Medicare Outpatient Prospective Payment System

CY2023 Proposed Payment Rule Brief provided by the Wisconsin Hospital Association

Overview

The proposed calendar year (CY) 2023 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on July 15, 2022. 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 will:

- Use CY 2019 cost report data to set the payment rates due to the effect of the COVID–19 public health emergency (PHE);
- Remove 10 services from the Inpatient-Only (IPO) list and add 8 services;
- Add a new service category for prior authorization;
- Eliminate the 340B payment reduction (not included in proposals due to timing but alternative files were provided);
- Exempt rural Sole Community Hospitals (SCH) from the reduced payment rate for clinic visit services furnished in excepted off-campus Provider-Based Departments (PBDs);
- Establish a permanent 5% cap on wage index decreases;
- Changes to the calculation of organ acquisition costs;
- Outline provider enrollment requirements, quality program requirements, and payment methodologies 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/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-p. Comments are due to CMS by September 13, 2022 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "1772–P".

An online version of the CY 2023 OPPS proposed rule is available at https://www.federalregister.gov/d/2022-15372. Page numbers noted in this summary are from the *Federal Register*. A brief summary of the major hospital OPPS sections of the proposed rule is provided below. CMS estimates a $6.2B increase in OPPS payments for CY 2023 over CY 2022.

Note: Text in italics is extracted from the July 26, 2022 proposed rule.

OPPS Payment Rate

Federal Register pages 44,505, 44,526 – 44,528, 44,534 – 44,536, and 44,680 – 44,682

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 the use of CY 2021 claims data to approximate CY 2023 outpatient service utilization. However, to avoid using cost report data that is impacted by the COVID–19 PHE, CMS is proposing to use CY 2019 Healthcare Cost Report Information System (HCRIS data from the June 2020 extract. This includes cost report data from prior to the pandemic, unlike the CY 2020 cost report data. This is the same data used to set CY 2022 OPPS rates.

CMS is also requesting comments on the use of cost report data that CMS normally would have used for CY 2023 ratesetting and alternative files for this approach included with the proposed rule.

The tables below show the proposed CY 2023 conversion factor compared to final CY 2022 and the components of the CY 2023 update factor:

	Final CY 2022	Proposed CY 2023	Percent Change
OPPS Conversion Factor	$84.177	$86.785	+3.10%
OPPS Conversion Factor (340B Alternative)		$83.865	-0.37%

Proposed CY 2023 Update Factor Component	Value	Value (340B Alternative)
Marketbasket (MB) Update	+3.1%	
Affordable Care Act (ACA)–Mandated Productivity	–0.4 percentage points (PPT)	
Wage Index Budget Neutrality (BN) Adjustment	+0.10%	
Wage Index 5% Stop Loss BN	–0.05%	
N95 Respirators BN Adjustment	-0.01%	
340B Alternative BN	-	-4.04%
Pass–through Spending / Outlier BN Adjustment	+0.34%	+1.04%
Cancer Hospital BN Adjustment	+0.00%	
Overall Proposed Rate Update	**+3.10%**	**-0.37%**

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes** ***(Federal Register pages 44,528 – 44,530)*****:** As in past years, for CY 2023 OPPS payments, CMS is proposing to continue to use the federal fiscal year (FFY) 2023 inpatient PPS (IPPS) wage indexes, including all reclassifications, add–ons, rural floors, and budget neutrality adjustments.

  In the FFY 2022 IPPS final rule, CMS reinstated the imputed floor wage index adjustment for hospitals in all–urban states effective for discharges on or after October 1, 2021. Specifically, the area wage index applicable under the IPPS to any hospital in an all–urban state may not be less than the minimum area wage index for the fiscal year for hospitals in that state. This impacts the following states for 2022: New Jersey, Rhode Island, Delaware, Connecticut, Puerto Rico, and Washington, D.C.

  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 will continue to increase the wage index value of low-wage index hospitals for CY 2023. 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 will continue to offset these increases by applying a budget neutrality adjustment to the national standardized amount. In the FFY 2023 IPPS proposed rule, the value of the 25th percentile wage index is 0.8401.

  In the past, CMS implemented wage index transition policies with limited duration in order to phase in significant changes to labor market areas with the intent to mitigate short-term negative impact to affected providers. Additionally, CMS recognizes that there are also year-to-year fluctuations in wage indexes that can occur due to external factors beyond a provider's control. In order to reduce large swings in year-to-year wage index changes and increase the predictability of OPPS payments, in the FFY 2023 IPPS proposed rule, CMS proposed to apply 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 proposed for OPPS.

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

  CMS is proposing a wage index and labor-related share budget neutrality factor of 1.0010 for FFY 2023 to ensure that aggregate payments made under the OPPS are not greater or less than would otherwise be made if wage adjustments had not changed. CMS is also proposing a separate budget neutrality factor of 0.9995 for the impact of the proposed 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 2023, CMS is proposing to continue to use a labor–related share of 60%.

- **Payment Increase for Rural SCHs and EACHs** ***(Federal Register pages 44,531)*****:** CMS is proposing to continue the 7.1% budget neutral payment increase for rural SCHs and Essential Access Community Hospitals (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** ***(Federal Register pages 44,528 and 44,531 – 44,533):*** 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).

  Due to the effects of the COVID–19 PHE, CMS is holding the target PCR equal to that of CY 2022. In order to determine a budget neutrality factor for the cancer hospital payment adjustment for CY 2023, CMS calculated a PCR of 0.90. The application of the 1.0 percentage point reduction mandated by the 21st Century Cures Act results in the proposed target PCR being equal to 0.89 for each cancer hospital. Since this is the same target PCR as that of CY 2022, CMS proposed a 0.00% adjustment to the CY 2023 conversion factor to account for this policy.
- **Outlier Payments** ***(Federal Register pages 44,533 – 44,534)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is proposing to use CY 2021 claims to calculate a CY 2023 outlier fixed–dollar threshold of $8,350. This is a 35.2% increase compared to the current threshold of $6,175. 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

Federal Register pages 44,510 – 44,526 and 44,537 – 44,661

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 2023 are available in Addenda A and B of the proposed rule at https://www.cms.gov/license/ama?file=/files/zip/2023-nprm-opps-addenda.zip.

The table below shows the update in the number of APCs per category from CY 2022 to CY 2023 (Addendum A):

APC Category	Status Indicator	Final CY 2022	Proposed CY 2023
Pass–Through Drugs and Biologicals	G	100	98
Pass–Through Device Categories	H	14	8
OPD Services Paid through a Comprehensive APC	J1	68	69
Observation Services	J2	1	1
Non–Pass–Through Drugs/Biologicals	K	350	356
Partial Hospitalization	P	2	2
Blood and Blood Products	R	39	40
Procedure or Service, No Multiple Reduction	S	81	81
Procedure or Service, Multiple Reduction Applies	T	29	28
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		**824**	**823**

- **Calculation of Cost-to-Charge Ratios (CCRs)** ***(Federal Register page 44,510 – 44,511):*** For CY 2023, CMS proposes 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 nonstandard cost centers in OPPS ratesetting when hospitals have reported this data on cost report lines that do not correspond to the cost center number. CMS is

requesting comment on the inclusion of these nonstandard cost center lines, including comments related to the accuracy of the data.

- **Blood and Blood Products** ***(Federal Register page 44,512)*****:** For CY 2023, 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** ***(Federal Register pages 44,513– 44,520)*****:** Comprehensive Ambulatory Payment Classifications (C-APCs) provide 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 (SADs); certain preventive services; and procedures assigned to a New Technology APC either included on a claim with a "J1" or when packaged into payment for comprehensive observation services assigned to status indicator "J2" when included on a claim with a "J2" indicator.

  CMS is proposing to add one new C-APCs for CY 2023 for a total of 70 C-APCs:

  - Level 2 Urology and Related Services (C-APC 5372).

  A list of the proposed 70 C–APCs for CY 2023 C-APCs can be found on *Federal Register* pages 44,518 – 44,519..

  In the "Additional Policy and Regulatory Revisions in Response to the COVID-19 PHE" interim final rule with comment period (IFC), CMS implemented an exception to the OPPS C-APC policy to ensure separate payment for new COVID-19 treatments that meet certain criteria. Specifically, CMS will always separately pay and not package into a C-APC any new COVID-19 treatment that meets the following criteria:

  - The treatment is an FDA approved (or indicated in the "Criteria for Issuance of Authorization") drug or biological product (which could include a blood product) authorized to treat COVID-19; and
  - The emergency use authorization for the drug or biological product must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting.

  This is in effect from the effective date of the IFC until the end of the pandemic.

- **Composite APCs** ***(Federal Register pages 44,520 – 44,525):*** 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 2023, 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 the maximum partial hospitalization per diem payment rate for a hospital.

  For CY 2023, CMS is proposing to also continue its current composite APC payment policies for multiple imaging services from the same family and on the same date. Table 2 (*Federal Register* pages 44,522 – 44,525) 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.

- **Payment Policy for Low–Volume New Technology APCs** ***(Federal Register pages 44,551 – 44,552)*****:** For CY 2023, CMS is proposing to continue the universal low-volume APC payment methodology for services assigned to New Technology APCs with fewer than 100 claims. This policy applies to clinical APCs and brachytherapy APCs in addition to New

Technology APCs and 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** ***(Federal Register pages 44,526 and 44,717 – 44,721)*****:** CMS is proposing to continue its efforts 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.

  For CY 2023 CMS is proposing 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 (and not pay separately for these drugs when furnished in the Hospital Outpatient Department [HOPD] setting). CMS is unpackaging these drugs in order to address the decreased utilization of non–opioid pain management drugs and to encourage their use rather than that of prescription opioids.

  CMS continues to request comment on potentially expanding this policy to HOPDs.

- **Reporting of Discarded Amounts of Single-dose or Single-use Drugs** ***(Federal Register pages 44,658 – 44,659)***: In the CY 2023 Medicare Physician Fee Schedule (MPFS) proposed rule CMS proposed that hospital outpatient departments would be required to report the JW modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS payment system. The JW modifier would be used to determine the total number of billing units of the HCPCS code of the specified drug that were discarded for dates of service during a relevant quarter to calculating the refund amount. The rule also proposes modifier JZ in cases where no billing units were discarded and for which the JW modifier would be required if there were discarded amounts.

- **Payment for Medical Devices with Pass–Through Status** ***(Federal Register pages 44,577 – 44,622)***: There are currently eleven device categories eligible for pass–through payment:
  - C1823 – Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads (expires 12/31/2021);
  - 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;
  - C1748 – Endoscope, single–use (that is disposable), Upper GI, imaging/illumination device (insertable);
  - 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); and
  - C1761 – Catheter, transluminal intravascular lithotripsy, coronary.

  CMS received 9 applications for device pass–through payments since the March 1, 2022 quarterly deadline, one of which was already approved:

  - aprevo™ Intervertebral Body Fusion Device (approved);
  - MicroTransponder® ViviStim® Paired Vagus Nerve Stimulation (VNS) System (Vivistim® System);
  - The BrainScope TBI (model: Ahead 500);
  - NavSlim™;
  - NavPencil;
  - SmartClip™;
  - Evoke® Spinal Cord Stimulation (SCS) System;
  - Pathfinder® Endoscope Overtube; and
  - The Uretero1.

  CMS is soliciting public comment and final determinations on these 8 applications will be made in the CY 2023 OPPS final rule.

  To increase transparency, streamline evaluation processes, and enable increased interested party engagement, CMS is proposing to, where possible, publicly post future applications and related materials for device pass-through payments online beginning with applications submitted on or after January 1, 2023. On the application, the applicant would be required to provide a representation of copyright ownership or license to material included with the

application. Those applications that are publicly posted would be summarized in the proposed rule with a cross-reference to the publicly posted application. CMS is also requesting comment on if a delay to this policy of March 1, 2023 should be considered.

- **Device–Intensive Procedures** ***(Federal Register pages 44,622 – 44,624)*****:** 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 procedures that were assigned device–intensive status in CY 2022, but were assigned a default device–intensive offset percentage of 31% or a device offset percentage based on claims from a clinically similar code in the absence of CY 2019 claims data (which was used for ratesetting), CMS assigned a device offset percentage based on CY 2020 data for 14 procedures, if available. For CY 2023, since CMS is returning to historical practice by using claims data two years prior to the year under study (CY 2021 in this case), CMS proposes to use CY 2021 claims data to set device offset percentages and assigning device-intensive status.

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

- **Device Edit Policy** ***(Federal Register pages 44,624 – 44,625)*****:** CMS requires 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 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.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices** ***(Federal Register page 44,625)*****:** 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 2023, CMS is not proposing any major changes to the no cost/full credit and partial credit device policies.

- **Payment for Drugs, Biologicals and Radiopharmaceuticals** ***((Federal Register pages 44,578 – 44,579 and 44,625 – 44,647)*****:** 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 2023, CMS is proposing a packaging threshold of $135. Drugs, biologicals, and radiopharmaceuticals that are above the $135 threshold are paid separately, using individual APCs, and those below the threshold are packaged; the baseline payment rate for CY 2023 is proposed to be the average sales price (ASP) + 6%.

  Separately payable drugs and biological products that do not have pass–through status and are not acquired under the 340B program are proposed to be paid wholesale acquisition cost (WAC) + 3%, instead of WAC + 6%.

  For CY 2023, CMS is proposing to also 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.

  Lastly, CMS is proposing that the pass–through status expire by December 31, 2022 for 32 drugs and biologicals, listed in Table 39 on *Federal Register* pages 44,628 – 44,630; by December 31, 2023 for 43 drugs and biologicals listed in Table 40 on *Federal Register* pages 44,632 – 44,636; and is proposing to continue/establish pass–through status in CY 2023 to 32 others shown in Table 41 on *Federal Register* pages 44,638 – 44,640.

  In the CY 2022 OPPS final rule, CMS finalized a proposal to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass–through payment status will expire between December

31, 2021 and September 30, 2022 due to the use of CY 2019 claims data rather than CY 2020 claims data in CY 2022 ratesetting. In this rule, CMS is proposing to resume the regular update process of using claims data from 2 years prior to the year of ratesetting. In this case, CMS would use CY 2021 claims and not provide additional quarters of separate payment for any device category whose pass-through payment status will expire between December 31, 2022 and September 30, 2023.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes** ***(Federal Register pages 44,649 – 44,657)*****:** 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 2022 to the high cost group in CY 2023 as well. CMS is also proposing to assign those with pass-through payment status to the high cost category.

  In the CY 2023 Physician Fee Schedule proposed rule, there is a proposal to treat all skin substitute products consistently across healthcare settings as incident-to supplies. If finalized, manufacturers would no longer report ASPs for skin substitute products starting in CY 2023 and therefore CMS would no longer be able to use ASP + 6% for pricing a graft skin substitute product to determine whether it should be assigned to the high cost or low cost group. Since manufacturers would continue to report WAC and average wholesale price (AWP), CMS would instead use its alternative process (WAC + 3% or 95% of AWP) to assign groups when cost data is not available.

  The list of proposed packaged skin substitutes and their group assignments may be found in Table 44 on *Federal Register* pages 44,652 – 44,655.

  In the CY 2021 final rule, CMS adopted the inclusion of both synthetic and biological skin graft sheet products in the description of skin substitutes, and therefore these products could be reported with graft skin substitute procedure codes. With this, CMS created HCPCS code C1849 to facilitate payment for synthetic graft skin substitute products and assigned the code to the high cost group. However, in the April 2022 Update of the Hospital OPPS – Change Request 12666, CMS changed the status indicator of all skin substitute products described in the HCPCS A2XXX series, including synthetic graft skin substitutes, to "N" so that those codes would be packaged under OPPS. Since CMS now pays for HCPCS A-codes for synthetic graft skin substitutes under OPPS, HCPCS code C1849 is no longer necessary and CMS is proposing to delete it.

  CMS is seeking comments on policy objectives for creating a consistent approach for treatment of skin substitutes and a 1 to 5 year phased approach for potential changes, described on *Federal Register* pages 44,656 – 44,657. CMS is also requesting a change to the terminology used for the suite of "skin substitutes" to instead use the term "wound care management".

- **Payment for Drugs Purchased under the 340B Drug Discount Program** ***(Federal Register pages 44,647 – 44,649)*****:** 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.

  Currently, CMS pays a reduced rate of ASP – 22.5% of the products ASP, rather than ASP + 6% for nonpass-through for separately payable drugs and biosimilar biological products, if purchased under the 340B program. This includes those drugs (other than vaccines and drugs on pass-through payment status) provided at non-excepted off-campus provider-based departments.

  Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. The 340B-acquired drug payment policies have been involved in a continuing lawsuit, *American Hospital Association v. Becerra.* In December 2018, the District Court concluded that CMS exceeded its authority with its large reduction to Medicare payments for CY 2018 and CY 2019 for drugs acquired through the 340B program unless the Secretary obtained drug acquisition cost survey data from hospitals proving otherwise. CMS disagreed and appealed the decision, and on July 31, 2020 the D.C. Circuit Court of Appeals reversed the district court decision. However, on July 15, 2022 the Supreme

Court reversed the Court of Apppeals decision stating that payment rates for drugs and biologicals may not vary among groups of hospitals in the absence of survey of hospitals' acquisition cost.

CMS lacked the necessary time to incorporate adjustments to the proposed payment rates and budget neutrality calculations to account for the Supreme Court's decision before issuing this proposed rule and therefore, will continue with its proposal to pay ASP – 22.5 percent for drugs and biologicals acquired under the 340B program for CY 2023.

However, as CMS fully anticipates applying a rate of ASP + 6% for the final rule, CMS provided alternative 340B supporting files that include the impacts of the effects of removing the 340B payment policy for CY 2023. CMS estimates that the payment differential would be an increase of $1.96 billion and therefore would apply a budget neutral factor of 0.9596 to the OPPS conversion factor, for a revised conversion factor of $83.279.

CMS has not yet decided how to apply the Supreme Court's decision to prior cost years. CMS is requesting comments on the best way potential remedies for CYs 2018-2022.

The 340B adjustment also applies to those drugs for which pricing is determined based on WAC and AWP. With the formal proposal to continue ASP drug reductions, CMS is also proposing to continue that drugs acquired under WAC pricing be paid at WAC – 22.5%, while those acquired under AWP pricing be paid at 69.46% of AWP. Similar to ASP drug reductions, CMS anticipates this changing in the final rule.

As in previous years, rural sole-community hospitals (SCHs), critical access hospitals (CAHs), children's hospitals, and PPS–exempt cancer hospitals are exempt from the 340B adjustment and receive drug payments based on ASP + 6%.

Modifiers "JG" and "TB" are still proposed to apply. Modifier "JG" is used by non–exempt hospitals to report separately payable drugs that were acquired through the 340B program, and thus paid the reduced rate. Modifier "TB" is used by hospitals exempt from the 340B payment adjustment to report separately payable drugs that were acquired through the 340B program.

Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services** ***(Federal Register pages 44,661 – 44,668)*****:** 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.

  The table below compares the final CY 2022 and proposed CY 2023 PHP payment rates:

	Final Payment Rate 2022	Proposed Payment Rate 2023	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$142.70	$130.54	-8.5%
APC 5863: Partial Hospitalization (3+ services) for Hospital–based PHPs	$265.97	$261.73	-1.6%

  In the April 30, 2020 Additional Policy and Regulatory Revisions in Response to the COVID–19 PHE interim final rule, hospital and CMHC staff were given the ability to furnish certain PHP services, incident to a physician's services, to beneficiaries in temporary expansion locations (including the beneficiary's home) as long as the location meets conditions of participation that are not waived. These provisions were as of March 1, 2020 and exist for the duration of the COVID–19 PHE. These services can be furnished using telecommunications technology if the beneficiary is registered as outpatient.

  CMS is requesting comment on the use of remote mental health services for patients who receive care from CMHCs and HOPDs. Specific areas for comment are listed on *Federal Register* page 44,667.

  Consistent with CMS' proposal to use CY 2019 cost data in rate setting for OPPS (which was also used for CY 2022), CMS is proposing to calculate the CMHC and hospital-based PHP geometric mean per diem costs using CY 2021 claims data and the same cost data that was used for CY 2022.

  CMS is also proposing not to include data from nonstandard cost center lines that do not correspond to the cost center number for CY 2023 due to the concerns about significant changes in APC geometric mean costs if those lines were included. CMS is request comment about use of this data in future ratesetting.

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 is proposing to apply an 8 percent outlier payment cap to the CMHC's total per diem payments.

- **Inpatient–Only List** ***(Federal Register pages 44,668 – 44,674)*****:** The IPO list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2023, CMS is proposing to remove the following services from the IPO list:
    - CPT 16036: Escharotomy; each additional incision (list separately in addition to code for primary procedure);
    - CPT 22632: Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure);
    - CPT 21141: Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft;
    - CPT 21142: Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft;
    - CPT 21143: Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft;
    - CPT 21194: Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft);
    - CPT 21196: Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation;
    - CPT 21347: Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches);
    - CPT 21366: Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft); and
    - CPT 21422: Open treatment of palatal or maxillary fracture (lefort i type).

    CMS is also proposing to add the following 8 services to the IPO list:

    - CPT 157X1: Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma;
    - CPT 228XX: Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure);
    - CPT 49X06: Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated;
    - CPT 49X10: Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated;
    - CPT 49X11: Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible;
    - CPT 49X12: Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, Cincarcerated or strangulated;
    - CPT 49X13: Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible; and
    - CPT 49X14: Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated.

    The list of measures that are proposed to be removed from the list and those that are proposed to be added are on *Federal Register* pages 44,672 – 44,674.

- **Payment for Off–Campus Outpatient Departments** ***(Federal Register pages 44,661 and 44,696 – 44,698)*****:** 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 2023, CMS is proposing that excepted off-campus PBDs of rural SCHs would 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. If finalized, 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 2022. These excepted PBDs continue to bill HCPCS code G0463 with modifier "PO".

- **Prior Authorization Process** ***(Federal Register 44,802 – 44,807)***: In an effort to control for unnecessary increases in the volume of covered OPD services, specifically blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation, in the CY 2020 final rule CMS adopted a prior authorization process when furnishing these services to ensure that Medicare is only paying for these services when medically necessary.

  CMS is proposing to add a new service category to this policy: Facet Joint Interventions. The requirement for this service category would begin for dates of service on or after March 1, 2023.

  A list of the services that require prior authorization, included in the proposed category, can be found in Tables 79 and 80 on *Federal Register* pages 44,804 – 44,807.

Updates to the Hospital Outpatient Quality Reporting (OQR) Program

Federal Register pages 44,726 – 44,740

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.

In the CY 2015 final rule, CMS finalized the OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure for voluntary reporting. In the CY 2022 final rule, finalized mandatory of reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. In this rule, CMS is proposing to keep OP-31 as voluntary instead due to the burden of this measure with the PHE:

CMS requests comment on several topics listed below with references to comment page numbers:

- *"Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) Measure or Adoption of Another Volume Indicator*" (*Federal Register* pages 44,730 – 44,732)*; and*
- *"Readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) Measure or Other Volume Indicator in the Hospital OQR Program"* (*Federal Register* pages 44,731 – 44,732).

CMS included a Request for Information in the FFY 2023 IPPS proposed rule, "Overarching Principles for Measuring Healthcare Quality Disparities across CMS Quality Programs" requesting comment on health equity in five key areas across all CMS quality programs. Detail is included in the FFY 2023 IPPS proposed rule but comments specific to the OQR program should be submitted under this OPPS rule.

Beginning with CY 2024 reporting period/CY 2026 payment determination, CMS is proposing to align the OQR program patient encounter quarters for chart-abstracted measures to the calendar year. If finalized, all four quarters of data would be based on the calendar year 2 year prior to payment determination. To transition, CMS is proposing to only use 3 quarters of data for CY 2025 payment determination. Submission deadlines would remain the same.

With regards to validation target criteria, beginning with CY 2023 reporting/CY 2025 payment determination, CMS is proposing an additional criteria used to select the additional 50 hospitals. Specifically, CMS proposes that a *"hospital with less than four quarters of data subject to validation due to receiving an [Extraordinary Circumstances Exception] for one or more quarters and with a two-tailed confidence interval is less than 75 percent would be targeted for validation in the subsequent validation year."* This criteria is necessary because hospitals with less than 4 quarters of data may have results that are inconclusive for payment determination.

A table listing the 15 measures to be collected for CY 2024 payment determinations is on *Federal Register* page 44,728. A table listing the 19 measures to be collected for CY 2024 payment determinations is on *Federal Register* page 44,729. Finally, a table listing the 19 measures to be collected for CY 2026 payment determinations is on *Federal Register* pages 44,729 – 44,730.

Remote Mental Health Services

Federal Register pages 44,674 –44,679

During the COVID-19 PHE, many beneficiaries received mental health services in their homes using communications technology under the flexibilities adopted. In order to avoid negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided remotely by hospital staff and to avoid potential disruptions to continuity of care for those beneficiaries who have become accustomed to receiving these services in their home, CMS is proposing to cover certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital to a beneficiary in their home.

Specifically, CMS is proposing to create OPPS-specific coding for these services, the descriptions of what specify that a beneficiary must be in their home and that there is no associated professional service billed under the MPFS. All hospital staff performing these services must be licensed to furnish these services and must be physically located in the hospital while furnishing these services. The proposed codes are listed in Table 47 on *Federal Register* page 44,677 and are proposed to be assigned to APCs for the following codes:

- CPT 96159: Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service); and
- CPT 96158: Health behavior intervention, individual, face-to-face; initial 30 minutes.

CMS also proposes the requirement that the 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 would permit 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.

The telecommunications system also must, at a minimum, include audio and video equipment permitting two-way, real-time interactive communications. However, audio-only communications may be used given an individual patient's technological limitations, abilities, or preferences.

Comment Solicitation on Intensive Outpatient Mental Health Treatment

Federal Register pages 44,679 – 44,679

CMS is asking for comment on whether services for intensive outpatient mental health treatment, including substance use disorder treatment furnished by intensive outpatient programs is described by the existing CPT codes paid under OPPS, or whether there are gaps in coding that limit access to needed levels of care. In addition, CMS is interested in information about intensive outpatient program services, including the settings of care these services are furnished, the range of services offered, and who furnishes the services.

Direction Supervision of Certain Cardiac and Pulmonary Rehabilitation Services

Federal Register pages 44,679 – 44,680

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 pulmonary, cardiac, and intensive cardiac rehabilitation when the use of technology reduces exposure risks for the patient or the provider. This flexibility was set in the CY 2021 OPPS final rule to continue until the later of the end of the calendar year in which the PHE ends or December 31, 2021. The final rule also clarified this excluded the presence of the supervising practitioner virtually.

CMS is seeking comment on whether these policies should be continued through the end of CY 2023 and if there are safety and/or quality of care concerns with adopting this policy beyond the end of the PHE.

Category B Investigational Device Exemption (IDE) Clinical Devices and Studies

Federal Register pages 44,683 – 44,684

In the CY 2020 OPPS final rule CMS created a temporary HCPCS code C9758 to describe the V-Wave Interatrial Shunt procedure assigned to New Technology APC 1589. CMS has created similar codes and used similar payment methodologies for other similar IDE studies over time.

Beginning CY 2023, CMS is proposing to make a single blended payment, and establish a new HCPCS code or revise an existing HCPCS code for devices and services in Category B IDE studies when certain criteria are met and CMS determines a new or revised code is necessary.

OPPS Payment for Software as a Service

Federal Register pages 44,684 – 44,689

For many services paid under the OPPS, payment for analytics that are performed after the main procedure are packaged into payment for the primary service. Over the past few years, several codes have been displayed that describe software as a service procedures.

CMS believes that the costs associated with the add-on codes exceed the costs of the imaging service with which they would be billed, and therefore the add-on codes should be paid separately. CMS is thus proposing to not recognize the software as a service CPT codes and instead establish HCPCS codes to describe the services, listed on *Federal Register* page 44,688.

CMS is also requesting comment on payment approaches for these services. Specific areas for comment are listed on *Federal Register* page 44,688.

Domestic NIOSH-Approved Surgical N95 Respirators

Federal Register pages 44,689 – 44,696

In the FFY 2023 IPPS proposed rule, CMS requested comment on potential payment adjusts for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators for IPPS and OPPS to offset costs incurred by hospitals when acquiring such equipment.

CMS is proposing to make such an adjustment in this rule beginning January 1, 2023 in a budget neutral manner. This adjustment would be a biweekly interim lump-sum payment to the hospital and would be reconciled at cost report settlement. The payments would initially be based on the estimated difference in reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators. In future years, the payment would be based on information from the prior year's surgical N95 supplemental cost reporting form (which would be a new cost reporting form collected from hospitals). Payment amounts would be determined by the MAC.

Organ Acquisition Payment

Federal Register pages 44,765 – 44,773

Organ acquisition costs are excluded from the Medicare Severity Diagnosis Related Groups (MS-DRGs) and instead are paid based on reasonable and necessary costs. According to the Medicare reasonable cost principles and the prohibition of cross-subsidization, the cost of services for organ acquisition costs must be borne by the appropriate payer.

In the CY 2022 IPPS proposed rule, CMS made several proposals regarding transfer hospitals (THs) and hospital based organ procurement organizations (HOPOs). Based on public comment to those proposals and in order to improve payment accuracy and lower the costs to procure and provide research organs, CMS is proposing to require that THs/OPOs exclude organs used for research from the numerator (Medicare usable organs) and the denominator (total usable organs) of the calculation used to determine Medicare's share of acquisition costs on the Medicare cost report. THs and OPOs would also be required to deduct the cost incurred in procuring an organ for research from their total organ acquisition costs to ensure research organ procurement costs are not allocated across all transplantable organs and that Medicare is not paying for non-allowable research activities. With this, CMS also proposes that the determination of an organ being unusable can be made by any surgeon, rather than solely the excising surgeon.

In addition, CMS is proposing that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors in order to increase organ procurement and promote equity.

CMS is clarifying that *"when a TH receives an organ from an OPO or other TH, the receiving TH must exclude from its accumulated cost statistic the cost associated with these organs because these costs already include A&G costs."*

Lastly, CMS is asking for comments on an alternative methodology for counting organs for Medicare's share of organ acquisition costs, Independent Organ Procurement Organization (IOPO) kidney standardized acquisition charges (SACs), and reconciliation of all organs for IOPOs.

Overall Hospital Quality Star Rating

Federal Register pages 44,807 – 44,809

The Overall Star Rating was first introduced in July 2016 and was made publically available on the Care Compare website. It provides a summary of existing hospital quality measure results reported to CMS through the existing quality programs. Hospitals are assigned one to five stars, five being the highest. The Overall Star Rating is published annually.

In the CY 2021 OPPS final rule CMS began including Veterans Health Administration (VHA) hospitals in the quality measure data for the calculation of the star ratings beginning with CY 2023. Since then, CMS has conducted an internal analysis with measure data from all VHA hospitals in the calculation of the star ratings. CMS found that including VHA hospitals did not have a significant impact on non-VHA hospital star ratings (over 90 percent did not experience a change in their star rating and no hospital gained or lost more than one star) and therefore CMS intends to continue to include VHA hospitals in the calculation for future star ratings.

CMS is also clarifying that the Overall Star Rating will be published once annually using data publically reported on Care Compare, or its successor website, from a quarter within the previous 12 months, rather than within the prior year (which could indicate a Care Compare refresh from the prior calendar year).

CMS intends to publish star ratings in 2023, but may suppress the ratings if the data is substantially impacted by the COVID-19 PHE.

Request for Information – Use of CMS Data to Drive Competition in Healthcare Marketplaces

Federal Register pages 44,800 – 44,802

CMS is looking to address excessive concentration, abuses of market power, unfair competition, and the impacts of monopoly and monopsony. Therefore, CMS is seeking guidance on how their data can be used to promote competition across the health care system or to protect the public from harmful effects of consolidation within healthcare. Specific areas for comment are on *Federal Register* pages 44,801– 44,802.

Rural Emergency Hospitals

Federal Register pages 44,755 – 44,765 and 44,774 – 44,800

The Consolidated Appropriations Act (CAA) of 2021 established REHs as a new provider type beginning January 1, 2023 that provides emergency department 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.

Critical Access Hospitals (CAHs) and rural hospitals with less than or equal to 50 beds are eligible to convert to an REH. The REH also must meet the following requirements:

- *"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."*

Conditions of Participation

Federal Register pages 44,787 – 44,788

On July 6, 2022 CMS published the Medicare and Medicaid Programs; Conditions of Participation (CoP) for REHs and Critical Access Hospital CoP Updates that outlined the health and safety standards for REHs. All of the final health and safety policies will be published in the CY 2023 OPPS final rule.

Enrollment Requirements

Federal Register pages 44,788 – 44,789

A REHs enrollment remains in effect until either the REH elects to convert back to its prior designation or the Secretary determines the facility does not meet the REH requirements, listed at the beginning of this section.

In order to ensure that CMS' enrollment authority is to the same extent as for all other Medicare provider and supplier types, CMS is proposing that an REH must comply with all applicable provision and requirements in order to enroll and maintain enrollment in Medicare, including:

- Submission of all required supporting documentation with the enrollment application;
- Completion of any applicable state surveys, certifications, and provider agreements;
- Reporting changes to any of the REH's enrollment information;
- Revalidation of enrollment; and
- Undergoing risk-based screening.

An REH would submit Form CMS-855A to enroll, but would not have to pay an application fee since this would be a change of information form rather than an initial enrollment form, if the REH is converting from a CAH or a hospital. This would also help expedite the conversion process.

REHs will also not be required to provide notification under the Medicare Outpatient Observation Notice when an individual receives observation services as outpatients for more than 24 hours because REHs are excluded from the definition of "hospital".

Physician Self-Referral Law

Federal Register pages 44,789 – 44,800

As REHs are required by their CoPs to furnish radiology and certain imaging services, clinical laboratory services, and outpatient prescription drugs, they would be subject to the physician self-referral law. This law *"…prohibit[s] a physician from making a referral for designation health services to the REH if the physician (or an immediate family member of the physician) has a financial relationship with the REH…"* unless an exception is made. CMS is proposing a new exception and revisions to existing exceptions to the law for REHs when requirements to the exception are satisfied as described on *Federal Register* pages 44,792 – 44,798, in order to avoid inhibiting access to medically necessary designated health services.

REH Payment

Federal Register pages 44,776 – 44,786

REHs are proposed to be paid for all covered OPD services at the OPPS rate + 5.0%. Copayments will be calculated based on the OPPS rate excluding the 5.0% increase. CMS is proposing that REHs would utilize the OPPS claims processing system to process REH payments, with an REH-specific payment flag.

Services that are not covered OPD services would be paid at the same rate the service would be paid if performed in an HOPD but paid under a fee schedule other than the OPPS, with no 5.0% increase. Post-hospital extended care services provided by a REH would receive payment through the skilled nursing facility PPS without a 5.0% increase.

Additionally, REHs would not be subject to the reduced rate for services furnished by off-campus PBDs and would instead be paid at OPPS + 5.0% for these services.

In addition, REHs will receive a payment made monthly and determined based on the excess of the total amount paid to all CAHs in CY 2019 over the estimated total amount that would have been paid to CAHs in CY 2019 if payment were made for inpatient, outpatient, and skilled nursing facility services under the PPS (both proposed to be calculated using CAH claims data). That value is divided by the amount of CAHs (also proposed to be determined using claims data). In future years, the additional payment will be adjusted by the hospital market basket percentage increase. REHs will be required to maintain detailed information as to how the payments are used.

For the estimated prospective payment amount, CMS proposes to include services and items that are not paid through OPPS. CMS also proposes to estimate prospective payment add-ons such as IPPS new technology payments, outlier claim payments, clotting factor payments, indirect medical education payments, DSH payments, uncompensated care payments, and low-volume hospital payments. CMS would still use the CY schedule even when calculating skilled nursing facility and inpatient payments, which are both based on FFY. The payments would also include both amounts paid to CAHs from the Medicare program and from beneficiary copayments.

CMS estimates that the estimated prospective payment for CAHs in 2019 is 58.2% of total CAH spending in 2019 and the REH monthly facility payment would be 72% of the estimated prospective payment for CAHs in 2019.

Details on the proposed methodology for estimated CY 2019 prospective payments for CAHs can be found *on Federal Register* pages 44,783 – 44,786.

REHs are also required by law to maintain documentation on how the facility used the additional monthly payment, which CMS is proposing can be tracked through the cost report and therefore requires no additional reporting or data collection.

Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

Federal Register pages 44,755 – 44,765

The REHQR program is mandated by the CAA of 2021.

CMS is requesting comment on potential measures that are already reported under OQR or Medicare Beneficiary Quality Improvement Project for the REHQR program, listed below with page numbers:

- OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (*Federal Register* page 44,760);
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (*Federal Register* pages 44,760 – 44,761);
- OP-4: Aspirin on Arrival (*Federal Register* page 44,761);
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (*Federal Register* page 44,761);
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional (*Federal Register* pages 44,761 – 44,762);
- OP-22: Left Without Being Seen (Federal *Register* page 44,762);
- Emergency Department Transfer Communications (EDTC) (*Federal Register* page 44,762);
- OP-10: Abdomen Computed Tomography (CT) – Use of Contrast Material (*Federal* Register pages 44,762); and
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (*Federal Register* page 44,762).

CMS is also requesting comment on additional topics for quality measurement and several other topics including telehealth, maternal health, mental health, ED services, equity, and low volume.

In order for a hospital to participate in the REHQR, CMS is proposing that the hospital must have a QualityNet account and have a Security Official (an individual who has responsibility for security and account management requirements at the facility). A hospital that already has an account can update the existing account with the new CMS certification number (CCN). The hospital will need to request SO access for the new CCN (instructions are on QualityNet).

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