

Medicare Program: 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2022¹ proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on July 19, 2021. Policies in the proposed rule will generally go into effect on January 1, 2022 unless otherwise specified. The proposed rule will be published in the August 4, 2021 issue of the *Federal Register*. **The public comment period will end on September 17, 2021.**

The proposed rule updates OPPS payment policies that apply to outpatient services provided to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals, as well 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 as requests for information on digital quality information, interoperability and rural emergency hospitals.

Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website at: [CMS-1736-FC | CMS](#). Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

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

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I. Overview

A. Estimated Impact on Hospitals

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

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

Hospitals that satisfactorily report quality data will qualify for the full update of 2.3 percent, while hospitals that do not will be subject to 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 3,662 facilities (3,555 hospitals excluding CMHCs and cancer and children's hospitals are held harmless to their pre-OPPS payment to cost ratios). Table 71 in the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows an estimated increase in expenditures of 1.8 percent for all facilities and hospitals. The following table shows components of the 1.8 percent total:

	% Change All Facilities
Fee schedule increase factor	2.3
Difference in pass through estimates for 2021 and 2022	-0.40
Difference from 2021 outlier payments (1.06% vs. 1.0%)	-0.06
All changes	1.8

CMS estimates that pass-through spending for drugs, biologicals and devices for 2022 will be \$1.09 billion, or 1.32 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 1.32=−0.40 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 1.06 percent of total OPPS payments compared to the 1.0 percent set aside, a -0.06 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 1.8 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	1.8%
All Facilities (includes CMHCs and cancer and children's hospitals)	1.8%
Urban	1.8%
Large Urban	1.9%
Other Urban	1.8%
Rural	1.8%
Beds	
0-99 (Urban)	2.0%
0-49 (Rural)	1.7%
500+ (Urban)	1.7%
200+ (Rural)	2.1%
Major Teaching	1.7%
Type of ownership:	
Voluntary	1.8%

Facility Type	2022 Impact
Proprietary	2.0%
Government	2.4%

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 18.1 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 (\$1,484 in 2021) 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 March 30, 2021 to determine the OPPS relative weights for the 2022 OPPS proposed 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 is proposing to use Medicare claims and cost reports from prior to the PHE to determine the 2022 proposed rule relative weights. See section X. E. for details. Otherwise, CMS is not changing its methodology for how it determines the APC relative weights.

CMS proposes to use claims data with a date of services between January 1, 2019 and December 31, 2020 to set the APC relative weights. These are final action claims. After applying exclusionary criteria, CMS is using approximately 93 million claims to develop the proposed 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 proposed rule payment rates, including the number of claims available at each stage of the process: [Medicare CY 2022 Outpatient Prospective Payment System \(OPPS\) Proposed Rule Claims Accounting \(cms.gov\)](https://www.cms.gov/Regulations-and-Rules/Proposed-Rules/Outpatient-Prospective-Payment-System-OPPS/OPPS-Proposed-Rule-Claims-Accounting).

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 174 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.

In the 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), CMS created distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. However, in response to public comment, CMS removed claims from providers that use a cost allocation method of "square feet" to calculate CCRs used to estimate costs associated with the CT and MRI APCs (78 FR 74847) because of concerns about the accuracy of this cost allocation method. CMS indicated that it would provide hospitals with 4 years to transition to a more accurate cost allocation method and would use cost data from all providers, regardless of the cost allocation statistic employed, beginning in 2018. CMS later extended the transition policy through 2018 and 2019.

In the 2020 OPPS final rule, CMS adopted a policy to apply 50 percent of the payment impact from ending the transition in 2020 and 100 percent of the payment impact from ending the transition in 2021. For 2020, CMS calculated the imaging payment rates based on 50 percent of the transition methodology (excluding square feet CCRs) and 50 percent of the standard methodology (including square feet CCRs). For 2021, CMS proposed to set the imaging APC payment rates at 100 percent of the payment rate using the standard payment methodology under the policy it adopted in the 2020 OPPS final rule. CMS is not proposing any further changes for 2022 and will continue to set imaging APC payment using the standard payment methodology.

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 proposed 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 and 2019, 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 mm². For 2020, CMS proposed to set the payment rate for HCPCS code C2645 at \$1.02 per mm² based on 2018 claims data. However, in response to public comments, CMS used its equitable adjustment authority to continue using a rate of \$4.69 per mm² for 2020. CMS maintained this rate for 2021 and proposes to continue it in 2022.

In section X.C. below, this summary further discusses CMS' proposal to use up to four years of claims data for APCs with fewer than 100 single claims 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 proposes to create 5 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.

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 is not proposing 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.

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 proposing any changes to its composite APC policies for 2022.

3. Changes to Packaged Items and Services

a. Packaging Policies and Non-Opioid Treatment Alternatives

CMS is not proposing any changes to its packaging policies outside of its policies on 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. Under this authority, CMS is paying separately in the ASC setting only (not the hospital outpatient department) for two products: Exparel and Omidria.

For the 2022 OPPS proposed rule, CMS repeats analysis done in prior years regarding whether to unpackage payment for non-opioid treatment alternatives from OPPS or ASC payments. The results of CMS’ 2022 review were similar to the results in previous years. CMS is not proposing to unpackage any additional non-opioid treatment alternatives from OPPS or ASC payments. Nevertheless, CMS reiterates its same request for public comments on this issue that were in prior proposed rules—asking for evidence that packaging non-opioid treatment alternatives is a disincentive to their use and unpackaging them will lead to reduced use of opioids in either the ASC or outpatient department setting.

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

For 2022 and subsequent years, CMS proposes 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 and must meet the annual cost threshold for separately payable drugs. The proposed criteria are 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.

To meet the FDA approval requirements CMS is proposing 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 indicates 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. CMS indicates that both Exparel and Omidria would meet the proposed criteria and proposes to continue paying separately for both of these products under this policy in the ASC in 2022.

The proposed 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.

Pass-through drugs and biologicals would not be eligible for separate payment under this proposal while separate payment is already being made 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.

The policy only applies to non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure that are ancillary items integral to a covered surgical procedure and for which separate payment is allowed. The payment rate for non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure are paid an amount derived from the payment rate for the equivalent item or service under the OPPS, and if such a payment amount is unavailable, are contractor priced.

CMS is further soliciting comment on potential policy modifications and additional criteria that may help further align this policy with the intent of the SUPPORT Act. Specifically, CMS requests comment on:

- Whether it should continue to use utilization as an indicator of whether the product should be unpackaged.
- 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.
- 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.
- 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.
- 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.

4. Calculation of OPPS Scaled Payment Weights

As in past years, CMS proposes to standardize 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 proposes giving APC 5012 a relative weight of 1.0 and dividing 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 proposed to 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 proposed to follow its past practice to determine budget neutrality for changes in the OPPS relative weights. Holding all other variables constant, CMS multiplies the 2021 and 2022 proposed relative weights respectively for each APC by its associated volume from 2019. It sums the 2021 and proposed 2022 relative weights respectively, and then divides the 2021 aggregate relative weights by the proposed 2022 aggregate relative weights to determine the weight scaler. Using this process, CMS proposes adopting a weight scaler of 1.4436. CMS will update these calculations for the final rule. The unscaled proposed 2022 relative payments are multiplied by 1.4436 to determine the proposed 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. For the proposed rule, the components of the update are shown in the below table:

2021 Conversion Factor (CF)	\$82.7970	Resulting CF
Remove pass-through and outliers from prior year CF	1.0196	\$84.418
Wage Index Budget Neutrality	1.0012	\$84.519
Cancer Hospital Adjustment	1.0000	\$84.519
Rural Hospital Adjustment	1.0000	\$84.519
Update	1.0230	\$86.463
Pass-Through and Outlier Adjustment	0.9768 ²	\$84.457
2022 Conversion Factor		\$84.457

² The budget neutrality adjustment for pass-through comes from the claims accounting that reflects an adjustment of -1.32 percent. However, on page 90 of the display copy of the proposed rule, CMS says that pass-through payments are 1.24 percent of total OPPS spending. If an adjustment of -1.24 percent were used in place of -1.32 percent, the proposed rule CF would be \$84.5260.

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 1.0012 (0.12 percent). The update of 1.023 (2.3 percent) equals the market basket of 2.5 percent less 0.2 percentage points for MFP. CMS estimates that pass-through spending for drugs, biologicals and devices for 2022 will be \$1,024.7 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 0.9768 (-2.32 percent).

CMS reports that the reduced conversion factor for hospitals not meeting the OQR requirements will be \$82.810. However, if the full update of 2.3 percent (1.023) is reduced by 2.0 percentage points to 0.3 percent (1.003) and substituted for 1.0230 (2.3 percent) in the above table, the resulting conversion factor for hospitals that do not meet the OQR requirements would be \$83.227. CMS calculates the conversion factor for hospitals that do not meet the OQR requirements by multiplying the full conversion factor (\$84.457) by a "reporting ratio" of 0.9805. The rule does not explain the calculation of the reporting ratio. Ostensibly, it is the ratio of the reduced update to the full update considering all of the adjustment factors above. While \$82.810/\$84.457 does equal 0.9805, it is not equivalent to a reporting of 0.9846 that would result from dividing the correct reduced CF of \$83.227 by \$84.457.

C. Wage Index Changes

CMS proposes to continue using a labor share of 60 percent and the fiscal year IPPS post-reclassified wage index for the OPPS in 2022. For non-IPPS hospitals paid under the OPPS for 2022, CMS proposes to continue 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 proposes to 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 proposes 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 also proposes to 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 proposes to continuing 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 proposes to continue applying 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. Consistent with 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 proposes to continue using the same cost data to determine the target PCR for 2022 that it used for 2021. Therefore, CMS proposes a target PCR of 0.90 reduced by 1.0 percentage point to 0.89.

Table 4 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2022 ranging from 9.9 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 proposes to continue setting aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It proposes calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2021 and previous years. CMS proposes to 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 calculates a proposed rule fixed-dollar threshold of \$6,100 (compared to \$5,300 in 2021).

CMS again proposes to 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. CMS proposes to continue its policy that 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, CMS proposes to continue its policy that 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 proposes to use data predating the 2020 PHE to determine the proposed rule outlier threshold. To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied a charge inflation factor of 1.20469 to approximate 2022 charges from 2019 claims. CMS proposes to adjust 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 proposed rule fixed loss threshold.

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 \$1,484 in 2021. 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. The proposed status indicators, APC assignments, and payment rates can be found in Addendum B of this proposed rule.³

1. April 2021 Codes - CMS Solicits Public Comments in this Proposed Rule

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 5). For the April 2021 update, there were no new CPT codes.

2. July 2021 HCPCS Codes - CMS Solicits Public Comments in this Proposed Rule

In the July 2021 OPPS quarterly update, CMS made 55 new codes effective and assigned them to interim OPPS status indicators and APCs (Table 6).

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

CMS proposes to provide interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that will become effective October 1, 2021 in Addendum B to the 2022 final rule. These codes will be flagged with comment indicator “NI” in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2022. CMS proposes that these status indicators and APC assignments would be applicable in 2022. **CMS will invite public comment in the 2022 OPPS final rule** about the status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2023 OPPS final rule.

4. January 2022 HCPCS Codes

a. New Level II HCPCS Codes – CMS Will Be Soliciting Public Comments in the 2022 Final Rule with Comment Period

CMS will solicit comments on the new Level II HCPCS codes that will become effective January 1, 2022 in the 2022 OPPS final rule. 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 will be flagged with comment indicator “NI” in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2022. CMS proposes that these status indicators and APC assignments will be applicable in 2022. **CMS will invite public comment in the 2022 OPPS final rule** about the

³ Addendum D1 includes the complete list of status indicators and corresponding definitions. Addendum D2 includes the complete list of comment indicators and definitions.

status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2023 OPPS/ASC final rule.

b. CPT Codes - CMS Will Be Soliciting Public Comments in This Proposed Rule

For the 2022 OPPS update, CMS received the CPT codes that will be effective January 1, 2022 in time to be included in this proposed rule (available in Addendum B of this proposed rule). CMS will continue to assign a new comment indicator “NP” and is requesting 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 proposes to finalize the status indicators and APC assignments for these codes in the 2022 OPPS final rule.

Because the CPT code descriptors in Addendum B are short descriptors, the long descriptors for the new and revised CPT codes are available in Addendum O. CMS notes that these new and revised CPT procedure codes have a placeholder for the fifth character and the final CPT code numbers will be included in the final rule.

Table 7 (reproduced below) summarizes the process used by CMS for updating codes.

Table 7: 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 will be discussed in the 2022 OPPS final rule.

For 2022, CMS has identified APCs with violations of the 2 times rules and proposes 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 reassessments and associated APC configurations for 2022 are related to changes in costs of services that were observed in the 2019 claims data.

2. Proposed 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.

Table 8 (reproduced below) lists the 23 APCs that CMS proposes to exempt from the 2 times rule for 2022 based on claims data from January 1, 2019, through December 31, 2019 and processed on or before June 30, 2020.

Table 8: Proposed 2021 APC Exceptions to the 2 Times Rule	
Proposed CY 2021 APC	Proposed CY 2021 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

Table 8: Proposed 2021 APC Exceptions to the 2 Times Rule	
Proposed CY 2021 APC	Proposed CY 2021 APC Title
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
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 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.

The proposed payment rates for these New Technology APCs are included in Addendum A to this proposed rule.

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. For 2022, CMS proposes to continue this policy:

- 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.

3. Procedures Assigned to New Technology APC Groups for 2022

CMS proposes to continue the current policy to retain services within New Technology APC groups until they obtain 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 2021, CMS only identified 35 paid claims for the 4-year period of 2016 through 2019 (the same data used to determine the payment rate for 2021). All three estimates of the cost of the Argus II procedure fall within the cost band for New Technology APC 1908, with an estimated cost between \$145,001 and \$160,000. For 2022, using its equitable adjustment authority, CMS proposes to maintain the assignment of CPT code 0100T to APC 1908 with a proposed payment

rate of \$152,500.50 (Table 9). 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, using its equitable adjustment authority, CMS proposes to continue assign C9770 to New Technology APC 1561 (Table 10).

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 proposes to continue to assign HCPCS code C9751 to APC 1562 (New Technology Level 265 (\$3,501-\$4,000)) with a proposed payment rate of \$3,750.00 (Table 11).

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 proposes to continue to assign CPT code 0503T to New Technology APC 1511 (New Technology – Level 11 (\$901-\$1000)), with a payment rate of \$950.50 (Table 12).

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 proposes to continue to maintain the 2021 assignments for these codes (Table 13).

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, C9758⁴, 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 proposes to continue to assign C9758 to APC 1590 (Level 39 (\$15,001-\$20,000) with a proposed payment rate of \$17,500.50 (Table 14).

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.⁵ For 2021, CMS assigned HCPCS code C9760 to New Technology APC 1592 (New Technology Level 41 (\$25,001-\$30,000)).

⁴ 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.

⁵ 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

For 2022, CMS proposes to continue to assign HCPCS code C9760 to New Technology APC 1592 (New Technology Level 41 (\$25,001-\$30,000), with a proposed payment of \$27,500.50 (Table 15).

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 proposes to continue to assign HCPCS code G2082 to New Technology APC 1508 (New Technology- Level 8 (\$601-\$700) and assign HCPCS code G2083 to New Technology APC 1511 (New Technology – Level 11 (\$902-\$1000) (Table 16).

D. APC-Specific Policies

Stromal Vascular Fraction (SVF) Therapy is intended to treat knee osteoarthritis. To process SVF, the patient's body fat is processed and used as an autologous cellular implant for injection into the knee. SVF therapy is described by CPT code 0565T and 0566T. For 2021, CDPT code 0565T is assigned to APC 5733 (Level 3 Minor Procedures) and CPT code 0566T is assigned to APC 5441 (Level 1 Nerve Injections).

For 2022, CMS proposes not to pay for either code under the OPPS. CMS proposes to change the SI for CPT code 0565T and 0566T to “E1” to indicate that the code is not payable by Medicare. Based on information from the FDA there are no FDA-approved autologous cellular product derived from autologous body fat. In addition, review of the clinical trial.gov website indicates that SVF therapy is currently under clinical trial but has not received CMS approval as an IDE study.

guidance performed in an approved IDE study.

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 17 (reproduced below) lists the devices and their pass-through expiration.

Table 17: Expiration of Transitional Pass-Through Payments for Certain Devices

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021*
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable) nonrechargeable with carotid sinus baroreceptor simulation lead(S)	1/1/2021	12/1/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

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

The pass-through payment status for HCPCS code C1823 is scheduled to expire on December 31, 2021. Typically, CMS would propose 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 proposes to use 2019 claims data instead of 2020 claims data for establishing 2022

payment rates. For 2022, CMS proposes 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.

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 been 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 from 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 current 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 subregulatory 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 notes it is also available to meet with applicants or potential applicants to discuss research trial design in advance of submitting any application.

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 were approved under the alternative pathway: the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter, effective July 1, 2021. The summary below provides a high-level discussion of each application; readers are advised to review the final rule for more detailed information. **CMS invites comments on whether these technologies meet the newness, cost, and substantial clinical improvement criteria (when appropriate).**

i. *Alternative Pathway Device Pass-Through Applications*

(1) RECELL System⁶

Avita Medical submitted an application for RECELL, a standalone, single-use, battery-powered device used to process an autologous skin cell suspension that is immediately applied to a surgically prepared acute thermal burn. The applicant states 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 from the patient's skin and is applied to treat acute thermal burns (Table 18 compares the two products).

Newness. RECELL was granted Expedited Access Pathway (EAP) by FDA (which is considered part of the Breakthrough Devices Program by FDA⁷) 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.

Eligibility. According to the applicant, RECELL meets all the eligibility requirements. CMS notes that based on the applicant's description of RECELL as a device that processes tissue into an autograft, the RECELL system may not be surgically implanted or inserted (either permanently or temporarily) because it is applied in or on a wound or other skin lesion.

⁶ 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.

⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program>

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.

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.

(2) Shockwave C² Coronary Intravascular Lithotripsy (IVL) Catheter⁸

Shockwave Medical Inc. submitted an application for the Shockwave C² Coronary IVL catheter⁹, 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, 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.

Eligibility. According to the applicant, the Coronary IVL Catheter meets all the eligibility requirements.

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 preliminary approved the Coronary IVL Catheter for transitional pass-through payment under the alternative pathway effective July 1, 2021. **CMS invites comments on whether this device should continue to receive transitional pass-through payment under the alternative pathway.**

⁸ 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).

⁹ The Shockwave C² Coronary IVL System is comprised of the IVL Generator, IVL connect cable, and a coronary IVL Catheter.

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 monitors 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 communicates 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). The applicant anticipates the device will be available for US markets in the third quarter of 2021. CMS received the application on February 28, 2021, which is within 3 years of the date of the initial marketing authorization.

Eligibility. According to the applicant, the Guardian® System meets all the eligibility requirements.

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.

CMS summarizes this information and discusses specific concerns with the submitted information. CMS discusses how one study¹⁰ did not demonstrate statistically significant

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.

superiority of the intervention; this might have been based on a lower-than-expected frequency of events and early termination of the study. The second study¹¹ was based on a post hoc analysis of data from the first study; **CMS seeks comments on whether a post-hoc analysis provides sufficient evidence to support the claim of substantial clinical improvement.** CMS also notes concerned the primary efficacy endpoint was a composite of three outcomes related to rate for ED visits and CMS is concerned that this endpoint is not an appropriate measure to evaluate substantial clinical improvement in patients with ACS events.

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

(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 §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. CMS does 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 does 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

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.

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.

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 believes that the BONEBRIDGE is 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).

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.

CMS summarizes this information and discusses specific concerns with the submitted information. CMS notes that because the studies did not involve a direct comparison 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. The small number of participants in the studies may also affect the generalizability to the Medicare population. CMS is also concerned about the studies comparing the complication rates, which included a white paper authored by the manufacturer.¹³ CMS is 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.

Cost. CMS believes the BONEBRIDGE System meets all the cost criteria.

(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.

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)

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. Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the Eluvia™ System. The applicant proposed a category descriptor of “Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system.” *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). CMS summarizes this information and refers 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 notes 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

As previously discussed in the 2020 OPPS/ASC final rule, CMS is 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.

Cost. Section 419.66(d) establishes three cost significance criteria that must be met. The applicant stated that the Eluvia™ System would be reported with CPT code 37266 (APC 5193) and CPT code 37227 (APC 5194) (Table 23). CMS believes the Eluvia™ System meets the first cost significance requirement but does not meet the second and third cost significance requirements.

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.

(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 processor, 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. CMS does 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 does not include the Osia® 2 System. According to the applicant, the devices described by this category do not include either the Osia® 2 System or 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. For these devices, the applicant proposed a device pass-through category descriptor "Auditory osseointegrated device, including implanted transduce/actuator with radiofrequency link to external sound processor"

CMS believes that the Osia® 2 System and BONEBRIDGE are 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).

Substantial Clinical Improvement. The applicant stated that 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 notes 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.

CMS is 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 is concerned it is unable to make a substantial clinical improvement determination.

Cost. CMS believes the Osia® 2 System meets all the cost criteria.

(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 states 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.

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.

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).

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

CMS notes 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.

Cost. CMS believes the Pure-Vu® System meets all the cost criteria.

(6) Articulating Xenoscope Laparoscope (Xenoscope™)

Xencor Inc., submitted an application for the Xenoscope™, a disposable laparoscope used for diagnostic and therapeutic laparoscopic procedures. 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.

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.

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 asserts 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”.

CMS is 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 do not involve the clinical use of the Xenoscope™ and did not compare the device to a reusable laparoscope. CMS concludes there is insufficient evidence to determine whether the Xenoscope™ offers a substantial clinical improvement over a reusable laparoscope.

Cost. CMS believes the Xenoscope™ meets all the cost criteria.

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

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.

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.

As previously discussed, CMS proposes to use 2019 claims data to establish 2022 OPPS rates. If 2020 claims information is available, CMS proposes 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. For 2022, CMS proposes to assign device offset percentages using 2020 claims data for the 11 procedures listed in the table below.

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

The full listing of proposed 2020 device-intensive procedures provided in Addendum P.¹⁸ For 2021 CMS is not proposing any changes to the device-intensive policy. CMS' claims accounting narrative contains a description of its device offset percentage calculation. The claims accounting narrative can be found under supporting documentation for this proposed rule on the CMS website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospital/OutpatientPPS/index.html>.

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

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

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 is not proposing any changes to the device edit policy.

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 is not proposing 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 proposes 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 (section X rule). Under the proposed universal low volume APC policy, CMS would establish a payment rate using the highest of the median cost, arithmetic mean cost, or the geometric mean cost. In conjunction with this policy, CMS proposes 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

A. Transitional Pass-Through Payment: Drugs, Biologicals and Radiopharmaceuticals

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 proposed rule.

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 27 of the proposed rule lists 25 drugs and biologicals for which CMS is ending pass-through payment after 2021. Each of the products will have received at least the full 3 years of pass-through payments once the additional payments expire.

Table 28 of the proposed 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 29 of the proposed rule lists 46 drugs and biologicals where CMS will be continuing pass-through payment in 2022. For 2022, CMS will continue average sales price (ASP)+6 percent as payment for pass-through drugs and biologicals. As separately payable drugs and biologicals will be paid at ASP+6 percent with or without pass-through payment (except when acquired through the 340B drug discount program), no APC offset is required. If ASP data are not available, CMS proposes to provide pass-through payment at wholesale acquisition cost (WAC)+3 percent. If WAC information also is not available, CMS proposes to provide payment for pass-through drugs and biologicals at 95 percent of their most recent average wholesale price (AWP).

Except when paid on pass-through, payment for policy packaged drugs and biologicals is always packaged with the APC. Policy packaged drugs include anesthesia; medical and surgical supplies and equipment; surgical dressings; devices used for external reduction of fractures and dislocations; drugs, biologicals, and 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.

For policy packaged drugs, CMS proposes that the pass-through payment amount would equal ASP+6 percent for 2022 minus a payment offset for any predecessor drug products included in the APC. CMS also proposes to pay for diagnostic and therapeutic radiopharmaceuticals receiving pass-through payment at ASP+6 percent. As diagnostic radiopharmaceuticals are also policy packaged, CMS proposes a payment offset from the associated APC.

Table 30 of the proposed 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](#). (At the time of this writing, the offset file was not yet posted.)

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

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

CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through payment status in one of two ways: packaged into the payment for the associated service or separate payment (individual APCs). Hospitals do not receive a separate payment for packaged items and 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.

Cost Threshold for Packaging of “Threshold-Packaged Drugs”

“Threshold-packaged drugs” under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug’s average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2022, CMS proposes a packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status of \$130.

To calculate the 2022 threshold, CMS proposes to use 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, 2020¹⁹, 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 proposed rule, CMS uses ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 4th quarter of 2020 (data that were used for drugs and biologicals payment in physicians’ offices effective April 1, 2021). CMS is continuing to use 2020 ASP data collected during the PHE stating that ASP data are not affected by changes in utilization the way non-drug services are for setting payment rates. For products that do not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS will use their mean unit cost derived from 2019 hospital claims data. CMS will package products with 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.

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 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.

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 31 of the proposed rule.

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

Except for separately payable, non-pass-through drugs acquired with a 340B discount, CMS proposes to continue paying for separately payable drugs and biologicals at ASP+6 percent in 2022. For drugs acquired under the 340B drug discount program, CMS proposes to continue paying ASP-22.5. Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Consistent with policy in the PFS, CMS again proposes to pay for drugs under the OPPS during an initial sales period (2 quarters) in which ASP pricing data are not yet available from the manufacturer at WAC+3 percent. Consistent with PFS policy, CMS is proposing to limit this WAC+3 percent policy under the OPPS only 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. CMS proposes that drugs paid using WAC and that are acquired under the 340B program would be paid at WAC-22.5 percent. If ASP and WAC are unavailable, CMS proposes that Medicare will pay 95 percent of AWP or 69.46 percent of AWP if the drug is acquired under the 340B program.

CMS also proposes to 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 proposed 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 proposed rule for which there was no ASP information available for the 4th quarter of 2020 are based on mean unit cost in the available 2019 claims data (not stated but presumably CMS is using 2019 utilization data rather than 2020 utilization data that spans the PHE). 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.

Biosimilar Biological Products

CMS pays for biosimilar biological products using parallel policies that it uses 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 percent 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 proposes to continue 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. CMS is not proposing any changes to this policy.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2022, CMS proposes to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS also proposes to determine 2022 payment rates based on 2019 geometric mean unit costs (not stated but presumably CMS is using 2019 data rather than 2020 data for geometric mean unit cost to avoid using data from 2020 that spans the PHE).

4. Payment for Blood Clotting Factors

For 2022, CMS proposes to continue paying for blood clotting factors at ASP+6 percent and 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: [Medicare Part B Drug Average Sales Price | CMS](#)

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

CMS is proposing to continue 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, which was

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 minus 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 minus 28.7 percent. CMS stated that maintaining the policy of paying ASP minus 22.5 percent for 340B drugs was appropriate in order to maintain consistent and reliable payment for both 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 use for 340B drug payment.

For 2022, CMS is proposing to continue 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.

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 is proposing to continue 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 proposes to use 2019 data for this purpose (presumably CMS is not using 2020 data that span the PHE for this purpose consistent with its other proposals).

The proposed 2022 MUC threshold is \$48 per cm² rounded to the nearest \$1, and the proposed 2022 PDC threshold is \$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 proposes to continue assigning it to the high-cost group in 2022. Otherwise, CMS proposes assigning the skin substitute to the low-cost group.

Table 32 displays the 2022 cost category assignment for each skin substitute product. For 2022, CMS is proposing 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.

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 is not making a proposal at this time.

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 \$552.3 million in 2022 for devices—\$307.9 million for those recently eligible for pass-through payments that will continue for 2022 and \$244.4 million for those CMS knows or projects could be approved for pass-through status in 2021.

One additional device has expiring pass-through payment in 2022. CMS is proposing to extend pass-through to this product in 2022 due to the PHE (see discussion below). This product is estimated to increase device pass-through spending an additional \$3.5 million in 2022.

B. Drugs and Biologicals

CMS estimates pass-through spending of \$472.4 million in 2022 for drugs and biologicals—\$462.4 million for those recently eligible for pass-through payments that will continue for 2022 and \$10 million for those CMS knows or projects could be approved for pass-through status in 2022.

Twenty-one additional drugs and biologicals will have expiring pass-through payment in 2022. CMS is proposing to extend pass-through for these drugs and biologicals in 2022 due to the PHE. These drugs and biologicals are estimated to increase pass-through spending an additional \$61.5 million in 2022.

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

As discussed in section X.E., CMS is proposing to use 2019 claims data instead of 2020 claims data in establishing the 2022 OPPS rates. If CMS’ proposal to use 2019 data rather than 2020 data for rate-setting is finalized, the 2019 data that CMS is using for 2022 rate-setting purposes would not reflect the costs of devices and drugs receiving pass-through payment in 2021 where the additional payment expires in 2022.

For 2022, CMS is proposing 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 will expire in 2022. As 2023 OPPS rates will be 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 \$65 million for 2022. Table 33 of the proposed rule lists the drugs, biologicals, and device for which CMS proposes 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 is not proposing any expansions to this policy for 2022.

VIII. Partial Hospitalization Program (PHP) Services

A. Background

CMS provides an extensive description of the evolution of its payment policies for 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 rate-setting 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 floor was not necessary, and it did not finalize the proposed cost floors.

In the April 30, 2020 interim final rule with comment, 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, CMS proposes to continue 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 proposes 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 would continue 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, 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 rate-setting for 2022. CMS noted sharp declines in the number of PHP days in its trimmed 2020 claims dataset (53 percent less and 45 percent less for hospitals and CMHCs respectively). Thus, CMS proposes 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 proposes to continue its policy to exclude 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 and to exclude hospital-based PHP service days when a CCR>5 is used to calculate costs for at least one of the component services. CMS also proposes to default 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 proposed rule, CMS divided costs from Worksheet C, Line 50, Column 5 by charges from Worksheet C, Line 50, Column 4. Additionally, CMS proposes for 2022 and subsequent years to use HCRIS as the source for CMHC cost information used for calculating the geometric mean per diem cost for CMHC APC 5853; 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 was excluded for missing wage index data, and one provider was excluded from rate-setting 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 rate-setting. The calculated geometric mean per diem cost for all CMHCs for providing 3 or more services per day is \$130.41 which represents a decrease from the 2021 geometric mean per diem cost. CMS is concerned generally by any significant fluctuation in the geometric mean per diem costs over time, and, particularly 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, it proposes to use the 2021 CMHC geometric mean per diem cost of \$136.14 as a floor for 2022 year. It would substitute the 2022 CMHC geometric mean per diem cost calculated in the final rule if it is greater than \$136.14.

2. Hospital-based PHP Providers

For hospital-based PHP providers, CMS removed 72 providers as follows: 1 with all service days having a CCR greater than five, 68 with no PHP payment, 2 with no allowable PHP HCPCS codes, and 1 with geometric mean costs per day outside the ± 3 standard deviation limit. The calculated geometric mean per diem cost for 2022 for all hospital-based PHP providers for providing 3 or more services per day is \$253.08 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 proposes to use the 2021 hospital-based PHP provider geometric mean per diem cost as a floor for 2022. It would substitute the 2022 geometric mean per diem cost calculated in the final rule if it is greater than \$253.76.

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

2022 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$136.14	\$143.42
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	\$253.76	\$267.31

* Table 34 of the proposed rule shows the proposed PHP APC geometric mean per diem costs.

** The proposed payment rates are from Addendum A to the proposed rule.

C. Outlier Policy for CMHCs

For 2022, CMS proposes 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. In the preamble to the rule, CMS provides a more detailed explanation of the steps involved in calculating the CMHC outlier percentage.

CMS projects that CMHCs will receive 0.02 percent of total hospital outpatient payments in 2022 (excluding outlier payments), and it proposes to designate 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 proposes to set 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 will calculate 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 proposes to continue 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 plus or minus 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 proposes to continue this policy for 2022. This payment cap only impacts CMHCs.

CMS does not propose to set a fixed-dollar threshold for CMHC outlier payments that it proposes to apply 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 1.6 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 included 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 longstanding criteria for removal.

B. Changes to the IPO List for 2022

The proposed rule reviews commentary on eliminating the IPO list. 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.

Following the 2021 OPPS final rule, stakeholders continued to express concerns about elimination of the IPO list. These concerns 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 that CMS 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 proposes to halt the elimination of the IPO list beginning in 2022. As CMS is halting elimination of the IPO list beginning in 2022, it also believes that the criteria for removing a procedure from the IPO list should be reinstated. CMS proposes to reinstate the criteria for removing a procedure from the IPO list beginning in 2022.

CMS further evaluated the 298 procedures removed from the IPO list in 2021 against the proposed reinstated criteria and determined that none of the removed procedures met those criteria. For this reason, CMS proposes to add all 298 procedures back to the IPO list for 2022. Table 35 lists these 298 procedures.

If commenters believe any of these 298 procedures should be removed from the IPO list, CMS requests that commenters submit corresponding evidence to support their position. 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 indicates 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.

The proposed rule further requests comments from stakeholders 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?

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 Recovery Audit Contractors (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 Beneficiary and Family-Centered Care Quality Improvement Organizations (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 228 musculoskeletal procedures from the list. In conjunction with that policy, CMS heard from many commenters last year 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 than inpatient.

2. Policy for 2022 and Subsequent Years

In section IX of the proposed rule, CMS discusses its proposal to halt elimination of the IPO list, reinstate the 228 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 proposing to return 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 proposes 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, 2021.

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.

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 proposes 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 advises commenters to respond to this issue as part of the PFS rulemaking process rather than the OPPS.

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 proposes 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 proposes 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 proposes to determine relative weight based on the higher of the *APC*'s geometric mean, median or the arithmetic mean. CMS will 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 proposes not using utilization data that spans the PHE. For 2022, CMS proposes 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 is not proposing to apply the low volume APC policy to APC 5853 Partial Hospitalization for CMHCs or APC 5863 Partial Hospitalization for Hospital-based PHPs. CMS is also not applying this policy to APC 2698 for brachytherapy sources “not otherwise specified” that is priced using external data sources.

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 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 proposed 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, during the PHE, have become accustomed to receiving these services in their homes. For this reason, CMS seeks 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.

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.

CMS seeks 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.
- 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.

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.

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

The Secretary is required by statute to revise the APCs and 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 proposed rule, CMS is proposing 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 is nearly identical to the analysis provided in the FY 2022 IPPS proposed rule. CMS cites the following reasons for proposing to use 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 concludes 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 presents a complex analysis of how case-mix would be impacted by using the 2019 versus the 2020 utilization. From this analysis, CMS concludes 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 Medicare hospital cost report 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 notes that many FY 2019 cost reporting periods actually end in 2020 during the period of the COVID-19 PHE. CMS is proposing to use cost report data from the FY 2018 HCRIS file in determining the proposed 2022 OPPS relative weights.

While CMS is proposing to use 2019 outpatient claims and the FY 2018 HCRIS to set the 2002 OPPS relative weights, it is also considering continuing with its historical practice of always using the latest available data for these purposes. To facilitate comment on this alternative for 2022, CMS is making 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 is providing the OPPS Impact File, cost statistics files, addenda, and budget neutrality factors. These files can be accessed through the link provided at the beginning of this summary.

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 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 proposing 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 is proposing to extend pass-through payment for up to four quarters for these products. CMS is proposing a one-time equitable adjustment under section 1833(t)(2)(E) 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 these products, CMS believes providing separate payment for up to a full year in 2022 is warranted to ensure there is a full year of data for rate-setting in 2023. For devices, drugs and biologicals that would otherwise be packaged, the extended pass-through payment will ensure the cost of these products is incorporated into the APC. 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 38 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.

XI. OPPS Payment Status and Comment Indicators

OPPS Payment Status Indicator Definitions

For 2022, CMS is not proposing 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 whether particular OPPS policies 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 2020:

“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 proposed rule.

XII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Update: 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 proposes adopting an OPPS update of 2.3 percent (2.5 percent market basket less 0.2 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 2.3 percent in the proposed 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 to 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 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 is not proposing any cost reporting requirements for ASCs.

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		0.9993
2022 Update		
Hospital market basket update		2.5%
Multi-factor productivity adjustment (MFP)		-0.2%
Net MFP adjusted update		2.3%
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.3%	0.3%
2022 Proposed ASC Conversion Factor	\$50.043	\$49.064

CMS estimates that under the proposed rule, total ASC Medicare payments for 2022 will be approximately \$5.16 billion, a decrease of \$20 million compared with 2021 levels inclusive of changes in enrollment, utilization, and case mix changes.

As with the rest of the OPPS proposed 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/medicare/fee-service-payment/hospital/outpatient/pps/hospital-outpatient-regulations-and-notices/cms-1753-p>. All ASC Addenda to the proposed rule are contained in the zipped folders entitled Addendum AA, BB, DD1, and DD2.

A. Background

Covered surgical procedures in an ASC are 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 the ASC-CPL criteria under 42 CFR 416.166, retaining the general standard criteria 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.

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 proposals for new codes in two categories:

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

Table 42 in the proposed 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 Solicits Public Comments in this 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 39 displays the codes, descriptors, and the 2022 proposed 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 (Table 40). Table 40 and 41 lists the codes, descriptors, and the 2022 proposed 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 proposes to continue 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 will invite 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.

²⁰Table 39 in the proposed rule lists 9 HCPCS codes.

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

CMS seeks comment on proposed new and revised CPT codes effective January 1, 2022 that were received in time to be included in this proposed rule. They will be 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 is not proposing to assign permanent office-based designations for 2022 to any covered surgical procedure currently assigned a payment indicator of “G2”. Moreover, CMS is also proposing not to use 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 proposes to continue to designate these nine procedures, shown in Table 43 in the proposed rule, as temporarily office-based for 2022.

For 2022, CMS proposes to designate two new 2022 CPT codes for ASC covered surgical procedures as temporarily office-based. This includes CPT code 42XXX (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 proposes to add CPT code 53XX4 (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.

Proposed 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 proposes 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 proposes 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. **CMS seeks comments on its proposed changes related to designating surgical procedures as device-intensive under the ASC payment system.**

The ASC covered surgical procedures that CMS proposes to designate 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 proposed rule. This policy expands the number of device-intensive ASC procedures; CMS proposes 444 ASC procedures as device intensive in this rule compared with 373 in 2021.

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 proposes 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.

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

For 2022, CMS proposes to re-adopt the ASC Covered Procedures List (CPL) criteria that were in effect in 2020 and to remove 258 of the 267 procedures that were added to the ASC CPL in 2021. CMS states that it concluded that many of the procedures added in 2021 would only be appropriate for Medicare beneficiaries who are healthier and have less complex medical conditions than the typical beneficiary. After evaluating the 267 surgery or surgery-like codes that were added last year, CMS clinicians determined 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. Table 45 in the proposed rule lists the surgical procedures proposed for removal from the list of ASC covered surgical procedures for 2022.

CMS proposes 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.*

CMS requests comments on whether any of the 258 procedures meet the 2020 criteria that it is proposing to reinstate. It requests any clinical evidence or literature to support commenters' views that any of these procedures meet the proposed revised 2022 criteria and should remain on the ASC CPL for 2022.

CMS also proposes 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 proposal, 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 proposes to address nominated procedures beginning in the 2023 rulemaking cycle. It also proposes to 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 seeks 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. For example, whether it should prioritize the nominations that have codes nominated by multiple organizations or individuals, codes recently removed from the IPO list, codes accompanied by evidence that other payers are paying for the service on an outpatient basis or in an ASC setting, or a variety of other factors.

D. Payment Update

Proposed ASC Payment for Covered Surgical Procedures

CMS proposes 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 will be phased in beginning January 1, 2022 and discussed in the 2022 Medicare PFS proposed rule.

Proposed 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 proposes a low volume APC policy for 2022 and subsequent calendar years. Under this proposal, 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 proposes to 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 would 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 proposes to eliminate its low volume device-intensive procedure policy and subsume the ratesetting issues associated with HCPCS code 0308T within its broader low volume APC proposal. Consequently, CMS proposes to modify 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.

CMS seeks comments on its proposal to modify its existing regulations at §416.171(b)(4) and limit the ASC payment rate for services assigned to low volume APCs to the payment rate for the OPPS.

Proposed Payment for Covered Ancillary Services

CMS proposes 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 proposes a policy 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 proposed new §416.174. CMS also proposes to continue 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 proposes to continue 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 with the proposed new comment indicator "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.

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

CMS proposes to continue 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, 0.8591, is the proposed weight scaler for 2022. The scaler would apply 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 would 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, 0.9993, is the proposed wage index budget neutrality adjustment to the conversion factor for 2021.

To update ASC rates, CMS would utilize the hospital market basket update of 2.5 percent minus the MFP factor of 0.2 percent. This yields an update of 2.3 percent for ASCs meeting quality reporting requirements. CMS would continue 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 proposed 2022 ASC conversion factor is \$50.043 for ASCs reporting quality data, and \$49.064 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 0.9993
Net MFP-adjusted update	x 1.023	x 1.003
2022 Proposed ASC conversion factor	\$50.043	\$49.064

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 72 of the proposed 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 proposed for 2022. The second largest group, nervous system, is estimated to see a 3 percent increase.

Table 72 – Estimated Impact of the Proposed 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	\$5,681	2%
Eye	\$1,918	-1%
Nervous system	\$1,211	3%
Gastrointestinal	\$948	4%
Musculoskeletal system	\$727	4%
Genitourinary system	\$213	4%
Skin	\$157	3%

CMS provides estimated increases for 30 selected procedures in Table 73 in the proposed 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 a 1 percent increase in payment. The second largest aggregate payment procedure, CPT code 63685, is expected to see a 2 percent increase.

Excerpt from Table 73: Estimated Impact of the 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	1
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	3
43239	Egd biopsy single/multiple	\$186	3

Excerpt from Table 73: Estimated Impact of the 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
0191T	Insert ant segment drain int	\$128	0
64483	Inj foramen epidural l/s	\$122	3
66982	Xcapsl ctrc rmvl cplx wo ecp	\$96	1
64635	Destroy lumb/sac facet jnt	\$86	4

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/medicare-fee-service-payment/asc-payment-asc-regulations-and-notices/cms-1753-p>. They include:

- AA – Proposed ASC Covered Surgical Procedures for 2022 (Including surgical procedures for which payment is packaged)
- BB – Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2022 (Including Ancillary Services for Which Payment is Packaged)
- DD1 – Proposed ASC Payment Indicators for 2022
- DD2 – Proposed ASC Comment Indicators for 2022
- EE – Surgical Procedures to be Excluded from Payment in ASCs for 2022

XIV. Request for Information (RFI): Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability (FHIR) in Outpatient Quality Programs

CMS requests 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 eCQMs; and changes under consideration to advance digital quality measures. Examples of questions from each category are presented at the end of this section; readers are referred to the rule for the full question list. CMS indicates that it will not respond to comments received about this RFI through the 2022 OPPS/ASC final rule, but will consider the input received when drafting future regulations and policies.

By way of background, CMS notes its ongoing collaboration with the Office of the National Coordinator (ONC) for Health Information Technology in support of health information technology (health IT) standards to enable nationwide interoperable health information exchange (HIE). CMS highlights their joint selection of FHIR Release 4.0.1 as the standard to support policies related to application programming interfaces (APIs) for use during HIE. Also highlighted is the alignment of certified electronic health record technology (CEHRT) using ONC-specified certification criteria between the facility Promoting Interoperability programs of CMS and the Promoting Interoperability performance category of the Quality Payment Program for clinicians.

CMS notes 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 lists multiple examples of dQM data sources (e.g., electronic health records - EHRs, wearable

medical devices). CMS offers an updated dQM definition: a software that processes digital data to produce one or more measure scores. Also discussed is the potential role of FHIR-based standards for efficient HIE across clinical settings through APIs. CMS is actively studying API use for accessing quality data it already collects and for transitioning its extant electronic clinical quality measures to FHIR-based standards. Other areas of focus by CMS are self-contained dQMs, third party data aggregation, internal alignment of measures throughout CMS, and measure alignment externally with other federal and state health care programs and private payers.

CMS closes the RFI with a commitment to using policy levers and collaborating with stakeholders to transition to fully digital quality measurement across the agency, with staged implementation of a cohesive portfolio of dQMs and incorporation of principles from the HHS National Health Quality Roadmap.

Questions posed by CMS include the following:

- Definition of Digital Quality Measures
 - Do you have feedback on CMS' dQM definition?
 - Do you agree dQM software solutions should be self-contained tools? (Desirable software characteristics and functions are listed in the RFI.)
- Use of FHIR for Current eCQMs
 - Would the transition to FHIR-based quality reporting reduce provider burden?
 - Would access to near real-time quality measure scores benefit your practice?
- Changes Under Consideration to Advance Digital Quality Measurement
 - Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements?
 - How important is inclusion of patient generated health data and other non-standardized data within a FHIR-based standard framework?
 - What role should data aggregators play in CMS quality reporting?
 - What are initial priority areas for the agency's dQM portfolio (e.g., measurement requirements, tools)?

XV. Hospital Outpatient Quality Reporting (OQR) Program

CMS provides references to the legislative and regulatory histories of the 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.

CMS proposes removal of two measures and addition of three, along with resumption of two measures previously adopted but for which implementation was delayed. One of the proposed new measures is an electronic clinical quality measure (eCQM), and CMS proposes policies applicable to this and any future OQR eCQMs. Additionally, the agency proposes to expand

applicability of the OQR program's policy for extraordinary circumstances exceptions (ECE) to eCQMs. Updated data validation requirements also are proposed.

No changes are 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; and requirements for participation in and withdrawal from the OQR program. No changes are proposed to the Overall Hospital Quality Star Rating methodology. CMS requests stakeholder input into future OQR changes such as developing measures focused on transitions from inpatient to outpatient care and expanding use of its Disparities Methods to the outpatient setting through quality measure stratification by social risk factors.

A. OQR Program Measure Changes

1. Measure Removal

CMS proposes the removal of two 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 are chart-abstracted and endorsed by the National Quality Forum (NQF). CMS cites measure removal Factor 4, availability of a more broadly applicable, electronic measure focused on the same topic (optimal initial treatment of possible myocardial infarction), and later proposes to adopt the broader measure for the 2023 reporting period (see below). CMS anticipates that replacing two chart-abstracted measures with a single eCQM would reduce burden.

2. Measure Addition

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

Measure Details. CMS proposes to add a new facility-level process measure to the Hospital OQR Program for the 2024 payment determination and subsequent years to track the percentage of healthcare personnel (HCP) in non-long-term care facilities (including outpatient hospitals) who receive a complete COVID-19 vaccination course. The measure would be calculated as:

Numerator. The cumulative number of HCP eligible to work in the hospital for at least one day in the submission period and who received a complete vaccination course against SARS-CoV-2.

Denominator. The cumulative number of HCP eligible to work in the hospital for at least one day during the submission period, excluding persons with contraindications to COVID-19 vaccination as described on the website of the Centers for Disease Control and Prevention (CDC).²¹ Acute care facilities would count all HCP working in all inpatient or outpatient

²¹ Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, Appendix B. <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B>.

units that share a hospital's CMS Certification Number (CCN), regardless of a unit's size or type.

Risk adjustment is not required for this process measure. Full specifications are available on the NQF's website at <https://www.cdc.gov/nhsn/nqf/index.html>.

Measure Rationale. In discussing the proposed measure, CMS reviews the declaration of COVID-19 as a PHE, methods of viral transmission, vulnerable patient groups, and guidelines for prioritizing vaccine recipients. CMS regards HCP vaccination rates as being of interest to beneficiaries and caregivers during their healthcare decision-making and as an aid to facilities in tracking their efforts to reduce COVID-19 transmission.

Pre-rulemaking. CMS describes following the usual pre-rulemaking process for stakeholder input. The proposed measure was included on the December 2020 MUC list. The NQF-convened Measure Applications Partnership (MAP) conditionally supported the measure contingent upon clarification of measure specifications, and CMS returned to the MAP with results from further measure testing and updated specifications in March 2021. The MAP again recommended conditional support for rulemaking, contingent upon NQF endorsement. CMS states its intention to seek NQF endorsement of the measure, but proposes to promptly adopt the measure for 2022 reporting given ongoing COVID-19 PHE impacts and having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical.

Data Reporting and Submission. CMS proposes to require data reporting beginning January 1, 2022, through December 31, 2022, for use in 2024 OQR program payment determinations, followed by quarterly reporting periods. Data submission also would be required quarterly, via entry into the CDC's National Health Safety Network (NHSN) web-based surveillance system for at least one self-selected week each month. The CDC would report data quarterly to CMS, and CMS plans to publicly report the CDC-calculated vaccination rates.

b. Breast Screening Recall Rates

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

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

Denominator. Medicare fee-for-service (FFS) beneficiaries who underwent screening mammography or DBT at a facility paid under the OPPS (the index image).

This measure has no exclusions. CMS states that risk adjustment is not required for this process measure and that adjustment for social risk factors could mask potentially important inequities

(e.g., variable rates for minority subpopulations). Full measure specifications are available on the CMS QualityNet website at <https://www.QualityNet.cms.gov>.

Measure Rationale. When breast screening tests are positive, patients are typically recalled for confirmation of the abnormal results through additional diagnostic studies, which in turn may lead to sequential follow-up imaging or breast biopsy. Some screening test results will be inaccurate, suggesting cancer is present when in fact it is not (false-positive). Recall rates reflect the balance between the benefit of early cancer detection and potential harms from unnecessary imaging or biopsy and are expressed as a range. CMS cites literature suggesting appropriate recall rates ranging from 5 to 12 percent. CMS notes that this proposed measure addition fills the gap left by removal of a prior OQR program measure (Mammography Follow-up Rates, OP-9), and offers providers with feedback that is locally actionable for quality improvement purposes.

Pre-rulemaking. CMS describes following the usual pre-rulemaking process for stakeholder input. The proposed measure was included on the December 2020 MUC list. The MAP conditionally supported the measure for rulemaking contingent upon NQF endorsement. CMS states it will consider seeking NQF endorsement in the future but proposes prompt measure adoption, having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical. CMS responds to MAP concerns by committing to development of educational materials to facilitate measure understanding by the public (e.g., a range result rather than a specific value) and to annual measure re-evaluation for consistency with current clinical practice and for the propriety of adding social risk factor adjustments.

Data Reporting and Submission. This claims-based measure does not require additional data submission by facilities. The measurement period is 12 months. For the 2023 payment determination, CMS proposes to use final claims from July 1, 2020, to June 30, 2021. For each subsequent year, the claims data collection period would be from July 1 through June 30, and the period would start on July 1 in the year that is 3 years prior to the applicable payment CY.

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

Measure Details. CMS proposes to add a new facility-level, electronic process measure to the Hospital OQR Program for the 2023 payment determination and subsequent years to track the percentage of Emergency Department (ED) patients with a diagnosis of STEMI who received timely delivery -- absent contraindications -- of guideline-based reperfusion therapies appropriate for the care setting. The measure would be calculated as:

Numerator. All STEMI patients aged 18 years or over who meet any of the following criteria:

- 1) ED-based STEMI patients whose time from ED arrival to fibrinolytic therapy is 30 minutes or fewer; or
- 2) Non-transfer ED-based STEMI patients who received percutaneous coronary intervention (PCI) at a PCI-capable hospital within 90 minutes of arrival; or
- 3) ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI-capable hospital.

Denominator. All ED patients aged 18 or older diagnosed with STEMI and who do not have contraindications to fibrinolytic, antithrombotic, and anticoagulation therapies. Full measure specifications are available on the Electronic Clinical Quality Improvement Resource Center website at <https://ecqi.healthit.gov/pre-rulemaking-eh-oqr-ecqms>.

Measure Rationale. This measure more comprehensively captures the population of interest (STEMI patients receiving timely therapy, regardless of ED transfer) than the two current measures proposed for removal (OP-2 and OP-3).

Pre-rulemaking. CMS describes following the usual pre-rulemaking process for stakeholder input. The proposed measure was included on the December 2020 MUC list. The MAP conditionally supported the measure for rulemaking, contingent upon NQF endorsement. The measure was submitted to NQF in January 2021; however, CMS proposes measure adoption without NQF endorsement given the superiority of the new measure over available extant measures and the public health importance of the measure topic.

Data Reporting and Submission. This eCQM is designed to use routinely collected EHR data, is calculated by hospitals' CEHRT, and submitted electronically to CMS. It has been tested with two different EHR platforms. CMS proposes voluntary submission of the measure for the 2023 reporting period/2025 payment determination then mandatory submission for the 2024 reporting period/2026 payment determination and subsequent years. During the voluntary year (2023), hospitals would submit data for any self-selected quarter(s). Once mandatory reporting begins, if finalized, required data submission would increase annually by one quarter, starting with one self-selected quarter for 2024 and reaching four-quarter (full CY) reporting for the 2027 reporting period/2029 payment determination and subsequent years.

3. Modifications of Previously Adopted Measures

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

This measure uses pre- and post-operative visual function survey results to assess the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery. The measure was first finalized for adoption into the OQR measure set beginning with the 2016 payment determination. Concerns arose about the burden of visual function survey administration and about the impact on measure results of inconsistencies across the multiple validated surveys permitted for use. As a result, CMS excluded but did not remove the measure from the OQR measure set for the 2016 payment determination and subsequent years.

Beginning with the 2017 payment determination, voluntary reporting of the measure has been permitted. CMS notes that the measure has been consistently reported voluntarily by some facilities and the data publicly displayed. CMS also notes that published research has shown that the validated visual function surveys all are able to detect clinically important vision changes. Therefore, CMS proposes to return the measure to the OQR measure set for use beginning with the 2023 reporting period/2025 payment determination and subsequent years and to make

reporting mandatory for 2023 and all subsequent years. CMS proposes that data submission for all years would be through a CMS web-based tool according to existing policies for the Hospital Quality Reporting (HQR) System (formerly known as the QualityNet Secure Portal).

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

The OAS CAHPS survey set includes five measures designed to assess a patient's experience with care following a procedure or operation performed in a hospital outpatient department (HOPD). The set was first adopted into the OQR program during 2017 OPPS/ASC rulemaking, for use beginning with the 2020 payment determination. 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.

CMS notes that subsequent results from the national voluntary program have confirmed that patients were able to reliably respond to the survey questions. CMS, therefore, is proposing to restart use of the OP 37a-e measure beginning with voluntary reporting for the 2023 reporting period/2025 payment determination followed by mandatory reporting for the 2024 reporting period/2026 payment determination and subsequent years. CMS clarifies that hospitals who report voluntarily for 2023 would do so as part of the OQR program rather than the national voluntary program.

Updated OAS CAHPS Reporting Requirements

CMS proposes to add two data collection modes (web-based with either mail or telephone follow-up of non-respondents) for the 2023 reporting period/2025 payment determination and subsequent years to the existing three modes (mail-only, telephone-only, and mixed -- mail with telephone follow-up of non-respondents). Web-based survey modes are associated with similar response rates and results and with lower collection costs than other modes.

For all five modes, CMS proposes that:

- Hospitals required to report must do so through a CMS-approved survey vendor. No new vendor requirements are being proposed with resumption of the measure.
- Data collection must be initiated no later than 21 calendar days after the month in which the procedure or operation occurred and must be completed within 42 days after initial contact of an eligible patient begins.
- 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 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.

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

CMS proposes that eCQM technical specifications related to the OQR program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs. Specification updates would generally occur through the Annual Update. The Annual Update and its associated implementation guidance documents are available through the eCQM resource center website <https://ecqi.healthit.gov>.

CMS proposes several requirements for reporting eCQMs under the OQR program for the 2023 reporting period/2025 payment determination and subsequent years. The OQR eCQM requirements would align with those of the hospital inpatient quality reporting (IQR) program and the Medicare Promoting Interoperability (PI) program for hospitals. Hospitals would:

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

CMS invites comment on an alternative eCQM data submission deadline of May 15 (rather than end of February) to align with OQR measure reporting using the program's web-based tool.

When a hospital's EHR is certified to a particular eCQM but the hospital has no patients to report who met the measure's denominator, the hospital may submit the eCQM with a zero denominator and the measure would still count towards the OQR program's required eCQM total. Alternatively, the hospital may have reportable patients for the eCQM but not enough to satisfy the denominator's threshold criterion. If the hospital has five or fewer outpatient all-payer discharges to which the measure is applicable for the quarter, or 20 or fewer for the year, the hospital may declare a case threshold exemption for the eCQM.

C. Review and Corrections Periods and Educational Review Process

CMS proposes no changes to its data review and corrections period policies for OQR chart-abstracted measures, measures submitted via the CMS web-based tool (HQR system), or OAS CAHPS measures. CMS does propose a new review and corrections period for eCQM data that would run concurrently with the data submission period. From the time the HQR system opens

for QRDA I file submission up until the submission deadline, hospitals would be able to run pre-submission test files as well as submit and review their actual data files and make corrections.

D. Hospital OQR Program Validation Requirements

Under the current data validation process for OQR chart-abstacted measures, CMS selects a random sample of 450 hospitals for validation and selects another 50 hospitals using targeted criteria. Hospitals selected for validation have 45 days to submit medical record documentation. The validation requirement is met if the hospital achieves at least a 75 percent reliability score.

CMS proposes several changes to the OQR data validation process beginning with the 2022 reporting period/2024 payment determination and for subsequent years. The changes would further align the OQR program with the hospital IQR program.

- Discontinue the option for hospitals to transmit medical records for validation to the CMS Clinical Data Abstraction Center (CDAC) as paper copies or on CDs, DVDs, or flash drives. Only direct electronic submission of records stored as Portable Document Format (pdf) files via a CMS-approved, CDAC-directed, secure file transmission process would be permitted.
- Reduce the time period given to hospitals to submit records for validation to the CDAC contractor from 45 to 30 calendar days.
- Add to the targeting criteria used to select additional hospitals for validation.
 - Current criteria are 1) having failed the previous year's validation or 2) having an outlier value for a measure.
 - Proposed additional 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.

E. Extraordinary Circumstances Exception (ECE) Policy

Concomitant with the adoption of the STEMI eCQM measure for mandatory reporting beginning with the 2024 reporting period/2026 payment determination, CMS proposes to expand the OQR program's ECE policy to cover eCQMs. Hospitals would be allowed to request hardship exceptions (e.g., due to insufficient internet access, health IT vendor loss of certification) under the ECE policy from required eCQM reporting for the 2024 reporting period and subsequent years. CMS further proposes that the exception be requested by April 1 following the end of the reporting CY in which the hardship occurred (e.g., April 1, 2025 for 2024 hardships).

F. Payment Reductions for Hospitals that Fail to Meet OQR Program Requirements

Existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements would be continued for the 2022 update factor. The reduction ratio for hospitals that fail to meet OQR Program requirements, called the “reporting ratio”, is 0.9805. It is calculated by dividing the proposed reduced conversion factor

of \$82.810 by the proposed full conversion factor of \$84.457. CMS proposes to calculate the reporting ratio to four decimals for 2022 and subsequent years rather than the previously used three. Continuing previous policies, the reporting ratio would be applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

The reporting ratio would continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services for hospitals that fail to meet the OQR program's reporting requirements. All other applicable standard adjustments to the OPPS national unadjusted payment rates apply, and OPPS outlier eligibility and outlier payment are based on the reduced payment rates. Beneficiaries and secondary payers share in the reduced payment to hospitals whose payments are reduced.

CMS reports that for 2021 payment, 77 of 3,163 hospitals failed to meet the OQR Program requirements for a full update factor, compared to 78 of 3,144 hospitals failing in 2020.

G. Request 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. Stakeholders have urged reconsideration, citing safety and quality concerns. CMS has been persuaded and has proposed earlier in this rule to halt the IPO list's elimination and to return the 298 services removed for year 1 to the reinstated IPO list. However, continued advances in surgical techniques and medical technology likely will support appropriate further evolution of care delivery from inpatient to outpatient settings. **CMS, therefore, seeks comment on the potential future adoption of measures that assess quality of care for services whose delivery is shifting from inpatient to HOPD settings.**

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

Elective primary total hip arthroplasty and total knee arthroplasty transitioned off the IPO list in 2020 and 2018, respectively, and are performed on large numbers of Medicare beneficiaries. CMS seeks comment on the future adoption into the OQR program of a measure of patient reported outcomes after these two procedures -- Hospital-Level Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) – as respecified from its current inpatient application for use in the HOPD setting. CMS views this measure as a prototype for future assessment of site-of-service transitions. **Questions posed by CMS address the following:**

- **Barriers and solutions to data collection for patient-reported outcomes;**
- **Utility of measures aligned across service settings, such as identical patient-reported outcomes, but stratified for inpatient or outpatient settings; and**
- **Considerations that may be unique to THA/TKA performed in the HOPD.**

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

CMS invites public comment on the following:

- The potential future application to the Hospital OQR Program measures of the two CMS Disparity Methods currently used in the Hospital Readmissions Reduction Program to confidentially report measures stratified by dual eligibility.
- The possibility of reporting stratified results confidentially in facility-specific reports using dual eligibility as a proxy for social risk.
- The possibility of reporting stratified results using dual eligibility as the proxy for social risk publicly on Care Compare in future years.
- The potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual eligibility) for facility-level disparity reporting, until more accurate forms of self-identified demographic information are available.
- The possibility of collection by the facility, on the day of service, of a minimum set of demographic and social risk factor data using standardized and interoperable electronic health record standards.

As background for this RFI, CMS cites evidence for worse health outcomes that could stem from disparate care across patient populations (e.g., higher COVID-19 complication rates for black, Latino, and Indigenous and Native Americans relative to whites). CMS adopts an expansive definition of equity from Executive Order 13985 and focuses the ensuing discussion on the potential for expanding use of CMS Disparity Within-Hospital and Across-Hospital methods. These methods are currently used for confidential stratified reporting of hospital readmission measures by dual eligibility.

CMS reports having identified six OQR program measures as high-priority candidates for further exploration of disparities reporting stratified by dual eligibility: MRI Lumbar Spine for Low Back Pain (OP-8); Abdomen CT – Use of Contract Material (OP-10); Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP-13); Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32); Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35); and Hospital Visits after Hospital Outpatient Surgery (OP-36). These measures were chosen based on analyses by CMS of known disparities, procedure volumes, and statistical reliability.

CMS notes the availability of several tools for capturing race and ethnicity and compares them to the gold-standard of self-reported data. Relatedly, the agency reports its work on indirect estimation methods applicable to filling gaps in CMS administrative databases for race and ethnicity, citing the very high reliability of the Medicare Bayesian Improved Surname Geocoding (MBISG) model for white, black, and Hispanic data prediction. CMS also discusses the significant potential value of a standardized demographic and social risk factor data set to be collected by facilities on the day of hospital outpatient service delivery. CMS ends by exploring the potential creation of a Facility Equity Score, a composite of multiple quality measures and multiple social risk factors for future display on Care Compare.

XVI. Ambulatory Surgery Center Quality Reporting (ASCQR) Program

The Ambulatory Surgery Center Quality Reporting (ASCQR) Program is a Medicare quality measurement program 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., 2020 reporting is linked to 2022 payment). There is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet all of the program's quality reporting requirements. An exemption from program participation and payment reduction is given to an ASC that has fewer than 240 Medicare claims per year during an annual reporting period (the minimum case volume threshold).²² CMS provides references to the legislative and regulatory histories of the ASCQR program.

In this rule, one measure is proposed for addition for reporting in 2022 and no measures are proposed for removal. CMS proposes resumption of reporting for four previously suspended measures, and modifies the reporting status of one measure and of the OAS CAHPS ASC survey measure subset (5 measures). No changes are proposed to previously finalized ASCQR program 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); ASCQR 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 requests stakeholder input into future ASCQR measure development, including calling attention to social risk factors that may influence health disparities in the ASC setting and to pain management procedures performed in ASCs.

A summary table of ASCQR measures appears at the end of Section XVI. 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)

Measure Details. CMS proposes to add a new facility-level process measure to the ASCQR program for the 2024 payment determination and subsequent years to track the percentage of healthcare personnel (HCP) in non-long-term care facilities (including outpatient hospitals) who receive a complete COVID-19 vaccination course. The measure would be calculated as:

Numerator. The cumulative number of HCP eligible to work at the ASC for at least one day in the submission period and who received a complete vaccination course against SARS-CoV-2.

22 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.

Denominator. The cumulative number of HCP eligible to work at the ASC for at least one day during the submission period, excluding persons with contraindications to COVID-19 vaccination as described on the website of the Centers for Disease Control and Prevention (CDC).²³ Facilities would count all HCP working in all facilities that share the same CMS Certification Number (CCN).

Risk adjustment is not required for this process measure. Full specifications are available on the NQF's website at <https://www.cdc.gov/nhsn/nqf/index.html>.

Measure Rationale. In discussing the proposed measure, CMS reviews the declaration of COVID-19 as a PHE, methods of viral transmission, vulnerable patient groups, and guidelines for prioritizing vaccine recipients. CMS regards HCP vaccination rates as being of interest to beneficiaries and caregivers during their healthcare decision-making and as an aid to facilities in tracking their efforts to reduce COVID-19 transmission.

Pre-rulemaking. CMS describes following the usual pre-rulemaking process for stakeholder input. The proposed measure was included on the December 2020 MUC list. The NQF-convened Measure Applications Partnership (MAP) conditionally supported the measure contingent upon clarification of measure specifications, and CMS returned to the MAP with results from further measure testing and updated specifications in March 2021. The MAP again recommended conditional support for rulemaking, contingent upon NQF endorsement. CMS states its intention to seek NQF endorsement of the measure, but proposes to promptly adopt the measure for 2022 reporting given ongoing COVID-19 PHE impacts and having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical.

Data Reporting and Submission. CMS proposes to require data reporting beginning January 1, 2022 for use in 2024 ASCQR program payment determinations, followed by quarterly reporting periods. CMS considered but rejected the alternative of annual reporting periods due to the immediacy of ongoing COVID-19 PHE impacts. Data would be entered by the ASC into the CDC's National Health Safety Network (NHSN) web-based surveillance system for at least one self-selected week each month. The CDC would report results quarterly to CMS, and CMS plans to publicly report the CDC-calculated quarterly vaccination rates. CMS acknowledges that NHSN submission may be more burdensome for ASCs than other facility types but believes the public health benefit of reporting this measure outweigh the imposed burden.

²³ Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, Appendix B. <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B>.

2. Modifications 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 proposes to return four previously adopted but subsequently suspended ASCQR measures to reporting beginning with the 2023 reporting/2025 payment determination period: 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). Data submission would be via a CMS web-based tool (the Hospital Quality Reporting System (HQR), previously known as the QualityNet Secure Portal). CMS believes that changing to web-based submission would address data completeness and accuracy concerns that arose during claims-based submission.

These measures were adopted into the ASCQR program during 2012 rulemaking with reporting to begin in 2012 for the 2014 payment year determination. They were reported by attaching measure-specific Quality Data Codes (QDCs) to ASC facility claims. For the 2019 reporting/2021 payment determination year, CMS proposed to remove all four measures from the program, describing the measures as having become “topped out”²⁴, and due to concerns about the completeness and accuracy of claims-based data submission. Stakeholders strongly objected to measure removal, since all four are applicable to all ASCs and address uncommon but sentinel events. CMS accepted the high value of these measures to stakeholders and did not finalize measure removal but did suspend their reporting beginning in 2019, and they remain suspended currently.

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

This measure uses pre- and postoperative visual function survey results to assess the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery. The measure was first finalized for adoption into the ASCQR measure set beginning with the 2016 payment determination. Before implementation, concerns arose about the burden of visual function survey administration and about the impact on measure results of inconsistencies across the multiple validated surveys permitted for use. As a result, CMS excluded but did not remove the measure from the ASCQR measure set for the 2016 payment determination and subsequent years.

Beginning with the 2017 payment determination year, voluntary reporting of the measure has been permitted. CMS notes that the measure has been consistently reported voluntarily by some facilities and the data publicly displayed. CMS also notes that published research has shown that the validated visual function surveys all are able to detect clinically important vision changes. Therefore, CMS proposes to return the measure to the ASCQR measure set for continued voluntary use during the 2022 reporting period/2024 payment determination year and moving to mandatory reporting for 2023 and all subsequent years. CMS proposes that data submission for all years would be through a CMS web-based tool according to existing HQR system policies.

²⁴ “Topped out” correlates with ASCQR program measure removal Factor 1: measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

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

The OAS CAHPS survey set includes five measures designed to assess a patient's experience with care following a procedure or operation performed in an ASC. The 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.

CMS notes that subsequent results from the national voluntary program have confirmed that patients were able to reliably respond to the survey questions. CMS, therefore, is proposing to restart use of the ASC 15a-e measure set beginning with voluntary reporting for the 2023 reporting period/2025 payment determination year followed by mandatory reporting for the 2024 reporting period/2026 payment determination and subsequent years. CMS clarifies that ASCs who report voluntarily for 2023 would do so as part of the ASCQR program rather than the national voluntary OAS CAHPS program. CMS considered but rejected a two-year period of voluntary ASCQR program reporting given the upcoming facility participation options for 2022 voluntary reporting via the national OAS CAHPS program followed by a year of ASCQR program voluntary reporting, if the latter is finalized.

Updated OAS CAHPS Reporting Requirements

CMS proposes to add two data collection modes (web-based with either mail or telephone follow-up of non-respondents) for the 2023 reporting period/2025 payment determination year and subsequent years to the existing three modes (mail-only, telephone-only, and mixed -- mail with telephone follow-up of non-respondents). Web-based survey modes are associated with similar response rates and results and with lower collection costs than other modes.

For all five modes, CMS proposes that:

- Facilities required to report must do so through a CMS-approved survey vendor. No new vendor requirements are being proposed with resumption of the survey measure set.
- Data collection must be initiated no later than 21 calendar days after the month in which the procedure or operation occurred and must be completed within 42 days after initial contact of an eligible patient begins.
- Multiple contact attempts must be made unless the patient refuses or the survey vendor learns the patient is ineligible for survey participation.
- Facilities that do not qualify for the OAS-CAHPS low-volume exemption or the ASCQR minimum case volume threshold 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 facility CCN level.
 - Facilities anticipating more than 300 completed surveys can choose to randomly sample their eligible patients as directed on the OAS CAHPS web site.

- One exemption to the survey requirement is applicable to facilities that qualify for the ASCQR program's minimum case volume threshold exemption (fewer than 240 Medicare claims per year during an annual reporting period, as described above). Another exemption is possible for facilities that qualify under the OAS-CAHPS low-volume exemption policy by treating 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.

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 the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

CMS reports that for the 2021 payment determination year, all 6,811 ASCs eligible for ASCQR program participation received the annual payment update because of nationwide data submission exceptions granted by CMS under the ASCQR program's ECE policy in response to the COVID-19 PHE.

C. Request 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. Persuaded by stakeholders' quality and safety concerns, elsewhere in this rule CMS proposes to halt the IPO list's elimination and to return the 298 services removed for year 1 to the reinstated IPO list.

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. Now, in conjunction with the proposed restoration of the IPO list, CMS earlier in this rule proposes to reinstate for 2022 and subsequent years the CY 2020 criteria used for decision making about adding procedures to the ASC CPL. Concomitant with CPL criteria restoration, CMS also proposes to remove 258 of 267 procedures that were added to the ASC CPL as part of the IPO list phased elimination that is now proposed for reversal.

CMS acknowledges, however, 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, seeks comment 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.

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

Elective primary total hip arthroplasty and total knee arthroplasty 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 are performed on substantial numbers of Medicare beneficiaries and are actively transitioning from inpatient performance nearly always to more frequent performance in various outpatient settings.

CMS seeks comment on the future adoption into the ASCQR program of a measure of patient reported outcomes after these two procedures when performed in ASCs: ASC-Level Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). This measure is being respecified from its current inpatient application for use in the ASC setting. CMS views this measure as a prototype for future assessment of site-of-service transitions but notes that ASC volumes for THA and TKA among Medicare beneficiaries are not yet sufficient for measure reliability. CMS notes that the claims-based measure ASC-17 Hospital Visits After Orthopedic ASC Procedures offers some insights into unplanned and unwanted postoperative outcomes after ASC operations.

Questions posed by CMS address the following:

- **Barriers and solutions to data collection for this and other patient reported outcomes measures;**
- **Utility of measures aligned across service settings, such as identical patient-reported outcomes, but stratified for inpatient or specific outpatient settings; and**
- **Considerations that may be unique to THA/TKA when performed in an ASC.**

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

CMS invites public comment on the following:

- **Ways to address the unique challenges of measuring disparities in the ASC setting, such as small sample sizes, ASC specialization, and the relatively smaller proportion of patients with social risk factors.**
- **The utility of neighborhood-level socioeconomic factors toward measuring disparities in quality-of-care outcomes for ASCs.**
- **Ways social risk factors influence access to care, quality of care and outcomes for ASC patients in general or for specific ASC services.**

As background for this RFI, CMS cites evidence for worse health outcomes that could stem from disparate care across patient populations (e.g., higher COVID-19 complication rates for black, Latino, and Indigenous and Native Americans relative to whites). CMS adopts an expansive definition of equity from Executive Order 13985 and focuses the ensuing discussion on the potential for expanding use of CMS Disparity Within-Hospital and Across-Hospital methods into

the ASC setting. These methods are currently used for confidential stratified reporting of hospital readmission measures by dual eligibility.

CMS reports having modeled application of the two disparities methods to ASCQR program measures using actual Medicare claims data. This simulation uncovered some challenges for conducting disparities assessment unique to the ASC setting, most notably 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. CMS indicates interest in exploring neighborhood-level social determinants of health (e.g., poverty, housing quality) as contributors to equity gaps in ASC care through tools such as the neighborhood socioeconomic status index developed by the Agency for Healthcare Research and Quality.

4. Future Development and Inclusion of a Pain Management Measure

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 invites comment on the development and future inclusion of a measure to assess pain management surgical procedure performed in ASCs.**

Table HPA XVI-1. ASCQR Program Measures by Payment Determination Year

CY 2022 proposed rule changes are shown in Italic Font *X*

(Created by HPA from Tables 52-54 in the rule and other sources)

	2020	2021	2022 2023	2024	2025	2026
CMS WEB-BASED TOOL REPORTING						
ASC-1: Patient Burn (NQF #0263)+	X	Suspended*		<i>X*</i>	X	
ASC-2: Patient Fall (NQF #0266) +	X	Suspended*		<i>X*</i>	X	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)+	X	Suspended*		<i>X*</i>	X	
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)+	X	Suspended*		<i>X*</i>	X	
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)+	Voluntary				<i>X*</i>	X
ASC-13: Normothermia Outcome	X	X	X	X	X	X
ASC-14: Unplanned Anterior Vitrectomy	X	X	X	X	X	X
CLAIMS-BASED REPORTING						

Table HPA XVI-1. ASCQR Program Measures by Payment Determination YearCY 2022 proposed rule changes are shown in *Italic Font X*

(Created by HPA from Tables 52-54 in the rule and other sources)

	2020	2021	2022 2023	2024	2025	2026
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-15 Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures**					X <i>vol</i>	X
CDC NHSN WEB REPORTING						
COVID-19 Vaccination Coverage Health Care Personnel				X	X	X

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

* Data collection suspended 2021 through 2024, resumed for 2025 with initial voluntary year then mandatory reporting.

**Mandatory reporting on a set of OAS CAHPS measures scheduled to begin for the 2020 payment determination, was indefinitely delayed (82 FR 59450). Proposed for return to voluntary reporting for payment 2025 then mandatory beginning for payment 2026. The measures are OP-37a: About Facilities and Staff; OP-37b: Communication About Procedure; OP-37c: – Preparation for Discharge and Recovery; OP-37d: Overall Rating of Facility; and OP-37e: 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. Request for Information on Rural Emergency Hospitals (REHs)

A. Background

Section 125 of the CAA of 2021 establishes rural emergency hospitals (REHs) as a new Medicare provider type that will furnish emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week. In addition, an REH may elect to furnish other medical and health services on an outpatient basis as the Secretary may specify through rulemaking. REHs may not provide acute care inpatient services, with the exception of skilled nursing facility services that are furnished in a distinct part unit.

An REH must have a transfer agreement in effect with a level I or level II trauma center and meet other conditions, including certain licensure requirements, emergency department staffing requirements, staff training and certification requirements, and conditions of participation (CoPs) applicable to hospital emergency departments and critical access hospitals (CAHs) for

emergency services. REHs must have an annual per patient average of 24 hours or less in the REH. Providers that are CAHs and small rural hospitals (i.e., with 50 or fewer beds) as of December 27, 2020, may convert to REH provider status.

Medicare payment to REHs applies to items and services furnished on or after January 1, 2023. Payment for rural emergency hospital services is comprised of two components; the first is a payment rate for the services equal to the OPPS rate increased by 5 percent; the second is an additional monthly facility payment referred to as the Medicare subsidy amount. The Medicare subsidy amount for 2023 is equal 1/12th to the difference of (i) all payments to CAHs in 2019 and (ii) the estimated amounts those CAHs would have been paid in 2019 had the payments been made under the IPPS, OPPS and SNF-PPS payment systems. The difference is divided by the total number of such CAHs. For 2024 and subsequent years, the additional facility payments will be increased from the previous year by the hospital market basket percentage increase.

B. Solicitation of Public Comments

CMS seeks public comments through this RFI to inform its policy making on the following issues; the preamble to the proposed rule provides greater detail on each topic.

1. Type and Scope of Services Offered

CMS seeks comment on:

- Different or additional CoPs for REHs to address issues such as staffing shortages, transportation, sufficient resources and other concerns that may present barriers and challenges to furnishing emergency department services usually provided by hospitals and CAHs in rural and underserved communities; and
- The additional services that are appropriate for an REH to provide to improve access to care for Medicare beneficiaries in rural areas, such as behavioral health services, mental health services, Opioid Treatment Programs, and telehealth services.

2. Health and Safety Standards, Including Licensure and Conditions of Participation

CMS seeks feedback on:

- Which hospital emergency department requirements (at §482.55) should apply to REHs and whether other health and safety standards should apply;
- Whether CAH staff training and certification requirements are appropriate for REH staff or whether other requirements should be considered;
- Other factors CMS should take into account, including lessons learned from the COVID-19 pandemic; and
- State licensure requirements, and supports and timelines for states to establish licensing rules.

3. Health Equity

CMS seeks comment on:

- How REHs can address and be held accountable for health equity;
- With respect to the type and scope of services offered and health and safety standards issues discussed above, the additional factors CMS should consider for specific patient groups (e.g., the elderly, children, the homeless, minorities, veterans, and persons with disabilities);
- How to ensure the executive leadership of an REH (i) is invested in and held accountable for reducing health disparities, (ii) uses diversity and inclusive strategies to ensure a diverse workforce, and (iii) embeds health equity in strategic planning and quality improvement;
- How to address health equity in the care planning and discharge planning processes, including partnering with community-based organizations;
- Appropriate staff training to provide culturally competent patient care; and
- How to ensure full accessibility to services in terms of physical, communication and language access.

4. Collaboration and Care Coordination. CMS seeks feedback on how it and other federal agencies can encourage and incentivize collaboration and coordination between an REH and its regular healthcare provider partners. These partners may include FQHCs, RHCs, VA and IHS providers, primary care and oral health providers, faith-based entities and providers of transportation, education, housing and employment services.

5. Quality Measurement

CMS seeks broad input on a range of issues relating to quality measurement for REHs, including quality reporting requirements, specification of quality measures, and public availability of quality reporting data, including the following:

- Use of existing quality measures under the IQR and OQR programs;
- Barriers to quality reporting (including electronic quality reporting) by small rural hospitals and CAHs, and strategies to mitigate the barriers;
- The factors to consider in establishing a baseline set of measures and its expansion over time;
- Nonpayment incentives (or disincentives) for quality reporting, such as limits based on case volume, case mix, or geographic distance; and
- How to publicly report REH quality measure data.

6. Payment Provisions

CMS seeks stakeholder input on the following issues:

- The likelihood of rural SCHs converting to REH status;

- Claims and other payment reporting issues in calculating the hypothetical estimated payment amounts for CAH services in 2019 under the IPPS, OPPS and SNF PPS;
- Whether claims used by CAHs to report services paid under the IPPS, OPPS and SNF PPS have all the requisite information to be processed under those systems and what burden CAHs may face in collecting any missing information; and
- Challenges that REHs may face to maintain and submit information on how their facilities spend the additional facility payment for rural emergency hospitals (as required by section 1834(x)(2)(D) of the Act), and the assistance or guidance CMS should provide to help REHs meet this reporting requirement.

7. Enrollment Process. The statute requires that a facility applying for enrollment as an REH provider must provide an action plan for initiating REH services, including a detailed transition plan that lists the specific services that the facility will retain, modify, add and discontinue. Facilities considering REH status are encouraged to make suggestions to CMS regarding enrollment requirements, including considerations for the steps and timing for conversion to an REH.

CMS intends to consider the comments received in response to this RFI to inform the development of a proposed rule that will solicit comments on the implementation of this new provider type. Proposed and final rulemaking on this issue will be completed for implementation on January 1, 2023.

XVIII. 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 Model from beginning before January 1, 2022. In this proposed rule, CMS proposes provisions related to the additional delayed implementation due to the CAA, as well as modifications to certain RO Model policies not related to the delay.²⁵

A. Background

The Radiation Oncology (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

²⁵On 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.

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 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 Proposed Regulations

1. Proposed Model Performance Period

CMS proposes 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. CMS also proposes that 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.

2. Proposed Definitions

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

Term	Definition
Extreme and Uncontrollable Circumstances (EUC)	EUC stands for “extreme and uncontrollable circumstance” and means a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants’ ability to deliver care in accordance with the RO Model’s requirements and affects an entire region or locale.
Legacy CCN	Legacy CCN means a CMS certification number (CCN) that an RO participant that is a hospital outpatient department (HOPD) or its predecessor(s) previously used to bill Medicare for included radiotherapy (RT) services but no longer uses to bill Medicare for included RT services.
Legacy TIN	Legacy TIN means a taxpayer identification number (TIN) that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.
Track One	Track One means an Advanced APM and MIPS APM track for Dual participants and Professional participants that meet all RO Model requirements as specified in §512.220, including use of CEHRT.
Track Two	Track Two means an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at §512.220; and for all Technical participants.
Baseline period	“Baseline period” means the three calendar year (CY) period that begins on January 1 no fewer than 5 years but no more than 6 years prior to the start of the model performance

Term	Definition
	period during which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments for the model performance period, and the participant-specific professional and technical case mix adjustments for PY1. The baseline period would be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period would be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).
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. Proposed RO Model Participant Exclusions

At §512.210(b), CMS excludes from the RO Model any 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 puts forth proposals to modify 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 proposes 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 would 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.

b. Community Health Access and Rural Transformation Model

CMS proposes 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 proposes to exclude 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.

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 proposes 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 across all CBSAs selected for participation. CMS proposes this change to remove any incentive for RO participants to change their TIN or CCN in an effort to become eligible for the low volume opt-out.

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 proposes 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 also proposes that 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, assuming the reorganization of §512.230(a) and (b) that addresses the criteria for determining including cancer types is finalized. 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. Proposal to Remove Brachytherapy from Included RT Services

CMS also proposes to amend §512.240 to remove brachytherapy as an included modality in the RO Model. If finalized as proposed, CMS would continue to monitor utilization of brachytherapy, both as a single modality and multimodality among RO participants compared to non-participants. It would 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, particularly 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 proposal to remove brachytherapy from the RO Model, if finalized, would render its waiver of section 1833(t)(2)(H) of the Act (codified at § 512.280(f)(4)) moot. Therefore, CMS proposes to withdraw this waiver if its proposal to remove brachytherapy is finalized as proposed. 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 proposed removal of brachytherapy. These are listed in Table 56 in the proposed rule.

d. Exclusion of Intraoperative Radiotherapy (IORT)

CMS finalizes that Intraoperative Radiotherapy (IORT)—a technique that involves precise delivery of a large dose of ionizing radiation to the tumor or tumor bed during surgery—would not be included in the RO Model. CMS 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 solicits 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 states that it does not intend to 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. Proposal to Construct Episodes Using Medicare FFS Claims and Calculation of Episode Payment

CMS proposes updating 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 proposes to amend §512.255(c)(13) by removing the percentage amount and indicating that sequestration will be applied in accordance with applicable law.

c. Proposed National Base Rates

To simplify episode construction, attribution, and pricing, CMS proposes to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims in the same manner: before episodes are constructed and attributed to an RT provider or RT supplier. CMS also proposes to exclude all claims of an HOPD participating in 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 do not have more than \$0 in total allowed amount 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' proposed national base rates for the model performance period are based on the criteria set forth for cancer type inclusion and are summarized in Table 58 (reproduced below).

Table 58: National Base Rates			
RO Model-Specific Codes	Professional or Technical	Included Cancer Type	National Base Rate
M1072	Professional	Anal Cancer	\$3,104.11
M1073	Technical	Anal Cancer	\$16,800.83
M1074	Professional	Bladder Cancer	\$2,787.24
M1075	Technical	Bladder Cancer	\$13,556.06
M1076	Professional	Bone Metastases	\$1,446.41
M1077	Technical	Bone Metastases	\$6,194.22
M1078	Professional	Brain Metastases	\$1,651.56
M1079	Technical	Brain Metastases	\$9,879.40
M1080	Professional	Breast Cancer	\$2,059.59
M1098	Professional	Pancreatic Cancer	\$2,480.83
M1099	Technical	Pancreatic Cancer	\$13,636.95
M1100	Professional	Prostate Cancer	\$3,378.09
M1101	Technical	Prostate Cancer	\$20,415.97
M1102	Professional	Upper GI Cancer	\$2,666.79
M1103	Technical	Upper GI Cancer	\$14,622.66
M1104	Professional	Uterine Cancer	\$2,737.11
M1105	Technical	Uterine Cancer	\$14,156.20

d. Proposed 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 proposes modifications given the delay in the performance period and the proposal to update the model baseline period.

CMS proposes that the numerator of the trend factor be the product of (a) the component's FFS payment rate (as paid under OPPS or PFS) for the CY of the upcoming PY and (b) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished 3 years prior to the CY used to determine the FFS payment rates. The denominator of the trend factor would be the product of (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in the most recent year of the baseline period and (b) the corresponding FFS payment rate for the most recent year of the baseline period.

For PY1, the calculation would be the following:

$$2022 \text{ Trend factor} = (2019 \text{ volume} * 2022 \text{ corresponding FFS rates as paid under OPPS or PFS}) / (2019 \text{ volume} * 2019 \text{ corresponding FFS rates as paid under OPPS or PFS})$$

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

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

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

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.

f. Proposal for 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 proposed baseline period, CMS proposes to modify this stop-loss limit policy such that it applies to RO participants that have fewer than 60 episodes during the proposed baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation and would amend §512.255(c)(7)(iv) accordingly.

g. Proposal to Apply Adjustments for HOPD or Freestanding Radiation Therapy Center

CMS proposes modifications to the participant-specific adjustments for changes in TINs or CCNs (as specified at §512.255(c)(14)). It proposes to calculate the RO participant's case mix adjustments based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy 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. Similarly, CMS proposes to calculate the RO participant's historical experience adjustments based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the baseline period.

CMS proposes to eliminate 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. It proposes to add §512.210(e) requiring 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.

CMS invites comments on the proposal related to change how the case mix adjustments and historical experience adjustments are calculated for an entity that has a change in TIN or CCN. CMS also invites comment on the proposal requiring an RO participant to furnish CMS written notice of a change in TIN or CCN.

h. Proposed Discount Factor

CMS proposes 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, if finalized, 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. If the proposals to remove brachytherapy and liver cancer are not both finalized, CMS states that it would not finalize the lowered discounts as proposed.

i. Proposed 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. In this proposed rule, CMS proposes 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 XVIII.C.6 of the proposed rule.

j. Proposed Adjustment for Geography

With respect to the geographic adjustment in the RO Model, CMS proposes to align the proposed model performance period so that the final year of the baseline period would be used to calculate the implied 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 Table 59 (reproduced below).

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

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, 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 proposed updated national base rate for lung cancer and proposed discount rate.

Table 61 (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

	Amount	Formula
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	$t = s * 0.98$
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	$w = u + v + 2r$

Table 62 in the proposed rule summarizes the data sources and time periods used to determine the values of key pricing components for a baseline period of 2017 through 2019 as a result of the proposed modifications to the pricing methodology.

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

CMS proposes that Professional participants and Dual participants submit quality measure data starting in PY1 during the proposed model performance period. Under this proposal, if the proposed 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 would allow RO participants to use their MIPS data submission to meet the RO Model requirements.

For PY1, Professional participants and Dual participants would be required to submit data for three pay-for-performance measures: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. They would also have to submit data on a pay-for-reporting measure: Treatment Summary Communication—Radiation Oncology. Data collected from this measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure for PY3. CMS proposes 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 model performance period, CMS proposes to amend existing policy such that the CMS-approved contractor will begin administering the CAHPS® Cancer Care Survey for Radiation Therapy on behalf of the RO participants and CMS as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

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

CMS invites comments on these proposals, including whether there are associated changes to the burden or costs with submitting CDEs.

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

CMS discusses proposed modification and its potential impact on the determination of the RO Model as an Advanced APM or a 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. 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 notes that the proposed changes to the stop-loss policy do not affect the satisfaction of the Financial Risk criterion.

CMS clarifies that Professional participants and Dual participants who meet the RO Model requirements, including use of CEHRT, and who are eligible clinicians on a Participation List, will fall into a category called “Track One” of the RO Model. CMS proposes to define “Track One” to mean an Advanced APM and MIPS APM track for Dual participants and Professional participants that use CEHRT. CMS proposes to define “Track Two” to mean an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at §512.220; and for all Technical participants. RO participants that fall into Track Two will not be participating in an Advanced APM or MIPS APM for the RO Model. As such, CMS will not make QP determinations for the eligible clinicians on the RO Model Participation List for Track Two.

CMS recognizes that any failure, however minor, to comply with the RO Model requirements set forth at §512.220(a)(2) will have an impact on whether an RO Model participant is in Track One versus Track Two. A participant’s noncompliance, however, may not be discovered until APM incentive payments have been made based on Track One status. These would be considered

overpayments, but CMS is concerned that overpayment liability may be too harsh and is considering whether to modify some of the requirements. CMS is considering, for example, modifying certain requirements to permit payment of some or all the payments made based on the QP status of the RO participant's eligible clinicians pursuant to its Track One participation, depending on the severity of noncompliance and other factors.

CMS welcomes comments on these considerations, including whether the RO Model can meaningfully improve the quality of care if any of the requirements specified in §512.220(a)(2) are modified, which requirements would be appropriate for modification, the impact of recoupment, and if there are more effective ways to encourage quality improvement and Track One participation.

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 and fall into Track Two of the RO Model. CMS proposes that if the Technical participants that are freestanding radiation therapy centers (as identified by a TIN) begin providing the PC at any point during the model performance period, then they must notify CMS within 30 days, in a form and manner specified by CMS. CMS proposes that they would 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 proposes to codify this policy at §512.275(d).

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 proposes 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 proposes to modify these policies so that RO participants will have the ability to review their individual practitioner list and add or drop the necessary NPIs from the list up until the last 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 proposes 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

CMS proposes that the CEHRT requirement would begin in PY1 of the proposed model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY. It is also proposing 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. To align with the QPP, CMS also proposes to amend §512.220(a)(1) to state that RO participants must satisfy the requirements to be included in Track One of the RO Model. If RO participants do not meet those requirements in a PY, the participant will be in Track Two for the applicable PY.

8. Proposed 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 proposed change in model performance period, CMS expects to conduct the initial reconciliation each August for the preceding PY. For example, for PY1, CMS would conduct the initial reconciliation as early as August of PY2. Given the proposed change in model performance period due to the delay and its proposal that the application of a quality withhold would begin in PY1, CMS proposes 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. Proposed 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 proposes to revise this policy and reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for 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 proposes to modify §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 proposes 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 would 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 proposes to codify this policy on overlaps at §512.292.

10. Proposed Extreme and Uncontrollable Circumstances Policy

CMS proposes 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 proposes 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. CMS proposes that if it declares an EUC for a geographic region, CMS 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 would 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 would 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 would 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 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 would announce that the extreme and uncontrollable circumstances policy applies to one or more RO participants within an affected geographic area. CMS would communicate this decision via the RO Model website and written correspondence to RO participants.

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 proposes it may delay the start date of the model performance period by up to one CY. RO participants would 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 proposes to not change the model performance period, but instead only to delay or exempt requirements.

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 proposes 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 proposes 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 proposes that it could choose to repay the quality withhold during the next reconciliation and award all possible points in the subsequent AQS calculation for affected RO participants, which would potentially increase episode payments during this time.

Trend Factor Adjustments: CMS proposes 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 proposals, 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 \$160 million for Medicare relative to earlier estimates. This is \$60 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 proposed 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.

XIX. 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. In this proposed rule, CMS is proposing 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. CMS is also soliciting 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 is proposing to use a scaling factor to establish the CMP amount for a noncompliant hospital.

CMS proposes to use the noncompliant hospital's number of beds, as specified in hospital cost

report data as the scaling factor to establish CMP amounts. “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 will be:

- \$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.
- \$55,500 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. The above amounts would be adjusted annually beginning in 2023 using the multiplier determined by OMB for adjusting CMPs.

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 proposes 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.

D. Prohibiting Barriers to Accessing Machine-Readable Files

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 signs).
- Requiring the user to agree to all terms and conditions in a legal disclaimer prior to permitting the machine-readable file and its contents to be downloaded.
- Developing file constructs and web forms that obscure access to the data in a single machine-readable file through the use of Application Programming Interfaces.

To address its concerns, CMS is proposing 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.

E. Clarifications and Requests for Comment

1. 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.

To address CMS' concerns, the proposed rule seeks comment on:

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

2. Definition of “Plain Language”

In reviews of hospital compliance with the price transparency requirements, CMS has found that not all hospitals appear to be using what could reasonably be considered “plain language” to describe shoppable services. While CMS recommends using federal plain language guidelines ([Federal plain language guidelines | plainlanguage.gov](#)), it does not require it. CMS seeks public comment on whether to require specific plain language standards.

3. Highlighting Hospital Exemplars

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

4. Improving Standardization of the Machine-Readable File

Since implementation of the final rule, CMS has received feedback from stakeholders indicating that more standardization of the machine-readable file may be necessary to meet the goal of permitting comparisons of standard charges from one hospital to the next. CMS seeks comment on:

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

XX. RFI: Hospital Quality Reporting Program, Safer Use of Opiods 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 seeks input on the following:

- Potential future updates of the measure, and
- Required reporting and submission requirements for the measure.

By way of background for this RFI, CMS reprises the history of this 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.

The measure assesses the proportion of inpatient hospitalizations of patients aged 18 years or older who are prescribed or continued on two or more opioids or an opioid plus a benzodiazepine concurrently at discharge. As part of the response to the nationwide opioid epidemic, this measure seeks to discourage concurrent prescribing unless medically necessary or appropriate; the measure is not expected to have a rate of zero since some concurrent prescribing is appropriate. Patients with cancer or receiving palliative care are excluded. Stakeholders have expressed concern that appropriate concurrent prescribing is inhibited by the measure.

XXI. RFI: Promoting Interoperability Program, Safer Use of Opiods Measure

CMS seeks to maintain alignment of eCQM reporting under the hospital IQR and Promoting Interoperability (PI) programs and 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 repeats its hospital IQR RFI about this measure in the context of the hospital PI program, posing identical questions (see above section). Similar stakeholder concerns have been expressed about the measure's required reporting under the PI program as for reporting under the IQR program.

XXII. Files Available to the Public via the Internet

Addenda for the 2022 OPPS proposed rule are available on the following CMS website: [CMS-1753-P | CMS](https://www.cms.gov/Regulations-and-Rules/Proposed-Rules-and-Notices/2022-OPPS-Proposed-Rule/2022-OPPS-Proposed-Rule-Addenda)

For addenda related to the 2022 ASC proposed rule payments, please see: [CMS-1753-P | CMS](https://www.cms.gov/Regulations-and-Rules/Proposed-Rules-and-Notices/2022-ASC-Proposed-Rule/2022-ASC-Proposed-Rule-Addenda)

TABLE 71—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*	3,622	0.0	0.0	2.3	1.8
ALL HOSPITALS (excludes hospitals held-harmless and CMHCs)	3,555	0.0	0.0	2.3	1.8
URBAN HOSPITALS	2,803	0.0	0.0	2.3	1.8
LARGE URBAN (GE MILLION)	1,448	0.0	0.1	2.4	1.9
OTHER URBAN (LE 1 MILLION)	1,355	0.0	-0.1	2.2	1.8
RURAL HOSPITALS	752	0.1	0.0	2.3	1.8
SOLE COMMUNITY	369	0.0	-0.1	2.2	1.7
OTHER RURAL	383	0.1	0.1	2.5	2.0
BEDS (URBAN)					
0 - 99 BEDS	958	0.2	0.0	2.5	2.0
100-199 BEDS	786	0.1	-0.1	2.3	1.8
200-299 BEDS	447	0.1	0.0	2.4	1.9
300-499 BEDS	386	0.0	0.0	2.3	1.9
500 + BEDS	226	-0.1	0.0	2.2	1.7
BEDS (RURAL)					
0 - 49 BEDS	330	0.1	-0.3	2.2	1.7
50- 100 BEDS	256	0.1	-0.1	2.3	1.8
101- 149 BEDS	90	0.0	-0.2	2.1	1.7
150- 199 BEDS	38	0.0	0.1	2.4	1.9
200 + BEDS	38	0.0	0.4	2.6	2.1
REGION(URBAN)					
NEW ENGLAND	132	0.0	-0.3	2.0	1.5
MIDDLE ATLANTIC	326	0.0	-0.4	1.9	1.4
SOUTH ATLANTIC	455	0.0	0.2	2.6	2.1
EAST NORTH CENTRAL	440	0.0	0.0	2.3	1.8
EAST SOUTH CENTRAL	163	0.0	0.0	2.3	1.8
WEST NORTH CENTRAL	186	0.0	0.3	2.6	2.2
WEST SOUTH CENTRAL	474	0.1	-0.2	2.2	1.7
MOUNTAIN	213	0.0	-0.1	2.2	1.6
PACIFIC	366	0.1	0.3	2.7	2.2
PUERTO RICO	48	0.3	-0.4	2.3	1.8
REGION(RURAL)					
NEW ENGLAND	20	-0.1	-0.3	1.9	1.4
MIDDLE ATLANTIC	50	0.1	0.1	2.4	1.9
SOUTH ATLANTIC	113	0.1	0.6	3.0	2.5
EAST NORTH CENTRAL	120	0.1	-0.1	2.3	1.8
EAST SOUTH CENTRAL	146	0.1	-0.1	2.3	1.8
WEST NORTH CENTRAL	91	0.0	-0.4	1.9	1.5
WEST SOUTH CENTRAL	141	0.3	-0.1	2.5	2.0
MOUNTAIN	48	-0.1	0.4	2.6	1.5
PACIFIC	23	-0.1	-0.1	2.1	1.6
TEACHING STATUS					
NON- TEACHING	2,388	0.1	0.0	2.5	2.0
MINOR	792	0.0	-0.1	2.3	1.8
MAJOR	375	-0.1	0.0	2.2	1.7

	(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
DSH PATIENT PERCENT					
0	14	0.0	-0.4	1.9	1.4
0 – 10%	270	0.2	-0.1	2.3	1.9
10% - 16%	235	0.1	-0.2	2.2	1.7
16% -23%	577	0.2	0.0	2.5	2.0
23%- 35%	1,100	0.0	0.0	2.3	1.8
>35%	901	0.0	0.1	2.4	1.8
DSH NOT AVAILABLE	458	0.3	0.1	2.7	2.2
URBAN TEACHING/DSH					
TEACHING & DSH	1,048	0.0	0.0	2.2	1.8
NO TEACHING/DSH	1,303	0.1	0.1	2.5	2.0
NO TEACHING/NO DSH	14	0.0	-0.4	1.9	1.4
DSH NOT AVAILABLE ²	438	0.3	0.1	2.7	2.2
TYPE OF OWNERSHIP					
VOLUNTARY	1,975	0.0	0.0	2.3	1.8
PROPRIETARY	1,131	0.3	-0.1	2.5	2.0
GOVERNMENT	449	0.0	0.1	2.4	2.4
CMHCs	39	0.6	-0.8	2.1	1.6