California Hospital Association

Federal Regulatory Summary

from the California Hospital Association

SUMMARY OF PROPOSED RULE – AUGUST 2021

CY 2022 Outpatient Prospective Payment System

Overview

In the August 4 *Federal Register*, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule addressing rate updates and proposed policy changes to the Medicare outpatient prospective payment system (OPPS) for calendar year (CY) 2022. The policy and payment provisions would generally be effective for CY 2022 discharges, beginning January 1, 2022.

The following is a comprehensive summary of the proposed rule's acute care hospital provisions. In addition to annual payment and quality updates, the summary details proposals related to the inpatient-only list, hospital price transparency regulation compliance, the establishment of a new provider type called the rural emergency hospital and modifications to the radiation oncology model.

To Comment

Comments are due to CMS on September 17 by 2 p.m. (PT) and can be submitted electronically at www.regulations.gov; search the site for "CMS-1753-P."

Member Forum

Register for CHA's CY 2022 OPPS proposed rule webinar at 9 a.m. (PT) on August 26 to learn more about these policies and provide input for CHA's comments. Registration is available on the CHA website.

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.

Contents

Summary of Key Provisions

The proposed rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates, as well as regulations that implement new policies. The proposed rule includes policies that will:

- Use CY 2019 claims and FY 2018 cost report data to set the CY 2022 payment rates due to the effect of the COVID–19 public health emergency (PHE)
- Reverse the elimination of the inpatient-only (IPO) list and add back in services removed in CY 2021
- Create a universal low volume Ambulatory Payment Classification (APC) policy
- Continue the reduction in payment to 340B hospitals for separately payable Part B drugs
- Amend price transparency requirements, increasing penalties for non-compliance
- Make changes to the radiation oncology model
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The increase in OPPS spending due only to changes in the 2022 OPPS proposed rule is estimated to be approximately $1.35 billion. Taking into account estimated changes in enrollment, utilization, and case-mix for 2022, CMS estimates that OPPS expenditures, including beneficiary cost-sharing will be approximately $82.7 billion, which is approximately $10.8 billion higher than estimated OPPS expenditures in 2021.

CY 2022 Proposed OPPS Payment Update

CMS typically uses the most up-to-date claims data and cost report data to set OPPS rates for the upcoming year. To avoid using claims data that is impacted by the COVID–19 PHE, CMS is proposing to use CY 2019 data to approximate CY 2022 outpatient service utilization instead of CY 2020 data.

The tables show the proposed CY 2022 conversion factor compared to CY 2021 and the components of the update factor:

	Final CY 2021	Proposed CY 2022	Percent Change
OPPS Conversion Factor	$82.797	$84.457	+2.00%

Proposed CY 2022 Update Factor Component	Value
Market Basket (MB) Update	+2.5%
Affordable Care Act (ACA)–Mandated Productivity MB Reduction	–0.2 percentage points (PPT)
Wage Index BN Adjustment	+0.12%
Pass–through Spending/Outlier BN Adjustment	–0.38%
Cancer Hospital BN Adjustment	+0.00%
Overall Proposed Rate Update	**+2.00%**

CMS estimates that the update to the conversion factor net of the multifactor productivity adjustment (MFP) will increase payments 2.3% in 2022 (market basket of 2.5% less 0.2 percentage points for MFP). Including changes to outlier payments, pass-through payment estimates and the application of the frontier state wage adjustment, CMS estimates a 1.8% increase in payments between 2021 and 2022.

CMS notes the following estimated impacts in Table 71 of the proposed rule.

Facility Type	Estimated 2022 Impact (Proposed)
All Hospitals	1.8%
Urban – All	1.8%
Urban – Pacific Region	2.2%
Rural – All	1.8%
Rural – Pacific Region	1.6%

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

Impact Analysis	Dollar Impact	Percent Change
Estimated CY 2021 OPPS Payments	*$6,051,773,100*	
Marketbasket Update	$124,243,300	2.05%
ACA-Mandated Marketbasket Reduction	($9,939,700)	-0.16%
Other BN Adjustments	($14,666,900)	-0.24%
Wage Index (Wage Data and Reclassification)	$3,759,400	0.06%
Application of the Imputed Floor	$0	0.00%
Increasing Bottom Quartile Wage Index Values	$0	0.00%
Change in Rural Adjustment	$0	0.00%
APC Factor/Updates	$20,878,400	0.34%
Estimated CY 2022 OPPS Payments	*$6,176,047,600*	
Total Estimated Change CY 2021 to CY 2022	***$124,274,500***	***2.05%***
The impact shown above does not include the impact of the 2.0% sequestration reduction to all lines of Medicare payment authorized by Congress through FFY 2031. It is estimated that the impact of sequestration on CY 2022 OPPS PPS payments would be: -$123,521,300		

Source: CHA DataSuite Analysis, August 2021

Updates Affecting OPPS Payments

Recalibration APC Relative Payment Weights

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

The proposed payment weights and rates for CY 2022 are available in Addenda A and B of the proposed rule on the CMS website.

The table below shows the shift in the number of APCs per category from CY 2021 to CY 2022 (Addendum A):

APC Category	Status Indicator	Final CY 2021	Proposed CY 2022
Pass–Through Drugs and Biologicals	G	94	81
Pass–Through Device Categories	H	10	11
OPD Services Paid through a Comprehensive APC	J1	68	68
Observation Services	J2	1	1
Non–Pass–Through Drugs/Biologicals	K	344	354
Partial Hospitalization	P	2	2
Blood and Blood Products	R	37	37
Procedure or Service, No Multiple Reduction	S	79	81
Procedure or Service, Multiple Reduction Applies	T	29	29
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		**804**	**804**

Blood and Blood Products

For CY 2022, CMS proposes continuing its policy to establish payment rates for blood and blood products using a blood–specific CCR methodology.

Comprehensive APCs (C-APCs) for 2022

C–APCs provide all–inclusive payments for certain procedures. A C–APC covers payment for all Part B services that are related to the primary procedure (including items currently paid under separate fee schedules). The C–APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un–coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. 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. This includes 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.

A list of the proposed 69 C–APCs for CY 2022 C–APCs can be found in Table 1 on page 42033 of the proposed rule.

In the Additional Policy and Regulatory Revisions in Response to the COVID–19 public health emergency 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. CMS will always separately pay 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
    - 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.

Calculation of Composite APC Criteria-Based Costs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Currently, there are six composite APCs for:

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

CMS is not proposing any changes to its composite APC policies for 2022.

Changes to Packaged Items and Services

CMS proposes continuing its efforts to package more ancillary services when they occur on a claim with another service and only pay for them separately when performed alone.

For CY 2022, to address decreased utilization of non–opioid pain management drugs and encourage their use rather than prescription opioids, CMS proposes continuing unpackaging, and paying separately at ASP plus 6%, the cost of non–opioid pain management drugs that function as surgical supplies when they are furnished in the ambulatory surgical center (ASC) setting. CMS also proposes continuing to not pay separately for these drugs when furnished in the hospital outpatient department (HOPD) setting.

However, CMS is requesting comment on expanding the policy to HOPDs. CMS is further investigating whether products should be treated the same depending on if they are furnished in an ASC or HOPD.

Separately, in order to identify non–opioid pain management drugs and biologicals that function as supplies in surgical procedures for which revised payment under the ASC payment system would be appropriate, for CY 2022 and subsequent years CMS is proposing two eligibility criteria:

- FDA approval and indication for pain management or analgesia
- Per–day cost exceeds the drug packaging threshold

Currently, two products receive separate payment in the ASC setting, Exparel and Omidria. CMS proposes that both would be eligible for separate payment in CY 2022 under the proposed criteria.

CMS proposes that non–opioid drugs and biologicals currently receiving transitional drug pass–through status in the OPPS would not be candidates for this policy. Once pass–through status expires, the drug may qualify for separate payment under the ASC payment system if it meets the proposed eligibility requirements.

CMS seeks comment on whether there are any other non–opioid drug or biological products that meet the proposed criteria and on an application process through which an external party could submit an application for a non–opioid pain management drug to receive separate payment.

Wage Index Changes

CMS proposes to continue using a labor share of 60% and the fiscal year inpatient prospective payment system (IPPS) post-reclassified wage index for the OPPS in 2022. For non-IPPS hospitals paid under the OPPS for 2022, CMS proposes continuing 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.

For Community Mental Health Centers (CMHCs), CMS proposes continuing to calculate the wage index by using the post-reclassification IPPS wage index based on the core-based statistical area (CBSA) where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment, but it does not include the out-migration adjustment, which only applies to hospitals.

Sole Community Hospital (SCH) Adjustment

For 2022, CMS proposes continuing 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. CMS is proposing to maintain this for future years until data supports a change to the adjustment.

Cancer Hospital Adjustment

CMS proposes continuing providing payment increases to the 11 hospitals identified as exempt cancer hospitals by adjusting payments so 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 COVID–19 PHE, CMS is holding the target PCR equal to that of CY 2021. To determine a budget neutrality factor for the cancer hospital payment adjustment for CY 2021, CMS calculated a PCR of 0.90. After applying the 1.0 percentage point reduction mandated by the 21st Century Cures Act, this results in the proposed target PCR being equal to 0.89 for each cancer hospital. Since this is the same target PCR as CY 2021, CMS proposed a 0% adjustment to the CY 2022 conversion factor to account for this policy.

Outpatient Outlier Payments

To maintain total outlier payments at 1% of total OPPS payments, CMS is using CY 2019 claims to calculate a proposed CY 2022 outlier fixed–dollar threshold of $6,100. This is an increase compared to the current threshold of $5,300. Outlier payments are proposed to continue to be paid at 50% of the amount by which the hospital's cost exceeds 1.75 times the APC payment amount when both the 1.75 multiplier threshold and the fixed–dollar threshold are met.

Establishing Payment Rate for Low-Volume New Technology Procedures

For CY 2022, CMS proposes continuing its policy (with modification outlined below) established in CY 2019 that created a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims. This methodology may use up to four years of claims data to establish a payment rate (based on either the geometric mean, median, or arithmetic mean) for assigning services to a New Technology APC.

However, CMS proposes to utilize this policy through a proposed universal low-volume APC policy that is similar to the current New Technology APC low-volume policy but applies to clinical APC and brachytherapy APCs in addition to New Technology APCs. It also 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. If the universal low-volume APC policy is finalized, CMS will end the separate New Technology APC low-volume policy.

Pass-Through Payments for Devices

There are currently 11 device categories eligible for pass–through payment:

Table 17: Expiration of Transitional 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	12/31/2021*

Table 17: Expiration of Transitional Pass-Through Payments for Certain Devices			
HCPCS Codes	**Long Descriptor**	**Effective Date**	**Pass-Through Expiration Date**
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 (that is, disposable), upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
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

**CMS proposes to continue to provide separate payment for C1823 through 2022.*

The pass-through payment status for HCPCS code C1823 is scheduled to expire on December 31, 2021. For 2022, CMS proposes to use its equitable adjustment authority to provide separate payment for C1823 until December 31, 2022.

New Device Pass-Through Applications

CMS received eight applications for device pass–through payments since the March 1, 2021, quarterly deadline. These include:

- RECELL System
- Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) Catheter (has received preliminary approval effective July 1, 2021)
- AngelMed Guardian® System
- BONEBRIDGE Bone Conduction Implant System
- Eluvia™ Drug–Eluting Vascular Stent System
- Cochlear™ Osia® 2 System
- Pure–Vu® System
- Xenocor Xenoscope™

CMS solicits public comment. Final determinations on these eight applications will be made in the CY 2022 OPPS final rule.

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 procedures that were assigned device–intensive status 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, CMS proposes assigning a device offset percentage based on CY 2020 data for the 11 procedures listed below, if available, instead of the proposed CY 2019 data used for rate setting.

Proposed 2022 Device Offset Percentages Using 2020 Claims Data	
HCPCS Code	**Code Descriptor**
0266T	Implantation or replacement of carotid sinus baroflex activation device; total system
0414T	Removal and replacement of cardiac contractility modulation system pulse generator
0511T	Removal and reinsertion of sinus tarsi implant
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming and imaging guidance, posterior tibial nerve
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, imaging guidance, percutaneous
0614T	Removal and replacement of substernal implantable defibrillator pulse generator
66987	Extracapsular cataract replacement with insertion of intraocular lens prosthesis, complex
66988	Extracapsular cataract replacement with insertion of intraocular lens prosthesis, manual or mechanical technique
C9757	Laminectomy (hemilaminectomy), with decompression of nerve roots
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement, including angioplasty when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement, and atherectomy, including angioplasty when performed

The full list of proposed 2020 device-intensive procedures is provided in Addendum P. For 2021, CMS is not proposing any changes to the device-intensive policy.

Device Edit Policy

CMS requires claim processing edits when any of the device codes used in the previous device–to–procedure edits are present on the claim with a device–intensive procedure that includes an implantation of a device. CMS created HCPCS code C1889 (implantable/insertable device, not otherwise classified) to recognize devices used during device–intensive procedures that are not described by a specific Level II HCPCS Category C–Code. This HCPCS code satisfies the edit requirement. For 2022, CMS is not proposing any changes to the device edit policy.

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

CMS reduces the APC payment for outpatient services that include certain medical devices if the hospital received a manufacturer credit. 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 2022, CMS is not proposing any major changes to the no cost/full credit and partial credit device policies.

Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

Drugs and biologicals that do not have pass–through status are paid for by CMS 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.

For CY 2022, CMS proposes a packaging threshold of $130. Drugs, biologicals, and radiopharmaceuticals above the $130 threshold are paid separately using individual APCs, and those below the threshold are packaged; the baseline payment rate for CY 2022 is the average sales price (ASP) plus 6%.

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

For CY 2022, CMS proposes to continue to pay for therapeutic radiopharmaceuticals with pass–through payments status as well as blood clotting factors, based on ASP plus 6%. If ASP data are not available, payment instead will be made based on WAC plus 3% or 95% of average wholesale price (AWP) if WAC data are also not available.

Finally, CMS proposes that pass–through status expire by December 31, 2021, for 25 drugs and biologicals listed in Table 27 (page 42118 of the proposed rule) and by December 31, 2022, for 26 drugs and biologicals listed in Table 28 (page 42121 of the proposed rule). CMS also proposed to continue/establish pass–through status in CY 2022 to 46 others, shown in Table 29 (page 42124 of the proposed rule).

OPPS Payment Methodology for 340B-Purchased Drugs

Payment rates under the OPPS for drugs are typically based on their average acquisition cost (e.g., ASP plus 6%).

The 340B Drug Pricing Program allows participating hospitals and other health care providers to purchase certain “covered outpatient drugs” at discounted prices from drug manufacturers. CMS pays a reduced rate of ASP minus 22.5% of the product’s ASP, rather than ASP plus 6% for non-pass–through, separately payable drugs and biosimilar biological products, if purchased under the 340B program. This includes drugs (other than vaccines and drugs on pass–through payment status) provided at non–excepted off–campus provider–based departments.

The 340B–acquired drug payment policies are involved in a continuing lawsuit. In the case of *American Hospital Association et al. v. Azar et al.*, 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. On January 10, 2021, the appellees filed a petition for a writ of certiorari in the Supreme Court. On July 2, 2021, the Supreme Court granted the petition.

For CY 2022, CMS proposes continuing to pay ASP minus 22.5% for separately payable drugs and biologicals acquired under the 340B program. The 340B adjustment applies to drugs priced based on WAC and average wholesale price. CMS proposes to continue drugs priced under WAC pricing be paid at WAC –minus22.5%, while those acquired under AWP pricing be paid at 69.46% of AWP.

As in previous years, rural sole–community hospitals (SCHs), children's hospitals, and PPS–exempt cancer hospitals are proposed to be exempt from the 340B adjustment and receive drug payments based on ASP plus 6%. Critical access hospitals (CAHs) are exempt as well. However, CMS mentions revisiting these exemptions in future rulemaking.

Modifier "JG" is used by non–exempt hospitals to report separately payable drugs that were acquired through the 340B program, and thus paid the reduced rate. Modifier "TB" is used by hospitals exempt from the 340B payment adjustment to report separately payable drugs that were acquired through the 340B program. CMS continues to require the use of these modifiers as appropriate.

High/Low-Cost Threshold for Packaged Skin Substitutes

Skin substitutes are divided 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 proposes continuing to assign skin substitutes that did not exceed the thresholds but were assigned to the high-cost group in CY 2021 to the high-cost group in CY 2022 as well. CMS is proposing to assign those with pass–through payment status to the high-cost category.

The list of proposed packaged skin substitutes and their group assignments may be found in Table 32 on page 42139 of the proposed rule.

Hospital Outpatient Visits and Critical Care Services

For off-campus provider-based departments exempted from being paid a physician fee schedule equivalent rate, CMS is continuing to pay 40% of the full OPPS rates. This policy was upheld by a

federal circuit court in 2020, and the Supreme Court denied certiorari. CMS is not proposing any expansions to this policy for 2022.

Inpatient Only (IPO) List

In response to opposition from comment related to the removal of the IPO list, CMS proposes to halt the elimination of the IPO list. Further, CMS proposes reinstating the 266 musculoskeletal services and 32 other HCPCS codes that were removed in CY 2021.

CMS proposes codifying in regulation the five criteria to determine if a procedure or service should be removed from the IPO list. CMS requests comment on whether to continue eliminating the IPO list or maintain the list and continue removing services as needed.

Finally, CMS solicits comments on services that were removed in CY 2021 and should remain off the list, but are proposed to be reinstated for CY 2022. Based on the criteria, none of these procedures meets the criteria for removal from the IPO list. These services can be found in Table 35 on page 42160 of the proposed rule.

Nonrecurring Policy Changes

Medical Review of Certain Inpatient Hospital Admissions

CMS presumes that hospital stays expected to be two midnights or longer are appropriate for inpatient admission. Therefore, they are not subject to medical necessity reviews. Procedures that are on the IPO list are not subject to the two–midnight policy for purposes of inpatient payment and, therefore, are not subject to medical necessity reviews. Once procedures are removed from the IPO list, the two–midnight rule is applicable, and the procedures are subject to reviews.

In the CY 2020 final rule, CMS established a two–year exemption from medical review activities, including referrals to recovery audit contractors (RACs), site–of–service claim denials, and RAC reviews for "patient status" for procedures removed from the IPO list for CY 2020 and forward. In the CY 2021 rule, CMS finalized an indefinite exemption from medical review activities for procedures removed from the IPO list on or after January 1, 2021.

Given the proposal halting the elimination of the IPO list, CMS proposes rescinding the indefinite exemption period and reinstating the two–year exemption from medical review activities for procedures removed from the IPO list beginning on or after January 1, 2021.

Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Beginning January 1, 2022, the Consolidated Appropriations Act (CAA) of 2021 reduces coinsurance for screening flexible sigmoidoscopies and screening colonoscopies regardless of the code that is billed when a beneficiary is diagnosed due to the results of a test, or if the colorectal cancer screening test calls for the removal of tissue or other matter or other procedure in the same clinical encounter.

After a nine-year phase-in period, Medicare will pay 100% of the amount established under the relevant payment methodology, and the beneficiary is not required to pay Part B coinsurance (except for barium enemas) for these screening tests as illustrated in the table below.

Year	Medicare Payment %	Beneficiary Coinsurance %
2022	80	20
2023 through 2026	85	15
2027 through 2029	90	10
2030 and subsequent years	100	0

If these services are furnished as diagnostic tests rather than screening tests, patients are responsible for 20% of the associated coinsurance. Providers must continue to report HCPCS modifier "PT" to indicate a planned colorectal cancer screening service converted to a diagnostic service. CMS proposes all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy could be viewed as part of this policy for the purposes of determining the coinsurance required of Medicare beneficiaries.

Comment Solicitation on Temporary COVID-19 Policies

CMS seeks feedback on whether the temporary emergency policies established during the COVID–19 PHE should be made permanent. Specifically, CMS seeks comment on:

- Mental health services furnished by hospital staff to beneficiaries in their homes through use of communication technology
- The need for direct supervision for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services when the supervising practitioner is available through two–way, audio/video communication technology
- Whether COVID–19 specimen collection (HCPCS code C9803) should be permanent

Use of 2019 Claims Data for 2022 Rate-Setting

CMS believes 2020 outpatient utilization has been significantly affected by the COVID-19 PHE. As it did for the FY 2022 IPPS proposed rule, CMS proposes using 2019 outpatient claims and FY 2018 hospital cost report data to set the OPPS relative weights for 2022. CMS' analysis of these issue in the CY 2022 OPPS proposed rule is nearly identical to the analysis provided in the FY 2022 IPPS proposed rule.

Extending Expiring 2021 Pass-Through Payment for 2022

As noted above, CMS proposes using 2019 claims data in establishing the CY 2022 OPPS rates. These data will not reflect a full three years of pass-through payment for products with expiring pass-through payments after 2021. Therefore, CMS proposes to extend pass-through payment for up to four quarters for these products.

If finalized, extended pass-through would apply to one device and 21 drugs — three of which would be packaged after pass-through expires. Extended pass-through payment would be made for between one and four quarters, depending on when the pass-through period expires. Table 38 (on page 42192 of the proposed rule) lists drugs, biologicals, and the device that will receive extended pass-through payment.

Request for Information on Rural Emergency Hospitals (REHs)

The CAA of 2021 established REHs as a new provider type beginning on January 1, 2023, that provide 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 conditions of participation (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*

REHs will be paid at the OPPS rate plus 5%. Copayments will be calculated based on the OPPS rate excluding the 5% increase.

REHs will also receive a monthly payment based on the excess of the total amount paid to all CAHs in 2019 over the estimated total amount that would have been paid to CAHs in 2019 if payment were made for inpatient, outpatient, and SNF services under the PPS. That value is divided by the number of CAHs. 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.

CMS seeks comment on the health and safety standards, payment policies, REH enrollment process, health equity, and quality measures and reporting requirements. Comments will be used to inform future rulemaking related to the REH model.

Radiation Oncology Model

The CAA of 2021 included a provision prohibiting the Radiation Oncology (RO) Model from beginning before January 1, 2022. CMS proposes provisions related to the additional delayed implementation due to the CAA, as well as modifications to certain RO Model policies not related to the delay.[1]

Background

The RO Model is designed to test whether prospective episode-based payments for radiotherapy (RT) services (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. Under the RO Model,

[1]On September 29, 2020, CMS published in the *Federal Register* the final rule entitled "Specialty Care Models to Improve Quality of Care and Reduce Expenditures," referred to as the Specialty Care Models Rule (85 FR 61114) and codified policies at 42 CFR part 512.

Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for service (FFS) beneficiaries diagnosed with certain cancer types. The RO Model will include 30% of all eligible RO episodes (these occur in 204 eligible CBSAs in 48 states and the District of Columbia). Base payment amounts for RT services included in the RO Model would be the same for HOPDs and freestanding radiation therapy centers.

RO Model Proposed Regulations

Proposed Model Performance Period

CMS proposes that the model performance period would begin on January 1, 2022, and end December 31, 2026. No new RO episodes may begin after October 3, 2026, in order for all RO episodes to end by December 31, 2026. Each PY will be a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period.

Proposed Definitions

CMS proposes to codify at §512.205 definitions for the RO Model, detailed in the table below.

Term	Definition
Extreme and Uncontrollable Circumstances (EUC)	EUC stands for "extreme and uncontrollable circumstance" and means a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements and affects an entire region or locale.
Legacy CCN	Legacy CCN means a CMS certification number (CCN) that an RO participant that is a hospital outpatient department (HOPD) or its predecessor(s) previously used to bill Medicare for included radiotherapy (RT) services but no longer uses to bill Medicare for included RT services.
Legacy TIN	Legacy TIN means a taxpayer identification number (TIN) that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.
Track One	Track One means an Advanced APM and MIPS APM track for Dual participants and Professional participants that meet all RO Model requirements as specified in §512.220, including use of CEHRT.
Track Two	Track Two means an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at §512.220; and for all Technical participants.
Baseline period	"Baseline period" means the three calendar year (CY) period that begins on January 1 no fewer than 5 years but no more than 6 years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments for the model performance period, and the participant-specific professional and technical case mix adjustments for PY1. The baseline period would be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period would be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

Term	Definition
Model performance period	Model performance period means the five performance years (PYs) during which RO episodes must initiate and terminate. The model performance period begins on January 1, 2022 and ends on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period begins on the earliest date permitted by law that is January 1, April 1, or July 1.
Performance ear	PY stands for performance year and means each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) begins on that date and ends on December 31 of the same year.
Stop-loss reconciliation amount	This is the amount set forth in §512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

Proposed RO Model Participant Exclusions

CMS excludes from the RO Model any physician group practice (PGP), freestanding radiation therapy center, or HOPD that only furnishes RT in either Maryland, Vermont, or the U.S. territories. Also excluded from the model are RT providers classified as ASC, CAH, or PPS-exempt cancer hospital or that participate in or are identified by CMS as eligible to participate in the Pennsylvania Rural Health Model.

CMS puts forth proposals to exclude HOPDs related to the Pennsylvania Rural Health Model (PARHM), Community Health Access and Rural Transformation Model, and the low volume opt out.

Further, a PGP, freestanding radiation therapy center, or HOPD may choose to opt out of the RO Model for a given PY if it has fewer than 20 episodes or RO episodes; this is based on the most recent claims data available (two years prior to the PY). At least 30 days prior to the start of each PY, CMS will notify RO participants eligible for the low-volume optout for the upcoming PY. If the RO participant wishes to opt out, it must attest that it intends to do so prior to the start of the upcoming PY.

CMS proposes that during the model performance period, an entity is not eligible for the low-volume opt out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes in the two years prior to the applicable PY across all CBSAs selected for participation.

Certain Changes to RO Model Episodes

Removal of Liver Cancer from Included Cancer Types

CMS will remove liver cancer from the RO Model as an included cancer type, assuming the changes discussed above for determining including cancer types are finalized.

Proposal to Remove Brachytherapy from Included RT Services
CMS also proposes to remove brachytherapy as an included modality in the RO Model. If finalized as proposed, CMS would continue to monitor utilization of brachytherapy, both as a single modality and multimodality among RO participants compared to non-participants.

Exclusion of Intraoperative Radiotherapy (IORT)
CMS finalizes that Intraoperative Radiotherapy (IORT) — a technique that involves precise delivery of a large dose of ionizing radiation to the tumor or tumor bed during surgery — would not be included in the RO Model. CMS received feedback this modality is only provided in one practice setting and is, therefore, not site neutral. CMS states that, as such, it does not meet the goals of the RO Model.

Pricing Methodology

Assignment of Cancer Types to an Episode
CMS clarifies that if there are not at least two claim lines for brain metastases, at least two claim lines for bone metastases, or at least two claim lines for any other secondary malignancy, then it will assign the episode the cancer type with the highest line count among all other cancer types.

Proposed National Base Rates
CMS proposes to exclude all Maryland, Vermont, and U.S. territory claims and all CAH, inpatient, ASC, and PPS-exempt claims in the same manner: before episodes are constructed and attributed to an RT provider or RT supplier. CMS also proposes to exclude all claims of an HOPD participating in the Pennsylvania Rural Health Model before episodes are constructed and attributed to an RT provider or RT supplier. CMS also clarifies that it will exclude episodes from the RO Model's pricing methodology that are attributed to an RT provider or RT supplier that is in a ZIP code not assigned to a CBSA, not assigned an included cancer type, or that do not have more than $0 in total allowed amount for professional or technical services from Model pricing.

CMS' proposed national base rates for the model performance period are based on the criteria set forth for cancer type inclusion and are summarized in Table 58 (reproduced below).

Table 58: National Base Rates

RO Model-Specific Codes	Professional or Technical	Included Cancer Type	National Base Rate
M1072	Professional	Anal Cancer	$3,104.11
M1073	Technical	Anal Cancer	$16,800.83
M1074	Professional	Bladder Cancer	$2,787.24
M1075	Technical	Bladder Cancer	$13,556.06
M1076	Professional	Bone Metastases	$1,446.41
M1077	Technical	Bone Metastases	$6,194.22
M1078	Professional	Brain Metastases	$1,651.56
M1079	Technical	Brain Metastases	$9,879.40
M1080	Professional	Breast Cancer	$2,059.59

M1098	Professional	Pancreatic Cancer	$2,480.83
M1099	Technical	Pancreatic Cancer	$13,636.95
M1100	Professional	Prostate Cancer	$3,378.09
M1101	Technical	Prostate Cancer	$20,415.97
M1102	Professional	Upper GI Cancer	$2,666.79
M1103	Technical	Upper GI Cancer	$14,622.66
M1104	Professional	Uterine Cancer	$2,737.11
M1105	Technical	Uterine Cancer	$14,156.20

Proposed Trend Factors

CMS applies a trend factor to each of the national base rates, which is intended to adjust these rates to reflect current trends in the OPPS and physician fee schedule (PFS) rates for RT services.

CMS proposes that the numerator of the trend factor be the product of (a) the component's FFS payment rate (as paid under OPPS or PFS) for the CY of the upcoming PY, and (b) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished three years prior to the CY used to determine the FFS payment rates.

The denominator of the trend factor would be the product of (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in the most recent year of the baseline period, and (b) the corresponding FFS payment rate for the most recent year of the baseline period.

For PY1, the calculation would be the following:
*2022 Trend factor = (2019 volume *2022 corresponding FFS rates as paid under OPPS or PFS)/(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS)*

CMS clarifies that the trended national base rates will be made available on the RO Model website prior to the start of the applicable PY, after CMS issues the annual OPPS and PFS final rules that establish payment rates for the upcoming CY.

CMS also proposes that the denominator of the trend factor be based on the third year of the proposed baseline period, and the numerator of the trend factor would be based on FFS payment rates for the same CY. For example, for a model performance period starting in 2022, the trend factor's denominator for PY1 would be based on 2019 FFS payment rates and 2019 utilization, while the numerator would be based on 2022 FFS payment rates and 2019 utilization. The trend factor's denominator would not change and remains based on 2019 FFS payment rates and 2019 utilization over the course of the model performance period. The numerator, however, would change as its volume and utilization would be based on years that roll forward (as finalized previously). For instance, for a model performance period starting in 2022, the numerator of the PY3 trend factor would be based on 2024 FFS payment rates and 2021 utilization.

CMS clarifies that it will use the allowed charges in the claims data to calculate these average paid amounts for contractor-priced RT services under Medicare PFS.

Applying the Adjustments

CMS clarifies that the total number of RO participant-specific episode payments for dual participants, and the total number of RO participant-specific episode payments for professional and technical participants, will vary depending on the number of included cancer types. For example, 15 included cancer types would yield a total of 30 RO participant-specific episode payment amounts for dual participants and a total of 15 RO participant-specific episode payment amounts for professional and technical participants.

Proposal for HOPD or Freestanding Radiation Therapy Center with Fewer Than 60 Episodes During the Baseline Period

To align its stop-loss limit policy with the new performance period and proposed baseline period, CMS proposes to modify this stop-loss limit policy such that it applies to RO participants that have fewer than 60 episodes during the proposed baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

Proposal to Apply Adjustments for HOPD or Freestanding Radiation Therapy Center

CMS proposes to calculate the RO participant's case mix adjustments based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy taxpayer identification number (s) (TIN) or legacy CMS certification number(s) (CC), and current TIN or CCN, during the three-year period that determines the case mix adjustment for each PY. Similarly, CMS proposes to calculate the RO participant's historical experience adjustments based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the baseline period.

Proposed Discount Factor

CMS proposes to lower the discount factor for the professional component from 3.75% to 3.5% and the discount factor for the technical component from 4.75% to 4.5%.

Proposed Withholds

CMS proposes that beginning in PY1, a 2% quality withhold for the PC would be applied to the applicable trended national base rates after the case mix and historical experience adjustments. RO participants would submit quality measure data starting in PY1.

Proposed Adjustment for Geography

With respect to the geographic adjustment in the RO Model, CMS proposes to align the proposed model performance period so that the final year of the baseline period would be used to calculate the implied relative value unit (RVU) shares. For example, for a baseline period of 2017-19, 2019 would be used to calculate the implied RVU shares. RVU shares are shown in Table 59 (reproduced below).

Table 59: RVU Shares					
Professional Component			Technical Component		
WORK	PE	MP	WORK	PE	MP
0.65	0.31	0.04	0	0.99	0.01

Quality – Proposed Form, Manner, and Timing for Quality Reporting

CMS proposes that professional participants and dual participants submit quality measure data starting in PY1 during the proposed model performance period.

For PY1, professional and dual participants would be required to submit data for three pay-for-performance measures:

1) Plan of Care for Pain
2) Screening for Depression and Follow-Up Plan
3) Advance Care Plan

They would also have to submit data on a pay-for-reporting measure: Treatment Summary Communication — Radiation Oncology. Data collected from this measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure for PY3.

Given the change in model performance period, CMS proposes to amend existing policy such that the CMS-approved contractor will begin administering the CAHPS® Cancer Care Survey for Radiation Therapy on behalf of the RO participants and CMS as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

In addition, CMS proposes that professional and dual participants submit clinical data elements (CDEs) starting in PY1.

The RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit-Based Incentive Payment System APM (MIPS APM)

CMS expects the RO Model to meet the criteria to be an Advanced APM and a MIPS APM beginning in PY1, beginning January 1, 2022. Final CMS determinations of Advanced APMs and MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website.

Technical Participants and the Quality Payment Program

Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the TC are not required to report quality measures under the RO Model. CMS proposes that if the technical participants that are freestanding radiation therapy centers (as identified by a TIN) begin providing the PC at any point during the model performance period, then they must notify CMS within 30 days. They then would also be required under the RO Model to report quality measures by the next reporting period.

Individual Practitioner List

Upon the start of each PY, CMS creates and provides to each dual participant and professional participant an individual practitioner list that identifies by National Provider Identifier (NPI) each individual practitioner associated with the RO participant. CMS proposes to modify this policy to include that technical participants that are freestanding radiation therapy centers will also be provided an individual practitioner list.

The RO participant must notify CMS within 30 days when there are any additions or removals of eligible clinicians to the individual practitioner list. CMS proposes to modify these policies so that RO participants will have the ability to review their individual practitioner list and add or drop the necessary NPIs from the list up until the last Qualifying APM Participant (QP) determination snapshot date.

RO Model Requirements

CMS proposes that the certified electronic health record technology (CEHRT) requirement would begin in PY1 of the proposed model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY. The agency also proposes that if an RO participant begins participation in the RO Model at any time during an ongoing PY, it must certify its use of CEHRT by the last QP determination snapshot date.

Proposed Reconciliation Process

Initial Reconciliation

Reconciliation is the process to calculate reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. CMS expects to conduct the initial reconciliation each August for the preceding PY. For example, for PY1, CMS would conduct the initial reconciliation as early as August of PY2, given the proposed change in model performance period due to the delay and its proposal that the application of a quality withhold would begin in PY1.

True-Up Reconciliation

The true-up reconciliation is the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY. CMS expects to conduct the true-up reconciliation as early as August of the CY following an initial reconciliation for a PY. For example, for PY1, CMS would conduct the true-up reconciliation as early as August of PY3.

Proposed Reconciliation Amount Calculation

If traditional Medicare ceases to be the primary payer for an RO beneficiary after the TC of the RO episode has been initiated but before all included RT services in the RO episode have been furnished, each RO participant would be paid only the first installment of the episode payment.

The RO participant would not be paid the end of episode (EOE) PC or TC for these RO episodes. CMS proposes to revise this policy and reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for RT services using

no-pay claims. CMS also proposes to specify that the coinsurance for all incomplete episodes is 20% of the FFS amount applicable to the RT services that were furnished.

Proposed Extreme and Uncontrollable Circumstances Policy

CMS proposes to adopt an extreme and uncontrollable circumstance policy for the RO Model that would allow CMS to revise the model performance period, grant certain exceptions to RO Model requirements to ensure the delivery of safe and efficient health care, and revise the RO Model's payment methodology.

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 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 2021 and proposed CY 2022 PHP payment rates:

	Final Payment Rate 2021	Proposed Payment Rate 2022	Percent Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$139.75	$143.42	+2.6%
APC 5863: Partial Hospitalization (3+ services) for Hospital-Based PHPs	$260.49	$267.31	+2.6%

Due to the COVID–19 PHE, CMS proposes a cost floor equal to the per diem cost finalized in CY 2021 for both CHMC- and hospital–based PHPs. CMS is also proposing to use CY 2019 claims and cost report data, rather than CY 2020, for rate setting.

CMS proposes to continue to make outlier payments to CMHCs for 50% of the amount by which the cost for the PHP service exceeds 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year. As in prior years, CMS will apply an 8% outlier payment cap to the CMHC's total per diem payments.

Finally, 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 conditions of participation 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 outpatient.

Hospital Outpatient Quality Reporting (OQR) Program

CMS proposes several changes to the Outpatient Quality Reporting (OQR) Program, including the removal of two measures, the addition of three new measures, and the resumption of reporting for two previously delayed measures. CMS also proposes updated data validation

requirements and to expand applicability of the OQR Program's policy for extraordinary circumstances exceptions (ECE) to eCQMs.

CMS proposes no changes to previously finalized OQR Program policies for measure selection, retention, and removal, data submission via the CMS web-based tool, 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 adopted and OQR Program measures for payment determinations 2021 through 2024.

Proposed Measures for Removal

CMS proposes to remove two chart-abstracted OQR measures beginning with the 2023 reporting period: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3). CMS proposed to add a new eCQM measure beginning with 2023 — described in more detail below — that it says is more broadly applicable and less burdensome than the existing measures.

Proposed Measure Additions

CMS proposes to adopt three new measures for the OQR Program: COVID-19 Vaccination Coverage Among Health Care Personnel, Breast Screening Recall Rates, and ST-Segment Elevation Myocardial Infarction (STEMI) eCQM.

COVID-19 Vaccination Coverage Among Health Care Personnel

CMS proposes to add a new process measure to the Hospital OQR Program beginning with the CY 2024 payment determination to track the percentage of health care personnel (HCP) who receive a complete COVID-19 vaccination course, calculated as:

> Numerator: The cumulative number of HCP eligible to work in the health care facility for at least one day in the submission period and who received a complete vaccination course against SARS-CoV-2
> Denominator: The cumulative number of HCP eligible to work in the health care facility for at least one day during the submission period, excluding persons with contraindications to COVID-19 vaccination as described by the CDC
>
> Acute care facilities would count all HCP working in all inpatient or outpatient units that share a hospital's CCN, regardless of a unit's size or type.

CMS proposes to require an initial data reporting of January 1, 2022, through December 31, 2021, for the CY 2024 payment year. Data submission would be required quarterly, and data would be submitted through the CDC National Health Safety Network (NHSN) web-based surveillance system for at least one week each month; if a hospital were to report more than one week per month, the most recent week of data would be used. If finalized, CMS would publicly report the CDC-calculated vaccination coverage rates on a quarterly basis on *Care Compare*. Full measure specifications are available on the CDC website.

Notably, CMS has finalized the addition of this measure in the inpatient QRP, SNF QRP, inpatient rehabilitation facility QRP, and inpatient psychiatric hospital QRP beginning with the FFY 2023 payment year.

Breast Screening Recall Rates

CMS proposes to add a new claims-based, facility-level process measure to the Hospital OQR Program beginning with the 2023 payment determination to track the percentage of patients who are recalled after traditional mammography or digital breast tomosynthesis (DBT) screening for additional outpatient imaging. The measure would be calculated as:

> Numerator: Beneficiaries who underwent screening mammography or DBT at a facility paid under the OPPS followed by diagnostic mammography, DBT, breast ultrasound, or breast MRI in an outpatient or office setting on the same day or within 45 days of the index image
> Denominator: Medicare FFS beneficiaries who underwent screening mammography or DBT at a facility paid under the OPPS (the index image)

This measure has no exclusions. CMS states that risk adjustment is not required for this process measure and that adjustment for social risk factors could mask potentially important inequities (e.g., variable rates for minority subpopulations). Full measure specifications are available on the CMS QualityNet website.

This claims-based measure does not require additional data submission by facilities. For the 2023 payment determination, CMS proposes to use final claims from July 1, 2020, to June 30, 2021. For each subsequent year, the claims data collection period would be from July 1 through June 30, and the period would start on July 1 in the year that is three years prior to the applicable payment CY.

ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

CMS proposes to add a new facility-level, electronic process measure beginning with the 2023 reporting period to track the percentage of emergency department (ED) patients with a diagnosis of STEMI who received timely delivery — absent contraindications — of guideline-based reperfusion therapies appropriate for the care setting. The measure would be calculated as:

> Numerator: All STEMI patients aged 18 years or over who meet any of the following criteria:
> 1) ED-based STEMI patients whose time from ED arrival to fibrinolytic therapy is 30 minutes or fewer; or 2) Non-transfer ED-based STEMI patients who received percutaneous coronary intervention (PCI) at a PCI-capable hospital within 90 minutes of arrival; or 3) ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI-capable hospital
> Denominator: All ED patients aged 18 or older diagnosed with STEMI who do not have contraindications to fibrinolytic, antithrombotic, and anticoagulation therapies. Full measure specifications are available on the Electronic Clinical Quality Improvement Resource Center website.

CMS proposes an initial voluntary reporting period beginning in 2023 for the 2025 payment determination. Mandatory submission would be required for the 2024 reporting period/2026 payment determination and subsequent years. During the voluntary reporting period, hospitals would submit data for any self-selected quarter. Once mandatory reporting begins, required data submission would increase annually by one quarter, starting with one self-selected quarter for 2024 and reaching four quarters of full calendar year data reporting for the 2027 reporting period/2029 payment determination and subsequent years.

Proposed Modifications to Previously Adopted Measures

CMS proposes to modify reporting requirements for two previously adopted measures: Cataracts, Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536), and Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e).

Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31)

CMS initially adopted OP-31 in the OQR measure set since the 2016 payment determination; however, the measure was subsequently excluded — but not removed — and since 2017 voluntary submissions has been permitted. CMS notes that the measure has been consistently reported voluntarily by some facilities and the data publicly displayed. Therefore, CMS proposes to return the measure to the OQR measure set for use beginning with the 2023 reporting period/2025 payment determination and to make reporting mandatory for 2023 and all subsequent years. CMS proposes that data submission for all years would be through a CMS web-based tool according to existing policies for the Hospital Quality Reporting (HQR) System (formerly known as the QualityNet Secure Portal).

Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e)

The OAS CAHPS survey set includes five measures designed to assess a patient's experience with care following a procedure or operation performed in a hospital outpatient department. The set was first adopted into the OQR Program in the 2017 OPPS final rule, for use beginning with the 2020 payment determination. However, CMS delayed implementation to allow time for further accrual of operational experience and implementation data from the National OAS CAHPS voluntary reporting program that began in 2016.

CMS states that results from voluntary reporting have confirmed that patients were able to reliably respond to the survey questions and, therefore, proposes to implement the OP 37a-e measure beginning with voluntary reporting for the 2023 reporting period/2025 payment determination. CMS proposes to begin mandatory reporting beginning with the 2024 reporting period/2026 payment determination. CMS clarifies that hospitals that report voluntarily for 2023 would do so as part of the OQR Program rather than the national voluntary program.

CMS proposes to add two data collection modes (web-based with either mail or telephone follow-up of non-respondents) for the 2023 reporting period/2025 payment determination and subsequent years to the existing three modes (mail-only, telephone-only, and mixed — mail with telephone follow-up of non-respondents).

Hospitals would be required to report through a CMS-approved survey vendor. Data collection must be initiated no later than 21 calendar days after the month in which the procedure or operation occurred and must be completed within 42 days after initial contact of an eligible patient begins. CMS proposes that multiple contact attempts must be made unless the patient refuses or the survey vendor learns the patient is ineligible for survey participation. Hospitals that do not qualify for the low-volume exemption must collect survey data monthly and meet the established quarterly deadlines for data reporting to CMS. The low-volume exception would apply to hospitals with fewer than 60 survey-eligible patients during the calendar year just prior to the data collection period — hospitals must be approved by CMS following submission of a completed participation exemption request form. Hospitals anticipating more than 300 completed surveys can choose to randomly sample their eligible patients as directed on the OAS CAHPS website.

Electronic Clinical Quality Measure (eCQM) Reporting under the OQR Program

CMS proposes several requirements for reporting eCQMs under the OQR Program beginning with the 2023 reporting period/2025 payment determination. OQR eCQM requirements would align with those of the hospital Inpatient Quality Reporting (IQR) Program and the Medicare Promoting Interoperability (PI) Program for hospitals. Hospitals would:

- Be required to register and submit data through the HQR system
- Be required to complete their eCQM data submission by the end of two months following the close of the reporting year (e.g., by February 29, 2024, for 2023)
- Be required to use CEHRT updated to the 2015 Edition Cures Update
- Be required to submit their eCQM data formatted according to the Quality Reporting Document Architecture Category I (QRDA I) content exchange standard
    - Hospitals may use chart abstraction of data or pull data from non-certified sources for entry into CEHRT and subsequent QRDA I file reporting.
    - Files would reflect data for one patient per file per quarter and contain all required identifiers, including hospital CCN.
    - Hospitals may engage third parties to submit data on their behalf.

CMS seeks comment on an alternative eCQM data submission deadline of May 15 (rather than end of February) to align with OQR measure reporting, using the program's web-based tool. CMS also proposes a new review and corrections period for eCQM data that would run concurrently with the data submission period. From the time the HQR system opens for QRDA I file submission up until the submission deadline, hospitals would be able to run pre-submission test files as well as submit and review their actual data files and make corrections.

In addition, CMS proposes to expand the OQR Program's extraordinary circumstances exception (ECE) policy to cover eCQMs. Hospitals would be allowed to request hardship exceptions (e.g., due to insufficient internet access, health IT vendor loss of certification) under the ECE policy from required eCQM reporting for the 2024 reporting period and subsequent years. CMS further proposes that the exception be requested by April 1 following the end of the reporting CY in which the hardship occurred (e.g., April 1, 2025, for 2024 hardships).

Hospital OQR Program Validation Requirements

CMS proposes several changes to the OQR data validation process beginning with the 2022 reporting period/2024 payment to further align the OQR Program with the hospital IQR Program. CMS propose to discontinue the option for hospitals to transmit medical records for validation to the CMS Clinical Data Abstraction Center (CDAC) as paper copies or on CDs, DVDs, or flash drives. Only direct electronic submission of records stored as Portable Document Format (pdf) files via a CMS-approved, CDAC-directed, secure file transmission process would be permitted.

CMS also proposes to reduce the time for hospitals to submit records for validation to the CDAC contractor from 45 to 30 calendar days. Finally, CMS proposes to add to the following additional targeting criteria used to select hospitals for validation: 1) not having been randomly selected for validation in any of the previous three years, and 2) having passed validation in the previous year with a two-tailed confidence interval that included 75%. The latter criterion identifies hospitals whose accuracy falls within the statistical margin of error and captures both passing and failing facilities.

Additional Requests for Comment

CMS seeks comments on several topics for informing future OQR Program rulemaking, including potential future adoption of measures to assess quality of care for services whose delivery is shifting from inpatient to outpatient settings, as well as the future adoption of a Hospital-Level Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty respecified from its current inpatient application for use in the outpatient setting. CMS also seeks comments on addressing health equity in the hospital OQR Program, including expansion of its current disparities methods — currently used in the Hospital Readmissions Reduction Program — to include reports stratified by race and ethnicity, and the possibility of hospital collection of standardized demographic information for quality reporting and measure stratification.

Request for Information (RFI) on Advancing Digital Quality Measurement

CMS requests input into the agency's planning for transformation to a fully digital quality enterprise by 2025, posing numerous questions grouped into three categories: definition of digital quality measures, use of Fast Healthcare Interoperability Resources (FHIR) for current eCQMs, and other changes under consideration to advance digital quality measures.

As part of its discussion, CMS offers a definition for digital quality measures (dQMs): "quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems." CMS notes that a dQM score includes a calculation that processes digital data. The agency also lists multiple examples of dQM data sources (e.g., electronic health records, wearable medical devices). CMS also discusses the potential role of FHIR-based standards for efficient exchange of clinical information across clinical settings through APIs. CMS says it is actively studying the use of FHIR-based APIs to access quality data it already collects as well as transitioning to FHIR-based quality reporting through APIs for eCQMs already adopted into several of the agency's quality reporting and value-based programs. Notably, CMS solicited comments on this RFI in its FFY 2022 IPPS proposed rule, which CHA responded to in its comment letter.

RFI: Hospital Inpatient Quality Reporting (IQR) Program and Promoting Interoperability Program - Safe Use of Opioids eCQM

CMS requests input on potential measure updates for the Safe Use of Opioids Concurrent Prescribing eCQM as it prepares for NQF re–endorsement in 2022. Under both the hospital IQR and Promoting Interoperability programs, hospitals are required to report three self–select eCQMs and the Safe Use of Opioids eCQM beginning with the 2022 reporting period. CMS notes that stakeholders have expressed concern about potential unintended consequences associated with requiring reporting on the measure — specifically, that requiring reporting on the Safe Use of Opioids eCQM could disincentivize clinicians from appropriately concurrently prescribing medications for the treatment of opioid use disorder, such as methadone and buprenorphine.

CMS seeks comments on additional information or considerations to inform future measure updates to the Safe Use of Opioids eCQM, such as additional measure exclusions. CMS is also requesting feedback on whether reporting the Safe Use of Opioids eCQM should be required or self–selected by hospitals as part of the available eCQM measure set.

Updates to Hospital Price Transparency Requirements

CMS proposes several updates to its Hospital Price Transparency requirements. Specifically, CMS proposes to increase civil monetary penalties (CMPs) for noncompliance with price transparency requirements and prohibit certain conduct that the agency believes is a barrier to accessing the standard charge information. In addition, CMS proposes to deem state forensic hospitals to have met the price transparency requirements, and CMS seeks additional comments on improvements to the usefulness of this initiative.

Increasing Civil Monetary Penalties

CMS provides an overview of the current process for enforcement of the hospital price transparency requirements, including issuance of a written warning notice to the hospital of the specific violation, submission of a corrective action plan from the hospital, and imposition of CMPs not to exceed $300 per day on the hospital if the hospital fails to provide or comply with its corrective action plan.

In response to what CMS deems as high rates of noncompliance with the requirements — which were effective January 1, 2021 — CMS proposes to increase the maximum CMP using a scaling factor to establish the CMP amount for a noncompliant hospital. CMS proposes to use the noncompliant hospital's number of beds as specified in hospital cost report data as the scaling factor to establish CMP amounts.

CMS proposes the following per-day CMPs for non-compliant hospitals:

- Noncompliant hospitals with 30 or fewer beds would have a maximum daily penalty of $300.
- Noncompliant hospitals with 31 to 550 beds would have a maximum daily penalty calculated as the number of beds times $10.
- Noncompliant hospitals with more than 550 beds would have a maximum daily penalty of $5,500.

If the number of beds for the hospital cannot be determined using the Medicare cost report (for example, for hospitals that do not participate in Medicare), CMS would use documentation provided by the hospital. CMS proposes to assess an additional CMP at the highest daily maximum amount for failure to provide documentation on the number beds. The above amounts would be adjusted annually beginning in 2023 using the multiplier determined by the Office of Management and Budget for adjusting CMPs.

Prohibiting Barriers to Accessing Machine-Readable Files

The hospital price transparency final rule requires hospitals to post to its website a machine-readable file that includes all standard charges (including gross charges, discounted cash prices, payer-specific negotiated rates defined as charges in the final rule, and de-identified minimum and maximum negotiated rates) for all hospital items and services. CMS also required that the standard charge information must be displayed prominently and clearly identify the hospital location with which it is associated; easily accessible, without barriers, including but not limited to being free of charge, without having to establish a user account or password, and without having to submit personal identifying information; and contained in a digital file, within which the standard charge information is digitally searchable.

CMS says that its review of hospital compliance has shown that hospitals have taken a number of actions that create barriers to accessing price transparency information. CMS provides the following examples of such barriers:

- Employing anti-automation tools such as form submission, or other technological devices that place a "locked door" in front of the content
- Requiring users to pass tests proving they are human users (for example, requiring the user to identify images that contain certain objects, such as vehicles, trees, or street signs)
- Requiring the user to agree to all terms and conditions in a legal disclaimer prior to permitting the machine-readable file and its contents to be downloaded
- Developing file constructs and web forms that obscure access to the data in a single machine-readable file through the use of Application Programming Interfaces

To address its concerns, CMS proposed to specify that the hospital must ensure that the standard charge information is easily accessible, without barriers, including but not limited to ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website. The additional requirement will prohibit practices CMS has encountered in compliance reviews, such as lack of a link for downloading a single machine-readable file, using "blocking codes," and requiring the user to agree to terms and conditions or submit other information prior to access. CMS notes that while the above are examples of prohibited practices, they are not intended to be an exhaustive list. CMS further requests comment on other actions it could take to improve accessibility of transparency data.

Additional Clarifications and Requests for Comment

CMS provides additional clarifications and seeks comments on its policy to allow a hospital to meet the shoppable services requirement by offering an internet-based price estimator tool, the definition of "plain language" to describe shoppable services, standardization of the machine-readable file and how to highlight hospital best practices in complying with the requirements.

Price Estimator Tools

Hospitals can meet the requirement to make available price information for "shoppable services" by offering an internet-based price estimator tool. Citing language in the preamble of the final rule, CMS clarifies that to satisfy the requirements using a price estimator tool, the tool must be "tailored to individuals' circumstances (whether an individual is paying out of pocket or using insurance) and provide real-time individualized out-of-pocket estimates that combine hospital standard charge information with the individual's benefit information directly from the insurer, or provide the self-pay amount."

CMS says that its review of hospital compliance has identified that some hospital price estimator tools do not tailor a single estimated amount based on the individual's circumstances. CMS provides examples of tools that do not combine hospital standard charges with the individual's benefit information directly from the insurer to create the estimate but use information from prior reimbursements or require the user to input benefit information. Others indicate that the price is not what the hospital anticipates that the individual would be obligated to pay, even in the absence of unusual or unforeseeable circumstances.

CMS is considering whether it should add additional requirements for the use of an online price estimator tool as an alternative to making public the standard charges for shoppable services in a consumer-friendly format. CMS seeks comments on the specific questions to inform future policy:

- What best practices should online price estimator tools be expected to incorporate?
- Are there common data elements that should be included in the online price estimator tool to improve functionality and consumer-friendliness?
- What technical barriers exist to providing patients with accurate real-time out-of-pocket estimates using an online price estimator tool? How could such technical barriers be addressed?

Definition of "Plain Language"

CMS states that its reviews of hospital compliance with the price transparency requirements indicate that not all hospitals appear to be using what could reasonably be considered "plain language" to describe shoppable services. While CMS recommends using federal plain language guidelines, it does not require it. CMS seeks public comment on whether to require specific plain language standards.

Highlighting Hospital Exemplars

CMS says that in its review of hospital compliance, it has identified certain hospitals that are "not only fully complying with the hospital price transparency requirements but are also embracing and exemplifying the spirit of consumer price transparency." CMS believes that identifying these hospitals may draw attention to developing best practices that other hospitals may choose to adopt, or that could be used to establish criteria for assessing hospital compliance in the future. CMS seeks public comment on ways to highlight such hospital practices and lists several ideas that it is considering, including publicizing their example through various CMS websites.

Improving Standardization of the Machine-Readable File

Since implementation of the final rule, CMS has received feedback from stakeholders indicating

that more standardization of the machine-readable file may be necessary to meet the goal of permitting comparisons of standard charges from one hospital to the next. CMS seeks comments on the following questions to inform its future policies:

- Is there a specific data format that should be required to be used across all hospitals?
- Are there additional data elements that should be required for inclusion in the future in order to ensure standard charge data are comparable across hospitals?
- Are there any specific examples of hospital disclosures that represent best practices?
- What other policies or incentives should CMS consider to improve standardization and comparability of these disclosures?
- What other policies should CMS consider to ensure the data posted by hospitals are accurate and complete?

Appendix – Hospital Outpatient Quality Reporting Program Measures Table

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES Payment Determination for 2021-2024					
NQF		**2021**	**2022**	**2023**	**2024**
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	Proposed Removal	
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	Proposed Removal	
0289+	OP-5: Median Time to ECG	Removed			
0514+	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X
	OP-9: Mammography Follow-up Rates	Removed			
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	Removed			
	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data	Removed			
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	Removed			
0491+	OP-17: Tracking Clinical Results between Visits	Removed			
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X
0499+	OP-22: ED- Left Without Being Seen	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
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Removed			
1536+	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery			Proposed	
	OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers			Proposed Voluntary	Proposed Mandatory

	and Systems (OAS CAHPS) Survey-Based Measures				
	COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)				Proposed
	Breast Screening Recall Rates			Proposed	
	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM			Proposed Voluntary	Proposed Mandatory

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