Medicare Outpatient Prospective Payment System

Calendar Year 2023 Final Rule Brief provided by the Wisconsin Hospital Association

Overview

The final calendar year (CY) 2023 payment rule with comment period for the Medicare Outpatient Prospective Payment System (OPPS) was released on November 1, 2022. The final rule includes annual updates to the Medicare fee–for–service (FFS) outpatient payment rates as well as regulations that implement new policies. The final 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 11 services from the Inpatient-Only (IPO) list and add 8 services;
- Add a new service category for prior authorization;
- Eliminate the 340B payment reduction;
- 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;
- Change 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 final 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 no later than January 3, 2023 at 5 pm and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "CMS-1772–FC".

An online version of the CY 2023 OPPS final rule is available at https://www.federalregister.gov/d/2022-23918. Page numbers noted in this summary are from the Display version of the final rule. A brief summary of the major hospital OPPS sections of the final rule is provided below. CMS estimates a $6.5 billion increase in OPPS payments for CY 2023 over CY 2022.

Note: Text in italics is extracted from the July 26, 2022 proposed rule and from the November 1, 2022 final rule.

OPPS Payment Rate

Display pages 17 - 19, 39, 98 – 108, and 806 – 818

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 will use 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 adopting the use of 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.

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

	Final CY 2022	Final CY 2023	Percent Change
OPPS Conversion Factor	$84.177	$85.585 (proposed at $86.785)	+1.67% (proposed at +3.10%)

Final CY 2023 Update Factor Component	Value
Marketbasket (MB) Update	+4.1% (proposed at +3.1%)
Affordable Care Act (ACA)–Mandated Productivity	–0.3 percentage points (PPT) (proposed at -0.4 PPT)
Wage Index Budget Neutrality (BN) Adjustment	+0.02% (proposed at +0.10%)
Wage Index 5% Stop Loss BN	-0.04% (proposed at –0.05%)
N95 Respirators BN Adjustment	-0.01% (as proposed)
340B Alternative BN	-3.09% (est. at -4.04% in alternative files)
Pass–through Spending / Outlier BN Adjustment	+1.09% (est. at +1.04% in alternative files)
Cancer Hospital BN Adjustment	+0.00% (as proposed)
Overall Final Rate Update	**+1.67% (est. at -0.37% in alternative files)**

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes *(Display pages 108 – 119)*:** As in past years, for CY 2023 OPPS payments, CMS will 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 under the IPPS applicable 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 2023: 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 final rule, the value of the 25th percentile wage index is 0.8427 (proposed at 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 IPPS payments, in the FFY 2023 IPPS final rule, CMS finalized 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 adopted 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 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, a new hospital would 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 adopting a wage index and labor-related share budget neutrality factor of 1.0002 for FFY 2023 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 adopting a separate budget neutrality factor of 0.9996 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 2023, CMS will continue to use a labor–related share of 60%.

- **Payment Increase for Rural SCHs and EACHs** ***(Display pages 120 - 123)*****:** CMS will 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** ***(Display pages 20 and 123 – 129):*** CMS will 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 adopted target PCR being equal to 0.89 for each cancer hospital. Since this is the same target PCR as that of CY 2022, CMS finalized a 0.00% (as proposed) adjustment to the CY 2023 conversion factor to account for this policy.

- **Outlier Payments** ***(Display pages 129 – 137)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS will use CY 2021 claims to calculate a CY 2023 outlier fixed–dollar threshold of $8,625 (proposed at $8,350). This is a 39.7% increase compared to the current threshold of $6,175. Outlier payments will 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 39 – 98, 151 – 719, and 998 – 1,012

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 final payment weights and rates for CY 2023 are available in Addenda A and B of the final rule at https://www.cms.gov/license/ama?file=/files/zip/2023-nfrm-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	Final CY 2023
Pass–Through Drugs and Biologicals	G	100	96
Pass–Through Device Categories	H	14	12
OPD Services Paid through a Comprehensive APC	J1	68	69
Observation Services	J2	1	1
Non–Pass–Through Drugs/Biologicals	K	350	389
Partial Hospitalization	P	2	2
Blood and Blood Products	R	39	40
Procedure or Service, No Multiple Reduction	S	81	82
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**	**859**

- **Calculation of Cost-to-Charge Ratios (CCRs)** ***(Display pages 42 – 48):*** For CY 2023, CMS will 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 proposed rule, CMS requested comment on the inclusion of these non-standard cost center lines, including comments related to the accuracy of the data. Comments can be found on Display page 46.

- **Blood and Blood Products** ***(Display pages 48 - 51)*****:** For CY 2023, CMS will continue its policy to establish payment rates for blood and blood products using a blood–specific CCR methodology.

- **New Comprehensive APCs** ***(Display pages 55 – 80)*****:** 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 (SADs); 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 adopting one new C-APC for CY 2023 for a total of 70 C-APCs:

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

  A list of the final 70 C–APCs for CY 2023 C-APCs can be found on Display pages 77 – 80.

  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** ***(Display pages 80 – 90):*** 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 will 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 will 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 will also continue its current composite APC payment policies for multiple imaging services from the same family and on the same date. Table 3 on Display pages 86 – 90 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 (*Display pages 178 – 181)*:** For CY 2023, CMS will 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** ***(Display pages 90 – 94 and 988 – 1,012)*****:** CMS will 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.

  For CY 2023, CMS will continue to unpackage, and pay separately at ASP+6%, the cost of non–opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. CMS 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. Table 84 on Display pages 1,007 – 1,008 lists the products that are currently eligible for separate payment in the ASC setting under this policy.

  CMS solicited comments on potentially expanding this policy to HOPDs. Comments can be found on Display pages 93 – 94.

- **Reporting of Discarded Amounts of Single-dose or Single-use Drugs** ***(Display pages 700 – 701)***: 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 MPFS final rule finalizes modifier JZ in cases where no billing units were discarded and for which the JW modifier would be required if there were discarded amounts. Comments on these proposals can be found in the CY 2023 MPFS final rule.

- **Payment for Medical Devices with Pass–Through Status** ***(Display pages 390 – 567 and 703 - 719)***: There are currently 14 device categories that are eligible for pass–through payment:
  - C1823 – Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads;
  - 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);
  - 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; and
  - C1833 – Monitor, cardiac, including intracardiac lead and all system components (implantable).

  As of the final rule, CMS has approved 4 of 8 device pass–through payment applications for CY 2023, including one that was already approved:

  - aprevo™ Intervertebral Body Fusion Device (previously approved);
  - MicroTransponder® ViviStim® Paired Vagus Nerve Stimulation (VNS) System (Vivistim® System);
  - Evoke® Spinal Cord Stimulation (SCS) System; and
  - The Uretero1.

  To increase transparency, streamline evaluation processes, and enable increased interested party engagement, CMS is adopting its proposal to, where possible, publicly post online future applications and related materials for device pass-through payments. CMS has proposed a start date of applications submitted on or after January 1, 2023 but requested comment on if a delay to this policy of March 1, 2023 should be considered. Even though CMS did not receive any comments regarding this, CMS is finalizing an implementation date of March 1, 2023 in order to avoid confusion of a policy change mid-proposed rule year.

On the application, the applicant will 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. This would not include information included in a confidential section of the application.

- **Device–Intensive Procedures** ***(Display pages 567 – 579)*****:** 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 is finalizing its proposal 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 final rule.

- **Device Edit Policy** ***(Display pages 579 – 581)*****:** CMS will continue to require claim processing edits when any of the device codes used in the previous device-to-procedure edits are present on the claim with a device–intensive procedure that includes the implantation of a device. CMS previously created HCPCS code C1889 (implantable/insertable device, not otherwise classified) to recognize devices used during device–intensive procedures that are not described by specific Level II HCPCS Category C-Code. This HCPCS code satisfies the edit requirement.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices** ***(Display pages 581 – 583)*****:** 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 adopting any major changes to the no cost/full credit and partial credit device policies.

- **Payment for Drugs, Biologicals and Radiopharmaceuticals** ***((Display pages 391 – 402 and 584 – 642)*****:** 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 adopting a packaging threshold of $135 (as proposed). 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 the average sales price (ASP) + 6%.

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

  For CY 2023, CMS will 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 finalizing that the pass–through status expire by December 31, 2022 for 32 drugs and biologicals, listed in Table 57 on Display pages 589 – 591; by December 31, 2023 for 43 drugs and biologicals listed in Table 58 on Display pages 594 – 599; and is adopting its proposal to continue/establish pass–through status in CY 2023 to 49 (proposed at 32) drugs and biologicals shown in Table 59 on Display pages 602 – 606.

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 finalized its decision to resume the regular update process of using claims data from 2 years prior to the year of ratesetting. In this case, CMS will 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** ***(Display pages 664 – 694)*****:** 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 will 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 will also assign those with pass-through payment status to the high cost category.

  In the CY 2023 MPFS rule, all skin substitute products are finalized to be treated consistently across healthcare settings as incident-to supplies. Due to this, manufacturers will no longer report ASPs for skin substitute products starting in CY 2023 and therefore CMS will 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 will continue to report WAC and average wholesale price (AWP), CMS will instead use its alternative process (WAC + 3% or 95% of AWP) to assign groups when cost data is not available.

  The list of adopted packaged skin substitutes and their group assignments may be found in Table 62 on Display pages 685 – 688.

  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 finalizing its proposal to delete it. CMS is also finalizing that any graft skin substitute product that is currently or in the future assigned a product-specific code in the HCPCS A2XXX series and is appropriately described by HCPCS code C1849 now or in the future be assigned to the high cost skin substitute group.

  CMS sought 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. CMS also requested comments on a change to the terminology used for the suite of "skin substitutes" to instead use the term "wound care management". Comments can be found on Display pages 690 – 691 and 693 – 694.

- **Payment for Drugs Purchased under the 340B Drug Discount Program** ***(Display pages 642 – 664)*****:** 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.

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

However, in this final rule CMS is adopting a rate of ASP + 6% of a product's ASP, regardless of whether or not the product was acquired through the 340B program. To maintain OPPS budget neutrality and to offset the prior increase of 3.19% that was applied to the conversion factor when 340B payment reductions were first implemented in CY 2018, CMS is adopting a budget neutrality factor of 0.9691 (estimated as 0.9596 in the alternative files).

On September 28, 2022, the district court ruled to vacate the 340B reimbursement for the remainder of 2022. For 340B claims between January 1, 2022 and September 27, 2022, providers will need to submit adjustments for each claim that has a "JG" modifier, described at https://www.ngsmedicare.com/web/ngs/production-alert-details?alertid=5002380&lob=93617&state=97263&region=93623&rgion=93623.

CMS has not yet decided how to apply the Supreme Court's decision to prior cost years and requested comments on the best way potential remedies. Comments can be found on Display pages 650 – 653.

As CMS is reverting back to previous policy that does not reduce payment for 340B drugs, 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.

Modifiers "JG" and "TB" will still apply for CY 2023 for informational purposes, but will have no effect on payment rates. Modifier "JG" is used by non–exempt hospitals to report separately payable drugs that were acquired through the 340B program. Modifier "TB" is 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 sole–community hospitals (SCHs), children's hospitals, PPS–exempt cancer hospitals, and PPS-exempt critical access hospitals (CAHs).

Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services** ***(Display pages 719– 761)*****:** 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 final CY 2023 PHP payment rates (Addendum A):

	Final Payment Rate 2022	Final Payment Rate 2023	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$142.70	$142.70 (proposed at $130.54)	+0.0% (proposed at -8.5%)
APC 5863: Partial Hospitalization (3+ services) for Hospital–based PHPs	$265.97	$268.22 (proposed at $261.73)	+0.85% (proposed at -1.6%)

  Consistent with CMS' use of CY 2019 cost data in rate setting for OPPS (which was also used for CY 2022), CMS will calculate the hospital-based PHPs geometric mean per diem costs using CY 2021 claims data and the same cost data that was used for CY 2022. Based on public comment, CMS agreed not to finalize any rate cuts for CMHC PHP services in CY 2023 as CMS' goal is to support ongoing access to CHC PHPs, and therefore CMS is applying an equitable adjustment to hold the APC payment rate at the CY 2022 level for the CMHC's PHPs. This equitable adjustment is only for CY 2023 and not subsequent years.

  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 effective 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. In this rule, CMS is clarifying that PHP patients can continue to receive the new HCPCS codes that describe mental health services furnished to beneficiaries in their homes by clinical staff of the hospital and that the plan of care for these patients should be updated to reflect that remote services are being provided.

CMS requested 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 Display page 754. CMS did not respond to previously submitted comments in this rule.

CMS is also finalizing its proposal not to include data from non-standard 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.

Lastly, CMS will 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.

- **Inpatient–Only List** ***(Display pages 761 – 779)*****:** The IPO list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2023, CMS is adopting the removal of the following services from the IPO list:
    - 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);
    - CPT 47550: (Biliary endoscopy, intraoperative (choledochoscopy) (List separately in addition to code for primary procedure)); and
    - CPT 21255: Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts).

    CMS is not finalizing its proposal to remove the following services from the IPO list:

    - CPT 16036: Escharotomy; each additional incision (list separately in addition to code for primary procedure); and

    CMS is also adding the following 8 services to the IPO list:

    - CPT 15778: 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 22860: 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 49596: 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 49616: 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 49617: 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 49618: 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 49621: 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 49622: 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 finalized to be removed from the list and added to the IPO list are on Display pages 776 – 779.

- **Payment for Off–Campus Outpatient Departments** ***(Display pages 886 – 903)*****:** 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 finalizing 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 will 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 will 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** ***(Display 1,467 – 1,490)***: 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 adopting a new service category to be added to this policy: Facet Joint Interventions beginning with dates of service on or after July 1, 2023 (rather than the proposed March 1, 2023).

  A list of the services that require prior authorization, included in the adopted category, can be found in Table 103 on Display pages 1,487 – 1,490.

Updates to the Hospital Outpatient Quality Reporting (OQR) Program

Display pages 1,035 – 1,100

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, CMS finalized mandatory of reporting of the OP-31 measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this rule, CMS is finalizing to keep OP-31 as voluntary (the measure it current voluntary for CYs 2023 and 2024 reporting) instead due to the burden of this measure with the PHE.

CMS requested 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*" (CMS did not respond to comments)*; and*
- *"Readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) Measure or Other Volume Indicator in the Hospital OQR Program"* (Display pages 1,053 – 1,057).

CMS included a Request for Information (RFI) in the FFY 2023 IPPS proposed rule titled "Overarching Principles for Measuring Healthcare Quality Disparities across CMS Quality Programs". This RFI requested 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 are on Display pages 1,059 – 1,073.

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

With regards to validation target criteria, beginning with CY 2023 reporting/CY 2025 payment determination, CMS is adopting an additional criteria used to select the additional 50 hospitals. Specifically, 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 Display pages 1,045 – 1,046. A table listing the 19 measures to be collected for CY 2025 payment determinations is on Display pages 1,046 – 1,047. Finally, a table listing the 19 measures to be collected for CY 2026 payment determinations is on Display pages 1,047 – 1,048.

Remote Mental Health Services

Display pages 780 – 801

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 adopting its proposal 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 will 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 final codes are listed in Table 67 on Display page 790 and 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 is also adopting 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 will 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. This in-person 6 month visit requirement does 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.

In instances where there is an ongoing clinical relationship between a practitioner and beneficiary when the PHE ends, the in-person requirement for ongoing, not newly initiated, treatment will apply.

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

Display pages 801 – 803

CMS requested 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 was 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. Comments can be found on Display page 803.

Direction Supervision of Certain Cardiac and Pulmonary Rehabilitation Services

Display pages 803 – 806

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 sought 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. Comments can be found on Display pages 805 – 806.

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

Display pages 827 – 832

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 will 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

Display pages 833 – 854

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 finalizing its proposal with modification to recognize the software as a service CPT codes and pay for them separately, rather than establishing HCPCS codes to describe the services. The services are listed on Display pages 847 - 848.

CMS also requested comment on payment approaches for these services. Specific areas for comment are listed on Display pages 850 and comments are listed on pages 851 – 854.

Domestic National Institute for Occupational Safety & Health (NIOSH)-Approved Surgical N95 Respirators

Display pages 854 – 886

In the FFY 2023 IPPS proposed rule, CMS requested comment on potential payment adjustments for wholly domestically made NIOSH-approved surgical N95 respirators for IPPS and OPPS to offset costs incurred by hospitals when acquiring such equipment.

CMS is adopting its proposal to make such an adjustment beginning January 1, 2023 in a budget neutral manner. This adjustment will be a biweekly interim lump-sum payment to the hospital and will be reconciled at cost report settlement. The payments will 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 will 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 will be determined by the MAC.

Organ Acquisition Payment

Display pages 1,185 – 1,221

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 adopting its proposal 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 will also be required to deduct the cost incurred in procuring an organ for research from their total organ acquisition costs or by offsetting the total organ acquisition costs by the revenue received for these organs 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 states that the determination of an organ being unusable can be made by any surgeon, rather than solely the excising surgeon.

CMS clarified that "*the acquisition costs of organs that are initially intended for transplant, but subsequently determined unsuitable for transplant and instead furnished for research, are allowable acquisition costs."*

In addition, CMS is finalizing that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors, or a donor whose death is imminent, in order to increase organ procurement and promote equity.

In the proposed rule, CMS clarified 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."* However in this final rule, CMS is withdrawing that clarification to do additional analysis and evaluation on the topic.

Lastly, CMS asked 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. CMS did not respond to comments in this rule.

Overall Hospital Quality Star Rating

Display pages 1,490 – 1,509

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 will 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

Display page 1,467

CMS is looking to address excessive concentration, abuses of market power, unfair competition, and the impacts of monopoly and monopsony. Therefore, CMS sought 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. CMS did not respond to comments in the final rule.

Finalization of COVID-19 Interim Final Rules with Comment Period

Display page 1,509 – 1,553

CMS responded to comments and finalized policies for the following rules:

- Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC):
    - Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the Public Health Emergency (PHE) for the COVID-19 Pandemic (Display pages 1,509 – 1,515);
    - Counting Resident Time During the PHE for the COVID-19 Pandemic (Display pages 1,515 – 1,516);
    - Modification of the Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement for the PHE During the COVID-19 Pandemic (Display pages 1,516 – 1,519); and
    - Direct Supervision by Interactive Telecommunications Technology (Display pages 1,519 – 1,522).
- Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (CMS-5531-IFC):
    - Holding Hospitals Harmless from Reductions in Indirect Medical Education (IME) Payments Due to Increases in Bed Counts (Display pages 1,522 – 1,524);
    - Holding IRFs and IPFs Harmless From Reductions to Teaching Status Adjustment Payments Due to COVID–19 (Display pages 1,524 – 1,526);
    - Time Spent by Residents at Another Hospital During the PHE (Display pages 1,526 – 1,528);
    - CARES Act Waiver of the ‘‘3-Hour Rule’’ (Display pages 1,528 – 1,531);
    - Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE During the COVID–19 Pandemic (Display pages 1,531 – 1,537);
    - Hospital Outpatient and CMHC Therapy, Education, and Training Services (PHP) (Display pages 1,537 – 1,543);
    - Furnishing Hospital Outpatient Services Remotely for Services Other Than Mental Health (Display pages 1,543 – 1,546); and
    - Treatment of New and Certain Relocating Provider-Based Departments During the PHE (Display pages 1,546 – 1,550).
- OPPS Separate Payment for New COVID–19 Treatments Policy for the Remainder of the PHE (CMS-9912-IFC) (Display pages 1,550 – 1,553).

Rural Emergency Hospitals

Display pages 1,150 – 1,185 and 1,221 – 1,467

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.

CAHs and rural hospitals (or hospitals treated as rural) 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

Display pages 1,310 – 1,416

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. These CoP are modeled closely after the CoP for CAHs as well as the current hospital and ambulatory surgical center standards. Some of the specific requirements include:

- REHs must have a physician or other practitioner on-call at all times and available on-site within 30 or 60 minutes depending on if the facility is located in a frontier area;
- The REH emergency department must be staffed 24 hours per day and seven days per week by an individual that is competent to receive patients and activate the appropriate medical resources for the treatment of the patient;
- REHs must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program, and it must reflect improvement in quality indicators related to health outcomes and reductions in medical errors;
- Services furnished by an REH must not exceed an annual per-patient average length of stay of 24 hours in the REH; and
- REHs must have an infection prevention and control and antibiotic stewardship program that adhere to nationally recognized guidelines.

Page numbers for all finalized requirements are listed below:

- Definitions (Display pages 1,313 – 1,315);
- Basic Requirements (Display pages 1,315 – 1,316);
- Designation and Certification (Display pages 1,315 – 1,317);
- Compliance with Federal, State, and Local Laws and Regulations (Display pages 1,317 – 1,319);
- Governing Body and Organization Structure (Display pages 1,319 – 1,326);
- Provision of Services (Display pages 1,326 – 1,327);
- Emergency Services (Display pages (1,327 – 1,330);
- Laboratory Services (Display pages 1,330 – 1,332);
- Radiologic Services (Display pages 1,332 – 1,335);
- Pharmaceutical Services (Display pages 1,335 – 1,339);
- Additional Outpatient Medical and Health Services (Display pages 1,339 – 1,344);
- Infection Prevention and Control and Antibiotic Stewardship Programs (Display pages 1,344 – 1,353);
- Staffing and Staff Responsibilities (Display pages 1,353 – 1,356);
- Nursing Services (Display pages 1,356 – 1,358);
- Discharge Planning (Display pages 1,358 – 1,365);
- Patient's Rights (Display pages 1,365 – 1,373);
- Quality Assessment and Performance Improvement (QAPI) Program (Display pages 1,373 – 1,378);
- Agreements (Display pages 1,378 – 1,381);
- Medical Records (Display pages 1,381 – 1,383);
- Emergency Preparedness (Display pages 1,383 – 1,391);
- Physical Environment (Display pages 1,391 – 1,396); and
- Skilled Nursing Facility Distinct Part Unit (Display pages 1,396 – 1,398).

In addition, CMS finalized CoP policies for CAHs, including a change to the distance requirements in order to be eligible as a CAH. The current distance requirements state that a CAH must be located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or certified before January 1, 2006, by the State as being a necessary provider of health care services to residents in the area. CMS is adopting the definition of a "primary road" in the distance requirements such that the distance for a CAH to another hospital is more than a 35-mile drive on primary roads. CMS is finalizing the definition of primary road as *"…numbered Federal highway, including interstates, intrastates, expressways or any other numbered Federal highway with two or more lanes each way; or a numbered State highway with two or more lanes each way."*

CMS is also planning to establish a centralized, data-driven review procedure for recertification that will focus on hospitals being certified in proximity to a CAH, rather than focusing specifically on road classifications. All hospitals and CAHs within a 50-mile radius of each CAH will be reviewed initially, and then subsequently every 3 years.

Enrollment Requirements

Display pages 1,416 – 1,425

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 finalizing 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 must submit Form CMS-855A to enroll, but does 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 will 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

Display pages 1,425– 1,467

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 proposed a new exception and revisions to existing exceptions to the law for REHs when requirements to the exception are satisfied as described on Display pages 1,433 – 1,454, in order to avoid inhibiting access to medically necessary designated health service. However, CMS is not finalizing the exception for ownership or investment in an REH as that financial relationships permitted under the REH exception may present a risk of patient or program abuse. However, the rural provider exception that ensures the physician self-referral law does not create a barrier to care is still available to REHs.

REH Payment

Display pages 1,230 – 1,310

REHs will 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 states 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 will be paid at the same rate the service will 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 an REH would receive payment through the skilled nursing facility PPS without a 5.0% increase.

Additionally, REHs will not be subject to the reduced rate for services furnished by off-campus PBDs and will instead be paid at OPPS + 5.0% for these services. REHs will also not be eligible to participate in the 340B program. Provider-based rural health clinics will maintain their excepted status when converting to an REH.

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 calculated using CAH claims data). That value is divided by the number of CAHs (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 will include services and items that are not paid through OPPS. CMS will also 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 will still use the CY schedule even when calculating skilled nursing facility and inpatient payments, which are both based on FFY. The payments also include both amounts paid to CAHs from the Medicare program and from beneficiary copayments. CMS made one modification to eliminate the low-volume adjustment for CAHs that are within 15 miles of another provider in the calculation of estimated prospective payments.

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 57% of the estimated prospective payment for CAHs in 2019.

Details on the adopted methodology for estimated CY 2019 prospective payments for CAHs can be found *on* Display pages 1,267 – 1,296.

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

Display pages 1,150 – 1,185

The REHQR program is mandated by the CAA of 2021.

CMS requested 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 (Display pages 1,161 – 1,162);
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (Display pages 1,162 – 1,163);
- OP-4: Aspirin on Arrival (Display pages 1,163 – 1,165);
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (Display page 1,165);
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional (Display pages 1,165 – 1,166);
- OP-22: Left Without Being Seen (Display pages 1,166);
- Emergency Department Transfer Communications (EDTC) (Display page 1,167);
- OP-10: Abdomen Computed Tomography (CT) – Use of Contrast Material (Display page 1,168); and
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (Display page 1,168 – 1,169).

Comments can be found on Display pages 1,169 – 1,172.

CMS also requested comment on additional topics for quality measurement and several other topics including telehealth, maternal health, mental health, behavioral health, ED services, equity, and low volume. Comments can be found on Display pages 1,178 – 1,181.

In order for a hospital to participate in the REHQR, CMS is finalizing 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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