Medicare Program: 2022 Hospital Outpatient Prospective Payment and AmbulatorySurgical Center Payment Systems and Quality Reporting Programs Final Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2022[1] final rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1753-FC) on November 2, 2021. Policies in thefinal rule will generally go into effect on January 1, 2022 unless otherwise specified. The finalrule will be published in the November 16, 2021 issue of the *Federal Register*.

There is a 30-day public comment period on the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes that were not previously subject to comment for both the OPPS and ASC payment systems. **The public comment period will endon December 2, 2021.**

The final rule updates OPPS payment policies that apply to outpatient services provided to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatientpsychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals, aswell as for partial hospitalization services in community mental health centers (CMHCs). Also included is the annual update to the ASC payment system and updates and refinements to the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

CMS is also making changes to its hospital price transparency initiative including increasing penalties for non-compliance. Changes to the Radiation Oncology (RO) Model are included as well. The 2022 OPPS/ASC proposed rule included requests for information on digital quality information, interoperability and Rural Emergency Hospitals. CMS summarizes the public comments received on digital quality information and interoperability and indicated it would takethese comments into consideration in the future rulemaking. No information appears in the final rule on Rural Emergency Hospitals.

Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website at: CMS-1753-FC | CMS. Unless otherwise noted, this weblink can be used to access any information specified as being available on theCMS website.

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[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

I. Overview

A. Estimated Impact on Hospitals

The increase in OPPS spending due only to changes in the 2022 OPPS final rule is estimated to be approximately $1.27 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 $82.1 billion, which is approximately $5.9 billion higher than estimated OPPS expenditures in 2021.

CMS estimates that the update to the conversion factor net of the multifactor productivity adjustment (MFP) will increase payments 2.0 percent in 2022 (market basket of 2.7 percent less 0.7 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 1.6 percent increase in payments between 2021 and 2022.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.0 percent, while hospitals that do not will be subject to an update of 0.0 percent (a statutory reduction of 2.0 percentage points). All other adjustments are the same for the two sets of hospitals. Of the approximately 3,163 hospitals that meet eligibility requirements to report quality data, CMS determined that 77 hospitals will not receive the full OPPS increase factor.

Medicare makes payments under the OPPS to approximately 3,659 facilities (3,552 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 84 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows an estimated increase in expenditures of 1.6 percent for all facilities and hospitals. The following table shows components of the 1.6 percent total:

	% Change All Facilities
Fee schedule increase factor	2.0
Difference in pass through estimates for 2021 and 2022	-0.32
Difference from 2021 outlier payments (1.06% vs. 1.0%)	-0.07
All changes	1.6

CMS estimates that pass-through spending for drugs, biologicals and devices for 2022 will be $1.03 billion, or 1.24 percent of OPPS spending. For 2021, CMS estimates pass-through spending would be 0.92 percent of OPPS spending. The difference between these figures (0.92 and 1.24=-0.32 percentage point) is the required adjustment to ensure that pass-through spending remains budget neutral from one year to the next. In addition, CMS estimates that actual outlier payments in 2021 will represent 1.07 percent of total OPPS payments compared to the 1.0 percent set aside, a -0.07 percentage point change in 2022 payments.

Changes to the APC weights, wage indices, continuation of a payment adjustment for rural SCHs, including essential access community hospitals, and the payment adjustment for inpatient prospective payment system (IPPS)-exempt cancer hospitals do not affect aggregate OPPS payments because these adjustments are budget neutral. However, these factors have differential effects on individual facilities.

Although CMS projects an estimated increase of 1.6 percent for all facilities, the rule's impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	2022 Impact
All Hospitals	1.6%
All Facilities (includes CMHCs and cancer and children's hospitals)	1.6%
Urban	1.6%
Large Urban	1.7%
Other Urban	1.5%
Rural	1.6%
Beds	
0-99 (Urban)	1.7%
0-49 (Rural)	1.6%
500+ (Urban)	1.4%
200+ (Rural)	1.8%
Major Teaching	1.4%
Type of ownership:	
Voluntary	1.6%

Facility Type	2022 Impact
Proprietary	1.7%
Government	1.7%

The payment impacts are largely consistent between the different categories of hospitals. Generally, an increase or decrease larger than the average will be accounted for by recalibration of APC weights or changes to the wage index.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.2 percent for all services paid under the OPPS in 2022. The coinsurance percentage reflects the requirement for beneficiaries to pay a 20 percent coinsurance after meeting the annual deductible. Coinsurance is the lesser of 20 percent of Medicare's payment amount or the Part A inpatient deductible ($1,408 in 2022) which accounts for the aggregate coinsurance percentage being less than 20 percent.

II. Updates Affecting OPPS Payments

A. Recalibration of Ambulatory Payment Reclassification (APC) Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

For 2022, CMS is not following its usual process of using the latest available data to set the OPPS relative weights. Normally, CMS would use 2021 hospital final action claims for services furnished from January 1, 2020 through December 31, 2020 processed through the Common Working File as of June 30, 2021 to determine the OPPS relative weights for the 2022 OPPS rule. Cost reports from 2019—some of which end in calendar year 2020—would normally be used for cost to charge ratios (CCR) to adjust charges on claims to cost. As a result of the COVID-19 Public Health Emergency (PHE), CMS proposed to use Medicare claims and cost reports from prior to the PHE to determine the 2022 relative weights. See section X. E. for details. Otherwise, CMS is not changing its methodology for how it determines the APC relative weights.

CMS is using claims data with a date of services between January 1, 2019 and December 31, 2019 to set the 2022 relative weights. These are final action claims. After applying exclusionary criteria, CMS is using approximately 93 million claims to develop the final rule relative weights. Medicare cost reports from 2018 are continuing to be used for setting the 2022 relative weights.

In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the final rule payment rates, including the number of claims available at each stage of the process: 2022-nfrm-opps-claims-accounting.pdf (cms.gov).

Continuing past years' methodology, CMS calculated the cost of each procedure only from single procedure claims. CMS created "pseudo" single procedure claims from bills containing multiple codes, using date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to "pseudo" single procedure claims. Through bypassing specified codes that CMS believes do not have significant packaged costs, CMS is able to retrieve more data from multiple procedure claims.

For the 2022 rule, CMS is bypassing the 173 HCPCS codes identified in Addendum N. New bypass codes are identified with an asterisk. CMS indicates the list of bypass codes may include codes that were reported on claims in 2019 but were deleted for 2020 or 2021.

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

To convert billed charges on outpatient claims to estimated costs, CMS is multiplying the charges by a hospital-specific CCR associated with each revenue code and cost center. To calculate CCRs for 2022, CMS is employing the same basic approach used for APC rate construction since 2007. CMS applies the relevant hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy of CCRs for each revenue code. The current crosswalk is available for review and continuous comment on the CMS website at the link provided at the beginning of this summary. No new revenue codes were added for 2019, the year of claims data used for deriving the 2022 payment rates. CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report data at its most detailed level. Generally, the most detailed level will be the hospital-specific departmental level.

One commenter recommended that CMS provide specific instructions to hospitals for submitting charges for cardiac CT using revenue codes. The commenter indicated more accurate cost estimates are needed for cardiac CT services that have been underpaid for more than a decade as a result of inaccurate hospital reporting. CMS responded that it relies on hospitals to decide how to accurately report hospital costs and charges and it is making no changes to its instructions in response to this comment.

2. Data Development Process and Calculation of Costs Used for Rate Setting

In past years, to determine each APC's relative weight, CMS takes single procedure claims and adjusts charges to costs for each procedure within an APC and then calculates the APC's geometric mean cost. The relative weight is the geometric mean cost of the APC divided by the geometric mean cost across all APCs. CMS standardizes the relative weights to the APC for G0463, an outpatient hospital visit—the most commonly furnished service billed under the OPPS. CMS is continuing to follow this basic process for 2022. The 2019 claims data that CMS is using for 2022 includes data from off-campus provider-based departments paid at a PFS comparable amount under section 603 of the Bipartisan Budget Act (BBA) of 2015. As these

claims are not paid under the OPPS, CMS eliminates these claims from the relative weight calculation.

a. Calculation of single procedure APC criteria-based costs

The calculation of geometric mean costs for some APCs follows various special rules, as described below.

Blood and blood products

CMS is continuing to determine the relative weights for blood and blood product APCs by converting charges to costs using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not. CMS is also continuing to include blood and blood products in the comprehensive APCs, which provide all-inclusive payments covering all services on the claim. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of "R" (Blood and Blood Products) in Addendum B of the final rule.

Brachytherapy sources

The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source) – i.e., "brachytherapy sources" – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. 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 proposed no changes to its brachytherapy policy for 2022.

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 2021, 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 proposed to continue this rate for 2022. It received no comments and is finalizing a rate of $4.69 per mm^2 for 2022 for HCPCS code C2645.

In section X.C. below, there is more information on CMS' policy to use up to four years of claims data for APCs with fewer than 100 single claims in a single year that can be used for rate-setting. For these APCs, CMS will determine the relative weight based on the higher of the arithmetic mean cost, median cost or geometric mean cost. CMS is creating five low volume brachytherapy APCs under this policy.

Recommendations for HCPCS codes that describe new brachytherapy sources should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. CMS will continue to add new brachytherapy source codes and descriptors to its payment systems on a quarterly basis through program transmittals.

b. Comprehensive APCs (C-APCs) for 2022

A C-APC is defined as a classification for a primary service and all adjunctive services provided to support the delivery of the primary service. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are integral, ancillary, supportive, dependent, and adjunctive to the primary service. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim.

Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Qualifying services are reassigned from the originating C-APC to a higher paying C-APC in the same clinical family of comprehensive APCs. Currently, code combinations satisfying the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless (1) the APC reassignment is not clinically appropriate, or (2) the primary service is already assigned to the highest cost APC within the C-APC clinical family. CMS does not create new APCs with a geometric mean cost that are higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

CMS received public comments asking that it eliminate the 25-claim minimum threshold for a complexity adjustment and also that combinations of procedures with a primary service be eligible for a complexity adjustment. CMS responded that it did not propose any of these changes so it cannot adopt them in the final rule. In addition, CMS believes 25 claims is already a very low threshold to meet the threshold for a complexity adjustment and the current criteria are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service.

For 2019, CMS excluded procedures assigned to new technology APCs from being packaged into C-APCs because of a concern that packaging payment reduces claims for the new technology that are available for APC pricing. This policy includes new technology services that are assigned to the "Comprehensive Observation Services" C-APC.

CMS also adopted an exception to the C-APC policy in the November 6, 2020 interim final rule with comment (IFC) titled "Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency" for drugs and biologicals approved by the Food and Drug Administration (FDA) to treat COVID-19 for use in the outpatient department or not limited for use in inpatient settings. Such drugs and biologicals will be paid separately outside of the C-APC for the duration of the COVID-19 PHE.

As a result of its annual review of the services and the APC assignments under the OPPS, CMS did not propose to convert any conventional APCs to C-APCs in 2022. The full list of C-APCs, the data CMS used to evaluate APCs for being a C-APC, and C-APC complexity adjustments are found in Addendum J. C-APCs with a status indicator of "J1" or "J2" (only for the Comprehensive Observation Services C-APC) can be found in other Addenda as well.

One commenter requested that CMS designate APC 5372 (Level 2 Urology and Related Services) as a C-APC. Another commenter requested CMS discontinue the C-APC for surgical

insertion of brachytherapy given the complexity of coding, use of serial billing and the potential for different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services. CMS will consider the first comment in future rulemaking and disagreed with the second comment saying that it did not match how CMS calculates C-APC costs.

c. 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. At this time, CMS' composite APC policy applies only for mental health services and multiple imaging services. CMS is not making any changes to its composite APC policies for 2022.

3. Changes to Packaged Items and Services

a. Packaging Policies and Non-Opioid Treatment Alternatives

Section 6082 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act requires the Secretary to review payments under the OPPS to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives. CMS' current policy will allow separate payment for non-opioid treatment alternatives that function as supplies in the ASC only if public comments can provide evidence that packaging is a disincentive to their use. This policy applies only the ASC setting and not the hospital outpatient department. In the proposed rule, CMS requested public comment on whether to expand this policy to the OPPS.

MedPAC opposed expanding the policy to the OPPS stating that this policy is contrary to CMS's efforts to increase the size of payment bundles in the OPPS to increase incentives for efficient delivery of care. Other commenters supported expanding the policy stating that opioids were more cost effective for their HOPD facilities to use compared to non-opioid pain management drugs due to CMS payment policies. Separate payment for non-opioid pain management drugs under the OPPS could potentially increase access to these treatments.

CMS reiterated prior responses that it continues to observe increasing utilization of non-opioid treatment alternatives in the OPPS despite lack of separate payment. It further indicates that ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate making them more sensitive to payment issues than hospitals. CMS adds that its goal is to eliminate the disincentive to use non-opioid pain management drugs, rather than to incent use of them in the HOPD setting as one commenter suggested. CMS is not making any policy changes for 2022 but will continue to carefully analyze utilization data and engage with stakeholders.

b. Eligibility for Separate Payment for Non-Opioid Pain Management Drugs and Biologicals

For 2022 and subsequent years, CMS proposed that for a product to be eligible for separate payment under the non-opioid treatment alternatives policy, the drug or biological must be FDA

approved to treat pain management, must meet the annual cost threshold for separately payable drugs and not be paid on pass-through.

FDA Approval Criterion: This criterion is intended 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. The indication requirement would allow CMS to confirm that a drug or biological is a non-opioid used to treat pain.

To meet the FDA approval requirements CMS proposed that the drug must be approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act, generic drug application under an abbreviated new drug application under section 505(j), or, in the case of a biological product, licensed under section 351 of the Public Health Service Act. CMS indicated that the vast majority of drugs and biologicals on the market have undergone FDA review and approval. It does not anticipate this criterion would prevent otherwise eligible drugs or biologicals from qualifying.

While there were many comments in support of the FDA approval criterion, other commenters believe this requirement may limit the number of products to which the policy would apply. There were comments that raised concerns about how specific the FDA approval indication must be to meet the criterion for separate payment. A commenter asked whether a drug could be eligible for separate payment if administered post-operatively.

CMS responded to concerns about the FDA-approved indication by stating that any drug indicated for pain management or analgesia is appropriate for this policy. Drugs not approved for pain management or as an analgesic (such as anesthetics) would not qualify for separate payment. All items related to the surgical outcome provided during the hospital stay, including postsurgical pain management drugs, would be eligible for this policy. CMS is finalizing this policy as proposed.

Meeting the Annual Cost Threshold Criterion: The per-day drug packaging threshold for CY 2022 is $130. An FDA approved non-opioid drug or biological indicated for use as an analgesic to treat pain would need to have per day costs that exceed $130 to receive separate payment in the ASC. Below this threshold (as with all other drugs), CMS does not believe there is a sufficient disincentive to use the product as the costs are generally represented by the APC payment.

Public commenters generally supported that the per day cost of the non-opioid be above the packaging threshold to qualify for separate payment. There were comments suggesting that relative to opioids, non-opioids remain expensive and should be paid separately even when their per day costs do not exceed the packaging threshold. CMS disagrees and states that below the packaging threshold the cost of the drug is likely to represent a substantial portion of the payment rate of the primary procedure in which the product is used. CMS is finalizing this policy without modification.

Pass-Through Criterion: CMS proposed to make drugs and biologicals ineligible for separate payment under this policy while they are separately paid under the pass-through provisions. However, pass-through products may be eligible for separate payment under the non-opioid

treatment alternatives policy once pass-through expires. Commenters supported this policy but asked that CMS make determinations regarding separate payment after pass-through expires as soon as possible through rulemaking. CMS agreed and will determine whether a product is packaged or paid separately for the calendar year that follows the year when pass-through payment expires.

c. Additional Non-Opioid Pain Management Drugs and Biologicals Eligible for Separate Payment Beginning in 2022

For 2022, CMS did not propose to unpackage any additional non-opioid treatment alternatives from OPPS or ASC payments. CMS reiterated its request for public comments on this issue that were in prior proposed rules—asking for evidence that unpackaging non-opioid products will lead to reduced use of opioids in the ASC or outpatient department settings. However, CMS no longer appears to be applying the evidence standard to pay separately for non-opioid drugs and biologicals that function as a supply in the ASC setting. Instead, CMS is evaluating comments requesting separate payment under this policy against the three criteria described above:

- The drug or biological is FDA approved and indicated for pain management or analgesia;
- The per day cost of the drug or biological exceeds $130; and
- The drug or biological is not paid on pass-through.

CMS will make separate payment in the ASC setting for the following non-opioid products in 2022:

- Exparel: Meets the above criteria. Continuing separate payment approved in earlier years.
- Omidria: Meets the above criteria. Continuing separate payment approved in earlier years.
- Xaracoll: Meets the FDA approval criterion as the product is indicated for "placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair" and meets the $130 per day cost threshold. Not paid on pass-through.
- Zyrelef: Meets the FDA approval criterion as the product is indicated for "in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty" and meets the $130 per day cost threshold. Not paid on pass-through.

CMS denied separate payment for the following products in the ASC setting:

- Dextenza: Meets the FDA approval criterion as the product is indicated for "treatment of ocular pain following ophthalmic surgery and meets the $130 per day cost threshold. However, CMS denied separate payment under the non-opioid policy because Dextenza is currently receiving separate payment on pass-through.
- Dexycu: Denied because it does not meet the FDA criterion. Dexycu is approved for "postoperative inflammation" which CMS does not see as a pain indication.
- Anjesco: Meets the FDA approval criterion as the product is indicated for "use in adults for the management of moderate-to-severe pain, alone or in combination with non-

NSAID analgesics." However, CMS denied separate payment because Anjesco does not meet the cost threshold.

- Ofirmev: Meets the FDA approval criterion as the product is indicated for "management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever." However, CMS denied separate payment because Ofirmev does not meet the cost threshold.
- IV ibuprofen and IV ketorolac: CMS received comments asking these classes of drugs be paid separately although the request was not for specific products. CMS believes these classes of products would likely meet the FDA approval criterion but not the cost threshold.
- Prialt: Denied because it is not a drug that functions as a supply and is already receiving separate payment.
- Dsuvai: Denied because it contains an opioid.

CMS further solicited comment on potential policy modifications and additional criteria that may help further align this policy with the intent of the SUPPORT Act:

- Whether it should continue to use utilization as an indicator of whether the product should be unpackaged. Commenters opposed using utilization as an indicator of whether products should be unpackaged saying that it takes significant time for data to be available after a drug is on the market to evaluate whether separate payment is merited.
- Whether FDA-approved drugs and biologicals without a specific FDA-approved indication for pain management or as an analgesic drug should be allowed to receive separate payment. In lieu of an FDA indication for pain management or analgesia, CMS could include a drug or biological under this policy if the pain management or analgesia attributes of the drug or biological are recognized by a medical compendium. Similarly, CMS could consider specialty society or national organization (such as a national surgery organization) recommendations for this purpose. Public commenters supported this approach saying that an FDA-approved indication is too restrictive as some products may be used off-label.
- Whether the drug or biological's use in a surgical procedure as a non-opioid pain management product should be supported by peer-reviewed literature demonstrating a clinically significant decrease in sustained opioid usage compared to the standard of care, and the standards for use of that literature. Commenters generally opposed use of peer reviewed literature as unnecessary because an FDA-approved indication for pain management or analgesia should be sufficient. Other comments suggested peer reviewed literature should be used to demonstrate evidence that the non-opioid reduces opioid use (the standard that CMS previously was using).
- Whether to make a single, flat add-on payment, or separate APC assignment in place of separate payment based on ASP for products eligible for separate payment under this policy. Commenters generally supported ASP+6 percent payment for non-opioid products paid separately.
- Whether non-drug products should have to meet the same criteria for separate payment as drug products (revised as applicable for FDA approvals that apply to devices rather than drugs and biologicals) and suggestions for the payment mechanism if a non-drug product meets the criteria for separate payment. There were comments recommending that non-

drug products should meet the same criteria as drug products for separate payment while other comments requested separate payment for a variety of non-drug products or services.

CMS will consider all of these comments in future rulemaking.

4. Calculation of OPPS Scaled Payment Weights

As in past years, CMS is standardizing the relative weights based on APC 5012 and HCPCS code G0463 (a hospital outpatient clinic visit) which is the most commonly billed OPPS service. CMS will give APC 5012 a relative weight of 1.0 and divide the geometric mean costs of all other APCs by the geometric mean cost for APC 5012 to determine its associated relative payment weight. Even though CMS is paying for clinic visits furnished in an off-campus provider-based department at a PFS equivalent rate under a site neutral policy, CMS will continue to use visits in these settings to determine the relative weight scaler because the PFS adjuster is applied to the payment, not the relative weight. CMS' site neutral policy is not budget neutral while changes to the weights are budget neutral.

Specified covered outpatient drugs (SCODs) are included in the budget neutrality calculation to ensure that the relative weight changes between 2021 and 2022 do not increase or decrease expenditures. However, SCODs are not affected by the budget neutrality adjustment.

CMS is following its past practice to determine budget neutrality for changes in the OPPS relative weights. However, instead of using the most recent calendar year of available data from 2020, CMS is continuing to use 2019 utilization for reasons explained section X.E. Holding all other variables constant, CMS multiplies the 2021 and 2022 final rule relative weights respectively for each APC by its associated volume from 2019. It sums the 2021 and final 2022 relative weights respectively, and divides the 2021 aggregate relative weights by the final 2022 aggregate relative weights to determine the weight scaler. Using this process, CMS is adopting a weight scaler of 1.4416. The unscaled final 2022 relative payments are multiplied by 1.4416 to determine the final 2022 scaled relative weights that are shown in Addendum A and B.

B. Conversion Factor Update

The 2021 conversion factor is $82.7970 for hospitals receiving the full update for outpatient quality reporting. The components of the update are shown below:

	Full Update		Reduced Update	
2021 Conversion Factor (CF)	**$82.7970**	**Resulting CF**	**$82.7970**	**Resulting CF**
Remove pass-through & outliers from prior year CF	1.0196	$84.4180	1.0960	$84.4180
Wage Index Budget Neutrality	1.0001	$84.4260	1.0001	$84.4260
Cap on Wage Index Reductions	0.9999	$84.4180	0.9999	$84.4180
Cancer Hospital Adjustment	1.0000	$84.4180	1.0000	$84.4180
Rural Hospital Adjustment	1.0000	$84.4180	1.0000	$84.4180
340B	1.0000	$84.4180	1.0000	$84.4180
Update	1.0200	$86.1060	1.0000	$84.4180

	Full Update		Reduced Update	
2021 Conversion Factor (CF)	**$82.7970**	**Resulting CF**	**$82.7970**	**Resulting CF**
Pass-Through and Outlier Adjustment	0.9776	$84.1770	0.9776	$82.5269
2022 Conversion Factor		$84.1770		$82.5269

CMS removes the prior year's pass-through and outlier adjustment from the 2021 conversion factor which equals 1.0196 (1.96 percent). Wage index budget neutrality is 1.0001 (0.01 percent). There is a cap on reductions to the wage index that requires a budget neutrality adjustment of 0.9999 (-0.01 percent). CMS indicates no additional budget neutrality adjustment is needed for the cancer and rural hospital adjustments or 340B policies. The update of 1.020 (2.0 percent) equals the market basket of 2.7 percent less 0.7 percentage points for MFP (0.0 percent for hospitals that do not receive the full update). CMS estimates that pass-through spending for drugs, biologicals and devices for 2022 will be $1.03 billion, or 1.24 percent of OPPS spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9776 (-2.24 percent).

The final conversion factor for hospitals that submit quality data is $84.1770. The conversion factor for hospitals that do not submit quality data is subject to all of the same adjustments except the update is 1.0000 (0.0 percent) instead of 1.0200 (2.0 percent). The final conversion factor for hospitals that do not submit quality data is $82.5260 (HPA's calculation above is slightly different at $82.5269). CMS applies the reduced update as the "reporting ratio" to the full payment rate for hospitals that do not submit quality data or the ratio of the reduced CF to the full CF ($82.5260/$84.1770=0.9804).

C. Wage Index Changes

CMS is continuing to use a labor share of 60 percent and the fiscal year IPPS post-reclassified wage index for the OPPS in 2022. The final rule directs readers to the IPPS rule for more details regarding specific policies affecting the 2022 wage index. One issue addressed in the IPPS rule concerned impacts on the hospital wage index of revised labor market areas resulting from OMB Bulletin 18-04 that make changes to metropolitan statistical area designations. CMS transitioned the impact of these and other large reductions in the FY 2021 wage index over two years in both the IPPS and OPPS.

For FY 2022, the full impact of these changes would be realized under the IPPS under the original transition. However, CMS decided to continue the transition into FY 2022 and limit the reduction in the wage index to 5 percent for those hospitals that were subject to the transition in FY 2021. CMS requested comment on adopting a parallel policy under the OPPS. Public commenters supported this idea although, as in the IPPS, requested the limit on reductions to the wage index be applied more broadly for any reason there is a reduction in the wage index. Commenters also recommended the transition be adopted without applying budget neutrality.

CMS is following a parallel policy for the 2022 OPPS as it did for the FY 2022 IPPS. That is, hospitals that were subject to a 5 percent limit on the reduction in the 2021 wage index relative to the 2020 wage index will again be subject to 5 percent limit on the reduction in the 2022 wage index relative to the 2021 wage index. CMS will make this change budget neutral necessitating

the -0.01 percent budget neutrality adjustment to the conversion factor explained in the prior section.

For non-IPPS hospitals paid under the OPPS for 2022, CMS is 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 CMHCs, CMS will continue to calculate the wage index by using the post-reclassification IPPS wage index based on the 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.

D. Statewide Average Default Cost-to-Charge Ratios (CCRs)

In cases where there are no data to calculate a hospital's CCR, CMS will to continue using the statewide average CCR to determine outlier payments, payments for pass-through devices, and other purposes. The statewide average is used for hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS will also use the statewide average default CCRs to determine payments for hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status. Consistent with other policies to not use cost report data that span the COVID-19 PHE, CMS will continue using the same default statewide average CCRs for 2022 that it used for 2021. The table of statewide average CCRs can be found at: 2022 | CMS.

E. Sole Community Hospital (SCH) Adjustment

For 2022, CMS is continuing to apply a 7.1 percent payment adjustment under section 1833(t)(13)(B) of the Social Security Act (the Act) 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.

F. Cancer Hospital Adjustment

Eleven cancer hospitals meeting specific statutory classification criteria are exempt from the IPPS. Medicare pays these hospitals under the OPPS for covered outpatient hospital services. The Affordable Care Act requires an adjustment to cancer hospitals' outpatient payments sufficient to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals—the target PCR. The change in these additional payments from year to year is budget neutral. The 21st Century Cures Act reduced the target PCR by 1.0 percentage point and excludes the reduction from OPPS budget neutrality.

The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis. For 2021, CMS updated its calculations using the latest available cost data at the time of publication of the 2021 OPPS final rule and determined a target PCR of 0.90. Under

section 1833(t)(18)(C) of the Act, CMS reduced the target PCR from 0.90 to 0.89. Consistent with other policies to not use cost report data that span the COVID-19 PHE, CMS will continue using the same cost data to determine the target PCR for 2022 that it used for 2021. Therefore, CMS is using a target PCR of 0.90 reduced by 1.0 percentage point to 0.89. CMS did not receive any comments on this policy that it is finalizing without modification.

Table 6 in the final rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2022 ranging from 11.2 percent to 51.4 percent. No additional budget neutrality adjustment is required for the cancer hospital adjustment in 2022 compared to 2021.

G. Outpatient Outlier Payments

CMS makes OPPS outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2022, CMS will continue setting aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It is calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2021 and previous years. CMS will continue setting the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple payment threshold and the fixed-dollar threshold are met. For 2022, CMS calculated a proposed rule fixed dollar threshold of $6,100 (compared to $5,300 in 2021). For the final rule, CMS is calculating a fixed dollar loss threshold of $6,175.

CMS will set aside a portion of the 1.0 percent outlier pool, specifically an amount equal to less than 0.01 percent of outlier payments, for CMHCs for partial hospitalization program outlier payments. If a CMHC's cost for partial hospitalization services paid under APC 5853 (Partial Hospitalization for CMHCs) exceeds 3.40 times the payment rate for APC 5853, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals failing to satisfy the quality reporting requirements, a hospital's costs for the service are compared to the reduced payment level for purposes of determining outlier eligibility and payment amount.

Consistent with other policies to not use claims cost report data that span the COVID-19 PHE, CMS is using data predating the 2020 PHE to determine the rule outlier threshold. To model hospital outlier payments and set the outlier threshold for the final rule, CMS applied a charge inflation factor of 1.20469 to approximate 2022 charges from 2019 claims. CMS is adjusting hospital-specific overall ancillary CCRs available in the April, 2020 update to the Outpatient Provider-Specific File by 0.94964 to approximate 2022 CCRs. The CCR adjustment and charge-inflation factors are the same that were used to set the FY 2022 IPPS final rule fixed loss threshold.

CMS estimates that a fixed dollar amount threshold of $6,175 combined with the multiplier threshold of 1.75 times the APC payment rate, will allocate the 1.0 percent of aggregated total OPPS payments to outlier payments.

H. Calculation of an Adjusted Medicare Payment

This section provides step by step instructions for calculating an adjusted Medicare payment from the national unadjusted Medicare payment amounts shown in Addenda A and B. The steps show how to determine the APC payments that would be made under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and one that does not.

I. Beneficiary Coinsurance

Medicare law provides that the minimum coinsurance is 20 percent. The statute also limits a beneficiary's actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,408 in 2022. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index (e.g., the national estimated coinsurance amount could be above the inpatient deductible but could come below the capped amount once adjusted for the wage index). Addenda A and B include a column with a "*" to designate those APC and HCPCS codes where the deductible limit applies.

III. APC Group Policies

A. Treatment of New and Revised HCPCS Codes

CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly Change Requests. Generally, code changes are effective January 1, April 1, July 1, or October 1. CMS assigns the new codes to interim status indicators (SIs) and APCs; the interim assignments are finalized in the OPPS final rule. Status indicators, APC assignments, and payment rates can be found in Addendum B of this rule.[2]

1. April 2021 Codes

In the April 2021 OPPS quarterly update, CMS made effective 26 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (Table 7). For the April 2021 update, there were no new CPT codes.

2. July 2021 HCPCS Codes

In the July 2021 OPPS quarterly update, CMS made 55 new codes effective and assigned them to interim OPPS status indicators and APCs (Table 8). CMS notes that several of the HCPCS C-codes have been replaced with J-codes, effective October 1, 2021.

[2] Addendum D1 includes the complete list of status indicators and corresponding definitions. Addendum D2 includes the complete list of comment indicators and definitions.

3. October 2021 HCPCS Codes - CMS Solicits Comments

CMS continues its practice to provide interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that became effective October 1, 2021 in Addendum B to this final rule. These codes are flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2022. **CMS invites comment** about these interim status indicators, APC assignments, and payment rates for these codes; this information will be finalized in the 2023 OPPS final rule.

4. January 2022 HCPCS Codes

a. New Level II HCPCS Codes – CMS Solicits Comments

CMS solicits comments on the new Level II HCPCS codes that will become effective January 1, 2022. Unlike the CPT codes that are effective January 1 and included in the OPPS proposed rules, and except for G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until November to be effective January 1 and CMS is not able to include them in the proposed rule.

New Level II HCPCS codes that will be effective January 1, 2022 are flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2022. **CMS invites comments** about these interim status indicators, APC assignments, and payment rates for these codes; this information will be finalized in the 2023 OPPS final rule.

b. CPT Codes

For the 2022 OPPS update, CMS received the CPT codes that will be effective January 1, 2022 in time to be included in the proposed rule (available in Addendum B of this proposed rule). CMS assigned a new comment indicator "NP" and requested comments on the proposed APC assignment, payment rates and status indicators. NP indicates that the code is new for the next CY or the code is an existing code with substantial revision to its code descriptor in the next CY as compared to the current CY, with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator. CMS received comments about several of the new CPT codes; these comments are discussed below in section D.

Table 9 (reproduced below) summarizes the process used by CMS for updating codes.

Table 9: Comment Timeframe for New or Revised HCPCS codes

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2021	HCPCS (CPT and Level II Codes)	April 1, 2021	2022 OPPS/ASC proposed rule	2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II Codes)	July 1, 2021	2022 OPPS/ASC proposed rule	2022 OPPS/ASC final rule with comment period

October 2021	HCPCS (CPT and Level II Codes	October 1, 2021	2022 OPPS/ASC final rule with comment period	2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	2022 OPPS/ASC proposed rule	2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2022	2022 OPPS/ASC final rule with comment period	2023 OPPS/ASC final rule with comment period

B. Variations within APCs

1. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act, CMS annually reviews the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost item or service within an APC group is more than 2 times greater than the lowest cost item or service within that same group. In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers significant only those HCPCS codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost.

The Secretary is also required to consult with an expert outside advisory panel composed of appropriate representatives of providers to review the clinical integrity of the APC groups and the relative payment weights and advise the Secretary about any issues. The Panel recommendations for specific services for the 2021 OPPS and CMS' responses are discussed throughout this rule.

For 2022, CMS identified APCs with violations of the 2 times rules and proposed changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator "CH"). CMS notes that in many cases, the proposed procedure code reassignments and associated APC configurations for 2022 were related to changes in costs of services that were observed in the 2019 claims data.

2. APC Exceptions to the 2 Times Rule

CMS may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS uses the following criteria to decide whether to propose exceptions:

- resource homogeneity;
- clinical homogeneity;
- hospital outpatient setting utilization;
- frequency of service (volume); and
- opportunity for upcoding and code fragments.

CMS notes that in cases in which a recommendation by the Panel appears to result in a violation of the 2 times rule, CMS generally accepts the Panel's recommendations because the Panel's recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

In response to a commenter requesting that CMS only require 500 single claims instead of 1,000 single claims for examining 2 times rule violations, CMS believes its current definitions are appropriate.

Table 10 (reproduced below) lists the 23 APCs that CMS finalizes to exempt from the 2 times rule for 2022 based on claims data from the updated 2019 claims data file used for this rule.

Table 10: 2022 APC Exceptions to the 2 Times Rule	
CY 2022 APC	**CY 2022 APC Title**
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. New Technology APC Groups

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.

2. Establishing Payment Rate for Low-Volume New Technology Procedures

One of CMS' objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure for assignment to an appropriate clinical APC. CMS considers procedures with fewer than 100 claims annually as low volume procedures. CMS is concerned that there is a higher probability that the payment data for these procedures may not have a normal statistical distribution, which could affect the quality of the standard cost methodology used to assign services to an APC. CMS also notes that services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC rate setting calculations and are not included in the assessment of the 2 times rule.

CMS has used its equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how it determines the costs for low-volume services assigned to New Technology APCs (82 FR 59281). Instead of using this authority on a case-by-case basis, in the 2019 OPPS final rule (83 FR 58892 – 58893), CMS finalized a different payment methodology for these low-volume services using its equitable adjustment authority:

- Use 4 years of claims data to establish a payment rate for each applicable service both for assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC;
- Use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service;
- The results of each statistical methodology will be included in annual rulemaking and it will solicit public comment on which methodology should be used to establish the payment rate; and
- Assign the service to the New Technology APC with the cost band that includes its finalized payment rate.

For 2022, CMS proposed to continue this policy. CMS also proposed to utilize its equitable adjustment authority through a universal low volume APC policy. The proposed universal low volume APC policy was similar to the New Technology low volume policy except that the universal low volume APC policy would also apply to clinical APCs and brachytherapy APCs and would use the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. CMS proposed to end its separate New Technology APC low volume policy if the proposed universal low volume APC policy was finalized.

CMS finalizes the proposed universal low volume APC policy; this policy will apply to procedures assigned to New Technology, clinical, and brachytherapy APCs (discussed in section X.C.).

3. Procedures Assigned to New Technology APC Groups

CMS continues its policy to retain services within New Technology APC groups until sufficient claims data is obtained to justify reassignment of the service to a clinically appropriate APC. CMS notes, that in cases where it determines, based on additional information, the initial New Technology APC assignment is no longer appropriate it will reassign the procedure or service to a different New Technology APC that more appropriately reflects its costs. This policy allows CMS to reassign a service in less than 2 years if sufficient claims data are available and also retain a service in a New Technology APC for more than 2 years if there is not sufficient claims data to base a reassignment.

a. Retinal Prosthesis Implant Procedure (Argus II Retinal Prosthesis System)

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis. The retinal prosthesis device, the Argus II, is described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external component). Pass-through status was granted for HCPCS code C1841 beginning October 1, 2013 and expired on December 31, 2015. For 2016, the procedure described by C1841 was assigned to OPPS status indicator "N" (the payment for the procedure is packaged) and CPT code 0100T was assigned to New Technology APC 1599 (New Technology – Level 48 ($90,001 - $100,000)) with a 2016 OPPS payment of $95,000.

For 2022, CMS finalizes its proposal to maintain the assignment of CPT code 0100T to APC 1908 with a payment rate of $152,500.50 (Table 11). CMS notes that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus II device (HCPCS code C1841).

b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1561)

Effective January 1, CMS established C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned this HCPCS code to New Technology APC 1561 (New Technology Level 24 ($3001- $3500)). This procedure may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). Voretigene neparvovec-rzyl (Luxturna®) was approved by the FDA in December 2017 as an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. This therapy is administered by a subretinal injection. For 2021, CMS finalized a new HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this procedure. CMS assigned C9770 to New Technology APC 1561 (New Technology Level 24 ($3001- $3500)).

For 2022, CMS finalizes its proposal to maintain the assignment of HCPCS code C9770 to New Technology APC 1561 with a payment rate of $3,250.50 (identical information in Tables 12 and 13).

c. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS established HCPCS code C9751 for bronchoscopy with transbronchial microwave ablation for treatment of lung cancer. For 2021, based on 2019 claims data, CMS identified 4 claims. All three estimates of the cost of the procedure were within the cost band of New Technology APC 1562 (New Technology Level 265 ($3,501-$4,000)).

For 2022, CMS finalizes its proposal to continue to assign HCPCS code C9751 to APC 1562 (New Technology Level 265 with a payment rate of $3,750.50 (Table 14).

d. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

FFRCT (trade name HeartFlow) is a noninvasive diagnostic service that measures coronary artery disease by CT scans (CPT code 0503T). Although payment for analytics performed after the main diagnostic/imaging procedures are packaged into the payment for the primary procedure, CMS determined in 2018 that HeartFlow should receive a separate payment because the procedure is performed by a separate entity. CMS explains the provider performing the CT scan does not do the analysis; instead, a HeartFlow technician conducts computer analysis offsite.

For 2021, CMS identified 3,188 claims with 465 single frequency claims. Using its standard methodology, CMS determined a geometric mean cost of $804.35 and proposed to assign CPT code 0503T to New Technology APC 1510 (New Technology Level 10 ($801- $900) with a proposed payment rate of $850.50. Based on comments from providers and other stakeholders indicating that the FFRCT service costs $1,100 and the need for providers to learn how to bill for artificial intelligence services, CMS assigned CPT code 0503T to New Technology APC 1511 (New Technology – Level 11 ($901-$1000).

For 2022, CMS finalizes its proposal to continue to assign CPT code 0503T to New Technology APC 1511 with a payment rate of $950.50 (Table 15).

The developer of HeartFlow and other commenters suggested assigning the procedure to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a payment rate of approximately $1,270. Commenters thought that the HeartFlow procedure had enough clinical similar to other procedures in this APC and that cardiac CT procedures were also assigned to this APC. CMS disagrees with this suggestion because APC 5593 describes procedures generally requiring imaging where radiopharmaceuticals and other nuclear materials are critical supplies for these procedures. In comparison, HeartFlow is a computer algorithm that does not directly take images. CMS notes that there may be a limited number of examples where a procedure may have only a limited clinical similarity to other procedures in the same APC, but it attempts to make those rare exceptions. CMS also disagrees with the developer's alternative suggestion to assign the service to APC 5724 (Level 4- Diagnostic Tests and Related Services) with a payment rate of $896.09. CMS continues to believe the service is appropriately assigned to a New Technology APC as it continues to obtain more cost data, including additional staff costs, before assigning to a clinical APC.

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

Effective January 1, 2020, CMS assigned three CPT codes (78431- 78433) describing services associated with cardiac PET/CT studies to New Technology APCs (APCs 1522, 1523, and 1523, respectively). For 2021, CMS did not receive any claims with these CPT codes and continued to maintain the 2020 assignment for 2021.

For 2022, CMS finalizes its proposal to continue to maintain the 2021 assignments for these codes (Table 16).

f. V-Wave Interatrial Shunt Procedure

CMS discusses a randomized, double-blinded control IDE study in progress for the V-Wave interatrial shunt. The developer of the V-Wave was concerned that the current coding of services would reveal to the study participants whether they received the interatrial shunt because an additional procedure code, CPT 93799 (Unlisted cardiovascular procedure), would be included on the claims for participants receiving the interatrial shunt. As a result, for 2020, CMS created a temporary HCPCS code, C9758[3], to describe the V-wave interatrial shunt procedure for both the experimental and control group in the study. CMS assigned the code to New Technology APC 1589 (New Technology -Level 38 ($10,001- $15,000)). In 2021, reassigned HCPCS code C9758 to New Technology APC 1590 (New Technology -Level 39 ($15,001-$20,000).

For 2022, CMS finalizes its proposal to continue the assignment of C9758 to APC 1590 (Level 39 ($15,001-$20,000) with a payment rate of $17,500.50 (Table 17).

g. Corvia Medical Interatrial Shunt Procedure

Corvia Medical pivotal trial for their interatrial shunt procedure which is scheduled to continue through 2021. CMS established HCPCS code C9760 to facilitate the implantation of the Corvia Medical interatrial shunt.[4] For 2021, CMS assigned HCPCS code C9760 to New Technology APC 1592 (New Technology Level 41 ($25,001-$30,000).

For 2022, CMS finalizes its proposal to continue to assign HCPCS code C9760 to New Technology APC 1592 with a payment of $27,500.50 (Table 18).

The manufacturer requested that CPT code 0613T (the CPT code that will be used to report the procedure once FDA approval is obtained) be assigned to comprehensive APC 5194 (Level 4 Endovascular Procedures for 2022 and assigned a status indicator of "J1". CMS states it will

[3] The long descriptor for HCPCS code C9758 is Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography/intracardiac echocardiography, and all imaging with or without guidance performed in an approved IDE study.

[4] The long descriptor for HCPCS code 9760 is non-randomized, non-blinded procedure for NYHA class II -IV heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography/intracardiac echocardiography, and all imaging with or without guidance performed in an approved IDE study.

assign CPT code 06137 to a payable status indicator and assign the service to a clinically appropriate APC when the procedure has received approval from the FDA

h. Supervised Visits for Esketamine Self-Administration (HCPCS codes G2082 and G2083); APCs 1508 and 1511)

Spravato™ (esketamine) nasal spray, was approved by the FDA on March 5, 2019 for treatment of depression in adults with treatment-resistant depression (TRD). Because of the risk of serious outcomes resulting from sedation and dissociated from Spravato administration and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours and can be administered only in a certified medical office.

Effective January 1, 2020, CMS created two HCPCS codes (G2082 and G2083) for an outpatient visit for the evaluation and management of an established patient that requires supervision of a physician or other qualified health care professional, provision of esketamine nasal self-administration and 2 hours post-administration observation (G2082 includes 56 mg of esketamine and G2083 is for administration of more than 56 mg esketamine). For 2021, CMS did not receive any OPPS claims for either HCPCS code G2082 or G2083 and continued to assign HCPCS code G2082 to New Technology APC 1508 and assign HCPCS code G2083 to New Technology APC 1511.

For 2022, CMS finalizes its proposal to continue to assign HCPCS code G2082 to New Technology APC 1508 and assign HCPCS code G2083 to New Technology APC 1511 (New Technology – Level 11 (Table 19).

The manufacturer requested CMS utilize 2020 claims data to finalize payment rates for these codes. In response to this comment, CMS reviewed the available 2020 claims data but decided there was not sufficient data to determine a change in the APC assignments. CMS states it would like another year of claim's data to assess the reliability of the cost information for 2020 and 2021 before using claims data for APC assignments for these services.

i. DARI Motion Procedure (APC 1505)

The DARI Motion Procedure consist of eight cameras that surround a patient to obtain a live video that is analyzed to create a 3D reconstruction of the patient. The technology is intended to guide providers on surgical interventions, physical therapy and rehabilitation. CPT code 0693T will be effective January 1, 2022. CMS proposed assignment of CPT code 0693T to APC 5721 (Level 1 Diagnostics and Related Services) with a payment rate of $143.21.

The manufacturer requested CMS assign the CPT code to APC 5723 (Level 3 Diagnostics and Related Services) with a payment rate of $498.53. CMS agrees with the manufacture that the proposed payment rate may be too low. CMS notes that some Category III CPT codes describe services that it determines are not compatible with an existing clinical APC yet are appropriately provided in the outpatient setting and it estimates an appropriate New Technology APC. Based on information from the manufacturer and input from CMS' clinical advisors, the resources

involved for the procedure described by CPT code 0693T appear to be higher than the payment rate for APC 5721.

CMS finalizes the assignment of CPT code 0693T to New Technology APC 1505 (New Technology-Level 5 with a payment rate of $350.50 (Table 20).

j. Histotripsy Service (APC 1575)

Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy targeted cancerous liver tumors. CPT code 0686T was effective July 1, 2021. CMS proposed assignment of CPT code 0686T to APC 5311 (Level 1 Lower GI Procedures) with a payment rate of $814.44.

The manufacturer provided a description of the procedure and associated resources and stated that the total cost for the procedure is $22,782.51 and requested assignment to New Technology APC 1577. Based on its evaluation, CMS estimated the cost of histotripsy, after removing the device cost, is within the cost band between $10,001 and $15,000.

CMS finalizes the assignment of CPT code 0686T to New Technology APC 1575 with a payment rate of $12,500.50.

k. LiverMultiscan Service (APC 1511)

LiverMultiScan is a Software as a medical Service (SaaS) that aids in the diagnosis and management of chronic liver disease. The SaaS receives MR images, analyzes them using their proprietary AI algorithms, and then sends the provider a quantitative metric report of the patient's liver fibrosis and inflammation. CPT codes 0648T and 0649T were effective July 1, 2021. CMS proposed assignment of CPT code 0648T to APC 5523 (Level 3 Imaging without Contrast with a status indicator of "S"; CPT code 0649T is an add-on procedure and is packaged (Table 21).

Several commenters stated that LiverMultiScan is a new technology that provides an MRI measure of hepatic steatosis equivalent to liver biopsy. Commenters reported that hospital outpatient costs for this service are between $1,300 to $1,500 and they requested assignment of the LiverMultiScan to a New Technology APC. One commenter referenced CMS's decision on HeartFlow and requested CMS recognize LiverMultiScan as a distinct service.

Based on its evaluation of the service, CMS agrees that LiverMultiScan and HeartFlow share similar characteristics: both require the acquisition of radiologic images as well as analysis of images using proprietary AI algorithms to assist clinicians in appropriately diagnosing a medical condition. CMS estimates the cost associated for this service is between $901 and $1,000.

CMS finalizes the assignment of CPT code 0648T to New Technology APC 1511, the same APC assignment for HeartFlow. CMS finalizes CPT code 0649T, an add-on code, as a packaged service (status indicator "N").

l. Minimally Invasive Glaucoma Surgery (MIGS) (APCs 5491 and 5492)

For 2022, two new Category I CPT codes were created for extracapsular cataract removal with insertion of intraocular lens prosthesis (66989 and 66991) and one Category III code (0671T) for insertion of anterior segment aqueous drainage device. CMS proposed the following assignments: CPT code 66989 was assigned to APC 5492 (Level 2 Intraocular Procedures with a proposed status indicator of "J" and a proposed payment rate of $4,08.82; CPT code 66991 was also assigned to APC 5492; and CPT code 0671T was assigned to APC 5491 with a payment rate of $2,131.25.

Most commenters opposed the proposed APC assignment for these services. At the August 2021 HOP Panel Meeting, a presenter requested reassigning CPT codes 66989 and 66991 to APC 5493 (Level 3 Intraocular Procedures) with a proposed payment rate of $7,529 and reassign 0671T to APC 5492. The HOP Panel supported these recommendations. Commenters also supported these recommendations but also suggested that CMS could consider assignment of these services to a New Technology APC.

CMS does not believe that the costs associated with these procedures are accurately reflected by APC 5493. CMS agrees with commenters that reassignment to a New Technology APC will maintain payment accuracy for these services and allow collection of cost data to support reassignment to the relevant clinical APC. CMS continues to believe that CPT code 0671T is similar to services in APC 5491.

CMS finalizes the assignment of CPT codes 66989 and 6691 to New Technology APC 1526 (New Technology-Level 26) with a payment rate of $4,250.50 and CPT code 0671T to APC 5491.

m. Scalp Cooling (APC 1520)

CPT code 0662T describes initial measurement and calibration of a scalp cooling device for use during chemotherapy; the code was effective July 1, 2021. CMS proposed assigning CPT code 0662T to APC 5732 (Level 2 Minor Procedures) with proposed payment rate of $34.72.

At the August 2021 HOP Panel Meeting a presenter requested reassignment of CPT code 0662T to one of four APCs and the HOP Panel recommended that CMS assign CPT code 0662T to a New Technology APC.

CMS notes that National Coverage Determination (NCD) 110.6 classifies the scalp cooling cap as an incident to supply to a physician service and would not be paid under the OPPS. Stakeholder have indicated that there are substantial resource costs associated with calibration and fitting of the cap. Based on the estimates of costs provided by the commenter, without taking into account the costs of the cap, the overall costs associated with CPT code 0662T is between $1,900 and $2,400.

CMS finalizes assignment of CPT code 0662T to APC New Technology 1520 (New Technology-Level 20) with a proposed payment rate of $1,850.50.

D. APC-Specific Policies

This section discusses comments and CMS' response for 36 APC-specific proposals (listed in table below). Highlights of CMS' discussions are summarized; the numbering is consistent with the preamble format. The reader is referred to the final rule for more specific details.

	TOPIC*	APC
1.	AccuCinch Ventricular Restoration Procedure	NA
2.	Administration of Lacrimal Ophthalmic Insert into Lacrimal Canaliculus	5694
3.	Allergy Testing	5724
4.	Blood Not Otherwise Classified	9537
5.	Bone Substitute Material Injection	5113
6.	Calculus Aspiration with Lithotripsy Procedure	5376
7.	Cardiac Computed Tomography (CT)	5571
8.	Cardiac Magnetic Resonance (CMR) Imaging	5523, 5524, 5572, & 5573
9.	Chimeric Antigen Receptor Therapy (CAR-T)*	5694, 9035, 9194,9391, 9413, & 9422)
10.	ClariFix Procedure	5164
11.	Dilapan-S Cervical Dilation Procedure	5412
12	Ellipsys System Hemodialysis Arteriovenous Fistula	5194
13.	Esophagogastroduodenoscopy	5331
14.	External Electrocardiogram (ECG)	5733 & 5734
15.	Eye-Movement Analysis Without Spatial Calibration	5734
16.	FemSelect Enplace Procedure	5415
17.	Hypoglossal Nerve Neurostimulator (HGNS) Procedure	5465
18.	IDx-DR: Artificial Intelligence System to Detect Diabetic Retinopathy	5733
19.	Intravascular Lithotripsy (IVL) Procedure	5193 & 5194
20.	Lixelle Apheresis	NA
21.	Low Dose Computed Tomography (LDCT)	5522
22.	Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)	5463
23.	Medical Physics Dose	5612
24.	MiMu Mucosal Integrity Testing System	5303
25.	Musculoskeletal Procedures	5111-5116
26.	Non-Highly Enriched Uranium (non-HEU) Sources	1442
27.	Single-Photon Emission Computed Tomography (SPECT) Studies	5593
28.	Pathogen Test(s) for Platelets	5733
29.	Pulmonary Rehabilitation	5733
30.	Sclerotherapy	5054
31.	Stromal Vascular Fraction (SCF) Therapy	NA
32.	Synthetic Resorbable Skin Substitute*	NA
33.	Therapeutic Ultrafiltration	5241
34.	Transcatheter Implantation of Coronary Sinus Reduction Device	NA
35.	Tympanostomy Using an Automated Tube Delivery System	5163

	TOPIC*	APC
36.	Urology and Related Services	5371-5378
37.	VisONE Synchronized Diaphragmatic Stimulation (SDS) System	NA
*Discussed in HPA Summary		

(9). Chimeric Antigen Receptor Therapy (CAR-T) (APCs 5694, 9035, 9194, 9391, 9413, and 9422)

Effective January 1, 2019, the AMA created four Category III CPT codes that are related to CAR T-cell therapy. As discussed in the 2019, 2020, and 2021 OPPS/ASC final rules, CMS assigns procedures described by CPT codes 0537T, 0538T, and 0539T to status indicator "B" to indicate that these services are not paid under the OPPS. These codes describe the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. CMS also finalized that the procedures described by CPT code 0540T would be assigned status indicator "S" (not discounted when multiple) and assigned to APC 5694 (Level 4 Drug Administration). The National Uniform Billing Committee (NUBC) established CAR T-cell related revenue codes and a value code to be reportable on HOPD claims effective for claims received on or after April 1, 2019. CMS did not propose any changes for 2022.

Two commenters opposed CMS' proposal to continue to assign status indicator "B" to CPT codes 0537T, 0538T, and 0539T and recommended status indicator "Q1". One commenter believed that these codes did not represent manufacturing steps but represented services provided by hospitals. CMS continues to believe that separate payment is not appropriate for these procedures. CMS notes that the current HCPCS coding for approved CAR T-cell therapies include leukapheresis and dose preparation procedures (Table 24). CMS notes the CPT codes can still be reported for tracking purposes. Table 25 in the final rule summarizes the status indicators and APC assignments for the CAR-T cell CPT codes.

(32). Synthetic Resorbable Skin Substitute

CMS discusses its policies related to skin substitute products. The 2014 OPPS/ASC final rule described skin substitutes as "…a class of products that we treat as biologicals…" but did not specifically mention whether synthetic skin products could be considered as biological products because there were no synthetic products at that time. In 2018, a manufacturer requested that an entirely synthetic product used as a biological skin substitute receive a HCPCS code that would allow the product to be billed with graft skin substitute procedure codes. CMS notes that initially the synthetic product was not described as a graft skin substitute product.

CMS now believes that both biological and synthetic products could be considered skin substitutes for Medicare payment purposes. For 2021, CMS established a policy to include synthetic products in addition to biological products in its description of skin substitutes. For 2022, CMS proposed to continue report synthetic graft skin substitute products using HCPCS code C1849 (skin substitute, synthetic, resorbable, cm^2) the same manner as in 2021.

As previously requested for 2021, several commenters requested that CMS establish product-specific HCPCS codes for synthetic graft skin substitute products and requested deletion of

HCPCS code C1849 because the code is not product-specific. Commenters believe that product-specific codes would allow assignment of synthetic products to either the high-cost or low-cost skin substitute group based on the cost of each individual product in a similar manner to biological skin substitute products.

In response, CMS discusses the reasons HCPCS code C1849 was created. CMS acknowledges that multiple synthetic graft skin substitute products are now identified by HCPCS code C1849 and it averages the pricing data from the various products to determine an amount for the products described by HCPCS code C1849 to compare against the MUC threshold. This comparison determines if HCPCS code C1849 should be assigned to the high cost or low-cost skin substitute category. CMS appreciates the commenters concerns that one service code for synthetic products could lead to low-cost synthetic graft products receiving excess payment if HCPCS code C1849 is assigned to the high-cost group or high-cost products being underpaid if C1849 is assigned to the low-cost group. CMS states it will consider these concerns in future rulemaking.

As an alternative to product specific HCPCS codes, a commenter suggested that CMS delete C1849 and establish two new HCPCS codes; one code for high-cost synthetic graft skin substitute products and another for low-cost synthetic graft skin substitute products. CMS will also consider this suggestion for future rulemaking.

CMS disagrees with a comment suggesting revising the definition of synthetic graft skin substitute products to reduce the possibility that synthetic dressings or non-resorbable polymeric sheets could be considered synthetic skin substitutes and be reported using HCPCS C1849. CMS notes that if it finds that synthetic graft products that do not function as skin substitutes are being reported using C1849 it will consider this suggestion.

IV. Payment for Devices

A. Pass-Through Payments for Devices.

1. Beginning Eligibility Date and Expiration of Transitional Pass-Through Payments

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. To allow a pass-through payment period that is as close to a full 3 years as possible, in the 2017 OPPS final rule (81 FR 79655), CMS finalized a policy change to allow for quarterly expiration of pass-through payments status for devices. Except for brachytherapy sources, for devices that are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates. Currently, there are 11 device categories eligible for pass-through payment. Table 31 (reproduced below) lists the devices and their pass-through expiration.

Table 31: 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
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

The pass-through payment status for HCPCS code C1823 was scheduled to expire on December 31, 2021. Typically, CMS proposes to package the cost of the device described by C1823 into the costs related to the procedure reporting the device in the hospital claims data for 2022, 2020 outpatient claims data processed through December 31, 2020. However, due to the PHE, CMS finalizes its proposal to use 2019 claims data instead of 2020 claims data for establishing 2022 payment rates. For 2022, CMS finalizes its proposal to use its equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for C1823 until December 31, 2022 (discussed in Section X.F.).

2. New Device Pass-Through Applications

a. *Background*

Criteria for New Device Pass-Through Applications

Existing regulations at §419.66(b)(1) through (b)(3) specify that, to be eligible for transitional pass-through payment under the OPPS a device must meet the following criteria:

1. If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has be classified as a Category B device by the FDA), or meets another appropriate FDA exemption from premarket approval or clearance; and the pass-through application must be submitted within 3 years form the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in the US market availability in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
2. The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury to improve the functioning of a malformed body part; and
3. The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to §419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following:

1. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or
2. A material or supply furnished incident to a service (e.g., a suture, customized surgical kit, or a clip, other than a radiological site marker).

Separately, CMS also uses the following criteria established at §419.66(c) to determine whether a new category of pass-through devices should be established:

- Not appropriately described by an existing category or any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Has an average cost that is not "insignificant" relative to the payment amount for the procedure or service with which the device is associated as determined under §419.66(d) by demonstrating:
    (1) The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices;
    (2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and
    (3) The difference between the estimated average reasonable cost of the device in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, exempted from the cost requirements at §419.66(c)(3) and §419.66(e)); and
- Demonstrates a substantial clinical improvement: substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part

compared to the benefits of a device or devices in a previously established category or other available treatment.

In 2020, CMS finalized an alternative pathway for devices that receive FDA marketing authorization and are granted a Breakthrough Device designation (84 FR 61295). Under this alternative pathway, devices granted an FDA Breakthrough Device designation are not evaluated in terms of the substantial clinical improvement criterion but need to meet the other requirements for pass-through payment status.

Annual Rulemaking Process in Conjunction with Quarterly Review Process for Device Pass-Through Payment Applications

In 2016, CMS changed the OPPS device pass-through payment evaluation and determination process. Device pass-through applications are still submitted through the quarterly sub-regulatory process, but the applications are subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. All applications that are preliminary approved during the quarterly review are automatically included in the next rulemaking cycle. Approved applications will continue to be granted access to pass-through payment at the beginning of the next quarter following approval. Submitters of applications that are not approved during the quarterly review have the option of being included in the next rulemaking cycle or withdrawing their application. Applicants may submit new evidence for consideration during the public comment period.

The current deadline for device pass-through payment applications continues to be the first business day in March, June, September, and December of a year for consideration for the next quarter (at the earliest) of the calendar year involved. More details on the requirements for device pass-through applications are included in the application form on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/HospitalOutpatientPPS/passthrough_payment.html. CMS is also available to meet with applicants or potential applicants to discuss research trial design in advance of submitting any application.

A commenter recommended that for devices designated by the FDA as Breakthrough Devices, CMS remove the requirement that the device prove it is not described by an existing transitional pass-through category. The commenter stated that Breakthrough Device designation implies that a device is first of its kind in addressing the indicated condition. In response, CMS notes that section 1833(t)(6)(B)(ii) requires the Secretary to establish categories of medical devices such that no medical device is described by more than one category and to establish a new category of medical devices for any new medical device without an appropriate category in effect or previously in effect. CMS also notes that it did not propose to eliminate this requirement in the CY 2022 OPPS/ASC proposed rule. Another commenter recommended CMS refrain from factoring a procedure off-set amount into the calculation of transitional pass-through payments. CMS continues to believe it is appropriate to apply the device offset amount.

b. *Applications Received for Device Pass-Through Payments for 2020*

CMS received eight applications by the March 1, 2021 quarterly deadline, the last quarterly deadline in time for this proposed rule; two of the applications were for devices eligible under the alternative pathway. One of the applications was approved under the alternative pathway: the Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) catheter, effective July 1, 2021. Applications received for the later deadlines for the remaining 2021 quarters (June 1, September 1, and December 1will be discussed the 2023 OPPS/ASC proposed rule.

The summary below provides a high-level discussion of each application; readers are advised to review the final rule for more detailed information.

- **Under the alternative pathway, CMS finalizes 2022 device pass-through payments for the RECELL System and the continuation of the device pass-through payment status for the Coronary IVL Catheter**.

- **Under the traditional pathway, CMS finalizes 2022 device pass-through payments for the Guardian System.**

i. Alternative Pathway Device Pass-Through Applications

(1) RECELL System[5]
Avita Medical submitted an application for RECELL, a standalone, single-use, battery-powered device used to process autologous donor tissue into a suspension that is immediately applied to a surgically prepared acute thermal burn. The applicant stated that a significantly smaller autograft harvest is needed for procedures involving RECELL as compared to procedures involving split-thickness skin graft without RECELL. According to the applicant there is one commercially available product (Epicel) that is also used to create an autograft form the patient's skin and is applied to treat acute thermal burns (Table 32 compares the two products).

Newness. RECELL was granted Expedited Access Pathway (EAP) by FDA (which is considered part of the Breakthrough Devices Program by FDA[6]) on December 10, 2015 for use at the patient's point-of-care for preparation of an autologous epithelial cell suspension to be applied to a prepared wound bed. RECELL received FDA PMA on September 20, 2018 for the treatment of acute thermal burn wounds; a narrower indication but within the scope of the EAP indication. CMS received the pass-through application for RECELL on August 7, 2020, which is within 3 years of the date of the initial FDA marketing authorization. CMS agrees that the RECELL meets the newness criterion.

Eligibility. According to the applicant, RECELL meets all the eligibility requirements. In the proposed rule, CMS was concerned that based on the applicant's description of RECELL as a

[5] The applicant also applied for a New Technology Add-on Payment (NTAP) under the Alternative Pathway for Breakthrough devices discussed in the FY 2022 IPPS proposed rule (86 FR 25385-25388). In the proposed rule, CMS was concerned that the device did not meet the eligibility for NTAP because the 3-year anniversary date of entry into the US market will be September 20, 2021.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

device that processes tissue into an autograft, the RECELL system may not be surgically implanted or inserted (either permanently or temporarily) because it is the suspension that is applied and that this suspension might not qualify as a device.

Many commenters stated that the purpose of harvesting, creating and applying the suspension as one continuous process would not be possible without the device components and that the device components and suspension are tightly integrated. In addition to reiterating these comments, the applicant provided additional information about the skin cell suspension. Specifically, the regenerative epidermal suspension contains autologous skin cells and buffer solution which is directly applied in or on a wound. The buffer solution is a pH neutral solution in liquid form that carries, expands and delivers the harvested skin cells in the suspension. According to the applicant, RECELL could not accomplish its intended use without the buffer which is a necessary component of the device. The applicant contented that the suspension qualifies as a device under FDA's definition.

Based on this information, CMS concludes that the buffer is a component of the device and it is part of the suspension that is applied to a wound. CMS agrees that the RECELL device meets the eligibility criterion.

Establishing a New Device Category
Existing payment category. CMS did not identify any existing pass-through payment category that may be applicable to the RECELL and that the RECELL meets this criterion

Substantial clinical improvement. Devices that apply under the alternative pathway for devices are not subject to evaluation for substantial clinical improvement.

Cost. CMS believes RECELL meets all the cost criteria.

CMS finalizes approval for device pass-through payment status for RECELL under the alternative pathway for devices, effective January 1,2022.

(2) Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) Catheter[7]

Shockwave Medical Inc. submitted an application for the Shockwave C^2 Coronary IVL catheter[8], a proprietary lithotripsy device delivered through the coronary artery system that generates intermittent sonic waves within the target treatment site and disrupts calcium. This allows subsequent placement of a coronary stent.

Newness. Shockwave IVL System with the Coronary IVL Catheter was designated as a Breakthrough Device in August 2019 for lithotripsy-enabled, low-pressure dilation of calcified,

[7] The applicant also applied for a New Technology Add-on Payment (NTAP) under the Alternative Pathway for Breakthrough devices discussed in the FY 2022 IPPS proposed rule (86 FR 25388-25389). In the FY 2022 IPS PPS final rule, CMS determined that the RECELL device did not meet the newness criterion and was not eligible for new technology add-on payments (86 FR 45151).
[8] The Shockwave C^2 Coronary IVL System is comprised of the IVL Generator, IVL connect cable, and a coronary IVL Catheter.

stenotic de novo coronary arteries prior to stenting. The Coronary IVL catheter received FDA approval as a PMA Class III device on February 12, 2021. CMS received the pass-through application for the Coronary IVL Catheter on February 26, 2021, which is within 3 years of the date of the initial FDA marketing authorization. CMS agrees that the Coronary IVL Catheter meets the newness criterion

Eligibility. According to the applicant, the Coronary IVL Catheter meets all the eligibility requirements. CMS concludes the Coronary IVL Catheter meets the device eligibility requirement.

CMS disagrees with a commenter's statement that CMS did not consider if the Generator, an excluded piece of capital equipment is the "key therapeutic component" of the Shockwave System and that the system as a whole should not be eligible for device pass-through status. CMS notes that the applicant submitted an application for transitional pass-through payments for the Coronary IVL Catheter, and not for the remainder of the Coronary IVL System which included the Generator. CMS states that it does not determine which portion of a combination product is the key therapeutic or diagnostic component but if it were to consider the Shockwave Coronary IVL System as a whole it would conclude that the Coronary IVL Catheter is the key therapeutic component because it is the component introduced into the lesion where the lithotripsy is delivered.

Establishing a New Device Category
Existing payment category. CMS did not identify any existing pass-through payment category that may be applicable to the Coronary IVL Catheter.

Substantial clinical improvement. Devices that apply under the alternative pathway for devices are not subject to evaluation for substantial clinical improvement.

Cost. CMS believes the Coronary IVL Catheter meets all the cost criteria.

CMS disagrees with the applicant's request to remove the device offset for four additional HCPCS codes (92933, 92943, C9602, and C9607) published in Transmittal 10998, dated September 16, 2021. CMS notes that in these additional procedures, the Coronary IVL Catheter is used in lieu of atherectomy to achieve a therapeutic process.

As discussed in the final rule, CMS disagrees with concerns raised by a commenter about the cost analysis. CMS also disagrees with the commenter's assertion that the quarterly determination process is invalid and the quarterly, sub-regulatory determination to grant pass-through status for the Coronary IVL Catheter is invalid following the Allina decision.[9] CMS notes that the quarterly approval process does not establish or change a substantive legal standard governing the scope of benefits or the payment for services, but only applies substantive legal standards adopted through notice and comment rulemaking to determine whether a particular device should qualify for pass-through status.

[9] Azar v. Allina Health Services, 139 S. Ct. 1894 (2019).

CMS preliminary approved the Coronary IVL Catheter for transitional pass-through payment under the alternative pathway effective July 1, 2021. **CMS finalizes approval** for continuing in 2022 device pass-through payment status for the Coronary IVL Catheter under the alternative pathway for devices.

ii. Traditional Device Pass-Through Applications

(1) AngelMed Guardian® System

Angel Medical Systems submitted an application for the Guardian® System, a proactive diagnostic technology that monitor's the electrical activity of a patient's heart for changes that may indicate an Acute Coronary Syndrome (ACS event) related to the blockage of a coronary artery. The Guardian® System consists of an implantable medical device (IMD) that is implanted in the upper left chest and connects to an intracardiac lead attached to the apex of the right ventricle, an external device that communications with the IMD and provides patient notification using auditory and visual alarms, and a physician programmer (a capital device) that can be used to program the IMD and download data captured by the IMD. According to the applicant, the Guardian® System detects a statistically abnormal acute change in heart activity and notifies the patient of a potential ACS event; patients are instructed to seek urgent medical assistance when the system activates, even in the absence of ASC symptoms.

Newness. The Guardian® System received FDA 510(k) clearance on April 9, 2018. The manufacturer received a Category B IDE on January 27, 2020 for the use of the device in their continued access study, AngelMed for Early Recognition and Treatment of STEMI (ALERTS). CMS received the application on February 28, 2021, which is within 3 years of the date of the initial marketing authorization and agrees the device meets the newness criterion.

Eligibility. According to the applicant, the Guardian® System meets all the eligibility requirements. CMS agrees that the device meets the eligibility criterion.

Establishing a New Device Category.
Existing payment category. CMS has not identified any existing pass-through payment category that may be applicable to the Guardian® System.

Substantial Clinical Improvement. The applicant stated the Guardian® System represents a substantial clinical improvement because it can diagnose a medical condition in a patient population where the medical condition is currently undetectable. The Guardian® System also offers the ability to diagnose a medical condition earlier in a patient population which results in better outcomes.

The applicant provided two published studies. Based on these studies, the applicant asserts that the Guardian® System provides the following: (1) allows patients with asymptomatic ACS events to respond to the ED faster with a median pre-hospital delay of 1.4 hours; (2) offers more rapid beneficial resolution of the disease process; and (3) decreases the number of future hospitalizations or physician visits.

In the proposed rule, CMS discussed specific concerns with the submitted information. CMS discussed how one study[10] did not demonstrate statistically significant superiority of the intervention. The second study[11] was based on a post hoc analysis of data from the first study; CMS sought comments on whether a post-hoc analysis provides sufficient evidence to support the claim of substantial clinical improvement. CMS also was concerned the primary efficacy endpoint was a composite of three outcomes related to rate for ED visits and CMS was concerned that this endpoint is not an appropriate measure to evaluate substantial clinical improvement in patients with ACS events.

Commenters offered support for the substantial clinical improvement criterion citing published studies and unpublished results from their clinical practices. The applicant provided additional information, including an expanded analysis with an increased number of endpoint events showing faster visits for real events while not increasing unnecessary emergency department visits. Based on this additional information, CMS determines that the Guardian® System meets the substantial clinical improvement criterion.

Cost. CMS believes the Guardian® System meets all the cost criteria.

CMS **finalizes** device pass-through payment status for the Guardian® System beginning January 1, 2022.

(2) BONEBRIDGE Bone Conduction Implant System

MED-EL Corporation submitted an application for the BONEBRIDGE Bone Conduction Implant System, a transcutaneous, active auditory osseointegrated device that replaces the function of a damaged outer or middle ear canal. The device consists of a bone conduction implant and an externally worn audio processor. The bone conduction implant is surgically attached to the skull and is connected to the external audio processor by transcutaneous magnetic attraction. The audio processor converts sounds to a radiofrequency signal that is transmitted to the implant and the implant converts the signal to controlled vibrations that are perceived as sound.

Newness. The FDA granted a *de novo* request classifying the BONEBRIDGE as a Class II device on July 20, 2018. The BONEBRIDGE is indicated for use in patients 12 years or older and patients who have a conductive or mixed hearing loss and can benefit from sound amplification. CMS received the application on December 10, 2020, which is within 3 years of the initial FDA approval.

Eligibility. According to the applicant, the BONEBRIDGE System meets all the eligibility requirements. CMS agrees with the applicant that BONEBRIDGE is not subject to the Medicare hearing aid exclusion at §411.15(d)(1). CMS believes the implant meets the criterion at

[10] Gibson, C.M., Holmes, D. et. al. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. JACC, 73(150, 1919-1927.
[11] Holmes, D.R., Krucoff, M.W. et.al. (2019). Implanted Monitoring Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. JACC, 74(160, 2047-2055.

§411.15(d)(2)(2)(i)[12]; the BONEBRIDGE device meets the criteria of a Medicare prosthetic device.

Establishing a New Device Category

Existing payment category. In the proposed rule, CMS discussed why it did not agree with the applicant's statement that a previous category, L8690 (Auditory osseointegrated devices, includes all internal and external components) which was effective from January 1, 2007-December 31,2008 did not include the BONEBRIDGE. According to the applicant, the devices described by this category do not include BONEBRIDGE because they are implant systems composed of an external sound processor connected via a percutaneous abutment to a titanium skull implant; the titanium abutment allows the sound processor to transmit sound and create vibrations within the skull. CMS believed that the BONEBRIDGE was described by L8960 because all the devices have a similar mechanism of action - vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear).

In a comment, the applicant asserted that even through the mechanism of action is the same between the BONEBRIDGE and previous device category L8690 (replace the function of the middle ear by transmitting mechanical energy from the external transduce/audio processor to the cochlea), there are significant differences between the devices related to technologic advances since 2007. The applicant noted that when L8690 was established in 2007, the technology to fully implant a transducer did not exist and the devices were percutaneous passive devices. The applicant stated that FDA created a new device classification for active implantable bone conduction hearing systems in 2018 specifically for active systems. The applicant also asserted that CMS has previously modified broadly worded device categories to recognize technological advances within a device class and grant transitional pass-through payment status to these technologies; the applicant discussed examples in the neurostimulator category. Several commenters agreed with the applicant.

After reviewing the comments, CMS agrees based on the technologic advances there is no existing pass-through payment category that appropriately describes the BONEBRIDGE. CMS concludes the BONEBRIDGE meets the eligibility criterion. As discussed below, CMS makes a similar determination for the Osia®2 system.

Substantial Clinical Improvement. The applicant stated that BONEBRIDGE represents a substantial clinical improvement, as compared to currently available treatments, because it reduces the rate of device-related complications and has a more rapid beneficial resolution of the disease process treated. The applicant submitted six studies to support these claims (including a study of 100 patients in Beijing China with congenital microtia-atresia (CMA)) and four retrospective case studies of complications with bone-anchored hearing aids.

In the proposed rule, CMS summarized this information and discussed specific concerns with the submitted information. CMS noted that because the studies did not involve a direct comparison

[12]Chapter 16, section 100 of the Medicare Benefit Policy Manual states that certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as a prosthetic device.

to other currently available treatments including percutaneous or passive, transcutaneous auditory osseointegrated devices, it was difficult to determine whether BONEBRIDGE provided a substantial clinical improvement over existing devices. CMS was also concerned about the studies comparing the complication rates, which included a white paper authored by the manufacturer.[13] CMS was concerned that the differences in complication rates reported in the white paper could be due to the differences in treatment or to the differences in the study characteristics, including patient population and follow-up time. CMS also notes that the study from China of young patients with congenital hearing loss may not be generalizable to the Medicare population.

The applicant submitted a comment in response to CMS' concerns. The applicant agreed with CMS that the occurrence of both overall and minor adverse events was lower for BONEBRIDGE than with other devices but disagreed with CMS' concerns about the major adverse event rate because they are not frequent events. The applicant believed that the study results were generalizable to the Medicare population. CMS reiterates it concerns and concludes it is not able to make a substantial clinical improvement determination.

Cost. CMS did not evaluate whether the BONEBRIDGE System met the cost criteria.

CMS **does not approve** device pass-through payment status for the BONEBRIDGE System.

(3) Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for the Eluvia™ Drug-Eluting Vascular Stent System which is comprised of an implantable endoprosthesis, a non-bonded freely dispersed drug layer (paclitaxel in a polymer matrix), and a stent delivery system (SDS).[14] The drug-eluting stent system is indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and or proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm. According to the applicant, paclitaxel, helps prevent the artery from restenosis, and the drug delivery system is designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA.

Newness. The Eluvia™ Drug-Eluting System received FDA approval (PMA) on September 18, 2018. CMS received the application on February 26, 2021, which is within 3 years of the initial FDA approval.

Eligibility. According to the applicant, the Eluvia™ System meets all the eligibility requirements. CMS notes it has previously determined that the Eluvia™ System meets the eligibility criteria.

[13] MED-EL Medical Electronics. (2019). Safety outcomes of bone conduction implants: A systemic review [White paper].
[14] The applicant previously submitted a pass-through application for 2020 (84 FR 61286-61292)

Establishing a New Device Category

Existing payment category. In the 2020 OPPS/ASC final rule (84 FR 61286 – 61287) CMS had not identified an existing pass-through payment category that described the Eluvia™ System. The applicant proposed a category descriptor of "Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system."

A commenter (a manufacturer of a competing product) stated that CMS had previously determined that drug-eluting stents fell into an existing pass-through payment category. Specifically in 2002, CMS concluded that coronary drug-eluting stents were described by existing pass-through device categories C1874 and C1875. In 2012, Zilver PTX DES was denied pass-through payment status because CMS concluded it was also previously described by device-pass-through category C1874 (Stent, coated/covered with delivery system). According to the commenter, FDA has grouped the Eluvia™ System and Zilver PTX DES into the same product code NIU. The commenter asserted that both devices are self-expanding nitinol stents coated with the drug paclitaxel.

After considering this comment, CMS is concerned that the applicant's proposed long descriptor may not differentiate the Eluvia™ System from Zilver PTX. Given CMS' previous determinations, including the denial of pass-through status to Zilver PTX, and that the FDA classifies the products into the same code, CMS believes the same pass-through category C1874 describes the Eluvia™ System. CMS concludes that the Eluvia™ System does not meet this eligibility criterion.

Substantial clinical improvement. The applicant asserted that the Eluvia™ stent is a substantial clinical improvement over existing technologies because it achieves superior primary patency; reduces the rate of subsequent therapeutic interventions; decreases the number of future hospitalizations or physician visits; reduces hospital readmissions; reduces the rate of device-related complications; and achieves similar functional outcomes and EQ-5D index values with only half the rate of target lesion revascularization (TLRs).

The applicant submitted the results of the MAJESTIC study, a prospective, multi-center, single-arm, open-label study (57 patients) and the results of the IMPERIAL study which compared the Eluvia™ stent to the Zilver® Drug-Eluting Peripheral Stent in a global, multi-center randomized control study (465 subjects). In the proposed rule, CMS summarized this information and referred the reader to the 2020 OPPS/ASC final rule for a complete discussion of the applicant's previous submission regarding substantial clinical improvement (84 FR 61287-61292). CMS noted it did not approve the Eluvia™ System for transitional payment due to the potential increased long-term mortality signal the FDA was evaluating. As discussed in the FY 2021 IPPS final rule (85 FR 58657), the FDA concluded that the benefits of paclitaxel-coated devices should be considered in individual patients along with the potential risks, and clinicians should determine the benefit vs. the risk for individual patients.[15]

[15] In the 2020 IPPS final rule, after consideration of public comments and the latest information from the FDA advisory panel, CMS does not approve the Eluvia stent for a new technology add-on payment.

As previously discussed in the 2020 OPPS/ASC final rule, CMS remained concerned the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for non-inferiority and not superiority. In response to this concern, the applicant stated that a non-inferiority study is consistent with accepted research methodology and is a typical trial design for medical devices.

A commenter, a manufacturer of a competitor device, asserted that the Eluvia™ System does not meet the substantial clinical improvement criterion for a variety of reasons, including lack of long-term safety results. The applicant noted that in the FYT 2021 IPPS final rule, CMS determined that the Eluvia™ System represented a substantial clinical improvement over existing technologies and that the regulations governing the substantial clinical improvement criterion for NTAP and for transitional device pass-through status are similar. The applicant believes there is no evidence-based rational that would lead CMS to reach a different conclusion regarding substantial clinical improvement in the two payment systems. CMS reiterates its conclusions from the FY 2021 IPPS final rule and concludes that the Eluvia™ System meets the substantial clinical improvement criterion.

Cost. Section 419.66(d) establishes three cost significance criteria that must be met (discussed above). The applicant stated that the Eluvia™ System would be reported with CPT code 37266 (APC 5193) and CPT code 37227 (APC 5194) (Table 36). For its calculations, CMS used APC 5193 (Level 3 Endovascular Procedures) which had a 2021 payment rate of $10,042.94. In the proposed rule, CMS discussed its concerns that the Eluvia™ System met the first cost significance requirement but did not meet the second and third cost significance requirements.

The applicant stated that CMS overestimated the device-related portion (DRP) used in the second and third cost significant tests. According to the applicant, CMS has an established policy of only subtracting as the DRP cost of those devices that are replaced by the transitional pass-through device and this policy should be applied to calculating cost significance for the cost criterion. The applicant stated that the intent of the DRP in the cost significance test is to compare the cost of the pass-through device to the costs of the device(s) the pass-through would replace and not to compare the costs of the device to the total costs of all devices used in a procedure including those that are unrelated and not replaced by the candidate device. The applicant provided examples of previous decisions not to apply a device offset when calculating payment for pass-through devices and concluded that based on these decisions, CMS has the authority to define the DRP calculation methodology, and also has established a precedent for defining the DRP as only those devices that are replaced by the pass-through device. For the Eluvia™ System, the applicant contends that the non-stent devices should not be considered in the DRP because the system is not replacing the costs associated with the non-stent devices. The applicant concludes that if $3,406.93 (the average stent device cost) is used as the DRP, the Eluvia™ System passes the second and third cost significance tests.

In response, CMS reiterates that for a device to be eligible for pass-through payments the device must have an average cost that is not “insignificant” relative to the payment amount for the procedure or service with which the device is associated. CMS notes that except in rare circumstances, CMS has consistently applied the full device offset amount associated with the applicable APC used to evaluate the cost significance tests at §419.66(d). CMS disagrees that the

prior precedents identified by the applicant apply to the Eluvia™ System and the applicant's request for a partial device offset. CMS states that to its knowledge, it has never utilized a partial device offset in the manner requested by the applicant. In addition, if CMS wanted to change the cost criterion evaluation it would need to go through notice and comment rulemaking. CMS concludes that because the applicant did not meet the second and third cost significance tests, the Eluvia™ System does not meet the cost significance criterion.

CMS **does not approve** device pass-through payment status for the Eluvia™ System.

(4) Cochlear™ Osia® 2 System (Osia® 2 System)

Cochlear American submitted a pass-through application for the Osia® 2 System, a transcutaneous, active auditory osseointegrated device that replaces the function of the middle ear by providing mechanical energy to the cochlea. The device consists of an external sound process, an implanted transducer, an osseointegrated implant for anchoring and single point transmission, and a fixation screw for attaching the transducer to the osseointegrated implant which is implanted in the skull. The external sound processor captures environmental sounds and converts the sound signal into a digital signal transmitted as a radiofrequency. The transducer detects the radiofrequency signals and transforms the signal to vibrations, which are transmitted to the bone-implanted fixation screw. The screw vibrates the skull bone which stimulates the cochlea (inner ear) to transmit the information to the brain which perceives the vibrations as sound. The applicant stated the Osia® 2 System can improve hearing clarity and improve hearing at higher frequencies.

Newness. The Osia® 2 System received FDA 510(k) clearance on November 15, 2019. The Osia® 2 System is indicated for use in patients 12 years or older and patients who have a conductive or mixed hearing loss and can benefit from sound amplification. CMS received the application on December 1, 2020, which is within 3 years of the initial FDA approval.

Eligibility. According to the applicant, the Osia® 2 System meets all the eligibility requirements. CMS agrees with the applicant that Osia® 2 System is not subject to the Medicare hearing aid exclusion at §411.15(d)(1). CMS reiterates its prior discussion about BONEBRIDGE. CMS believes the Osia® 2 System device meets the criteria of a Medicare prosthetic device.

Establishing a New Device Category.

Existing payment category. As discussed above, CMS agrees based on the technologic advances there is no existing pass-through payment category that appropriately describes the Osia®2 system.

Substantial Clinical Improvement. The applicant stated the Osia® 2 System represents a substantial clinical improvement, as compared to currently available treatments, because it reduces the rate of device-related complications as compared to available treatments. The applicant submitted five retrospective case studies that examined the long-term complications associated with percutaneous osseointegrated bone conduction hearing devices. The applicant also submitted five clinical studies and case series involving the use of osseointegrated bone

conduction hearing devices. CMS noted three of these five references involved the BONEBRIDGE device (see the BONEBRIDGE discussion in the rule), one involved the BAHA Attract device, and one involved an earlier version of the Osia® 2 System.

As discussed in the proposed rule, CMS was concerned that the applicant did not submit studies demonstrating substantial clinical improvement of the current Osia® 2 System. In addition, the evidence submitted did not directly compare the Osia® 2 System to other currently available systems. CMS was concerned it is unable to make a substantial clinical improvement determination.

The applicant provided additional information to address substantial clinical improvement for the Osia® 2 System. After reviewing this information, CMS concludes it is unable to make a substantial clinical improvement determination.

Cost. CMS did not evaluate whether the Osia® 2 System met the cost criteria.

CMS **does not approve** device pass-through payment status for the Osia® 2 System.

(5) Pure-Vu® System

Motus GI holdings, submitted an application for the Pure-Vu® System, an FDA cleared system designed to connect to currently marketed colonoscopes to avoid aborted and delayed colonoscopies due to poor visualization of the colon mucosa by providing high intensity intra-procedural cleansing of the colon during a colonoscopy.[16] The Pure-Vu System is comprised of a Workstation (WS) that controls the function of the system and a disposable Oversleeve that is mounted on a colonoscope and inserted into the patient. The applicant stated that the Pure-Vu® System is indicated in patients requiring therapeutic or diagnostic colonoscopies where the bowel has not been adequately prepared and would be used in situations that do not allow adequate bowel preparations, such as lower gastrointestinal bleed.

Newness. The Pure-Vu® System first received FDA 510(k) clearance on September 22, 2016 and was not sold until January 27, 2017. The applicant stated the device was initially allocated for clinical evaluations, but 10 institutions purchased the device outside of a clinical study. Additional minor modifications were made and the system received additional 510(k) clearances on December 12, 2017 and June 21, 2018. The current marketed Pure-Vu® System was granted 510(k) clearance on June 6, 2019 and was commercially available as of September 19, 2019.

Eligibility According to the applicant, the Pure-Vu® System meets all the eligibility requirements; CMS agrees.

Establishing a New Device Category

Existing payment category. CMS has not identified any existing pass-through payment category that may be applicable to the Pure-Vu® System.

[16] The applicant applied for a NTAP in the FY 2023 IPPS proposed rule (86 FR 25299-25304).

Substantial clinical improvement. The applicant asserted that the Pure-Vu® System allows rapid and full visualization of the colon, which will improve diagnosis and the effectiveness of treatment. The applicant submitted three outpatient clinical studies to demonstrate the Pure-Vu® System's ability to convert patients to adequate preparation when the previous preparation was inadequate, and visualization was poor based on the Boston Bowel Preparation Scale (BBPS).

In the proposed rule, CMS noted that although the applicant provided studies in support of the Pure-Vu® System improvement of bowel preparation, it did not provide data indicating that the improved BBPS directly leads to improved clinical outcomes based on the use of the Pure-Vu® System. In addition, no studies compared the efficacy of the Pure-Vu® System to other existing methods or products for bowel irrigation.

The applicant provided additional information responding to CMS' concerns. Based on this additional information, CMS concludes that the BBPS is a well validated scoring tool, but it is still concerned that the studies do not direct indicate that the improved BBPS directly leads to improved clinical outcomes. CMS reiterates its concerns about the lack of studies comparing the efficacy of the Pure-Vu® System to other existing methods or products for bowel irrigation. CMS concludes that the evidence does not support a substantial clinical improvement over existing technologies.

Cost. CMS did not evaluate whether the Pure-Vu® System met the cost criteria.

CMS **does not approve** device pass-through payment status for the Pure-Vu® System.

(6) Articulating Xenoscope Laparoscope (Xenoscope™)

Xencor Inc., submitted an application for the Xenoscope™, a disposable laparoscope used for diagnostic and therapeutic laparoscopic procures. The device is paired with an image processing unit, the Xenobox.

Newness. The Xenoscope™ received FDA 510(k) clearance on January 27, 2020. CMS received the application on August 6, 2020. which is within 3 years of the initial FDA approval.

Eligibility According to the applicant, the Xenoscope™ meets all the eligibility requirements; CMS agrees.

Establishing a New Device Category

Existing payment category. CMS has not identified any existing pass-through payment category that may be applicable to the Xenoscope™.

Substantial clinical improvement. The applicant asserted that the Xenoscope™ provides a substantial clinical improvement over reusable laparoscopes because as a disposable, single-use device it provides less risk of scope-related contamination and infection from improperly handled or reprocessed scopes. The applicant also asserted the Xenoscope™ eliminated risk and patient burns and drape fires associated with hot Xenon bulbs used in available laparoscopes.

The applicant submitted four articles and a draft manuscript, "Novel Laparoscopic System for Quality Improvement and Increased Efficiency".

As discussed in the proposed rule, CMS was concerned that the articles submitted as evidence of substantial clinical improvement discuss potential adverse effects from laparoscopic procedures without any evidence that shows clinical improvement from using the Xenoscope™. The articles did not involve the clinical use of the Xenoscope™ and did not compare the device to a reusable laparoscope. CMS concluded there is insufficient evidence to determine whether the Xenoscope™ offers a substantial clinical improvement over a reusable laparoscope.

A commenter representing Xencor provided information about the safety profile for the Xenoscope™. CMS agrees that improved patient safety and a reduction in complications are clinical outcomes that may represent a substantial clinical improvement, but the applicant did not provide any data demonstrating improved outcomes using the Xenoscope™. CMS concludes that the Xenoscope™ does not meet the substantial clinical improvement criterion.

Cost. CMS did not evaluate whether the Xenoscope™ met the cost criteria.

CMS **does not approve** device pass-through payment status for the Xenoscope™.

B. Device-Intensive Procedures

1. Device-Intensive Procedure Policy for 2019 and Subsequent Years

For 2019 and subsequent years, in the 2019 OPPS final rule (83 FR 58944 through 58948, CMS finalizes that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device-offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost.

To align the device-intensive policy with the criteria used for device pass-through status, CMS also finalized its proposal for 2019 and subsequent years, for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 – 405.207 and 405.211 – 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

1. Equipment, an instrument, Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or
2. A material or supply furnished incident to a service (e.g., a suture, customized surgical kit, or a clip, other than a radiological site marker).

CMS also finalized lowering the default device offset from 41 to 31 percent until claims data are available to establish the HCPCS code-level device offset. CMS will continue its current policy of temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.[17] Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent.

CMS also reiterates that the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. In addition, when a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, CMS uses the clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code. Additional information about new HCPCS codes, such as pricing data or invoices from a manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, CMS, 7500 Security Blvd, Baltimore, Md 21244-1850 or electronically at outpatientpps@cms.hhs.gov.

CMS finalizes its proposal to use 2019 claims data to establish 2022 OPPS rates (discussed in section X.E). If 2020 claims information is available, CMS finalizes its proposal to assign a device offset percentage based on 2020 data, for procedures that were assigned device intensive status with a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically similar code.

Many commenters supported the proposal to establish the 2022 device offset percentage using 2020 claims data for device-intensive procedures with no claims in the 2019 claims data. Commenters suggested other options including using 2020 claims when the 2020 claims volume is greater than the 2019 claims data. CMS continues to believe 2019 represents the best full year of claims data for ratesetting and any alternative for determining device offset percentage should be limited to procedures without claims data in 2019.

Many commenters requested device offset percentage for several new procedures using the predecessor's code device offset percentage based on 2019 claims data. CMS received several recommendations for assigning existing codes as device-intensive. CMS corrects the device

[17] Additional information for consideration of an offset percentage higher than the default can be submitted to outpatientpps@cms.hhs.gov. Additional information can be submitted prior to the issuance of an OPPS proposed rule or as a public comment to a proposed rule.

offset percentages for several new device-intensive procedures to reflect available claims data from predecessor codes. CMS agrees with two recommendations and assigns HCPCS code C9778 and CPT code 66179 to device-intensive status. The full listing of proposed 2020 device-intensive procedures provided in Addendum P.[18]

Some commenters submitted invoices and requested a greater device offset amount and greater device offset percentage to reflect the invoice price of a particular device. Other commenters recommended utilizing invoice prices for procedures with low or no claims volume. One commenter recommended using invoice prices to correct hospital confusion for reporting HCPCS code C1889 (Implantable/insertable device, NOC). CMS does not believe that any of the submitted invoice prices support application of its policy of temporarily applying a higher device offset percentage if warranted by additional information. In addition, CMS states it would be inappropriate to apply a higher device offset percentage or increase the payment rate in the ASC because a device's invoice price is greater than the amount of the procedure's device offset. CMS reiterates that it expects hospitals to follow correct coding guidelines and append the correct device code to the claim when applicable.

For 2022, CMS finalizes its proposal to assign device offset percentages using 2020 claims data to the 14 procedures listed in the table below, 11 procedures were previously proposed and three additional procedures were added based on the review of updated 2020 claims data.

Final List of 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

[18] Addendum P is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

Final List of 2022 Device Offset Percentages Using 2020 Claims Data	
HCPCS Code	**Code Descriptor**
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
0519T*	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)
0618T*	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens replacement or intraocular lens exchange
C9761*	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy and vacuum aspiration of the kidney, collecting system and urethra if applicable
*Procedures added based on updated claims data for the final rule.	

2. Device Edit Policy

In the 2017 OPPS final rule, CMS finalized it would apply the device claims editing policy on a procedure level rather than APC level, consistent with its finalized policy to make device-intensive determinations at the HCPCS code level. For 2017 and subsequent years, CMS applies the device coding requirements to the newly defined device-intensive procedures. In addition, CMS created HCPCS code C1889 to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. Any device code, including C1889, when reported on a claim with a device-intensive procedure, will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. For 2019 and subsequent years, the description of HCPCS code C1889 is: "Implantable/insertable device, not otherwise classified. For 2022, CMS did not propose any changes to the device edit policy.

In response to commenters recommending that CMS reinstate specific device-to-procedure edits, CMS continues to believe that the elimination of these edits is appropriate because hospitals have experience in coding and reporting these claims. CMS notes it has not observed any increase in frequency of procedures with device offset percentages that are nearly 100 percent and it does not believe that the absence of these edits has resulted in inaccurate device cost statistics.

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

CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit in the amount portion for value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or

greater than the cost of the device. For 2019 and subsequent years, CMS finalized its proposal to apply the no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under the proposed modified criteria discussed above.

In the 2014 OPPS final rule (78 FR 75005 through 75007), CMS adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. CMS made conforming changes to the regulation text at §419.45(b)(1) and (2). For 2022, CMS did not propose any changes to this policy.

4. Payment Policy for Low Volume Device-Intensive Procedures

In the 2017 OPPS final rule, CMS finalized that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost. For 2020 and 2021, CMS finalized continuation of this policy for establishing the payment rate for any device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. In 2020 and 2021, this policy only applied CPT code 0308T (Insertion of ocular telescopic prosthesis).

For 2022, CMS finalizes its proposal to establish a universal low volume APC policy for clinical APCs, brachytherapy APCs and New Technology APCs with fewer than 100 single claims in the claims data used for rate setting (discussed in section X.C.). Under the universal low volume APC policy, CMS will establish a payment rate using the highest of the median cost, arithmetic mean coast, or the geometric mean cost. In conjunction with this policy, CMS finalizes its proposal to eliminate the payment policy for low-volume device-intensive procedures for 2022 and subsequent years. CMS notes that CPT code 0308T is the only code subject to the low-volume device-intensive policy.

V. Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

CMS currently pays for drugs, biologicals, and radiopharmaceuticals in one of three ways: packaged (either policy packaged or threshold packaged); separately paid above a cost threshold; or on pass-through. When a drug, biological or radiopharmaceutical is packaged into the payment for the associated service or separate payment (individual APCs), hospitals do not receive a separate payment for the packaged items. Hospitals may not bill beneficiaries separately for any packaged items; these costs are recognized and paid within the OPPS payment rate for the associated procedure or service.

Some drugs are policy packaged meaning they are always packaged into payment for the APC except when paid on pass-through. Policy packaged drugs and biologicals include:

- Anesthesia;
- Medical and surgical supplies and equipment;
- Surgical dressings; devices used for external reduction of fractures and dislocations;

- Drugs, biologicals, radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and
- Drugs and biologicals that function as supplies when used in a surgical procedure.

Other drugs are threshold packaged meaning that their per day costs must exceed a fixed threshold ($130 for 2022) to be paid separately. For a separately payable drug that exceeds the packaging threshold, CMS will make payment at average sales price (ASP)+6 percent (unless the drug or biological is acquired under the 340B drug discount program).

Other drugs and biologicals may be paid transitional pass-through payments.

A. Transitional Pass-Through Payment

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. For pass-through payment purposes, radiopharmaceuticals are "drugs." As required by statute, transitional pass-through payments for a drug or biological can be made for at least 2 years, but not more than 3 years, after the payment was first made under the OPPS. Pass-through drugs and biologicals for 2022 and their designated APCs are assigned status indicator "G" in Addenda A and B of the final rule. For 2022, CMS will continue to use ASP+6 percent as payment for pass-through drugs and biologicals. CMS will also pay for diagnostic and therapeutic radiopharmaceuticals receiving pass-through payment at ASP+6 percent.

CMS approves pass-through payments quarterly and expires pass-through payments in the calendar quarter that is not more than 3 years after payment was first made for the hospital outpatient service under Medicare. Table 37 of the final rule lists 25 drugs and biologicals where pass-through payment will expire during 2021. Each of the products will have received at least the full 3 years of pass-through payments once the additional payments expire. Table 38 of the final rule lists 26 drugs and biologicals for which CMS will end pass-through payment in 2022. Each of the products will have received at least the full 3 years of pass-through payments once the additional payments expire. Table 39 of the final rule lists 46 drugs and biologicals where CMS will be continuing pass-through payment in 2022.

When policy packaged or threshold drugs and biologicals are paid on pass-through, CMS makes an offset to the APC payment for the cost of the predecessor drug products. As diagnostic radiopharmaceuticals are also policy packaged, CMS will apply a payment offset to the associated APC. No offset is required for a separately payable drug paid on pass-through as either way it is paid ASP+6 percent. There is no payment included in the APC for the drug.

Table 40 of the final rule lists the APCs where CMS will apply an offset for policy packaged drugs paid on pass-through. CMS directs readers to the following link for a file of APC offset amounts used to evaluate cost significance for candidate pass-through device categories and drugs and biologicals and for establishing any appropriate APC offset amounts: 2022 | CMS

B. Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

Cost Threshold for Packaging of "Threshold-Packaged Drugs"

For 2022, CMS is establishing a packaging threshold of $130 for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status. The packaging threshold was initially set at $50 in 2005. To calculate the 2022 threshold, CMS used the most recently available four quarter moving average Producer Price Index forecast levels for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) to trend the $50 threshold forward from the third quarter of 2005 to the third quarter of 2022. CMS rounds the resulting dollar amount ($132.44) to the nearest $5 increment ($130).

CMS will use the following process to determine the 2022 packaging status for all non-pass-through drugs and biologicals that are not policy packaged (with the exception of those drugs and biologicals with multiple HCPCS codes that include different dosages as described below). Using 2019 claims data processed through June 30, 2020,[19] CMS calculates, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in 2019 and were paid (either as packaged or separate payment) under the OPPS.

To calculate the per day cost for the final rule, CMS uses ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 2nd quarter of 2021 (data that will be used to pay for drugs and biologicals in physicians' offices effective October 1, 2021). For products that do not have an ASP, such as some therapeutic radiopharmaceuticals, CMS will use their mean unit cost derived from 2019 hospital claims data. CMS will package products with a per day cost of $130 or less and pay separately for items with a per day cost greater than $130 in 2022. CMS uses quarterly ASP updates as follows:

- 4th quarter of 2020: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2022 OPPS proposed rule;
- 2nd quarter of 2021: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2022 OPPS final rule; and
- 3rd quarter of 2021: Payment rates effective January 1, 2022 for separately payable drugs and non-implantable biologicals; these are the same ASP data used to calculate payment rates effective January 1, 2022 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS is continuing its policy of making an annual packaging determination for a

[19] CMS would normally use 2020 claims processed through December 31, 2020 for determining the average daily cost of drugs and biologicals. However, consistent with other policies announced throughout the rule, CMS is not using 2020 claims data that is affected by the COVID-19 PHE.

HCPCS code in the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes which are identified as separately payable in the 2022 final rule are subject to quarterly updates.

As in past years, CMS is applying the following policies to determine the 2022 packaging status of a threshold-packaged drug when the drug's packaging status, as calculated for the final rule using more current data, differs from its status in the proposed rule.

- HCPCS codes that are separately payable in 2021 and were proposed for separate payment in 2022 are separately payable in 2022 even if the updated data used for the 2022 final rule indicate per day costs equal to or less than the $130 threshold.
- HCPCS codes that are packaged in 2021, proposed for separate payment in 2022, and have per day costs equal to or less than $130 based on the updated data used for the 2022 final rule are packaged in 2022.
- HCPCS codes for which CMS proposed packaged payment in 2022 and have per day costs greater than $130 based on the updated data used for the 2022 final rule are separately payable in 2022.

CMS received a number of public comments that were the same as those received in prior years. These comments asked CMS to pay always separately for diagnostic radiopharmaceuticals or reinstate edits that ensured a hospital could only bill for a nuclear medicine procedure that also included the diagnostic radiopharmaceutical. CMS did not make a proposal like those suggested in these comments and is not making any policy changes in 2022 in response to these comments.

Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages

For 2022, CMS is continuing its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 41 of the final rule.

2. Payment for Drugs and Biologicals without Pass-Through Status that Are Not Packaged

As indicated above, CMS will pay for separately payable drugs and biologicals at ASP+6 percent in 2022 except when the drugs or biologicals are acquired under the 340B drug discount program. For drugs acquired under the 340B drug discount program, CMS will continue paying ASP-22.5 percent. Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Consistent with policy in the PFS, CMS will pay for drugs under the OPPS during an initial sales period (2 quarters) for which ASP pricing data are not yet available from the manufacturer at wholesale acquisition cost (WAC)+3 percent. The WAC+3 percent payment under the OPPS will only apply to new drugs in an initial sales period. Other drugs and biologicals where ASP data are not available will continue to be paid at WAC+6 percent. Drugs that are paid using WAC and acquired under the 340B program will be paid at WAC-22.5 percent. If ASP and

WAC are unavailable, Medicare will pay 95 percent of AWP or 69.46 percent of AWP if the drug is acquired under the 340B program.

CMS will continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler). However, the weight scaler is not applied to separately payable drugs due to the statutory requirement that drug and biological payments be based on acquisition costs or the amount required by statute in physician's offices when hospital acquisition costs are unavailable.

The payment rates shown for drugs and biologicals in Addenda A and B of the final rule are not the payment rates that Medicare will pay on January 1, 2022. Payment rates effective January 2022 will be released near the end of December 2021 and will be based on ASP data submitted by manufacturers for the third quarter of 2021 (July 1, 2021 through September 30, 2021). Payment rates for drugs and biologicals in Addenda A and B of the final rule for which there was no ASP information available for the 2nd quarter of 2021 are based on mean unit cost in the available 2019 claims data (CMS is using 2019 utilization data rather than 2020 utilization data that spans the PHE for this purpose). If ASP information becomes available for the quarter beginning in January 2022, CMS will pay for these drugs and biologicals based on the newly available ASP information.

There were public commenters asking for greater than a 6 percent add-on to ASP and a higher add-on than 3 percent to WAC specifically for radiopharmaceuticals during their initial sales period for the higher costs of handling these products. CMS rejected these comments noting that the 6 percent add-on to ASP is generally accepted as the additional costs associated with overhead and handling of for separately payable drugs. As WAC is higher than ASP, CMS believes the 3 percent add-on to WAC during the initial sales period is a sufficient add-on for overhead and handling costs of radiopharmaceuticals.

Biosimilar Biological Products

CMS pays for biosimilar biological products using policies that parallel those used for other drugs and biologicals with one important distinction. The 6 percent add-on to ASP is based on the ASP of the reference product, not the ASP of the biosimilar. The 6 percent add-on is consistent with the statutory requirement in section 1847A of the Act that applies to drugs and biologicals furnished in physicians' offices.

If a biosimilar is acquired under the 340B program, CMS pays the biosimilar at ASP-22.5 percent of its own ASP rather than doing the subtraction from the reference product ASP. If WAC is used for pricing, the add-on will be +3 or +6 percent of the reference product WAC depending on whether the biosimilar is in an initial sales period or -22.5 percent of its own WAC if acquired under the 340B drug discount program. CMS is continuing all of these policies in 2022.

Biosimilars are eligible for pass-through payment like any other drug or biological. Pass-through would apply to each new biosimilar irrespective of whether a second product is biosimilar to the same reference product as another biosimilar that already received pass-through payment. Under

pass-through, a biosimilar would be paid ASP+6 percent of the reference product's ASP even when acquired under the 340B drug discount program.

Most commenters supported CMS continuing all of the above policies. One commenter opposed pass-through payment for biosimilars acquired under the 340B drug discount program being made at ASP+6 percent instead of ASP-22.5 percent. This commenter said that this payment provides an unfair advantage to the biosimilar relative to the reference product that will be paid at ASP-22.5 percent when acquired under the 340B program. CMS disagrees and stated pass-through payment status reflects the unique, complex nature of biosimilars and is important as biosimilars become established in the market, just as it is for all other new drugs and biologicals.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2022, CMS will continue to pay for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS will determine 2022 payment rates based on 2019 geometric mean unit cost.

4. Payment for Blood Clotting Factors

For 2022, CMS will continue to pay for blood clotting factors at ASP+6 percent and is updating the $0.238 per unit furnishing fee from 2021 by the Consumer Price Index (CPI) for medical care. The CPI won't be available until after publication of the 2022 OPPS final rule, so CMS will announce the updated fee through program instructions and will post the updated rate on the CMS website at: Blood Clotting Factor Furnishing Fee | CMS

5. Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but without OPPS Hospital Claims Data

CMS is continuing the same payment policy in 2022 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data as in earlier years. In priority order, CMS' policy is to pay for these products using ASP+6 percent if ASP is reported, WAC+6 percent if WAC is available and at 95 percent of AWP if ASP and WAC are unavailable. The 2022 payment status of each of the non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B of the final rule.

6. OPPS Payment Methodology for 340B Purchased Drugs

CMS provides the regulatory and litigation history regarding its policy to pay for drugs acquired under the 340B program at ASP-22.5 percent. In summary:

- Beginning in 2018, CMS adopted a policy to pay for drugs acquired under the 340B program at ASP-22.5 percent to approximate a minimum average discount for 340B drugs based on findings of the General Accountability Office and MedPAC that hospitals acquire drugs at a significant discount under the 340B program.

    - For policy reasons explained in prior rulemaking, CMS exempts CAHs, rural SCHs and cancer hospitals from the 340B payment adjustment.
    - Pass-through drugs and vaccines acquired under the 340B program are also exempted from the adjustment.
- In 2019, CMS applied the policy to off-campus provider-based departments that are subject to section 603 of the Bipartisan Budget Act (BBA) of 2015 and not paid under the OPPS.
- On December 27, 2018, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacked authority to bring the default rate in line with average acquisition cost. While the initial decision applied only to CMS' 2018 policy, the district court later made the same finding for CMS' 2019 policy.
- On July 31, 2020, the United States Circuit Court for the District of Columbia entered an opinion reversing the district court's judgment.
- On July 2, 2021, the Supreme Court granted a petition for a writ of certiorari, and directed the parties to argue whether the petitioners' suit challenging the 340B drug payment adjustment is precluded by section 1833(t)(12) of the Act.

In 2019 and 2020, CMS undertook a survey to collect drug acquisition cost data for the 4th quarter of 2018 and the 1st quarter of 2019. CMS stated that the survey would confirm what no 340B hospital has disputed—that ASP-22.5 percent is a conservative adjustment representing the minimum discount that hospitals receive for drugs acquired through the 340B program.

Based on the survey results, CMS proposed, but did not finalize, a payment rate for 340B drugs of ASP-28.7 percent for 2021. CMS stated that maintaining the policy of paying ASP-22.5 percent for 340B drugs was appropriate in order to maintain consistent and reliable payment for the remainder of the PHE and after its conclusion. CMS further stated that continuing the existing policy will provide the agency more time to conduct further analysis of hospital survey data for potential future 340B drug payment use.

For 2022, CMS is continuing its current 340B policies without modification. CMS may revisit its policy to exempt rural SCHs, as well as other hospital types, from the 340B drug payment reduction in future rulemaking.

Several commenters stated that CMS has not considered changes in utilization or volume since 2018 when it adopted the 340B budget neutrality adjustment. These commenters contend that CMS has not provided evidence that the payment policy remains budget neutral by recalculating the policy's impact to make sure the conversion factor is properly adjusted over time to reflect changes in inflation or 340B drug utilization.

CMS responded that OPPS budget neutrality is generally developed by isolating the effect of any changes in payment policy or data under the OPPS with all other factors held constant. Since the 2018 implementation of the 340B drug payment policy, the adjusted percentage payment has remained at ASP-22.5 percent. As a result, while some of the claims may change based on drug payment and billing, as indicated by the "JG" modifier, these drugs, including their utilization and expected payments, would be included as part of the broader budget neutrality adjustments. There would not be a separate budget neutrality adjustment specifically for the 340B drug payment policy.

7. High/Low-Cost Threshold for Packaged Skin Substitutes

CMS has been packaging skin substitutes as drugs and biologicals that function as supplies when used in a surgical procedure since 2014. The packaging methodology also divides skin substitutes into high and low-cost groups in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures. Skin substitutes assigned to the high-cost group are billed with HCPCS codes 15271, 15273, 15275 and 15277. Skin substitutes assigned to the low-cost group are billed with HCPCS codes C5271, C5273, C5275 and C5277. Based on the geometric mean costs, these HCPCS codes are assigned to APCs as follows:

APC	HCPCS	2021 Geometric Mean Cost
5053 (Level 3 Skin Procedures)	C5271, C5275, C5277	$524.17
5054 (Level 4 Skin Procedures	C5273, 15271, 15275,15277	$1,715.36
5055 (Level 5 Skin Procedures)	15273	$3,522.15

For 2022, CMS proposed to determine the high cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. CMS proposed to use 2019 data for this purpose consistent with other proposals not to use claims data that span the COVID-19 PHE.

The proposed 2022 MUC threshold was $48 per cm^2 rounded to the nearest $1, and the proposed 2022 PDC threshold was $949 rounded to the nearest $1. A skin substitute with a MUC or a PDC that exceeds either the MUC threshold or the PDC threshold will be assigned to the high-cost group. If the product is assigned to the high-cost group in 2021, CMS proposed to continue assigning it to the high-cost group in 2022. Otherwise, CMS proposed assigning the skin substitute to the low-cost group.

For 2022, CMS proposed to continue the following policies:

- Skin substitutes with pass-through payment status will be assigned to the high-cost category.
- Skin substitutes with pricing information but without claims data will be assigned to either the high or low-cost categories based on the product's ASP+6 percent payment rate (WAC+3 percent if ASP is unavailable, or 95 percent of AWP if neither ASP or WAC is available) as compared to the MUC threshold.
- New skin substitutes without pricing information would be assigned to the low-cost category until pricing information is available.

The Hospital Outpatient Panel (HOP) and others commented that CMS should end the packaging of graft skin substitutes as packaging eliminates payment variation based on the size of the wound being treated. CMS disagrees stating that the OPPS is a prospective payment system where a single payment is made for all of the services billed with the primary medical procedure. In assigning the skin substitute add-on codes to an APC, CMS takes into account the associated

cost of the skin substitute. While a given case may be more expensive than the average, another case may be less expense than the average. This system gives incentives to control costs as opposed to a system that pays based on the procedure's costs.

There were also comments from the HOP Panel and others recommending that distinctions in procedure coding based on where the skin substitute is applied on the patient's body be eliminated. These commenters do not believe the cost of the procedure varies based on the part of the anatomy where the skin substitute is applied. CMS responded that a number of the skin substitute application codes have been assigned to the same APC (5054) within which payment will not vary. Others are assigned to a lower-paying APC (APC 5054) within which payment will not vary. Historical cost data has supported the APC to which the skin substitute application procedure codes have been assigned.

There was one comment asking that the high and low-cost groups be eliminated on the basis that the current two-tier system provides incentives for providers to use higher-cost graft skin substitute products instead of lower-cost products that have similar efficacy to the higher-cost products. CMS disagreed stating that establishing high cost and low-cost groups makes the payment for skin substitute products more homogeneous and reduces the risk of excessive overpayment or underpayment to a provider when a skin substitute product is used.

In response to a comment, CMS confirmed that manufacturers of HCT/Ps need not consult with the FDA Tissue Reference Group (TRG) or make request for designation about whether HCT/Ps are appropriately regulated under section 361 of the PHS Act and the regulations in 21 CFR part 1271 if the products have a section 510(k) clearance, premarket approval (PMA), or biological license approval (BLA) from the FDA. CMS' recommendation only applies to those HCT/Ps that do not have either a 510(k) clearance, a PMA, or a BLA approval from FDA.

There are various comments about the assignment of specific codes to the high or low-cost group. CMS either confirmed the code was already assigned as the commenter requested or why it would not change the assignment (e.g., because it met the criteria for the group to which it was assigned).

CMS is finalizing all of its proposed policies without modification. Table 42 displays the 2022 cost category assignment for each skin substitute product.

CMS briefly summarizes two of four policy ideas for skin substitutes it has considered in the past: 1) To make a single episode payment that would cover all skin substitute application services for a given period of time (e.g., 4 weeks or 12 weeks) or 2) eliminate the high and low-cost skin substitute categories. CMS is continuing to consider each of these ideas but did not make a proposal and is not making any changes for 2022.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates total pass-through spending for pass-through payments under the proposed 2022 rule will be approximately $1,089.7 million, or 1.32 percent of total OPPS projected payments

(approximately $82.6 billion), which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS estimates pass-through spending of $484.30 million in 2022 for devices—$307.9 million for those recently eligible for pass-through payments that will continue for 2022, $141.9 million for those CMS knows or projects could be approved for pass-through status in 2022 and $34.5 million for one device category approved for extended pass-through payment in 2022. For the latter device category, pass-through payment would have expired in 2022 except CMS is extending pass-through due to the PHE (see discussion below).

B. Drugs and Biologicals

CMS estimates pass-through spending of $531.1 million in 2022 for drugs and biologicals—$466.7 million for those recently eligible for pass-through payments that will continue for 2022 and $20 million for those CMS knows or projects could be approved for pass-through status in 2022.

Pass-through payment will expire for 21 additional drugs and biologicals in 2022. CMS is extending pass-through status for these drugs and biologicals due to the PHE (see discussion below). These drugs and biologicals are estimated to increase pass-through spending an additional $44.4 million in 2022.

C. Extended Pass-Through Due to the COVID-19 PHE

As discussed in section X.E., CMS will use 2019 claims data instead of 2020 claims data to establish the 2022 OPPS rates. The 2019 data that CMS is using for 2022 rate-setting purposes does not reflect the costs of devices and drugs receiving pass-through payment in 2021 where the additional payment expires in 2022.

For 2022, CMS proposed to use its equitable adjustment authority under 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for these 21 drugs and biologicals and 1 device that are eligible for pass-through payment in 2021 where pass-through status will expire in 2022. As 2023 OPPS rates will based on 2021 utilization—the 3rd year that these products will have received pass-through payment—Medicare's OPPS rates will fully reflect the costs of these products and pass-through payment will no longer be needed.

CMS estimates additional pass-through spending for these 21 drugs and biologicals and one device will be approximately $78.9 million for 2022. Table 43 of the final rule lists the drugs, biologicals, and the device for which CMS is extending pass-through payment.

VII. Hospital Outpatient Visits and Critical Care Services

CMS solicited comments but did not propose any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care

services when these services are provided on the campus of a hospital. For off-campus provider-based departments exempted from being paid a physician fee schedule equivalent rate, CMS is continuing to pay 40 percent of the full OPPS rates under the authority of section 1833(t)(2)(F) of the Act. This policy was upheld by a federal circuit court in 2020 and the Supreme Court denied certiorari. CMS did not propose any expansions of this policy for 2022.

VIII. Partial Hospitalization Program (PHP) Services

A. Background

CMS describes the evolution of its payment policies for partial hospitalization program (PHP) services. In the past two rulemaking cycles, it adopted policies to protect against significant reductions in payment rates for PHP services, and, in response to the COVID-19 pandemic, it provided greater flexibility for the delivery of PHP services by Community Mental Health Centers (CMHCs) and hospital-based providers.

In the 2020 OPPS/ASC final rule (84 FR 61339 through 61350), it calculated the 2020 CMHC geometric mean per diem cost and the 2020 hospital-based PHP geometric mean per diem cost consistent with its existing methodology, but it established a cost floor equal to the 2019 final geometric mean per diem costs as the basis for developing the 2020 PHP APC per diem rates. Similarly, in the 2021 rulemaking cycle, it proposed, for 2021 and subsequent years, to use the 2021 CMHC geometric mean per diem cost calculated using its existing methodology, but with a cost floor equal to the per diem cost calculated for 2020 ratesetting as the basis for developing the 2021 CMHC APC per diem rate. Because the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, the floors were not necessary; thus, the agency did not finalize the proposed cost floors in the final rule.

In the April 30, 2020 interim final rule with comment period, effective as of March 1, 2020 and for the duration of the COVID-19 PHE, hospital and CMHC staff may furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. Additionally, a hospital or CMHC may furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient.

B. PHP APC Update for 2022

For 2022, CMS continues 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. For 2022 only, CMS finalizes its proposal to use the 2021 final geometric mean per diem cost for CMHCs and hospital-based PHPs ($136.14 and $253.76, respectively) as a floor in developing the PHP APC per diem rates for each provider type for 2022.

CMS continues to use CMHC APC 5853 (Partial Hospitalization (3 or more services per day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or more services per day)) for each provider type for PHP service days providing 3 or more services. This rate setting methodology was finalized in the 2016 OPPS/ASC final rule (80 FR 70462-70466) as modified in the 2017 OPPS/ASC final rule, including the application of a ±2 standard deviation trim on costs per day for all CMHCs and a CCR greater than 5 (CCR>5) trim for hospital-based PHP providers.

As discussed in detail in section X.E. of the proposed rule (86 FR 42188 through 42190), cost and claims information for 2019 and 2020 were analyzed to understand the impact of the COVID-19 PHE on outpatient services and to identify the best data to use in ratesetting for 2022. CMS noted sharp declines in the number of PHP days in its trimmed 2020 claims dataset (51 percent less and 49 percent less for hospitals and CMHCs respectively) from its trimmed 2019 claims dataset. The agency also notes that its trimmed 2020 claims dataset for this final rule contains cost and claim information from 31 fewer hospital-based PHP providers than are in the 2019 data. CMS finalizes its proposal to use 2019 PHP claims and cost data from before the COVID-19 PHE as a better approximation of expected 2022 PHP services.

1. CMHCs

CMS continues its policy of excluding data from any CMHC when the CMHC's costs are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. CMS also defaults any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR. Because CMHCs are now reporting their costs using the newer cost reporting form (Form CMS 2088-17) which has different lines and columns than the previous form (Form CMS 2088-92) to calculate each CMHC's CCR for this final rule, CMS divided costs from Worksheet C, Line 50, Column 5 by charges from Worksheet C, Line 50, Column 4. Additionally, CMS finalizes its proposal to use HCRIS as the source for CMHC cost information used for calculating the geometric mean per diem cost for CMHC APC 5853 for 2022 and subsequent years; this is because CMHC cost reports are now available in HCRIS.

Of the 40 CMHCs in the PHP claims data file, CMS excludes data from two CMHCs with geometric mean costs per day of more than ±2 standard deviations from the geometric mean cost per day for all CMHCs (one higher and one lower). No CMHC is excluded for missing wage index data, and one provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. CMS adjusts the CCR for 15 CMHCs to the applicable statewide hospital CCR based on its urban/rural designation and state location; three CMHCs had CCRs greater than one, and 12 CMHCs had missing CCR information.

Thirty-seven CMHCs were included in the 2022 calculation. CMS removed 564 CMHC claims which left 10,370 CMHC claims for the 2022 ratesetting. The geometric mean per diem cost for all CMHCs for providing 3 or more services per day calculated in the final rule is $129.93 which represents a decrease from the 2021 geometric mean per diem cost of $136.14. CMS is concerned generally by any significant fluctuation in the geometric mean per diem costs over time, and it worries about the impact of a substantial decrease on beneficiary access to PHP services from CMHCs. It is also concerned with the ongoing disruption of the COVID-19 PHE

on CMHCs. Thus, CMS applies the 2021 CMHC geometric mean per diem cost of $136.14 as a floor for 2022 year.

2. Hospital-based PHP Providers

CMS continues its policy of excluding hospital-based PHP service days when a CCR>5 is used to calculate costs for at least one of the component services. CMS removes 72 hospital-based PHP providers as follows: one with all service days having a CCR greater than five, 68 with no PHP payment, two with no allowable PHP HCPCS codes, and one with geometric mean costs per day outside the ±3 standard deviation limit. Thus, 377 hospital-based PHP providers were included in the data used to calculate rate setting. The calculated geometric mean per diem cost for 2022 for all hospital-based PHP providers for providing 3 or more services per day is $253.02 which is only slightly less than the 2021 geometric mean per diem cost for these providers ($253.76). CMS is nonetheless concerned about the disruptive effects of the COVID-19 PHE on the operations of hospital-based PHP providers, and it uses the 2021 hospital-based PHP provider geometric mean per diem cost as a floor for 2022.

The final 2022 geometric mean per diem costs and payment rates are as follows:

2022 APC	Group Title	Final PHP APC Geometric Mean Per Diem Costs*	Final Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$136.14	$142.70
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$253.76	$265.97

* Table 44 of the final rule shows the 2022 PHP APC geometric mean per diem costs.
** The 2022 payment rates are from Addendum A to the final rule.

C. Outlier Policy for CMHCs

For 2022, CMS finalizes its proposals to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold pursuant to established policies. CMS provides a more detailed explanation of the steps involved in calculating the CMHC outlier percentage in the preamble to the final rule.

CMS projects that CMHCs will receive 0.02 percent of total hospital outpatient payments in 2022 (excluding outlier payments), and it designates less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers. The preamble provides more detail on the methodology the agency uses to calculate the CMHC outlier percentages.

CMS sets the cutoff point for outlier payments for CMHCs for 2022 at 3.4 times the highest CMHC PHP APC payment rate (CMHC PHP APC 5853), and to pay 50 percent of CMHC geometric mean per diem costs over the threshold. Specifically, CMS calculates a CMHC outlier

payment equal to 50 percent of the difference between the CMHC's cost for the services and the product of 3.4 times the APC 5853 payment rate.

CMS continues its outlier reconciliation policy to address charging aberrations related to OPPS outlier payments established in the 2009 OPPS/APC final rule (73 FR 68594 through 68599). The policy requires outlier reconciliation for providers whose outlier payments meet a specified threshold ($500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by ±10 percentage points or more, pending approval of the CMS Central Office and Regional Office.

In the 2017 OPPS/ASC final rule (81 FR 79692 through 79695), CMS implemented an outlier payment cap of 8 percent; thus, an individual CMHC may not receive more than 8 percent of its total per diem payments in outlier payments. CMS continues this policy for 2022 which only impacts CMHCs.

CMS does not set a fixed-dollar threshold for CMHC outlier payments that it applies to other OPPS outlier payments; this is due to the relatively low cost of CMHC services.

D. Regulatory Impact

CMS estimates that payments to CMHCs will increase by 1.1 percent in 2022. The estimate includes the impact of the trimming methodology, wage index, and other adjustments.

IX. Inpatient Only (IPO) List

A. Background

The IPO list was created based on the premise that Medicare should not pay for procedures furnished as outpatient services that are not reasonable and necessary to be performed in any other setting than inpatient. Services on the IPO list are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care.

CMS has historically worked with interested stakeholders, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed. Stakeholders were encouraged to request reviews for a particular code or group of codes. CMS has asked that requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals.

Prior to 2021, CMS traditionally used the following five criteria to determine whether a procedure should be removed from the IPO list:

- Most outpatient departments are equipped to provide the service to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient

departments.
- The procedure is related to codes that have already removed from the IPO list.
- The procedure is being furnished in numerous hospitals on an outpatient basis.
- The procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed for addition to the ASC list.

A procedure is not required to meet all of the established criteria to be removed from the IPO list but it should meet at least one of these criteria.

In the 2021 OPPS final rule with comment period (85 FR 86084 through 86088), CMS adopted a policy to eliminate the IPO list over three years. As part of the first phase of eliminating the IPO list, CMS removed 298 codes from the list beginning in 2021. The removed procedures were not assessed against the above criteria.

B. Changes to the IPO List for 2022

Following the 2021 OPPS final rule, stakeholders continued to express concerns about elimination of the IPO list. The proposed rule reviewed this commentary. Commenters were overwhelmingly opposed to the policy. A minority of comments supported the policy. Opponents of the policy generally noted that the IPO list serves as an important programmatic safeguard and maintains a common standard of medical judgment in the Medicare program. Commenters supporting elimination of the IPO list stated that deference should be given to physicians' judgment on site-of-service decisions.

Concerns about elimination of the IPO list included:

- The pace at which the IPO list would be eliminated.
- The perceived lack of transparency in determining the order of removal of procedures over the course of the elimination process.
- Insufficient details concerning rate setting for procedures for which payment would be made when furnished in the outpatient setting, as well as the accuracy of those rates.

These comments asked CMS to reconsider the elimination of the IPO list, to reevaluate procedures removed from the IPO list due to safety and quality concerns, and, at a minimum, to extend the timeframe for eliminating the list. After further consideration of the policy and the concerns stakeholders have raised since the final rule was issued, CMS proposed to halt the elimination of the IPO list beginning in 2022 and reinstate the criteria for removing a procedure from the IPO list.

There were comments both in support of and opposed to reinstating the IPO list. These comments largely reiterated comments from earlier years. There were common themes in comments from both supporters and opponents of the policy including acknowledgement that the decision to admit the patient is a complex medical judgment. Supporters of reinstating the IPO list indicated that physicians are in the best position to make safety determinations for their patients but CMS must make policies for the broader, beneficiary population. Opponents of reinstating the IPO list stated that while there will be patients for whom an inpatient procedure

remains the safest and most clinically appropriate option, other patients may be clinically appropriate to be treated outpatient. Clinicians should be provided with the sufficient flexibility to select the appropriate clinical treatment site.

Another theme that was common in the comments was administrative and operational burden associated with the IPO list. Supporters of reinstating the IPO list expressed concerns about payers requiring procedures removed from the IPO list to be performed outpatient regardless of patient characteristics or the physician's clinical assessment. Opponents of reinstating the IPO list stated that eliminating the list reduces administrative and operational burden and would increase patient choice and access to advances in surgical care that have made outpatient procedures safe, effective and efficient. A number of commenters also said that CMS should provide robust stakeholder education on procedures removed from the IPO list. These commenters referenced prior CMS guidance as a useful tool for providers and hospitals.

CMS reiterated its prior guidance that removal of a service from the IPO list does not require the service to be performed only on an outpatient basis. Services that are removed from the IPO list can be and are performed on individuals who are admitted as inpatients when the patient's condition warrants inpatient admission. Medicare will pay for inpatient procedures in these instances.

In that past, CMS has provided general educational information regarding billing and payment rules for procedures that come off the IPO list including: Medicare Learning Network (MLN) Booklet 909065: Major Joint Replacement (Hip or Knee) (cms.gov). Further, in the initial period that a procedure is removed from IPO list—two years under the 2020 policy and indefinitely under the 2021—it is exempt from payment denials based on site-of-service. During the exemption period, the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) may conduct medical reviews for education purposes but will not deny claims or make referrals to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule. CMS indicated plans to engage stakeholders in developing educational materials for services that are newly removed from the IPO list if that would be helpful.

CMS is finalizing its proposal to halt the elimination of the IPO list.

CMS also proposed to codify in the regulation text the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list. A majority of commenters supported reinstating the prior criteria without change. Other commenters suggested specific changes to the criteria. CMS may consider the suggested changes in future rulemaking but is finalizing its proposal without modification due in part to the overwhelming support for reinstating the prior criteria without change. The final rule notes the five criteria were adopted through notice and comment rulemaking and engagement with stakeholders. CMS provides the history and rationale for each of the criteria indicating that it intends to continue engaging stakeholders and consider feedback on future modifications.

CMS further evaluated the 298 procedures removed from the IPO list in 2021 against the five criteria, determined that none met the criteria and proposed to add all 298 procedures back to the IPO list for 2022. In the proposed rule, CMS requested evidence to support any comments asking

that any of these 298 procedures remain payable in the outpatient department. Evidence may include but is not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria, and patient selection protocols. CMS recognizes that some of the 298 procedures being reinstated to the IPO list may be safe to perform outpatient in particular instances. Nevertheless, the proposed rule indicated that commenters should specifically demonstrate that the procedure is safe to perform on the typical Medicare beneficiary on an outpatient basis as well as the other criteria.

Most comments supported returning all 298 services back to the IPO list for 2022. Other commenters opposed returning all 298 services to the IPO list. Some commenters raised operational concerns about surgical procedures that are scheduled outpatient prior to the effective date of the policy change. CMS recognizes that there may be operational challenges (including scheduling) to reinstating the IPO list. However, CMS continues to share the concerns expressed by commenters regarding the speed at which CMS previously planned to eliminate the IPO list.

There were comments requesting that 120 services (listed in Table 46 of the final rule) not be placed back on the IPO list. These commenters indicated that they are currently performing some of these procedures on an outpatient basis in both the HOPD and ASC setting on non-Medicare patients. Of the approximately 120 services requested to remain off of the IPO list, supportive evidentiary studies were provided for several CPT codes. Commenters stated that low utilization of the majority of services removed from the IPO list in 2021 confirms physicians are using clinical judgment to determine when the hospital outpatient setting is clinically appropriate.

CMS evaluated the procedures commenters requested be removed from the IPO list against the five criteria. Based on this evaluation, CMS is keeping the following CPT codes off the IPO list in 2022: 22630 (Lumbar spine fusion), 23472 (Reconstruct shoulder joint), and 27702 (Reconstruct ankle joint) and their corresponding anesthesia codes (01638 and 01486). For the other 115 services requested to remain off the IPO list, CMS is finalizing its proposal to add the procedures back to the IPO list. For many of these services, public commenters provided conflicting feedback regarding the ability of providers to safely furnish them in the hospital outpatient setting.

The proposed rule further requested comments on:

- Should CMS maintain the longer-term objective of eliminating the IPO list? If so, what is a reasonable timeline for eliminating the list? What method do stakeholders suggest CMS use to approach removing codes from the list?
- Should CMS maintain the IPO list but continue to remove codes, or groups of codes, that can safely and effectively be performed on a typical Medicare beneficiary in the hospital outpatient setting so that inpatient only designations are consistent with current standards of practice?
- What effect do commenters believe the elimination or scaling back of the IPO list would have on safety and quality of care for Medicare beneficiaries?
- What effect do commenters believe elimination or the scaling back of the IPO list would have on provider behavior, incentives, or innovation?
- What information or support would be helpful for providers and physicians in their

considerations of site-of-service selections?
- Should CMS's clinical evaluation of the safety of a service in the outpatient setting consider the safety and quality of care for the typical Medicare beneficiary or a smaller subset of Medicare beneficiaries for whom the outpatient provision of a service may have fewer risk factors?

The overwhelming majority of commenters that responded to this solicitation supported maintaining the IPO list. Some comments suggested improvements to the IPO list maintenance process, as well as the criteria, evidence and data that should be required to support removing a procedure from the IPO list. CMS will consider these comments in future rulemaking.

There were commenting suggesting that some codes never be removed from the IPO list (radical mastectomy, heart-lung transplants, lung transplants and other open-heart surgeries). Other comments suggested some procedure codes that remained on the IPO list in 2021 be removed from the list in 2022. On the additional procedures requested to be removed from the IPO list, CMS believes it is appropriate to consider removal of these services from the IPO list in future rulemaking in order to allow further public discussion and evaluation.

X. Nonrecurring Policy Changes

A. Medical Review of Certain Inpatient Hospital Admissions

1. Background and Current Policy

Under the 2-midnight rule, services would generally be considered appropriate for inpatient hospital admission and Medicare Part A payment when the physician expects the patient to require at least 2 midnights of hospital care. Services on the IPO list continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay.

In some cases, an inpatient admission may be appropriate even if the patient needs less than 2 midnights of hospital care based on the physician's judgment considering:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

For the inpatient stay to be considered reasonable and necessary, documentation in the medical record must support either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified above that the patient nonetheless requires care on an inpatient basis. The decision to formally admit a patient to the hospital is subject to medical review.

In 2020, CMS finalized a policy to exempt procedures that have been removed from the IPO list from eligibility for referral to RACs for noncompliance with the 2-midnight rule within the 2

calendar years following their removal from the IPO list. Procedures removed from the IPO list will not be considered by the BFCC-QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for "patient status." BFCC-QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule during the 2-year period.

In 2021, CMS adopted a policy to eliminate the IPO list over 3 years. During the first phase of the IPO list's elimination in 2021, CMS removed 298 musculoskeletal procedures from the list. In conjunction with that policy, CMS heard from many commenters that the 2-year exemption from the 2-midnight rule is appropriate when removing a small volume of procedures from the IPO list. However, commenters believed that the unprecedented volume of procedures becoming subject to the 2-midnight rule with the phased elimination of the IPO list would necessitate a longer exemption period.

CMS agreed and adopted a policy to indefinitely exempt procedures removed from the IPO list after January 1, 2021 from site-of-service claim denials, eligibility for BFCC-QIO referrals to RACs for noncompliance with the 2-midnight rule, and RAC reviews for "patient status." This exemption would last until Medicare claims data indicate that the procedure is more commonly performed outpatient (50 percent or more of the time) than inpatient.

2. Policy for 2022 and Subsequent Years

In section IX of the final rule, CMS discusses its policy to halt elimination of the IPO list, reinstate nearly all of the 298 procedures removed from the IPO list, and return to its prior policy of selectively removing procedures from the IPO list based on whether the surgical procedure meets the specific criteria previously used. Now that CMS is returning to its prior policy of selectively removing procedures from the IPO list, the agency believes that an indefinite exemption from medical review activities related to the 2-midnight rule may no longer be warranted. Accordingly, CMS proposed to rescind the indefinite exemption and instead apply a 2-year exemption from 2-midnight medical review activities for services removed from the IPO list on or after January 1, 2022.

CMS notes that whether the timeframe is limited or indefinite, the exemption is from medical review and denials based on site-of-service or referral to the RACs. The exemption is not from the 2-midnight rule itself. Providers are still expected to comply with the 2-midnight rule. Further, the 2-midnight rule does not prohibit procedures from being performed or billed on an inpatient basis. CMS indicates that the decision to admit a patient remains a complex medical judgment. Providers are still expected to use their judgment to determine the appropriate site of service for each patient and to bill in compliance with the 2-midnight rule.

There were comments in support of the indefinite exemption to the 2-midight rule until IPO list procedures are routinely performed outpatient and comments in support of only the 2-year exemption. CMS responded that it continues to believe that a 2-year exemption is appropriate when CMS is removing a smaller, more targeted population of procedures from the IPO list. As CMS is finalizing its proposal to halt the elimination of the IPO, it is also reinstating the 2-year

exemption period for procedures removed from the IPO list on January 1, 2022 or later.

B. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Medicare pays 100 percent of the payment amount for certain colorectal cancer screening tests that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. Thus, a beneficiary pays no cost-sharing (and the application of the deductible is waived) for these screening tests.

When the colorectal cancer screening test benefit category was enacted into law, the statute specifically provided that if, during the course of a screening flexible sigmoidoscopy or screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but rather shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. The result was that beneficiaries faced unexpected coinsurance charges because the procedure was classified as a diagnostic test instead of a preventive service screening test.

Section 4104 of the ACA addressed this issue with respect to the deductible but not for any coinsurance that may apply. Section 122 of the CAA addresses this issue for the coinsurance by successively reducing, over a period of years, the percentage amount of coinsurance for which the beneficiary is responsible so that for services furnished on or after January 1, 2030, the coinsurance will be zero. The phased-in increases in the amount the Medicare program pays for these services on or after January 1, 2022 are as follows:

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

CMS proposed to codify its regulations to implement the changes to the Medicare statute. As this policy applies under both the PFS and the OPPS, CMS discusses its colorectal screening cancer policies in both the 2022 PFS rule and the 2022 OPPS rule. CMS advised commenters to respond to this issue as part of the PFS rulemaking process rather than the OPPS.

Public commenters supported CMS' proposal. Several commenters requested that CMS allow providers to waive coinsurance even earlier than 2030 or accelerate the reduction in the coinsurance amounts. Such a policy would be similar to another one where the statute allowed hospitals to voluntarily charge less coinsurance than was due from the beneficiary under the transition to OPPS in the early 2000's.

CMS responded that prior to the complete phaseout of Medicare coinsurance amounts for colorectal cancer screening tests in 2030, suppliers may waive coinsurance amounts only if they comply with applicable law, including the Federal Anti-Kickback Statute and the civil monetary penalty provision prohibiting inducements to beneficiaries. The election to reduce beneficiary coinsurance during the transition to OPPS allowed hospitals to voluntarily charge a minimum of

20 percent coinsurance when coinsurance for many services was otherwise higher than 20 percent. This provision is not applicable to colorectal screening tests.

Under the final rule policy, all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy are considered as furnished in connection with, as a result of, and in the same clinical encounter as the screening test for the purposes of determining beneficiary coinsurance. Providers must continue to report HCPCS modifier "PT" to indicate that a planned colorectal cancer screening service converted to a diagnostic service. CMS will examine the claims data, monitor for any increases in surgical services unrelated to the colorectal cancer screening test performed on the same date as the screening test for a notable increase or abuse of this policy.

C. Low Volume Policy for Clinical, Brachytherapy, and New Technology APCs

In the past, CMS has selectively used the equitable adjustment authority at section 1833(t)(2)(E) of the Act to determine costs for low-volume services. The use of this authority was intended to mitigate annual payment fluctuations among these services. In recent years, CMS has used the equitable adjustment authority more broadly for categories of low-volume services rather than specific services. For instance:

- In 2017, CMS began to base the payment rate on the median instead of the geometric mean for low-volume device dependent APCs with fewer than 100 single claims available for rate-setting annually.
- In 2019, CMS began to base payment rates on up to four years of claims data for low-volume procedures assigned to new technology APCs with fewer than 100 claims available for rate-setting annually. CMS uses the higher of the geometric mean, median or arithmetic mean cost for the procedure to determine a new technology APC assignment.

CMS believes these policies have mitigated concerns regarding payment rates for low-volume new technologies and device-intensive procedures and should be expanded to all low-volume APCs with fewer than 100 single procedure claims available for rate-setting annually. For 2022, CMS proposed to designate clinical APCs, brachytherapy APCs, and new technology APCs with fewer than 100 single claims that can be used for rate-setting as low-volume.

For low-volume new technology procedures, CMS proposed to determine the higher of the *procedure's* cost based on the geometric mean, median or the arithmetic mean to assign the procedure to a new technology APC. For clinical and brachytherapy APCs, CMS proposed to determine relative weight based on the higher of the *APC's* geometric mean, median or the arithmetic mean. CMS proposed to use up to four years of data to make these determinations when a new technology procedure, clinical APC or brachytherapy APC is designated as low volume.

The differential policy respectively—procedure level vs. APC level calculation—for new technology procedures from clinical APCs and brachytherapy APCs is explained as being due to new technology procedures being assigned to a new technology APC based on a cost band with

procedures that may not be clinically similar. Procedures in clinical APCs and brachytherapy APCs are clinically similar but do not have sufficient claims upon which to be priced under the standard methodology.

For clinical APCs, brachytherapy APCs and new technology procedures considered to be low-volume, CMS will use up to four years of data to determine the higher of the geometric cost, median cost or arithmetic mean cost. Consistent with other policies, CMS proposed not using utilization data that spans the PHE. For 2022, CMS proposed to use utilization and cost data from 2016 to 2019 to assign a new technology procedure to a new technology APC, or determine the relative weight for a clinical APC or brachytherapy APC designated as low-volume.

Given the different nature of policies that affect the PHP, CMS did not propose to apply the low-volume APC policy to APC 5853 Partial Hospitalization for CMHCs or APC 5863 Partial Hospitalization for Hospital-based PHPs. CMS also proposed not applying this policy to APC 2698 for brachytherapy sources "not otherwise specified" that is priced using external data sources.

Public commenters supported CMS' proposal. One commenter recommended that new technology C-codes with fewer than 100 claims be eligible for the low-volume adjustment. Another commenter recommended that the threshold for brachytherapy APCs be increased to fewer than 500 claims. CMS responded that it will not apply the policy to new technology C-codes with fewer than 100 claims as these codes are generally assigned to clinical APCs when there is resource and clinical similarity with other procedures but there is not a CPT code to describe the technology. CMS does not believe it is necessary expand this policy to any services with more than 100 claims. Services with more than 100 claims are likely to have a normal statistical distribution. CMS is finalizing these policies as proposed.

For the final rule, CMS is applying this policy to four clinical APCs and five brachytherapy APCs listed in Table 49 of the final rule. Table 49 also provides the APC's geometric mean cost without the low-volume APC designation, the median, arithmetic mean, and geometric mean cost using up to four years of claims data, as well as the statistical methodology being used to finalize the APC's cost. Table 50 lists the same information for the APCs that will be considered low-volume under the ASC system in 2022. The APC list for the ASC system is slightly different than for the OPPS.

D. Comment Solicitation on Temporary COVID-19 Policies

In response to the COVID-19 pandemic, CMS issued waivers and undertook emergency rulemaking to implement a number of temporary policies to address the pandemic, including policies to prevent the spread of the infection and support diagnosis of COVID-19. CMS is seeking comment on whether any of the temporary policies described below should be made permanent.

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in their Homes

Due to the circumstances of the COVID-19 pandemic, particularly the need to maintain physical

distance to avoid exposure to the virus, CMS waived provisions of the hospital conditions of participation and the provider-based rules that permitted hospital staff to provide outpatient hospital services through an interactive telecommunications system for patients located in the home.

Mental health services are among the services that have been consistently provided remotely via telecommunications technology according to CMS data presented in the rule. However, these data relate to the telehealth benefit and not mental health services provided by hospital staff. CMS has not required any claims-based modifier identifying specifically when a service is furnished by clinical staff of the hospital to a beneficiary in their home through communications technology. Therefore, CMS is not able to gauge the magnitude of how often mental health services are being provided remotely by hospital staff to patients located in the home.

The flexibility to provide mental health and other services by a hospital to a patient in the home is tied to waivers and other temporary policies that expire at the end of the PHE. In instances where a beneficiary may be receiving mental health services from hospital clinical staff who cannot bill Medicare independently for their professional service, the beneficiary would then need to physically travel to the hospital to continue receiving the services post-PHE. CMS is concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided by hospital staff and have become accustomed to receiving these services in their homes during the PHE. For this reason, CMS requested comment on:

- The extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE; and
- Whether hospitals would anticipate continuing demand for this model of care following the conclusion of the PHE.

Public comments supported continuing OPPS payment for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital through the use of communication technology as a permanent policy post-PHE. CMS will consider the public comments for future rulemaking and, in addition, will continue to explore how hospital payment for virtual services could support access to care in underserved and/or rural areas,

2. Direct Supervision by Interactive Communications Technology

During the PHE, CMS waived the requirement for direct supervision to be provided through the physical presence of a physician or non-physician practitioner for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. CMS is allowing the direct supervision requirement to be met through a virtual presence with audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or practitioner.

In the proposed rule, CMS requested comment on:

- Whether and to what extent hospitals have relied upon this flexibility during the PHE;

- Whether providers expect this flexibility would be beneficial outside of the PHE;
- Whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE; and
- Whether a service-level modifier should be required to identify when the requirements for direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services were met using audio/video real-time communications technology.

Commenters supported allowing direct supervision of cardiac rehabilitation and pulmonary rehabilitation, and intensive cardiac rehabilitation services through two-way, audio/video communication technology on a permanent basis, or, for a period of time following the conclusion of the PHE, such as until the end of 2022. Most commenters supported development of a service-level modifier to track and collect data but a few commenters stated that it would be unnecessary and burdensome. CMS will consider these comments for future rulemaking.

3. Payment for COVID-19 Specimen Collection in Hospital Outpatient Departments

CMS created HCPCS code C9803 for COVID-19 specimen collection to be used only during the COVID-19 PHE and only when no other service is provided by the hospital except a clinical diagnostic laboratory test. While CMS plans to retire this code at the conclusion of the PHE, it is requesting comment on whether CMS should continue this code and payment. Public commenters supported retaining this code permanently for hospitals. CMS plans to consider the public comments for possible future rulemaking.

E. Use of 2019 Claims Data for 2022 Rate-Setting

The Secretary is required by statute to revise the APCs and relative weights annually to reflect changes in technology, medical practice, the addition of new cost data and other factors. CMS ordinarily uses the Outpatient Standard Analytic File from the 2nd year preceding the rate-setting year (e.g., 2020 for 2022) in combination with hospital cost reports from FY 2019 to set the APC relative weights. However, CMS believes that 2020 outpatient utilization has been significantly affected by the COVID-19 PHE. Like it did for the FY 2022 IPPS, CMS proposed to use 2019 outpatient claims and FY 2018 hospital cost report data to set the OPPS relative weights for 2022. CMS' analysis of this issue in the 2022 OPPS proposed rule was nearly identical to the analysis provided in the FY 2022 IPPS rulemaking. CMS cites the following reasons for using claims data that precede the PHE:

- 2020 Utilization Data is Atypical: CMS' analysis shows a decline in total outpatient claims in 2020 compared to 2019 and a particularly sharp decline in claims for emergency department and clinic visits. However, there was a very high increase in billing for the telehealth originating site facility fee and the initiation of ventilation. Further, CMS saw a large increase in billing of APC 5731 that includes a newly established code to collect a specimen for COVID-19 testing. This analysis and a further analysis of case-mix shows that 2020 utilization was significantly different compared to 2019 utilization. CMS concluded from an analysis of vaccination rates among the U.S.

population that 2022 is likely to be a more typical year (e.g., more similar to 2019 than 2020).

- Differential Impact of 2020 Utilization Data on Rate-Setting: CMS presented a complex analysis of how case-mix would be impacted by using the 2019 versus the 2020 utilization. From this analysis, CMS concluded that there would be a material effect on OPPS rate-setting from using atypical 2020 outpatient utilization rather than continuing to use the more typical utilization patterns from 2019.

The other major data source that CMS uses in setting the OPPS relative weights is data from the most recent quarterly Hospital Cost Report Information System (HCRIS) release. Typically, CMS would use cost reports beginning 3 fiscal years prior to the year that is the subject of the rulemaking (FY 2019 for 2022). However, CMS noted that many FY 2019 cost reporting periods actually end in 2020 during the period of the COVID-19 PHE. CMS proposed to use cost report data from the FY 2018 HCRIS file in determining the 2022 OPPS relative weights.

While CMS proposed to use 2019 outpatient claims and the FY 2018 HCRIS to set the 2020 OPPS relative weights, it also considered continuing with its historical practice of always using the latest available data for these purposes. To facilitate comment on this alternative for 2022, CMS made available 2020 data and supporting files that it would ordinarily have provided were it to have used the latest available data to set 2022 rates. CMS provided the OPPS Impact File, cost statistics files, addenda, and budget neutrality factors.

Public commenters supported CMS' proposal. There were public comments requesting specific exceptions to use 2020 claims:

- For certain HCPCS codes that only have volume or significant volume in the 2020 claims but not in the 2019 claims data;
- For specific APC series;
- To make an APC assignment but not to determine the APC relative weight; and
- Use either 2019 or 2020 claims data based on which year provides a higher device offset percentage.

CMS responded that it will generally use 2019 claims data for ratesetting purposes unless there is a specific reason to selectively use 2020 data. For instance, CMS proposed to use 2020 data for 11 device intensive procedures because it provides information not available in the 2019 claims data. With the 2020 data, CMS could set a more precise device offset rather than use a 31 percent default percentage or the one from a clinically similar procedure code. Similarly, CMS is establishing an additional limited exception in this final rule with comment period. If no significant 2019 claims data is available to make an APC assignment, CMS will use 2020 data for this purpose. CMS is finalizing its proposal as modified in response to public comments.

F. Extending Expiring 2021 Pass-Through Payment for 2022

In the 2021 OPPS/ASC final rule, CMS discussed the public comments regarding use of the equitable adjustment authority under section 1833(t)(2)(E) of the Act to extend pass-through payment for the period of time that utilization for the devices, drugs and biologicals was reduced

due to the PHE. Public comments supported extending pass-through payments for both devices and drugs and biologicals.

As noted in section X.E., CMS proposed to use 2019 claims data in establishing the 2022 OPPS rates. As these data will not reflect a full three years of pass-through payment for products with expiring pass-through payments after 2021, CMS proposed to extend pass-through payment for up to four quarters for these products. CMS proposed a one-time equitable adjustment under section 1833(t)(2)(E) of the Act to continue separate payment for the remainder of 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022.

For devices, drugs and biologicals that would otherwise be packaged, CMS believes providing separate payment for up to a full year in 2022 will allow continued pass-through payment until the data that CMS is using to set rates in a future year incorporates the products' costs. For drugs and biologicals that would otherwise be separately payable (other than when furnished in conjunction with a C-APC), extended pass-through would allow separate payment when billed in conjunction with a C-APC and to avoid being paid at ASP-22.5 percent when acquired under the 340B drug discount program.

Extended pass-through would apply to one device and 21 drugs—three of which would be packaged after pass-through expires. Because pass-through status can expire at the end of a quarter, extended pass-through payment would be made for between one and four quarters, depending on when the pass-through period expires. Separate payment would be made for a full year for one device and 6 drugs for which pass-through status will expire on December 31, 2021, three quarters for the 12 drugs and biologicals for which pass-through status will expire on March 31, 2022, two quarters for the 7 drugs for which pass-through status will expire on June 30, 2022, and one quarter for the 2 drugs for which pass-through status will expire on September 30, 2022.

Table 52 lists drugs, biologicals and the device that will receive extended pass-through payment. The table provides the effective and end date of extended pass-through payment, as well as the number of quarters of additional pass-through payment that will be provided.

Public commenters overwhelming supported CMS' proposal. Multiple commenters requested expanding or limiting the scope of the proposal. Examples of expansions requested included applying the policy to all radiopharmaceuticals or all products currently on pass-through. There was a comment asking that extended pass-through not be implemented in a budget neutral manner. Another commenter stated that extended pass-through should not be available to products that have already received more than three years of pass-through payment. One commenter stated that CMS should not extend pass-through payment for drugs, biologicals or biosimilars that would otherwise be separately paid.

CMS is not expanding its proposed policy to additional items and services receiving pass-through as it does not see a disadvantage for products that are continuing to receive pass-through in the same way as other products where pass-through is ending between December 31, 2021 and September 30, 2022. It agrees with not applying the policy to products that have already received

more than three years of pass-through payment although CMS does not believe that any product receiving extended pass-through payment would have already received the payments for more than three years. CMS cannot implement the policy without applying a budget neutrality adjustment. It is finalizing its proposed policy without modification.

XI. OPPS Payment Status and Comment Indicators

OPPS Payment Status Indicator Definitions

For 2022, CMS did not propose any changes to status indicators. Status indicators and their definitions can be found in Addendum D1 of the final rule. Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and also the particular OPPS policies that apply to the code. The 2022 payment status indicator assignments for APCs and HCPCS codes are shown in Addenda A and B respectively.

Comment Indicator Definitions

For 2022, CMS is continuing to use the following comment indicators that are unchanged from 2021:

"CH"—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
"NC"— New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year for which CMS is requesting comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
"NI"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
"NP"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the OPPS comment indicators for 2022 are listed in Addendum D2 of the final rule. CMS is making no changes to these indicators from prior years.

XII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Update: In its March, 2021 "Report to Congress: Medicare Payment Policy," MedPAC recommended that Congress update Medicare OPPS payment rates in 2022 by 2 percent, with the difference between 2 percent and the update amount specified in current law to be used to increase payments in a new recommended Medicare quality program, the "Hospital Value Incentive Program." CMS indicates that MedPAC's recommended update would require a

change in law and is adopting an OPPS update of 2.0 percent (2.7 percent market basket less 0.7 percentage points for multifactor productivity) consistent with current law.

ASC Update: MedPAC indicates that payments to ASCs are adequate and recommended no payment update. CMS is adopting an ASC update of 2.0 percent in the final rule consistent with its approach for updating hospital inpatient and outpatient services.

CMS has the authority to select the market basket used in the update but once selected is required to use that market basket less multifactor productivity in the update. In 2019, CMS began using the hospital market-basket in place of the CPI-U to update ASC rates for five years.

ASC Cost Data: MedPAC recommended that Congress require ASCs to report cost data which would enable the Commission to examine ASCs' costs relative to Medicare payments over time to evaluate the costs of efficient providers. CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or if an ASC specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program. CMS recognizes that the submission of cost data places additional administrative burden on ASCs and did not propose any cost reporting requirements for ASCs.

MedPAC commented that it is feasible for ASCs to provide cost information and that smaller providers, such as hospices, currently provide such information to CMS. MedPAC suggested CMS could create a streamlined process of reporting limited cost data and variables rather than a formal, and more time-consuming, cost report. Other commenters suggested that CMS recognize that cost experience can differ greatly depending on factors such as the size of the facility, location, and the specialties served. Further, if CMS were to collect ASC cost reports, commenters request that it consider developing a single market basket update that could be applied to both ASCs as well as outpatient departments.

XIII. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2022		
	ASCs reporting quality data	**ASCs not reporting quality data**
2021 ASC Conversion Factor	$48.952	
Wage index budget neutrality adjustment	0.9997	
2022 Update		
Hospital market basket update	2.7%	
Multi-factor productivity adjustment (MFP)	-0.7%	
Net MFP adjusted update	2.0%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.0%	0.0%
2022 ASC Conversion Factor	$49.916	$48.937

CMS estimates that under the final rule, total ASC Medicare payments for 2022 will be approximately $5.41 billion, an increase of $40 million compared with 2021 levels inclusive of changes in enrollment, utilization, and case mix changes.

As with the rest of the OPPS final rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1753-fc. All ASC Addenda to the final rule are contained in the zipped folders entitled Addendum AA, BB, DD1, and DD2.

A. Background

Prior to 2021, covered surgical procedures in an ASC were those that would not be expected to pose a significant risk to the beneficiary, require an overnight stay or active medical monitoring and care at midnight following the procedures. Payment for ancillary items and services (with some exceptions) are packaged into the ASC payment. The ASC payment is generally a percentage of the OPPS payment rate unless the service is "office-based." Payment for office-based services is capped based on the PFS non-facility payment.

CMS provides quarterly update change requests (CRs) for ASC services throughout the year and makes new codes effective outside the formal rulemaking process via these quarterly updates. The annual rulemaking process is used to solicit comments and finalize decisions.

Until 2019, CMS defined a surgical procedure as any procedure in the surgery CPT code range (CPT codes 10000 through 69999) or Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that meet the criteria to be paid in an ASC. Beginning with 2019, CMS included "surgery-like" procedures outside the CPT surgical range that meet the criteria to be on the ASC list.

In 2021, CMS significantly revised its policy for adding surgical procedures to the ASC Covered Procedures List (CPL) greatly expanding the number of surgical procedures that could be performed in the ASC setting. Specifically, CMS revised 42 CFR 416.166 to eliminate the regulatory criteria that the procedure would not pose a significant risk to the beneficiary, require an overnight stay or active medical monitoring and care at midnight following the procedure and eliminating five of the general exclusion criteria. Using these revised criteria, CMS added approximately 267 potential surgery or surgery-like codes to the CPL that were not on the 2020 IPO list. In this year's rule as discussed further below, CMS reinstates the general standards and exclusion criteria at §416.166 that were in place prior to 2021 and removes almost all of the added 2021 codes from the ASC CPL.

B. ASC Treatment of New and Revised Codes

CMS evaluates new codes for inclusion on the ASC list or as separately paid ancillary services and whether to pay them as office-based services. CMS sets out policies for new codes in two categories:

- Codes previously identified during the year in the quarterly update process and on which it requested comments in the proposed rule; and
- New codes for which it will be seeking comments in this final rule with comment period.

Table 57 in the final rule (shown below) provides the process and timeline for ASC list updates:

Comment and Finalization Timeframes for New or Revised HCPCS Codes				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 2021	HCPCS (CPT and Level II codes)	April 1, 2021	2022 OPPS/ASC proposed rule	2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II codes)	July 1, 2021		
October 2021	HCPCS (CPT and Level II codes)	October 1, 2021	2022 OPPS/ASC final rule with comment period	2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	2022 OPPS/ASC proposed rule	2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2022 OPPS/ASC final rule with comment period	2023 OPPS/ASC final rule with comment period

April and July 2021 Codes - CMS Solicited Public Comments in the Proposed Rule

In the April 2021 ASC quarterly update, CMS states it made effective 11 new Level II HCPCS codes and one new CPT code. Table 53 displays the codes, descriptors, and the 2022 final payment indicators.[20] In the July 2021 ASC quarterly update, CMS added 11 separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Tables 54 and 55 lists the codes, descriptors, and the 2022 final payment indicators.

CMS notes that the payment rates, where applicable, can be found in Addendum BB for the Level II HCPCS codes and in Addendum AA for the new Category III codes at the CMS website referenced above.

October 2021 and January 2022 HCPCS Codes - CMS Will Be Soliciting Public Comments in the 2022 Final Rule with Comment Period

CMS continues to assign comment indicator "NI" in Addendum BB to the 2022 OPPS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2021. This indicates that CMS has assigned the codes an interim OPPS payment status for 2022. CMS invites comments in the 2022 OPPS/ASC final rule with comment period on the interim payment indicators which will then be finalized in the 2023 OPPS/ASC final rule with comment period.

[20]Table 53 in the final rule lists 9 HCPCS codes.

CPT Codes for which Public Comments are Solicited in the Proposed Rule

CMS sought comment on proposed new and revised CPT codes effective January 1, 2022 that were received in time to be included in the proposed rule. These are finalized in the 2022 OPPS/ASC final rule with comment period.

For the 2022 ASC update, the new and revised codes can be found in Addenda AA and BB. The codes are assigned comment indicator "NP" indicating that it is new or has had substantial revision. In addition, long descriptors are available in Addendum O.

C. Update to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

Covered Surgical Procedures Designated as Office-Based

Given its concerns with 2020 claims data as a result of the PHE, CMS did not propose to assign permanent office-based designations for 2022 to any covered surgical procedure currently assigned a payment indicator of "G2". Moreover, CMS is also not using the most recent claims volume and utilization data and other information for procedures designated as temporarily office-based and temporarily assigned one of the office-based payment indicators, specifically "P2", "P3" or "R2". Instead, CMS continues to designate these eight procedures, shown in Table 58 in the final rule, as temporarily office-based for 2022.

For 2022, CMS finalizes its proposal to designate two new 2022 CPT codes for ASC covered surgical procedures as temporarily office-based. This includes CPT code 42975 (Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic), which CMS states is similar to CPT code 31505. In addition, CMS adds CPT code 53454 (Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume) as temporarily office-based as it is similar to CPT code 0551T.

Several commenters requested that CMS modify its approach to incorporate PFS non-facility PE RVUs in response to CMS' proposal to update clinical labor pricing in the 2022 PFS proposed rule. They recommended given the disparate impacts on these services that CMS delay or transition the changes in non-facility PE RVUs under the ASC payment system. CMS did not accept this recommendation and stated that its office-based policy is meant to achieve payment parity between the ASC and physician office settings. CMS also notes that it is updating the clinical labor pricing over a four-year transition in the 2022 Medicare PFS final rule.

Device-Intensive ASC Covered Surgical Procedures

Surgical procedures designated as device-intensive are subject to a special payment methodology. The device portion of the payment is determined by applying the device offset percentage to the standard OPPS payment. The service portion of the ASC payment for device-intensive procedures is determined by applying the uniform ASC conversion factor to the non-device portion of the OPPS relative payment weight. The ASC device portion and ASC non-device portion are summed to establish the full payment for the device-intensive procedure under

the ASC payment system. This policy applies only when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices)—a policy CMS inadvertently omitted from the 2019 final rule. In the 2019 OPPS/ASC final rule, CMS lowered the device offset percentage threshold from 40 percent to 30 percent and aligned the device-intensive policy with the criteria used for device pass-through status.

CMS notes, however, that the different ratesetting methodologies used under the OPPS and ASC payment system can create conflicts when determining device-intensive status and can cause confusion among stakeholders. For example, procedures with device offset percentages greater than 30 percent under the OPPS may not have device offset percentages greater than 30 percent when calculated under the standard ASC ratesetting methodology. Under current policy, procedures must be device-intensive in the OPPS setting to be eligible for device-intensive status under the ASC payment system. While CMS believes that the device-intensive policies under the ASC payment system should align with those under the OPPS, CMS believes device-intensive status under the ASC payment system should, at a minimum, reflect a procedure's estimated device costs under the ASC standard ratesetting methodology.

Therefore, for 2022 and subsequent years, CMS finalizes its proposal to assign device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. In addition, CMS also finalizes its proposal that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. CMS believes that this is appropriate to give deference to the OPPS designation given that OPPS packages a greater amount of non-device costs into the primary procedure.

The ASC covered surgical procedures that CMS designates as device-intensive, and, therefore subject to the device-intensive procedure payment methodology for 2022, are assigned payment indicator "J8" and are included in ASC Addendum AA to the final rule.

Many commenters supported CMS' proposed changes related to designating surgical procedures as device-intensive under the ASC payment system. Some requested that CMS apply the device offset percentage for several new procedures with the predecessor code's device offset percentage based on 2019 claims data. CMS agrees with the commenters and the HOP Panel's recommendation and notes that it was inadvertent that it did not apply the device offset percentage to these codes. One commenter recommended that CMS publish an Addendum to its proposed and final rule that displays the device offset percentage for both device-intensive and non-device procedures under the ASC payment system. CMS accepts this recommendation and creates Addendum FF for this final rule and for subsequent proposed and final rules for this purpose.

Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

CMS is making no changes to its policy for devices furnished with full or partial credit in the ASC system:

- When the device is furnished at no cost or with full credit from the manufacturer, the contractor would reduce payment to the ASC by 100 percent of the device offset amount, which is the amount that CMS estimates as the cost of the device. The ASC would append the HCPCS "FB" modifier on the claim line with the procedure to implant the device.

- When the device is furnished with partial credit of 50 percent or more of the cost of the new device, the contractor would reduce payments to the ASC by 50 percent of the device offset amount. In order to report a partial credit, the ASC would have the option of either submitting the claim after the procedure, but prior to manufacturer acknowledgement of credit for the device, and having the contractor make a claim adjustment, or holding the claim for payment until a determination is made by the manufacturer. The ASC would then submit the claim with a "FC" modifier if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount.

CMS notes that it inadvertently omitted language that its policy for partial credits would apply not just in 2019 (when finalized) but also in subsequent years. Specifically, for 2022 and subsequent calendar years, CMS will continue to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device.

CMS did not receive any comments on its policies related to no/cost full credit or partial credit devices, and it continues its existing policies for 2022 and subsequent years.

Changes to the List of ASC Covered Surgical Procedures for CY 2022

For 2022, CMS finalizes its proposal to re-adopt the ASC -CPL criteria that were in effect in 2020. CMS finalizes that effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards (as specified at §416.166(b)) and do not meet the general exclusions (at §416.166(c)). These general standards and exclusion criteria are detailed below.

1. Meets general standards specified in 42 CFR 416.166(b): Surgical procedures specified by Secretary and published in the Federal Register and/or via the Internet on the CMS website that are separately paid under OPPS.

- *a. Not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC*
- *b. Beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure*

2. Follows the general exclusion criteria set out in 42 CFR 416.166(c): ASC covered surgical procedures do not include surgical procedures that : (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15.

After evaluating the 267 surgery or surgery-like codes that were added last year, CMS clinicians determined for the proposed rule that 258 of these surgical procedures may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC, and that nearly all would likely require active medical monitoring and care at midnight following the procedure. During the public comment period, commenters recommended that 140 surgical procedures either remain on, or be added to the ASC CPL including 3 codes that have been on the ASC CPL that it did not propose to remove in 2022. CMS is retaining 3 codes (CPT codes 0499T, 54650, and 60512) of the 258 codes proposed for removal after its detailed review of these codes. Thus, CMS removes the remaining 255 of the 258 codes proposed for removal. These procedures are shown in Table 62 of 2022 OPPS/ASC final rule with comment period.

Commenters were largely split on the issue of reinstating the general standards and exclusion criteria at §416.166 that were in place prior to 2021. Those opposed to this proposal contend that the policy may substitute administrative criteria for physician clinical judgement, reduce beneficiary choice, and increase costs if these procedures were done instead in a higher-cost hospital setting. Numerous other commenters, however, support CMS' proposal to reinstate the general standards and exclusion criteria due to patient safety and quality of care concerns. In response, CMS believes that reinstating the longstanding general standards and exclusion criteria that were in place prior to 2021 is the most appropriate way to ensure that procedures that cannot be safely performed on an ambulatory bases for the typical Medicare beneficiary are not added to the ASC CPL and payable under the ASC payment system.

CMS also finalizes its proposal to change the notification process adopted in 2021 to a nomination process, under which stakeholders could nominate procedures they believe meet the requirements to be added to the ASC CPL (added as a new paragraph (d)(1) of §416.166). Under this policy, CMS would solicit recommendations from external stakeholders, such as medical specialty societies and other members of the public for suitable candidates to add to the ASC CPL.

Nomination process would occur annually through the proposed rule (nominations received by March 1st) and final determinations regarding nominated procedures would be in the final rule.

CMS would add the procedures that meet the requisite criteria to the ASC CPL in the final rule. For example, stakeholders would need to send in nominations by March 1, 2022, to be considered for the 2023 rulemaking cycle and potentially have their nomination effective by January 1, 2023. CMS will address nominated procedures beginning in the 2023 rulemaking cycle. It also will include in the applicable proposed rule, a summary of the justification for proposing to add or not add each nominated procedure and may also defer a proposal until it has sufficient time to evaluate. CMS sought comment on how it might prioritize its review of nominated procedures, in the event it receives an unexpectedly or extraordinarily large volume of nominations for which CMS has insufficient resources to address in the annual rulemaking.

The majority of commenters, which included device manufacturers, hospital associations, and ambulatory surgery associations, supported the proposal to establish a process for the public to nominate procedures for additions to the ASC CPL. Commenters offered a wide range of suggestions on different approaches for CMS to consider when developing criteria on prioritizing procedures including prioritizing procedures endorsed by physician specialty societies, ASC specialty societies, and/or multi-specialty physician organizations that can directly attest to the safety profile of procedures furnished in an ASC; take into account current length of stay requirements of a procedure, among other factors. CMS agrees with commenters that a formalized process would provide more transparency and increase opportunities for CMS to engage with providers and external stakeholders in adding procedures to the ASC CPL.

D. Payment Update to ASC Covered Surgical Procedures and Covered Ancillary Services

ASC Payment for Covered Surgical Procedures

CMS finalizes its proposal to continue its policy to update payments for office-based procedures and device-intensive procedures using its established methodology and using its modified definition for device-intensive procedures for all but low volume device-intensive procedures. Payment for office-based procedures will be the lesser of the 2022 PFS non-facility practice expense payment amount, or the 2022 ASC payment amount. CMS continues its policy for device removal procedures – such procedures that are conditionally packaged in the OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

CMS also notes changes to beneficiary coinsurance for certain colorectal cancer screening tests that may apply. The CAA, 2021 waives coinsurance for screening flexible sigmoidoscopies and screening colonoscopies whether or not a lesion or growth is detected during the screening which results in a biopsy or removal of the lesion or growth; this policy will be phased in beginning January 1, 2022 and is discussed in the 2022 Medicare PFS proposed and final rules and section X. B. of this summary.

Limit on ASC Payment for Low Volume Device-Intensive Procedures

Data anomalies for low volume procedures can result in inappropriate payment rates using the standard ASC methodology for rate-setting. CMS finalizes its low volume APC policy for 2022 and subsequent calendar years. Under this policy, a clinical APC, brachytherapy APC, or new

technology APC with fewer than 100 claims per year would be designated as a low volume APC. For those items and services, CMS will use up to 4 years of claims data to establish a payment rate for each item or service as it currently does for low volume services assigned to New Technology APCs. The payment rate for a low volume APC will be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data. CMS also eliminates its low volume device-intensive procedure policy and subsumes the ratesetting issues associated with HCPCS code 0308T – the only code designated as a low volume device intensive procedure – within its broader low volume APC proposal. Consequently, CMS modifies its existing regulations at §416.171(b)(4) to apply its ASC payment rate limitation to services assigned to low volume APCs rather than low volume device-intensive procedures. This policy is consistent with the OPPS policy and is described in section X. C. of this summary.

Payment for Covered Ancillary Services

CMS finalizes its proposal to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. Under a new policy adopted in 2019, opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting are unpackaged and paid separately at ASP+6. For 2022, CMS finalizes it proposal to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under new §416.174. See section II. A. for more information on the specific drugs that qualify for separate payment. CMS also continues its policy to set the 2022 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for 2022 and subsequent year payment rates.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2022 by the annual deadline (March 1, 2021 due date, announced in last year's final rule). CMS is not making any change to its payment adjustment of $50 per lens for a 5-year period from the implementation date of a new NTIOL class.

F. Payment and Comment Indicators

CMS continues using the current comment indicators "NP" and "CH." Category I and III CPT codes that are new and revised for 2022 and any new and existing Level II HCPCS codes with substantial revisions were labeled "NP" to indicate that these codes are open for comment as part of the 2022 proposed rule.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators for 2022.

CMS did not receive any public comments on the proposed ASC payment and comment indicators and finalizes their use as proposed without modification.

G. Calculation of the ASC Payment Rates and ASC Conversion Factor

CMS continues to update relative weights using the national OPPS relative weights and the PFS non-facility PE RVU-based amounts when applicable. CMS scales the relative weights as under prior policy. Holding ASC use and mix of services constant, CMS computes the ratio of:

- Total payments using the 2021 relative payment rates, to
- Total payments using the 2022 relative payment rates.

The resulting ratio, 0.8552, is the weight scaler for 2022. The scaler applies to the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes. The scaler does not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights (e.g., drugs and biologicals that are separately paid and services that are contractor-priced or paid at reasonable cost in ASCs). The supporting data file is posted on the CMS Web site at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.

Updating the ASC Conversion Factor

CMS continues to compute the budget neutrality adjustment factor for provider level changes (notably for changes in wage index values) to the conversion factor in the same manner as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. Holding constant ASC use and mix of services in 2019 and the 2022 national payment rates after application of the weight scaler, CMS computes the ratio of:

- ASC payments using the 2021 ASC wage indices, to
- ASC payments using the 2022 ASC wage indices.

The resulting ratio, 0.9997, is the final wage index budget neutrality adjustment to the conversion factor for 2021.

To update ASC rates, CMS utilizes the hospital market basket update of 2.7 percent minus the MFP factor of 0.7 percent. This yields an update of 2.0 percent for ASCs meeting quality reporting requirements. CMS continues its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.3 percent for such ASCs. The resulting 2022 ASC conversion factor is $49.916 for ASCs reporting quality data, and $48.937 for those that do not, computed as follows:

	ASCs reporting quality data	ASCs not reporting quality data
2021 ASC conversion factor	$48.952	
Wage adjustment for budget neutrality	x 0.9997	
Net MFP-adjusted update	x 1.020	x 1.00
2022 ASC conversion factor	$49.916	$48.937

Impact

CMS provides the estimated aggregate increases for the six specialty groups that account for the most ASC utilization and spending, assuming the same mix of services from the 2019 claims data. (Table 85 of the final rule and reproduced below.) The eye surgical specialty group remains the largest source of payments, with -1 percent decrease in payments attributable to the changes being adopted for 2022. The second largest group, nervous system, is estimated to see a 2 percent increase.

Table 85 – Estimated Impact of the 2022 Update to the ASC Payment System on Aggregate 2022 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group		
Surgical Specialty Group	Estimated 2021 ASC Payments (in Millions)	Estimated 2022 Percent Change
Total	**$5,682**	**2%**
Eye	$1,918	-1%
Nervous system	$1,211	2%
Gastrointestinal	$948	2%
Musculoskeletal system	$727	3%
Cardiovascular	$280	6%
Genitourinary system	$213	3%

CMS provides estimated increases for 30 selected procedures in Table 86 in the final rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have no increase in payment. The second largest aggregate payment procedure, CPT code 63685, is expected to see a 2 percent increase.

Excerpt from Table 86: Estimated Impact of the Final 2022 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2021 ASC Payments (in Millions)	Estimate 2022 Percent Change
66984	Xcapsl ctrc rmvl w/o ecp	$1,293	0
63685	Insrt/redo spine n generator	$293	2
45380	Colonoscopy and biopsy	$251	3
45385	Colonoscopy w/lesion removal	$187	3
63650	Implant neuroelectrodes	$187	2
43239	Egd biopsy single/multiple	$186	2

Excerpt from Table 86: Estimated Impact of the Final 2022 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2021 ASC Payments (in Millions)	Estimate 2022 Percent Change
64483	Inj foramen epidural l/s	$122	3
66982	Xcapsl ctrc rmvl cplx wo ecp	$96	-1
64635	Destroy lumb/sac facet jnt	$86	3
64493	Inj paravert f jnt 1/s 1 lev	$79	3

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details; they are at https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1753-fc. They include:

- AA –ASC Covered Surgical Procedures for 2022 (Including surgical procedures for which payment is packaged)
- BB –ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2022 (Including Ancillary Services for Which Payment is Packaged)
- DD1 –ASC Payment Indicators for 2022
- DD2 –ASC Comment Indicators for 2022
- EE – Surgical Procedures to be Excluded from Payment in ASCs for 2022
- FF – Device Offset Percentages Calculated Under the Standard ASC Ratesetting Methodology

XIV. Advancing to Digital Quality Measurement and Fast Healthcare Interoperability (FHIR)

CMS requested input into the agency's planning for transformation to a fully digital quality enterprise by 2025, posing questions grouped into three categories: definition of digital quality measures; use of FHIR for current electronic clinical quality measures (eCQMs); and changes under consideration to advance digital quality measures.

Definition of Digital Quality Measures

CMS had formerly stated that digital quality measures (dQMs) use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems and advanced a broad view of sources (e.g., electronic health records (EHRs), patient-wearable devices), For this RFI, CMS offered an expanded dQM definition -- a software that processes digital data to produce one or more measure scores.

Commenters generally supported CMS' expanded dQM definition and intent to transition to digital quality assessment. Many suggested that providers be incented to adopt dQMs. High-level concerns were raised about readiness of providers and their technical capabilities as well as added burden imposed on providers during the transition. Some sought semantic clarifications of the expanded dQM definition. Feasibility of the proposed timeline for transition completion by 2025 was not universally accepted.

Use of FHIR for Current eCQMs
Changes under Consideration to Advance Digital Quality Measures

In the RFI CMS noted its ongoing collaboration with the Office of the National Coordinator (ONC) for Health Information Technology to identify health IT standards that would enable nationwide interoperable health information exchange (HIE). CMS and ONC have selected FHIR Release 4.0.1 as the standard to support policies related to application programming interfaces (APIs) for use during HIE. In this rule, CMS states an intent to align dQMs across its Promoting Interoperability programs for facilities and the Promoting Interoperability performance category of its Quality Payment Program for clinicians.

Support for the use of FHIR-based quality reporting was mixed, and some voiced concerns that not all EHR or health IT vendors have adopted FHIR. Burden and costs associated with FHIR adoption were seen as impediments to the dissemination of FHIR-based APIs. Safety and security concerns were expressed about APIs. Some commenters suggested that to facilitate interoperability, dQM data elements should conform to the elements and classes already adopted into the United States Core Data for Interoperability (USCDI). Some voiced support for designing dQMs as end-to-end self-contained tools. Strong support for measure alignment across CMS quality programs was expressed by many commenters, along with recommendations to expand the alignment to include federal, state, and other payer quality platforms. Some commenters supported a role for third-party data aggregators in facilitating nationwide HIE of data derived from many sources.

Many commenters viewed the CMS timeline for digital quality transformation to be ambitious, and several recommended a phased approach. Some suggested identifying existing measures that can be quickly modified to become dQMs as a first step, noting that CMS has been exploring conversion of existing eCQMs to FHIR-based reporting for several years. Several commenters recommend that a slower timeline be set for dQM reporting by Ambulatory Surgery Centers (ASCs), as many ASCs are at a less-developed stage of EHR implementation, having not received support for meaningful use under the American Recovery and Reinvestment Act of 2009.

CMS responds that all of the feedback provided to this RFI will inform the development of future regulatory proposals or other guidance as the agency moves to digital quality reporting.

XV. Hospital Outpatient Quality Reporting (OQR) Program

Section 1833(t)(17)(A) of the Act provides a 2.0 percentage point reduction in the annual Outpatient Department (OPD) fee schedule increase factor for any subsection (d) hospital that does not submit data as required for the OQR program's measures. In this rule, CMS reports a final conversion factor of $82.526 for hospitals failing to meet the OQR program's reporting requirements.

CMS finalizes the removal of two measures and the addition of three to the OQR program's measure set. The additions include the program's first electronic clinical quality measure

(eCQM) and a measure tracking COVID-19 vaccination rates among healthcare personnel. CMS also finalizes restoring two measures to active use in the program's measure set; these measures were previously adopted but their implementation dates were delayed.

To operationalize the new eCQM, CMS finalizes as proposed policies applicable to this and any future OQR eCQMs (e.g., technical specifications updates, review and corrections period). Changes to the program's policy for extraordinary circumstances exceptions (ECE) also are finalized as proposed to extend the policy's applicability to eCQMs.

No changes were proposed 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; or requirements for participation in and withdrawal from the OQR program.

Finally, CMS reviews comments and provides responses related to three Requests for Information (RFIs) about potential future OQR program changes that were included in the proposed rule. These RFIs posed questions about measures addressing transitions in care settings, patient reported outcomes after primary elective lower extremity joint replacement, and efforts to address health equity through the hospital OQR program.

A. OQR Program Measure Changes

1. Measure Removal: 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 finalizes as proposed the removal of two chart-abstracted 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). Both measures address optimal initial treatment of possible myocardial infarction; later in this rule, CMS finalizes the adoption of an eCQM that deals more broadly with the same topic.

Most commenters were supportive. Concern was expressed about increasing burden for smaller and more rural hospitals with fewer electronic reporting resources by replacing chart-abstracted measures with an eCQM. Delayed removal of the two measures and delayed adoption of their successor eCQM for one year were suggested to allow hospitals sufficient time to implement the successor eCQM and for the eCQM to gain endorsement from the National Quality Forum (NQF).

CMS states its belief that adopting eCQMs into the OQR program advances the agency's overall strategic goals of expanding its eCQM portfolio and reducing reporting burden. CMS notes that reporting of the successor eCQM is voluntary for 2023, allowing hospitals an additional year to prepare before reporting becomes mandatory beginning with 2024. The agency further responds that small and rural hospitals may be exempt from reporting the eCQM if their clinical volumes

fail to satisfy the case minimum for the measure (i.e., a "case threshold exemption", discussed in section XV.D.6.d.(3) of the rule and later in this summary). Finally, CMS also notes that the successor eCQM has been supported for rulemaking by the Measure Applications Partnership (MAP) contingent upon NQF endorsement and that NQF endorsement is being sought.

2. Measure Additions

a. COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

CMS finalizes adding the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure to the OQR program's measure set for reporting beginning with the 2022 reporting period/2024 payment determination. The pay-for-reporting measure is designated as OP-38 and tracks hospital reporting of vaccination rates. CMS modifies the proposed measure reporting process such that data will be reported by each facility to the CDC's National Health Safety Network (NHSN) by its enrolled facility OrgID. CDC will then roll up the data at the CMS Certification Number (CCN) level before transmitting the results to CMS.[21]

CMS also finalizes, with modification, its proposal for public reporting of the COVID Vaccination HCP measure results on *Care Compare*; results are scheduled to first appear with the October 2022 website data refresh. Only results from the most recent quarter will be displayed, rather than showing results from the most recent four quarters on a rolling basis as proposed. The results will be displayed at the CCN level, as transmitted from CDC to CMS.

Commenters supported the potential public health value of the COVID Vaccination HCP measure's results. Several concerns were raised, including the following:

- Measure adoption is premature since it is not NQF-endorsed, vaccines have not yet received full FDA authorization, and measure specifications would soon need revision to accommodate booster dose recommendations.
- Measure adoption pressures hospitals to coerce or to require employees to be vaccinated.
- Results reporting should be confidential to hospitals rather than publicly available until hospitals gain experience with the measure.
- Monthly data collection and quarterly reporting frequency, plus required reporting at the CCN level rather than facility level, is excessively burdensome.

CMS responses include the following:

- Secretarial discretion for measure addition (sections 1833(t)(17)(C)(i) and (ii) of the Act) permits the addition of measures without NQF endorsement, and CDC has submitted the measure for the fall 2021 endorsement cycle.
- The vaccines were rigorously tested prior to FDA Emergency Use Authorization and have since been awarded full use authorization for most age groups.

21 A Data Tracking Worksheet for COVID-19 Vaccination among Healthcare Personnel is available from CDC to help hospitals log and track their numbers of vaccinated HCP. The worksheet will automatically create a Reporting Summary for submission to the NHSN.

- The measure numerator clearly specifies a completed vaccine course without booster doses and awaiting definitive booster recommendations would delay timely adoption of a significant public health measure.
- Hospitals are not being pressured since the measure simply tracks whether vaccination rates have been reported; facilities are not scored on their vaccination rates and no payment reductions would occur based on the rates themselves.
- The measure results are of significant interest and value for beneficiaries as well as important to the public as a metric of the impact of vaccination, so that public display of the measure results should not be delayed.

Further, in response to comments concerning reporting burden, CMS adopts two modifications to its proposal. First, the measure results to be publicly displayed will be aligned with the requirement recently finalized in the FY 2022 IPPS/LTCH final rule; namely, only the single most recent quarter's results will be made public. Second, hospitals will report to CDC using their NHSN identifier (Org ID), and CDC will aggregate the data by CCN for transmission to CMS to be used for public display at the CCN level.

b. Breast Screening Recall Rates

CMS finalizes adding the claims-based Breast Cancer Screening Recall Rates measure to the OQR measure set for reporting beginning with the 2023 reporting period/2025 payment determination. The measure is designated as OP-39 and tracks the rates at which patients are recalled for further imaging after initial screening mammography. CMS refines the measure name from Breast Screening Recall rates as appeared in the proposed rule but adopts no other modifications.

Many commenters were supportive. Concerns raised included lack of NQF endorsement and quality of the measure's evidence base as well as the impact of data collected during the COVID-19 PHE on the measure's results. A recommendation was made for risk-adjustment for variable access to mammography due to demographic and social risk factors.

CMS responds that the measure was conditionally supported the measure for rulemaking by the MAP, contingent upon NQF endorsement. However, to fill the measure gap left by removal of the prior OQR program measure Mammography Follow-up Rates (OP-9), CMS finalizes adding the new measure prior to seeking NQF endorsement, having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical. CMS notes that a technical expert panel (TEP) was convened and a stakeholder listening session held to develop the measure's specifications based on available pertinent evidence.

CMS further notes that Q1 and Q2 2020 data will be excluded from the measure's first performance period, consistent with the CMS suspension of quality data collection during those quarters due to the PHE's impact.[22] Finally, CMS states its concern that adjustment for social

22 For the 2023 payment determination, CMS will use final claims from July 1, 2020, to June 30, 2021. For each subsequent year, the claims data collection period will be from July 1 through June 30, and the period will start on July 1 in the year that is 3 years prior to the applicable payment determination.

risk factors could mask potentially important inequities, but will monitor the results to assess the need for future risk adjustment.

c. ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

CMS finalizes adding as proposed the new ST-Segment Elevation Myocardial Infarction (STEMI) eCQM to the OQR program's measure set for voluntary reporting during the 2023 reporting period and mandatory reporting beginning with the 2024 reporting period/2026 payment determination. The measure, designated as OP-40, tracks the percentage of Emergency Department (ED) patients with diagnoses of STEMI who received timely delivery -- absent contraindications -- of guideline-based reperfusion therapies appropriate for the care setting. It replaces two measures related to the topic of initial therapy for STEMI that have been finalized for removal earlier in this rule (as described above): 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).

Many commenters supported adding the new measure as a replacement for OP-2 and OP-3 and the phased introduction OP-40 first as a voluntary measure for a year before its reporting becomes mandatory. Concerns were voiced about NQF endorsement and about costs and burden for hospitals as they implement the OQR program's first eCQM measure.

CMS responds that OP-40 was conditionally supported by the MAP for rulemaking, contingent upon NQF endorsement. The measure was submitted to NQF in January 2021 and, having passed the NQF's Cardiovascular Standing Committee, it will be reviewed by the NQF's Consensus Standards Advisory Committee later in 2021. CMS has decided to proceed with measure adoption without final NQF endorsement given the superiority of the new measure over available extant measures and the public health importance of the measure topic.

CMS acknowledges potential costs and burden to hospitals with implementing the OQR program's first electronic measure. The agency reiterates the phased implementation plan for OP-40 and points out that hospitals are already quite familiar with eCQM reporting processes through the Hospital Inpatient Quality Reporting Program (IQR).

Finally, CMS clarifies that the contraindications to fibrinolytic therapy for which STEMI patients would be excluded from the measure's patient population (e.g., ischemic stroke) are listed on the eCQI Resource Center (https://ecqi.healthit.gov/ecqm/eh/oqr/2023/cms996v2).

Reporting Requirements for the STEMI eCQM

CMS finalizes as proposed a phased, progressive approach to STEMI eCQM reporting and data submission requirements as shown in the table below. The number of required reporting quarters will be increased by one quarter annually until full year (4-quarter) reporting is reached beginning with reporting period 2027/payment determination 2028, after which full year reporting continues for subsequent years.

HPA Table XV-1. STEMI eCQM Phased Reporting Requirements*		
Calendar Periods	**Reporting Quarters Required**	**Measure Status**
2023 Reporting / 2025 Payment	Any quarter(s)	Voluntary
2024 Reporting / 2026 Payment	One self-selected quarter	Mandatory
2025 Reporting / 2027 Payment	Two self-selected quarters	Mandatory
2026 Reporting / 2028 Payment	Three self-selected quarters	Mandatory
2027 Reporting / 2029 Payment and subsequent years	Four quarters (full year)	Mandatory
* Table 68 reproduced from the rule with modifications by HPA		

Commenters suggested more rapid progression and that reporting quarters be CMS-specified rather than self-selected by hospitals. CMS states that the more gradual and flexible proposed schedule better is less burdensome and allows hospitals to gain experience with eCQM reporting under the OQR program.

3. Modifications to Previously Adopted Measures

a. Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536)

CMS finalizes with modification its proposal to restore OP-31 Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery to the OQR program's measure set for required reporting. As modified, required reporting instead will begin with reporting period 2025/payment determination 2027 rather than reporting period 2023/payment determination 2025 as proposed. Additionally, CMS finalizes as proposed that OP-31 will be reported through a CMS web-based tool according to existing policies for the Hospital Quality Reporting (HQR) System (formerly known as the QualityNet Secure Portal).

OP-31 uses pre- and post-operative visual function survey results to assess the percentage of patients aged 18 years and older who have had cataract surgery and believe that they have improved visual function within 90 days following the cataract surgery. The measure was first finalized for adoption into the OQR program's measure set beginning with the 2016 payment determination, but implementation subsequently was delayed due to concerns about visual function survey administration burden and inconsistencies among the multiple validated surveys permitted for use. CMS first excluded but did not permanently remove the measure from the OQR program's measure set for the 2016 payment determination and subsequent years, then permitted voluntary reporting beginning with the 2017 payment determination.

Support from commenters about restoring mandatory reporting of OP-31 was divided. Some suggested that the measure was designed for physician-level reporting and therefore should be considered instead for inclusion in Medicare's physician quality programs. Others objected to the associated measure burden due to complexity of data sharing among physicians and hospital outpatient departments and the lack of standardization among permissible surveys.

CMS disagrees with commenters and notes that several facilities have consistently been able to report results voluntarily for multiple years. CMS refers to a published paper showing that all of the permissible visual function surveys are able to detect clinically important vision changes. The

agency emphasizes that the surveys measure patient-reported visual function, not visual acuity as measured by an eye care professional. In response to the burden concerns expressed, CMS modifies its proposal and delays the start date for OP-31 mandatory reporting to the 2025 reporting period/2027 payment determination.

No comments were received regarding the proposal for measure submission via the HQRS.

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

CMS finalizes its proposal to implement reporting of the OAS CAHPS OP-37a-e measure set as part of the OQR program. Voluntary reporting will begin for the 2023 reporting period followed by mandatory reporting beginning with the 2024 reporting period/2026 payment determination. The survey measure set contains includes five measures designed to assess a patient's experience with care following certain procedures or operations performed in the hospital outpatient department (HOPD) setting.

The five measures target patient experiences with the facilities and staff, efficacy of communication about the procedure, adequacy of patient preparation for discharge and postoperative recovery, overall rating of the facility, and whether the patient would recommend the facility to others. The 5-measure set was first adopted into the OQR program during 2017 OPPS/ASC rulemaking, for use beginning with the 2020 payment determination. However, CMS later delayed implementation indefinitely to allow time for further accrual of operational experience and implementation data from the National OAS CAHPS voluntary reporting program that had started in 2016.

Some commenters were supportive of restoring the OAS CAHPS 5-measure set to the OQR program as required measures. Others were opposed; their major concerns related to 1) survey reliability and design (e.g., too long, overlap with CAHPS versions for other sites of care); and 2) survey-related administrative burden and costs, especially those accruing from the requirement for survey administration by a third-party vendor.

CMS states that survey reliability has been confirmed by results generated under the National OAS CAHPS voluntary reporting program.[23] CMS also states that the most recent nonresponse rate due to terminated telephone survey interviews, a measure of survey fatigue, is under 1 percent. Finally, the agency asserts that the Survey Instructions materials for each CAHPS version are sufficiently clear to permit patients to correctly identify the healthcare encounters about which they are being surveyed.

CMS acknowledges that some burden and costs are inherent to OP-37-a-e survey administration but emphasizes that the value of the patient experience of care data acquired outweighs the burden and costs. The agency also notes the use of third-party vendors avoids bias that would otherwise be introduced if patients were surveyed directly by the treating facility, thus limiting

23 Information about the National OAS CAHPS voluntary reporting program may be found at https://oascahps.org/General-Information/National-Implementation and https://oascahps.org/Training/Training-Materials.

the value of the data collected. Third party vendor involvement also facilitates maintaining confidentiality of patient responses. CMS provides a hyperlink to the full list of approved OAS CAHPS vendors to facilitate vendor comparisons by hospitals (https://oascahps.org).

Updated OAS CAHPS Reporting Requirements

Relatedly, CMS finalizes as proposed the addition of two survey data collection modes -- web-based with either mail or telephone follow-up of non-respondents – to the three existing survey modes beginning with the 2023 reporting period/2025 payment determination -- mail-only, telephone-only, and mixed (i.e., mail with telephone follow-up of non-respondents). CMS also finalizes as proposed for all five survey modes that:

- Hospitals that are required to report must do so through a CMS-approved survey vendor; no new vendor requirements were proposed.
- Data collection must be initiated no later than 21 calendar days after the month in which the index procedure or operation occurred and must be completed within 42 days after efforts at initial contact of an eligible patient begin.
- 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.
    - Data must be reported for all locations that offer outpatient services; reporting is at the hospital CCN level.
    - The low-volume exemption is potentially applicable to hospitals with fewer than 60 survey-eligible patients during the calendar year just prior to the data collection period and requires CMS approval 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 web site or survey their entire eligible patient population.

Commenters supported the use of web-based technology into permissible survey administration modes. Several recommended that CMS add a web-only mode. Also suggested were web with mail or telephone follow-up for nonrespondents. Many suggested that CMS monitor all modes with regards to reliability and refine the survey items as needed.

CMS expresses concern that a web-only mode would create response bias based on Internet availability and patient's computer literacy, though will continue to consider this option. CMS also indicates an intention to explore other modes and to monitor the results from all modes. Finally, in response to a commenter, CMS clarifies that payments to a hospital will not be reduced for patient refusals to complete surveys, as long as the hospital's survey vendor has properly administered the survey and has submitted all data from completed surveys to CMS by the submission deadline.

4. Finalized Hospital OQR Program Measure Set by Payment Determination Years

The table below shows the OQR program's newly finalized measure set by payment determination year for 2021 through 2026.

TABLE HPA XV-2. Hospital OQR Program Measures by Payment Determination Year
CY 2022 final rule changes are shown in Italic Font *X* for first payment determination year
(Created by HPA from Tables 63-66 in the final rule and other sources)

NQF	Measure	2021	2022	2023	2024	2025	2026
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X	Removed	
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	Removed	
0289+	OP-5: Median Time to ECG	Removed					
0514+	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X	X
	OP-9: Mammography Follow-up Rates	Removed					
	OP-10: Abdomen CT – Use of Contrast Material	X	X	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	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	X	X
0499+	OP-22: ED- Left Without Being Seen	X	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	X
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Removed					

TABLE HPA XV-2. Hospital OQR Program Measures by Payment Determination Year
CY 2022 final rule changes are shown in Italic Font *X* for first payment determination year
(Created by HPA from Tables 63-66 in the final rule and other sources)

NQF	Measure	2021	2022	2023	2024	2025	2026
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery[a]					*Delayed to 2027*	*Delayed to 2027*
2539	OP-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X	X
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	Removed				
	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery	X	X	X	X	X	X
	OP-37a-e Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures[b]					*Voluntary*	X
	OP-38 COVID-19 Vaccination Coverage Health Care Personnel				*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.
[a] Mandatory reporting of this measure was originally adopted for the CY 2016 payment determination (78 FR 75102 through 75104). OP-31 was later excluded temporarily from the measure set beginning with the CY 2016 payment determination, but voluntary reporting of this measure was allowed beginning with the CY 2017 payment determination (79 FR 66947 through 66948). Mandatory reporting beginning with the CY 2023 payment determination was proposed (86 FR 42247) but in response to comments is now finalized to begin with the CY 2025 reporting period/CY 2027 payment determination.
[b] Mandatory reporting on a set of OAS CAHPS measures, once scheduled to begin in 2018 for the 2020 payment determination, was indefinitely delayed (82 FR 59432). The measures are OP-37a: OAS CAHPS – About Facilities and Staff; OP-37b: OAS CAHPS – Communication About Procedure; OP-37c: OAS CAHPS – Preparation for Discharge and Recovery; OP-37d: OAS CAHPS – Overall Rating of Facility; and OP-37e: OAS CAHPS – Recommendation of Facility. CMS implemented a voluntary national reporting program for the OAS CAHPS Survey in January 2016; ore information is available at https://oascahps.org/General-Information/National-Implementation. Voluntary reporting is now finalized for the 2023 reporting period, with mandatory reporting to begin with reporting period 2024/payment determination 2026.

B. Policies for Electronic Clinical Quality Measure (eCQM) Reporting

1. Technical Specifications

CMS finalizes as proposed that eCQM technical specifications related to the OQR program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs. The Annual Update will include specification updates and guidance for hospitals and electronic health record (EHR) about data collection and submission from hospital EHRs. The Annual Update and its associated implementation guidance documents are available through the eCQM resource center website at https://ecqi.healthit.gov.

2. Reporting Process Requirements and Data Submission Deadline

CMS finalizes several eCQM reporting process requirements to begin with the 2023 reporting period/2025 payment determination and continue for subsequent years. Hospitals will be required:

- To register and submit data through the HQR system;
- To use CEHRT updated to the 2015 Edition Cures Update; and
- 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 will 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 notes having received either no or only supportive comments on the above requirements.

Additionally, CMS finalizes an OQR program submission deadline for eCQM data of May 15 in the CY following the close of the program's applicable reporting period. CMS had proposed to use either February 29, to align with the Hospital IQR Program and Medicare Promoting Interoperability Program deadline, or May 15, to align with the OQR program's data submission deadline for measures reported via the program's web-based tool. The sole commenter favored alignment with the IQR program but CMS instead finalizes the May 15 deadline to allow hospitals more time each year to review and submit their data.

3. eCQM Reporting for Hospitals with Low Data Volumes

CMS finalizes policies for two low-data-volume scenarios: 1) when a hospital has no data to report for a specific eCQM (zero denominator declaration); and 2) when a hospital does not meet the case threshold of discharges for a specific eCQM (case threshold exemption).

When a hospital has zero patients meeting the denominator criteria of a given eCQM, the hospital can submit a zero denominator for the measure. A zero denominator declaration counts as a successful submission for that eCQM.

When a hospital has 1) reportable patients but not enough to satisfy a measure's denominator threshold criterion (case minimum) and 2) the hospital has five or fewer outpatient all-payer discharges to which the measure is applicable for the reporting quarter (or 20 or fewer for the year), the hospital may declare a case threshold exemption from reporting for that eCQM.

CMS notes that the sole commenter was supportive of the proposed policies.

C. Review and Corrections Periods and Educational Review Process

CMS finalizes as proposed a new review and corrections period for OQR program 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 will be able to run pre-submission test files as well as submit and review their actual data files and make corrections.

CMS notes receiving no comment on this proposal. CMS further notes that no changes were proposed to the data review and corrections period policies for chart-abstracted measures, measures submitted via the CMS web-based tool (HQR system), or OAS CAHPS measures.

D. Hospital OQR Program Validation Requirements

CMS finalizes as proposed the changes listed below to the OQR program's data validation process beginning with the 2022 reporting period/2024 payment determination and for subsequent years. These changes will align the OQR and IQR validation process requirements.

- Discontinues 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 will be permitted.
- Reduces the time period given to hospitals to submit records for validation to the CDAC contractor from 45 to 30 calendar days.
- Adds to the targeting criteria used to select additional hospitals for validation.
    - Current criteria will be retained: 1) having failed the previous year's validation or 2) having an outlier value for a measure.
    - Newly finalized criteria are: 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 percent. The latter criterion identifies hospitals whose accuracy falls within the statistical margin of error, and captures both passing and failing facilities.

Each change was supported by some commenters. Concern was expressed about reducing the time allowed for submitting records for validation to the CDAC. Refinements to the additional validation targeting criteria were suggested, including that a hospital may not be selected simultaneously for validation under both the OQR and IQR programs.

CMS refers to CDAC data showing that the majority of hospitals selected for OQR program data validation already complete their data submissions in less than 30 calendar days. CMS states that simultaneous selection for OQR and IQR data validation is uncommon, ranging from 10 to 15 hospitals annually. The agency further states that the actual case records initially chosen for simultaneous validation processes are reviewed to remove overlapping record requests.

E. Extraordinary Circumstances Exception (ECE) Policy

CMS finalizes as proposed expansion of the OQR program's ECE policy to cover eCQMs. Hospitals will be allowed to request hardship exceptions (e.g., due to insufficient internet access, health IT vendor loss of certification) from required eCQM reporting beginning with the 2024 reporting period. Exceptions must 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).

All comments received were supportive of ECE policy expansion to cover eCQMs.

F. Penalty for Hospitals that Fail to Meet OQR Program Requirements

CMS finalizes as proposed to continue its established policies for computing and applying the statutory payment reduction to the 2022 update factor for hospitals that fail to meet the Hospital OQR Program reporting requirements. CMS also finalizes as proposed to begin calculating the reporting ratio to four decimals for 2022 and subsequent years rather than the current three decimal places.

Payments to hospitals satisfying the OQR Program's requirements are determined using the "full conversion factor", based on a full annual update factor increase, while payments to hospitals failing to meet requirements use a "reduced conversion factor", based on a 2 percent reduction to the full update factor increase. A "reporting ratio", equal to the reduced conversion factor divided by the full conversion factor, is applied to OPPS payments to failing hospitals for HOPD services to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, but excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T. Per established policy, the reporting ratio is applicable to beneficiary copayments.

For the 2022 reporting period, CMS announces a final reporting ratio of 0.9804. Multiplication of the final full conversion factor of $84.177 by the final reporting ratio produces a final reduced conversion factor of $82.526, applicable to hospitals failing to meet the OQR program's reporting requirements. CMS states having assumed for CY 2022 economic impact modeling purposes that the number of hospitals failing to meet requirements for 2022 payment will be the same as the number who failed for CY 2021 -- 77 of 3,163 hospitals.

G. Requests for Comment

1. Measures Addressing Transitions in Care Settings

In the proposed rule, CMS stated that continued advances in surgical techniques and medical technology likely will support appropriate further evolution of care delivery from inpatient to outpatient settings. CMS, therefore, requested comment on the potential future adoption of measures that assess quality of care for services whose delivery is shifting from inpatient to HOPD settings.

In this final rule, CMS reports having received numerous suggestions for measures to address care setting transitions. Multiple commenters recommended the adoption of several Ambulatory Surgery Center Quality Reporting Program (ASC QRP) measures into the Hospital OQR Program, such as wrong side surgery and patient fall. Commenters argued that a set of measures aligned across settings that are relevant to both settings would facilitate comparisons of quality for procedures that may be performed in both settings. Another group of commenters recommended that CMS focus on development of patient-reported outcome-based measures and patient experience-of-care measures as a superior means of obtaining direct, patient-centered feedback. Others urged CMS to consider measures addressing a wide variety of quality topic areas (e.g., nutrition, breast screening tests) and look for opportunities to assess potential inequities.

CMS indicates that the feedback provided will inform future OQR program rulemaking.

2. Patient Reported Outcomes after Primary Elective Lower Extremity Joint Replacement

Elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) are high-volume procedures among Medicare beneficiaries. Once performed exclusively on an inpatient basis, both are transitioning to outpatient performance and Medicare reimburses for their performance in HOPDs. In the proposed rule, CMS requested input on measures relevant to safe and successful performance of these procedures, including the utility of measures aligned across all potential care settings (i.e., inpatient hospital, HOPD, and ASC). CMS specifically asked whether the NQF #3559 Hospital-Level Elective Primary THA/TKA patient-reported outcome-based performance measure (PRO-PM) could be respecified for use in outpatient settings. The measure uses validated questionnaires administered pre- and postoperatively to assess patient-reported pain and functional outcomes on standardized scales.

Multiple commenters were supportive of adding a measure based on NQF #3559 to the OQR program's measure set. A few were strongly opposed, citing excess burden for clinicians and HOPDs, particularly that caused by postoperative questionnaire administration that is repeated at intervals during a 12-month follow-up period. Leveraging provider participation in the existing the American Joint Replacement Registry was suggested as a means of cost mitigation for providers. Some commenters noted the difficulties encountered with use of a similar measure in CMS' Comprehensive Care for Joint Replacement (CJR) model, especially the high completed questionnaire submission rates that are required for scoring under that model. Other commenters described the generally sicker, more frail patient population operated upon as inpatients and emphasize the importance of accurate risk adjustment of measures, to include social risk factors. Some commenters asserted that any future THA/TKA measure be designed to measure outcomes at the clinician level.

CMS notes that the data submission requirements of the CJR model's THA/TKA PRO-PM measure were gradually increased over time to allow model participants to gradually build up the infrastructure needed to support reporting this measure. CMS adds that this measure was carefully considered before its selection for inclusion in the CJR model because of its low patient burden and lack of survey fatigue. CMS agrees that the differences described in the inpatient versus outpatient THA/TKA populations will require careful attention to risk adjustment for each

care delivery setting. CMS notes that its analysis showed greater effect of social risk factors on whether patients completed the PRO surveys than on actual clinical outcomes. CMS indicates that the feedback provided to this RFI will inform future policy development.

3. Potential Future Efforts to Address Health Equity in the Hospital OQR Program

As part of its initiative to address health inequities across the entire CMS quality enterprise, including the OQR program, the agency invited input through the proposed rule on incorporating quality measure results reporting stratified by demographic and social risk factors into the OQR program; the use of dually eligible status as a proxy for social risk; confidential followed by public reporting of stratified results; using indirect estimation as a technique to impute missing patient demographic data; collection by the HOPD from patients on the day of service of a standardized set of demographic and social risk factor data; and designing a Facility Equity Score for OQR program participants to be publicly reported.

Many commenters offered conceptual support for and general advice about efforts by CMS to promote health equity (e.g., obtaining robust stakeholder input), without answering the more granular questions raised by CMS (e.g., the value of reporting stratified results for the OQR program's "Abdomen CT-Use of Contrast Material" measure).

Support was expressed for reporting results stratified by demographic and social risk factors with the use of pilot testing to identify measures and risk factors more likely to yield significant and actionable data. Many commenters expressed concern over the added burden and costs of required reporting on new measures and of voluminous data collection from patients. Some commenters supported one or more of the six OQR program's measures suggested by CMS as high-priority items for stratified reporting. Concerns were cited about the current lack of timely feedback about measure results from CMS to HOPDs.

Some commenters supported the use of indirect estimation techniques for imputing missing values in various CMS datasets, while others questioned the validity of imputed data and the potential for inherent bias in such data. Support for expanded data collection from patients by HOPDs was mixed; some commenters stated that CMS and other payers were better suited to this activity. Others suggested multiple putative risk factors for collection by HOPDs. Concerns were raised about patient privacy, data confidentiality, and data security. Most commenters did not support development of a Facility Equity Score.

CMS responds by stating its commitment to prioritize minimizing provider burden imposed by its efforts to improve equity and to ensure stakeholder involvement in all such initiatives. CMS notes that the six OQR program measures it has identified as good candidates for stratified reporting are claims-based and calculated by CMS, so that burden added by their stratified reporting would be minimal for facilities. The agency also states an intent to begin confidential reporting to hospitals of some of these measures with results stratified by dual eligibility status during the upcoming year. CMS ends by noting that the feedback received from all commenters will be considered during future policy development.

XVI. Ambulatory Surgery Center Quality Reporting (ASCQR) Program

The Ambulatory Surgery Center Quality Reporting (ASCQR) Program is authorized under sections 1833(i)(2)(D)(iv) and (i)(7) of the Act. Payment determinations are linked to a quality reporting period that occurs two years in advance of the payment determination year (i.e., 2022 reporting determines 2024 payment). A 2.0 percentage point reduction to the update factor is applied to payments to ASCs that fail to meet all of the program's quality reporting requirements. An exemption from program participation and payment reduction is given to ASCs having fewer than 240 Medicare claims per year during an annual reporting period (the minimum case volume threshold).[24]

In this rule, CMS finalizes adoption of one new ASC QRP measure and resumption of reporting for four previously suspended safety measures. CMS also modifies the reporting status of a measure related to cataract surgery outcomes and the 5-item patient experience survey Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS).

No changes were proposed to previously finalized ASC QRP policies for measure selection, retention, and removal; standard adjustments of program deadlines for holidays; the review and corrections period for data submitted via the CMS web-based tool; reconsiderations; extraordinary circumstances exceptions (ECE); public reporting; ASC QRP participation status requirements; data collection methods and submission types; and administrative requirements for designating a security official to be responsible for an ASC's QualityNet account maintenance.

CMS shares stakeholder responses to requests for comments on topics including the role of ASC quality measures in identifying health disparities and development of measures applicable to pain management procedures performed in ASCs.

A summary table of ASCQR measures appears at section XVI.D of this summary. Full measure specifications can be downloaded at https://qualitynet.cms.gov/asc/ascqr.

A. ASCQR Program Measure Changes

1. Measure Addition: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

CMS finalizes adding the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure to the ASC QRP's measure set for reporting beginning with the 2022 reporting period/2024 payment determination. The pay-for-reporting measure is designated as ASC-20 and

24 ASCs may also elect to withdraw from ASCQR program participation for a year but will be subject to the 2.0 percent payment reduction for that year. To withdraw, an ASC must submit a completed withdrawal request to CMS before or on August 31 of the year just prior to the payment determination year for which withdrawal is being sought.

simply tracks ASC reporting of vaccinated personnel; it does not score the measure based on the percentage of staff members vaccinated.
CMS also finalizes, with modification, its proposal for public reporting of ASC-20 results. Only results from the most recent quarter will be displayed, rather than those from the most recent four quarters on a rolling basis as was proposed. The policy to display only a single quarter of ASC data aligns with policies recently adopted for the hospital inpatient and outpatient quality reporting programs (IQR and OQR programs, respectively). Results will be displayed at the CCN level, as calculated by the CDC and transmitted to CMS quarterly.

Commenters supported the potential public health value of ASC-20 measure results. Several concerns were raised, including the following:

- ASCs have not been shown to contribute to the spread of COVID-19 infections, based on low test positivity results within two weeks after procedures performed in ASCs.
- Measure adoption is premature since it is not NQF-endorsed, vaccines have not yet received full FDA authorization, and measure specifications would soon need revision to accommodate booster dose recommendations.
- Measure adoption pressures facilities to coerce or require employees to be vaccinated, and required vaccination would conflict with equal employment opportunity (EEO) laws.
- Monthly data collection and quarterly reporting frequency, plus required reporting to CDC via the NHSN at the CCN level rather than using each ASC's billing NPI, is excessively burdensome.
- ASC quality data are difficult for consumers to locate.

CMS responses include the following:

- The ASC test positivity survey data cited by commenters were collected early in the PHE and cannot be generalized to later time periods.
- Secretarial discretion for ASC QRP measure addition (sections 1833(t)(17) and 1833(i)(7)(B) of the Act) permits the addition of measures without NQF endorsement, and CDC has submitted the measure for the fall 2021 endorsement cycle.
- The vaccines were rigorously tested prior to FDA Emergency Use Authorization and have since been awarded full use authorization for most age groups.
- The measure numerator is written sufficiently broadly to include future boosters once clear recommendations emerge; awaiting definitive booster recommendations would delay timely adoption of a significant public health measure.
- Facilities are not being pressured since the measure simply tracks whether vaccination rates have been reported; ASCs are not scored on their actual staff vaccination rates and no payment reductions would occur based on those vaccination rates. There is no conflict with EEO laws; see recently issued guidance available at https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.
- Although there are no ASC QRP measures currently reported through the NHSN, ASCs have previously been required to submit data through the NHSN (e.g., ASC HCP influenza vaccination), so that ASCs do have experience with NHSN reporting processes. Resources available from the CDC can streamline reporting and reduce burden, including

a look-up tool mapping NPI to CCN (https://www.qualityreportingcenter.com/en/ascqr-program/data-dashboard/ccn).
- The measure results are of significant interest and value for beneficiaries in choosing among ASCs as well as important to the public as a metric of the impact of vaccination; hence, public display of the measure results should not be delayed.
- CMS is seeking an alternate site to which ASC quality data can be added for public reporting, as the current location on the CMS Provider Data Catalog is difficult for consumers to navigate.

2. Modifications to the Status of Previously Adopted Measures

a. Patient Burn (ASC-1), Patient Fall (ASC-2), Wrong Site/Wrong Side/Wrong Patient/Wrong Procedure/Wrong Implant (ASC-3), and All-Cause Hospital Transfer/Admission (ASC-4)

CMS finalizes its proposal to return four previously adopted but subsequently suspended ASC QRP measures to the program's data set: Patient Burn (ASC-1), Patient Fall (ASC-2), Wrong Site/Wrong Side/Wrong Patient/Wrong Procedure/Wrong Implant (ASC-3), and All-Cause Hospital Transfer/Admission (ASC-4). CMS also finalizes that data submission will be through its web-based Hospital Quality Reporting (HQR) System, previously known as the QualityNet Secure Portal.

The measures were adopted beginning with 2014 payment determinations but proposed for removal beginning with 2021 payment determinations because they had become topped out. Stakeholders strongly objected to removal, citing the important safety data applicable to all ASCs that were generated and publicly reported from these measures. Measure removal therefore was suspended rather than finalized in the CY 2019 OPPS/ASC final rule.

CMS provides two clarifications in response to commenter queries. First, data collection will resume beginning in 2023 with data reporting in 2024 and use for ASC payment determinations in 2025. Second, consistent with other measures reported using the HQR System, the measures' denominators now will include all ASC admissions, rather than only Medicare FFS beneficiaries as occurred previously with QDC claims-based data submission.

CMS adds that most commenters supported return of these four ASC QRP measures to active reporting. A few were opposed based on loss of NQF endorsement. Batch data submission using the HQR System was described as problematic.

CMS responds that NQF endorsement was not withdrawn, but lapsed for lack of routine measure maintenance. The agency believes that continued use of the measures by the Ambulatory Surgical Center Association's members for benchmarking provides evidence of stakeholder consensus about the value of these measures, even though NQF endorsement has lapsed and the measures meet the criteria for topped out designation. CMS reports that restoring the batch submission functionality of the HQR System is in progress. Finally, CMS highlights that web-based submission allows data review and correction by ASCs up until the submission deadline, a

process that was not feasible previously with QDC claims-based submission under which paid claims were no longer available for correction.

b. Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11) (NQF #1536)

CMS finalizes with modification its proposal to restore ASC-11 Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery to the ASC QRP measure set for required reporting. As modified, required reporting will begin with reporting period 2025/payment determination 2027 rather than reporting period 2023/payment determination 2025 as proposed. CMS notes that the submission mechanism for ASC-11 has been previously established to be the CMS web-based tool (HQR System).

ASC-11 uses pre- and post-operative visual function survey results to assess the percentage of patients aged 18 years and older who have had cataract surgery and believe that they have improved visual function within 90 days following the cataract surgery. The measure was first finalized for adoption into the ASC QRP measure set beginning with the 2016 payment determination, but implementation subsequently was delayed due to concerns related to the burden of visual function survey administration and inconsistencies among the multiple validated surveys permitted for use. In response, CMS first excluded but did not permanently remove the measure from the program's measure set for the 2016 payment determination and subsequent years, then permitted voluntary reporting beginning with the 2017 payment determination.

Many commenters did not support restoring mandatory reporting of ASC-11. Some suggested that the measure was designed for physician-level reporting and therefore should be considered instead for inclusion in Medicare's physician quality programs. Others objected to the associated burden of data sharing among physicians and hospital outpatient departments and to the lack of standardization among permissible surveys. Many perceived that most hospitals had not been voluntarily reporting the measure and had limited experience with its successful implementation.

CMS responds that several facilities have consistently been able to report results voluntarily for multiple years. However, the agency does acknowledge that physician-ASC collaboration is required for successful reporting and modifies the start date of mandatory reporting to be the 2025 reporting period/2027 payment determination. CMS believes that the additional two years will be sufficient for physicians and ASCs to develop and implement data-sharing processes.

CMS refers to a published paper showing that all of the permissible visual function surveys are able to detect clinically important vision changes. The agency disagrees with commenters' criticisms of the paper. CMS also emphasizes that the surveys measure patient-reported visual function, not visual acuity as measured by an eye care professional.

c. Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (ASC-15a-e)

CMS finalizes its proposal with modification to implement reporting of the OAS CAHPS ASC-15a-e measure set as part of the ASC QRP. As modified, voluntary reporting will be delayed for

one year and will instead begin for the 2024 reporting period followed by mandatory reporting beginning with the 2025 reporting period/2027 payment determination. The survey measure set contains includes five items designed to assess a patient's experience with care following certain procedures or operations performed in the ASC setting, and no changes are being made to those items. As previously established, the survey must be fielded on each ASC's behalf by a CMS-approved third-party vendor, who submits the data directly to CMS.

The five items target patient experiences with ASC facilities and staff, efficacy of communication about the procedure, adequacy of patient preparation for discharge and postoperative recovery, overall rating of the facility, and whether the patient would recommend the facility to others. The 5-item set was first adopted into the ASCQR program during 2017 OPPS/ASC rulemaking, for use beginning with the 2020 payment determination year. However, CMS then delayed implementation to allow time for further accrual of operational experience and implementation data from the National OAS CAHPS voluntary reporting program that had started in 2016.

Many commenters requested a delay of voluntary reporting due to the ongoing COVID-19 PHE impacts on ASCs as well as concerns about survey reliability and length. Many also cited the survey-related administrative burden and costs, especially those accruing from the requirement for survey administration by a third-party vendor, stating that the survey costs could exceed the 2 percent ASC payment penalty for incomplete ASC QRP reporting. Concern was voiced about vendor challenges in properly using CPT codes as required by the survey vendor protocol.

CMS states that survey reliability has been confirmed by results generated under the National OAS CAHPS voluntary reporting program. CMS also states that the most recent nonresponse rate due to terminated telephone survey interviews, a measure of survey fatigue, is under 1 percent. The agency also provides a detailed response to a technical scoring concern about Top-Box versus Net Promoter Score methodology.

CMS acknowledges that some burden and costs are inherent to ASC-15a-e survey administration but emphasizes that the value of the patient experience of care data acquired outweighs the burden and costs. The agency also notes the use of third-party vendors avoids bias that otherwise would be introduced if patients were surveyed directly by the treating facility, thus limiting the value of the data collected. Third party vendor involvement also facilitates maintaining confidentiality of patient responses. CMS provides a hyperlink to the full list of approved OAS CAHPS vendors to facilitate vendor comparisons by ASCs (https://oascahps.org).

Updated OAS CAHPS Reporting Requirements

Relatedly, CMS finalizes as proposed the addition of two survey data collection modes -- web-based with either mail or telephone follow-up of non-respondents – to the three existing survey modes beginning with the 2023 reporting period/2025 payment determination -- mail-only, telephone-only, and mixed (i.e., mail with telephone follow-up of non-respondents). CMS also finalizes as proposed for all five survey modes that:

- ASCs that are required to report must do so through a CMS-approved survey vendor; no new vendor requirements were proposed.
- Data collection must be initiated no later than 21 calendar days after the month in which the index procedure or operation occurred and must be completed within 42 days after efforts at initial contact of an eligible patient begin.
- Multiple contact attempts must be made unless the patient refuses or the survey vendor learns the patient is ineligible for survey participation.
- ASCs 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.
    - Data must be reported for all locations that offer outpatient services; reporting is at the ASC CCN level.
    - The low-volume exemption is potentially applicable to ASCs with fewer than 60 survey-eligible patients during the calendar year just prior to the data collection period and requires CMS approval of a completed participation exemption request form.
    - ASCs anticipating more than 300 completed surveys can choose to randomly sample their eligible patients as directed on the OAS CAHPS web site or survey their entire eligible patient population.

In response to commenters, CMS also finalizes setting the survey completion threshold at 200 surveys rather than the current 300/year.

Commenters supported the adding the use of web-based technology into permissible survey administration modes. Several recommended that CMS add a web-only mode. Also suggested were web with mail or telephone follow-up for nonrespondents. Many suggested that CMS monitor all modes with regards to reliability and refine the survey items as needed. Many commenters requested that the required survey completion threshold applicable to all ASC be reduced to 100/reporting period. A request also was made to change from CCN-level reporting to NPI-based reporting to allow the public to directly match data to individual facilities.

CMS expresses concern that a web-only mode would create response bias based on Internet availability and patients' computer literacy, though it will continue to consider this option. CMS also indicates an intention to explore other modes and to monitor the results from all modes.

Based on internal data analyses, CMS now finalizes reducing the survey completion threshold from 300/year to 200/year, a level the agency believes properly balances survey burden with scoring precision. ASCs anticipating more than 200 completed surveys now may opt for random sampling of their patient population. CMS reminds ASCs of the low-volume exception (described above), and that Medicare-certified ASCs who submit fewer than 240 Medicare claims per year (primary and secondary payer) also qualify for an OAS CAHPS survey exemption for the related reporting period.

CMS clarifies that payments to a facility will not be reduced for patient refusals to complete surveys, as long as its survey vendor has properly administered the survey and has submitted all data from completed surveys to CMS by the submission deadline. Finally, CMS indicates that

consideration will be given to the feasibility of NPI-based reporting as well as any associated added burden; any changes will be brought forward through rulemaking.

B. Payment Reduction for ASCs that Fail to Meet the ASCQR Program Requirements

No changes are proposed to the policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. Medicare law requires that a 2.0 percentage point reduction to the ASC annual update be applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators for which payments are not calculated using the conversion factor, including separately payable drugs and biologicals, pass through devices that are contractor-priced, brachytherapy sources that are paid based on OPPS payment rates, and others. When an update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate. The CY 2022 ASC conversion factor is $49.916 for ASCs that successfully meet the ASC QRP requirements.

CMS reports finding that of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 3,494 were required to participate in the Program and did so in CY 2020. Also, 689 ASCs that were not required to participate in the ASC QRP did so that year, for a total of 4,183 participating facilities. For the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the full annual payment update due to data submission requirements being excepted under the ASCQR Program's ECE policy in consideration of the COVID-19 PHE. Without the PHE exception, 3,957 of these ASCs would have been required to participate. Therefore, for the CY 2022 payment determination, CMS estimates that 4,646 ASCs (3,957 plus 689) will submit data for the ASCQR Program.

C. Requests for Comment

1. Measures Addressing Transitions in Care Settings

CMS finalized the phased elimination over three years of the Inpatient Only (IPO) list during the 2021 OPPS rulemaking cycle and removed 298 services during year 1. With elimination of the IPO list, the companion ASC Covered Procedures List (CPL) grew as procedures were transferred to it from the shrinking IPO list. Persuaded by stakeholders' quality and safety concerns, elsewhere in this rule CMS finalizes recreating an IPO list and restoring a process for evaluating procedures for addition to the ASC CPL. Because continued advances in surgical techniques and medical technology likely will support appropriate further evolution of care delivery from inpatient to outpatient settings, CMS sought input on the potential future adoption of measures that assess quality of care for services whose delivery is shifting from inpatient to outpatient setting such as ASCs.

Commenters supported the development of measures that will allow the comparison of outcomes across care settings. They urged that measure development be collaborative and noted the importance of measure alignment between HOPD measures (the hospital OQR program) and

ASC measures (the ASC QRP). They further stated that transparency through public reporting of safety and quality data from all care settings is essential.

Commenters recommended CMS reconsider previously proposed measures as a way of jumpstarting quality comparisons across settings. Examples specifically suggested that are relevant to HOPD and ASC settings included the Toxic Anterior Segment Syndrome and Ambulatory Breast Procedure Surgical Site Infection measures.

CMS concurs with commenters that measure development must be collaborative, measure alignment across settings is essential, and results must be shared through transparent processes.

2. Patient Reported Outcomes after Primary Elective Lower Extremity Joint Replacement

CMS notes that elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) have transitioned off the IPO list in 2020 and 2018, respectively, and were added to the ASC CPL in 2021 and 2020, respectively. THA and TKA performance on Medicare beneficiaries is actively transitioning from most often performed on an inpatient basis to various outpatient settings. CMS also notes that well-developed, standardized, patient-reported, outcome-based performance measure (PRO-PM) tools already are available for these procedures (e.g., HOOS for THA and KOOS for TKA).

The agency requested input into the potential future adoptions of an ASC-Level, Risk-Standardized PRO-PM Following Elective Primary THA or TKA. The ASC-level measure could take the form of a respecified version of a similar measure already under consideration for assessing inpatient procedures and would be implemented when THA and TKA volumes performed in ASCs grow sufficiently to allow facility-level measurement.

Commenters supported development of a PRO-PM for application to THA/TKA procedures performed in ASCs. They suggested partnering with the American Joint Replacement Registry (AJRR) in which participation is high nationwide. Concerns were voiced related to data collection and reporting thresholds, citing the high complete submission threshold set by CMS for voluntary reporting of a similar THA/TKA PRO-PM as part of the agency's Comprehensive Care for Joint Replacement (CJR) model. Other concerns involved ensuring risk adjustment of measures reflects the patient populations of outpatient versus inpatient settings, since the latter group tends to be older and more frail.

Some commenters opposed PRO-PM development for comparison of outcomes across inpatient and outpatient operative settings. They stated that valid comparisons are impeded by the different set of services delivered postoperatively after inpatient versus ASC procedures, differences that are inherent given the short time that ASC patients remain in the facility after THA/TKA versus time spent in the hospital.

CMS agrees that leveraging extant databases (e.g., the AJRR) should be maximized. The agency states that the high CJR PRO-PM survey submission requirement was reasonable as it was phased in over several years to allow participating hospitals to build effective data collection processes. CMS indicates that the necessity for risk adjustment according to site of service will

be investigated during measure development and that variation in immediate postoperative services provided based on site of service will also be considered. CMS concludes by stating that all input received will be taken into account in future measure development.

3. Potential Future Efforts to Address Health Equity in the ASCQR Program

CMS reprises its ongoing efforts to address health equity across its quality management enterprise and notes it has not yet expanded disparities reporting to the ASC setting. The agency shares results of internal analyses that highlight challenges of measuring inequities in ASC settings; these include relatively low volumes of dually eligible beneficiaries cared for in many ASCs and substantial heterogeneity in ASC types and patient mix that results from ASC specialization (e.g., ophthalmologic or gastrointestinal endoscopic procedures). Few ASCs were able to generate enough cases to allow statistically reliable stratified analyses based on dual eligibility.

Many commenters offered support for the agency's efforts to promote health equity, including in the ASC setting. Many factors were suggested as candidates for stratified quality measurement results reporting by ASCs. Most agreed that standardized data collection about demographic and social risk factors was necessary to permit valid disparity analyses, and some suggested that CMS should incent ASCs and other facilities to collect those data.

A few commenters supported incorporating neighborhood-level socioeconomic factors into methods for measuring disparities when samples sizes are small, as appears likely to be the case for many ASCs. Support for imputing missing data by indirect estimation techniques was muted. Others supported a facility-level rather than measure-specific approach to ASC equity measurement, such as aggregating results for similar types of procedures. Some recommended using structural measures of ASC commitment to collecting social risk factor data and other interventions to identify efforts addressing inequities at the individual facility-level. Others highlighted the impact on ASC access of differential reimbursements for ASC procedures among different payer types (e.g., Medicaid versus commercial insurance) and varying regulations applicable to ASCs at the state and federal levels.

Many raised concerns about privacy of social risk factor data and about consequences of decisions by patients not to share their data. Some questioned whether data mining of facility EHRs for social risk factor information would represent a HIPAA violation and whether prohibiting data mining could be construed as information blocking.

CMS indicates that the input received will be taken into consideration during policy development about using quality measures and stratified results reporting to identify potential health inequities in ASCs.

4. Future Development and Inclusion of a Pain Management Measure

CMS notes that the opioid misuse epidemic has focused attention on pain management procedures, an increasing volume of which are being performed in ASCs. These procedures constituted the third most commonly performed procedure category in 2019 and 2020 based on

Medicare claims analyses, but also represent a quality measurement gap as there are no measures directly relevant to pain management procedures in the current ASCQR program measure set. CMS requested comment on the development and future inclusion of a measure to assess pain management surgical procedure performed in ASCs.

Many commenters supported development of a measure to assess pain management surgical procedures performed in ASCs. They urged CMS to collaborate with professional associations and ASC industry representatives. PRO-PMs were recommended as a preferred measure type for use in assessing pain management.

CMS noted its support for increasing the use of PRO-PMs. CMS also noted that comments received will be considered as development of a quality measure(s) applicable to pain management procedures performed in ASCs progresses.

D. ASC QRP Measure Summary Table by Payment Determination Year through 2026

Table HPA XVI-1. ASCQR Program Measures by Payment Determination Year
CY 2022 proposed rule changes are shown in Italic Font
(Created by HPA from Tables 69-72 in the rule and other sources)

	2020	2021	2022 2023	2024	2025	2026
CMS WEB-BASED TOOL REPORTING						
ASC-1: Patient Burn (NQF #0263)+	*V**					
ASC-2: Patient Fall (NQF #0266) +						
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)+						
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)+						
ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)	X	X	X	X	X	X
ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)+	*V***					
ASC-13: Normothermia Outcome	X	X	X	X	X	X
ASC-14: Unplanned Anterior Vitrectomy	X	X	X	X	X	X
CLAIMS-BASED REPORTING						
ASC-12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539)	X	X	X	X	X	X
ASC-17: Hospital Visits After Orthopedic ASC Procedure (NQF #3470)			X	X	X	X
ASC-18: Hospitals Visits After Urology ASC Procedure (NQF #3366)			X	X	X	X
ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (NQF #3357)				X	X	X
OAS CAHPS SURVEY-BASED REPORTING						
ASC-15a-e Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures**	*V****					

Table HPA XVI-1. ASCQR Program Measures by Payment Determination Year CY 2022 proposed rule changes are shown in Italic Font (Created by HPA from Tables 69-72 in the rule and other sources)						
	2020	**2021**	**2022 2023**	**2024**	**2025**	**2026**
CDC NHSN WEB REPORTING						
COVID-19 Vaccination Coverage Health Care Personnel				*X*	X	X
+ CMS notes that NQF endorsement for the measure has been was allowed to lapse by the measure steward. *V** Data collection suspended beginning with 2020 payment determination, resumed for 2024 reporting period with initial voluntary reporting followed by mandatory reporting beginning with 2025 reporting period/2027 payment determination. *V*** Voluntary reporting allowed through 2024 reporting period; finalized for mandatory reporting beginning with 2025 reporting period/2027 payment determination. *V**** Mandatory reporting on a set of OAS CAHPS measures, scheduled to begin for the 2020 payment determination, was indefinitely delayed (82 FR 59450). Same set is now finalized for voluntary reporting for the 2024 reporting period followed by mandatory reporting beginning with the 2025 reporting period/2027 payment determination. The measures are ASC-15a: About Facilities and Staff; ASC-15b: Communication About Procedure; ASC-15c: Preparation for Discharge and Recovery; ASC-15d: Overall Rating of Facility; and ASC-15e: Recommendation of Facility. CMS implemented a voluntary national reporting program for the OAS CAHPS Survey in January 2016. More information is available at https://oascahps.org/General-Information/National-Implementation.						

XVII. Radiation Oncology Model

Section 133 of the Consolidated Appropriations Act (CAA), 2021, enacted on December 27, 2020, included a provision that prohibits the Radiation Oncology (RO) Model from beginning before January 1, 2022. In this final rule, CMS finalizes 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.[25]

A. 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, 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 percent of all eligible RO episodes (these occur in 204 eligible Core-Based Statistical Areas (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 hospital outpatient departments (HOPDs) and freestanding radiation therapy centers.

Initially, CMS finalized that the model performance period for the RO Model would be five performance years (PYs), beginning January 1, 2021, and ending December 31, 2025, with final data submission of clinical data elements and quality measures in 2026 to account for episodes ending in 2025. In the 2021 OPPS/ASC final rule, CMS changed the duration of the model

[25]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.

performance period from 5 years to 4.5 years; changed the timelines for the submission of clinical data elements, quality measures and Certified Electronic Health Record Technology (CEHRT) requirements; and modified the eligibility dates of the RO Model as an Advanced Alternative Payment Model (APM) and Merit-based Incentive Payment System (MIPS) APM (85 FR 85866). The CAA included a provision that prohibits implementation of the RO Model before January 1, 2022. This Congressional action supersedes the RO Model delayed start date established in the 2021 OPPS/ASC final rule.

B. RO Model Regulations

1. Model Performance Period

CMS finalizes its proposal to begin the RO Model as soon as it is permitted to do so by law, on January 1, 2022. 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, unless the initial model performance period starts mid-year, in which case PY1 will begin on that date and end on December 31 of that year.

Many commenters stated that they would not have sufficient time to prepare for the implementation of the RO Model for various reasons including the impact of the COVID-19 PHE, time needed to meet quality and clinical data element (CDE) requirements, and time needed to meet the billing processes required for the model. CMS is not swayed by comments to delay the RO model another time noting that it already delayed the model performance period twice: from January 1, 2021 to July 1, 2021 in the 2021 OPPS/ASC final rule (85 FR 85866); and from July 1, 2021 to January 1, 2022 in this final rule. It also reiterates that RO participants have had more than a year to prepare for their participation in the RO Model; believes that it has provided sufficient education on the QPP, quality measures, and CDEs; and created a billing process that will be easily implemented within current systems. CMS finalizes these provisions without modification.

2. Definitions

CMS codifies 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.

Term	Definition
Track One	Track One means a track for Professional participants and Dual participants that meet all RO Model requirements as specified in §512.220, including use of CEHRT.
Track Two	Track Two means a track for Professional participants and Dual participants that meet all RO Model requirements as specified in §512.220, except for use of CEHRT.
Track Three	Track Three means a track for Professional participants and Dual participants who do not meet one or more of the RO Model requirements set forth at §512.220(a); and for all Technical participants.
Baseline period	"Baseline period" means the three calendar year period that begins on January 1 no fewer than five years but no more than six 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, each RO participant's historical experience adjustment for the PC or TC or both for the model performance period, and the RO participant's case mix adjustment for the PC or TC or both for PY1. The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in calendar year (CY) 2022, in which case the baseline period will be delayed based on the new model performance period (for example, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).
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 Year	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.

3. RO Model Participant Exclusions

At §512.210(b), CMS excludes from the RO Model any Physician Group Practice (PGP), freestanding radiation therapy center, or HOPD that furnishes RT only in Maryland; furnishes RT only in Vermont; furnishes RT only in United States (U.S.) Territories; is classified as an ambulatory surgical center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model (PARHM).

CMS modifies its exclusions for HOPDs related to the Pennsylvania Rural Health Model (PARHM), Community Health Access and Rural Transformation Model, and the low volume opt-out.

a. Pennsylvania Rural Health Model (PARHM)

CMS finalizes its proposal to modify §512.210(b)(5) to exclude from the RO Model only the HOPDs that are participating in PARHM, rather than excluding both HOPDs that are participating in PARHM and those that have been identified by CMS as eligible to participate in PARHM. CMS continues to believe that HOPDs that are participating in PARHM should be excluded from the RO Model because these hospitals receive global budgets, and these global

budgets would include payments for RT services and as such would overlap with the RO Model payment. After further consideration, CMS believes including in the RO Model those HOPDs that have been identified as eligible to participate in PARHM, but that are not actually participating in PARHM would not affect the PARHM evaluation.

CMS clarifies that if a rural hospital identified as eligible to participate in PARHM later initiates its participation in PARHM by signing a PARHM participation agreement with CMS, then the HOPDs participating in PARHM as part of that participating rural hospital would be excluded from participation in the RO Model as of the start of the next CY quarter that follows the date that the HOPD begins participating in PARHM. Similarly, if an HOPD no longer participates in PARHM as part of a participating rural hospital, and the HOPD otherwise meets the definition of an RO participant, then the HOPD would be required to participate in the RO Model as of the start of the next CY quarter.

CMS will continue to use the list on the PARHM website at https://innovation.cms.gov/initiatives/pa-rural-health-model/, which is updated quarterly, to identify the hospitals that are participating in PARHM, and therefore identifies the specific HOPDs excluded from participation in the RO Model.

A few commenters support CMS' proposal while others opposed the inclusion in the RO Model of only HOPDs participating in PARHM, stating that they believe that participation in the RO Model should be voluntary. CMS notes that it did not solicit comments on mandatory participation under the RO Model but notes that mandatory participation avoids the selection bias inherent to any model in which providers and suppliers may choose whether or not to participate. With respect to its proposal, CMS no longer believes that including those hospitals in the RO Model will impact the PARHM evaluation because such HOPDs do not receive global budgets under PARHM. CMS finalizes its proposal without modification.

b. Community Health Access and Rural Transformation Model

CMS finalizes its proposal to exclude from the RO Model the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model. CMS excludes these "CHART HOPDs" to avoid double payment for the same services. The participating hospitals will be listed and updated on the CHART Model website at https://innovation.cms.gov/innovation-models/chart-model. CMS notes that for the CHART ACO Transformation Track, it will follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs, which was finalized at 85 FR 61260. All commenters supported this exclusion.

c. Low Volume Opt-Out

CMS clarifies the dates of the data used to determine eligibility for the low volume opt-out. 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 (2 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 opt-out 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 further clarifies that episodes furnished prior to the start of the model performance period in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY1 and PY2. If PY1 begins on January 1, RO episodes will be used to determine the eligibility of the low volume opt-out for PY3. RO episodes of PY2 and PY3 will be used to determine the eligibility of the low volume opt-out for PY4 through PY5, respectively.

CMS also finalizes its proposal that during the model performance period, an entity would not be 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, as applicable, of RT services in the 2 years prior to the applicable PY across all CBSAs selected for participation. CMS believes this change removes any incentive for RO participants to change their TIN or CCN in an effort to become eligible for the low volume opt-out.

Some commenters noted that the low volume opt-out will not protect all small and rural facilities as many will not be eligible to opt out under this policy. CMS performed a separate analysis to examine this issue and uncovered no evidence that participation in the RO Model may be burdensome or financially infeasible for RO participants that furnish RT care in rural areas such that a change in its low volume opt-out policy specific to rural areas is warranted.

4. Certain Changes to RO Model Episodes

a. Criteria for Determining Included Cancer Types

CMS reorganizes §512.230(a) and (b) to improve the clarity and internal consistency of the regulatory text with respect to the criteria for determining included cancer types. It finalizes its proposal to amend §512.230(a) and (b) such that to be included in the RO Model, a cancer type must be commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; associated with current ICD-10 codes that have demonstrated pricing stability, which is determined by analyzing the interquartile ranges of the episode prices across cancer types as described in the Specialty Care Models final rule at 85 FR 61155; and the Secretary must not have determined that the cancer type is not suitable for inclusion in the RO Model. CMS will remove from the RO Model a cancer type that does not meet all three of these criteria or for which CMS discovers a > 10 percent error in established national base rates.

b. Removal of Liver Cancer from Included Cancer Types

CMS will remove liver cancer from the RO Model as an included cancer type. It notes that RT may represent a promising treatment for certain types of liver cancers, but there are few prospective, randomized controlled trials. Some guidelines, for example, do not include radiotherapy as a first-line therapy for the treatment of the most common type of liver cancer, hepatocellular carcinoma. After continued conversations with radiation oncologists consulting on the RO Model and additional reviews of the latest literature, CMS now believes that the inclusion of liver cancer does not meet the inclusion criteria at §512.230(a)(1) because liver cancer is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines.

c. Removal of Brachytherapy from Included RT Services

CMS also finalizes as proposed to amend §512.240 to remove brachytherapy as an included modality in the RO Model. CMS states that it will continue to monitor utilization of brachytherapy, both as a single modality and multimodality among RO participants compared to non-participants. It will also consider whether there is opportunity to adjust pricing for multimodality episodes, without disrupting the RO Model design, and potentially add brachytherapy to the RO Model in the future. Stakeholders had expressed concern that RO episode-based payment does not adequately account for multimodality care, particular concerns were raised about cases where the RO participant furnishing the external beam radiation therapy is different from the RO participant providing brachytherapy.

CMS states that its policy to remove brachytherapy from the RO Model will render its waiver of section 1833(t)(2)(H) of the Act (codified at § 512.280(f)(4)) moot. Therefore, CMS finalizes its proposal to withdraw this waiver given that its proposal to remove brachytherapy is finalized. This waiver would no longer be necessary solely for the purposes of testing the RO Model.

CMS also makes conforming edits to the HCPCS list of included RT services to account for the removal of brachytherapy. These are listed in Table 74 in the final rule.

Commenters were in support of CMS' proposal to remove brachytherapy from the RO Model's list of included modalities and no commenters opposed removing brachytherapy.

d. Exclusion of Intraoperative Radiotherapy (IORT)

In the Specialty Care Models final rule (85 FR 61114) CMS finalized 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 states that it has received comments from stakeholders requesting that it re-evaluate this decision and include IORT in the RO Model for certain cancer types, particularly early-stage breast cancer. Given that this modality is only provided in one of those locations, it is not site neutral, and therefore CMS states that it does not meet the goals of the RO Model. Modalities that are not included in the RO Model, including IORT, would continue to be paid under Medicare FFS.

CMS solicited comments on whether and how it might include IORT in its pricing methodology in future years of the RO Model, for example whether CMS should include cancer-specific modalities in the RO Model. CMS does not respond to these comments in this 2022 OPPS/ASC final rule, but states that comments will inform potential changes to the RO Model.

5. Pricing Methodology

a. Assignment of Cancer Types to an Episode

CMS reviews its claims-based process for assigning a cancer type to an episode (as finalized at 85 FR 61179). Since the publication of the Specialty Care Models Rule, a stakeholder has asked for clarification on how to identify when there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies. CMS clarifies that if there are not at least two claim lines for brain metastases or 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.

CMS notes that it identifies ICD–10 diagnosis codes for cancer during an episode from E&M services, and treatment planning and delivery services that have a cancer diagnosis code from the road cancer diagnosis list. It assigns a cancer type to the episode and then excludes those episodes that are not assigned an included cancer type. It does not exclude claims of excluded cancer types prior to episode construction, as this could lead to an episode being included in the RO Model where most of the RT services were related to treating an excluded cancer type.

b. Constructing Episodes Using Medicare FFS Claims and Calculation of Episode Payment

CMS finalizes its proposal to update how it describes its approach to constructing episodes using Medicare FFS claims. It removes references to specific CYs from the definition of baseline period. It would continue to weigh episodes that initiated in the first year of the baseline period at 20 percent, episodes that initiated in second year of the baseline period at 30 percent, and episodes that initiated in the third year of the baseline period at 50 percent.

CMS also amends §512.255(c)(13) by removing the percentage amount and indicating that sequestration will be applied in accordance with applicable law.

c. National Base Rates

To simplify episode construction, attribution, and pricing, CMS finalizes its proposal 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 will also exclude all claims of an HOPD participating in PARHM (during the period of their participation in PARHM) 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 does not have more than $0 in total allowed amounts for professional or technical services from Model pricing.

CMS provides a summary level, de-identified file titled the "RO Episode File (2017 to 2019)," on the RO Model website at https://innovation.cms.gov/innovation-models/radiation-oncology-model to further facilitate understanding of the RO Model's pricing methodology.

CMS' national base rates for the model performance period are based on the criteria set forth for cancer type inclusion and are summarized in Table 75 (reproduced below).

Table 75: 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

Table 75: National Base Rates			
RO Model-Specific Codes	**Professional or Technical**	**Included Cancer Type**	**National Base Rate**
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
M1081	Technical	Breast Cancer	$10,001.84
M1084	Professional	CNS Tumor	$2,558.46
M1085	Technical	CNS Tumor	$14,762.37
M1082	Professional	Cervical Cancer	$3,037.12
M1083	Technical	Cervical Cancer	$13,560.15
M1086	Professional	Colorectal Cancer	$2,508.30
M1087	Technical	Colorectal Cancer	$12,200.62
M1088	Professional	Head and Neck Cancer	$3,107.95
M1089	Technical	Head and Neck Cancer	$17,497.16
M1094	Professional	Lung Cancer	$2,231.40
M1095	Technical	Lung Cancer	$12,142.39
M1096	Professional	Lymphoma	$1,724.07
M1097	Technical	Lymphoma	$7,951.09
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

d. Trend Factors

As codified at §512.255(c)(1), 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 PFS rates for RT services. CMS describes the current calculation and modifications given the delay in the performance period and the model baseline period.

CMS finalizes its proposal 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 3 years prior to the CY used to

determine the FFS payment rates. The denominator of the trend factor will 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 will 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 finalizes its proposal that the denominator of the trend factor will be based on the third year of the baseline period, and the numerator of the trend factor will 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 will be based on 2019 FFS payment rates and 2019 utilization, while the numerator will be based on 2022 FFS payment rates and 2019 utilization. The trend factor's denominator will not change and remains based on 2019 FFS payment rates and 2019 utilization over the course of the model performance period. The numerator, however, will change as its volume and utilization will 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 will 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.

Many commenters disagreed with the proposed modification of the trend factor because it did not include guardrails to prevent significant shifts in payment rates; many suggested a guardrail of +/- 2 percent to help establish rate stability. Another commenter suggested CMS should establish an add-on payment to account for new technologies given that it will likely take several years before new technology or treatments are reflected in sufficient volume to impact and be reflected in FFS rates. CMS responds that setting up guardrails risks paying significantly more under the Model than to non-participants. It also notes that to the extent that new technologies and new equipment are billed under new HCPCS codes, these codes could be added to the list of RT services through rulemaking.

e. 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 participants 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 participants and Technical participants. CMS did not solicit comment on this clarification.

f. HOPD or Freestanding Radiation Therapy Center with Fewer Than Sixty Episodes During the Baseline Period

To align its stop-loss limit policy with the new performance period and baseline period, CMS finalizes its proposal to modify this stop-loss limit policy such that it applies to RO participants that have fewer than 60 episodes during the 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 and amends §512.255(c)(7)(iv) accordingly. Some commenters disagreed with the stop-loss policy and believe that it should apply to all RO participants, not just to RO participants that have fewer than 60 episodes during the baseline period. CMS notes that it proposed to modify the stop-loss policy in a narrow way by expanding one criterion of eligibility in that RO participants had to be furnishing included RT services "before the start of the model performance period in the CBSAs selected for participation."

g. Apply Adjustments for HOPD or Freestanding Radiation Therapy Center

CMS finalizes modifications to the participant-specific adjustments for changes in TINs or CCNs (as specified at §512.255(c)(14)). It will calculate the RO participant's case mix adjustments based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the 3-year period that determines the case mix adjustment for each PY (at§512.255(c)(14)(i)). Similarly, CMS will 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 (at§512.255(c)(14)(ii)).

CMS eliminates the requirement that RO participants provide a notification regarding all new clinical or business relationships that may or may not constitute a change in control. CMS believes that requiring RO participants to report changes to TINs or CCNs will capture the types of changes that pose risks of gaming in the RO Model. CMS will also require an RO participant to furnish to CMS written notice of a change in TIN or CCN in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

h. Discount Factor

CMS finalizes its proposal to lower the discount factor for the PC from 3.75 percent to 3.5 percent and the discount factor for the TC from 4.75 percent to 4.5 percent (at §§512.205 and 512.255(c)(8)). By removing brachytherapy from the list of included modalities and liver cancer from the included cancer types, CMS states this will enable it to lower these discounts without increasing the size of the RO Model due to a reduction in pricing variability. CMS now expects to be able to detect a savings of 3.2 percent or greater at a significance level of 0.05 and with a power of 0.8.

No commenters agreed with the proposed discounts, and many proposed that the discount factor be set to 3 percent or less. They argued that the RO pricing methodology fails to recognize that radiation oncology services rely heavily on the use of advanced technology and equipment that requires a significant financial investment. Others stated that a discount factor of 3 percent or less would be more in line with other payment models. CMS in its reply states that it has made

every effort to be responsive to stakeholder requests to lower the discount from what was finalized but that it cannot further reduce the discounts beyond 3.5 and 4.5 percent for the PC and TC, respectively, without changing other aspects of the model, such as increasing the size of the model. CMS also states that it will continue to monitor the RO model for unintended consequences such as reduced access to services for beneficiaries.

i. Withholds

CMS established at §512.255(c)(10) that it would apply a 2 percent quality withhold from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. In the 2021 OPPS/ASC final rule, CMS delayed RO Model quality measure requirements to what would have been PY2 (January 1, 2022, through December 31, 2022) under the model performance period and thus delayed the application of the quality withhold to that PY2. CMS finalizes its proposal that beginning in PY1 a 2 percent 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 (when the model performance period begins) as described in section XVII.C.6 of the final rule.

Commenters disagreed with the proposal stating concerns that RO participants may not be able to earn back the full amount withheld no matter how good the performance. Others recommended that the 2 percent quality withhold should not occur until PY2, as was originally proposed. CMS believes that the upfront quality withhold provides the incentive for participants to provide high-quality care and allows the RO Model to link quality to payment, which is the requirement of QPP.

j. Adjustment for Geography

With respect to the geographic adjustment in the RO Model, CMS finalizes its proposal to align the model performance period so that the final year of the baseline period would be used to calculate the implied RVU shares. For example, for a baseline period of 2017-2019, 2019 would be used to calculate the implied RVU shares. RVU shares are shown in the table below. CMS did not receive any comments on this issue.

RVU Shares					
Professional Component			**Technical Component**		
WORK	**PE**	**MP**	**WORK**	**PE**	**MP**
0.65	0.31	0.04	0	0.99	0.01

k. Example of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1

CMS provides Table 60 and Table 61 in the proposed rule, which are updated versions of Table 8 and Table 9 included in the Specialty Care Model Rule, to illustrate examples of technical and professional participant-specific episode payments. These updated tables reflect the updated national base rate for lung cancer and proposed discount rate. CMS did not reproduce these

tables in the final rule, which may have been an unintentional omission. The calculations should be the same based on the policies CMS finalized.

Table 61 from the proposed rule (reproduced below) details the participant-specific technical episode payment paid by CMS to a single TIN or single CCN for the furnishing of RT technical services to an RO beneficiary for an RO episode of lung cancer. CMS states that it is currently analyzing whether the COVID-19 pandemic resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historical levels. At this time, CMS is not considering the exclusion of 2020 from the case mix adjustment, because the case mix episodes are weighted equally (unlike the baseline period, where more recent episodes are given more weight than earlier episodes), and the case mix adjustment does not rely on the volume of RT services furnished.

Table 61: Example: Participant-Specific Technical Episode Payment for Lung Cancer in PY1 (All numbers are illustrative only.)

	Amount	Formula
National Base Rate (a)	$12,142.39	
Trend Factor (b)	1.04	
Subtotal (c)	$12,628.09	c = a * b
SPLIT for SOE/EOE payments (d)	$6,314.04	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$6,440.32	f = d * e
Case Mix Adjustment (g)	0.02	e.g. (102-100) / 100
Historical Experience Adjuster (h)	0.11	e.g. (113-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.12	j = g + (h * i) + 1
Subtotal (k)	$7,206.72	k = j * f
Discount Factor (l)	0.9550	
Subtotal (m)	$6,882.42	m = l * k
Withhold #1 (Incorrect Payment) (n)	0.99	
Withhold #2 (Patient Experience) - not applied until PY3 (o)		
Total Withhold (p)	0.99	p = 1-((1-n)+(1-o))
Half of Total Episode Payment to RO Participant without sequestration (q)	$6,813.60	q = p * m
Beneficiary Coinsurance for SOE payment Determined (r)	$1,362.72	r = q * 0.20
SOE Participant Payment	$5,450.88	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$5,341.86	t = s * 0.98

	Amount	Formula
Episode Payment 1: SOE (u)	**$5,341.86**	**u = t**
Episode Payment 2: EOE (v)	**$5,341.86**	**v = t**
Total Episode Payment to RO Participant (w)	**$13,409.16**	**w = u+v+2r**

6. Quality – Form, Manner, and Timing for Quality Reporting

CMS finalizes its proposal that Professional participants and Dual participants submit quality measure data starting in PY1 during the model performance period. Under this policy, if the model performance period starts mid-year, the CY collection period would remain. For example, if the model performance period starts in July, RO participants would collect quality measure data for that CY starting in January. This allows RO participants to use their MIPS data submission to meet the RO Model requirements.

For PY1, Professional participants and Dual participants will 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; and (3) Advance Care Plan. They will 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. CMS finalizes its proposal that if it updates the specifications of this measure then any non-substantive updates to the specifications for this measure would be communicated in a form and manner specified by CMS, and that any substantive changes to measure specifications would be addressed through notice and comment rulemaking.

Given the change in the model performance period, CMS amends 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 finalizes its proposal that Professional participants and Dual participants submit Clinical Data Elements starting in PY1.

In response to many comments that RO participants will not be ready to start gathering quality measure data on January 1, 2022 in order to report for PY1, CMS states that given the year delay RO participants have had adequate time to prepare. CMS also stressed that using all-payer data for the finalized quality measures is important to improve and drive the quality of furnished care to all patients, including Medicare beneficiaries. CMS also states that any segmentation to solely focus on the Medicare populations would be inconsistent with the measure and add substantial reporting burden to RO participants.

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

Despite the delay required by section 133 of the CAA 2021, 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. For a RO Model to be an Advanced APM it must use certified electronic health record technology (CEHRT), payment must be linked to quality measures, and participants must be subject to financial risk. (It notes that final CMS determinations of Advanced APMs and MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website at https://qpp.cms.gov/. CMS also notes that the changes to the stop-loss policy do not affect the satisfaction of the Financial Risk criterion.

After consideration of comments and to provide further clarification, CMS finalizes with modification the definitions of Track One and Track Two and adds a definition for Track Three.

- Track One is defined as a track for Professional participants and Dual participants that meet all RO Model requirements set forth at §512.220, including use of CEHRT. CMS anticipates that RO Model participants in Track One will be considered to be participating in an Advanced APM and MIPS APM under the RO Model, and it will make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO Model Participation List for Track One. It also anticipates that Track One of the RO Model would also meet the criteria to be a MIPS APM.

- Track Two is defined as a track for Professional participants and Dual participants that meet all RO Model requirements set forth at § 512.220, except for use of CEHRT. That is, a Dual participant or Professional participant who does not use CEHRT but meets all other RO Model requirements set forth at § 512.220 would be in Track Two. CMS anticipates that RO participants in Track Two will be considered to be participating in a MIPS APM under the RO Model.

- Track Three is defined as a track for Professional participants and Dual participants who do not meet one or more of the RO Model requirements set forth at § 512.220(a); and for all Technical participants. For example, a Professional participant or Dual participant that does not adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate would be in Track Three. CMS anticipates that RO participants that fall into Track Three will be considered to be participating in an APM, but not in an Advanced APM or MIPS APM, under the RO Model. As such, CMS will not make QP determinations for the eligible clinicians on the RO Model Participation List for Tracks Two and Three.

a. Technical Participants and the Quality Payment Program

Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the technical component (TC) are not required to report quality measures under the RO Model. CMS finalizes its proposal 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, in a form and manner

specified by CMS. They will also be required under the RO Model to report quality measures by the next reporting period. Once a Technical participant that is a freestanding radiation therapy center begins providing the professional component, the freestanding radiation therapy center becomes a Dual participant as defined in §512.205. CMS will monitor these RO participants for compliance with the requirement to report quality measures if they begin providing the professional component. CMS codifies this policy at §512.275(d).

CMS received many comments asking that Technical participants be eligible for QP determination as it would help support practice transformation essential for meaningful APM participation. CMS disagrees that Technical participants should be eligible for QP determinations under the RO Model and continues to believe that eligibility for QP determination should be limited to Professional participants and Dual participants. CMS clarifies text in the 2022 OPPS/ASC proposed rule to state that technical participants will not be participating in Track One or Track Two of the RO Model and therefore would not be considered participants in an Advanced or MIPS APM under the RO Model.

b. Individual Practitioner List

CMS codified the requirements concerning the review and certification of the individual practitioner list at §512.217. Upon the start of each PY, CMS creates and provides to each Dual participant and Professional participant an individual practitioner list which identifies by NPI each individual practitioner associated with the RO participant. CMS finalizes its proposal to modify this policy to include that Technical participants that are freestanding radiation therapy centers will also be provided an individual practitioner list.

CMS codified at §512.217(b) and (c)(1) that the RO participant must review and certify the individual practitioner list within 30 days of receipt. 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 finalizes its proposal 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 QP determination snapshot date.

CMS codified at §512.217(c)(3) that if the Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, RO participants on the unverified list are not recognized as participants on a participation list of either a MIPS APM or Advanced APM. CMS finalizes its proposal to add §512.217(c)(3)(iii) that if individual practitioners who participate in the RO Model with Technical participants that are freestanding radiation therapy centers are not included on a verified list, they will not be eligible to receive Improvement Activity credit under MIPS.

c. RO Model Requirements

After considering public comments, CMS finalizes with modification that RO participants must satisfy the requirements set forth at §512.220 to be included in Track One of the RO Model. RO participants that meet all of these RO Model requirements in a PY, except for use of CEHRT, will be in Track Two for the applicable PY. RO participants that do not meet one or more of the RO Model requirements in paragraph (a) of this section will be in Track Three for the applicable PY. This policy is codified at §512.220(a)(1). CMS also finalizes as proposed that the CEHRT

requirement would begin in PY1 of the model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY. This policy is codified at §512.220(b)(1) and (2). Finally, CMS finalizes as proposed that if an RO participant begins participation in the RO Model at any time during an ongoing PY, they must certify their use of CEHRT by the last QP determination snapshot date specified at §414.1325. This policy is codified at §512.220(c).

8. Reconciliation Process

a. Initial Reconciliation

Reconciliation is the process to calculate reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. Given the change in model performance period, CMS expects to conduct the initial reconciliation each August for the preceding PY. For example, for PY1, CMS will conduct the initial reconciliation as early as August of PY2. Given the change in model performance period due to the delay and CMS' policy that the application of a quality withhold will begin in PY1, CMS finalizes its proposal to amend §512.285(d) such that the quality reconciliation payment amount will apply to all PYs.

b. 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. Given the proposed change in model performance period due to the delay, 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.

c. Reconciliation Amount Calculation

CMS codified at §512.285(c)(3) that in the case that 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 finalizes its proposal 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 those RT services using no-pay claims. CMS stated that upon further review the data did not support paying RO participants only the first installment of an episode for this type of incomplete episode. Accordingly, CMS also modifies §512.255(c)(12)(iv) to specify that the coinsurance for all incomplete episodes is 20 percent of the FFS amount applicable to the RT services that were furnished.

CMS also finalizes its proposal to modify the definition for "stop-loss reconciliation amount" to mean the amount owed to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation for the loss incurred under the RO Model. This will make this definition consistent with the updated model performance period.

9. Potential Overlap with Other Models Tested Under Section 1115A Authority and CMS Programs

CMS states that it continues to see no need to adjust the prospective episode payments made under the RO Model to reflect payments made under the Shared Savings Program or under any other models tested under section 1115A of the Act. Thus, CMS finalizes its proposal to codify this policy on overlaps at §512.292.

10. Extreme and Uncontrollable Circumstances Policy

CMS finalizes its proposal to adopt an extreme and uncontrollable circumstance policy for the RO Model which 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.

a. Extreme and Uncontrollable Circumstance Affects the Nation, Region, or a Locale

CMS finalizes its proposal to define an extreme and uncontrollable circumstance (EUC) as 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. Under this policy, if CMS declares an EUC for a geographic region, it may: (1) amend the model performance period; (2) eliminate or delay certain reporting requirements for RO participants; and (3) amend the RO Model's pricing methodology. Application of the modifications would be based on the severity and types of challenges that the circumstance imposes on RO participants. In every circumstance, CMS states it will seek to minimize impact on the RO participants not affected by the EUC, while supporting those that are affected.

In a national, regional, or local event, CMS will apply the extreme and uncontrollable circumstance policy only if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care. To help identify RO participants that are experiencing an extreme and uncontrollable circumstance, CMS will consider the following factors:

- Whether the RO participants are furnishing services within a geographic area considered to be within an "emergency area" during an "emergency period" as defined in section 1135(g) of the Social Security Act.
- Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the section 1135 waiver authority, or the National Emergencies Act.
- Whether a state of emergency has been declared in the relevant geographic area.

If one or more of these conditions are present, CMS will announce that the extreme and uncontrollable circumstances policy applies to one or more RO participants within an affected geographic area. CMS will communicate this decision via the RO Model website and written correspondence to RO participants.

CMS received many comments on this proposal expressing support.

b. Model Performance Period

In instances where an EUC is nation-wide and impacts RO participants' ability to implement the requirements of the RO Model at the start of the model performance period, CMS finalizes its proposal that it may delay the start date of the model performance period by up to one CY. RO participants will be notified of any changes to the model performance period on the RO Model website no later than 30 days prior to the original start date. In the case of a regional EUC, CMS finalizes its proposal to not change the model performance period, but instead only to delay or exempt requirements.

A few commenters asked whether, if we were still in a PHE on January 1, 2022, CMS would use this authority to change any RO Model requirements. CMS states that it will continue to monitor the impacts of COVID-19 on radiation oncology to determine whether the EUC policy may need to be invoked, and if so, which flexibilities to invoke. This information would be communicated via the RO Model website and written correspondence to RO participants.

c. Reporting Requirements

Quality Measures and Clinical Data Elements: If an EUC impacts RO participants' ability to comply with the RO Model's quality measure or clinical data element reporting requirements, CMS finalizes its proposal that it may delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, and/or extend the time for RO participants to report data to CMS, as applicable.

Other Participation Requirements: Because RO participants must focus on direct care, CMS finalizes its proposal that it may waive compliance with or adjust the requirement that RO participants actively engage with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback) on treatment plans.

d. Pricing Methodology

Adjusting the Quality Withhold: If CMS decides to remove (not merely extend) quality and clinical data submission requirements for affected RO participants due to a national, regional, or local event, CMS finalizes its proposal that it could choose to repay the quality withhold during the next reconciliation and award all possible points in the subsequent Aggregate Quality Score calculation for affected RO participants, *or not apply the quality withhold to RO participants during the EUC*, which would potentially increase episode payments during this time. CMS omitted the italicized phrase above and finalized this policy with this modification in the final rule.

Trend Factor Adjustments: CMS finalizes its proposal that it may modify the trend factor calculation for the PC and/or TC of an included cancer type when RO participants experience significant, aggregate-level disruptions to their service utilization on a nation-wide basis and the trend factor (specific to a cancer type and component) for the upcoming PY has increased or decreased by more than 10 percent compared to the prior year.

11. Impact of RO Model

CMS estimates that its policies, which include a change to a revised model performance period that begins January 1, 2022 and ends December 31, 2026, a revised baseline period, the removal of brachytherapy and liver cancer, as well as the lowered discounts, will reduce savings to $150 million for Medicare relative to earlier estimates. This is $70 million less than what CMS estimated for a 4.5 year model performance period in the 2021 OPPS/ASC final rule (85 FR 86296).

CMS believe that the changes will not affect the total cost of learning the billing system for the RO Model but will, however, affect the burden estimate for reporting quality measures and clinical data elements. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model is estimated to be approximately $1,845 per entity per year based on 2020 wages. The total estimate is $922,500 for a total of $4,612,500 over 5 years based on 500 Professional participants and Dual participants collecting and reporting this data.

XVIII. Updates to Hospital Price Transparency Requirements

A. Introduction and Overview

Section 2718(e) of the PHS Act requires each hospital operating within the United States to make its standard charges publicly available. CMS proposed to: (1) increase civil monetary penalties (CMPs) for noncompliance with price transparency requirements; (2) deem state forensic hospitals to have met the price transparency requirements; and (3) prohibit certain conduct that CMS believes is a barrier to accessing the standard charge information. In the proposed rule, CMS also solicited comments on various issues to improve the usefulness of this initiative.

B. Increasing Civil Monetary Penalties

Under current regulations, CMS takes the following actions (in order) when hospitals are non-compliant with the price transparency requirements:

- Provides a written warning notice to the hospital of the specific violation(s);
- Requests a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements;
- Imposes a CMP not to exceed $300 per day on the hospital if the hospital fails to provide or comply with its correction action plan; and
- Publicizes on the CMS website that the hospital has been assessed a CMP for failing to comply with the price transparency requirements.

In the 2020 hospital price transparency final rule, CMS considered either imposing a fixed CMP per day or a sliding scale based on the size of the hospital. CMS selected the fixed fee of $300 but indicated that it would revisit this penalty if it was an insufficient incentive to be in compliance with the price transparency requirements.

Based on initial experience with enforcing the hospital price transparency final rule CMS is

concerned by the high rate of noncompliance. Therefore, CMS considered: (1) increasing the maximum CMP amount from $300 per day per day to $1,000 per day, or (2) establishing a minimum penalty amount and applying a scaling factor (based on bed count or hospital revenue) to increase the penalty in a manner uniquely tailored to the noncompliant hospital. After considering these two general approaches, CMS proposed to use a scaling factor to establish the CMP amount for a noncompliant hospital.

CMS proposed to use the noncompliant hospital's number of beds, as specified in hospital cost report data as the scaling factor to establish CMP amounts. "Beds" will include an adult bed, pediatric bed, the portion of inpatient labor/delivery/postpartum room (also referred to as birthing room) bed when used for services other than labor and delivery, or a newborn ICU bed (excluding newborn bassinets) maintained in a patient care area for lodging patients in acute, long term, or domiciliary areas of the hospital. "Beds" do not include beds in post-anesthesia rooms, post-operative recovery rooms, outpatient areas, emergency rooms, ancillary departments (except as noted for labor and delivery beds), nurses' and other staff residences, and other such areas which are regularly maintained and utilized for only a portion of the stay of patients (primarily for special procedures or not for inpatient lodging).

The proposed per day CMP for a non-compliant hospital was:

- $300 for a hospital with 30 or fewer beds.
- The product of the number of beds and $10 for a hospital with 31 or more beds and less than 550 beds.
- $5,500 for a hospital with 550 or more beds.

CMS believes these penalties are commensurate with the severity level of the potential violation, taking into consideration that nondisclosure of standard charges does not rise to the level of harm to the public as other violations (such as safety and quality issues).

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. An additional CMP at the highest daily maximum amount would be assessed for failure to provide documentation on the number beds. Beginning in 2023, using the multiplier determined by OMB for adjusting CMPs, CMS would update the above amounts.

Public comments supported and opposed CMS' proposal to increase CMPs for non-compliance with the Hospital Price Transparency Program. Opponents of the proposal indicated that hospitals need more time to be in compliance particularly since the January 1, 2021 effective of date of this provision was during the COVID-19 PHE. These commenters also suggested a number of actions that CMS could undertake to improve compliance other than increasing CMPs. These actions largely focused on outreach and education and further specificity regarding actions hospitals could take to be in compliance with the Hospital Price Transparency Program. There were also comments recommending delays in enforcement of the hospital transparency provisions pending enforcement of the No Surprises Act and Transparency in Coverage (TiC) rules.

CMS responded that rules regarding the Hospital Price Transparency Program were adopted on November 1, 2019 with a delayed effective date until January 1, 2021 giving hospitals sufficient time to be in compliance. In response to comments related to the need for additional guidance and adequately preparing hospitals, the final rule indicates that CMS has engaged in a number of education and outreach activities including several Open Door Forums. The final rule refers readers to the CMS website: Hospital Price Transparency | CMS for more information.

CMS indicated that circumstances surrounding the delay of the TiC Final Rules are not analogous to, and therefore do not warrant, a delay in enforcement the Hospital Price Transparency requirements. The Departments of Labor, Health and Human Services and Treasury are deferring enforcement of the machine-readable file requirements in the TiC which are more extensive and overlapping with the No Surprises Act requirements than the Hospital Price Transparency machine-readable file requirement.

Many commenters supported using bed count to scale CMPs. Others offered alternatives to CMS' proposal for how the number of beds could be used to scale CMPs. Opponents of using bed counts to scale the CMPs also suggested alternative measures that could be used. Some commenters suggested that judgment be applied on a case-by-case basis and be based on the scope, nature, or severity of noncompliance and consideration of whether the hospital is demonstrating a good faith effort to be in compliance. Several commenters disagreed with using factors such as scope, nature, or severity of deficiencies because that could result in inequitable penalties. Others suggested putting Medicare enrollment status or Medicare reimbursement at risk for noncompliance, or withholding "federal infrastructure research" until hospitals become compliant.

CMS believes using bed count is an effective way to ensure compliance, consistency and fairness in application of penalties across noncompliant hospitals. Using bed count as a scaling factor takes into consideration the size of the hospital which can help avoid overly penalizing smaller hospitals. CMS indicated that use of other or multiple scaling factors might have advantages, such as being able to tailor the amount of the CMP to account for unique hospital circumstances and the potential to assess a greater CMP for egregious noncompliance. CMS will consider use of these alternative factors should it be necessary to refine the determination of the penalty amount.

There were several comments concerned about using the hospital cost report count of beds because the date of submission of the cost report varies and may not reflect an 'official count.' A few commenters requested clarification about what field in the cost report file would be used to determine bed count. One commenter suggested using the number of state licensed beds that could be used for both enrolled and hospitals not unenrolled in Medicare.

CMS responded that it will use the most recently available cost report to scale CMPs because it is routinely submitted by Medicare-enrolled hospitals, is certified by a hospital official, and is reviewed by a Medicare Administrative Contractor. The final rule quoted the precise hospital cost report instructions for how to count beds (also provided above in the description of the proposed rule).[26] CMS agrees that state licensed beds could be used for the bed count for

[26] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S–3—HOSPITAL AND

hospitals not enrolled in Medicare.

There were comments suggesting much higher CMPs than CMS proposed. Others suggested lower penalties than CMS proposed because noncompliance should not be viewed as a patient safety issue, and does not rise to the level of a Health Insurance Portability and Accountability Act of 1996 related violation. CMS responded that its proposal represents a good balance between these suggestions and is commensurate with the level of severity of the potential violation. It will continue to monitor and assess the impact of this penalty and may revisit in future rulemaking.

CMS is finalizing all of its proposals without modification.

C. State Forensic Hospitals

Hospital price transparency requirements are not applicable to hospitals owned and operated by the Indian Health Service, Department of Veterans Affairs and Department of Defense. CMS proposed to also exempt "state forensic hospitals" from the price transparency requirements. "State forensic hospitals" are public psychiatric hospitals that exclusively provide treatment for individuals who are in the custody of penal authorities. There are approximately 111 such institutions. All public comments supported this proposal that CMS is finalizing without modification.

D. Improving Access to the Machine-Readable File

In the 2020 hospital price transparency final rule, CMS finalized regulations that a hospital would have discretion to choose the Internet location it uses to post its transparency file containing the list of standard charges. 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.

Despite these rules, CMS has found that hospitals have taken a number of actions that create barriers to accessing price transparency information. Among them are:

- 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

HOSPITAL HEALTH CARE COMPLEX STATISTICAL DATA AND HOSPITAL WAGE INDEX INFORMATION, section 4005.1, Part 1—Hospital and Hospital Health Care Complex Statistical Data, Column 2

signs). These tests are known as CAPTCHA.
- 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. The above are examples of prohibited practices and not intended to be an exhaustive list. CMS further requests comment on other actions it could take to improve accessibility of transparency data.

Many commenters strongly supported CMS finalizing the additional proposed requirement that the machine-readable file be accessible "to automated searches and direct file downloads through a link posted on a publicly available website." Commenters that opposed the additional requirements indicated that it would prohibit the use of pop-up disclaimers and agreements as a prerequisite to accessing the machine-readable file that are necessary to avoid misleading or confusing consumers. There were comments saying that CMS' proposal will prevent hospitals from using security features (like CAPTCHA) to safeguard the overall web-based hosting environment. Due to the size of some of the files, repeated automated attempts by external sources could place stress on the bandwidth of hospital networks and could result in the shutdown and interrupt patient access to the website. There were comments that stated APIs should be permitted because machine-readable file information that is searchable through an API is beneficial to the end-user.

CMS continues to believe that pop-ups (including pop-up disclaimers) present a barrier to both automated and manual access to the machine-readable file by preventing direct download of the file via a link on the hospital's webpage. There are ways other than pop-ups to provide disclaimers. In response to concerns about server security, CMS stated that access to machine-readable files from websites is not unusual, nor are direct downloads. Moreover, accounting for bandwidth considerations and preventing attempted denial of service attacks is within the scope of routine server administration. Server administrators have mitigation strategies to address both issues.

Hospitals are not prohibited under the final rule from making public standard charges via API technology, or using such technology for a consumer-friendly display of standard charges. Hospitals must still make public their standard charges in a single machine-readable file. Under this finalized accessibility policy, such single machine-readable files must be accessible to automated searches and direct file downloads through a link on the hospital website.

There were a variety of comments outlining various technical challenges in identifying and searching for the location of the file related to website domain names, hospitals that don't

maintain websites, and search results that include links to third party aggregators of the files. Several commenters requested more guidance related to what is acceptable to meet the current 'prominently displayed' requirement. Others provided detailed suggestions for improving future requirements related to file 'findability.'

CMS acknowledged that hospitals may be experiencing technical challenges as they implement the hospital price transparency requirements and it will continue to educate hospitals about the requirements, including use of the CMS-specified naming convention. Regarding the request for additional guidance related to how a hospital should ensure that the machine-readable file is displayed 'prominently,' CMS refers hospitals to the detailed discussion in the 2020 Hospital Price Transparency final rule (84 FR 65561). CMS provides the following guidance for meeting the requirement that machine-readable files are 'prominently displayed:'

- Review and use, as applicable, the HHS Web Standards and Usability Guidelines (available at: https://webstandards.hhs.gov/), which are research-based and are intended to provide best practices over a broad range of web design and digital communications issues.
- Post a link to machine-readable file on a website where the value and purpose of the web page and its content is clearly communicated, for example, a dedicated price transparency webpage or a webpage devoted to patient billing or financing healthcare services.
- While "breadcrumbs" (for example, secondary navigation aids) can be useful for navigating a website, they should not be relied upon in order for consumers to find the link to the machine-readable file. Instead, facilitate user navigation by including searchable terms on the webpage such as "price transparency," "standard charges," or "machine-readable file."
- Ensure that the link to the machine-readable file is visually distinguished on the web page, and that its purpose is to open the single machine-readable file for a clearly indicated hospital location.

CMS is finalizing, as proposed, 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.

E. Price Estimator Tools

In the 2020 hospital price transparency final rule, CMS adopted a policy allowing a hospital to meet the shoppable services requirement by offering an internet-based price estimator tool. Among other requirements, the price estimator tool must allow healthcare consumers to obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service at the time of using the tool.

CMS' 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. Others 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. Still 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.

Public commenters both supported and opposed CMS' clarification of policy related to price estimator tools. Supporters urged CMS to permit such tools to satisfy the requirements for all hospital price transparency rules, including the machine-readable file requirements. Opponents of the special exemptions for hospitals that use price estimator tools believe that hospitals are using such tools to continue to obfuscate and avoid making public their standard charges. Many commenters, including several providers and provider organizations, expressed strong support and agreement with the clarification that price estimator tools must take into consideration the individual's insurance information when providing an out-of-pocket estimate. Others noted that since finalization of the Hospital Price Transparency final rule, the adoption of such real-time tools has increased. Commenters noted that both the TiC rule as well as the No Surprises Act have requirements for payers to establish price comparison tools. The No Surprises Act includes requirements for providers to communicate "good faith estimates" Commenters suggested that CMS adopt similar "good faith estimate" requirements for the Hospital Price Transparency Program rules.

CMS appreciates comments related to changes that it may consider in future rulemaking. The rule further indicates that there may be an opportunity in the future to align requirements for a consumer-friendly display of standard charges with the requirements of the TiC regulations and the implementation of the No Surprises Act. CMS notes that nothing in the rule prevents a hospital from developing an accurate and reliable cost estimate using prior claims information or from providing additional information that may be useful to the end-user, such as the range of out-of-pocket costs for the population to which the individual belongs. However, the estimate of "the amount" the individual would be obligated to pay must be displayed as a single dollar out-of-pocket amount within the tool. The tool could require the consumer to manually submit such information in order to generate the estimated out-of-pocket amount.

F. Requests for Comment

CMS requested comment on:

1. Input for future consideration related to the price estimator tool policies;
2. Requiring specific plain language standards;
3. Potential ways to highlight exemplar hospital price transparency practices; and
4. Recommendations for improving standardization of the machine-readable file.

CMS received approximately 396 timely comments. It did not summarize or respond to the comments.

XIX. Hospital Quality Reporting Program, Safer Use of Opioids Measure

In preparation for introduction during 2022 of the measure Safe Use of Opioids - Concurrent Prescribing eCQM to the NQF for routine maintenance review for re-endorsement, CMS sought input on potential future updates of the measure and the required reporting and submission requirements for the measure.

Reporting under the IQR program is required for the CY 2022 reporting period/FY 2024 payment determination. In addition to this measure, hospitals must select and report on three additional eCQMs, from eight available, and data reporting will be required for three self-selected quarters for all four eCQMs. Reporting is scheduled to increase to four quarters of data beginning with the 2023 reporting period/2025 payment determination.

Recommendations from commenters included: 1) cancel mandatory reporting and restore the Safe Opioids eCQM to the list from which hospitals may self-select their required total number of eCQMs; 2) pause mandatory reporting pending NQF re-endorsement; 3) refine the measure's specifications; and 4) retain the current reporting requirements and convert all eCQMs to mandatory reporting (i.e., remove hospitals' ability to self-select measures to report).

CMS indicates that the input received will be considered for future rulemaking.

XX. Promoting Interoperability Program, Safer Use of Opioids Measure

CMS seeks to maintain alignment of eCQM reporting under the hospital IQR and Promoting Interoperability (PI) programs. The Safe Use of Opioids – Concurrent Prescribing measure is required under both programs for the CY 2022 reporting period/FY 2024 payment determination. To support continued alignment, the agency repeated its hospital IQR RFI about this measure in the context of the hospital PI program, posing identical questions (see above section).

Respondents to the PI program RFI echoed the comments submitted in response to the RFI for the hospital IQR program.

CMS again indicates that the input received will be considered for future rulemaking.

XXI. Files Available to the Public via the Internet

Addenda for the 2022 OPPS final rule are available on the following CMS website: CMS-1753-FC | CMS

For addenda related to the 2022 ASC final rule payments, please see: CMS-1753-FC | CMS

TABLE 84—ESTIMATED IMPACT OF 2022 OPPS CHANGES

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes with Market Basket**	**All Changes**
ALL PROVIDERS*	3,659	0.0	0.1	2.1	1.6
ALL HOSPITALS (excludes hospitals held-harmless and CMHCs)	3,552	0.0	0.1	2.1	1.6
URBAN HOSPITALS	2,803	0.0	0.1	2.1	1.6
LARGE URBAN (GE MILLION)	1,448	0.0	0.1	2.1	1.7
OTHER URBAN (LE 1 MILLION)	1,355	0.0	0.1	2.1	1.5
RURAL HOSPITALS	749	0.0	0.3	2.3	1.6
SOLE COMMUNITY	368	0.0	0.4	2.3	1.5
OTHER RURAL	381	0.0	0.2	2.3	1.7
BEDS (URBAN)					
0 - 99 BEDS	958	0.1	0.2	2.2	1.7
100-199 BEDS	786	0.1	0.1	2.2	1.7
200-299 BEDS	447	0.1	0.2	2.2	1.7
300-499 BEDS	386	0.0	0.2	2.2	1.6
500 + BEDS	226	-0.1	-0.1	1.8	1.4
BEDS (RURAL)					
0 - 49 BEDS	327	0.1	0.3	2.4	1.6
50- 100 BEDS	256	0.0	0.3	2.4	1.5
101- 149 BEDS	90	-0.1	0.2	2.1	1.4
150- 199 BEDS	38	0.0	0.4	2.4	1.8
200 + BEDS	38	0.0	0.2	2.2	1.8
REGION(URBAN)					
NEW ENGLAND	132	0.0	0.0	2.0	1.6
MIDDLE ATLANTIC	326	-0.1	0.1	2.0	1.6
SOUTH ATLANTIC	455	0.0	0.3	2.2	1.8
EAST NORTH CENTRAL	440	0.0	-0.2	1.8	1.4
EAST SOUTH CENTRAL	163	0.0	-0.1	1.9	1.5
WEST NORTH CENTRAL	186	0.0	0.9	2.9	1.5
WEST SOUTH CENTRAL	474	0.1	-0.3	1.7	1.3
MOUNTAIN	213	0.0	0.3	2.3	1.5
PACIFIC	366	0.0	0.1	2.2	1.7
PUERTO RICO	48	0.2	-0.5	1.8	1.4
REGION(RURAL)					
NEW ENGLAND	20	-0.1	-0.2	1.7	1.2
MIDDLE ATLANTIC	50	0.0	0.0	2.1	1.7
SOUTH ATLANTIC	113	0.1	0.5	2.6	2.2
EAST NORTH CENTRAL	119	0.0	-0.3	1.8	1.4
EAST SOUTH CENTRAL	146	0.0	-0.2	1.8	1.4
WEST NORTH CENTRAL	91	-0.1	1.1	3.0	1.4
WEST SOUTH CENTRAL	140	0.2	0.6	2.8	2.4
MOUNTAIN	47	-0.1	2.1	4.0	1.4
PACIFIC	23	-0.1	-0.4	1.6	1.2
TEACHING STATUS					
NON- TEACHING	2,385	0.1	0.2	2.2	1.7
MINOR	792	0.0	0.2	2.2	1.6
MAJOR	375	-0.1	0.0	1.8	1.4
DSH PATIENT PERCENT					

	Number of Hospitals	APC Recalibration	New Wage Index and Provider Adjustments	All Budget Neutral Changes with Market Basket	All Changes
0	13	0.3	-0.1	2.1	1.6
0 – 10%	266	0.0	0.1	2.2	1.6
10% - 16%	240	0.1	0.0	2.1	1.6
16% -23%	579	0.1	0.1	2.2	1.6
23%- 35%	1,099	0.0	0.2	2.1	1.6
>35%	897	-0.1	0.1	2.0	1.6
DSH NOT AVAILABLE	458	0.1	0.0	2.2	1.7
URBAN TEACHING/DSH					
TEACHING & DSH	1,048	0.0	0.1	2.0	1.5
NO TEACHING/DSH	1,304	0.1	0.1	2.2	1.7
NO TEACHING/NO DSH	13	0.3	-0.1	2.1	1.6
DSH NOT AVAILABLE[2]	438	0.1	0.0	2.1	1.7
TYPE OF OWNERSHIP					
VOLUNTARY	1,973	0.0	0.2	2.2	1.6
PROPRIETARY	1,131	0.2	0.1	2.3	1.7
GOVERNMENT	448	-0.1	-0.2	1.7	1.7
CMHCs	39	0.4	-1	1.4	1.1
Column (1) shows total hospitals and/or CMHCs.					
Column (2) includes all CY 2022 OPPS policies and compares those to the CY 2021 OPPS.					
Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2022 hospital inpatient wage index. The rural SCHadjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the CY 2022 target payment-to-cost ratio is the same as the CY 2021 PCR target (0.89)					
Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.0 percent OPD fee schedule update factor (2.7 percentreduced by 0.7 percentage points for the productivity adjustment).					
Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adjustment to provideseparate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021 and September 30, 2022, and adding estimated outlier payments. Note that previous years included the frontieradjustment in this column, but we have added the frontier adjustment to Column 3 in this table.					
These 3,659 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.					
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term carehospitals.					