, including a three- or six-month lookback, or requiring hospitals to use a rolling 12-month period prior to posting the MRF. CMS believes that limiting the lookback period to no more than 12 months prior to posting

the MRF would be consistent with section 2718(e) of the Public Health Service Act that refers to “for each year,” and the current requirement that hospitals must update the MRF at least annually (42 CFR 180.50(e) and 180.60(e)).

CMS seeks comment on these proposals.

#### **Proposal for Hospitals to Encode the Count of Allowed Amounts**

As part of its proposal to require hospitals to encode the median, 10th percentile, and 90th percentile allowed amounts if a hospital’s payer-specific negotiated charge is based on an algorithm or percentage, **CMS proposes to require hospitals to encode the count of allowed amounts that were used to calculate the median, 10th percentile, and 90th percentile allowed amounts when the standard charge is based on a percentage or algorithm.** Under this proposal, hospitals would be required to encode this data element based on the actual number of allowed amounts within the EDI 835 ERA transaction data utilized to calculate the allowed amount data elements, excluding zero-dollar claims from the count of allowed amounts. CMS believes that if zero-dollar claims were included, they would result in misleading and skewed calculations.

CMS explains that encoding the count of allowed amounts in the EDI 835 ERA transaction data would help MRF users determine whether the data displayed provide reasonably good approximations of what typically would be generated by the payer-specific negotiated charge percentage or algorithm.

Related to this, **CMS also proposes the following:**

- Hospitals would be required to use the same count of allowed amounts to calculate the median, 10th percentile, and 90th percentile allowed amounts.
- In the event that a hospital has a “0” count of allowed amounts from the most recent 12-month time period from which to derive the allowed amounts, the hospital would be required to encode “0” as the value for the count of allowed amounts for a specific payer and may leave the median, 10th, and 90th percentile allowed amounts in the MRF blank.
- In the event a hospital must encode a “0” as the value for the count of allowed amounts for a specific payer, the hospital would be required to encode information to explain the hospital’s insufficient claim remittance history in the “additional notes” data element. If the reason is due to a new or revised payer contract, the hospital should encode “new or recently revised payer contract.” CMS notes that nothing would preclude a hospital from updating its MRF once it has generated one or more remittances for an item or service under a new contract.

CMS discusses an alternative approach it considered that would require hospitals to provide the range, or categories, of the count of allowed amounts, rather than a precise count. For example, ranges could include: less than 10, 10-49, 50-99, 100-149, 150-199, 200-499, and 500 and over. **CMS is seeking comment on this alternative approach.** CMS is interested in whether a precise count of allowed amounts would be helpful to determine the volatility of the price encoded in allowed amount data elements, or if knowing that allowed counts fell within a particular range would be sufficient. Additionally, CMS seeks comment on specific range criteria. If CMS finalizes this alternative, comments related to specific ranges could be incorporated into guidance on the CMS Hospital Price Transparency – Data Dictionary GitHub Repository website.

#### **Proposal to Modify the MRF Affirmation Statement**

Currently, existing regulation at 45 CFR §180.50(a)(3)(i) and (ii) requires each hospital to: make a good faith effort to ensure that the standard charge information encoded in the MRF is true, accurate, and

complete as of the date indicated in the MRF; and affirm in its MRF that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in accordance with the requirements of this section, and that the information encoded is true, accurate, and complete as of the date indicated in the MRF.

In the CY 2024 OPPTS/ASC final rule, CMS expressed its belief that an affirmation in the hospital's MRF, which the agency finalized in that rulemaking, would lessen public confusion related to the accuracy and completeness of the data in the file and improve CMS' ability to assess both the completeness and accuracy of the MRF; by improving assessment of compliance, CMS would improve its enforcement capabilities. However, CMS describes myriad questions and concerns raised by users of the files that have led CMS to question the sufficiency of the current affirmation requirement. In light of these concerns, **CMS proposes to supplant the existing affirmation and good faith effort requirements by, instead, specifying at new 45 CFR §180.50(a)(3)(iii) that, beginning January 1, 2026, each hospital would be required to attest in its MRF to the following:**

“The hospital has included all applicable standard charge information in accordance with the requirements of § 180.50, and the information encoded is true, accurate, and complete as of the date in the file. The hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the machine-readable file or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula.”

CMS intends for this public declaration to establish for MRF users and for CMS actionable certainty on the accuracy and completeness of the standard charge information displayed. CMS believes that the proposed attestation requirement would mandate significantly heightened hospital recognition of the hospital's responsibilities and would reduce public confusion related to whether all standard charges for hospital items and services, where possible, are included within the MRF as dollar amounts. CMS notes that such greater assurance would not, however, diminish CMS' role as the hospital price transparency enforcer or alter its view that the False Claims Act is outside the scope of this proposed rule just as CMS has expressed in prior rulemaking.

Additionally, **CMS proposes — at new §180.50(a)(3)(iv) — that, beginning January 1, 2026, the hospital must encode within the MRF the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate and complete data** as directed in §180.50(a)(3)(iii). CMS believes that this requirement would establish that the data was reviewed and verified by the hospital's leadership. This information could also be used by CMS to expedite the agency's ability to quickly identify an individual at the hospital to obtain, where necessary, further clarity regarding the MRF data. To implement this requirement, CMS proposes to add a new general data element, specifically “attester name” to the MRF. If finalized, CMS intends to provide instruction on how to encode this data element on the Hospital Price Transparency – Data Dictionary GitHub Repository website.

CMS acknowledges two related but different current requirements. First, CMS notes that in the 2024 OPPTS/ASC final rule, CMS extended its compliance authority to require, upon CMS request, an authorized hospital official to submit to CMS a certification as to the accuracy and completeness of

the standard charge information posted in the MRF.<sup>19</sup> CMS believes that this separate requirement is both necessary and complementary to the attestation proposal. CMS notes that an attestation would not alter the agency's use of existing tools, such as the certification, to monitor and enforce hospital compliance with its requirements. Second, CMS notes that there is already an existing requirement<sup>20</sup> that hospitals disclose a hospital point of contact in the .txt file, which CMS added in the CY2024 OPPS/ASC final rule as part of its effort to improve MRF automated accessibility. However, CMS states that this point of contact is intended to be an individual that is capable of answering technical questions about the hospital's MRF, rather than an individual with authority that can assure the public of the completeness and accuracy of the MRF data. CMS seeks comments on whether this existing .txt contact could also provide the necessary assurance of MRF accuracy and completeness.

Finally, CMS considered two alternatives. First, CMS considered proposing that hospitals be required to submit an MRF attestation directly to CMS, using a CMS-developed template that would provide evidence of the accuracy and completeness of the MRF. CMS is not proposing this alternative because it believes that the attestation statement and the name of the authorized hospital official should remain within the MRF to streamline the agency's compliance process and reassure users of the MRF about the accuracy and completeness of the information. CMS also believes that this alternative would be duplicative of the CMS' existing authority at §180.70(a)(2)(iv), under which it can require submission of certification by an authorized hospital official as to the accuracy and completeness of the standard charge information in the MRF.

Second, CMS considered whether, on its publicly available websites that host the hospital MRF, hospitals should be required to post a standalone attestation document that would be signed by a hospital's senior official. Because MRFs are not particularly consumer-friendly, there may be merit to requiring a separate, easily retrieved attestation document. However, CMS believes that separating the attestation from the MRF could add complexity to existing automation processes, introduce more public confusion about the intent of the attestation, and defeat one of the agency's primary objectives of having hospitals better assure the public of the accuracy and completeness of hospitals' MRFs.

CMS seeks comments on these proposals and on the alternatives considered.

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

Currently, under the existing §180.50(b)(2)(i)(A), hospitals must encode in their MRFs certain general information including the hospital's name, license number, and location name(s) and address(es). Under existing §180.50(d)(5), the MRF's naming convention requires hospitals to include the Employer Identification Number (EIN). While these elements help to identify the hospital, interested parties have told CMS that they 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. In particular, CMS has been told that the hospital MRF's lack of a standard identifier under the HPT initiative hinders efforts to compare standard charge data with data displayed in Transparency in Coverage (TiC) payer MRFs and limits opportunities to automate the comparison and analysis of MRF data.

Additionally, CMS notes that Executive Order 14221 requires HHS to ensure that pricing information is standardized and easily comparable across hospitals and health plans. To this end, CMS believes it is important to align the HPT and TiC identifiers. CMS explains that under the TiC final rule (85 FR 72158),

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<sup>19</sup> §180.70(a)(2)(iv)

<sup>20</sup> §180.50(d)(6)(i)(D)

most group health plans and health insurance issuers must post pricing information, and such pricing information must be associated with a provider's NPI. CMS cites several examples for how comparisons across the HPT and TiC MRFs could be useful for various specific types of users of these datasets. CMS believes that it must take additional steps to remove barriers to effective use of this data.

**CMS therefore proposes to revise §180.50(b)(2)(i)(A) to require hospitals, beginning January 1, 2026, to report a unique identifier, specifically their Type 2 (organizational) NPI(s), in their MRFs.** CMS believes that having hospitals add their NPI(s) to the MRF would improve the comparability of hospital MRF and other health care data, including health plan transparency data from the TiC MRFs.

CMS explains that an NPI is a unique 10-digit number used to identify health care providers and organizations, including hospitals. All health care providers that are Health Insurance Portability and Accountability Act (HIPAA)-covered entities must obtain an NPI. Health care providers who are individuals are assigned a Type 1 NPI and health care providers that are organizations are assigned a Type 2 NPI (also known as an organizational NPI). "Subparts" of organizations, which are components of the same organization that may be separately licensed or identified, may also obtain a Type 2 NPI if they conduct HIPAA standard transactions separately from the main organization. Entities and individuals maintain NPIs unless they are deactivated upon request, death, or dissolution, and NPIs do not change if provider name, EIN, or state licensure changes. There are several internet-based NPI lookup tools available online, including CMS' National Plan & Provider Enumeration System (NPPES) NPI registry. NPIs are commonly used in other CMS systems for financial transactions, and for other health care data sets, including claims, utilization, and quality data sets.

In conjunction with this proposal, **CMS also proposes that:**

- Hospitals would specifically be required to include in their MRFs any Type 2 NPI(s) 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.
- Type 2 NPI(s) display would be limited to only those that meet the taxonomy criteria proposed above, because — while hospitals may have more NPIs beyond these criteria for other departments or units — these taxonomy codes limit the number of NPIs to only those indicating hospital or hospital unit.
- In cases where hospitals have more than one NPI that meet the proposed criteria above, hospitals would be required to report all active Type 2 NPIs meeting the criteria.
- CMS would include additional technical instructions in the CMS data dictionary and JSON schema in the Hospital Price Transparency – Data Dictionary GitHub Repository.<sup>21</sup>

CMS notes that, based on a review of data in CMS enrollment and identifier systems,<sup>22</sup> only approximately 10% of hospital enrollment applications reported multiple NPIs. Moreover, the median number of NPIs with a hospital or hospital unit taxonomy was two; the average number of NPIs with a hospital or hospital unit taxonomy was 1.9. For this reason, CMS believes that requiring hospitals to include NPIs that meet the proposed criteria would not pose a significant burden or, for most hospitals, significantly increase the amount of data stored in the MRFs.

In developing this proposal, CMS considered alternative approaches. First, CMS considered, as an alternative, that should a hospital have multiple NPIs, the hospital would be required to report only one of them. Under this alternative approach, MRF users could crosswalk the reported NPI to identify

<sup>21</sup> Available at <https://github.com/CMSgov/hospital-price-transparency>

<sup>22</sup> CMS's Provider Enrollment, Chain, and Ownership System (PECOS) and National Plan & Provider Enumeration System (NPPES) NPI registry

additional NPIs. Second, CMS considered proposing that hospitals include in the MRF a Place of Service code and the Taxpayer Identification Number (TIN), because such identifiers are required for TiC payer MRFs. CMS explains that Place of Service Codes are used on professional claims to indicate the setting where an item or service was furnished. However, because hospitals are already required to indicate the setting of the item or service in the MRF, CMS does not believe the Place of Service Codes would provide any additional information. Similarly, CMS does not believe there would be a benefit to requiring hospitals to encode their TIN within the MRF, which would be duplicative of the requirement that hospitals include its EIN (the hospital's employer TIN) as part of the MRF's naming convention. Third, CMS considered proposing that hospitals include the CMS Certification Number (CCN) in the MRF. CMS explains that CCNs are assigned by CMS and used to identify health care facilities participating in the Medicare Part A and Medicaid programs. Hospitals primarily have assigned CCNs as entities, but CCNs can also be used to identify specific hospital locations or units, especially when those units operate under the same organizational umbrella but at different sites. CCNs do not change when hospital ownership changes, but hospital mergers, acquisitions, and consolidations can result in CCN changes. CMS elected not to propose to require that hospitals encode CCNs because CCNs are limited to Medicare- or Medicaid-participating hospitals, while the HPT regulations apply to all hospitals in the United States. CMS further notes that CCNs are not included in payer MRFs under TiC, which would limit alignment.

**CMS seeks comments** on these proposals, as well as any additional, or alternative, taxonomy codes that commenters believe would be necessary or helpful to consider. CMS seeks comment on other standard identifiers that may be useful in providing needed context and streamlining the alignment of price transparency data.

### **Increasing HPT Enforcement**

In the CY 2020 HPT final rule,<sup>23</sup> CMS established actions that would address hospital noncompliance with the requirements under §§180.50 and 180.60, which may include issuing a written warning notice, requesting a corrective action plan (CAP), and imposing civil monetary penalties (CMPs) on noncompliant hospitals and publicizing these penalties on a CMS website.<sup>24</sup> CMS summarizes the updates it has made to its enforcement capabilities through subsequent rulemaking as well as enforcement actions and outcomes it has taken that are posted publicly on the CMS website.<sup>25</sup>

Currently, CMS has authority to issue a CMP when a noncompliant hospital fails to respond to CMS' request to submit a CAP or comply with its requirements.<sup>26</sup> The HPT regulations set forth the criteria CMS uses to determine the CMP amount<sup>27</sup> and permits hospitals to appeal the CMP within 30 days of issuance of the notice of imposition of a CMP.<sup>28</sup> As of May 2025, CMS has issued CMP notices to 27 hospitals, 20 of which have exercised their right to appeal the CMP to an administrative law judge (ALJ).<sup>29</sup> Hospitals may elect to mount an appeal for many reasons, including disagreeing with CMS' assessment of the law or facts underlying its determination, seeking to protect their reputation and/or avoid other civil or state regulatory actions, or other reasons.

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<sup>23</sup> 84 FR 65524

<sup>24</sup> These requirements are codified at §180.70.

<sup>25</sup> Information on enforcement actions as a result of CMS' assessment of a hospital's compliance with the HPT regulations may be found here: Hospital Price Transparency Enforcement Activities and Outcomes | CMS Data

<sup>26</sup> §180.90(a)

<sup>27</sup> §180.90(c)

<sup>28</sup> §§180.100 and 180.110

<sup>29</sup> CMS posts the CMP notices on its website at: Enforcement Actions | CMS. Hospitals designated as "Under Review" have exercised their right of appeal.

CMS notes that some other CMS enforcement programs offer entities subject to CMPs the ability to waive appeal rights in exchange for a 35% discount in the amount of the CMP owed. CMS cites the FY 2024 Skilled-Nursing Facility Prospective Payment System final rule<sup>30</sup> in which the agency discussed its experience over the years with the CMP reduction pertaining to long-term care facilities, and respondents' widespread invocation of the long-term care facility enforcement appeal waiver provision. Given this, CMS considered whether offering hospitals the opportunity to receive a reduced penalty — in some circumstances, and in exchange for their acknowledging their HPT noncompliance — could expedite timely CMP payment. Among its considerations, the agency believes that hospitals electing such a waiver opportunity would be demonstrating their acceptance of responsibility for HPT noncompliance and their corresponding commitment to timely achieving future compliance, which would be key to helping the agency achieve its overarching HPT goal of ensuring this information, in compliant form, is accessible to health care consumers.

**CMS is therefore proposing to establish, at new §180.90(c)(4), and subject to the exceptions discussed below, that the amount of a CMP would be reduced by 35% should a hospital submit to CMS a written notice requesting to waive its right to a hearing under §180.100 within 30 calendar days of the date of the notice of imposition of the CMP.**

CMS expects that this proposed policy would benefit both CMS and the hospital by reducing or eliminating the time, resources, expenses, and other potential burden otherwise attributable to prosecuting or defending the administrative appeals processes. CMS notes that this proposal would not preclude a hospital, so long as it did not seek a waiver, from requesting a hearing, nor would waiving the right to a hearing remove from the hospital's record the fact of its HPT noncompliance. Rather, under this proposal, should a hospital choose to waive its right to a hearing, it would accept CMS' determination that it was noncompliant. Significantly, hospitals would still be required to achieve compliance to avoid the potential imposition of additional CMPs pursuant to existing regulations — regardless of whether they elected to waive the right to a hearing.<sup>31</sup>

Under this proposal, **CMS proposes** that if a hospital waives its right to appeal a CMP and receives a 35% reduction in accordance with new §180.90(c)(4), the hospital would:

- Not be eligible to receive a 35% reduction on any CMPs issued under §180.90(f) that result from the same instance(s) of noncompliance (that is, continuing violations)
- Waive its right to appeal CMPs for any such continuing violations

**CMS is also proposing, at new §180.90(c)(4)(i) and (ii), certain situations in which it would decline to make this waiver available.** Specifically, CMS proposes that a hospital would not be eligible to request that CMS reduce the amount of a CMP if either:

- The hospital does not request to waive its right to a hearing within 30 calendar days of the date of the notice of imposition of the CMP.
- CMS imposed the CMP because the hospital failed to make public either an MRF or a consumer-friendly list of standard charges.<sup>32</sup>

CMS believes that the proposed time frame of 30 calendar days would provide a hospital ample opportunity to elect whether to exercise its option to waive a hearing. Additionally, CMS notes that, four years into the HPT initiative, the agency continues to issue CMPs to hospitals for failing the most fundamental of requirements, which are to make public an MRF and also make public a consumer-

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<sup>30</sup> 88 FR 53200, 53326

<sup>31</sup> At §180.90(f)

<sup>32</sup> As required at §180.40(a) and (b).

friendly display.<sup>33</sup> CMS believes that in such cases, the hospital should be ineligible to avail itself of an opportunity to waive its hearing rights and receive a CMP reduction.

Finally, **CMS proposes to make conforming revisions** to §180.90(d)(1) and to add a new §180.90(d)(2) to account for the proposed provisions at new §180.90(c)(4), which would allow for a reduction to the CMP amount were certain criteria to be met, as discussed above. CMS also proposes to redesignate current §180.90(d)(2) and (3) as §180.90(d)(3) and (4), respectively.

## Other Updates Affecting OPPTS Payments

### Updates to the APC Relative Payment Weights

As required by law, CMS must review and revise the APC relative payment weights annually. CMS must also revise the APC groups each year to account for drugs and medical devices that no longer qualify for pass-through status, new and deleted Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, advances in technology, new services, and new cost data.

The proposed payment weights and rates for CY 2026 are available in Addenda A and B within Addendum P of the proposed rule at <https://www.cms.gov/license/ama?file=/files/zip/2026-nprm-opps-addenda.zip>.

For CY 2026, CMS is proposing to recalibrate payment weights for services furnished on or after January 1, 2026, and before January 1, 2027, using the CY 2024 claims data.

The table below, based on Addendum A, shows the update in the number of APCs per category from CY 2025 to CY 2026:

APC Category	Status Indicator	Final CY 2025	Proposed CY 2026
Pass-Through Drugs and Biologicals	G	107	97
Pass-Through Device Categories	H	17	14
Non-Opioid Medical Devices for Post-Surgical Pain Relief	H1	5	6
OPD Services Paid through a Comprehensive APC	J1	71	72
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	490	482
Non-Opioid Drugs and Biologicals for Post-Surgical Pain Relief	K1	5	5
Partial Hospitalization	P	8	8
Blood and Blood Products	R	41	41
Procedure or Service, No Multiple Reduction	S	80	64
Slom Substitute Products	S1	-	3
Procedure or Service, Multiple Reduction Applies	T	29	29
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		994	962

<sup>33</sup> In the preamble, CMS presents Table 91, showing that the agency has issued 266 (11.8%) violations for “No MRF” and 72 (3.2%) violations for “No Consumer-friendly Display” from 2022 to March 2025.



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**Blood and Blood Products**

For CY 2026, CMS is proposing to continue its policy to establish payment rates for blood and blood products using a blood-specific CCR methodology.

**Brachytherapy Sources**

For CY 2026, CMS is proposing to continue its policy to use the costs derived from the most recent set of claims data (CY 2024) to set payment rates for brachytherapy sources. With the exception of brachytherapy source C2645 and low-volume brachytherapy APCs, CMS is proposing to base payment rates on the geometric mean unit costs (MUCs) for each source. For CY 2026 and future years, CMS is also proposing to “...pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis....”

Additionally, for CY 2026, CMS is proposing to designate six brachytherapy APCs as low-volume APCs.

**Radioisotopes Derived from Non-Highly Enriched Uranium Sources**

Historically, most of the supply of molybdenum (Mo-99) (used in the creation of Technetium-99m [Tc-99m], a commonly used diagnostic imaging radioisotope) used in the United States is sourced from reactors outside of the country using highly enriched uranium. In the CY 2025 OPPTS final rule CMS adopted a new add-on payment of \$10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 to eliminate reliance on these foreign reactors.

CMS is proposing to clarify several criteria for classifying a TC-99m Radiopharmaceutical dose as domestically produced. Among the proposed include defining:

- “...domestically produced Mo-99 to mean Mo-99 that was both irradiated and processed in the United States..
- ...“irradiated,” as the process of bombarding a uranium or molybdenum target with radiation in order to produce Mo-99, and to specify that irradiation is typically performed with a nuclear reactor or particle accelerator...
- ...“processed” in this context to refer to the purification of Mo-99 from irradiated material...”

Additionally, CMS is proposing to establish a new HCPCS C-code C917X (Tc-99m from domestically produced non-HEU Mo-99, [minimum 50%], full cost recovery add-on, per study dose), effective January 1, 2026. Hospitals would be able to report the new HCPCS C-code C917X once per dose, along with any diagnostic scans furnished using Tc-99m derived from domestically produced Mo-99. Hospitals could bill the add-on code if they can certify that at least 50% of the Mo-99 in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99.

CMS aims to limit administrative burden for hospitals while accounting for the per-dose cost of Tc-99m derived from domestically produced Mo-99 and seeks comments on questions outlined on page 33,563 of the proposed rule.

**Comprehensive APCs**

A Comprehensive Ambulatory Payment Classification (C-APC) provides all-inclusive payments for certain procedures. A C-APC covers payment for all applicable Part B services that are related to the primary procedure, including items currently paid under separate fee schedules. The C-APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary

procedure; visits and evaluations performed in association with the procedure; coded and un-coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C-APCs when they appear on the same claim as those services assigned to a C-APC. The C-APCs do not include payments for services that are not covered by Medicare Part B, nor those that are not payable under OPPTS, such as: certain mammography and ambulance services; brachytherapy sources; pass-through drugs and devices; charges for self-administered drugs; certain preventive services; and procedures assigned to a New Technology APC either included on a claim with a “J1” or included on a claim with a “J2” indicator and packaged into payment for comprehensive observation services assigned to status indicator “J2.”

For CY 2026, CMS is soliciting comments on potential refinements to the C-APC complexity adjustment criteria outlined on page 33491.

For CY 2026 and subsequent years, CMS is proposing to exclude payment for cell and gene therapies from C-APC packaging listed in Table 1 on page 33493 into the payment for the primary C-APC service on the same claim when those cell and gene therapies are not functioning as integral, ancillary supportive, dependent, or adjunctive to the primary C-APC service. CMS is also proposing those products on this list with a pass-through status expiring in CY 2026 will be excluded from C-APC packaging after their pass-through status expires, which can be found in Table 57 on pages 33613–33614.

Each year CMS reviews and revises the services within each APC group and APC assignments under the OPPTS. CMS is not proposing to convert any standard APCs to C-APCs. The proposed CY 2026 C-APCs can be found in Table 2 on pages 33,495–33,496 of the proposed rule.

### **Calculation of Composite APC Criteria-Based Costs**

Composite APCs are another type of packaging to provide a single APC payment for groups of services that are typically performed together during a single outpatient encounter. Currently, there are six composite APCs:

- Mental Health Services (APC 8010)
- Multiple Imaging Services (APCs 8004, 8005, 8006, 8007, and 8008)

For CY 2026, CMS is proposing to continue its policy that when the aggregate payment for specified mental health services provided by a hospital to a single beneficiary on a single date of service exceeds the maximum per diem payment rate for partial hospitalization services, those services will continue to instead be paid through composite APC 8010. In addition, CMS is proposing that the payment rate for composite APC 8010 will continue to be set to that established for APC 5864 (four or more hospital-based partial hospitalization services per day) as it is the maximum partial hospitalization per diem payment rate for a hospital.

CMS is proposing to continue its current composite APC payment policies for multiple imaging services from the same family and on the same date for CY 2026. Table 3 on pages 33,499–33,502 of the proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging procedure composite APC policy, their respective families, and each family’s geometric mean cost.

### **Universal Low-Volume APC Payment Policy**

For CY 2026, CMS proposes to continue the universal low-volume APC payment methodology for services assigned to new technology, clinical, and brachytherapy APCs with fewer than 100 single

claims. This policy uses the highest of the geometric mean, arithmetic mean, or median based on up to four years of claims data to set the payment rate for the APC.

The proposed 11 low volume APCs for CY 2026 can be found in Table 39 on page 33,562 of the proposed rule.

### **Changes to Packaged Items and Services**

CMS is proposing to continue to conditionally package costs of selected newly identified ancillary services into payment for a primary service where it believes the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service.

For CY 2026, CMS proposes to continue to unpackage, and pay separately at ASP plus 6%, the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. CMS is unpackaging these drugs to address the decreased utilization of non-opioid pain management drugs and to encourage their use rather than prescription opioids. These drugs are only eligible if the drug or biological does not have transitional pass-through payment status and the drug must not already be separately payable in the OPPTS or ASC payment system.

Table 82 on page 33,746 of the proposed rule lists the products that CMS proposes would have separate payment in the ASC setting under this policy for CY 2026.

### **Sole Community Hospital and Essential Access Community Hospital Adjustment**

CMS proposes to continue the 7.1% budget-neutral payment increase for rural SCHs and essential access community hospitals. This payment add-on excludes separately payable drugs, biologicals, brachytherapy sources, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. CMS would maintain this for future years until data supports a change to the adjustment.

### **Cancer Hospital Adjustment**

CMS provides payment increases to the 11 IPPS exempt cancer hospitals to address higher outpatient costs incurred by these hospitals. CMS does this by providing a budget-neutral payment adjustment such that the cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for other non-cancer hospitals paid under the OPPTS.

In the CY 2024 OPPTS final rule, CMS adopted a policy to reduce the target PCR by 1 PPT each calendar year until the target PCR equals the PCR of non-cancer hospitals using the most recent data minus 1 PPT, as required by the 21<sup>st</sup> Century Cures Act. For CY 2025, CMS adopted a cancer hospital target PCR of 0.87. Since the target PCR based on OPPTS payments to other hospitals furnishing services under the OPPTS would be 0.87 after applying the 1 PPT reduction, and would equal the CY 2025 target PCR, CMS feels it is no longer necessary to continue the transition policy of gradually reducing the pre-COVID-19 public health emergency target PCR by 1 PPT. As such, CMS proposes a target PCR of 0.87 for CY 2026. Table 7 on page 33,517 of the proposed rule outlines the estimated percentage increase in OPPTS payments for each cancer hospital for CY 2026 due to the cancer hospital payment adjustment policy.

### **Outlier Payments**

To maintain total outlier payments at 1% of total OPPTS payments, CMS used CY 2024 claims to calculate a proposed CY 2026 outlier fixed-dollar threshold of \$6,450, a 19.4% decrease from the current threshold of \$8,000. Outlier payments would continue to be paid at 50% of the amount by

which the hospital's cost exceeds 1.75 times the APC payment amount when both the 1.75 multiplier threshold and the fixed-dollar threshold are met.

## Wage Index Changes

### Wage Index and Labor-Related Share

As in past years, CMS proposes to continue to use FFY 2026 IPPS wage indexes, including all reclassifications, add-ons, and rural floors to be applied to the labor-related share of CY 2026 OPPTS payments in a budget-neutral manner.

CMS applies a 5% cap on any decrease in the hospital wage index, compared to the previous year's wage index. The cap is applied regardless of the reason for the decrease and implemented in a budget-neutral manner nationally. This also means that if a hospital's prior CY wage index is calculated with the application of the 5% cap, the following year's wage index will not be less than 95% of the hospital's capped wage index in the prior year. Lastly, a new hospital will be paid the wage index for the area in which it is geographically located for its first full or partial year with no cap applied, because a new hospital will not have had a wage index in the prior year. CMS proposes a budget neutrality factor of 0.9955 for the impact of the 5% cap on wage index decreases.

CMS is proposing a wage index and labor-related share budget-neutrality factor of 1.0116 for CY 2026 to ensure that aggregate payments made under the OPPTS are not greater or less than would otherwise be made if wage index adjustments had not changed.

The wage index is applied to the portion of the OPPTS conversion factor that CMS considers to be labor-related. For CY 2026, CMS is proposing to continue to use a labor-related share of 60%.

### Low-Wage Index Hospital Policy

In the FFY 2020 IPPS final rule, CMS made a variety of changes to reduce the disparity between high and low wage index hospitals where hospitals with a wage index value in the bottom quartile of the nation would have that wage index increased by a value equivalent to half of the difference between the hospital's post-rural floor, post-reclassification wage index and the 25th percentile wage index value across all hospitals. As adopted, this policy was to be in effect for a minimum of four years (through FFY 2024) in order to be properly reflected in the Medicare cost report for future years. In the FFY 2025 final rule, CMS adopted to continue this policy for at least three more years, beginning in FFY 2025, in order for sufficient wage data from after the end of the COVID-19 public health emergency to become available.

This policy is subject to litigation (*Bridgeport Hospital, et al., v. Becerra*) in which the court found that the secretary did not have the authority to adopt this low wage index policy and has ordered additional briefing on an appropriate remedy. On July 23, 2024, the U.S. Court of Appeals for the D.C. Circuit affirmed the lower court's ruling, holding that this policy for FFY 2020 was unlawful and that CMS had no statutory authority to issue it. As a result, the court ordered that the rule be vacated and that hospitals affected by the budget-neutrality adjustment are entitled to back-payments, including interest.

At the time, CMS believed that its statutory authority in the OPPTS setting differed from the IPPS setting. As such, in the CY 2025 OPPTS final rule, CMS adopted to continue the policy that hospitals with a wage index value in the bottom quartile of the nation would have their OPPTS wage index increased by a value equivalent to half of the difference between the hospital's pre-adjustment wage index and the 25th percentile wage index value across all hospitals. CMS acknowledged the differences between the OPPTS and IPPS wage index values for FFY 2025 and noted its intentions to explore options to realign the wage index values in future rulemaking.

For CY 2026 and subsequent years CMS proposes to realign the IPPS and OPPTS wage index values and eliminate the low wage index hospital policy under the OPPTS. CMS is proposing that the 5% cap that will apply to the CY 2026 OPPTS wage index will be based off the IPPS wage index for FFY 2025 rather than the OPPTS wage index for CY 2025. CMS notes that because the CY 2025 OPPTS wage index was different than the FFY 2025 IPPS wage index, using the FFY 2026 IPPS wage index for CY 2026 OPPTS wage index would result in decreases greater than 5% to some hospitals' wage indexes under the OPPTS. Under CMS' proposal, the 5% cap on wage index decreases in the CY 2026 OPPTS would apply in a similar manner to years prior to the CY 2025 OPPTS, in which IPPS hospitals would receive the same wage index with the cap on wage index decreases as they would under the IPPS, and non-IPPS hospitals and Community Mental Health Centers (CMHCs) would receive a similar corresponding wage index with the cap on wage index decreases policy under the broader wage index adoption.

Additionally, in the FFY 2026 IPPS proposed rule CMS proposed a narrow transitional exception to the calculation of the FFY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. The temporary payment exception is meant "to mitigate short-term instability and payment fluctuations that can negatively impact hospitals consistent with principles of certainty and predictability under the prospective payment systems."

To address the same concerns under OPPTS, CMS is proposing a transitional payment exception for CY 2026. The transitional payment exception policy would apply to hospitals that benefitted from the CY 2024 low wage index hospital policy. If the hospital's proposed CY 2026 wage index decreases by more than 9.75% from the hospital's CY 2024 wage index, the transitional payment exception would be set to 90.25% of the CY 2024 wage index. The transitional payment exception would be applied after the application of the 5% cap. CMS proposes to make this policy budget neutral under the OPPTS.

In cases where hospitals report the payer-specific negotiated share as a percentage or algorithm in the MRF, CMS is proposing that hospitals would instead use the proposed "median allowed amount" to calculate the negotiated charges to report on the Medicare cost report.

## Payment for Medical Devices

### Payment for Medical Devices with Pass-Through Status

Currently, 17 device categories are eligible for pass-through payment:

- C1826 – Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
- C1827 – Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
- C1747 – Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)
- C1600 – Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)
- C1601 – Endoscope, single-use (i.e. disposable), pulmonary, imaging/illumination device (insertable)
- C1602 – Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)
- C1603 – Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)
- C1604 – Graft, transmural transvenous arterial bypass (implantable), with all delivery system components
- C1605 – Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation

- C1606 – Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
- C8000 – Support device, extravascular, for arteriovenous fistula (implantable)
- C1735 – Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components
- C1736 – Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components
- C1737 – Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)
- C1738 – Powered, single-use (i.e. disposable) endoscopic ultrasound-guided biopsy device
- C1739 – Tissue marker, probe detectable any method (implantable), with delivery system
- C9610 – Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)

CMS received eight applications for device pass-through payment applications by the March 3, 2025, quarterly deadline; two were approved for pass-through payment:

- VasQ
- SCOUT MD™ Surgical Guidance System

### Device-Intensive Procedures

CMS defines device-intensive APCs as procedures that require the implantation of a device and are assigned an individual HCPCS code-level device offset of more than 30% of the procedure's mean cost, regardless of APC assignment. In the CY 2025 final rule, CMS modified its proposed device policy for new HCPCS codes for procedures that require the implantation/insertion of a single-use device meeting CMS' device-intensive requirements. If the procedures lack claims data, CMS will apply a default device offset percentage that is the greater of 31% or the APC's devices offset percentage. CMS also updated its device edits policy so that procedures that cannot use the "CG" modifier will have their offset percentage calculated based on hospital claims that include a device code.

Additionally, claims data from procedures with a status indicator "EI" during the rate-setting year will be excluded and the process for applying device offset percentages will be refined to use claims data from predecessor codes' annually until successor code data is available. CMS is proposing to continue these policies for CY 2026.

The full list of proposed CY 2026 device-intensive procedures can be found in Addendum P of the proposed rule.

### Device Edit Policy

In CY 2025 OPPTS final rule CMS adopted a device edit policy with modifications to apply the policy permanently once a procedure is designated as a device-intensive procedure in a given year. Additionally, CMS also adopted a policy to reinstate the device edits policy for procedures that have been device-intensive since CMS began assigning device-intensive status at the HCPCS code level on or after January 1, 2017. CMS does not propose any changes to the device edit policy for CY 2026.

### Adjustment to OPPTS Payment for No Cost/Full Credit and Partial Credit Devices

For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital receives a credit from the manufacturer. The offset can be 100% of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer; or 50% when a

hospital receives partial credit of 50% or more. CMS determines the procedures to which this policy applies using three criteria:

- All procedures must involve implantable devices that will be reported if device-insertion procedures were performed.
- The required devices must be surgically inserted or must be implanted devices that remain in the patient's body after the conclusion of the procedure (even if temporarily).
- The procedure must be device-intensive (devices exceeding 30% of the procedure's average cost).

For CY 2026, CMS does not propose any changes to the no cost/full credit and partial credit device policies.

## Payment Policies for Drugs, Biologicals, and Radiopharmaceuticals

CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately; the determination is based on the packaging threshold. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved to both grant a pass-through period as close to three full years as possible and eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

For CY 2026 and subsequent years CMS proposes to use the same methodology finalized in CY 2025 to calculate the per-day costs for diagnostic radiopharmaceuticals. Consistent with methodology and practices, CMS also proposes to update the diagnostic radiopharmaceutical packaging threshold of \$630 to \$655 for CY 2026. In addition, CMS proposes to continue to pay radiopharmaceuticals with per-day costs above the diagnostic radiopharmaceutical packaging threshold, based on their arithmetic MUC, derived from CY 2024 claims data.

Separately for CY 2026, CMS is proposing a packaging threshold of \$140. Drugs, biologicals, and radiopharmaceuticals (excluding diagnostic radiopharmaceuticals) that are above the \$140 threshold would be paid separately, using individual APCs, and those below the threshold would be packaged; the baseline payment rate for CY 2026 is the ASP plus 6%. Separately payable drugs and biological products that do not have pass-through status would be paid wholesale acquisition cost (WAC) plus 3%, instead of WAC plus 6%.

For CY 2026, CMS is proposing to continue paying for blood clotting factors and therapeutic radiopharmaceuticals without pass-through payment status at ASP plus 6%. If ASP data are not available, payment instead would be made at WAC plus 3%; if WAC data are also not available, payment would be made at 95% of average wholesale price (AWP).

For CY 2026 and subsequent years, for those HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals that are impacted by the updated drug packaging threshold, CMS is proposing:

- *“HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2025 and that are finalized for separate payment in CY 2026, and that then have per day costs equal to or less than the CY 2026 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would continue to receive separate payment in CY 2026.*
- *HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2025 and that are finalized for separate payment in CY 2026, and that then have per day costs equal*



*to or less than the CY 2026 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would remain packaged in CY 2026.*

- *HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we finalized packaged payment in CY 2026 but that then have per-day costs greater than the CY 2026 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would receive separate payment in CY 2026.”*

For CY 2026, CMS is proposing to continue to pay for non-pass-through diagnostic radiopharmaceuticals that are separately payable. CMS is proposing to continue to use MUC data for said radiopharmaceuticals that are finalized as separately payable due to their cost exceeding the per-day threshold.

Additionally, CMS is proposing to continue the policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis for HCPCS codes that describe the same drug or biological but different dosages. CMS is also proposing that this policy apply to diagnostic radiopharmaceuticals.

As there are often HCPCS codes for new drugs or biologicals that have received marketing approval, but for which no sales data are available, the affected drugs and biologicals are assigned a non-payable indicator. For separately payable drugs and biologicals for which CMS does not provide a payment rate, CMS finalized in the CY 2025 OPPS final rule that Medicare administrative contractors (MACs) will calculate the payment based on provider invoices (net acquisition cost, less any rebates, chargebacks, or post-sale concessions). MACs will use the invoice to determine that the drug is not policy-packaged, and that the per-day cost is above the threshold packaging amount, as applicable. For CY 2026 CMS proposes to clarify that it would determine whether the drug is not policy packaged, and the MAC would continue to determine whether the per-day cost is above the threshold packaging amount.

Lastly, CMS states that the pass-through status will expire by December 31, 2025, for 57 drugs and biologicals, listed in Table 57 on pages 33,613–33,614 of the proposed rule; by December 31, 2026, for 41 drugs and biologicals listed in Table 58 on pages 33,616–33,619 of the proposed rule; and will continue/establish pass-through status in CY 2026 for 41 drugs and biologicals shown in Table 59 on pages 33,621–33,623 of the proposed rule.

## Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Facilities

For CY 2026, CMS is proposing that IHS and tribal hospitals would continue to receive separate payment for high-cost drugs furnished in hospital OPDs through an additional add-on payment using the authority under which the annual all-inclusive rate (AIR) is calculated. This add-on payment would be applicable to all Medicare Part B-covered high-cost drugs furnished in IHS/tribal hospital OPDs that would otherwise be paid under OPPS, for whose per-day cost exceeds twice the lower 48 states' AIR in effect at the time of release of the CY 2026 OPPS final rule. This payment is in addition to the AIR and would have no impact on the calculation of the AIR.

Addendum Q includes a preliminary list of drugs qualifying for the proposed add-on payment and their respective payment rates for CY 2026.



## Skin Substitutes

Since 2014, skin substitutes have been divided into a high-cost group and a low-cost group in terms of packaging under the OPPS. CMS assigns to the high-cost group skin substitutes with a geometric MUC or a product's per-day cost (PDC) that exceeds either the MUC threshold or the PDC threshold.

Beginning January 1, 2026, CMS is proposing to separately pay for certain groups of skin substitute products as incident-to supplies under the PFS in the non-facility setting or the OPPS setting; this would include unpackaging the skin substitute products from the payment for administration of the skin substitute product separate from the skin substitute product itself. CMS is proposing to remove skin substitutes from the list of packaged items and services and specify that CMS would continue to package payment for products that aid wound healing that are not skin substitute products.

In addition, CMS is proposing to group skin substitutes that are not drugs or biologicals using three CMS payment categories based on FDA regulatory and proposing to create three new APCs:

- APC 6000 (PMA Skin Substitute Products)
- APC 6001 (510(k) Skin Substitute Products)
- APC 6002 (361 HCT/P Skin Substitute Products)

CMS is proposing to establish an initial payment rate of \$125.38 for the three newly proposed APCs and would update the rates for skin substitute categories annually using the most recently available calendar quarter of ASP data. CMS is also proposing to create three new unlisted C-codes and assigning them to existing codes to prevent delays in Medicare payments for new FDA approved or cleared skin substitute products as follows:

- QXXX1 (Unlisted PMA skin substitute product) assigned to APC 6000 (PMA Skin Substitute Products);
- QXXX2 (Unlisted 510(k) skin substitute product) assigned to APC 6001 (510(k) Skin Substitute Products); and
- QXXX3 (Unlisted 361 HCT/P skin substitute product) assigned to APC 6002 (361 HCT/P Skin Substitute Products).

Lastly, CMS is proposing to create a new status indicator, "S1" to indicate that the skin substitute product is paid separately from other procedure codes under the OPPS. The proposed "S1" indicator would be assigned to all skin substitute products assigned to APCs 6000, 6001, 6002. Table 65 on page 33,648 of the proposed rule details the proposed status indicator, the descriptor, and payment status.

## Radiation Therapy Services: Non-Excepted Off-Campus Provider Based Departments

### Background

Section 603 of the Bipartisan Budget Act of 2015 amended the Social Security Act<sup>34</sup> such that, as a general matter, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services for purposes of payment under the OPPS. Instead, such items are paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. As a result, CMS finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for

<sup>34</sup> Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74) (BBA, 2015) (referred to as "Section 603") amended section 1833(t) of the Social Security Act by adding a new clause (v) to paragraph (1)(B) and adding a new paragraph (21).

the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

To effectuate payment for nonexcepted items and services, CMS established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, CMS established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS relativity adjuster of 40% (that is, 60% less than the OPPS rate).<sup>35</sup>

CMS also created modifier “PN” to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS-equivalent rates for nonexcepted items and services. Nonexcepted off-campus PBDs bill for nonexcepted items and services on the institutional claim utilizing modifier “PN” to indicate that an item or service is a nonexcepted item or service.

### **Payment for Radiation Therapy Services Furnished at Nonexcepted Off-Campus PBDs**

The PFS relativity adjuster is not applied to radiation therapy services furnished by nonexcepted off-campus PBDs. Instead, when CMS implemented the Section 603 requirements, nonexcepted off-campus PBDs were instructed to bill the PFS G-codes for these services. As discussed in the 2026 PFS proposed rule, CMS is proposing 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. If finalized as proposed, the G-codes that nonexcepted off-campus PBDs currently use to report radiation therapy services would no longer be available after December 31, 2025.

To continue paying the PFS-equivalent rate for these services to these departments, CMS is proposing that, effective January 1, 2026, nonexcepted off-campus PBDs use the revised CPT codes described in the 2026 PFS proposed rule. CMS believes this policy would preserve the existing policy of paying nonexcepted off-campus PBDs a specific radiation treatment rate, which is the technical component for the code under the PFS. Nonexcepted off-campus PBDs should continue to append the “PN” modifier to each applicable claim line for these services. CMS emphasizes that this is not a new policy, but rather a continuation of current policy adjusting for the newly revised CPT codes and the corresponding deletion of the G codes.

Table 44 in the proposed rule contains the long descriptors of the G codes that will be deleted effective January 1, 2026 and Table 45 contains the current and revised long descriptors for CPT codes 77402, 77407, and 77412. The proposed 2026 payment rates for the radiation treatment delivery codes can be found in Addendum B to the proposed rule. Finally, crosswalk information between the G codes and the revised CPT codes is available under the downloads section of the PFS proposed rule, under “CY 2025 Analytic Crosswalk to CY 2026.”

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<sup>35</sup> For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, see the 2018 OPPS/ASC final rule (82 FR 52356 through 52637) and the 2019 PFS final rule (82 FR 59505 through 59513).

## Hospital Outpatient Visits

CMS is not proposing any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital for 2026. It also is not proposing any changes to its policy for how it pays for clinic visits provided in off-campus provider-based departments. As discussed in Section X.A., CMS is using its authority to control unnecessary increases in the volume of covered OPD services under section 1833(t)(2)(F) to expand its site-neutral payment to drug administration services furnished in an off-campus PBD.

## Market-Basket Medicare Severity-Diagnosis Related Groups (MS-DRG) Relative Weights

CMS is proposing a new market-based methodology for estimating the MS-DRG relative weights, beginning in FY 2029. The proposed market-based methodology would be the same methodology that was adopted in the FFY 2021 IPPS final rule where relative weights are calculated using the median payer-specific negotiated charge for Medicare Advantage organizations (MAOs) for each MS-DRG. CMS is also proposing to require hospitals to report the median payer-specific negotiated charge with all of its MAOs, by MS-DRG on the Medicare cost report beginning in CY 2026.

## Partial Hospitalization Program and Intensive Outpatient Services

PHPs are intensive outpatient (IOP) psychiatric programs that provide outpatient services in lieu of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding CMHC. PHP providers are paid on a per-diem basis, with payment rates calculated using CMHC- or hospital-specific data.

The Consolidated Appropriations Act (CAA) of 2023 established a new Medicare benefit category for IOP services. They are furnished under a distinct and organized outpatient program of psychiatric services for individuals who have an acute mental illness. IOP services are less intensive than PHP services and can be furnished to patients on an outpatient basis by a hospital, a CMHC, a federally qualified health center, or a rural health clinic. IOP services are not required to be provided in lieu of inpatient hospitalization.

Because the statutory definitions of both IOP and PHP generally include the same covered items and services, CMS aligns the programs using a consistent list of services; the only differentiating factor between PHP and IOP services is the level of intensity. To differentiate between IOP and PHP for billing purposes, CMS requires hospitals and CMHCs to report condition code 92 on IOP claims; hospitals and CMHCs report condition code 41 on their PHP claims.

For 2026, CMS proposes to maintain the existing payment rate methodology used for calculating PHP and IOP payment rates for hospital-based providers. However, the agency proposes to revise the methodology for calculating PHP and IOP payment rates for CMHCs. Specifically, CMS proposes applying the 40% MPFS relativity adjuster to calculate PHP and IOP payment rates for CMHCs. Under the proposed methodology, CMS would multiply the hospital-based PHP and IOP APCs by 0.4 to calculate the payment rates for the CMHC PHP and IOP APCs. CMS notes that its current methodology for determining CMHC rates resulted in an inversion where costs for three-service days was greater than four-service days, which may be the result of the small number of CMHCs that bill for PHP and IOP services. CMS also notes that the proposed methodology aligns with the

methodology applied to other nonexcepted OPPTS services furnished by nonexcepted off-campus hospital outpatient departments.

The following table compares the final CY 2025 and proposed CY 2026 PHP and IOP payment rates as found in Addendum A:

	Final Payment Rate 2025	Proposed Payment Rate 2026	Percent Change
APC 5851: Intensive Outpatient (3+ services) for CMHCs	\$111.24	\$134.26	+20.69%
APC 5852: Intensive Outpatient (4+ services) for CMHCs	\$168.32	\$167.23	-0.65%
APC 5853: Partial Hospitalization (3+ services) for CMHCs	\$111.24	\$134.26	+20.69%
APC 5854: Partial Hospitalization (4+ services) for CMHCs	\$168.32	\$167.23	-0.65%
APC 5861: Intensive Outpatient (3+ services) for Hospital-based IOPs	\$269.19	\$335.67	+24.70%
APC 5862: Intensive Outpatient (4+ services) for Hospital-based IOPs	\$408.55	\$418.09	+2.34%
APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	\$269.19	\$335.67	+24.70%
APC 5864: Partial Hospitalization (4+ services) for Hospital-based PHPs	\$408.55	\$418.09	+2.34

CMS proposes to continue to make outlier payments to CMHCs for 50% of the amount by which the cost for the PHP service exceeds 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year. As in prior years, CMS proposes to apply an 8% outlier payment cap to the CMHC's total per diem payments. The calculation of the CMHC outlier percentage would apply to both PHP and IOP.

## Inpatient-Only List

The IPO list specifies services/procedures that Medicare will pay for only when provided in an inpatient 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 before the patient can be safely discharged. Currently, the IPO list includes approximately 1,731 services. 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 using criteria specified annually in the OPPTS rule. However, in recent years, some stakeholders have advocated for the elimination of the IPO list. CMS had finalized a policy to phase out the IPO list in the CY 2021 OPPTS final rule but reversed the policy in the CY 2022 OPPTS final rule, restoring most of the codes that had been eliminated in 2021.

Beginning with CY 2026, CMS again proposes to eliminate the IPO list over a three-year period, completing the elimination by January 1, 2029. CMS asserts that that this change would ensure maximum availability of services to beneficiaries in the outpatient setting and argues that advances in medical technology have led to more services able to be safely performed in outpatient settings over time.

CMS proposes that musculoskeletal services would be the first group of services removed from the IPO list, as the agency did in the 2021 OPPTS final rule. For CY 2026, CMS proposes to remove

285 musculoskeletal services from the IPO list, as well as 16 non-musculoskeletal services that had been removed in 2021, then subsequently reinstated. These services are listed in Table 69 of the proposed rule.

In conjunction with the proposed removal of these services from the IPO list, CMS proposes to continue the indefinite exemption from site-of-service claim denials, initial medical review contractor referrals to recovery audit contractors (RACs), and RAC reviews for patient status (i.e. site-of-service) for services removed from the IPO list. This policy is described in more detail below.

CMS requests comments from stakeholders on whether three years is an appropriate time frame for the transition, whether there are other services that would be good candidates for removal from the IPO list in the near term, and the order of removal of additional clinical families of services, and/or specific services, for each of the 2027 and 2028 rulemakings, until the IPO list is completely eliminated. CMS also seeks comment on whether it should restructure or create any new APCs or C-APCs to allow for efficient OPPTS payment for services that are removed from the IPO list. Finally, while the agency asserts that eliminating procedures from the IPO list will not negatively affect patient safety given advances in clinical technology, and clinicians' professional judgement, it requests that commenters submit evidence on what effect, if any, they believe eliminating the IPO list may have on quality of care.

## Medical Review of Inpatient Hospital Admissions

Under the two-midnight rule, services are generally considered appropriate for inpatient hospital admission and Medicare Part A payment when the physician expects the patient to require at least two midnights of hospital care. Services on the IPO list continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay.

In 2020, CMS finalized a policy to exempt procedures that have been removed from the IPO list from eligibility for referral to RACs for noncompliance with the two-midnight rule within the two calendar years following their removal from the IPO list. When CMS adopted a policy to eliminate the IPO list over a three-year transitional period in the CY 2021 OPPTS final rule, it also finalized an indefinite exemption period rather than the two-year period for procedures removed from the IPO list after January 1, 2021. This policy was again modified when CMS reversed its decision to eliminate the IPO list in CY 2022, and the exemption period was returned to two years after removal from the IPO list.

As described above, CMS is again proposing to eliminate the IPO list over three years. In conjunction with this proposal, CMS proposes to return to an indefinite exemption from site-of-service claim denials, initial medical review contractor referrals to RACs, and RAC reviews for patient status (i.e. site-of-service) for procedures that are removed from the IPO list in 2021 or later. Procedures would be exempted from medical review for patient status until claim data demonstrates that the procedure is being performed more than 50% of the time in the outpatient setting in a single calendar year. CMS proposes to announce the end of the exemption period for a procedure through sub-regulatory guidance.

CMS notes that there is an exemption period from certain medical review activities, not an exception to the two-midnight rule. Providers are still required to comply with the two-midnight rule during the exemption period, and CMS or its contractors may still conduct patient status medical review in cases in which there is evidence of systemic fraud or abuse occurring. Other types of medical review, unrelated to patient status, will not be impacted by the proposed exemption. During the exemption

period, BFCC-QIOs may still review such claims to provide education for practitioners and providers regarding compliance with the two-midnight rule, but claims identified as noncompliant would not be denied with respect to the site-of-service under Medicare Part A.

### **Virtual Direct Supervision of Certain Hospital Outpatient Services**

Under current OPPTS policy, cardiac (CR), ICR, and pulmonary rehabilitation (PR) services must be provided under the direct supervision of a physician. The CAA of 2023 extended the authority for virtual supervision of these services furnished by physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists beginning January 1, 2024. For the duration of the COVID-19 public health emergency, CMS adopted that — for the purposes of direct supervision— a physician can be immediately present virtually through audio/video real-time communications technology for PR, CR, and ICR services when the use of technology reduces exposure risks for the patient or the provider; this flexibility was extended through CY 2024 by the CAA of 2023 and by CMS through the end of 2025 in the CY 2025 OPPTS final rule.

In the CY 2026 PFS proposed rule, CMS is proposing to permanently extend virtual direct supervision for CR, ICR, PR, and diagnostic services under the PFS, with an exception for services that have a global surgery indicator of 010 or 090. CMS proposes a conforming policy under the OPPTS, 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. CMS notes that its change in policy does not mean it is appropriate to use virtual direct supervision for every Medicare beneficiary in every scenario, but that the physician or nonphysician practitioner should use their complex professional judgment to determine the appropriate supervision modality on a case-by-case basis.

### **Cross-Program Quality Measure Policies**

CMS proposes to remove four quality measures across three programs: the Hospital Outpatient Quality Reporting (OQR) Program, the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program. CMS proposes to update extraordinary circumstance exception (ECEs) across all three programs and seeks comments on future measure concepts related to well-being and nutrition.

### **Proposed Removal of COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure**

CMS proposes to remove the COVID-19 Vaccination Coverage Among HCP measure from the OQR, ASCQR, and REHQR programs beginning with the CY 2024 reporting period/CY 2026 payment determination. CMS cites measure removal factor 8 — the costs associated with the measure outweigh the benefit of its continued use in the program — as its rationale. If the proposal is finalized, hospitals and ASCs that do not report 2024 reporting period data for the measure would not be penalized for 2026 payments and any 2024 reporting data for the measure received by CMS would not be used for public reporting or payment purposes.

### **Proposed Removal of Hospital or Facility Commitment to Health Equity Measure**

CMS previously adopted an attestation-based structural measure — the Hospital Commitment to Health Equity (HCHE) for outpatient hospital departments and the Facility Commitment to Health Equity (FCHE) for ASCs and rural emergency hospitals (REHs) — beginning with the CY 2025 reporting period/CY 2027 payment determination.



CMS now proposes to remove the measure from each program beginning with the CY 2025 reporting period/CY 2027 payment determination under measure removal factor 8. CMS says that it is refocusing on measurable clinical outcomes and identifying quality measures on topics of prevention, nutrition, and well-being. If this proposal is finalized, hospitals, REHs, and ASCs that do not report 2025 reporting period data for the HCHE or FHCE measure would not be penalized for 2027 payments and any 2025 reporting period HCHE or FCHE measure data received would not be used for public reporting or payment purposes.

### **Proposed Removal of Two Screening for Social Drivers of Health Measures**

In the CY 2025 OPPTS final rule, CMS adopted two process measures: the Screening for Social Drivers of Health (SDOH), which assesses the proportion of patients screened for health-related social needs in the outpatient setting, and the Screen Positive Rate for SDOH, which provides information on the percentage of patients who screened positive for at least one health-related social need. The measures were adopted into the three programs for voluntary reporting in the 2025 reporting period and mandatory reporting beginning with the 2026 reporting period/2028 payment or program determination.

CMS now proposes to remove both SDOH screening measures from the three programs beginning with the CY 2025 reporting period under measure removal factor 8. CMS cites feedback from facilities concerned with the costs associated with screening patients and manually storing the data, as well as staff training and workflow concerns. Further, CMS notes that the measures document an administrative process rather than demonstrating whether providers are connecting patients with needed resources.

### **Updates to the Extraordinary Circumstances Exception (ECE)**

Under the current ECE policy, CMS grants exceptions to data submission deadlines and requirements under the three outpatient quality reporting programs for extraordinary circumstances, such as natural disasters or systemic problems with CMS data collection systems that directly affect facilities' ability to submit data.

CMS proposes to update its policy to include that an ECE could be a deadline extension to allow a hospital, ASC or REH additional time to comply with a data reporting requirement if the agency determines such an extension would be appropriate. The policy would specify that CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance, defined as "an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the facility to comply with one or more applicable reporting requirements with respect to a fiscal year."

CMS states that the process for requesting and granting an ECE would remain the same as the current process. A hospital, ASC or REH would be able to request an ECE within 30 calendar days of the date the extraordinary circumstance occurred. In the preamble, the agency clarifies that CMS has the authority to grant an ECE at any time after the circumstance. In addition, CMS clarifies that it may grant an ECE to facilities that have not made a request for one if CMS determines that either a systemic problem with the CMS data collection system directly impacted the hospital's ability to comply with the requirements or if the circumstance has affected an entire region or locale. Any ECE granted would specify whether the hospital is (or hospitals are) exempted from reporting requirements or CMS has granted an extension for compliance.

## Hospital OQR Program

The hospital OQR program is mandated by law; hospitals that do not successfully participate are subject to a 2 PPT reduction to the OPPTS market basket update for the applicable year. CMS [posts the list](#) of individual hospitals meeting or failing to meet OQR reporting requirements annually.

In addition to the cross-program proposals described above, CMS proposes several changes to the OQR measures set, including the adoption of one new measure on emergency care, the removal of two related emergency department measures, and extended voluntary reporting for a previously adopted electronic clinical quality measure (eCQM).

CMS proposes no changes to previously finalized OQR program policies for:

- Measure selection, retention, and removal
- Data submission via the CMS web-based tool, the Centers for Disease Control and Prevention National Healthcare Safety Network tool
- The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey-Based Measures (OP-37a-e)
- Population and sampling requirements
- The educational review and correction process for chart-abstracted measures
- Reconsideration and appeals procedures, except for ECE policies previously summarized
- Public display of quality measures
- Requirements for participation in and withdrawal from the OQR program

A table in the appendix of this summary shows the previously and newly proposed OQR program measures for payment determinations from CYs 2026-2031.

## Proposed Adoption of Emergency Care Access & Timeliness eCQM

CMS proposes to adopt a new measure: the Emergency Care Access & Timeliness eCQM. CMS proposes to allow voluntary reporting beginning with the 2027 reporting period followed by mandatory reporting beginning with the 2028 reporting period/2030 payment determination.

The proposed measure would assess four different outcome metrics — intended to quantify access to and timeliness of care in an ED setting — against specified thresholds. As an eCQM, the measure would use data extracted from the hospital's EHR. The measure denominator and numerators are as follows:

- Denominator: All ED encounters associated with patients of all ages, for all payers, during a 12-month performance period; patients can have multiple encounters during a performance period. Each encounter would be eligible to contribute to the measure calculation.
- Numerator: Any ED encounter in the denominator where the patient experiences any of the following (an event can contribute only one to the numerator):
  1. Patient wait time longer than one hour after arrival to the ED until placement in a treatment room or dedicated treatment area that allows for audiovisual privacy during history-taking and physical exam.
  2. Patient left the ED without being evaluated.
  3. Patient boarding time in the ED (measured from a decision to admit (order) to ED to ED departure for admitted patients) longer than four hours.
  4. Patient ED length of stay (LOS) (time from ED arrival to ED physical departure, measured by the ED departure timestamp) longer than eight hours.



- Exclusions: ED encounters with ED observation stays are excluded from components #3 and #4, but are included in the denominator; patients who have a “decision to admit” after an ED observation stay are excluded from criteria #3.

The measure would be calculated at the individual ED level as the proportion of ED encounters where any one of the four numerator outcomes occurred. The scores are then standardized by ED case volume using z-scores (which indicates how many standard deviations a data point is from the mean of a normal distribution). The volume-adjusted z-score for the eCQM would show how an ED’s performance compares to the average for similar-volume EDs. If a CMS Certification Number (CCN) has more than one ED, the volume-adjusted z-scores would be combined as a weighted average for the CCN. The results of the eCQM would be stratified into four groups: two by age (18 and older and under 18) and two by mental health diagnoses (with and without).

For the initial voluntary CY 2027 reporting period for the proposed Emergency Care Access & Timeliness eCQM, CMS proposes that hospitals submit data for any quarter (up to all four quarters). Beginning with the CY 2028 reporting period/2030 payment determination, hospitals would be required to report all four quarters (full year) of data. Data would need to be submitted by May 15 of the year prior to the affected payment determination year (aligning with policies on eCQM submission deadlines).

### **Proposed Removal of Measures**

CMS proposes to remove two measures beginning with the CY 2028 reporting period/CY 2030 payment determination if the proposed Emergency Care Access & Timeliness eCQM is finalized:

- Median Time for Discharged ED Patients Measure
- Left Without Being Seen Measure

CMS believes that the newly proposed eCQM captures the information that these two measures assess (time patients spent in the ED before being sent home and the percentage of patients who leave the ED without being evaluated, respectively), in a less burdensome manner than these two chart-abstracted measures, which require human review and manual intervention to extract data. If the new measure is not finalized, CMS would retain these measures in the program.

### **Modify Excessive Radiation eCQM to Extend Voluntary Reporting**

The Excessive Radiation eCQM was finalized for adoption in the OQR program measure set in the 2024 OPPTS final rule, with voluntary beginning with the 2025 reporting period and mandatory reporting beginning with the 2027 reporting period/2029 payment determination.

In response to stakeholder concerns with the operational feasibility of implementing the eCQM, CMS proposes to maintain voluntary reporting of the measure indefinitely. CMS notes the delay is intended to allow hospital outpatient departments more time to integrate, adequately test, and gain experience with implementing the eCQM and give CMS more time to monitor implementation progress. CMS also brings attention to its [January 2025](#) notice that clarified hospitals and clinicians who choose to report this eCQM can use any vendor’s translation software to calculate the measure.

### **Overall Hospital Quality Star Rating**

In the CY 2025 OPPTS proposed rule, CMS issued a request for information on potential modifications to the Safety of Care measure group within the Overall Hospital Quality Star Rating to emphasize the contribution of that group to the overall star rating. After considering responses received and based on further internal analysis, CMS proposes modifications to the Overall Hospital Quality Star Rating

methodology. Specifically, CMS proposes a two-stage update to address its concerns with hospitals that perform poorly in the Safety of Care measure group continuing to receive high overall star ratings.

First, for 2026 Star Ratings, CMS proposes a four-star cap for hospitals in the lowest quartile of the Safety of Care measure group's performance. Any hospital that would have been assigned five stars but is in the lowest quartile of the group's score (based on at least three Safety of Care measures) would instead receive four stars. Using 2024 data, CMS determined that implementing this cap would result in 14 of the 2,847 hospitals receiving a lower overall quality star rating.

Second, beginning in 2027 and for subsequent years, CMS proposes a blanket one-star reduction for hospitals in the lowest quartile of Safety of Care measure group performance. Any hospital in the lowest quartile of the Safety of Care measure group scores (based on at least three measure scores) would have its overall star rating reduced by one star to a minimum one-star rating. This would replace the 2026 four-star cap. Using 2024 data, CMS determined that implementing this reduction would result in 459 out of 2,847 hospitals receiving a lower overall star rating.

## Graduate Medical Education Accreditation

To receive direct graduate medical education and indirect medical education payments from Medicare, hospitals must be in "approved medical residency training program." Under 42 CFR 415.152, a graduate medical education program may be an approved medical residency training program if it is accredited by the Accreditation Council on Graduate Medical Education (ACGME).

CMS states that to ensure compliance with federal law, it is proposing that accreditors may not require as part of accreditation, or otherwise encourage institutions to put in place, diversity, equity, and inclusion programs that encourage unlawful discrimination based on race effective January 1, 2026. The proposed rule indicates that CMS may recognize other organizations — presumably other than the ACGME — 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.

## RFI: Deregulation

The proposed rule references Executive Order (EO) 14192, "Unleashing Prosperity Through Deregulation," dated January 31, 2025. Consistent with EO 14192's focus on reducing regulatory compliance costs, the proposed rule requests public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. All comments should be made via CMS' [Medicare Regulatory Relief web page](#).

## RFI: Software as a Service (SaaS)

CMS currently does not have a payment methodology specifically for SaaS and is seeking comments and information on alternative and consistent payment methods for SaaS services to consider for future rulemaking. Specifically, CMS is requesting public comment on the following future SaaS payment ideas:

- *What factors could Medicare consider when setting payment rates for SaaS?*
- *What APCs, existing or new, should we use to pay for SaaS?*
- *How should we assess the costs of SaaS, and how can we account for hospital acquisition costs?*
- *What cost or claims data should be used to establish the payment rates for the services?*

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- *Why are the geometric mean costs, as provided in our claims data, for SaaS currently assigned to APCs (both clinical and New Technology APCs) consistently lower than the manufacturers' purported costs of the technologies?*
  - *Is there an alternative data source outside of the limited Medicare claims data currently available and hospital invoices provided by manufacturers, which may not fully depict total hospital acquisition costs, that can accurately reflect the costs of the SaaS?*
  - *What kinds of efficiencies, if any, would SaaS provide for services performed in hospital outpatient departments and ambulatory surgical centers?*
  - *In the context of setting Medicare payment rates, how can CMS best reflect the quality and efficacy of SaaS technologies?*

## Appendix I – Hospital Outpatient Quality Reporting Program Measures Table

**Table 1: Previously Finalized and Proposed HOQR Program Measure Sets for 2026 to 2031  
Payment Determinations**

CBE	Measure	2026	2027	2028	2029	2030	2031
	<b>Abdomen CT – Use of Contrast Material</b>	X	X	X	X	X	X
	<b>Median Time from ED Arrival to ED Departure for Discharged ED Patients</b>	X	X	X	X	Proposed for Removal	Proposed for Removal
	<b>Left Without Being Seen</b>	X	X	X	X	Proposed for Removal	Proposed for Removal
<b>4625e</b>	<b>Emergency Care Access &amp; Timeliness eCQM</b>				Proposed for Voluntary Reporting	Proposed for Mandatory Reporting	Proposed for Mandatory Reporting
<b>0661</b>	<b>ED- Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival</b>	X	X	X	X	X	X
<b>0658</b>	<b>Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients</b>	X	X	X	X	X	X
	<b>Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery</b>	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary

CBE	Measure	2026	2027	2028	2029	2030	2031
2539	Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X	X
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X	X
2687	Risk-Standardized Hospital Visits 7 Days After Hospital Outpatient Surgery	X	X	X	X	X	X
	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS)	Voluntary	X	X	X	X	X
3636	COVID-19 Vaccination Coverage Health Care Personnel	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Breast Cancer Screening Recall Rates	X	X	X	X	X	X
	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM	X	X	X	X	X	X
3663e	Excessive Radiation eCQM	X	Voluntary	Voluntary	Proposed for Voluntary Reporting	Proposed for Voluntary Reporting	Proposed for Voluntary Reporting
	Risk-Standardized			Voluntary	Voluntary	Voluntary	X

CBE	Measure	2026	2027	2028	2029	2030	2031
	<b>Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO-PM)</b>						
	<b>Hospital Commitment to Health Equity</b>		Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	<b>Screening for Social Drivers of Health (SDOH)</b>		Voluntary /Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	<b>Screen Positive Rate for SDOH</b>		Voluntary /Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
<b>4210</b>	<b>Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery PRO-PM (Information Transfer PRO-PM)</b>			Voluntary	X	X	X