# Medicare Outpatient Prospective Payment System

CY2024 Proposed Payment Rule Brief provided by the Wisconsin Hospital Association

## Overview

The proposed calendar year (CY) 2024 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on July 13, 2023. 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 10 services from the Inpatient-Only (IPO) list;
- Expand the partial hospitalization program (PHP) rate structure;
- Establish an Intensive Outpatient Program (IOP);
- Standardize the reporting of standard chart data using a CMS template;
- Outline quality program requirements for Rural Emergency Hospitals (REHs);
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) 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 are due to CMS by September 11, 2023 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "CMS-1786–P".

An online version of the CY 2024 OPPS proposed rule is available at https://www.federalregister.gov/d/2023-14768. 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 $6.0 billion increase in OPPS payments for CY 2024 over CY 2023.

In addition, this brief covers the "Remedy for the 340B-Acquired Drug Payment Policy" (340B Remedy) proposed rule, released on July 7, 2023, which is available online at https://www.federalregister.gov/d/2023-14623. Comments on that proposed rule are due to CMS by September 5, 2023 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "CMS-1793–P".

***Note:*** Text in italics is extracted from the July 13, 2023 Display copy of the OPPS proposed rule, or from the July 11, 2023 *Federal Register* for the "340B Remedy" proposed rule.

## OPPS Payment Rate

***Display pages 15 – 16, 82 – 113, and 457 – 461***

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 2022 claims data and CY 2021 Healthcare Cost Report Information System (HCRIS) data from the December 2022 extract.

The tables below show the final CY 2023 conversion factor compared to proposed CY 2024 and the components of the CY 2024 update factor:

| | Final CY 2023 | Proposed CY 2024 | Percent Change |
|---|---|---|---|
| OPPS Conversion Factor | $85.585 | $87.488 | +2.22% |

| Proposed CY 2024 Update Factor Component | Value |
|---|---|
| Marketbasket (MB) Update | +3.0% |
| Affordable Care Act (ACA)–Mandated Productivity | –0.2 percentage points (PPT) |
| Wage Index Budget Neutrality (BN) Adjustment | -0.26% |
| Wage Index 5% Stop Loss BN | -0.25% |

| | |
|---|---|
| Pass–through Spending / Outlier BN Adjustment | -0.10% |
| Cancer Hospital BN Adjustment | +0.05% |
| ***Overall Proposed Rate Update*** | **+2.22%** |

## Adjustments to the Outpatient Rate and Payments

- **Wage Indexes *(Display pages 88 – 95)*:** As in past years, for CY 2024 OPPS payments, CMS is proposing to continue to use the federal fiscal year (FFY) 2024 inpatient PPS (IPPS) wage indexes, including all reclassifications, add–ons, rural floors, and budget neutrality adjustments.

  Due to litigation determining that the Secretary does not have the authority to establish a rural floor lower than the rural wage index floor in a state, in the FFY 2024 IPPS proposed rule, CMS proposed to treat §412.103 (redesignated rural) hospitals the same as geographically rural hospitals for the rural wage index calculation, including those hospitals with other reclassifications.

  Additionally, CMS has a longstanding hold harmless policy to prevent the rural wage index of a state from being lowered by hospitals that reclassify to a state's rural area. Due to the proposal above, the rural wage index would no longer be held harmless from in-state hospitals reclassifying as rural under §412.103. However, for hospitals who have a state-to-state MGCRB reclass, in the FFY 2024 IPPS proposed rule, CMS proposed to continue this hold harmless policy to exclude the data of hospitals reclassifying into another state's rural area if doing so would reduce that state's rural wage index.

  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. These adopted changes are to be in effect for a minimum of four years in order to be properly reflected in future Medicare cost reports. As such, CMS is proposing to continue to increase the wage index value of low-wage index hospitals for CY 2024. 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. CMS is proposing continue to offset these increases by applying a budget neutrality adjustment to the national standardized amount. In the FFY 2024 IPPS proposed rule, the value of the 25th percentile wage index is 0.8615.

  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 is has been appealed by CMS. Given there is only one year of relevant data (FFY 2020) that CMS could use to evaluate any potential impacts of the policy on hospital wages, CMS believes it necessary to wait until usable data from additional fiscal years is available before making a decision to modify or discontinue the policy for additional years. CMS may take a different approach in the final rule for FFY 2024 than proposed above based on public comment and court decisions.

  In the FFY 2023 IPPS final rule, CMS finalized the application of a 5% cap on any decrease of the FFY 2023 hospital wage index, and all future wage indexes, compared with the previous year's wage index. This same cap is in place for OPPS. The cap is to be 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 would 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 0.9974 for CY 2024 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 0.9975 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 2024, CMS is proposing to continue to use a labor–related share of 60%.

- **Payment Increase for Rural Sole Community Hospitals (SCH) and Essential Access Community Hospitals (EACH) *(Display pages 96 – 97)*:** 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 will maintain this for future years until data supports a change to the adjustment.

- **Cancer Hospital Payment Adjustment and Budget Neutrality Effect** ***(Display pages 17 – 18, 85 – 86, and 97 – 103):*** 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 was budget neutral).

  In order to determine a budget neutrality factor for the cancer hospital payment adjustment for CY 2024, CMS reduced the CYs 2020 through 2023 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. CMS proposes that this policy will apply for CY 2024 and subsequent years, 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 0.88 for each cancer hospital. Therefore, CMS is proposing a 0.05% adjustment to the CY 2024 conversion factor to account for this policy.

- **Outlier Payments** ***(Display pages 104 – 108)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is proposing to use CY 2022 claims to calculate a CY 2024 outlier fixed–dollar threshold of $8,350. This is a 3.2% decrease compared to the current threshold of $8,625. 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 34 – 82, 121 – 342, and 518 – 535***

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 2024 are available in Addenda A and B within Addendum P of the proposed rule at https://www.cms.gov/license/ama?file=/files/zip/2024-nprm-opps-addenda.zip.

The table below shows the update in the number of APCs per category from CY 2023 to CY 2024 (Addendum A):

| APC Category | Status Indicator | Final CY 2023 | Proposed CY 2024 |
|---|---|---|---|
| Pass–Through Drugs and Biologicals | G | 96 | 75 |
| Pass–Through Device Categories | H | 12 | 7 |
| OPD Services Paid through a Comprehensive APC | J1 | 69 | 71 |
| Observation Services | J2 | 1 | 1 |
| Non–Pass–Through Drugs/Biologicals | K | 389 | 469 |
| Partial Hospitalization | P | 2 | 8 |
| Blood and Blood Products | R | 40 | 40 |
| Procedure or Service, No Multiple Reduction | S | 82 | 82 |
| 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** | | **859** | **921** |

- **Calculation of Cost-to-Charge Ratios (CCRs)** ***(Display pages 35 – 40):*** For CY 2024, CMS is proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios to convert charges to estimated costs. Historically, CMS has not included cost report lines for certain 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. In the CY 2023 proposed rule, CMS requested comment on the inclusion of these non-standard cost center lines, including

comments related to the accuracy of the data. CMS believes more information is needed before including these lines in OPPS ratesetting and therefore CMS is proposing not to include them.

- **Blood and Blood Products** ***(Display pages 40 – 42)*****:** For CY 2024, CMS is proposing to continue its policy to establish payment rates for blood and blood products using a blood–specific CCR methodology.

- **New Comprehensive APCs** ***(Display pages 46 – 61)*****:** A Comprehensive Ambulatory Payment Classification (C-APC) provides all–inclusive payments for certain procedures. 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 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 proposing to create two C-APCs for CY 2024 for a total of 72 C-APCs. In order to do this, CMS is proposing to split the Level 2 Intraocular APC (APC 5492) into two and assign the higher cost procedures previously within this APC to a new Level 3 Intraocular APC (APC 5493). The previous Level 3, Level 4, and Level 5 Intraocular APCs (APCs 5493, 5494, and 5495) will be renamed the Level 4, Level 5, and Level 6 Intraocular APC (APCs 5494, 5495, and 5496), respectively. Separately, CMS is proposing to add a new Level 2 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5342) to improve clinical and resource homogeneity in the Level 1 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5341). The proposed C-APCs derived from the new APCs are as follows:

  - Level 2 Abdominal/Peritoneal/Biliary and Related Procedures (C-APC 5342); and
  - Level 6 Intraocular Procedures (C-APC 5496).

  A list of the proposed 72 C–APCs for CY 2024 C-APCs can be found on Display pages 59 – 61.

- **Composite APCs** ***(Display pages 61 – 70):*** 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); and
  - Multiple Imaging Services (APCs 8004, 8005, 8006, 8007, and 8008).

  For CY 2024, CMS is proposing to continue its policy that when the aggregate payment for specified mental health services provided by a hospital to a single beneficiary on a single date of service exceeds the maximum per diem payment rate for partial hospitalization services, those services will continue to instead be paid through composite APC 8010. In addition, the payment rate for composite APC 8010 is proposed to continue to be set to that established for APC 5863, which is a partial hospitalization per diem payment rate for 3 partial hospitalization services furnished in a day by a hospital. CMS notes that APC 5863 would no longer be the maximum partial hospitalization per diem payment rate for a hospital, due to proposed APC 5864 (4 or more hospital-based partial hospitalization services per day), but still believes that APC 5863 is appropriate. However, since historically CMS has set the daily mental health cap for APC 8010 at the maximum partial hospitalization per diem payment rate or a hospital, CMS is soliciting feedback on whether proposed APC 5864 should be used instead.

  For CY 2024, 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 2 on Display pages 66 – 70 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 182 – 184*):** For CY 2024, CMS is proposing 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 years of claims data to set the payment rate for the APC.

- **Packaged Services** ***(Display pages 70 – 79 and 518 – 535)*****:** CMS is proposing to continue to create more complete APC payment bundles over time in order to package more ancillary services when they occur on a claim with another service, and to only pay for them separately when performed alone. With this, CMS is looking for comment on potential modifications to its current packaging policy, specifically on:
    - Access to Non-Opioid Treatments for Pain Relief (Display page 72);
    - OPPS Packaging Policy for Diagnostic Radiopharmaceuticals (Display pages 72 – 75);
    - Potential Issues Caused by Current Payment of Diagnostic Radiopharmaceuticals Under the OPPS (Display pages 75 – 76); and
    - New Approaches to Payment of Diagnostic Radiopharmaceuticals Under the OPPS (Display pages 76 – 79).

    For CY 2024, CMS is proposing to continue to unpackage, and pay separately at average sales price (ASP)+6%, the cost of non–opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. CMS will not pay separately for these drugs when furnished in the Hospital Outpatient Department (HOPD) 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.

    CMS is proposing that Posimir, HCPCS C9144, would no longer receive separate payment in the ASC setting under this policy, as this drug will be separately payable during CY 2024 under OPPS transitional pass-through status. Table 63 on Display page 528 lists the products that are proposed to continue to have separate payment in the ASC setting under this policy for CY 2024. CMS is soliciting comments on new products that meet the criteria for this policy.

    Separately, the Consolidated Appropriations Act (CAA) of 2023 states that in the case of surgical services furnished January 1, 2025 through December 31, 2027, additional payments should be made under the ASC payment system for non-opioid treatments for pain relief under OPPS. CMS is soliciting comment on any drug, biological, or medical device that a commenter believes would meet the definition of a non-opioid treatment for pain relief beginning CY 2025 and encourages the submission of submit evidence-based support with comments. In addition, CMS is asking for comment on the best way to obtain and evaluate peer-reviewed journals and clinical trial data. Lastly, CMS is seeking comment on how to determine the HOPD service or groups of services with which non-opioid treatments for pain relief are furnished for purposes of calculating the payment limitation for each treatment.

- **Payment for Medical Devices with Pass–Through Status** ***(Display pages 185 – 262 and 336 – 342)***: There are currently 15 device categories that are eligible for pass–through payment:
    - C1824 – Generator, Cardiac contractility modulation (implantable);
    - C1982 – Catheter, pressure–generating, one–way valve, intermittently occlusive;
    - C1839 – Iris prosthesis;
    - C1734 – Orthopedic/device/drug matrix for opposing bone–to–bone or soft tissue–to bone (implantable);
    - C2596 – Probe, image–guided, robotic, waterjet ablation;
    - C1052 – Hemostatic agent, gastrointestinal, topical;
    - C1062 – Intravertebral body fracture augmentation with implant (for example, metal, polymer);
    - C1825 – Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s);
    - C1761 – Catheter, transluminal intravascular lithotripsy, coronary;
    - 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; and
    - C1747 - Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable).

    CMS has received 6 applications for device pass–through payment applications since the March 1, 2023 quarterly deadline:

    - CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath;

- CERAMENT® G;
- Ambu® aScopeTM 5 Broncho HD;
- Praxis Medical CytoCore;
- EchoTip®; and
- FLEX Vessel Prep™ System.

- **Device–Intensive Procedures** ***(Display pages 262 – 270)*****:** 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.

  For CY 2024, CMS is not proposing any changes to the device-intensive policy.

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

- **Device Edit Policy** ***(Display pages 270 – 273)*****:** CMS is proposing to 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 Level 5 Intraocular APC (which CMS proposes to reassign to a new Level 6 Intraocular APC 5496) would 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 procedures assigned to APC 5496, listed below:

  - CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) describes the implantation of device HCPCS code C1840 (Lens, intraocular (telescopic));
  - CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens) describes the implantation of device HCPCS code C1839 (Iris prosthesis);
  - CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) describes the implantation of device HCPCS code C1840 (Lens, intraocular (telescopic)); and
  - CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens) describes the implantation of device HCPCS code C1839 (Iris prosthesis).

  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 273 – 275)*****:** 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 2024, CMS is not proposing any major changes to the no cost/full credit and partial credit device policies.

- **Payment for Drugs, Biologicals and Radiopharmaceuticals** ***(Display pages 275 – 318 and 336 – 342)*****:** 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 2024, CMS is proposing a packaging threshold of $140. Drugs, biologicals, and radiopharmaceuticals 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 2024 is the 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 2024, CMS is also proposing to continue to pay for therapeutic radiopharmaceuticals with pass–through payments status as well as blood clotting factors, based on ASP + 6%. 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.

CMS has concerns that packaging biosimilars when the reference biological or other marketed biosimilar are separately paid may create financial incentives for provides to select more expensive, but clinically similar, products. Therefore, CMS proposes that beginning CY 2024, biosimilars would be exempt from the OPPS threshold packaging policy when their reference biologicals are separately paid (CMS would paid separately for these biosimilars even if their per-day cost is below the packaging threshold). If a reference product's per-day cost falls below the threshold, CMS proposes that all the biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold in order to have consistent treatment of similar biological products.

Lastly, CMS is proposing that the pass–through status expire by December 31, 2023 for 43 drugs and biologicals, listed in Table 35 on Display pages 279 – 282; by December 31, 2024 for 25 drugs and biologicals listed in Table 36 on Display pages 284 – 287; and proposing to continue/establish pass–through status in CY 2024 to 42 drugs and biologicals shown in Table 37 on Display pages 289 – 293.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes** ***(Display pages 323 – 332)*****:** 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 products per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group.

  CMS is proposing to continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high cost group in CY 2023 to the high cost group in CY 2024 as well. CMS will also assign those with pass-through payment status to the high cost category.

  The list of proposed packaged skin substitutes and their group assignments may be found in Table 41 on Display pages 328 – 332.

- **Payment for Drugs Purchased under the 340B Drug Discount Program** ***(Display pages 318 – 323)*****:** The 340B Drug Pricing Program, administered by the Health Resources & Services Administration (HRSA), allows participating hospitals and other healthcare providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers.

  In CY 2018, due to a correlation between increases in drug spending and hospital participation in the 340B program, as well as CMS' belief that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs, CMS changed the Medicare Part B drug payment methodology for 340B hospitals to reduce payment.

  Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. The 340B-acquired drug payment policies were involved in a continuing lawsuit, *American Hospital Association v. Becerra.* On July 15, 2022, the Supreme Court stated that payment rates for drugs and biologicals may not vary among groups of hospitals in the absence of survey of hospitals' acquisition cost. On September 28, 2022, the district court ruled to vacate the 340B reimbursement for the remainder of 2022.

  Therefore, CMS proposes a rate of ASP + 6% for 340B drugs in CY 2024, regardless of whether or not the product was acquired through the 340B program. If ASP data are not available, payment instead would be made based on WAC + 3%; or 95% of AWP if WAC data are also not available.

  In July 2023, CMS published a "remedy proposed rule" to address the reduced payment amounts to 340B hospitals under the reimbursement rates in the CYs 2018 through 2022 OPPS final rules. The remedy proposed rule does not propose changes to CY 2024 OPPS drug payment policies nor the conversion factor, but does propose changes to the calculation of the OPPS conversion factor beginning in CY 2025. Please refer to the final section of this brief and the remedy proposed rule for additional information.

In CY 2023, modifiers "JG" and "TB" still applied for informational purposes, but had no effect on payment rates. Modifier "JG" was used by non–exempt hospitals to report separately payable drugs that were acquired through the 340B program. Modifier "TB" was used by hospitals exempt from the 340B payment adjustment to report separately payable drugs that were acquired through the 340B program. These exempt hospitals include rural SCHs, children's hospitals, PPS–exempt cancer hospitals, and PPS-exempt critical access hospitals (CAHs).

CMS now believes using a single modifier will allow for greater simplicity. Also, both modifiers are currently used to identify separately payable drugs and biologicals acquired under the 340B program. Therefore, CMS is proposing to only require a single modifier "TB" for 340B covered entities, effective January 1, 2025. The "JG" would remain effective through December 31, 2024 if a hospital desires to use it.

## Other OPPS Policies

- **PHP and IOP Services** ***(Display pages 343 – 389)*****:** The PHP is an intensive outpatient psychiatric program to provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding Community Mental Health Center (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 is proposing 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). Patient eligibility criteria would be as follows:

  - *"require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care;*
  - *are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;*
  - *do not require 24-hour care;*
  - *have an adequate support system while not actively engaged in the program;*
  - *have a mental health diagnosis;*
  - *are not judged to be dangerous to self or others; and*
  - *have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program."*

  CMS proposes to allow IOP services to include individual and group therapy, occupational therapy, drugs and biologicals furnished for therapeutic purposes, which cannot be self-administered, family counseling, beneficiary education, and diagnostic services. On Display pages 352 – 358 CMS describes the items and services available under the IOP benefit.

  CMS would allow CMHCs to be a participating provider of both PHP services and IOP services. CMS is proposing to add 18 HCPCS codes to the current list of codes that are recognized for PHP payments to address IOP services. These codes can be found in Table 43 on Display pages 365 – 366. CMS is soliciting comment on how the addition of IOP services for CMHCs may impact the potential to meet the requirement that 40% of a CMHCs services must be to individuals who are not eligible for Medicare Part B.

  Beginning CY 2024, CMS is proposing to establish four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-services days, and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days. This is because the standard PHP day is typically four services or more per day. CMS proposes to continue to calculate CMHC payment rates based solely on CMHC claims, in order to recognize differences in cost structures for different PHP providers. However, CMS is considering whether establishing a site-neutral payment for using data from all providers of IOP would be more appropriate in an effort to increase access to mental health services.

  CMS is also proposing to establish consistent coding and payment between the PHP and IOP benefits, and therefore is proposing to consider all OPPS data for PHP days and non-PHP days that include 3 services per day and 4 services per day, CMS is proposing to establish four separate IOP APC per diem payment rates at the same rates proposed for PHP APCs.

  The table below compares the final CY 2023 and proposed CY 2024 PHP and IOP payment rates (Addendum A):

| | Final Payment Rate 2023 | Proposed Payment Rate 2024 | % Change |
|---|---|---|---|
| APC 5851: Intensive Outpatient (3+ services) for CMHCs | - | $96.49 | - |
| APC 5852: Intensive Outpatient (4+ services) for CMHCs | - | $151.36 | - |
| APC 5853: Partial Hospitalization (3+ services) for CMHCs | $142.70 | $96.49 | -32.38% |
| APC 5854: Partial Hospitalization (4+ services) for CMHCs | - | $151.36 | - |
| APC 5863: Partial Hospitalization (3+ services) for Hospital–based PHPs | $268.22 | $280.80 | +4.69% |
| APC 5864: Partial Hospitalization (4+ services) for Hospital–based PHPs | - | $364.04 | - |
| APC 5861: Intensive Outpatient (3+ services) for Hospital–based IOPs | - | $280.80 | - |
| APC 5862: Intensive Outpatient (4+ services) for Hospital–based IOPs | - | $364.04 | - |

With the addition of payment rates for 4 services per day based on cost per day using all OPPS data, CMS is proposing not to apply PHP-specific trims and data exclusions, but instead to apply the same trims and data exclusions consistent with OPPS.

Separately, CMS is proposing to require the physician certification for PHP services to include a certification that the patient requires such services for a minimum of 20 hours per week after 18 days, with subsequent recertification's no less than every 30 days, as required by the CAA of 2023.

Lastly, 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. However, if the proposal to allow CMHCs to provide and bill for IOP services is adopted, CMS proposes to expand the calculation of the CMHC outlier percentage to include PHP and IOP.

- **RHC and FQHC** ***(Display pages 389 – 403)*****:** Beginning CY 2024, as required by the CAA of 2023, services of a marriage and family therapist or mental health counselor are covered under RHC and FQHC services if the MFT or MHC is employed or under contract with the RHC or FQHC at the time the services are furnished. Also starting CY 2024, IOP services are covered in both RHCs and FQHCs. CMS proposes the same standards for IOP services in RHC/FQHC as described in the section above.

  The CAA of 2023 also allows for special payment rules for furnishing intensive outpatient services in both FQHCs and RHCs, both equal to the amount that would have been paid under Medicare IOP services had they had been covered outpatient department services furnished by a hospital; that is the payment rates listed in the section above for 3 services per day for RHCs and for FQHCs would be the lesser of a FQHC's actual charges or the 3-services per day payment amount for hospital outpatient departments. Both facility types would be required to report condition code 92 to identify intensive outpatient claims.

- **Payment for IOP Services Furnished by Opioid Treatment Programs (OTPs)** ***(Display pages 403 – 421)*****:** OTP intensive outpatient services are defined as *"services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician certification and plan of care."*

  CMS is proposing to cover IOP services that are furnished in OTPs and meet the criteria specified. A weekly payment adjustment via an add-on code for IOP services furnished by OTPs for the treatment of opioid use disorder is proposed. IOP services provided by OTPs would be paid for as long as each service is medically reasonable and necessary, and not duplicative of any service paid for under any bundled payments billed for an episode of care in a given week.

- **Inpatient–Only List** ***(Display pages 423 – 427)*****:** The IPO list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2024, CMS is not proposing to remove any of the following services from the IPO list.

  CMS is proposing to add the following services to the IPO list:

  - CPT X114T: Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed;
  - CPT 2X002: Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments;

- CPT 2X003: Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments;
- CPT 2X004: Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed;
- CPT 619X1: Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s);
- CPT 7X000: Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic;
- CPT 7X001: Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report;
- CPT 7X002: placement, manipulation of transducer, and image acquisition only;
- CPT 7X003: interpretation and report only; and
- CPT 0646T: Transcatheter tricuspid valve implantation (ttvi)/replacement with prosthetic valve, ercutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed.

The list of measures that are proposed to be added to the IPO list is available on Display page 427.

- **Payment for Off–Campus Outpatient Departments** ***(Display pages 342 – 343, 421 – 423, and 431 - 436)*****:** 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 PBDs, CMS expanded the MPFS payment methodology to excepted off–campus PBDs for HCPCS code G0463.

  For CY 2024, CMS is proposing that excepted off-campus PBDs of rural SCHs be exempt from the clinic visit payment policy because 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 2024. These excepted PBDs continue to bill HCPCS code G0463 with modifier "PO".

  Separately, CMS is soliciting comment on whether it would be appropriate to apply a different methodology for calculating PHP and IOP rates for nonexcepted off-campus hospital outpatient departments.

  Lastly, CMS observed that this reduction to non-excepted PBDs for intensive cardiac rehabilitation (ICR) services resulted in an unintended reimbursement disparity between excepted and non-excepted sites of service. Therefore, beginning January 1, 2024, CMS is proposing to pay for ICR services provided by an off-campus, non-excepted PBD of a hospital at 100% of the OOPS rate for cardiac rehabilitation services, rather than 40% of the OPPS rate.

## Updates to the Hospital Outpatient Quality Reporting (OQR) Program

***Display pages 549 – 634***

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 marketbasket update for the applicable year.

CMS is proposing to remove one measure beginning with the CY 2024 reporting period/CY 2026 payment determination:

- Left Without Being Seen.

Additionally, CMS proposes to modify three previously adopted measures beginning with the CY 2024 reporting period/CY 2026 payment determination:

- COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure to use the term "up to date" in the HCP vaccination definition and to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines, including booster doses;
- Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure to allow HOPDs to use the Visual Function Patient Questionnaire (VF-14), the Visual Functioning Index Patient Questionnaire (VF-8R), or the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) survey instruments for administering and calculating the measure; and

- Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure to update the denominator by replacing the phrase “aged 50 years” with the phrase “aged 45 years”.

Lastly, CMS is proposing to add three new measures to the OQR program:

- Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures with modification to more granularly collect and publicly display data reported for the top five most frequently performed procedures among HOPDs within each category (voluntary CY 2025 reporting period with mandatory reporting CY 2026 reporting period/CY 2028 payment determination);
- Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM) (voluntary CYs 2025 and 2026 reporting periods with mandatory reporting CY 2027 reporting period/CY 2030 payment determination); and
- Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults measure (voluntary CY 2025 reporting period with mandatory reporting CY 2026 reporting period/CY 2028 payment determination).

In addition, CMS is proposing to publically report measure data for Median Time for Discharged Emergency Department (ED) Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate beginning with CY 2024.

CMS seeks comment on the following measurement topics with regard to the Hospital OQR program:

- Promoting safety (patient and workforce) (Display pages 603 – 607);
- Behavioral health (Display pages 607 – 611); and
- Telehealth (Display pages 611 – 613).

A table listing the 18 measures to be collected for CY 2026 payment determinations is on Display page 598. A table listing the 21 measures to be collected for CY 2027 payment determination is on Display page 599.

## Reporting Discarded Amounts of Certain Single-dose or Single-use Package Drugs

***Display pages 335 – 336***

In the CY 2024 Medicare Physician Fee Schedule (PFS) proposed rule, CMS proposed to implement section 90004 of the November 15, 2021 Infrastructure Act which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. This impacts both HOPDs and ASCs.

Hospitals can refer to Display pages 417 – 442 of the CY 2024 Medicare PFS proposed rule at https://www.federalregister.gov/d/2023-14624 for more detail on proposals regarding the date of the initial report to manufacturers and subsequent reports, method of calculating refunds amounts, increased applicable percentages for certain drugs with unique circumstances, a future application processes, and modification to the JW and JZ modifier policy for drugs payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug.

## Supervision by Nurse Practitioners (NP), Physician Assistants (PA), and Clinical Nurse Specialists (CNS) of Cardiac Rehabilitation (CR), ICR, and Pulmonary Rehabilitation (PR) Services Furnished to Hospital Outpatients

***Display pages 428 – 431***

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 proposed rule, CMS proposed to revise regulations in order to match the new requirements.

In the April 6th, 2020 “Policy and Regulatory Provisions in Response to the COVID-19 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 proposes to include PR, CR, and ICR with NPs, PAs, and CNSs under the above. CMS is also asking for comments on whether there are safety and/or quality of care concerns regarding

adopting this policy beyond the current or proposed extensions and what policies CMS could adopt to address those concerns if the policy were extended beyond 2023.

## OPPS Payment for Specimen Collection for COVID-19 Tests

***Display pages 436 – 437***

In the May 8th, 2020 COVID-19 interim final rule with comment period, CMS created a new E/M code, HCPCS code C9803: "Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–COV–2) (coronavirus disease [COVID–19]), any specimen source, to support COVID-19 testing during the public health emergency". As of May 11, 2023, the public health emergency ended, and therefore CMS is proposing to delete this code, effective January 1, 2024.

## Remote Services

***Display pages 438 – 442***

In the CY 2023 OPPS final rule, CMS created three HCPCS C-codes (C7900 – C7902) to describe mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. In order to reduce administrative burden and enhance access to these services, CMS is proposing to create a single new untimed, HCPCS C-code describing group therapy:

- C79XX: Group psychotherapy service for diagnosis, evaluation, or treatment of a mental health or substance use disorder provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service.

CMS is soliciting comment on whether or not the previously finalized three HCPCS C-codes would no longer be used to report group psychotherapy and therefore their code descriptors should be refined to stipulate that they are solely for services furnished to an individual beneficiary. CMS is also proposing to remove the word "initial" from the descriptors of these codes. The proposed descriptors are listed in Table 52 on Display page 440.

In the CY 2023 OPPS final rule, CMS also adopted the requirement that a beneficiary receive an in-person visit within 6 months prior to the first time a mental health service is provided remotely, and that there must be an in-person visit within 12 months of each mental health service furnished remotely by the hospital clinical staff. CMS also adopted exceptions to the latter requirement if the hospital clinical staff member and the beneficiary agree that the risks and burdens of an in-person service outweigh the benefits, which must be documented. This in-person 6 month visit requirement did not include beneficiaries who began receiving mental telehealth services in their homes during the PHE or the 151-day period after the end of the PHE before the in-person visit requirements go into effect.

The CAA of 2023 extended the delay in implementation of the in-person visit requirements until January 1, 2025.

Separately, the CAA of 2023 extended additional flexibilities for Medicare telehealth services, including *"retention of physical and occupational therapists and speech-language pathologists as telehealth distant site practitioners, through the end of CY 2024".* In addition, the CY 2024 PFS proposed rule proposes to continue to make payment for outpatient therapy services, diabetes self-management training, and medical nutrition therapy when furnished via telehealth by qualified employed staff of institutional providers through the end of CY 2024.

## OPPS Payment for Dental Services

***Display pages 442 – 457***

CMS adopted policies in the CY 2023 PFS final rule to allow for payment for certain dental services performed in outpatient settings. However, there are currently only 57 CDT codes that are assigned to APCs and payable under OPPS for dental services.

In the CY 2023 OPPS final rule, CMS created HCPCS code G0330 to describe facility services for dental rehabilitation procedure(s) furnished to patients who require monitored anesthesia and use of an operating room. This code cannot be used to describe or bill the facility fee for non-covered services.

To ensure that dental services can be paid under the OPPS, CMS is proposing to assign an additional 229 dental codes to APCs for CY 2024 that enable them to be paid for under OPPS, listed in Table 53 on Display pages 448 – 453.

CMS is proposing to package payments for dental services that are performed with another covered dental or medical service.

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

***Display pages 461 – 463***

Currently, IHS and Tribally-Owned facilities have been 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. Therefore, CMS is seeking comment on several areas, listed on Display pages 462 – 463:

- *"What universe of drugs would be appropriate for separate payment? How could CMS maintain that list and add or remove drugs from it?*
- *Would paying separately for all drugs over a certain cost threshold be easier to operationalize than paying separately for a specified list of drugs, while achieving the same policy objective? If so, what would be an appropriate cost threshold and how should it be updated?*
- *What would be the appropriate payment rate for any separately paid drugs? How should these rates be updated and should these rates be updated on an annual basis?*
- *Would the standard OPPS Average Sales Price (ASP) plus 6 percent payment methodology rate be too high of a payment rate if tribal and IHS facilities are able to acquire drugs at a discounted rate through the Federal Supply Schedule? Would a payment rate equivalent to the acquisition cost of the drug through the Federal Supply Schedule be a more appropriate approximation of the cost of these drugs?*
- *Should IHS remove the cost of any separately paid drugs from the calculation of the AIR? If the cost of these drugs was not removed from the AIR, would the government be paying twice for these drugs?*
- *How would IHS and tribally-owned facilities bill for separately paid drugs? Could they use the UB-04 form like standard OPPS hospitals?"*

## Hospital Price Transparency

***Display pages 752 – 808***

CMS is proposing to amend several hospital price transparency requirements to improve monitoring and enforcement capabilities that reduce the compliance burden on hospitals. Specifically, CMS is proposing to:

- Define several items related to the new proposals;
- Revise the standard charge information and data elements that hospitals must include in their machine-readable file (MRF) (summarized in Table 84 on Display pages 780 - 781), including the requirement of each hospital to affirm directly in the MRF that all applicable standard charge information is included and is accurate as of the date of the MRF, as well as require hospitals to use a template developed by CMS in order to standardize the displayed MRF data files. Each hospital must encode, as applicable, all standard charge information corresponding to each required data element in its MRF;
- Enforce a 60 day grace period for adoption and conformation to the new CMS template and encoding of standard charge information of the newly proposed data elements;
- Improve the accessibility of the hospital MRF by requiring hospitals to include a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available webpage that hosts the link to the MRF; and
- Improve enforcement processes by updating methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance.

CMS is seeking additional ideas for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives. Specific areas for comment are listed on Display pages 807 – 808:

- *"How, if at all, and consistent with its underlying legal authority, could the HPT consumer-friendly requirements at § 180.60 be revised to align with other price transparency initiatives?*
- *How aware are consumers about healthcare pricing information available from hospitals? We solicit recommendations on raising consumer awareness.*

- *What elements of health pricing information do you think consumers find most valuable in advance of receiving care? How do consumers currently access this pricing information? What are consumers' preferences for accessing this price information?*
- *Given the new requirements and authorities through TIC final rules and the NSA, respectively, is there still benefit to requiring hospitals to display their standard charges in a "consumer-friendly" manner under the HPT regulations?*
- *Within the contours of the statutory authority conferred by section 2718(e) of the PHS Act, should information in the hospital consumer-friendly display (including the information displayed in online price estimator tools) be revised to enhance alignment with price information provided under the TIC final rules and NSA regulations? If so, which data should be revised and how?*
- *How effective are hospital price estimator tools in providing consumers with actionable and personalized information? What is the minimum amount of personalized information that a consumer must provide for a price estimator tool to produce a personalized out-of-pocket estimate?*
- *How are third parties using MRF data to develop consumer-friendly pricing tools? What additional information is added by third parties to make standard charges consumer-friendly?*
- *Should we consider additional consumer-friendly requirements for future rulemaking, and to the extent our authorities permit? For example, what types of pricing information might give consumers the ability to compare the cost of healthcare services across healthcare providers? Is there an industry standard set of healthcare services or service packages that healthcare providers could use as a benchmark when establishing prices for consumers?"*

## Potential Payment under IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines

***Display page 818– 829***

CMS recognizes the importance of supporting practices that can limit drug shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries. Therefore, CMS is seeking comment on *"separate payment under IPPS for the IPPS share of the reasonable costs of establishing and maintaining access to a 3-month buffer stock of one or more essential medicine(s). Essential medicines for the potential IPPS separate payment would be the 86 essential medicines prioritized in the report Essential Medicines Supply Chain and Manufacturing Resilience Assessment. An adjustment under OPPS could be considered for future years."*

Based on review of comments received, CMS may finalize this beginning January 1, 2024. Specific areas for comment can be found on Display pages 827 – 829.

## Rural Emergency Hospitals

***Display pages 694 – 744 and 812 – 818***

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.

CAHs and rural hospitals (or hospitals treated as rural) with less than or equal to 50 beds and that meet the following requirements are eligible to convert to an REH.

- *"an annual per patient average of 24 hours or less in the REH;*
- *staff training and certification requirements established by the Secretary;*
- *emergency services CoPs applicable to CAHs;*
- *hospital emergency department CoPs determined applicable by the Secretary;*
- *the applicable SNF requirements (if the REH includes a distinct part SNF);*
- *a transfer agreement with a level I or level II trauma center; and*
- *any other requirements the Secretary finds necessary in the interest of the health and safety of individuals who are furnished REH services."*

## Payment for IHS and Tribal Hospitals

*Display pages 815 – 818*

Currently IHS and Tribal hospitals are excluded from OPPS and paid at the AIR. CMS is proposing that an IHS or Tribal hospital that converts to an REH will also be paid at the AIR. These hospitals would still receive the REH monthly facility payment as it is made to other REH facilities.

## Requirements for the REH Quality Reporting (REHQR) Program

*Display pages 694 – 744*

The REHQR program is mandated by the CAA of 2021.

CMS is proposing to adopt four measures into the REHQR program beginning CY 2024, all of which are currently part of the OQR program:

- Abdomen Computed Tomography (CT) – Use of Contrast Material;
- Median Time from ED Arrival to ED Departure for Discharged ED Patients;
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery.

CMS is also proposing to adopt a measure retention policy for the REHQR program where once adopted into the REHQR, measures would be retained for use until CMS proposes otherwise.

Specifically, CMS proposes to adopt eight conditions to determine if a measure should be removed from the program:

- *"Factor 1. Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures).*
- *Factor 2. Performance or improvement on a measure does not result in better patient outcomes.*
- *Factor 3. A measure does not align with current clinical guidelines or practice.*
- *Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.*
- *Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.*
- *Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.*
- *Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.*
- *Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program."*

With this, CMS is also proposing that if there is reason to believe the continued collection of a measure raises potential patient safety concerns, CMS has the right to take immediate action to remove the measure outside of rulemaking.

In addition, CMS is proposing to use a sub-regulatory process to make non-substantive updates to measures adopted for REHQR. Also, whenever CMS modifies the REHQR Program measures and measure sets, CMS proposes to also update the specifications manual for the REHQR Program.

Lastly, CMS is proposing to publically display measure data both on Care Compare and in downloadable data files located in the Provider Data Catalog. CMS is also proposing that REHs would have the opportunity to review they data before it is made public in a 30-day review and corrections period. An extraordinary circumstances exceptions process is also proposed for REHs where CMS may grant an exception to one or more data submission deadlines and requirements in the event of an extraordinary circumstance beyond the control of the REH. All of these policies align with the current policies in place for the OQR program.

CMS is requesting comment on the use of eCQMs in REHQR as well as specific eCQM measures that should be considered for inclusion, measures to include that are relevant to the coordination of care between REHs and other healthcare providers, and the potential implementation of a multi-tiered approach for quality measures and reporting requirements to incentive REH reporting.

# Remedy for the 340B-Acquired Drug Payment Policy for CY 2018-2022 Proposed Rule

***July 11, 2023 Federal Register pages 44,078 – 44,096***

As mentioned earlier in this brief, on July 15, 2022 the Supreme Court ruled against CMS in *American Hospital Association v. Becerra* stating that payment rates for drugs and biologicals may not vary among groups of hospitals in the absence of survey of hospitals' acquisition cost. Due to this ruling, CMS is required to reverse the impact to providers of the 340B-

acquired drug policy that was in effect for CYs 2018 – 2022. On July 11th, 2023, CMS released the CY 2022 Remedy for the 340B-Acquired Drug Payment Policy for CYs 2018 – 2022 proposed rule that lays out two separate sets of proposals regarding the rollback of the 340B-acquired drug policy.

First, CMS is proposing that hospitals adversely affected by the 340B-acquired drug payment reduction would receive a lump sum payment an amount equal to the difference between what they were paid for drugs with the "JG" modifier, and what they would have received had those drugs been paid at ASP+6%, WAC+3%, or 95% of AWP (as applicable). Payments would be based on claims from CYs 2018 – 2021, as well as claims from CY 2022 (prior to September 28, 2022) that had not yet been reprocessed. CMS is also proposing that these payments would include the amount that would have been paid by the Medicare beneficiary due to cost sharing under the OPPS. In total, CMS estimates that these lump sum payments would amount to $9 billion nationally. CMS additionally does not believe that it has the authority to pay interest on these payments.

CMS is proposing that, pending adoption of this proposed rule, these lump sum payments would be disbursed at the end of CY 2023, or beginning of CY 2024. CMS proposes that MACs would have 60 calendar days from the date that repayment instructions are received from CMS, to issue remedy payments to affected hospitals.

The proposed lump sum remedy payments to 340B hospitals can be found here:

https://www.cms.gov/files/zip/nprm-opps-remedy-340b-acquired-drug-payment-addendum-aaa.zip

The second set of proposals is in regards to the recovery of $7.8 billion in payments made to all OPPS hospitals over the course of CYs 2018-2022, resulting from the 3.19% increase to the OPPS conversion factor in CY 2018 to budget neutralize the reduction to payments made for drugs acquired under 340B. In order to accomplish this, CMS is proposing to implement a prospective reduction of 0.5% to the OPPS conversion factor to all providers, except providers that either enrolled in Medicare after January 1, 2018, for each of CYs 2025 – 2040 or were given a temporary OPPS classification during the PHE, until the $7.8 billion is recouped. Table 1 on page 44,089 of the July 11, 2023 *Federal Register* provides estimates of the total yearly reduction amounts that this proposal would result in.

The list of hospitals not subject to the prospective reduction to the OPPS conversion factor can be found here:

https://www.cms.gov/files/zip/nprm-opps-remedy-340b-acquired-drug-payment-addendum-bbb.zip

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