Medicare Outpatient Prospective Payment System

CY2025 Proposed Payment Rule Brief provided by the Wisconsin Hospital Association

Overview

The proposed calendar year (CY) 2025 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on July 10, 2024. 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 proposed rule includes policies that would:

- Add three services to the Inpatient-Only (IPO) list;
- Update the CBSAs used in determining a hospital's wage index;
- Add two new status indicators representing separately payable, non-opioid post-surgical pain management products;
- Change the Obstetrical Services Conditions of Participation;
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program;
- Update the requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program; and
- Update payment rates and policies for Ambulatory Surgical Centers (ASCs).

The proposed rule and other resources related to the OPPS are available on the Centers for Medicare and Medicaid Services (CMS) website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS. Comments to are due to CMS by September 9, 2024 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "CMS-1809–P".

On July 22, 2024, an online version of the CY 2025 OPPS proposed rule will be made available at https://www.federalregister.gov/d/2024-15087. Page numbers noted in this summary are from the *Display* copy of the proposed rule. A brief summary of the major hospital OPPS sections of the proposed rule is provided below. CMS estimates a $5.2 billion increase in OPPS payments for CY 2025 over CY 2024.

Note: Text in italics is extracted from the *Display* copy of the CY 2025 OPPS proposed rule, unless stated otherwise.

OPPS Payment Rate

Display pages 107 – 138

CMS typically uses the most up-to-date claims data and cost report data (one year behind claims data) to set OPPS rates for the upcoming year. CMS is proposing to use CY 2023 claims data and CY 2022 Healthcare Cost Report Information System (HCRIS) data for CY 2025 OPPS rate setting.

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

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

Proposed CY 2025 Update Factor Component	Change to OPPS Conversion Factor
Market Basket (MB) Update	+3.0%
Affordable Care Act (ACA)-Mandated MB Productivity Adjustment	–0.4 percentage points (PPT)
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%**

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes** ***(Display pages 113 – 120)*****:** As in past years, for CY 2025 OPPS payments, CMS is proposing to continue to use the federal fiscal year (FFY) 2025 inpatient PPS (IPPS) wage indexes, including all reclassifications, add–ons, rural floors, and budget neutrality adjustments.

  In order to address wage index disparities between high- and low-wage index hospitals, CMS had made a variety of changes that would affect the wage index and wage index–related policies in the FFY 2020 IPPS final rule. As adopted, this policy was to be in effect for a minimum of four years (through FFY 2024) in order to be properly reflected in the Medicare cost report for future years. CMS believes that the effects of the COVID-19 public health emergency (PHE) has complicated their ability to evaluate how successful this low wage index hospital policy was for increasing employee compensation. As such, CMS proposes to continue the policy that hospitals with a wage index value in the bottom quartile of the nation will have that wage index increased by a value equivalent to half of the difference between the hospital's pre-adjustment wage index and the 25th percentile wage index value across all hospitals. This continuation would be in effect for at least three more years, beginning in FFY 2025, so that the policy would be in effect for at least four full fiscal years after the end of the COVID-19 PHE.

  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.

  CMS proposes to continue to offset these wage index increases in a budget neutral manner by applying a budget neutrality adjustment to the national standardized amount. The value of the 25th percentile wage index for FFY 2025 is proposed to be 0.8879.

  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. Lastly, a new hospital would be paid the wage index for the area in which it is geographically located for its first full or partial CY with no cap applied, because a new hospital would not have had a wage index in the prior CY.

  CMS is proposing 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. CMS is also proposing a separate budget neutrality factor of 0.9982 for the impact of the 5% cap on wage index decreases.

  The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor–related. For CY 2025, CMS is proposing to continue to use a labor–related share of 60%.

  For CY 2025, in order to align with IPPS, CMS is also proposing to update the CBSA delineations used for the application of the wage index under OPPS. The next section of this brief details CMS' proposals regarding this from the FFY 2025 IPPS Proposed Rule.

  - **Updated CBSA Delineations (May 2, 2024** ***Federal Register (FFY 2025 IPPS PR) pages 36139 – 36150 and 36166 – 36181*****):** On July 21, 2023, the OMB issued OMB Bulletin No. 23-01 (https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf) that made a number of significant changes related CBSA delineations. To align with these changes, CMS is proposing to adopt the newest OMB delineations for the FFY 2025 IPPS wage index.

    If CMS adopts this proposal, 54 counties and 33 hospitals that are currently part of an urban CBSA would be considered located in a rural area (including one urban county in Connecticut being redesignated to a newly proposed rural CBSA), listed in the table on *FFY 2025 IPPS PR* pages 36143 – 36144. Along with this, CMS proposes that 17 of these counties be added to the list of "Lugar" counties whose hospitals are deemed to be in an urban area. The tables on *FFY 2025 IPPS PR* pages 36177 - 36181 show all of the counties proposed to change Lugar status for FFY 2025.

    Additionally, adopting this proposal would cause 54 counties and 24 hospitals that are currently located in rural areas to be considered located in urban areas, listed in the table on *FFY 2025 IPPS PR* pages 36145 – 36146. Due to these revisions, some critical access hospitals (CAH) previously located in rural areas may now be located in urban areas. Affected CAHs would have a two-year transition period that begins from the date the redesignation becomes effective and must reclassify as rural during this transition period in order to retain their CAH status

after the transition ends. Also, special statuses limited to hospitals in rural areas may be terminated unless the hospital is granted a rural reclassification prior to October 1, 2024.

Lastly, adopting these delineations would cause some urban counties to shift between new or existing urban CBSAs. In some cases, this would change the name or numbers of certain CBSAs. This detail can be found in the tables on *FFY 2025 IPPS PR* pages 36147 – 36150.

CMS is also proposing that for counties that are removed from a CBSA and become rural, a hospital that is reclassified to that CBSA with a current "home area" reclassification would receive the wage index applicable to other hospitals that reclassify into that CBSA, rather than the geographic wage index. CMS notes that this wage index may be lower than the wage index calculated for hospitals geographically located in that CBSA due to hold harmless provisions.

In the case where a proposed CBSA would add or lose a current rural county, a hospital with a current reclassification to the resulting CBSA would be maintained. CMS proposes to maintain Medicare Geographic Classification Review Board (MGCRB) "home area" reclassifications that would reclassify a hospital to one of these counties. Additionally, if a county is proposed to be removed from a CBSA and become rural, then a hospital in that county with a "home area" reclassification would no longer be geographically located in the CBSA to which they are reclassified. Thus, CMS proposes that these reclassifications would no longer be "home area" reclassifications. The table on *FFY 2025 IPPS PR* page 36167 shows the six hospitals for which CMS proposes to terminate reclassifications.

For hospitals which reclassify to CBSAs where one or more counties move to a new or different urban CBSA, CMS proposes that these hospitals would continue to be reclassified to each of their geographic "home area". These could differ from previous years, with affected providers listed in the table on *FFY 2025 IPPS PR* page 36168.

For a hospital that would receive a reclassification that could not continue to their reconfigured CBSA (not including "home area" reclassifications), CMS is proposing to assign the hospital to another CBSA under the revised delineations that contains at least one county from their previous reclassified CBSA and is generally consistent with rules that govern geographic reclassification. Table X on *FFY 2025 IPPS PR* page 36169 lists the eligible CBSAs that hospitals in CBSAs in the situation above could instead reclassify to. Table Y on *FFY 2025 IPPS PR* pages 36170 – 36171 shows all providers subject to this proposed policy. CMS is proposing similar policies to account for reclassifications that will be affected by the proposal to use Connecticut planning regions rather than counties, which can be found on *FFY 2025 IPPS PR* pages 36171 – 36173.

Hospitals in the case described above that wish to be reassigned to a different eligible CBSA, to which the applicable proximity criteria are met, may request reassignment within 45 days of the display date of this rule. This request must be sent to wageindex@cms.hhs.gov and include documentation establishing that they meet the proximity requirements for reassignment to an alternate CBSA that contains one or more counties from the CBSA to which they are currently classified. For hospitals that wish to withdraw or terminate their MGCRB reclassification, CMS is proposing that that providers would have to submit these requests within 45 days of the display date of this rule or within seven calendar days of receiving a decision from the MGCRB on their classification status, whichever is later.

Since CMS already applies a 5% cap on wage index loses from year to year, CMS does not believe any additional transition policies are needed to account for the changes in wage index.

- **Payment Increase for Rural Sole Community Hospitals (SCH) and Essential Access Community Hospitals (EACH)** ***(Display pages 121 – 122)*****:** CMS is proposing to continue the 7.1% budget neutral payment increase for rural SCHs and EACHs. This payment add–on excludes separately-payable drugs, biologicals, brachytherapy sources, devices paid under the pass–through payment policy, and items paid at charges reduced to costs. CMS is proposing to maintain this for future years until data supports a change to the adjustment.
- **Cancer Hospital Payment Adjustment and Budget Neutrality Effect** ***(Display pages 109 – 113 and 122 – 128):*** CMS is proposing to continue to provide payment increases to the 11 exempt cancer hospitals. CMS does this by providing a payment adjustment such that the cancer hospital's target payment–to–cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals (and thus the adjustment is budget neutral).

  In order to determine a budget neutrality factor for the cancer hospital payment adjustment for CY 2025, CMS reduced the CYs 2020 through 2024 PCR of 0.89 (which included the application of the 1.0 percentage point

reduction mandated by the 21st Century Cures Act) by an additional 1.0 percentage point beginning CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage points as required by the 21st Century Cures Act. This results in the proposed target PCR being equal to 0.87 for each cancer hospital for CY 2025. Therefore, CMS is proposing a +0.06% adjustment to the CY 2025 conversion factor to account for this policy.

- **Outlier Payments** ***(Display pages 128 – 132)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS used CY 2023 claims to calculate a proposed CY 2025 outlier fixed–dollar threshold of $8,000. This is a 3.2% increase compared to the current threshold of $7,750. Outlier payments are proposed to continue to be paid at 50% of the amount by which the hospital's cost exceeds 1.75 times the Ambulatory Payment Classification (APC) payment amount when both the 1.75 multiplier threshold and the fixed–dollar threshold are met.

Updates to the APC Groups and Weights

Display pages 35 – 107, 147 – 452, 526 – 529, and 577 – 596

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

The proposed payment weights and rates for CY 2025 are available in Addenda A and B within Addendum P of the proposed rule at https://www.cms.gov/license/ama?file=/files/zip/2025-nprm-opps-addenda.zip.

Effective CY 2025, CMS is proposing to create two new status indicator assignments (H1 and K1) used to identify HCPCS codes representing non-opioid post-surgical pain management products that qualify for separate payment as authorized by the CAA of 2023 (*Display* pages 526 – 529).

The table below shows the update 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**

- **Calculation of Cost-to-Charge Ratios (CCRs)** ***(Display pages 36 – 37 and 120 – 121):*** For CY 2025, CMS is proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios to convert charges to estimated costs. CMS is also proposing to not include cost report lines for non-standard cost centers in OPPS ratesetting when hospitals have reported this data on cost report lines that do not correspond to the cost center number.
- **Blood and Blood Products** ***(Display pages 39 – 41)*****:** For CY 2025, CMS is proposing to continue its policy to establish payment rates for blood and blood products using a blood–specific CCR methodology.
- **Brachytherapy Sources** ***(Display pages 41 – 44)*****:** For CY 2025, CMS is proposing to continue its policy to use the costs derived from the most recent set of claims data (CY 2023) to set payment rates for brachytherapy sources. With the

exception of brachytherapy source C2645 and low-volume brachytherapy APCs, CMS is proposing to base payment rates on the geometric mean unit costs for each source. For CY 2025 and future years, CMS is also proposing *"to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis."*

- **Radioisotopes Derived from Non-Highly Enriched Uranium (non-HEU) Sources *(Display pages 442 – 446)*:** Historically, most of the supply of molybdenum (Mo-99) (used in the creation of Technetium-99m (Tc99m), 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 HEU. In order to eliminate reliance on these foreign reactors, CMS is proposing a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc99m derived from *domestically* produced Mo-99 starting January 1, 2026.

- **Comprehensive APCs *(Display pages 45 – 67 and 582 - 590)*:** A Comprehensive Ambulatory Payment Classification (C-APC) provides all–inclusive payments for certain procedures. A C-APC covers payment for all applicable Part B services that are related to the primary procedure, including items currently paid under separate fee schedules. The C-APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un–coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C-APCs when they appear on the same claim as those services assigned to a C-APC. The C-APCs do not include payments for services that are not covered by Medicare Part B, nor those that are not payable under OPPS, such as: certain mammography and ambulance services; brachytherapy sources; pass–through drugs and devices; charges for self–administered drugs; certain preventive services; and procedures assigned to a New Technology APC either included on a claim with a "J1" or included on a claim with a "J2" indicator and packaged into payment for comprehensive observation services assigned to status indicator "J2".

  CMS is not proposing the creation of any new C-APCs for CY 2025. A list of the 72 existing C–APCs for CY 2025 can be found in Table 2 on *Display* pages 65 – 67.

  For CY 2025 only, CMS is proposing to exclude payment for cell and gene therapies from C-APC packaging listed in Table 1 on *Display* pages 61 – 62 into the payment for the primary C-APC service on the same claim. CMS is doing so in order to gather information on if this policy appropriately captures all unique therapies that function as primary treatments and do not support C-APC primary services. CMS is also proposing that products on this list with a pass-through status expiring in CY 2025 would be excluded from C-APC packaging after their pass-through status expires. Related to this, CMS seeks comment on the following:

  - *"…whether there are any additional cell and gene therapies that may be appropriate to exclude from C-APC packaging for CY 2025. Commenters should explain why any additional cell and gene therapies that they believe should be excluded from C-APC packaging are not integral, ancillary, supportive, dependent, or adjunctive to any C-APC primary service…*
  - *…whether this proposal should be extended beyond 1 year or if a different, expanded, or supplemental policy approach may be warranted in future rulemaking…*
  - *…whether interested parties believe it is appropriate for these other classes of drugs, biologicals, or medical devices to be excluded from packaging with all C-APCs or only specific C-APCs, such as the Comprehensive Observation Services C-APC (SI = "J2")…*
  - *Because the cell and gene therapies listed in Table 1 are not integral, ancillary, supportive, dependent, or adjunctive to any current C-APC procedure, how could CMS structure a new C-APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such by creating as a Chimeric Antigen Receptor (CAR) T-cell therapy administration C-APC, with which the CAR-T or gene therapy would be integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service?*
  - *What integral, ancillary, supportive, dependent, or adjunctive items and services are routinely provided as part of the administration of cell and gene therapies or in conjunction with cell and gene therapies generally?*
  - *…whether policy revisions to the C-APC policy may be appropriate in future rulemaking, such as a modified outlier payment policy specific to CAPCs to address related situations in the future."*

In accordance with the Consolidated Appropriations Act (CAA) of 2023, CMS is also proposing to exclude from the C-APC policy those non-opioid treatments for pain relief that satisfy the required payment criteria. This exclusion is required by law to last from January 1, 2025 through December 31, 2027. Additionally, CMS is proposing to apply the 18% payment limitation per date of service billed, rather than per HCPCS dosage unit, as typically multiple dosage units of each drug or biological are billed per claim.

- **Composite APCs** ***(Display pages 67 – 76):*** Composite APCs are another type of packaging to provide a single APC payment for groups of services that are typically performed together during a single outpatient encounter. Currently, there are six composite APCs:
    - Mental Health Services (APC 8010)
    - Multiple Imaging Services (APCs 8004, 8005, 8006, 8007, and 8008)

  For CY 2025, CMS proposes to continue its policy that when the aggregate payment for specified mental health services provided by a hospital to a single beneficiary on a single date of service exceeds the maximum per diem payment rate for partial hospitalization services, those services will continue to instead be paid through composite APC 8010. In addition, CMS is proposing that the payment rate for composite APC 8010 will continue to be set to that established for APC 5864 (4 or more hospital-based partial hospitalization services per day) as it is the maximum partial hospitalization per diem payment rate for a hospital.

  For CY 2025, CMS is also proposing to continue its current composite APC payment policies for multiple imaging services from the same family and on the same date. Table 3 on *Display* pages 72 – 76 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 APCs Payment Policy (*Display pages 216 – 217)*:** For CY 2025, CMS proposes to continue the universal low-volume APC payment methodology for services assigned to New Technology, clinical, and brachytherapy APCs with fewer than 100 claims. This policy uses the highest of the geometric mean, arithmetic mean, or median based on up to 4=four years of claims data to set the payment rate for the APC.

  The proposed 11 low volume APCs for CY 2025 may be found in Table 35 on *Display* page 217.

- **Payment for Medical Devices with Pass–Through Status** ***(Display pages 233 – 377)***: There are currently 13 device categories that are eligible for pass–through payment:
    - C1831 – Personalized, anterior and lateral interbody cage (implantable);
    - C1832 – Autograft suspension, including cell processing an application, and all system components;
    - C1833 – Monitor, cardiac, including intracardiac lead and all system components (implantable);
    - C1826 – Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system;
    - C1827 – Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller;
    - C1747 – Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable);
    - C1600 – Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable);
    - C1601 – Endoscope, single-use (i.e. disposable), pulmonary, imaging/illumination device (insertable);
    - C1602 – Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable);
    - C1603 – Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter);
    - C1604 – Graft, transmural transvenous arterial bypass (implantable), with all delivery system components;
    - C1605 – Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation; and
    - C1606 – Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope.

  CMS has received 14 applications for device pass–through payment applications since the March 1, 2023 quarterly deadline:

    - AGENTTM Paclitaxel-Coated Balloon Catheter;
    - AveirTM DR Dual Chamber Leadless Pacemaker System;
    - CANTURIO™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System;
    - The DETOUR™ System;
    - EndoSound Vision System™ (EVS™);

- iFuse Bedrock GraniteTM Implant System;
- Paradise® Ultrasound Renal Denervation (RDN) System;
- Precision GI;
- PulseSelect™ Pulsed Field Ablation (PFA) System;
- Symplicity Spyral™ RDN System;
- Ambu® aScope™ Gastro;
- OMEZA Wound Care Matrix (OCM™);
- OPN NC; and
- OSCAR® Peripheral Multifunctional Catheter.

- **Device–Intensive Procedures** ***(Display pages 377 – 387)*****:** CMS defines device–intensive APCs as those procedures which require the implantation of a device and are assigned an individual HCPCS code–level device offset of more than 30%of the procedures 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 lack 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.

  The list of proposed procedures this policy applies to is in Addendum P of this proposed rule.

- **Device Edit Policy** ***(Display pages 387 – 389)*****:** CMS will continue to require 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 is proposing 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); and
  - 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.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices** ***(Display pages 389 – 392)*****:** 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 temporarily); and
  - The procedure must be device–intensive (devices exceeding 30% of the procedure's average cost).

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

- **Payment for Drugs, Biologicals and Radiopharmaceuticals** ***(Display pages 78 – 103, 392 – 432, and 446 – 452)*****:** CMS pays for drugs and biologicals that <u>do not</u> 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 in order to grant a pass-through period as close to a full three 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, due to comments received with the CY 2024 OPPS final rule with comment period, and to ensure that Medicaid payment policy is not disincentivizing the use of clinically-appropriate, high-cost, low-utilization diagnostic radiopharmaceuticals as well as appropriate access, CMS is proposing a per-diem packaging threshold of $630 for diagnostic radiopharmaceuticals. Diagnostic radiopharmaceuticals with a per-day cost below this threshold would continue to be packaged as under existing policy. Following its current packaging threshold policy, beginning CY 2026, CMS proposes that this value would be updated annually based on the producer price index (PPI) for Pharmaceuticals for Human Use (Prescription) from IHS Global, Inc (IGI).

For CY 2025, CMS is proposing a packaging threshold of $140. Drugs, biologicals, and radiopharmaceuticals (excluding diagnostic radiopharmaceuticals, unless the separate threshold of $630 is not finalized) that are above the $140 threshold are paid separately, using individual APCs, and those below the threshold are packaged; the baseline payment rate for CY 2025 is the average sales price (ASP)+6%.

Separately payable drugs and biological products that do not have pass-through status are to be paid wholesale acquisition cost (WAC)+3%, instead of WAC+6%.

For CY 2025, CMS proposes to continue paying for blood clotting factors and therapeutic radiopharmaceuticals with pass-through payments status at ASP+6%. If ASP data are not available, payment instead would be made at WAC+3%; or 95% of average wholesale price (AWP) if WAC data are also not available.

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 is proposing that:

- *"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 is proposing a clarification that only ASP data or mean unit cost data (if ASP is unavailable) would be used to set payment rates under the OPPS for nonpass-through therapeutic radiopharmaceuticals that are separately payable. For CY 2025, this results in CMS proposing the use of mean unit cost 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 is proposing that 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 on *Display* pages 396 – 397; by December 31, 2025 for 28 drugs and biologicals listed in Table 63 on *Display* pages 400 – 402; and is proposing to continue/establish pass–through status in CY 2025 for 57 drugs and biologicals shown in Table 64 on *Display* pages 404 – 409.

- **Packaged Services** ***(Display pages 76 – 78 and 577 – 596)*****:** CMS is proposing continue to conditionally package more ancillary services when they occur on a claim with another service, and to only pay for them separately when performed alone.

For CY 2025, CMS proposes to continue to unpackage, and pay separately at ASP+6%, the cost of non–opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. CMS is unpackaging these drugs to address the decreased utilization of non–opioid pain management drugs and to encourage their use rather than prescription opioids. These drugs are only eligible if the drug or biological does not have transitional pass-through payment status and the drug must not already be separately payable in the OPPS or ASC payment system.

Tables 84 and 85 on *Display* pages 592 – 594 list the products that are proposed to continue to have separate payment in the ASC setting under this policy for CY 2025.

- **High-Cost/Low-Cost Threshold for Packaged Skin Substitutes *(Display pages 432 – 442)*:** CMS divides skin substitutes into a high-cost group and a low-cost group in terms of packaging. CMS assigns skin substitutes with a geometric mean unit cost (MUC) or a product's per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high-cost group.

  CMS proposes to continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high-cost group in CY 2024 to the high-cost group in CY 2025 as well. CMS would also assign those with pass-through payment status to the high-cost category.

  The proposed list of packaged skin substitutes and their group assignments may be found in Table 67 on *Display* pages 437 – 442.

Other OPPS Payment Policies

- **Payment for Off–Campus Outpatient Departments *(Display pages 452 – 453)*:** In CY 2019, in order to control what CMS deemed an unnecessary increase in OPPS service volume for a basic clinic visit representing a large share of the services provided at off–campus provider-based departments (PBDs), CMS expanded the Medicare Physician Fee Schedule (MPFS) payment methodology to excepted off–campus PBDs for HCPCS code G0463. 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 is proposing to continue its policy that excepted off-campus PBDs of rural SCHs be exempt from the clinic visit payment policy as CMS believes that the volume of the clinic visit service in these hospitals is driven by factors other than the payment differential for the service. These hospitals 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 is proposing 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".

- **PHP and IOP Services *(Display pages 454 – 472)*:** The PHP is an intensive outpatient psychiatric program that provides 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–specific or hospital–specific data.

  As required by the CAA of 2023, CMS adopted payment and program requirements for intensive outpatient program services beginning CY 2024. Intensive outpatient services are furnished under a distinct and organized outpatient program of psychiatric services for individuals who have an acute mental illness, called an IOP. IOP services are less intensive than PHP services and can be furnished by a hospital to its outpatients, 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 is proposing to continue to make outlier payments to CMHCs for 50% of the amount by which the cost for the PHP service exceeds 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year. As done 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.

- **Inpatient–Only List** ***(Display pages 472 – 476)*****:** The IPO list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2025, CMS did not propose to remove any of services from the IPO list.

  CMS is proposing to add the following services to the IPO list, beginning CY 2025:

  - CPT 0894T: Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion;
  - CPT 0895T: Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 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); and
  - CPT 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 measures that are proposed to be included on the IPO list is available in Addendum E of the proposed rule at https://www.cms.gov/license/ama?file=/files/zip/2025-nprm-opps-addenda.zip.

Remote Services

Display pages 477 – 484

- **Proposed HOPD Payment for Telemedicine Evaluation and Management Services** ***(Display pages 483 – 484)*****:** Due to the similarities between the new telemedicine E/M code set (discussed in the *Display* version of the CY 2025 PFS proposed rule, pages 157 – 169) and the office/outpatient E/M code set, CMS believes that telemedicine E/M codes fall within the scope of the hospital outpatient clinic visit policy as the preceding codes would be reported using HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient). As the CPT codes describing these E/M visits are unrecognized by the OPPS, CMS proposes not to recognize the telemedicine E/M code set under OPPS. However, as these services do utilize hospital resources, CMS is also seeking comment on any associated resource costs that would not otherwise be included in hospital payment for HCPCS code G0463.

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

Display pages 484 – 487

The Bipartisan Budget Act of 2018 required that services provided in a CR, ICR, or PR program can be provided under the supervision of a PA, NP, or CNS beginning January 1, 2024, rather than the current requirement that only physicians could supervise these services as part of the stated programs. In the CY 2024 Medicare PFS final rule, CMS adopted revisions to the regulations in order to match the new requirements.

In the April 6, 2020 "Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency (PHE)" interim final rule with comment period, CMS adopted that during a PHE, for the purposes of direct supervision, a physician can be present virtually through audio/video real-time communications technology for PR, CR, and ICR when the use of technology reduces exposure risks for the patient or the provider. The CAA of 2023 extends this policy through

the end of CY 2024. In order to maintain similar policies for OPPS as PFS, CMS proposed to include PR, CR, and ICR with NPs, Pas, and CNSs under the above.

In the CY 2025 PFS proposed rule, CMS proposed an extension of the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025. In order to maintain alignment between the PFS and OPPS, CMS is also proposing an extension to virtual direct supervision under the OPPS through December 31, 2025.

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

Display pages 487 – 495

Currently, IHS and tribal facilities are paid at a separate All-Inclusive Rate (AIR) for their services. Over time, these facilities have continued to expand their services to providing higher-cost drugs and providing more complex and expensive services, and in some specialty facilities the AIR might not be an accurate representation of the Medicare share of costs.

CMS proposes that, starting January 1, 2025, it will separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an additional add-on payment using the authority under which the annual AIR is calculated. This add-on payment would be applicable to all Medicare Part B-covered high-cost drugs furnished in IHS/Tribal hospital outpatient departments that would otherwise be paid for under OPPS, for whose per day cost exceeds twice the lower 48 states' AIR ($1,334 in CY 2024) and is in addition to the AIR and would have no impact on the calculation of the AIR. CMS also proposes that the amount of the add-on payment would be equivalent to the ASP for the drug, with no additional increase.

Request for Information - Paying all IHS and Tribally Operated Clinics the IHS Medicare Outpatient All Inclusive Rate

Display pages 495 – 498

In order to provide appropriate Medicare payments for similar services, and to provide ensure equitable access to healthcare for tribal Medicare beneficiaries, CMS is seeking information on:

- *"…the kinds of and number of facilities or clinics that the Medicare outpatient IHS AIR could apply to…*
- *whether the facilities in question are freestanding or provider-based…*
- *whether the clinics are physician offices, or whether they are recommending establishment of a new provider type…*
- *the relative operating costs of tribally operated outpatient clinics, as well as feedback and supporting evidence to address whether or why payment set at the IHS AIR would be more appropriate than payment rates under the FQHC PPS, the physician fee schedule, or other some other Medicare payment system…*
- *how the Medicare outpatient AIR, which is based upon a limited number of hospital cost reports, relates to costs in tribal clinics and the kinds of services that the clinics furnish…*
- *concerns that the AI/AN community may have regarding access to or inequity of care in situations where a payment differential exists…*
- *If the clinic or facilities in question are not enrolled in Medicare as an FQHC or provider-based to a hospital, are they physician practices? How are these facilities organized and related?…*
- *how tribally operated facilities participate in Medicare currently, which would help us to estimate the impacts of such a policy change."*

Coverage Changes for Colorectal Cancer (CRC) Screening Services

Display pages 498 – 502

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; and

- 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 is proposing the following changes to CRC screening coverage:

- Remove coverage for the barium enema procedure;
- Add coverage for the computed tomography colonography (CTC) 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 CRC screening test;
- Delete HCPCS codes G0106 and G0120 (screening barium enema); and
- Reassign CPT code 74263 (screening computed tomography colonography (CTC)/virtual coloscopy) to APC 5522 (Level 2 Imaging Without Contrast).

Table 70 on *Display* page 500 contains the proposed list of covered CRC screening HCPCS codes.

Request for Comment on Payment Adjustments under the IPPS and OPPS for Domestic Personal Protective Equipment (PPE)

Display pages 502 – 512

Currently, payment adjustments are available to offset the marginal costs faced by hospitals in acquiring domestically made surgical N95 respirators in order to assure that hospitals make use of higher quality respirators instead of less expensive, potentially poorly produced foreign ones. CMS is seeking comment regarding a variety of related topics, including, but not limited to:

- Changes to the payment adjustment methodology (*Display* pages 504 – 505)
- Changes to payment adjustment eligibility (*Display* pages 505 – 506)
- The types of N95 respirators covered (*Display* pages 506 – 507)
- The potential inclusion of nitrile gloves in the payment adjustment (*Display* pages 507 – 512)
- The potential inclusion of other forms of PPE and Medical Devices (*Display* page 512)

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

Display pages 512 – 520

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 on *Display* pages 512 – 513.

For CY 2025, CMS is proposing 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 to 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 is proposing to require that hospitals billing for the drug must 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 is also proposing that, if covered as an additional preventive service, all HCPCS codes describing pharmacy supplying fees for HIV PrEP to 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 (IDE) Clinical Trials Policy and Drugs/Devices with a Medicare Coverage with Evidence Development (CED) Designation

Display pages 520 – 526

Currently, CMS has a policy to make a single blended payment for devices and services in Category B 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 is proposing 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 off 95% of AWP, consistent with CMS payment for non-passthrough separately payable drugs under OPPS.

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

Display pages 611 – 643

- **Advancing Health Equity Using Quality Measures** ***(Display pages 611 – 642)*****:** CMS is committed to advancing health equity and improving health outcomes through quality reporting programs. In support of that commitment, CMS is proposing additional measures for use with the OQR, REHQR and ASCQR programs, shown in the table below.

Measure	Programs Affected	Reporting Period	Payment Determination
Hospital Commitment to Health Equity (HCHE) Measure	OQR / REHQR	CY 2025	CY 2027
Facility Commitment to Health Equity (FCHE) Measure	ASCQR	CY 2025	CY 2027
Screening for Social Drivers of Health (SDOH) Measure	OQR / REHQR / ASCQR	CY 2025 (voluntary)	-
	OQR / REHQR / ASCQR	CY 2026	CY 2028
Screen Positive Rate for Social Drivers of Health (SDOH) Measure	OQR / REHQR / ASCQR	CY 2025 (voluntary)	-
	OQR / REHQR / ASCQR	CY 2026	CY 2028

- **Modification to the Immediate Measure Removal Policy for OQR and ASCQR** ***(Display pages 642 – 643)*****:** In the CY 2024 OPPS Final Rule, CMS adopted an immediate measure suspension policy for the REHQR program in lieu of an immediate measure removal policy for events where a measure raises patient safety concerns.

  CMS believes that the same rationale also applies to the Hospital OQR and ASCQR programs, and therefore is proposing, beginning CY 2025, to modify the immediate measure removal policies for these programs so that they may be more appropriately referred to as immediate measure suspension policies.

Updates to the OQR Program

Display pages 643 – 673

The OQR program is mandated by law; hospitals that do not successfully participate are subject to a 2.0 percentage point reduction to the OPPS market basket update for the applicable year.

CMS is proposing the addition of three new health equity measures, listed in the section above, and one outcome-based measure to the OQR program:

- 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.

CMS is also proposing the removal of two measures:

- MRI Lumbar Spine for Low Back Pain Measure Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination; and
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination.

With regard to the three health equity measures being proposed for inclusion, CMS is proposing that HOPDs would be required to submit all required data for the calculation of each measure annually using a CMS-approved, web-based, data collection tool available within the HQR System during the period of January 1 through May 15 in the year prior to that measure's use in payment determination.

For Information Transfer PRO-PM, CMS is proposing that HOPDs would be required to submit all required data for the calculation of each measure annually during the period of January 1 through May 15 in the year prior to that measure's use in payment determination. CMS also proposes to require that HOPDs offer all patients meeting the denominator specifications the opportunity to complete the survey, with a proposed minimum random sample size of 300 completed surveys used to ensure the reliability of the measure. HOPDs unable to collect 300 completed surveys would instead be required to submit data on survey responses from all completed surveys received.

Table 90 on *Display* page 658 lists the 18 measures proposed to be collected for CY 2027 payment determinations. Table 91, listing the 19 measures to be collected for CY 2031 payment determination, is on *Display* page 659 – 660.

Beginning with the CY 2025 reporting period, CMS is proposing to require that electronic health record (EHR) technology be certified to all eCQMs available for reporting, and that HOPDs would be required to use the most recent version of the eCQM electronic measure specifications for the given reporting period, as available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website.

In addition, to monitor the time psychiatric patients spend in the emergency department (ED) relative to other patients, CMS is proposing to make data for the Psychiatric/Mental Health Patients stratification available on Care Compare, beginning CY 2025.

Updates to the REHQR Program

Display pages 673 – 683

The REHQR program is mandated by the CAA of 2021.

CMS is proposing the addition of three new health equity measures to the REHQR program, described in the sections above.

CMS is also proposing a modification to the reporting period of one measure:

- Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure
    - CMS is proposing to increase the reporting period for this measure from one year to two years beginning with the CY 2027 program determination. For CY 2027 determinations, this reporting period would be comprised of data from CYs 2024-2025.

For those hospitals converting to REH status, CMS is proposing that these hospitals must begin submitting data to the REHQR program on the first day of the quarter following the date that a hospital converted to an REH.

To align with the OQR program, CMS is proposing that for the three health equity measures being proposed for inclusion in the REHQR, REHs would be required to submit all required data for the calculation of each measure once annually using

a CMS-approved, web-based, data collection tool available within the HQR System during the period of January 1 through May 15 in the year prior to that measure's use in payment determination.

Table 92 on *Display* page 675 lists the four measures previously adopted for collection for CY 2026 program determinations. Additionally, Table 94 on *Display* pages 679 – 680 lists the seven measures proposed for collection for CY 2027 program determinations. Finally, Table 95 on *Display* page 680 lists the seven measures proposed for collection for CY 2028 program determinations.

Medicaid Clinic Services Four Walls Exception

Display pages 700 – 740

States may offer certain Medicaid benefits, including clinic services, at the individual determination of the state, 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.

In order to address concerns that CMS has heard from multiple parties, and to help states in strengthening and improving access to clinic services, CMS is proposing to add three exceptions to the four walls requirement.

- Clinic services furnished by IHS/Tribal clinics
    - Mandatory exception
    - Facilities operated by urban Indian organizations (UIOs) 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 is inviting comment on what definition of rural to use for this exception (*Display* pages 729 – 738)

Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

Display pages 740 – 742

CMS currently requires prior authorization for the following services: blepharoplasty, rhinoplasty, botulinum toxin injections, panniculectomy, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions. Upon receipt of the prior authorization request, the MAC issues a decision within specific timeframes.

CMS is proposing to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests from ten business days to seven calendar days.

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

Display pages 742 – 746

Continuous eligibility (CE) provides coverage protections for low-income children who are eligible for Medicaid or CHIP and has shown to reduce financial barriers to accessing health care for low-income families, promote health equity, and provide states with better tools to hold health plans accountable for quality care and improved outcomes.

CMS is proposing to update the Medicaid regulations to conform with changes to the CE policy implemented by the CAA of 2023. These changes would specify that a state must provide CE for the specified period of time and removes the option to limit CE to those younger than 19 years of age. Furthermore, CMS is proposing to remove the option to limit CE to a period of less 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 is also proposing to remove the option for states to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a CE period.

Health and Safety Standards for Obstetrical (OB) Services in Hospitals and CAHs

Display pages 746 – 788

- **Organization, Staffing, and Delivery of Services** ***(Display pages 754 – 759)*****:** CMS is proposing to require new conditions of participation (CoPs) that if a hospital or CAH offers OB services outside of an ED, those services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for both physical and behavioral health care of pregnant, birthing, and postpartum patients. If outpatient OB services are offered, these services must be consistent in quality with those provided on an inpatient basis based on the complexity of services offered. In addition, CMS is proposing that the OB services offered be appropriate to the scope of those offered by the facility and integrated with other departments of the hospital. The OB service must maintain a list of practitioners that specifies the privileges of each. OB services delivered must be consistent with the needs and resources of a facility, including the availability of basic resuscitation equipment, a call-in system, cardiac monitor, and fetal doppler or monitor within the labor and delivery room. CMS is further proposing that the service has readily available supplies and equipment consistent with the needs of OB emergencies, complications, immediate post-delivery care, and other patient health and safety events identified as part of a facility's Quality Assessment and Performance Improvement (QAPI) program. CMS also seeks comment on if these proposed requirements should be applicable to REHs.

- **Training for OB Staff in Hospitals and CAHs** ***(Display pages 759 – 767)*****:** Given the prevalence of health and safety concerns around maternal health outcomes, CMS is proposing a core set of requirements for facilities offering OB services in order to protect the health and safety of patients. CMS is thus proposing that hospitals and CAHs with OB services be required to develop policies and procedures to ensure that relevant OB services staff would be trained on select topics for improving maternal care delivery. These training topics would need to reflect the scope and complexity of services offered, including best practices and protocols to improve maternal care delivery. CMS further proposes that facilities providing OB services use findings from their QAPI programs to inform staff training needs. A governing body must identify and document those staff that must complete annual trainings, and staff personnel records must contain information as to if the training was completed successfully, including the demonstration of staff knowledge. CMS seeks public comment in if these requirements should be applicable to REHs, as well as to *"whether CMS should require specific training on person-centered care, trauma-informed care, cultural competency, and/or other topics as part of the evidence-based training."*

- **QAPI Program** ***(Display pages 767 – 777)*****:** CMS is proposing that a hospital or CAH that offers OB services be required to use its QAPI program in order to assess and improve health outcomes and disparities among OB patients on an ongoing basis. This would mean that a facility, at minimum, would have to:

    - analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the facility among OB patients;
    - measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among OB 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 when disparities exist among OB patients; and
    - conduct at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of OB patients annually.

    CMS is also proposing to require that these hospitals' leadership (facility, OB services, or their designees) must be engaged in the facility's QAPI activities. CMS is also asking for public comment on topic listed on *Display pages 776 – 777).*

- **Emergency Services Readiness** ***(Display pages 777 – 783)*****:** CMS is proposing that hospitals and CAHs that offer emergency services would be required to have adequate provisions and protocols to meet emergency needs of patients aligning with the complexity and scope of offered services. In addition, applicable emergency services personnel (as determined by the facility) would be required to be trained on these protocols and provisions annually. Once staff are identified, it is expected that the facility documents that the applicable staff members have successfully completed the training and have demonstrated knowledge on the topic. Finally, CMS is proposing that emergency provisions include equipment, supplies, and medication used in treating emergency cases. These provisions must be kept at the hospital and be readily available, and must include: drugs, blood and blood products and biologicals commonly used in life-saving procedures; commonly used life-saving equipment and supplies; and a call-in-system for each patient in each emergency services treatment area. Additionally, CMS is seeking public comment on the following:

- *"While REHs do have existing equipment, supply, and medication standards, should the above proposals related to provisions, protocols, and staff training apply to REHs as well?*
- *What would be the benefits versus burden of such an approach? How could any burdens be mitigated?"*

- **Transfer Protocols *(Display pages 783 – 788)*:** CMS is proposing to require that hospitals have written policies and procedures for transferring patients under their care. This would include transfers within the four walls of the hospital, as well as between different hospitals. CMS is also proposing that hospitals provide training to the appropriate staff regarding patient transfer policies and procedures. In addition, CMS is seeking comment on the following questions:
  - *"How often should staff be trained in transfer protocols?*
  - *What definitions or criteria exist to determine if a transfer is carried out 'promptly and without undue delay'?*
  - *Should hospitals be required to have written policies and procedures outlining their standards and conditions for accepting transfers?*
  - *Should all hospitals (inclusive of CAHs and REHs) be required to have a documented partnership with another hospital that provides OB services, as well as has a Medical Fetal Medicine (MFM) specialist available for consultations in urgent situations, if such service(s) are already offered directly by the hospital? What would be the benefits versus burden of such a policy? How could any burden be mitigated?"*

Modification to the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measures in the Hospital Inpatient Quality Reporting (IQR) Program

Display pages 788 – 794

Based on hospital performance during the most recent voluntary reporting period, CMS has determined that hospitals appear unprepared for mandatory reporting of the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measures under the Hospital IQR. CMS states that approximately one-third of IPPS hospitals participated during the voluntary reporting period, and other these, 75% would not have met the reporting thresholds for the core clinical data elements (CCDEs) and linking variables, and so would have received a 25% reduction to their annual payment update for the given fiscal year had reporting been mandatory.

Due to this information, CMS is proposing that the submission of CCDEs and linking variables remain voluntary for the FFY 2026 payment determination, with mandatory submission being established for the FFY 2027 payment determination.

Individuals Currently or Formerly in the Custody of Penal Authorities

Display pages 794 – 814

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 (unless that prisoner is legally obligated to pay for such services). 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 is proposing to update 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.

CMS is seeking comment to determine when individuals who are required to reside in halfway houses should be considered in custody for the purposes of this exclusion.

Lastly, CMS is proposing to update the special enrollment period (SEP) eligibility criteria to account for the proposals discussed earlier and to align the criteria with the criteria used by the Social Security Administration (SSA) to determine whether an individual is incarcerated. Specifically, CMS proposes that an individual who is released on or after January 1, 2025 from a jail, prison, or other penal institution or correctional facility would be eligible for the SEP.

Request for Information - Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Measure Group

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CMS is seeking public input on methodologic modifications regarding the Safety of Care measure group within the Overall Hospital Quality Star Rating. An analysis done by CMS has shown a strong relationship between the Safety of Care measure group and the Star Rating, however a provider can still obtain a 5-star rating even if the Safety of Care measure group score is in the bottom quartile. CMS seeks feedback on whether hospitals that fall into this scenario should continue to be eligible to receive a 5-star rating using one of the following methods:

- Reweighting the Safety of Care measure group so that it contributes to more to the Star Rating;
- A policy-based 1-star reduction for providers in the lowest quartile of Safety of Care; or
- A combination of the above approaches.

Specifically, CMS requests comment of the following:

- *"Do you support re-weighting the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care as described in option 1? Do you agree with the potential new weights for each measure group…?*
- *Do you support reducing the Star Rating for hospitals with a low Safety of Care score as described in option 2? Do you agree with the potential policy to apply a 1-star reduction to all hospitals in the lowest quartile of Safety of Care?*
- *Do you support a combination of reweighting the Safety of Care measure group with a 4-star maximum on Star Rating as described in option 3?*
- *Do you have feedback or preference towards an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2?*
- *What are other methodological approaches that could be used to emphasize the Safety of Care measure group?*
- *With respect to the potential changes to the Overall Hospital Quality Star Rating methodology, are there any special considerations for small, rural or safety net hospitals (including Critical Access hospitals)?"*

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