SUMMARY OF PROPOSED RULE – AUGUST 2024

CY 2025 Outpatient Prospective Payment System

Overview

In the July 22 *Federal Register,* 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) 2025. The policy and payment provisions are generally effective for CY 2025 services, beginning January 1, 2025, 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 list and payment for separately payable drugs acquired under the 340B Drug Pricing Program.

The proposed rule also includes provisions for ambulatory surgical centers (ASCs). A detailed summary of those proposals is available here.

To Comment

Comments are due to CMS by Sept. 9 and can be submitted electronically at www.regulations.gov. Search for "CMS-1809–P."

For Additional Information

Questions about this summary should be directed to Megan Howard, vice president federal policy, at (202) 488-3742 or 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.

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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. The rule includes proposed policies that will:

- Increase the market basket by a net 2.6%
- Add three services to the inpatient-only (IPO) list
- Clarify policies for certain remotely furnished outpatient therapy and self-management training services
- Create a separate payment for high-cost radiopharmaceuticals with a per day cost greater than $650
- Exclude qualifying therapies from comprehensive ambulatory payment classification (C-APC) packaging policies
- Narrow the definition of "custody" to reduce the population affected by the Medicare incarceration payment exclusion
- Create new Conditions of Participation for hospitals and critical access hospitals (CAHs) for obstetrical services
- Modify the Overall Hospital Quality Star Rating methodology to increase focus on the Safety of Care measure group
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The proposed rule and other related resources are available on the CMS website.

The increase in OPPS spending due only to proposed changes in the 2025 OPPS rule is estimated to be approximately $1.8 billion. Considering estimated changes in enrollment, utilization, and case mix for 2025, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $88.2 billion, which is approximately $5.4 billion higher than estimated OPPS expenditures in 2024.

CY 2025 OPPS Payment Update

CMS proposes using the most up-to-date claims data and cost report data (one year behind claims data) to set OPPS rates for CY 2025. CMS proposes the use of CY 2023 claims data and CY 2022 Healthcare Cost Report Information System data.

The tables below show the proposed CY 2025 conversion factor compared to final CY 2024 and the components of the update factor:

	Final CY 2024	Final CY 2025	Percent Change
OPPS Conversion Factor	$87.382	$89.379	+2.29%

Proposed CY 2025 Update Factor Component	Value
Market Basket Update	+3.0%
Affordable Care Act (ACA)–Mandated Productivity Adjustment	–0.4 percentage points
Wage Index Budget Neutrality (BN) Adjustment	+0.26%
Wage Index 5% Stop Loss BN	-0.18%
Pass–Through Spending/Outlier BN Adjustment	-0.45%
Cancer Hospital BN Adjustment	+0.06%
Overall Proposed Rate Update	**+2.29%**

CMS estimates the proposed update to the conversion factor net of the total factor productivity (TFP) will increase payments 2.6% in 2025 (market basket of 3.0%, less 0.4% for TFP).

CMS notes the following estimated impacts in Table 131 of the proposed rule:

Facility Type	Estimated 2025 Proposed Impact
All Hospitals	2.4%
Urban – All	2.4%
Urban – Pacific Region	1.4%
Rural – All	2.8%
Rural – Pacific Region	1.1%

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

OPPS CY 2025 Proposed Rule Analysis

CY 2025 Proposed Rule Compared to CY 2024 Final Rule

California

Impact Analysis	Dollar Impact	% Change
Estimated CY 2024 OPPS Payments	*$6,888,380,700*	
Market Basket Update	$159,381,200	2.31%
ACA-Mandated Productivity Adjustment	($21,250,000)	-0.31%
Budget Neutrality Adjustments	($16,719,700)	-0.24%
Wage Index (Removal of Previous Bottom Quartile and Stop Loss (including rural floor))	($313,700)	0.00%
Wage Index (Removal of Previous Rural Floor BN)	$85,644,800	1.24%
Wage Index (Removal of Previous Rural Floor Wage Index)	($377,228,800)	-5.48%
Wage Index (Change due to WI and LS prior to rural floor)	($125,785,800)	-1.83%
Wage Index (Current Rural Floor Wage Index Added)	$331,841,100	4.82%
Wage Index (Current Rural Floor Budget Neutrality Added)	($52,929,300)	-0.77%
Increasing Bottom Quartile Wage Index Values	$0	0.00%
Wage Index 5% Stop Loss	$2,783,400	0.04%
Change in Rural Add-On	$0	0.00%
APC Factor/Updates	$77,189,600	1.12%
Estimated CY 2025 OPPS Payments	*$6,950,993,500*	
Total Estimated Change From CY 2024 to CY 2025	**$62,612,800**	**0.91%**

The values shown in the table above do not include the 2.0% sequestration impact to all lines of Medicare payment authorized by Congress through FFY 2032. It is estimated that sequestration will reduce CY 2025 OPPS-specific payments by: $139,019,900

Source: CHA DataSuite Analysis, July 2024

Updates Affecting OPPS Payments

Recalibration of APC Relative Payment Weights

As required by law, CMS must review and revise the ambulatory payment classification (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 2025 are available in addenda A and B on the CMS website.

The table below shows the shift in the number of APCs per category from CY 2024 to CY 2025 (Addendum A):

APC Category	Status Indicator	Final CY 2024	Proposed CY 2025
Pass-Through Drugs and Biologicals	G	103	91
Pass-Through Device Categories	H	12	14
Non-opioid Medical Devices for Post-Surgical Pain Relief	H1	0	1
OPD Services Paid through a Comprehensive APC	J1	71	71
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	502	466
Non-Opioid Drugs and Biologicals for Post-Surgical Pain Relief	K1	0	2
Partial Hospitalization	P	8	8
Blood and Blood Products	R	40	40
Procedure or Service, No Multiple Reduction	S	81	81
Procedure or Service, Multiple Reduction Applies	T	28	28
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		**986**	**946**

Effective with CY 2025, CMS proposes creating two new status indicator assignments (H1 and K1) to identify HCPCS codes representing non-opioid post-surgical pain management products that qualify for separate payment, as authorized by the Consolidated Appropriations Act (CAA) of 2023.

Blood and Blood Products

For CY 2025, CMS proposes continuing its policy to establish payment rates for blood and blood products using a blood-specific, cost-to-charge ratio methodology.

Brachytherapy Sources

Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS did not propose changes to its brachytherapy policy for 2025.

If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. For 2018 through 2023, CMS used external data to set a payment rate for HCPCS code C2645 (brachytherapy planar source, palladium-103, per square millimeter) at

$4.69 per mm^2. CMS has no claims for HCPCS code C2645 in the 2023 utilization data. For this reason, CMS proposes to use its equitable adjustment authority under section 1833(t)(2)(E) to continue the rate of $4.69 per mm^2 for 2025 for HCPCS code C2645.

Beginning in 2022, CMS adopted a low volume APC policy to use up to four years of claims data for APCs with fewer than 100 single procedure claims that can be used for rate-setting in a year. For these APCs, CMS will determine the relative weight based on the higher of the arithmetic mean cost, median cost, or geometric mean cost. For 2025, CMS proposes to price six low-volume brachytherapy APCs under this policy (excluding those that are priced using external data).

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. CY 2025 is the final year of the current add-on payment for Tc-99m when the Tc-0mm is produced without the use of highly enriched uranium. To eliminate reliance on these foreign reactors, CMS proposes a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting January 1, 2026.

Comprehensive APCs

A C-APC covers payment for all 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 and 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 OPPS, such as:

- Certain mammography and ambulance services
- Brachytherapy sources
- Pass-through drugs and devices
- Charges for self-administered drugs
- Certain preventive services
- Procedures assigned to a New Technology APC either included on a claim with a "J1" or when packaged into payment for comprehensive observation services assigned to status indicator "J2" when included on a claim with a "J2" indicator

CMS proposes excluding specific gene therapies listed in Table 1 of the proposed rule from the C-APC policy for **2025 only**. If HCPCS codes for these cell and gene therapies appear on the same claim as a HCPCS code that is subject to the C-APC policy, CMS proposes to pay separately for the cell and gene therapy and not package payment into the C-APC. CMS' rationale for this proposal is that when these products are administered, they are the primary treatment being

administered to a patient and are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services.

The proposal is for one year only to allow CMS to gather more information from interested parties as to whether this proposed policy appropriately captures all of the unique therapies, such as the cell and gene therapies listed in Table 1, that function as primary treatments and do not support C-APC primary services. CMS will assess whether to continue this policy, or a modified version of this policy, beyond one year in future rulemaking.

CMS also proposes excluding non-opioid treatments for pain relief that meet the criteria for separate payment from C-APCs for three years beginning January 1, 2025, as required by the CAA.

CMS does not propose any new C-APCs for CY 2025. A list of the 72 existing C–APCs for CY 2025 can be found in Table 2 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 for:

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

For CY 2025, CMS proposes continuing 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 proposes 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 also proposes continuing its current composite APC payment policies for multiple imaging services from the same family and on the same date. Table 3 of the proposed rule includes the HCPCS codes that are subject to the multiple imaging procedure composite APC policy and their respective families, as well as each family's geometric mean cost.

Universal Low-Volume APC Payment Policy

For CY 2025, CMS proposes continuing the universal low-volume APC payment methodology for services assigned to new technology, clinical, and brachytherapy APCs with fewer than 100 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.

CMS does not apply this policy to APC 5853 (Partial Hospitalization for CMHCs) or APC 5863 (Partial Hospitalization for Hospital-based PHPs) because of the different nature of policies that affect partial hospitalization programs. CMS also excludes APC 2698 and 2999 for brachytherapy sources "not otherwise specified" from this policy because its methodology for determining non-specified brachytherapy sources is appropriate and uses external data sources.

For 2025, CMS proposes applying this policy to six clinical APCs and five brachytherapy APCs, all of which are low volume in the 2023 utilization used for developing the 2025 OPPS**.** The 11 low volume APCs for CY 2025 may be found in Table 35 in the proposed rule.

Changes to Packaged Items and Services

The proposed rule indicates that section 4135(a) and (b) of CAA of 2023 prohibits packaged payment for non-opioid pain relief treatments effective January 1, 2025, through December 31, 2027. CMS includes proposals to implement this CAA of 2023 provision in the 2025 OPPS rule. CMS expects this policy to operate similarly in the ASC and hospital outpatient department (HOPD) settings.

Proposed New OPPS/ASC Policy for Non-Opioid Drugs, Biologicals and Devices

Sections 4135(a) and (b) of the CAA of 2023 direct CMS to provide separate payment for three years beginning January 1, 2025, for non-opioid treatments for pain relief. A non-opioid treatment is defined as having a "demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal."

CMS proposes only to approve separate payment for drug or biological products with a Food and Drug Administration (FDA)-approved indication that closely aligns with the statutorily required indication language to reduce post-operative pain or produce post-surgical or regional analgesia. CMS lists the products that it expects to meet this criterion in Table 84 of the proposed rule, reproduced here.

Products Qualifying for Separate Payment as Non-Opioid Pain Relief Products

Brand Name	HCPCS Code	Long Descriptor
Exparel	C9290	Injection, bupivacaine liposome, 1mg
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Xaracoll	C9089	Bupivacaine, collagen-matrix implant, 1 mg
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
ON-Q Pump	C98X4	Elastomeric infusion pump, non-opioid pain management delivery system, including catheter and other system component(s)

For a drug or biological that qualifies for separate payment, the statute sets payment at the methodology used under section 1847A (generally, average sale price plus 6%) less the amount included in the OPPS or ASC payment for the product up to 18% of the OPPS or ASC payment.

In implementing this provision, CMS indicates the similarity between the statutory language to allow separate payment for non-opioid pain products and transitional pass-through products. While CMS will apply an offset to the APC for pass-through products paid separately, it will not do so for non-opioid products paid separately as some of these products are new and their costs may not be fully reflected in the data that CMS uses for rate-setting.

CMS proposes to apply the 18% payment limitation per date of service billed, rather than per HCPCS dosage unit. CMS also proposes to create new status indicators for non-opioid drugs and devices to implement this payment limitation. Under the OPPS, non-opioid drugs and biologicals under this policy would be assigned a status indicator of K1, while non-opioid devices would be assigned a status indicator of H1.

Wage Index Changes

CMS proposes continuing using a labor share of 60% and the fiscal year inpatient prospective payment system (IPPS) post-reclassified wage index for the OPPS in CY 2025. CMS proposes a wage index and labor-related share budget neutrality factor of 1.0026 for CY 2025 to ensure that aggregate payments made under the OPPS are not greater or less than would otherwise be made if wage index adjustments had not changed.

The proposed rule directs readers to the IPPS rule for more details regarding specific policies affecting the proposed 2025 wage index, including revisions to core-based statistical areas (CBSA) that serve as the labor market areas for determining the area wage index under both the IPPS and the OPPS.

CMS applies a 5% cap on any decrease of the hospital wage index, compared with 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 CY. CMS also proposes a budget neutrality factor of 0.9982 for the impact of the 5% cap on wage index decreases.

For non-IPPS hospitals paid under the OPPS for CY 2025, CMS proposes continuing its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment.

To address wage index disparities between high- and low-wage index hospitals (a.k.a. "bottom quartile policy"), in the federal fiscal year (FFY) 2020 IPPS final rule, CMS made a variety of changes that would affect the wage index and related policies. CMS will continue increasing the wage index for hospitals within the bottom quartile of the nation 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 is offsetting these increases by applying a budget neutrality adjustment to the national standardized amount. In the FFY 2025 IPPS proposed rule, the value of the 25th percentile wage index is 0.8879.

CMS notes that this policy is subject to pending 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. This court decision involves only FFY 2020, is not final, and has been appealed by CMS. For additional details on the bottom quartile please see CHA's summary of the FFY 2025 IPPS proposed rule.

Sole Community Hospital Adjustment

For CY 2025, CMS proposes continuing the 7.1% payment adjustment for rural sole community hospitals (SCHs) — including essential access community hospitals — for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Cancer Hospital Adjustment

CMS proposes to continue increasing payment to the 11 exempt cancer hospitals. CMS does this by providing a payment adjustment so that the exempt cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals (and thus the adjustment is budget neutral). CMS estimates a PCR of 0.87 (or 87%) for non-cancer hospitals. After reducing this PCR by 1 percentage point, the target PCR would be 0.86 (or 86%).

For 2024, the target PCR was appreciably lower than it had been since CMS began applying this methodology in 2012. CMS' concern was that the lower PCR reflected an aberration due to the COVID-19 public health emergency, rather than an ongoing trend. As a result, CMS adopted a policy to limit the reduction in the target PCR to 1 percentage point annually. As the 2024 target PCR including the 1 percentage point limit on the reduction was 0.88 and the otherwise applicable proposed 2025 PCR without a limit would be 0.86, CMS is proposing a target PCR of 0.87 that reflects a cap on the reduction of 0.01.

Table 8 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2025 ranging from 16% to 56.3%. CMS indicates that the reduction in the cancer hospital adjustment requires a budget neutrality adjustment of +0.06%.

Outpatient Outlier Payments

To maintain total outlier payments at 1% of total OPPS payments, CMS proposes using CY 2023 claims to calculate a CY 2025 outlier fixed-dollar threshold of $8,000, a 3.2% increase over the current threshold of $7,750. Outlier payments will 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.

New Technology APCs

Currently, there are 52 levels of New Technology APC groups with two parallel status indicators: one set with a status indicator of "S" (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of "T" (T = Significant procedure, multiple reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 [New

Technology – Level 1A ($0 - $10)] through the highest cost band assigned to APC 1908 [New Technology – Level 52 ($145,001 - $160,000)]. The proposed payment rates for these New Technology APCs are included in Addendum A to the proposed rule.

Establishing Payment Rates for Low-Volume New Technology Procedures

For 2025, CMS proposes to exempt services assigned to New Technology APCs with fewer than 10 claims in the four-year lookback period from the low-volume APC policy. To improve payment stability, CMS proposes to maintain the existing New Technology APC assignment when a new service has fewer than 10 claims in the four-year lookback period, rather than establish a New Technology APC based on the higher of the geometric mean, median, or arithmetic mean costs.

Pass-Through Payments for Devices

Currently, 15 device categories are eligible for pass-through payment. Table 42 of the proposed rule (reproduced below) lists the devices and their pass-through expiration.

Table 42: Devices with Pass-Through Status Expiring in 2024, 2025 or 2026

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1831	Personalized, anterior, and lateral interbody cage (implantable)	10/01/2021	09/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	01/01/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	01/01/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	01/01/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	01/01/2023	12/31/2025
C1747	Endoscope, single-use (i.e., disposable), urinary tract, imaging/illumination device (insertable)	01/01/2023	12/31/2025
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (i.e., disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (i.e., disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027

New Device Pass-Through Applications

CMS has received 14 applications for device pass–through payment applications since the March 1, 2024, quarterly deadline. CMS approved the following applications:

1. The DETOUR™ System: Preliminarily approved upon quarterly review under the alternative pathway, effective January 1, 2024.
2. AVEIR™ DR Dual Chamber Leadless Pacemaker System: Preliminarily approved upon quarterly review under the alternative pathway, effective July 1, 2024.
3. EndoSound Vision System® (EVS). Preliminarily approved upon quarterly review under the alternative pathway effective July 1, 2024.

Device-Intensive Procedures

Device-intensive APCs are 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.

As outpatient providers perform new procedures with significant device costs, CMS believes it appropriate to propose a modification to the default device offset percentage policy for new device-intensive procedures. Effective CY 2025, for new HCPCS codes for procedures that require the implantation/insertion of a single-use device meeting CMS' device-intensive requirements, if the procedure lacks claims data, CMS would apply a default device offset percentage of either 31% or the device offset percentage of the APC to which the procedure has been assigned, whichever is greater. Procedures to which this policy would apply are in Addendum P of this proposed rule.

Device Edit Policy

CMS will continue requiring claim processing edits when any of the device codes used in the previous device-to-procedure edits are present on the claim with a device-intensive procedure that includes the implantation of a device. CMS previously created HCPCS code C1889 (implantable/insertable device, not otherwise classified) to recognize devices used during device–intensive procedures that are not described by specific Level II HCPCS Category C-Code. This HCPCS code satisfies the edit requirement.

CMS believes that procedures associated with APC 5496 (Level 6 Intraocular Procedures) would continue to benefit from a procedure-to-device edit because payment stability for this Low Volume APC relies on accurate reporting of the procedure's associated costs. Therefore, CMS proposes a procedure-to-device edit for the following procedures assigned to APC 5496:

- CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis)
- CPT code 6X004 (Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed)

Hospitals would be required to report the correct device HCPCS codes when reporting any of the above procedures.

Adjustment to OPPS 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 received 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 would 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 temporary).
- The procedure must be device-intensive (devices exceeding 30% of the procedure's average costs).

For CY 2025, CMS does not propose any major changes to the no-cost/full credit and partial credit device policies.

Payment Changes 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 grant a pass-through period as close to three full years as possible, and to eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

For CY 2025, CMS proposes a packaging threshold of $140 (or $630 for diagnostic radiopharmaceuticals). Drugs, biologicals, and radiopharmaceuticals that are above the $140 threshold (or $630 for diagnostic radiopharmaceuticals) are paid separately, using individual APCs; those below the threshold are packaged using the baseline payment rate for CY 2025 of ASP+6%.

CMS will continue paying for separately payable drugs and biological products that do not have pass-through status at wholesale acquisition cost (WAC)+3%, instead of WAC+6%.

For 2025, CMS proposes to continue its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 65 of the proposed rule.

For CY 2025 and subsequent years, for those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals that are impacted by the updated drug packaging threshold, CMS proposes:

- *"HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would continue to receive separate payment in CY 2025.*

- *HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would remain packaged in CY 2025.*
    - *HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would receive separate payment in CY 2025."*

For CY 2025, CMS proposes a clarification that only ASP data or, if ASP is unavailable, mean unit cost (MUC) data would be used to set payment rates under the OPPS for non-pass-through therapeutic radiopharmaceuticals that are separately payable. For CY 2025, this results in CMS proposing the use of MUC data for said radiopharmaceuticals that are proposed to be separately payable due to their cost exceeding the per-day threshold.

As there are often HCPCS codes for new drugs or biologicals that have received marketing approval, but for which there is no sales data available, the affected drugs and biologicals are assigned a non-payable indicator. However, for CY 2026, for separately payable drugs and biologicals for which CMS does not provide a payment rate, CMS proposes Medicare administrative contractors (MACs) would calculate the payment based on provider invoices (net acquisition cost, less any rebates, chargebacks, or post-sale concessions). MACs would 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.

Lastly, CMS states that the pass–through status will expire by December 31, 2024, for 25 drugs and biologicals, listed in Table 62; and by December 31, 2025, for 28 drugs and biologicals listed in Table 63. The agency proposes to continue/establish pass–through status in CY 2025 for 57 drugs and biologicals shown in Table 64.

OPPS Payment Methodology for 340B-Purchased Drugs

CMS will continue paying for drugs acquired through the 340B program at ASP+6% in CY 2025. If ASP data are not available, payment instead would be made based on WAC+3%; or 95% of average wholesale price (AWP) if WAC data are also not available.

High/Low-Cost Threshold for Packaged Skin Substitutes

For 2025, CMS proposes to determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric MUC exceeding the threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the MUC, divided by the total number of days) exceeding its threshold. CMS proposes using 2023 claims data for this purpose.

The proposed 2025 MUC threshold is $50 per cm^2 rounded to the nearest $1, and the proposed 2025 PDC threshold is $840 rounded to the nearest $1. CMS proposes to assign a skin substitute with a MUC or a PDC that exceeds either threshold to the high-cost group. If the product is assigned to the high-cost group in 2024, CMS proposes to continue assigning it to the high-cost group in 2025. Otherwise, CMS proposes assigning the skin substitute to the low-cost group.

Table 67 of the proposed rule lists the high/low-cost group assignment for each skin substitute.

Hospital Outpatient Visits

CMS expanded the Medicare Physician Fee Schedule (MPFS) payment methodology to excepted off–campus provider-based departments (PBDs) for HCPCS code G0463 in the CY 2019 final rule. As of CY 2024, this policy has the following additional exemptions:

- Excepted off-campus PBDs belonging to rural SCHs
- Application of the community mental health center (CMHC) per-diem rates for hospital partial hospitalization program (PHP) and intensive outpatient (IOP) services provided at an off-campus PBD, instead of the MPFS rate for that service
- Payment made for intensive cardiac rehabilitation (ICR) services

For CY 2025, CMS proposes to continue these exemptions. Excepted off-campus PBDs of rural SCHs would continue to bill HCPCS code G0463 with modifier "PO," but CMS would pay these hospitals the full OPPS payment rate.

For all other excepted off-campus PBDs, CMS proposes to continue to pay 40% of the OPPS rate for basic clinic services in CY 2025. These excepted PBDs continue to bill HCPCS code G0463 with modifier "PO."

Inpatient-Only List

The IPO list specifies services/procedures that Medicare will pay for only when provided in an inpatient setting. For CY 2025, CMS does not propose removing any procedures from the IPO list. Further, in the rule CMS proposes adding the following services to the IPO list:

- 0894T - Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion
- 0895T - Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial four hours of monitoring time, including hourly physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)
- 0896T - Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)

The full list of procedures on the IPO list is available in Addendum E of the propose rule.

Partial Hospitalization Program and Intensive Outpatient Services

PHPs are IOP psychiatric programs that provide outpatient services in place 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 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 (FQHC), or a rural health clinic (RHC).

The table below compares the final CY 2024 and proposed CY 2025 PHP and IOP payment rates as found in Addendum A:

	Final Payment Rate 2024	Proposed Payment Rate 2025	% Change
APC 5851: Intensive Outpatient (3+ services) for CMHCs	$87.66	$114.79	+30.95%
APC 5852: Intensive Outpatient (4+ services) for CMHCs	$157.58	$159.43	+1.17%
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$87.66	$114.79	+30.95%
APC 5854: Partial Hospitalization (4+ services) for CMHCs	$157.58	$159.43	+1.17%
APC 5861: Intensive Outpatient (3+ services) for Hospital–based IOPs	$259.40	$270.77	+4.38%
APC 5862: Intensive Outpatient (4+ services) for Hospital–based IOPs	$358.21	$414.33	+15.67%
APC 5863: Partial Hospitalization (3+ services) for Hospital–based PHPs	$259.40	$270.77	+4.38%
APC 5864: Partial Hospitalization (4+ services) for Hospital–based PHPs	$358.21	$414.33	+15.67%

CMS proposes continuing 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 will apply an 8% outlier payment cap to the CMHC's total per diem payments. CMS will also expand the calculation of the CMHC outlier percentage to include PHP and IOP.

Coverage Changes for Colorectal Cancer Screening Services

Currently, the following tests and procedures for early detection of colorectal cancer are covered by Medicare:

- Screening fecal-occult blood tests
- Screening flexible sigmoidoscopies
- Screening colonoscopies, including anesthesia furnished in conjunction with the service
- Screening barium enemas
- Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations

For CY 2025, CMS proposes the following changes to colorectal cancer screening coverage:

- Remove coverage for the barium enema procedure
- Add coverage for the computed tomography colonography procedure (reassignment to status indicator 'S')

- Expand the existing definition of a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker colorectal cancer screening test
- Delete HCPCS codes G0106 and G0120 (screening barium enema)
- Reassign CPT code 74263 (screening computed tomography colonography/virtual coloscopy) to APC 5522 (Level 2 Imaging Without Contrast)

Table 70 contains the proposed list of covered colorectal cancer screening HCPCS codes.

Remote Services

Periodic In-Person Visits for Mental Health Visits Furnished by Hospital Staff to Beneficiaries in their Homes

In the CY 2023 OPPS final rule, CMS established three HCPCS C-codes for mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. Consistent with statutory requirements that apply to the Medicare telehealth benefit under the PFS, CMS requires an in-person visit within six months prior to or after the remote mental health service. The visit after the first encounter must occur within 12 months.

The CAA of 2023 delayed the application of the telehealth in-person visit requirements through December 31, 2024, for professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. CMS adopted the same delay for remote outpatient mental health services provided by hospitals and CAHs through December 31, 2024. Absent additional congressional action, this delay will expire on December 31, 2024, and the in-person requirements will be in effect beginning January 1, 2025. However, CMS notes that if Congress extends Medicare telehealth flexibilities beyond December 31, 2024, it intends to align policies that apply to hospital-based remote services through additional rulemaking.

Outpatient Therapy, Diabetes Self-Management Training, and Medical Nutrition Therapy

During the COVID-19 public health emergency, CMS allowed outpatient therapy services, diabetes self-management training (DSMT), and medical nutrition therapy (MNT) to be furnished by hospital-employed staff to patients in their homes through the use of real-time interactive telecommunications technology. CMS also added outpatient therapy, DSMT, and MNT to the list of telehealth services that could be paid under the PFS when provided by an eligible practitioner or supplier. In addition, physical and occupational therapists and speech language pathologists were temporarily designated as "eligible telehealth distant site practitioners" under the PFS via COVID-19 waivers. CMS extended these flexibilities beyond the public health emergency through December 31, 2024, under the CAA of 2023.

The telehealth waivers are slated to expire on December 31, 2024. At that time, the flexibilities for hospital-employed therapists and staff furnishing DSMT and MNT to patients in their homes will expire as well. If Congress extends telehealth waivers in future legislation, CMS expects to align payment policies for outpatient therapy, DSMT, and MNT services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services.

Proposed HOPD Payment for Telemedicine Evaluation and Management (E/M) Services

The CPT Editorial Panel created 17 new codes describing audio/video and audio-only telemedicine E/M services that are discussed in more detail in the 2025 PFS proposed rule. CMS

proposes not to pay for these codes under the PFS because it believes they would be duplicative of office E/M codes already paid under section 1834(m) of the Social Security Act telehealth benefit. Under the OPPS, CMS does not recognize the CPT E/M codes and instead uses HCPCS G0463 for all clinic visits. CMS believes the telemedicine E/M codes fall within the scope of the hospital outpatient clinic visit policy because they substitute for the office/outpatient E/M code set that would be reported by hospitals using HCPCS code G0463. Therefore, CMS proposes not to recognize the telemedicine E/M code set under OPPS.

However, CMS seeks comment on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for HCPCS code G0463. CMS may consider developing separate coding for resource costs that would be associated with those services, if it finalizes separate payment for these telemedicine E/M codes under the PFS.

Virtual Supervision of Cardiac and Pulmonary Rehabilitation Services

Under current OPPS policy, cardiac (CR), intensive cardiac (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 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.

CMS proposes to extend this flexibility and would allow direct supervision of CR, ICR, and PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) under the OPPS through December 31, 2025. In the CY 2025 PFS proposed rule, CMS similarly proposes to align this policy to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025.

Payment for Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments

On July 12, 2023, CMS proposed to cover PrEP to prevent HIV under Medicare Part B. This coverage, if adopted, would include HIV PrEP drugs, drug administration, HIV and hepatitis B screening, and individual counseling by either physicians or other health care practitioners. All components would be covered as an added preventative service without deductibles or co-pays. The final National Coverage Determination (NCD) has yet to be issued since the release of this proposal. The proposed HCPCS codes for these services may be found in Table 72 (below).

HCPCS	Long Descriptor
J0739	Injection, cabotegravir, 1mg, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV)
J0750	Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV)
J0751	Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV)

G0011	Individual counseling for pre-exposure prophylaxis (by physician or qualified health care professional (QHP)to prevent human immunodeficiency virus (HIV), includes HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes
G0012	Injection of pre-exposure prophylaxis drug for HIV prevention, under skin or into muscle
G0013	Individual counseling for pre-exposure prophylaxis by clinical staff to prevent HIV, includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence
J0799	FDA approved prescription drug, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV), not otherwise classified

For CY 2025, CMS proposes to pay for HIV PrEP drugs and services as additional preventive services under OPPS, if covered in the final NCD. Services listed in Table 72 that are furnished in HOPDs are proposed to be paid in a similar manner as if they were furnished in a physician office.

Drug products would be assigned to Status Indicator K and be priced using either the earlier proposed invoice pricing or the ASP/WAC methodology. If ASP data is unavailable, then CMS proposes to determine the payment amount using the most recently published value in the Medicaid National Average Drug Acquisition Cost (NADAC) survey, or the Federal Supply Schedule (FSS) if NADAC data is unavailable. In the case of drugs that are newly FDA-approved for HIV PrEP, CMS proposes to require that hospitals billing for the drug report the NDC for the product along with newly created HCPCS code J0799 to suspend the claim for manual pricing by the MAC. The claim would then be priced at 95% of the drug or biological's AWP.

Finally, CMS also proposes to assign all HCPCS codes describing pharmacy supplying fees for HIV PrEP, if covered as an additional preventive service, a status indicator of 'B' (code not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x); Not paid under OPPS).

Payment Policy for Devices in Category B Investigational Device Exemption Clinical Trials Policy and Drugs/Devices with a Medicare Coverage with Evidence Development Designation

Current CMS policy allows for a single blended payment for devices and services in Category B investigational device exemption (IDE) studies. This is done to preserve the scientific validity of these studies by avoiding differences in Medicare payment methods by blending payment made for both the treatment and control arms of the study.

For CY 2025, CMS proposes to use a payment methodology like the one developed for Category B IDE clinical trials for drugs and devices covered under a NCD that uses the coverage with evidence development (CED) paradigm. A payment adjustment is necessary to preserve the validity of such a study. This blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control. Payments for drug studies would be based on the ASP+6% payment methodology, or WAC+3% if the ASP is unavailable during an initial sales period, or WAC+6% otherwise. If the WAC is also unavailable, CMS would base payments on 95% of AWP, consistent with CMS payment for non-pass-through separately payable drugs under OPPS.

Medicaid Clinic Services Four Walls Exception

States may offer certain Medicaid benefits, including clinic services, to categorically needy and medically needy Medicaid beneficiaries. Federal Medicaid law prevents states from covering clinic care provided outside of the four walls of a clinic under Medicaid, barring an explicit exception.

To address concerns that CMS has heard from multiple parties and to help states in strengthening and improving access to clinic services, CMS proposes adding three exceptions to the four walls requirement:

- Clinic services furnished by Indian Health Service/Tribal clinics
  - Mandatory exception
  - Facilities operated by urban Indian organizations would be excluded.
- Clinic services furnished by a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use
  - Optional exception by state
- Clinic services furnished by a clinic located in a rural area
  - Excludes RHCs
  - Optional exception by state
  - CMS invites comments on what definition of rural to use for this exception.

Changes to the Review Time Frames for the Hospital Outpatient Department Prior Authorization Process

As part of the CY 2020 OPPS final rule, CMS established a nationwide prior authorization process and requirements for certain hospital outpatient department (HOPD) services. CMS currently requires prior authorization for:

- Blepharoplasty
- Rhinoplasty
- Botulinum toxin injections
- Panniculectomy
- Vein ablation
- Cervical fusion with disc removal
- Implanted spinal neurostimulators
- Facet joint intervention

Upon receipt of the prior authorization request, the MAC issues a decision within specific time frames. CMS proposes changing the current review time frame for provisionally affirmed or non-affirmed standard review requests from 10 business days to seven calendar days, so it aligns with the recently finalized CMS Interoperability and Prior Authorization rule, which applies to Medicare Advantage organizations and applicable integrated plans, Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, and CHIP managed care entities.

CMS is still considering the impact of aligning the expedited review decision time frame with the expedited review decision time frame in the CMS Interoperability and Prior Authorization final rule because, depending on when the expedited request is submitted, it may take longer for an HOPD provider to receive a decision using the 72-hour time frame than the current expedited time frame of two business days.

Provisions Related to Medicaid and the Children's Health Insurance Program

CMS proposes updating the Medicaid regulations to conform with changes to the continuous eligibility (CE) policy implemented by the CAA of 2023. These changes specify that a state must provide CE for the specified period and removes the option to limit CE to those younger than 19 years of age. Furthermore, CMS proposes removing the option to limit CE to a period of fewer than 12 months, as well as the option of ending a CE period for a person when they reach the state-specified maximum age.

CMS also proposes removing the option for states to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a CE period.

Individuals Currently or Formerly in the Custody of Penal Authorities

Currently, Medicare is prohibited from covering any Part A or Part B expenses incurred for items and services furnished to an individual for which that individual or other person has no legal obligation to pay, except for FQHC services. This includes services furnished to individuals in custody of penal authorities.

Currently, individuals who are in custody include, but are not limited to, "individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule."

CMS believes that certain classes of individuals should no longer be presumed to be in custody for the purposes of the "no legal obligation to pay" exclusion. Thus, CMS proposes updating the definition of "custody" as follows:

- Remove individuals who are under supervised release or required to live under home detention
- Remove the phrase "or confined completely or partially in any way under a penal statute or rule"

CMS also proposes that the rebuttal presumption that may be made if "State or local law requires those individuals or groups of individuals to repay the cost of medical services they receive while in custody" would apply to all items and services furnished to individuals in custody, regardless of by whom they are provided.

Individuals required to live in a mental health facility are proposed to be clarified as only being in custody for purposes of the exclusion if required to live there under a penal statute or rule. CMS is also proposing to define "penal authority" as "a police department or other law enforcement agency, a government agency operating under a penal statute, or a State, local or Federal jail, prison, penitentiary, or similar institution" for the purposes of the no legal obligation to pay exclusion.

Lastly, CMS proposes updating the special enrollment period eligibility criteria to account for the proposals discussed earlier and to align the criteria with the criteria used by the Social Security Administration to determine whether an individual is incarcerated. CMS proposes that an

individual who is released from a jail, prison, or other penal institution or correctional facility on or after January 1, 2025, would be eligible.

Payment Adjustments for Domestic Manufactured Personal Protective Equipment

The 2023 OPPS/ASC final rule implemented payment adjustments under the OPPS and IPPS to offset the marginal costs hospitals face in obtaining domestically made National Institute for Occupational Safety and Health (NIOSH)-approved and FDA-certified surgical N95 respirators. However, use of the payment adjustments has been limited (cost reporting periods beginning on or after January 1, 2023). Market data suggest that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made. HHS has conducted stakeholder outreach to understand barriers to awareness and uptake and to seek feedback on potential modifications to the payment adjustment to reduce reporting burden and achieve the policy goal of maintaining a baseline domestic production capacity of personal protective equipment (PPE).

Related to domestically produced PPE, CMS includes questions in the proposed rule for which it seeks comment. These questions are included in Appendix I and address three issue areas: payment adjustment methodology, payment adjustment eligibility, and types of N95 respirators.

Additionally, CMS expresses concern in the rule about the availability of domestically produced nitrile gloves and poses questions related to including them in the add-on payment for domestically produced PPE. These questions are summarized in Appendix 2.

Finally, in the 2023 OPPS/ASC final rule, CMS received many comments urging an expansion of the policy to cover other forms of PPE and critical medical supplies due to shortages similar to that of surgical N95 respirators. **CMS seeks comment on other PPE types and medical devices that could be appropriate for a similar payment adjustment.**

Cross-Program Quality Measure Proposals

CMS proposes the adoption of three health equity 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 also proposes to modify its policies for measures that raise patient safety concerns by imposing an immediate measure suspension policy.

Hospital or Facility Commitment to Health Equity Measure

CMS proposes to add 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. The HCHE measure is currently included in the Hospital IQR and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) programs and the FCHE measure is included in the inpatient psychiatric facility QRP and end-stage renal disease quality incentive program.

The HCHE and FCHE measures require a hospital or facility to attest to its commitment to health equity across five domains (equity in a strategic priority, data collection, data analysis, quality

improvement, and leadership engagement). Some domains have multiple elements. A point is awarded for each domain to which the hospital or facility attests affirmatively. For a hospital or facility to attest "yes" to a domain and receive credit for that domain, the hospital or facility will evaluate and determine whether it engages in each of the elements that comprise that domain. Tables 86 and 87 of the proposed rule offer a complete list of domains and elements for both measures.

While the two measures consist of the same five domains, their measure specifications differ in two ways:

- The HCHE measure specifications reference hospitals and the FCHE measure specifications reference facilities.
- Domain 2C of the HCHE measure requires hospitals to use certified electronic health record (EHR) technology (CEHRT) to attest "yes," while domain 2C of the FCHE measure requires facilities to use EHR technology to attest "yes," but does not require the EHR technology to be CEHRT.

The measure is calculated as:

- Numerator: Total number of domains for which the hospital or facility attests affirmatively ("yes"), meaning attests "yes" to all of the required elements of the domain. The hospital or facility would receive one point for each domain for which it attests affirmatively. If the hospital or facility is not able to attest "yes" for each element of a domain, it would receive zero points for that domain.
- Denominator: Five points (one for each domain available for attestation)
- Data Submission Requirements: Hospitals and ASCs would submit their attestation responses on these measures in the Hospital OQR, REHQR, and ASCQR programs, as applicable, by an annual deadline using the CMS-designated information system, which is currently the Hospital Quality Reporting (HQR) system.

Screening for Social Drivers of Health Measure

CMS proposes to adopt the Screening for Social Drivers of Health (SDOH) measure for the OQR, ASCQR, and REHQR programs beginning with a voluntary reporting period in 2025 and mandatory reporting in 2026. This measure has been adopted in other quality reporting programs, including the hospital IQR program, where mandatory reporting began in 2024.

The Screening for SDOH measure is a process measure that assesses the total number of patients (18 years of age or older on the date of service) screened for five health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. The measure is calculated as a percentage equal to the numerator over the denominator as follows:

- Numerator: Number of patients (18 or older) admitted to an HOPD, REH, or ASC who are screened during their receipt of services at the hospital or facility for all of the five HRSNs
- Denominator: Number of patients admitted to an HOPD, REH, or ASC, as applicable, who are 18 years or older
    - Exclusions: Patients who opt out of screening and patients who are unable to complete the screening themselves and lack a guardian or caregiver available to do so on the patient's behalf

- Data Sources, Submission and Reporting: CMS proposes that hospitals and other facilities use a self-selected screening tool to collect data on the measure. It points to the AHC HRSN Screening Tool as an example, as well as the Social Interventions Research and Evaluation Network (SIREN) website for information on HRSN screening tools. CMS proposes voluntary reporting of the measure during the 2025 reporting period, and would then require reporting beginning with the 2026 reporting period/2028 payment or program determination. Hospitals and other facilities would not be required to submit patient-level data but would instead aggregate data they collect for the numerator and denominator. Hospitals and other facilities would submit data on the measure annually using the CMS-designated information system, which is currently the HQR system.

CMS notes that it considered allowing hospitals to report the measure one time each year jointly for both the hospital IQR and OQR programs. However, CMS notes that because patient populations for each program are different, making the denominator different for each, and because separate Care Compare tool data for inpatient and outpatient departments could be useful for patients, it is proposing separate data submission for each of the hospital IQR and OQR programs. CMS does propose that HOPDs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, instead of rescreening a patient within the reporting period. If the information is in the EHR in another health setting during the same reporting period, CMS proposes that the HOPD could use that information to report the measure instead of screening the patient.

Screen Positive Rate for SDOH Measure

The Screen Positive Rate for SDOH process measure is a companion measure to the Screening for SDOH measure. While the Screening for SDOH measure enables identification of individuals with HRSNs, the Screen Positive Rate for SDOH measure captures the extent of such needs and estimates the impact of individual-level HRSNs on health care utilization. Like the Screening for SDOH measure, CMS proposes to adopt this measure for the OQR, ASCQR, and REHQR programs beginning with a voluntary reporting period in 2025 and mandatory reporting in 2026.

The Screen Positive Rate for SDOH provides information on the percent of patients, 18 or older on the date of receipt of services at the HOPD, REH, or ASC, who were screened for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) and who screened positive for at least one of the five HRSNs. Hospitals and facilities would report the measure as five separate rates, one for each screening domain, calculated as screen-positive patients divided by screened patients.

- Numerator: For each HRSN, the number of patients receiving care at the HOPD, REH, or ASC (18 years or older on date of admission) who were screened for all five HRSNs and who screen positive for having a need in one or more of the HRSNs (calculated separately for each of the five HRSNs). A patient who screens positive for more than one HRSN would be included in the numerator for each of such HRSNs.
- Denominator: For each HRSN, the number of patients receiving care at the respective hospital or facility who are 18 years or older on date of admission and are screened for all five HRSNs during their care.
- Data Collection, Submission, and Reporting: CMS proposes the same data sources for this measure as described for the Screening for SDOH measure. Even though hospitals and facilities would collect the patient-level data on their patients (enabling the hospitals and

facilities to address social needs among their patient populations) for reporting purposes, CMS proposes that hospitals and facilities would submit aggregated data representing the total numerator results for each of the five screening areas and the total number of patients screened for all five of the HRSNs. Information would be submitted through a CMS-designated information system, which is currently the HQR system.

Immediate Measure Removal Policy Beginning with 2025

Under both the Hospital OQR and ASCQR programs, a measure may be immediately removed based on evidence that the continued use of the measure raises patient safety concerns. In contrast, the REHQR program uses an immediate measure suspension policy under which CMS suspends a measure's use in the program until potential removal of the measure is considered under standard rulemaking if the agency believes the measure raises patient safety concerns. CMS proposes to replace the hospital OQR and ASCQR programs' removal policies with an immediate measure suspension policy in cases where the measure potentially raises patient safety concerns. Specifically, in cases in which CMS determines there is evidence that the collection and reporting activities related to a quality measure raises patient safety concerns, the agency would suspend the measure from the applicable program until the potential measure removal could be considered through the next feasible rulemaking cycle. CMS would notify HOPDs or ASCs and the public of any suspension through standard communication channels.

Hospital OQR Program

The hospital OQR program is mandated by law; hospitals that do not successfully participate are subject to a 2 percentage point reduction to the OPPS market basket update for the applicable year. CMS posts the list of individual hospitals meeting or failing to meet OQR reporting requirements.

CMS proposes several changes to the OQR measures set, including the adoption of the three health equity measures described above, the adoption of a new patient reported outcome-based measure (Pro-PM), and the removal of two measures. CMS also proposes policies related to EHR certification of electronic clinical quality measures (eCQMs) and data made available on Care Compare.

CMS makes no changes to previously finalized OQR Program policies for:

- Measure selection, retention, and removal, except for the immediate suspension policy described above
- 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)
- eCQMs
- Population and sampling requirements
- The educational review and correction process for chart-abstracted measures
- Reconsideration and appeals procedures
- 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 adopted OQR program measures for payment determinations from 2022 through 2028.

Proposed New Measures

Proposed Health Equity Measures

As discussed in detail above, CMS proposes to add three health equity measures to the OQR program: the HCHE measure, the Screening for SDOH measure, and the Screen Positive Rate for SDOH measure.

Proposed Information Transfer Pro-PM

CMS proposes to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure (Information Transfer Pro-PM) beginning with voluntary reporting for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

The Information Transfer PRO-PM assesses the level of clear, personalized recovery information provided to patients 18 years of age or older who had surgery or a procedure in an HOPD. The measure reports the average score of a patient's survey, which consists of three domains and nine corresponding items for patients and their caregivers to rate the clarity of information received about their post-discharge recovery. The three domains are:

- Applicability to patient needs – Assesses whether recovery information considered a patient's health needs and personal circumstances
- Medication – Examines the clarity of medication information provided (guidance on taking new medications, potential side effects, and discontinuing medication)
- Daily Activities – Assesses the clarity of guidelines provided around diet, physical activity, returning to work, and driving.

The measure would be calculated as follows:

- Numerator: The sum of all individual scores an HOPD receives from eligible respondents (patients or caregivers)
    - An individual score is calculated for each respondent as dividing (i) the sum of items for which the respondent gave the most positive response available ("Yes" or "Very Clear"); by (ii) the number of items applicable to the procedure (determined by subtracting the number of items for which the respondent said "Does not apply" from the total possible (9) items).
- Denominator: Total number of patients 18 years of age or older who had a procedure or surgery in an HOPD, left the HOPD alive, and fully completed the survey.
- Data Sources, Collection, Submission and Reporting: The Information Transfer PRO-PM would be a voluntary measure for the 2026 reporting period followed by mandatory reporting beginning with the 2027 reporting period/2029 payment determination. The measure would be calculated based on PRO data collected by HOPDs directly or through third-party vendors through a web-based survey instrument distributed to patients or their caregivers. CMS proposes that the survey be administered two to seven days after the procedure or surgery and for there to be a 65-day window for patient response.

  The performance period (i.e., reporting period) would be the period beginning January 1

and ending December 31 of the year that is two years before the payment determination (i.e., 2027 reporting period for the 2029 payment determination). The submission period would begin on January 1 and end on May 15 of the year before the payment determination year (i.e., January 1-May 15, 2028, for the 2029 payment determination). There would be a minimum random sample size of 300 completed surveys. HOPDs that do not collect the minimum would not perform random sampling and would be required to submit data from all completed surveys.

Proposed Removal of Measures

CMS proposes to remove two measures beginning with the CY 2025 reporting period/CY 2027 payment determination:

- MRI Lumbar Spine for Low Back Pain Measure: CMS says that its analysis of measure data has shown that that national performance on the measure has remained stable with low average volumes. The agency discusses studies showing the measure may not have any correlation with improving the appropriate use of imaging. CMS proposes to remove the measure because these results indicate continued use of the measure provides limited ability to improve the quality of care for patients.
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure: CMS proposes to remove the measure because its analysis has shown limitations for interpreting the performance trends because of the range of cases, that the measure may not be providing meaningful data, and there is not room for any significant improvement in national performance in the measure.

EHR Certification Requirements for eCQMs

The hospital IQR program and Medicare Promoting Interoperability Program require EHRs to be certified to all available eCQMs in the measure set of the respective program to ensure that the technology is up to date and tested on each eCQM. For HOPDs using EHR technology certified to the ONC health IT certification criteria, CMS proposes — beginning with the 2025 reporting period/2027 payment determination — to require that the technology is certified to all eCQMs that are available to report under the Hospital OQR program. CMS also proposes that HOPDs would be required to use the most recent version of the eCQM electronic measure specifications for the reporting period available on the Electronic Clinical Quality Improvement Resource Center website.

Public Reporting of Measure Data

The Median Time from ED Arrival to ED Departure for Discharged ED Patients measure is a chart-abstracted measure included in the current measure set that evaluates time from emergency department (ED) arrival to departure. The measure's data are stratified into four calculations: (i) median time for discharged ED patients—overall rate, (ii) median time for discharged ED patients—reporting measure (which excludes psychiatric/mental health and transfer patients), (iii) median time for discharged ED patients—psychiatric/mental health patients only, and (iv) median time for discharged ED patients—transfer patients only. In the CY 2024 OPPS final rule, CMS finalized that data on three of those strata (other than the psychiatric/mental health patients only strata) would be publicly reported on Care Compare (or a subsequent CMS-designated website). CMS now believes ED throughput time for this group of patients could benefit from additional improvement efforts, and patients and caregivers could use the information for making informed decisions. Therefore, CMS proposes, beginning in 2025, to

make data for the psychiatric/mental health patients' stratification available on Care Compare, including data that had been previously published on data.medicare.gov but not displayed on Care Compare.

Hospital Inpatient Quality Reporting Program

Hospital-Wide Hybrid All-Cause Readmission and Standardized Mortality Measures

CMS previously established two hybrid quality measures under the Hospital Inpatient Quality Reporting (IQR) Program: the hybrid hospital-wide readmissions (HWR) and hybrid hospital-wide mortality (HWM) measures. Hybrid measures use several data sources: 1) core clinical data elements (CCDEs), which are clinical variables derived from EHRs that can be used to adjust hospital outcome; 2) linking variables from administrative data that can be used to link the CCDEs and administrative claims data for measure calculation; and 3) claims data. Hospitals are required to submit linking variables on 95% of hospital discharges and CCDEs on 90% of discharges in a reporting period.

CMS established initial voluntary reporting periods for both measures. CMS previously finalized mandatory reporting beginning with the FFY 2026 payment determination — based on performance data from July 1, 2023, through June 30, 2024 — with data submission required by September 30, 2024. However, based on its experience during the voluntary reporting periods, CMS has noted that that about three-fourths of the participating hospitals would not have met the reporting thresholds for the CCDEs and linking variables and would have therefore been subject to a one quarter reduction to their annual payment update for the fiscal year.

To give hospitals an additional year to address issues and develop experience with reporting CCDEs and linking variables, CMS proposes that the submission of CCDEs and linking variables remains voluntary for the FFY 2026 payment determination and becomes mandatory beginning with the FFY 2027 payment determination. A hospital's annual payment determination for FFY 2026 would not be affected by the voluntary reporting of CCDEs and linking variables, but CMS would evaluate and assess the claims data portion of the measures (and those measures would be publicly reported based on claims data). In the spring, as a preview of public reporting, hospitals would continue to receive confidential hospital-specific reports, which would reflect the CCDEs and linking variables if hospitals chose to report them.

Rural Emergency Hospital Quality Reporting Program

The CAA of 2021 established REHs as a new provider type — beginning January 1, 2023 — that provides ED services, observation care, and potentially other medical and health services on an outpatient basis. REHs must not provide acute care inpatient services, with the exception of skilled-nursing facility services in a distinct unit. Notably, the state of California does not currently license the REH provider type.

The CAA of 2021 also required the establishment of the REH quality reporting program. In the CY 2024 OPPS final rule, CMS adopted and codified policies related to measure retention, removal, and modification; public reporting; the form, manner, and timing of data submission; a review and corrections period for submitted data; and an Extraordinary Circumstances Exception (ECE) process. CMS also adopted four initial measures for the REH quality reporting program

beginning with CY 2024. Each of the four measures is currently included in the hospital OQR program:

- Abdomen Computed Tomography (CT) – Use of Contrast Material
- Median Time from ED Arrival to ED Departure for Discharged ED Patients
- Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
- Risk-Standardized Hospital Visits Within Seven Days After Hospital Outpatient Surgery

As discussed above, CMS proposes to add three health equity measures to the REH quality reporting program: the HCHE measure, the Screening for SDOH measure, and the Screen Positive Rate for SDOH measure. CMS also proposes to modify the reporting period for the previously adopted Risk-Standardized Hospital Visits Within Seven Days After Hospital Outpatient Surgery measure. More detail on the REH quality reporting program is available in the proposed rule.

Hospital Quality Star Rating Request for Information (RFI)

The Overall Hospital Quality Star Rating is published on the provider comparison tool on Medicare.gov. It assigns hospitals a star rating (between one and five stars) based on publicly available quality measure results reported by the hospitals through the agency's quality measurement programs. CMS provides information on its analysis of the hospital overall star rating methodology, which found that some hospitals that performed in the bottom quartile of the safety and care group of measures still received an overall five-star rating.

CMS is considering potential adjustments to the Overall Hospital Quality Star Ratings methodology that would place more emphasis on the measures within the Safety of Care measure group. CMS seeks feedback on whether hospitals performing in the bottom quartile in the Safety of Care measure group should be eligible to receive a five-star rating, and specifically on the following three options for modifying the Overall Hospital Quality Star Rating methodology:

1. **Reweighting the Safety of Care Measure Group:** Under this option, the Safety of Care measure group's weight would be increased to 30% and the weights for the other groups would each be proportionally reduced (so that Mortality, Readmission, and Patient Experience would each be weighted to 19.7% and Timely and Effective Care to 10.8%). CMS' analysis shows that reweighting the groups would reduce the number of hospitals that both perform poorly in Safety of Care and receive a five-star rating but would reduce the influence of the other measure groups.
2. **Policy-Based One-Star Reduction for Poor Performance on Safety of Care:** Under this option, the star rating of any hospital in the lowest quartile of Safety of Care would be reduced by one star. The current minimum star rating of one star would still apply, so no hospital's score would be reduced below one star. Even hospitals that perform very well in all other measure groups would still be subject to the one-star reduction.
3. **Reweighting the Safety of Care Measure Group Combined with Policy-Based Star Rating Cap:** Under this option, the Safety of Care measure group would be reweighted according to the methodology outlined in bullet 1, above, with the addition of a policy limiting hospitals in the lowest quartile of Safety of Care to a maximum of four stars. CMS' analysis showed this option provided a more targeted approach that restricted the five-star rating to hospitals that achieve a minimum threshold in Safety of Care.

Health and Safety Standards for Obstetrical Services

CMS believes the Medicare statute provides authority for the agency to propose new conditions of participation (CoPs) for hospitals and CAHs to establish requirements that protect the health and safety of pregnant, birthing, and postpartum patients receiving obstetric services at these facilities. As part of its efforts to improve maternal health outcomes, CMS proposes new and updated CoPs that encompass organization, staffing, and delivery of care; staff training; quality assessment and performance improvement (QAPI); emergency services readiness; and transfer protocols. Notably, proposals related to emergency service readiness and transfer protocols apply to all hospitals, not just those that provide obstetrical services.

Organization, Staffing, and Delivery of Services

CMS proposes to add two new sections (§§482.59 and 485.649) to its CoP regulations for hospitals and CAHs offering obstetrical services outside of an emergency department. Generally, obstetrical services — if offered by the hospital or CAH — would have to be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care of pregnant, birthing, and postpartum patients. The proposal would include standards for physical and behavioral health. Additionally, outpatient obstetrical services would have to be consistent in quality with inpatient care in accordance with the complexity of services offered.

Standard: Organization and Staffing

CMS proposes to require the organization of the obstetrical services at a hospital or CAH to be appropriate to the scope of the services offered. Obstetrical services would also have to be integrated with other departments of the hospital, as applicable. For example, a labor and delivery unit must ensure good communication and collaboration with laboratory services, surgical services, and anesthesia services.

Labor and delivery rooms (including rooms for operative delivery) and postpartum or recovery rooms would have to be supervised by an experienced registered nurse (RN), certified nurse midwife (CNM), NP, PA, or a Doctor of Medicine (MD) or osteopathy (DO). CMS also proposes that hospitals and CAHs would have to delineate obstetrical privileges for all practitioners providing obstetrical care according to the competencies of each practitioner. The obstetrical service would have to maintain a roster of practitioners that specifies the privileges of each practitioner.

CMS reminds stakeholders that existing CoPs allow for the privileging and credentialling of practitioners other than physicians, including CNMs, to admit patients to a hospital (subject to state law). CMS does not require that these practitioners be employed by, under the supervision of, or associated with an MD or DO unless required by state law, regulations, or facility policy. CMS also does not require Medicaid or other non-Medicare patients admitted to a hospital by a nurse midwife to be under the care of an MD or DO. However, for CAHs, the statute requires physician oversight of patients.

Standard: Delivery of Service

CMS proposes to require that obstetrical services furnished by the facility be consistent with the needs and resources of the facility, and that facility policies governing obstetrical care must be designed to achieve and maintain high standards of medical practice and patient care and safety.

CMS proposes to establish minimum standards for equipment. Specifically, labor and delivery room suites would be required to have a call-in-system, cardiac monitor, and fetal doppler or monitor. Recognizing that facilities may offer different levels of care, CMS seeks input on an appropriate minimum set of equipment.

For obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events, CMS proposes to require additional equipment, supplies, and medication necessary to treat emergency cases, which would have to be kept on the premises of the facility and be readily available to treat emergencies. While not prescriptive, CMS provides examples including resuscitators, defibrillators, oxygen, intravenous therapy supplies, suction machines, analgesics, local anesthetics, anti-arrhythmics, antihypertensives, antiepileptics, and anticoagulants.

Training for Obstetrical Staff in Hospitals and CAHs

CMS proposes standards for obstetrical staff training that would require hospitals and CAHs to develop policies and procedures for training on select topics to improve maternal care services furnished at the facilities.

Concepts addressed in the training would reflect the scope and complexity of the services furnished by the facility. This would include evidence-based best practices and protocols identified by the facility to improve the delivery of maternal care. CMS suggests that facilities may participate in local or regional perinatal quality collaboratives (PQCs) — such as the California Maternal Quality Care Collaborative — and implement patient safety bundles for safer births. Additionally, hospitals and CAHs would have to use findings from their QAPI program to inform staff training needs and any changes to training topics on an ongoing basis.

CMS proposes that the facility's governing body identifies which obstetrical staff must complete the training and document that the training was successfully completed. Additionally, the hospital or CAH would have to be able to demonstrate staff knowledge on the topics for which training was provided. CMS does not propose to require a specific method for facilities to show their staff is knowledgeable and competent in improving maternal care delivery, but it notes this could be done through self-assessments, surveys, or questionnaires administered to staff. CMS expects hospitals and CAHs to use qualified trainers. It also cautions that this new training requirement is supplemental to the education and training necessary for clinicians to administer care within the scope of their practice or for a staff member to perform their job.

QAPI Program

CMS proposes to require a hospital or CAH that offers obstetrical services to use its QAPI program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. At a minimum, facilities would be required to do all of the following:

- Analyze data and quality indicators collected for the QAPI program by diverse subpopulations, as identified by the hospital, among obstetrical patients.
- Measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services, and operations among obstetrical patients.

- Analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained among obstetrical patients.
- Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

CMS also proposes to require the facility's obstetrical services leadership to engage in QAPI for obstetrical services, which would include participating in data collection and monitoring described above. Additionally, the facility leadership, obstetrical services leadership, or their designate(s) would need to have a process to incorporate maternal mortality review committee (MMRC) data and recommendations into the hospital QAPI program if an MMRC is available at the state or local jurisdiction where the facility is located, including the California Pregnancy-Associated Mortality Review. CMS notes that existing state statutes require facilities to report data to MMRCs and says that a facility could comply with this proposal by participating in a PQC or pursuing a quality improvement project based on information from an MMRC.

Emergency Services Readiness

CMS proposes to establish a new standard for readiness to set clear expectations for facilities and their delivery of emergency services. This standard would apply to all hospitals and CAHs offering emergency services without regard to whether they also offer obstetric services. Facilities would be required to have adequate provisions and protocols to meet emergency needs of patients — including, but not limited to, those of pregnant, birthing, and postpartum patients — which would vary depending on the complexity and scope of services offered.

Protocols would have to be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions; this would include patients with obstetrical emergencies, complications, and immediate post-delivery care. Provisions would include equipment, supplies, and medication used in treating emergency cases, which must be kept at the hospital and be readily available for treating emergency cases to meet patients' needs. CMS proposes that, at a minimum, this would include drugs, blood and blood products, biologicals, equipment, and supplies commonly used in life-saving procedures, as well as a call-in system for each patient in each emergency treatment area. Facilities would be expected to tailor their equipment and supplies to meet the needs of their patient populations, consistent with the needs, services, and resources of the facility.

CMS also proposes annual staff training on the protocols and provisions proposed for emergency services readiness. Similar to the proposed training requirements for obstetric staff described above, the facility's governing body would have to identify which staff must complete the training for emergency care and document that the training was successfully completed. Additionally, the hospital or CAH would have to be able to demonstrate staff knowledge on the topics for which training was provided. Finally, CMS proposes to require hospitals and CAHs to use findings from its QAPI program on an ongoing basis to inform training needs and any changes to training topics.

Transfer Protocols

CMS proposes to amend its discharge planning CoP regulation to impose requirements for transfer protocols. Hospitals and CAHs would be required to have written policies and procedures

for the transfer of patients under their care, including hospital inpatients. The standard would apply to transfers from the emergency department to inpatient admission or transfers between inpatient units in the same hospital as well as to transfers between inpatient units at different hospitals.

Hospitals and CAHs would also be required to train relevant staff on hospital policies and procedures for transferring patients under their care; the facilities would determine which staff should receive this training. CMS encourages all recipient hospitals to have policies and procedures in place for the acceptance of transfers. CMS also reminds hospitals of their obligations to comply with Emergency Medical Treatment and Labor Act and federal civil rights laws.

CMS seeks comments on the proposed standard, as well as on how often staff should be trained in transfer protocols, whether receiving hospitals should have written policies and procedures outlining their standards and conditions for accepting transfers, and whether all hospitals (including CAHs and REHs) should be required to have a documented partnership with another hospital that both provides obstetric services and a medical fetal medicine specialist available for consultations in urgent situations, if such service(s) are already offered directly by the hospital.

Appendix I: Request for Information on Domestically Produced N95 Respirators

1) Changes to Payment Adjustment Methodology
    a. Should CMS consider modifying the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis)?
    b. If so—
        i. How should CMS calculate that standard unit cost differential, and what should the current unit cost differential be?
        ii. Would it be appropriate to calculate the payment adjustment by multiplying the unit cost differential by the total quantity of domestic NIOSH-approved surgical N95 respirators used by the hospital, and then multiplying by the Medicare Part A hospital inpatient cost share (to calculate the IPPS payment adjustment) or the Medicare Part B hospital outpatient cost share (to calculate the OPPS payment adjustment)?
    c. Do hospitals need additional support to purchase domestic-made surgical N95 respirators, and if so, how much support is needed and in what form?

2) Changes to Payment Eligibility
    a. Do hospitals have sufficient access to information on which surgical N95 models on the market are wholly domestically made?
    b. Have hospitals been able to obtain written statements from manufacturers stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under the CMS definition?
    c. Would a publicly available list of products eligible for the payment adjustment—for example, if provided by CMS, NIOSH, or another government entity—make it easier for hospitals to locate products eligible for the payment adjustment?
    d. If CMS modified the payment adjustment so that hospitals that attested to purchasing respirators from such a list did not need to obtain a written statement from the manufacturer, would hospitals more easily be able to utilize the payment adjustment?

3) Types of Respirators Covered
    a. Do hospitals procure both surgical and non-surgical N95 respirators?
    b. Has the payment adjustment's current focus on surgical N95 respirators inhibited uptake of the payment adjustments?
    c. Are the quality differentials between domestic and non-domestic surgical respirators also applicable to non-surgical respirators, and is a sustained and reliable source of domestically made non-surgical N95 respirators important for strengthening hospitals' ability to protect personnel and patients in a public health emergency?
    d. Should CMS consider expanding the payment adjustments to include all domestic NIOSH-approved N95 respirators—that is, both non-surgical and surgical N95 respirators?
    e. If the payment adjustments were expanded to include all domestic NIOSH-approved N95 respirators, and if the payment adjustment methodology calculation provided a *national* standard unit cost differential between domestic and non-

domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis), would the unit cost differential for *non-surgical* N95 respirators be different than the one for surgical N95 respirators?

Appendix II: Request for Information on Domestically Produced Nitrile Gloves

- Would modifying the payment adjustment to include nitrile gloves—
    - Help offset the marginal costs that hospitals face in procuring high quality domestically made nitrile gloves?
    - Help sustain a baseline level of domestic manufacturing of nitrile gloves to ensure that hospitals and other stakeholders have ongoing, reliable access to an adequate supply?
- Would having access to a sustained and reliable source of domestically made nitrile gloves strengthen hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?
- Are there other reasons why hospitals would benefit from an extension of the payment adjustment to include nitrile gloves?
- Do stakeholders believe a significant portion of hospitals would use domestic nitrile gloves if the payment adjustment were offered?
- If the payment adjustment was modified to include nitrile gloves—
    - How should CMS define wholly domestically made nitrile gloves?
    - Would it be appropriate to categorize all nitrile gloves purchased by hospitals into two categories: (1) domestic nitrile gloves that (with the exception of nitrile butadiene rubber (NBR)) comply with the Infrastructure Investment and Jobs Act's Make PPE in America Act domestic content requirements; and (2) non-domestic nitrile gloves?
    - If so, would it be appropriate to eliminate the domestic content exception for NBR if domestic NBR production reaches a sufficient level to meet market needs?
    - Should a national standard unit cost differential between domestic and non-domestic nitrile gloves be used to calculate the payment adjustment, and if so, what should the current unit cost differential be (or what data source)?

Appendix III – Hospital Outpatient Quality Reporting Program Measures Table

Measure		Payment Determination				
CBE #		2024	2025	2026	2027	2028
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	Removed			
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	Removed	*	*	*
0514	OP-8: MRI Lumbar Spine for Low Back Pain*	X	Proposed Removal*			
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery*	X	Proposed Removal*	*	*	*
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X
0499	OP-22: ED - Left Without Being Seen	X	X	X	X	X
0661	OP-23: ED - Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients*	X	X	X	X	X
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
2539	OP-32: Facility Seven-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X
	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery	X	X	X	X	X
	OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures			Voluntary	X	X
	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)*		X	X	X	X
	OP-39: Breast Cancer Screening Recall Rates	X	X	X	X	X
	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM			X	X	X

	THA/TKA PRO-PM				Voluntary	Voluntary (Mandatory for CY 2031 payment)
3663e	Excessive Radiation eCQM				Voluntary	Voluntary (Mandatory for CY 2029 payment)
	Hospital Commitment to Health Equity*		X*	X*	X*	X*
	Screening for SDOH*		Voluntary*	X*	X*	X*
	Screen Positive Rate for SDOH*		Voluntary*	X*	X*	X*
	Information Transfer Pro-PM*					Voluntary* (Proposed Mandatory CY 2029 payment)

* Proposal