California Hospital Association

Federal Regulatory Summary

from the California Hospital Association

SUMMARY OF FINAL RULE – DECEMBER 2022

CY 2023 Outpatient Prospective Payment System

Overview

In the Nov. 23, 2022, *Federal Register,* the Centers for Medicare & Medicaid Services (CMS) published a final rule proposing updates and policy changes to the Medicare outpatient prospective payment system (OPPS) for calendar year (CY) 2023. The finalized policy and payment provisions are generally effective for CY 2023 discharges, beginning Jan. 1, 2023.

The following is a comprehensive summary of the final rule's acute care hospital provisions. In addition to annual payment and quality updates, the summary details policies related to the inpatient-only list, payment for separately payable drugs acquired under the 340B program, add-on payments for domestically manufactured N95 respirators, and rural emergency hospitals (REHs).

The final rule also includes provisions for ambulatory surgical centers (ASCs). For a detailed summary of those provisions, please contact cmulvany@calhospital.org.

For Additional Information

Questions about this summary should be directed to Megan Howard, vice president of federal policy, at (202) 488-3742 or mhoward@calhospital.org; or Chad Mulvany, vice president of federal policy, at (202) 270-2143 or cmulvany@calhospital.org. Facility-specific CHA DataSuite analyses were sent under separate cover. Questions about CHA DataSuite should be directed to Alenie Reth, data analytics coordinator, at areth@calhospital.org.

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Summary of Key Provisions

The 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 eight services
- Add a new service category for prior authorization
- Eliminate the 340B payment reduction
- Exempt rural sole community hospitals (SCHs) 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 REHs
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program
- Update payment rates and policies for ASCs

The increase in OPPS spending due only to changes in the 2023 OPPS final rule is estimated to be approximately $2.53 billion. Considering estimated changes in enrollment, utilization, and case mix for 2023, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $86.5 billion, which is approximately $6.5 billion higher than estimated OPPS expenditures in 2022.

CY 2023 Final OPPS Payment Update

CMS will use claims data from CY 2021 to set rates. However, due to concerns that the normal vintage of cost reports used for rate setting (for CY 2023, 2020 cost reports) is skewed by COVID-19, CMS is using cost report data from the June 2020 Healthcare Report Information System (HCRIS) data set (which only includes cost report data through 2019).

The tables below show the final CY 2023 conversion factor compared to CY 2022 and the components of the 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
Market Basket 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% (estimated at -4.04% in alternative files)
Pass–Through Spending/Outlier BN Adjustment	+1.09% (estimated at +1.04% in alternative files)
Cancer Hospital BN Adjustment	+0.00% (as proposed)
Overall Final Rate Update	**+1.67% (estimated at -0.37% in proposed rule alternative files)**

CMS estimates the update to the conversion factor net of the total factor productivity (TFP) will increase payments 3.8% in 2023 (market basket of 4.1%, less 0.3% for TFP). Including changes to outlier payments, pass-through payment estimates, and the application of the frontier state wage adjustment, reversal of 340B budget neutrality, CMS estimates a 4.5% increase in payments between 2022 and 2023.

CMS notes the following estimated impacts in Table 110 of the final rule:

Facility Type	Estimated 2023 Impact (Final)
All Hospitals	4.7%
Urban – All	4.9%
Urban – Pacific Region	5.1%
Rural – All	2.9%
Rural – Pacific Region	3.6%

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

OPPS CY 2023 Final Rule Analysis
CY 2023 Final Rule Compared to CY 2022 Final Rule

California

Impact Analysis	Dollar Impact	% Change
Estimated CY 2022 OPPS Payments	*$6,057,565,800*	
Marketbasket Update	$197,594,000	3.26%
ACA-Mandated Productivity Adjustment	($14,458,200)	-0.24%
Budget Neutrality Adjustments	$52,028,100	0.86%
340B Budget Neutrality Adjustment	($154,532,000)	-2.55%
Wage Index (Wage Data and Reclassification)	$27,043,700	0.45%
Application of the Imputed Floor	$0	0.00%
Increasing Bottom Quartile Wage Index Values	$0	0.00%
Wage Index 5% Stop Loss	$428,100	0.01%
Change in Rural Add-On	$0	0.00%
APC Factor/Updates*	$206,559,200	3.41%
Estimated CY 2023 OPPS Payments	*$6,372,228,700*	
Total Estimated Change From CY 2022 to CY 2023	**$314,662,900**	**5.19%**
	Dollar Impact	**% Change**
*Breakout of Removal of 340B Payment Reduction	$230,096,800	3.80%

The values shown in the table above do not include the 2.0% sequestration impact to all lines of Medicare payment authorized by Congress through FFY 2031. It is estimated that sequestration will reduce CY 2023 OPPS-specific payments by: $127,444,600

Source: CHA DataSuite Analysis, November 2022

Updates Affecting OPPS Payments

Recalibration of APC Relative Payment Weights

As required by law, CMS must review and revise the ambulatory payment classification (APC) relative payment weights annually. CMS must also revise the APC groups each year to account for drugs and medical devices that no longer qualify for pass–through status, new and deleted Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, advances in technology, new services, and new cost data. The final payment weights and rates for CY 2023 are available in Addenda A and B on the CMS website.

The table below shows the shift in the number of APCs per category from CY 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
Outpatient Department (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

APC Category	Status Indicator	Final CY 2022	Final CY 2023
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**

Blood and Blood Products

For CY 2023, CMS is continuing its policy to establish payment rates for blood and blood products using a blood-specific, cost-to-charge ratios methodology.

Brachytherapy Sources

Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS did not propose (and therefore did not finalize) changes to its brachytherapy policy for 2023. If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. For 2018 through 2022, CMS used external data to set a payment rate for HCPCS code C2645 (brachytherapy planar source, palladium-103, per square millimeter) at $4.69 per mm^2. CMS has no 2021 claims data for HCPCS code C2645 to set a rate for 2023. For this reason, CMS will continue using the rate of $4.69 per mm^2 for 2023 for HCPCS code C2645.

Comprehensive APCs (C-APCs)

A C-APC covers payment for all Part B services that are related to the primary procedure, including items currently paid under separate fee schedules. The C-APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un–coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products **are included** in the C-APCs when they appear on the same claim as those services assigned to a C-APC.

The C-APCs do not include payments for services that are not covered by Medicare Part B, nor those that are not payable under OPPS such as certain mammography and ambulance services; brachytherapy sources; pass-through drugs and devices; charges for self-administered drugs; certain preventive services; and procedures assigned to a New Technology APC either included on a claim with a "J1" or when packaged into payment for comprehensive observation services assigned to status indicator "J2" when included on a claim with a "J2" indicator.

CMS adds one new C-APC — Level 2 Urology and Related Services (C-APC 5372) — for CY 2023, for a total of 70 C-APCs. A list of the final 70 C-APCs for CY 2023 can be found in Table 2 of the final rule.

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 both of the following criteria:

- The treatment is a Food and Drug Administration (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.
- The emergency use authorization for the drug or biological product must authorize the use of the product in the outpatient setting; 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.

Calculation of Composite APC Criteria-Based Costs

Composite APCs are another type of packaging to provide a single APC payment for groups of services that are typically performed together during a single outpatient encounter. Currently, there are six composite APCs for:

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

For CY 2023, CMS is continuing its policy about aggregate payments for specified mental health services provided by a hospital to a single beneficiary on a single date of service. In that circumstance, when a payment 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 also continues its current composite APC payment policies for multiple imaging services from the same family and on the same date. Table 3 in the final rule includes the HCPCS codes that are subject to the multiple imaging procedure composite APC policy and their respective families, as well as each family's geometric mean cost.

Changes to Packaged Items and Services

CMS did not propose/finalize any changes to its packaging policies and separate payment for non-opioid treatment alternatives.

Wage Index Changes

CMS continues using a labor share of 60% and the fiscal year inpatient prospective payment system (IPPS) post-reclassified wage index for the OPPS in CY 2023. In the federal fiscal year (FFY) 2023 IPPS rule, CMS applied a 5% cap on reductions to a hospital wage index for any reason. CMS adopts this same policy under the OPPS for CY 2023. CMS makes this change in a budget-neutral manner, necessitating a -0.04% budget-neutrality adjustment to the conversion factor.

For non-IPPS hospitals paid under the OPPS for CY 2023, CMS continues its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment.

CMS finalizes 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 adjustments had not changed.

Sole Community Hospital (SCH) Adjustment

For CY 2023, CMS continues applying a 7.1% payment adjustment for rural SCHs, including essential access community hospitals, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Additionally, CMS exempts rural SCHs from being paid the physician fee schedule (PFS)-equivalent rate when services are delivered in an excepted off-campus PBD. CMS solicited comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds, from this policy. However, the final rule ***does not*** exempt hospitals other than rural SCHs from the site-neutral policy.

Excepting rural SCHs from this policy would result in an unadjusted payment for a clinic visit (G0463) in CY 2023 of approximately $121, with an approximate average copayment of $24 for the beneficiary. This compares to a final PFS-equivalent rate of $48, with an approximate average copayment of $10. CMS estimates that exempting rural SCHs from this policy will increase OPPS spending by approximately $71 million in 2023.

Cancer Hospital Adjustment

CMS continues providing payment increases to the 11 exempt cancer hospitals. CMS does this by providing a payment adjustment so that the cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals (and thus the adjustment is budget neutral).

The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis. Rather than using the latest available cost reports that would include data that span the COVID-19 PHE, CMS will continue using the same target PCR it used for 2021 and 2022. Under the final policy for CY 2023, the target PCR would remain at 0.89.

Outpatient Outlier Payments

To maintain total outlier payments at 1% of total OPPS payments, CMS is using 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 APC payment amount when both the 1.75-multiplier threshold and the fixed-dollar threshold are met.

New Technology APCs

Currently, there are 52 levels of New Technology APC groups with two parallel status indicators: one set with a status indicator of "S" (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of "T" (T = Significant procedure, multiple reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 (New Technology – Level 1A [$0 - $10]) through the highest cost band assigned to APC 1908 (New Technology – Level 52 [$145,001 - $160,000]). Payment for each APC is made at the mid-point of the APC's assigned cost band.

For CY 2023, CMS continues 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 four years of claims data to set the payment rate for the APC.

Pass-Through Payments for Devices

There are currently 14 device categories eligible for pass-through payment (three finalized in this rule). Separate payment for HCPCS code C1823 under the equitable adjustment authority will end on Dec. 31, 2022. Table 52 (reproduced below) lists the devices and their pass-through expiration.

Expiration of Pass-Through Payments for Certain Devices

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2022*
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to-bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (disposable), upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023

Expiration of Pass-Through Payments for Certain Devices			
HCPCS Codes	**Long Descriptor**	**Effective Date**	**Pass-Through Expiration Date**
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable) nonrechargeable with carotid sinus baroreceptor simulation lead(s)	1/1/2021	12/1/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/1/2021	9/30/3024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/22	12/31/2024
C1822	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/22	12/31/2024

*CMS used its equitable adjustment authority to provide separate payment for C1823 for four quarters of 2022 for C1823, whose pass-through payment status expired on Dec. 31, 2021. Adjusted separate payment for HCPCS code C1823 will end on Dec. 31, 2022.

New Device Pass-Through Applications

CMS has received eight 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) (approved)
- The BrainScope TBI model: (Ahead 500)
- NavSlim™ and NavPencil
- SmartClip™
- Evoke® Spinal Cord Stimulation (SCS) System (approved)
- Pathfinder® Endoscope Overtube
- The Ureterol (approved)

Device-Intensive Procedures

Device-Intensive Procedure Policy for 2019 and Subsequent Years

Device-intensive APCs are procedures that require the implantation of a device and are assigned an individual HCPCS code-level device offset of more than 30% of the procedure's mean cost, regardless of APC assignment.

For CY 2023, consistent with CMS' broader policy to use 2021 claims for 2023 OPPS/ASC rate-setting purposes, CMS will use 2021 claims information for determining device offset percentages and assigning device-intensive status.

The full listing of 2023 device-intensive procedures is provided in Addendum P.

Device Edit Policy

For CY 2023, CMS did not make any changes to the device edit policy.

Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital received a credit from the manufacturer. The offset can be 100% of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer, or 50% when a hospital receives partial credit of 50% or more. For CY 2023, CMS is not making any major changes to the no cost/full credit and partial credit device policies.

Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on the packaging threshold. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved to grant a pass-through period as close to three full years as possible, and to eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

For CY 2023, CMS finalizes 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 sale price (ASP) +6%.

CMS will continue paying for separately payable drugs and biological products that do not have pass-through status and are not acquired under the 340B program at wholesale acquisition cost (WAC) +3%, instead of WAC +6%.

For CY 2023, CMS continues paying for therapeutic radiopharmaceuticals with pass-through payment status as well as blood clotting factors, based on ASP +6%. If ASP data are not available, payment instead will be made based on WAC +3%, or 95% of average wholesale price (AWP) if WAC data are also not available.

Lastly, CMS finalized that the pass-through status will expire by Dec. 31, 2022, for 32 drugs and biologicals listed in Table 57 of the final rule; by Dec. 31, 2023, for 43 drugs and biologicals listed in Table 58 of the final rule; and will continue/establish pass–through status in CY 2023 to 49 (proposed at 32) others shown in Table 59 of the final rule.

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 Dec. 31, 2021, and Sept. 30, 2022, due to the use of CY 2019 claims data rather than CY 2020 claims data in CY 2022 rate setting. In this rule, CMS will resume the regular update process of using claims data from two years prior to the year of rate setting. 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 Dec. 31, 2022, and Sept. 30, 2023.

OPPS Payment Methodology for 340B-Purchased Drugs

Currently, CMS pays a reduced rate of ASP –22.5% of the product's ASP, rather than ASP +6% for non-pass-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 PBDs.

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 U.S. 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 U.S. District Court decision. However, on July 15, 2022, the U.S. Supreme Court reversed the appeals court decision, stating that payment rates for drugs and biologicals may not vary among groups of hospitals in the absence of a survey of hospitals' acquisition cost.

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

However, in this final rule, CMS applies a rate of ASP +6% in the final rule for drugs acquired under the 340B program. If ASP data are not available, payment instead would be made based on WAC +3%; or 95% of AWP if WAC data are also not available. 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 Sept. 28, 2022, the U.S. District Court ruled to vacate the 340B reimbursement for the remainder of 2022. For 340B claims between Jan. 1, 2022, and Sept. 27, 2022, providers will need to submit adjustments for each claim that has a "JG" modifier, described here.

CMS has not yet decided how to apply the U.S. Supreme Court's decision to prior cost years. The agency plans to issue a separate proposed rule detailing a remedy for 2018 to 2022 in advance of the 2024 OPPS/ASC proposed rule.

Modifiers "JG" and "TB" still apply for CY 2023 for informational purposes only. 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 SCHs, children's hospitals, PPS-exempt cancer hospitals, and PPS-exempt critical access hospitals (CAHs).

High/Low-Cost Threshold for Packaged Skin Substitutes

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 continues 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 PFS rule, CMS finalized its policy to treat all skin substitute products consistently across health care settings as incident-to supplies. 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 would continue to report WAC and AWP, CMS will instead use its alternative process (WAC +3% or 95% of AWP) to assign groups when cost data are not available.

Hospital Outpatient Visits

For off-campus PBDs excepted from being paid a PFS-equivalent rate, CMS continues to pay 40% of the full OPPS rates for clinic visits. As discussed above, CMS exempts rural SCHs from this policy. While CMS sought comments on other types of providers it should exempt, it did not exempt any other provider types in the CY 2023 OPPS final rule.

Inpatient-Only (IPO) List

The IPO list specifies services/procedures that Medicare will pay only when provided in an inpatient setting. For CY 2023, CMS removes the following 11 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 (e.g., for long face syndrome), without bone graft
- CPT 21142: Reconstruction midface, LeFort i; two pieces, segment movement in any direction, without bone graft
- CPT 21143: Reconstruction midface, LeFort i; three 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 (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)
- 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)
- 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 service from the IPO list:

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

CMS also adds the following eight services to the IPO list:

- CPT 15778: Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (i.e., 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) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., 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) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., 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) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., 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) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated
- CPT 49621: Repair of parastomal hernia, any approach (i.e., open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible
- CPT 49622: Repair of parastomal hernia, any approach (i.e., open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated

OPPS Payment for Software as a Service

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 procedure.

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 finalizing its proposal with modification to recognize the software as service CPT codes and pay for them separately, rather than establishing HCPCS codes to describe the services. The services are listed in Table 69 in the final rule.

Payment Adjustments: Domestic NIOSH-Approved Surgical N95 Respirator Masks

In the FFY 2023 IPPS proposed rule, CMS requested comment on potential payment adjustments 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.

In the CY 2023 OPPS final rule, CMS finalized its proposal to make a payment adjustment under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after Jan. 1, 2023. For the IPPS, the secretary would make the adjustment in a non-budget-neutral manner (e.g., no reduction in the IPPS base operating rate because of these additional payments). For the OPPS, the secretary is required by statute to make the payments in a budget-neutral manner, necessitating a reduction in the OPPS conversion factor.

This adjustment will be made via a biweekly interim lump-sum payment to the hospital and reconciled at cost report settlement. The payments will initially be based on the estimated difference in a hospital's reasonable costs 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 Medicare administrative contractor.

Organ Acquisition Payment

In the CY 2022 IPPS proposed rule, CMS made several proposals regarding transplant hospitals (THs) and hospital-based organ procurement organizations (HOPOs). Based on public comments to those proposals and in order to improve payment accuracy and lower the costs to procure and provide research organs, CMS finalized its proposal in the CY 2023 OPPS rule requiring 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 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 finalizes that the determination of an organ being unusable can be made by any surgeon, rather than just the excising surgeon.

CMS also clarifies 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 finalized that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors, or donors whose death is imminent, 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 (administrative and general) costs."* However, in the final rule, CMS withdraws 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.

Rural Emergency Hospitals

The Consolidated Appropriations Act (CAA) of 2021 established REHs as a new provider type beginning Jan. 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 (SNF) services in a distinct unit.

CAHs and rural hospitals with fewer than 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*
- *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

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, 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 Quality Assurance and Performance Improvement (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
- REHs must have an infection prevention and control and antibiotic stewardship program that adheres to nationally recognized guidelines

Below is a listing of COPs CMS finalized for REHs in the CY 2023 OPPS rule:
- Definitions
- Basic requirements
- Designation and certification
- Compliance with federal, state, and local laws and regulations
- Governing body and organization structure
- Provision of services
- Emergency services
- Laboratory services
- Radiologic services
- Pharmaceutical services
- Additional outpatient medical and health services
- Infection prevention and control and antibiotic stewardship programs
- Staffing and staff responsibilities
- Nursing services
- Discharge planning
- Patient's rights
- QAPI program
- Agreements
- Medical records
- Emergency preparedness
- Physical environment
- SNF distinct part unit

REH Payment

REHs will be paid for all covered OPD services at the OPPS rate of +5%. Copayments will be calculated based on the OPPS rate, excluding the 5% increase. REHs will 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 a hospital-based OPD and paid under a fee schedule other than the OPPS, with no 5% increase. Post-hospital extended care services provided by an REH would receive payment through the SNF PPS without a 5% 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% for these services.

In addition, REHs will receive a monthly payment 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 SNF services under the PPS (calculated using CAH claims data). That value is divided by the number of CAHs (also determined using

claims data). CMS finalized that the monthly facility payment for REHs for 2023 will be $272,866 (increased slightly from $268,294 as proposed). This amount would be increased in subsequent years by the hospital market basket. REHs will be required to maintain detailed information as to how the payments are used.

Enrollment Requirements

A REH's 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 at the same extent as for all other Medicare provider and supplier types, CMS is finalizing that an REH must comply with all applicable provisions 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
- Undergoing risk-based screening

A REH must submit Form CMS-855A to enroll but does not have to pay an application fee as 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.

Physician Self-Referral Law

REHs are required by CoPs to furnish radiology and certain imaging services, clinical laboratory services, and outpatient prescription drugs as they are 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,"* unless an exception is made. CMS proposed new exceptions and revisions to existing exceptions to the law for REHs when requirements to the exception are satisfied in order to avoid inhibiting access to medically necessary designated health services. CMS is not finalizing the exception for ownership or investment in an REH, as that financial relationship 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 Quality Reporting Program

The CAA requires that the secretary establish quality reporting requirements for REHs, including at least quarterly data submission and public reporting of performance data. While CMS is deferring requirements related to quality measure specifications and quality reporting requirements for future rulemaking, it finalized administrative requirements.

Administrative Requirements

CMS finalized that REHs that want to participate in the REH Quality Reporting (REHQR) Program must register for an account to use the agency's Hospital Quality Reporting (HQR) secure portal to submit data and must designate a security official for the account. Hospitals

converting to REH status that already have HQR access may register by updating their profiles using their new REH CMS certification number.

Potential REHQR Program Measures

In the proposed rule, CMS sought comments on several specific potential measures for the REHQR Program. CMS notes that the potential measures are already reported under the outpatient OQR Program or Medicare Beneficiary Quality Improvement Project.

- OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
- OP-4: Aspirin on Arrival
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
- OP-22: Left Without Being Seen
- Emergency Department Transfer Communications (EDTC)
- OP-10: Abdomen Computed Tomography (CT) – Use of Contrast Material
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (Display page 643)

Critical Access Hospital (CAH) Conditions of Participation – Distance Requirements

In addition to the REH CoPs, CMS finalized CoP policies for CAHs, including a change to the distance requirements to qualify 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 Jan. 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 finalizes 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 also plans 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 three years.

Partial Hospitalization Program Services

Partial hospitalization programs (PHPs) are intensive outpatient psychiatric programs that provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding community mental health center (CMHC). PHP providers are paid on a per diem basis, with payment rates calculated using CMHC- or hospital-specific data. The table below compares the final CY 2022 and CY 2023 PHP payment rates:

	Final Payment Rate 2022	Final Payment Rate 2023	Percent Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$142.70	$142.70	+0.0
APC 5863: Partial Hospitalization (3+ services) for Hospital-Based PHPs	$265.97	$268.22	+0.85

For CY 2023, CMS uses its established policies to calculate the PHP APC per diem payment rates for CMHCs and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type, with some modifications. CMS established the geometric mean per diem cost of $135.68 for CMHCs and geometric mean per diem cost of $275.83 as the basis for developing the 2023 hospital-based APC per diem rate.

Consistent with CMS' use of CY 2019 cost data in rate setting for the OPPS (which was also used for CY 2022), CMS calculated the CMHC and hospital-based PHP geometric mean per diem costs using CY 2021 claims data and cost report data from the June 2020 HCRIS data set (the same cost data that were used for CY 2022). However, in response to comments, CMS agreed not to finalize any rate cuts for CMHC PHP services in CY 2023, and therefore applied an equitable adjustment to hold the APC payment rate at the CY 2022 level for the CMHC's PHPs. CMS notes that this equitable adjustment is only for CY 2023 and not subsequent years.

CMS finalized its proposal to exclude data from nonstandard cost center lines that do not correspond to the cost center number for CY 2023 rate setting due to the concerns about significant changes in APC geometric mean costs if those lines were included.

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 in prior years, CMS will apply an 8% outlier payment cap to the CMHC's total per diem payments.

Remote Non-PHP Mental Health Services After the COVID-19 PHE

CMS reminds providers that under its interim final rule (CMS–1744–IFC), hospital and CMHC staff may 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 CoP that are not waived for the duration of the COVID-19 PHE. These services can be furnished using telecommunications technology if the beneficiary is registered as an outpatient.

However, CMS notes that all other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still (1) require an order by a physician, (2) must be supervised by a physician, (3) must be certified by a physician, and (4) must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice. CMS also notes that the longstanding requirements for documentation in the medical record of the reason for the visit and the substance of the visit still apply.

In addition, while elsewhere in the final rule CMS established policies to allow for payment of certain remote mental health services furnished by clinical staff of a hospital (described below),

CMS clarified that PHP services will not be eligible to be provided remotely using communications technology after the end of the PHE. CMS also clarified that PHP patients could receive non-PHP mental health services from a hospital remotely, but these would not count as PHP services.

In response to comments on the proposed rule, CMS further clarified that it understands there will be circumstances when a patient under a PHP plan of care may need to temporarily receive remote mental health services. CMS said that remote mental health services that are included in a PHP patient's plan of care will not limit a patient's eligibility for continued participation in a PHP if all other program requirements are met. Specifically, for a patient who needs at least 20 hours per week of PHP services, CMS will consider remote mental health services that are included in the patient's plan of care to be consistent with the regulation at §410.43(c)(1), which states that PHPs are intended for patients that require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. Thus, if a PHP patient receives non-PHP mental health remote services, the plan of care should reflect those services, and the inclusion of those services in the plan of care would not limit the patient's eligibility for continued participation in a PHP to the extent that other patient eligibility requirements are met.

Mental Health Services Furnished to Patients in their Homes

For the duration of the COVID-19 PHE, CMS waived certain requirements that allowed patients to receive mental health services in their homes using communications technology. In order to avoid negative impacts on access at the end of the PHE, CMS finalizes payment for 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 under the OPPS.

Specifically, CMS establishes OPPS-specific coding for these services, the descriptions of which specify that a beneficiary must be in their home, and that there is no associated professional service billed under the Medicare PFS. In response to comments on the proposed rule, which would have required that all staff providing these services be physically located in the hospital, CMS is revising its policy. Specifically, CMS is revising the regulations at 42 CFR 410.27(a)(1)(iii) to add the phrase "except for mental health services furnished to beneficiaries in their homes through the use of communication technology" and § 410.27(a)(1)(iv)(A) to add the phrase "or through the use of communication technology for mental health services." The physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

CMS assigns the new HCPCS codes to APCs based on the PFS facility payment rates for CPT codes because it believes that the costs associated with these remote services more closely resemble those under the PFS rather than the OPPS because the hospital is not accruing all the costs associated with in-person services.

The final HCPCS codes and APC rates are provided in the table below:

HCPCS Code	Description	CPT	PFS	APC	Final

		Comparison	Facility Rate		APC Rate
C7900	Remote mental health service, initial 15-29 minutes	96159	$19.52	5821	$30.48
C7901	Remote mental health service, initial 30-60 minutes	95158	$56.56	5822	$77.67
C7902	Remote mental health service, each additional 15 minutes	N/A			

CMS finalized its proposal to require that the beneficiary receive an in-person visit within six 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 these requirements 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 in the medical record.

CMS also finalized its proposal to require the hospital clinical staff to use telecommunications systems that include audio and video equipment permitting two-way, real-time interactive communications. However, CMS will allow audio-only communications depending on an individual patient's technological limitations, abilities, or preferences.

Remote Direct Supervision of Cardiac and Pulmonary Rehabilitation Services

Cardiac, intensive cardiac, and pulmonary rehabilitation services can be provided via telehealth under the PFS until Dec. 31, 2023. For 151 days after the end of the COVID-19 PHE, these services may originate from a patient's home in any area of the country, and the physician supervision of these services may take place via interactive telecommunications systems including audio-only. On or after the 152nd day after the end of the PHE, these services must originate from a health care setting and a rural area to be paid via telehealth under the PFS until Dec. 31, 2023. After that time, these services cannot be provided via telehealth.

Under current OPPS policy, cardiac, intensive cardiac, and pulmonary rehabilitation services may be provided in the hospital with the physician direct supervision being provided to a patient via a virtual presence for the duration of the PHE. CMS notes that it does not have the flexibility to allow the patient's home to be provider based to the hospital after the PHE ends. This means cardiac, intensive cardiac and pulmonary rehabilitation services will have to be provided in the hospital and will no longer be able to originate from the patient's home and paid under the OPPS when the PHE ends. However, CMS will retain the policy to allow the direct supervision requirement to be met by the presence of the supervising practitioner through two-way, audio/video when the beneficiary is physically located in the hospital until Dec. 31, 2023.

Nonphysician Practitioner Supervision of Hospital and CAH Diagnostic Services

The CY 2021 PFS final rule made permanent certain changes to supervision requirements for diagnostic services, initially implemented for the COVID-19 PHE. Specifically, CMS allowed diagnostic tests furnished in OPDs to also be supervised by non-physician practitioners (NPPs) to

the extent they are authorized under their scope of practice and applicable state law. To address regulatory inconsistencies, CMS finalizes its proposal to modify 42 CFR § 410.27 and 410.28 to include NPPs as supervising practitioners. This is in addition to physicians for diagnostic and therapeutic services furnished under personal or direct supervision to the extent that they are authorized to do so under their scope of practice and applicable state law.

Hospital OQR Program

The hospital OQR Program is mandated by law; hospitals that do not successfully participate are subject to a 2-percentage point reduction to the OPPS market basket update for the applicable year. CMS posts the list of individual hospitals meeting or failing to meet OQR reporting requirements. For the CY 2022 payment determination, 3,268 of 3,298 hospitals (99%) met all reporting requirements — including data submission — while 30 failed to do so. CAHs may choose but are not required to report OQR measures. For CY 2022, 1,291 of 1,354 (95%) CAHs reported data, while 63 opted not to submit.

CMS finalizes minor changes to the OQR, including modifying reporting requirements for one measure to allow for voluntary reporting, aligning the OQR Program's encounter quarters for chart-abstracted measures to the calendar year, and adding a targeting criterion for use in selecting hospitals for data validation.

CMS makes no changes to previously finalized OQR Program policies for measure selection, retention, and removal; data submission via the CMS web-based tool, the Centers for Disease Control and Prevention National Healthcare Safety Network tool; the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey-Based Measures (OP-37a-e); electronic clinical quality measures (eCQMs); population and sampling requirements; the educational review and correction process for chart-abstracted measures; reconsideration and appeals procedures; public display of quality measures; and requirements for participation in and withdrawal from the OQR Program. A table in the appendix of this summary shows the previously and newly adopted OQR Program measures for payment determinations from 2021 through 2026.

Modification of Reporting Requirements for Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536)

In response to ongoing stakeholder concerns with the burden of reporting this measure, as well as ongoing staffing and supply shortages, CMS finalized its proposal to change the reporting status of the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536) measure from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination and for subsequent years. The measure requires the collection of visual function surveys from patients both preoperatively and postoperatively. CMS emphasizes that its status change in this rule does not change the measure's voluntary status as previously finalized for CY 2023 and CY 2024 reporting, and states that it will revisit mandatory reporting of this measure in the future.

Aligning OQR Program Patient Encounter Quarters to the Calendar Year

CMS finalizes its proposal to align the patient encounter quarters for the OQR Program's chart-abstracted measures with the calendar year. As finalized, all four quarters will eventually be based

on the calendar year that is two years prior to the applicable payment determination year. CMS will phase in these changes beginning with the CY 2023 payment year. The table below provides the applicable dates for current and future years.

OQR PATIENT ENCOUNTER QUARTERS AND DATA SUBMISSION DEADLINES	
Encounter Quarter	**Data Submission Deadline***
CY 2024 – Current Methodology – Previously Finalized	
Q2 2022 (April 1-June 30)	*11/1/2022*
Q3 2022 (July 1-Sept. 30)	*2/1/2023*
Q4 2022 (Oct. 1-Dec. 31)	*5/1/2023*
Q1 2023 (Jan. 1-March 31)	*8/1/2023*
CY 2025 – Transition Year Methodology – Proposed	
Q2 2023 (April 1-June 30)	11/1/2023
Q3 2023 (July 1-Sept. 30)	2/1/2024
Q4 2023 (Oct. 1-Dec. 31)	5/1/2024
CY 2026 – Subsequent Years Methodology – Proposed (transition complete)	
Q1 2024 (Jan. 1-March 31)	8/1/2024
Q2 2024 (April 1-June 30)	11/1/2024
Q3 2024 (July 1-Sept. 30)	2/1/2025
Q4 2024 (Oct. 1-Dec. 31)	5/1/2025

*All deadlines occurring on a Saturday, Sunday, legal holiday, or any other day, all or part of which is declared to be a nonwork day for federal employees by statute or executive order, would be extended to the first day thereafter.

Hospital OQR Program Validation Requirements

CMS finalized its proposal to adopt an additional targeting criterion for use in hospital selection for OQR Program data validation beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years:

- Any hospital with a two-tailed confidence interval that is less than 75% and that had less than four quarters of data due to having received an extraordinary circumstances exception from OQR Program data submission for one or more quarters

CMS added this criterion because the hospital it describes would have less than four quarters of data available for validation and its validation results could be considered inconclusive for a payment determination. CMS clarified that a hospital with less than four quarters of data, but didn't receive an extraordinary circumstance exception for one or more quarters and does not meet the 75% reliability threshold, clearly is subject to both annual payment update (APU) reduction and targeting for validation in the subsequent year. Similarly, a hospital that has four quarters of data subject to validation and does not meet the 75% threshold clearly is subject to both APU reduction and targeting for validation in the subsequent year.

Current criteria for targeted selection are: (1) having failed the previous year's validation; (2) having an outlier value for a measure; (3) not having been randomly selected for validation in any of the previous three years; and (4) having passed validation in the previous year with a two-

tailed confidence interval that included 75%. The final criterion identifies hospitals whose accuracy falls within the statistical margin of error and captures both passing and failing facilities.

Overall Hospital Quality Star Rating

The Overall Hospital Quality Star Rating system was first introduced in July 2016, and the methodology was revised in the CY 2021 OPPS final rule. CMS finalized minor revisions to the regulation text for clarity and provided previously promised follow-up information about adding data from Veterans Health Administration (VHA) hospitals to the ratings. CMS also discussed the potential application of its measure suppression policy to ratings published in 2023 as needed to address COVID-19 PHE effects on the measure data underlying the ratings.

Regulation Text Amendment Regarding Frequency of Publication and Data Used

CMS clarified which data periods are used to refresh Overall Hospital Quality Star Ratings by referencing a quarter "within the prior 12 months" instead of a quarter "within the prior year." CMS believes the original language might have been construed to refer to a Care Compare refresh from the prior calendar year rather than the intended prior 12 months; the latter period could include months from two different calendar years.

Adding VHA Hospitals to Hospital Quality Star Ratings

In the CY 2021 OPPS final rule, CMS began including 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% 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.

Potential Data Suppression for 2023 Overall Hospital Quality Star Ratings

CMS acknowledges concerns about publishing Overall Hospital Quality Star Ratings inclusive of data impacted by the COVID-19 PHE. Current policy allows for suppression of one or more measures used for star ratings when extenuating circumstances affect numerous hospitals (e.g., natural disasters), when CMS makes calculation errors or has systemic issues (e.g., incorrect data processing), or when a PHE substantially affects the underlying measure data.

CMS notes that data for nearly all measures used for the 2021 and 2022 Care Compare refreshes of Overall Hospital Quality Star Ratings were collected prior to the COVID-19 PHE declaration because CMS issued a blanket exception from quality data reporting for Q1 and Q2 2020, including all data sources. However, quality data collection resumed with Q3 2020. CMS did not propose any changes to its policies and states its intention to complete a refresh of the ratings in 2023. However, CMS notes that the agency may choose to exercise its measure suppression authority should an analysis of the underlying measure data show it to have been substantially affected by the COVID-19 PHE.

Prior Authorization

In the CY 2020 OPPS final rule, CMS established a prior authorization process as a condition of payment for certain hospital-based services. Currently, prior authorization must be obtained for service dates on or after July 1, 2020, for the following service categories: (i) blepharoplasty, (ii) botulinum toxin injections, (iii) panniculectomy, (iv) rhinoplasty, and (v) vein ablation. Prior authorization must be obtained for service dates on or after July 1, 2021, for service categories: (i) cervical fusion with disc removal and (ii) implanted spinal neurostimulators.

CMS finalizes its proposal to add the service category — facet joint interventions — to the prior authorization list. However, in a change from the proposed rule, this policy will be effective for dates of service on or after July 1, 2023 (rather than March 1, 2023, as proposed). The facet joint interventions service category consists of facet joint injections, medial branch nerve blocks, and facet joint nerve destruction. A full list of the services that require prior authorization can be found in Table 103 of the final rule.

Appendix – Hospital Outpatient Quality Reporting Program Measures Table

NQF		2022	2023	2024	2025	2026
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	Removed	
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	Removed	
0514+	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X	X
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X
0499+	OP-22: ED - Left Without Being Seen	X	X	X	X	X
0661	OP-23: ED - Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery				Voluntary	Voluntary
2539	OP-32: Facility Seven-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X
	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery	X	X	X	X	X
	OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures				Voluntary	X
	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)			X	X	X
	OP-39: Breast Cancer Screening Recall Rates		X	X	X	X
	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM				Voluntary	X

+ CMS notes that NQF endorsement for the measure has been removed.