ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: July 28, 2021

RE: A&B Summary – Key Proposals of the CY 2022 OPPS/ASC Proposed Rule (CMS-1753-P)

On July 19, 2021, the Centers for Medicare & Medicaid Services (CMS) released its Calendar Year (CY) 2022 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs proposed rule (proposed rule).[1]

CMS proposes regulatory changes that would:

1. Update the OPPS and ASC payment rates by 2.3 percent;
2. Utilize CY 2019 data to set CY 2022 OPPS and ASC payment rates due to the impacts of the COVID-19 public health emergency (PHE);
3. Halt the elimination of the Inpatient Only (IPO) list and add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022;
4. Continue the reduced payment amount of average sales price (ASP) minus 22.5 percent for drugs and biologicals acquired under the 340B program;
5. Utilize CMS's equitable adjustment authority to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose payment status will expire between December 31, 2021 and September 30, 2022;
6. Update and refine the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) programs;
7. Increase penalties for noncompliance with hospital requirements to make public a list of standard charges (hospital transparency requirements); and
8. Implement the statutory delay of the Radiation Oncology (RO) Model.

In addition, CMS seeks comment on temporary policies for the PHE that should be made permanent.

Overall, CMS projects total payments to OPPS providers will be approximately $82.704 billion in CY 2022, an increase of approximately $10.757 billion compared to estimated CY 2021 payments. In the proposed rule, CMS states that comments will be due 60 days "after the date of filing for public inspection" (as opposed to the date of publication in the Federal Register, which is scheduled for August 4, 2021). As such, **comments to the proposed rule are likely due no later than 5 p.m. EDT on September 17, 2021.**

[1] Proposed Rule available at: https://www.federalregister.gov/d/2021-15496.

OPPS addenda available at: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p.

ASC addenda available at: https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1753-p.

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I. Proposed OPPS Payment Updates

For CY 2022, CMS proposes to update OPPS payment rates for hospitals that meet applicable quality reporting requirements by 2.3 percent. This proposed update is based on the projected hospital market basket increase of 2.5 percent minus a 0.2 percentage point adjustment for multi-factor productivity (MFP).

CMS proposes to update ASC payment rates by 2.3 percent as well, consistent with the agency's policy to update the ASC payment system using the hospital market basket update for CYs 2019 through 2023.

a. Recalibration of APC Relative Payment Weights

CMS primarily uses two data sources in OPPS ratesetting: claims data and cost report data. CMS notes that ordinarily, the best available full year of claims data would be two years prior to the calendar year that is the subject of the rulemaking. However, given concerns with CY 2020 data as a result of the COVID-19 PHE, unless otherwise indicated, CMS proposes to use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS.

For CY 2022, CMS proposes to recalibrate ambulatory payment classification (APC) relative payment weights for services furnished on or after January 1, 2022 to December 31, 2022 under the same basic methodology described in CY 2021 OPPS/ASC final rule, based on claims and cost report data for hospital outpatient department (HOPD) services using CY 2019 claims data to construct a database for calculating APC group weights. CMS proposes to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2022 OPPS payment rates are based.

Imaging Cost-to-Charge Ratios (CCRs) and impact on APCs for CT and MRI

In the CY 2014 OPPS/ASC final rule, CMS finalized its policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. In response to concerns from commenters that some hospitals used a less precise cost allocation method of "square feet" for the costs of large moveable equipment like CT scan and MRI machines and that the inclusion of claims from these providers would cause significant reductions in the imaging APC payment rates,[2] CMS removed claims from providers that used the "square feet" allocation methodology to calculate CCRs used to estimate costs associated with the APCs for CT and MRI. CMS imposed a transition policy beginning in CY 2014 (and subsequently extended) that would sunset the removal of such claims in four years to provide sufficient time for hospitals to transition to a more accurate cost allocation method. Beginning CY 2021, CMS uses all claims with valid CT and MRI cost center CCRs, including those using a "square feet" cost allocation method, to estimate costs for the APCs for CT and MRI. CMS proposes to continue to use the hospital-specific overall ancillary and departmental CCRs to convert changes to estimated costs through the application of a revenue code-to-cost center crosswalk.

This change will likely significantly reduce payment for CT and MRI APCs. Because the Deficit Reduction Act (DRA) of 2005 requires Medicare to limit payment for certain imaging services covered by the Physician Fee Schedule (PFS) to not exceed what Medicare pays for these services under OPPS, the payment reductions under OPPS could have significant payment impacts under the PFS where the technical component payment for many imaging services is capped at the OPPS payment amount.

[2] *See* CY 2021 OPPS/ASC proposed rule, Table 1 for percentage change in estimated cost for CT and MRI APCs when excluding claims from providers using "square feet" cost allocation method. 85 Fed. Reg. 48772 at 48780 (Aug. 12, 2020).

Brachytherapy Sources

For CY 2022 and subsequent calendar years, CMS proposes to establish a Low Volume APC policy for New Technology APCs, clinical APCs, and brachytherapy APCs. For these APCs with fewer than 100 single claims that can be used for ratesetting purposes in the existing claims year, CMS proposes to use up to four years of claims data to establish a payment rate for each item or service as the agency currently does for low volume services assigned to New Technology APCs. Further, CMS proposes to calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost. CMS proposes to designate 5 brachytherapy APCs as Low Volume APCs for CY 2022. For more information on CMS's Low Volume APC proposal, refer to section VIII.c of this summary.

Additional Comprehensive APCs (C-APCs) for CY 2022

CMS defines a comprehensive APC (C-APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. For CY 2022, CMS is not proposing to convert any standard APCs to C-APCs; therefore, the number of C-APCs for CY 2022 would be the same as the number for CY 2021, which is 69 C-APCs.

Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, 8008)

For CY 2022, CMS proposes to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. CMS continues to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

Table 2 of the proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2021.

b. Proposed Changes to Packaged Items and Services

Proposed Payment Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies Under the ASC Payment System

For CY 2022, CMS proposes to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

However, CMS notes that while packaging encourages efficiency and is a fundamental component of a prospective payment system, where there is an overriding policy objective to reduce disincentives for use of non-opioid products to the extent possible, CMS believes it may be appropriate to establish payment that reduces disincentives for use of nonopioid drugs and biologicals for pain management when there is evidence that use of those products reduces unnecessary opioid use. **Therefore, CMS is soliciting comments as to whether they should expand their current policy that only applies in the ASC setting—to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting—to the HOPD setting. Additionally, CMS seeks comments on what evidence supports the expansion of this policy to the HOPD setting, including the clinical benefit that Medicare beneficiaries may receive from the availability of separate or modified payment for these products in the HOPD setting. Finally, CMS seeks comments on if it should treat products the same depending on the setting,**

ASC or HOPD. For example, CMS seeks comments on whether products should have the same eligibility requirements to qualify for revised payment in the ASC and the HOPD settings.

Proposed Criteria for Eligibility for Separate Payment under the ASC Payment System for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies

The Department of Health and Human Services (HHS) Secretary is statutorily required to review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management.

CMS believes that in any future reviews the Secretary may conduct, it is important to establish the evidence-base for non-opioid alternatives for pain management when evaluating whether current payment policies result in an incentive for providers to use opioids instead of such evidence-based non-opioid alternatives for pain management. Therefore, for CY 2022 and subsequent years, CMS proposes two criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for a payment revision under the ASC payment system:

- Criterion 1: Food and Drug Administration (FDA) approval and indication for pain management or analgesia.
- Criterion 2: Per day cost of the product must exceed the OPPS/ASC drug packaging threshold.

CMS seeks comments on the proposed eligibility criteria.

Comment Solicitation on Policy Modifications and Potential Additional Criteria for Revised Payment for Non-Opioid Pain Management Treatments

CMS is soliciting comments on the proposed eligibility criteria, as well as comments on potential policy modifications and additional criteria that may enhance the proposed policy. CMS is also seeking comments on other barriers to access to non-opioid pain management products that may exist, and to what extent CMS policies under the OPPS or ASC payment system could be modified to address these barriers. Specifically, CMS is seeking comments on:

- **Utilization of the product**. CMS is soliciting comments on whether specific evidence of reduced utilization should be part of their evaluation and determination of whether a non-opioid pain management product should qualify for modified payment. CMS is also requesting comment on whether utilization data requirements should vary based on the newness of a product or its FDA marketing approval date.
- **FDA indication for pain management or analgesia for the drug or biological product**. CMS is soliciting comments on whether they should allow certain FDA-approved drugs and biologicals to be eligible for separate payment under this policy without a specific FDA-approved indication for pain management or as an analgesic drug. In lieu of an FDA indication for pain management or analgesia, CMS is seeking comment on whether it would be appropriate to approve a product for inclusion under this policy if the pain management or analgesia attributes of the drug or biological are recognized by a medical compendium.

- **Peer-reviewed literature requirement**. CMS is soliciting comments on whether they should only adopt a payment revision to drugs and biologicals that function as surgical supplies in the ASC setting when those products have evidence in peer reviewed literature supporting that the product actually decreases opioid.
- **Alternative payment mechanisms for non-opioid drugs and biologicals**. CMS seeks comments on additional payment mechanisms that may be appropriate aside from separate payment. For instance, CMS requests feedback from stakeholders as to whether a single, flat add-on payment, or separate APC assignment, for products or procedures that use a product that meets eligibility criteria would be preferable to separate payment.
- **Non-drug products**. CMS is soliciting comments on whether there are any non-opioid, non-drug products that may meet the proposed eligibility criteria and should qualify for separate or modified payment in the ASC setting.[3]

c. Conversion Factor Update

For CY 2022, CMS proposes to use a conversion factor of $84.457 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. This includes the proposed OPD fee schedule increase factor of 2.3 percent for CY 2022, the required proposed wage index budget neutrality adjustment of approximately 1.0012, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.32 percentage point of projected OPPS spending for the difference in pass-through spending, resulting in a proposed conversion factor for CY 2022 of $84.457.

d. Wage Index Changes

CMS accounts for relative differences in labor costs across geographic regions by adjusting the labor-related share of the OPPS payment rate, which consists of 60 percent of the national OPPS payment, by the hospital wage index for the area where Medicare makes the payment. CMS uses the same post-reclassified wage index that it uses under the Inpatient Prospective Payment System (IPPS) to standardize costs. Several changes were proposed in the fiscal year (FY) 2022 IPPS proposed rule,[4] primarily stemming from the reinstatement of the imputed floor for all-urban States, as required by the American Rescue Plan Act of 2021 (ARPA). Specifically, the ARPA provides that for discharges occurring on or after October 1, 2021, the area wage index applicable under the IPPS to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State. In the FY 2022 IPPS proposed rule, CNS determined that the following States would be considered all-urban States: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, D.C. Therefore, hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2022.

CMS notes that in the FY 2022 IPPS proposed rule, given the recent enactment of ARPA, there was not sufficient time available to incorporate the changes required by this statutory provision (the reinstatement of the imputed floor wage index) into the calculation of the IPPS provider wage index for the FY 2022 IPPS proposed rule. CMS will include the imputed floor wage index adjustment in the calculation of the IPPS

[3] Additional details on CMS comment solicitation regarding the policy modifications and potential additional criteria for revised payment for non-opioid pain management treatments can be found starting on page 78 of the display copy of the proposed rule.

[4] The FY 2022 IPPS proposed rule is available at https://www.govinfo.gov/content/pkg/FR-2021-05-10/pdf/2021-08888.pdf.

provider wage index in the FY 2022 IPPS final rule. Estimated imputed floor values by state for FY 2022 are available on the CMS website.[5]

Additionally, in the FY 2021 IPPS final rule, CMS adopted revised geographic area delineations as set forth in an Office of Management and Budget (OMB) Bulletin (No. 18-04) issued in September 2018. These revised delineations resulted in significant changes, including hospital reclassifications in impacted areas. To mitigate the impact of these changes, CMS adopted a policy to place a 5 percent cap on any decrease in a hospital's wage index for FY 2021. This transition is set to expire at the end of FY 2021.

CMS notes that in the FY 2021 IPPS proposed rule, they sought comment on whether to continue to apply this transition to the FY 2022 wage index for hospitals negatively impacted by the adoption of updates from OMB Bulletin No. 18-04, in light of the impact of COVID-19. For example, such hospitals could be held harmless from any reduction relative to their FY 2021 wage index. CMS also sought comment on making this transition budget neutral, as is their usual practice, in the same manner as the transition implemented for FY 2021.

For CY 2022, CMS proposes to adopt updates set forth in OMB Bulletin No. 20-01, issued March 6, 2020.[6] However, the revised geographic area delineations in OMB Bulletin No. 20-01 would not affect the Medicare wage index for FY 2022. Specifically, the updates consist of changes to New England City and Town Area (NECTA) delineations and the creation of a new Micropolitan Statistical Area, which was then added as a new component to an existing Micropolitan Statistical Area. Because CMS does not use NECTA definitions and includes Micropolitan Statistical Areas in each State's rural wage index, no specific wage index updates would be necessary as a result of adopting the changes in OMB Bulletin No. 20-01.

CMS proposes to use the FY 2022 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2022. Therefore, any adjustments for the FY 2022 IPPS post-reclassified wage index, including, but not limited to, the imputed floor adjustment and any transition that may be applied (as discussed above), would be reflected in the final CY 2022 OPPS wage index beginning on January 1, 2022.

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

Generally, CMS uses overall hospital-specific CCRs calculated from a hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under OPPS during the payment year. For certain hospitals, however, CMS uses the statewide average default CCRs to determine these payments where it is not possible to determine an accurate CCR for the hospital. Statewide average default CCRs are used for new hospitals, 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 uses the statewide average default CCRs to determine payments for hospitals whose CCR falls 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.

For CY 2022, CMS proposes to update the default ratios using cost report data from the same set of cost reports CMS originally used in the CY 2021 OPPS ratesetting, consistent with the proposal to use CY 2019 claims data and the data components related to it due to the COVID-19 PHE. CMS proposes to continue to use its standard methodology of calculating the statewide average default CCRs using the same hospital

[5] *See* https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.

[6] Available here: https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.

overall CCRs that it uses to adjust charges to costs on claims data for setting the proposed CY 2021 OPPS relative payment weights.[7]

f. Payment Adjustments

i. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs)

Keeping with longstanding policy, CMS proposes to continue the 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy.

ii. Certain Cancer Hospitals

For CY 2022, CMS proposes to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final payment-to-cost ratio (PCR) is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals, using the most recent submitted or settled cost report data that were available at the time of the development of this proposed rule, reduced by one percentage point, to comply with section 16002(b) of the 21st Century Cures Act.

CMS is not proposing an additional reduction beyond the one percentage point reduction required by section 16002(b) for CY 2022. Under their established policy, to calculate the proposed CY 2022 target PCR, CMS would use the same extract of cost report data from the Healthcare Cost Report Information System data used to estimate costs for the CY 2022 OPPS. This would be the most recently available hospital cost reports, which, in most cases, would be from CY 2020. However, given CMS's concerns with CY 2020 claims data as a result of the PHE, CMS believes a target PCR based on CY 2020 claims and the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2021 rulemaking cycle. Therefore, for CY 2022, CMS proposes to continue to use the CY 2021 target PCR of 0.89. This proposed CY 2022 target PCR of 0.89 includes the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2022.

Table 4 of the proposed rule shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2022. The actual amount of the CY 2022 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2022 payments and costs.

g. Hospital Outpatient Outlier Payments

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount—1.75 in CY 2021) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars—$5,300 in CY 2021). If the cost of a service exceeds both the

[7] Further details on CMS's process for calculating statewide average CCRs are available in the CY 2022 OPPS/ASC proposed rule Claims Accounting Narrative, available at https://www.cms.gov/files/document/2022-nprm-opps-claims-accounting.pdf.

multiplier threshold and fixed-dollar threshold, the outlier payment is 50 percent of the amount that exceeds 1.75 times the APC payment. CMS sets a projected target for aggregate outlier payments at one percent of the estimated aggregate total OPPS payments for the prospective year.

For CY 2022, CMS proposes to continue its policy of estimating outlier payments at one percent of the estimated aggregate total OPPS payments. CMS proposes a multiplier threshold of 1.75 and a fixed-dollar amount threshold of $6,100. For hospitals that fail to meet Hospital Outpatient Quality Reporting (OQR) Program requirements, CMS proposes to continue to use the reduced payment amounts for purposes of determining outlier eligibility and payment calculation.

With respect to Community Mental Health Center (CMHC) Partial Hospitalization Program (PHP) outlier payments, CMS proposes to allocate up to 0.01 percent of outlier payments (0.0001 percent of total OPPS payments) for such services. CMS proposes to continue its longstanding policy of paying outlier payments for CMHC PHP services paid under APC 5853 (Partial Hospitalization for CMHCs) for costs that exceed 3.4 times the payment rate for APC 5853.

h. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The payment rate for most services and procedures paid under the OPPS is the product of the conversion factor and the relative payment weight. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to the proposed rule and for most HCPCS codes paid separately under the OPPS set forth in Addendum B was calculated by multiplying the proposed CY 2022 scaled weight for the APC by the CY 2022 conversion factor.[8] Hospitals that do not meet the Hospital OQR Program requirements are subject to a two percent reduction in their unadjusted payment rate, which is calculated by multiplying the reporting ratio of 0.9805 times the full national unadjusted payment rate.

II. OPPS Ambulatory Payment Classification (APC) Group Policies

a. Proposed Treatment of New and Revised HCPCS Codes

CMS seeks comment on the proposed APC and status indicator assignments for the following codes:

- 26 new HCPCS codes established and made effective on April 1, 2021 (listed in Table 5 of the proposed rule).
- 55 new HCPCS codes established and made effective on July 1, 2021 (listed in Table 6 of the proposed rule). These new codes that were effective July 1, 2021 are assigned to comment indicator "NP" in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments.
- The new CPT and Level II HCPCS codes that will be effective October 1, 2021.
- The new CPT and Level II HCPCS codes that will be effective January 1, 2022.

The comment timeframe for new and revised HCPCS codes is as follows:

[8] Addenda available at https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p.

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

The proposed status indicator and APC assignment for these codes can be found in Addendum B to the proposed rule. Because the CPT codes listed in Addendum B appear with short descriptors only, CMS lists them again in Addendum O with long descriptors.[9]

b. Variations Within APCs

Section 1833(t)(2) of the Social Security Act (SSA) provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than two times greater than the lowest cost for an item or service within the same group (the "2 times rule"). When evaluating exceptions to the 2 times rule for affected APCs, CMS considers the following criteria:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and fragments.

Based on the CY 2019 claims data available, CMS found that 23 APCs violated the 2 times rule. However, CMS found that all 23 APCs met the criteria for an exception to the 2 times rule. Table 8 of the proposed rule lists the 23 APCs that CMS is proposing to make an exception for under the 2 times rule for CY 2022 based on the criteria cited above and claims data submitted between January 1, 2019, and December 31, 2019, and processed on or before June 30, 2020, and updated CCRs, if available.

[9] Available at https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p.

c. New Technology APCs

For CY 2022, CMS included the proposed payment rates for New Technology APCs 1491-1599 and 1901-1908 in Addendum A to this proposed rule.

For CY 2022, CMS proposes to continue its policy adopted in CY 2019 under which the Agency will utilize their equitable adjustment authority under section 1833(t)(2)(E) of the SSA to calculate the geometric mean, arithmetic mean, and median using multiple years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC.

However, CMS proposes to utilize their equitable adjustment authority through its proposed universal low volume APC policy described in section VIII.c. of this summary. The proposed universal low volume APC policy is similar to CMS's current New Technology APC low volume policy with the difference between the two policies being that the universal low volume APC policy would apply to clinical APCs and brachytherapy APCs, in addition to New Technology APCs, and would use the highest of the geometric mean, arithmetic mean, or median based on up to four years of claims data to set the payment rate for the APC. For New Technology APCs with fewer than 100 single claims at the procedure level that can be used for ratesetting, CMS would apply its proposed methodology for determining a low volume APC's cost, choosing the "greatest of" the median, arithmetic mean, or geometric mean at the procedure level, to apply to the individual services assigned to New Technology APCs and provide the final New Technology APC assignment for each procedure. CMS proposes to end its separate New Technology APC low volume policy if they adopt the proposed universal low volume APC policy, as it also applies to New Technology APCs.

Additionally, consistent with current policy, for CY 2022, CMS proposes to retain services within New Technology APC groups until it obtains sufficient claims data to justify reassignment of the service to a clinically appropriate APC. For CY 2022, CMS is proposing changes to New Technology APC assignment for eight procedures.[10]

d. APC-Specific Policies

For CY 2022, CMS is proposing changes to APCs for Stromal Vascular Fraction (SVF) Therapy. SVF therapy is currently described by CPT codes 0565T and 0566T, which were effective January 1, 2020. For CY 2021, CPT code 0565T is assigned to APC 5733 (Level 3 Minor Procedures) with a payment rate of $55.66, and CPT code 0566T is assigned to APC 5441 (Level 1 Nerve Injections) with a payment rate of $261.17. Based on recent information from the FDA, CMS found there is no current FDA-approved autologous cellular product derived from autologous body fat (referred to in CPT code 0565T and 0566T as "autologous cellular implant") associated with SVF therapy. In addition, review of the clinical trials website indicates that SVF therapy is currently under clinical trial (ClinicalTrials.gov Identifiers: NCT04440189 and NCT02726945), and has not received CMS approval as investigational device exemption (IDE) studies. Consequently, for CY 2022, CMS proposes not to pay under the OPPS for either code.

[10] CMS is proposing New Technology APC changes for the following procedures and corresponding codes: (1) Retinal Prosthesis Implant Procedure (CPT code 0100T); (2) Administration of Subretinal Therapies Requiring Vitrectomy (HCPCS code C9770); (3) Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (HCPCS code C9751); (4) Fractional Flow Reserve Derived from Computed Tomography (FFRCT) (CPT code 0503T); (5) Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (CPT codes 78431-78433); (6) V-Wave Interatrial Shunt Procedure (HCPCS code C9758); (7) Corvia Medical Interatrial Shunt Procedure (HCPCS code C9760); and (8) Supervised Visits for Esketamine Self-Administration (HCPCS codes G2082-G2083).

III. OPPS Payment for Devices

a. Proposed Pass-Through Payments for Devices

CMS provides transitional device pass-through payment to facilitate access for beneficiaries to new and innovative devices while necessary cost data are collected to incorporate the costs for such devices into the procedure APC rate. Unlike pass-through status applicable to drugs and biological products, which is granted on an individual product basis, devices are granted pass-through status by device category. Transitional pass-through payment status can be in effect for at least two years but not more than three years, and begins on the first date on which pass-through payment is made under OPPS for any medical device described by such category. CMS allows for quarterly expiration of pass-through payment status for device categories to afford a pass-through payment period that is as close to the maximum three years as possible. After the pass-through period, costs of the device(s) in the category are packaged into the costs of the procedures with which the devices are reported.

i. Extension of Device Transitional Pass-Through Status Due to the Effects of COVID-19

One device category's (C1823) transitional pass-through status is currently set to expire on December 31, 2021. In the CY 2021 proposed rule, CMS solicited comments on whether it should adjust future payments for devices that are currently eligible for transitional pass-through payments that may have been impacted by the COVID-19 PHE. As described in detail below, CMS is proposing to use its equitable adjustment authority under section 1833(t)(2)(E) of the SSA to provide separate payment for C1823 for four quarters of CY 2022, ending on December 31, 2022.

ii. Expiration of Transitional Pass-Through Payments for Certain Devices[11]

HCPCS Code	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; *separate payment extended to 12/31/2022*
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (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 (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

[11] Table 17 in the proposed rule.

iii. New Device Pass-Through Applications

Devices must meet the following criteria to be eligible for transitional pass-through status:[12]

- FDA premarket approval or clearance, or subject to an appropriate FDA exemption;
- Application for pass-through status submitted within three years from the date of initial FDA approval or clearance if required, or within three years from the date of market availability if there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted;
- Reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part;
- Integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted or applied in or on a wound or other skin lesion;
- Is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered as depreciable assets; or a material or supply furnished incident to a service (e.g., sutures, surgical kits, clips);
- Is not appropriately described in any existing or previously in effect device category;
- Demonstrates substantial clinical improvement or has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program; and
- The cost of the device is not "insignificant," as determined by satisfying each of the following three criteria:
    1. Estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices ("first cost criterion");
    2. Estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list) ("second cost criterion"); and
    3. The difference between estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related device ("third cost criterion").

Product	Applicant	Notes
Traditional Pathway		
AngelMed Guardian® System	Angel Medical Systems	CMS raises concerns regarding substantial clinical improvement criterion
BONEBRIDGE Bone Conduction Implant System	MED-EL Corp.	CMS believes the device is described by L8690; CMS raises concerns regarding substantial clinical improvement criterion
Eluvia™ Drug-Eluting Vascular Stent System	Boston Scientific Corp.	CMS raises concerns regarding substantial clinical improvement criterion; does not believe that the device meets the second and third cost criteria
Cochlear™ Osia® 2 System	Cochlear Americas	CMS believes the device is described by L8690; CMS raises concerns regarding substantial clinical improvement criterion
Pure-Vu® System	Motus GI	

[12] 42 CFR 419.66(b), (c).

Xenocor Xenoscope™	Xenocor Inc.	CMS raises concerns regarding substantial clinical improvement criterion
Alternative Pathway for Breakthrough Devices		
RECELL System	AVITA Medical	CMS is uncertain whether this product qualifies as a device
Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) catheter	Shockwave Medical	Preliminary Approval Granted effective 7/1/2021

b. Proposed Device-Intensive Procedures

Device-intensive status for procedures is determined at the individual HCPCS code level. A procedure qualifies as a device-intensive procedure if it requires the implantation of a device and additionally meets the following criteria:

- Procedure must involve an implantable device assigned a CPT or HCPCS code;
- The required device (including single-use devices) must be surgically inserted or implanted (regardless of whether the device remains in the patient's body after the conclusion of the procedure); and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost.

CMS applies a 31 percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data. Therefore, these codes are assigned device intensive status until claims data are available. Once claims data are available for a new procedure requiring the implantation of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent. In rare instances, CMS may temporarily assign a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer. Finally, CMS uses claims data from any predecessor code for a new HCPCS code, and in limited instances may use claims data from HCPCS codes that are clinically related or similar to a new HCPCS code but are not officially recognized as a predecessor code by CPT, as identified through CMS's clinical discretion.

As described elsewhere in this summary, CMS generally proposes to use CY 2019 claims data to establish CY 2022 prospective rates. However, in accordance with its policy of temporarily assigning a higher offset percentage if warranted by additional information, CMS proposes to use CY 2020 data for device-intensive procedure determinations in certain circumstances. Specifically, for procedures that were assigned device-intensive status, but were assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code in the absence of CY 2019 claims data, CMS proposes to assign a device offset percentage for such procedures based on CY 2020 data if CY 2020 claims information is available.

Under this proposal, the following 11 procedures would be assigned device offset percentages using CY 2020 claims data. **CMS seeks comment on this proposal.** The full listing of proposed CY 2022 device-intensive procedures can be found in Addendum P to the proposed rule.

HCPCS	Description
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
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 when performed, posterior tibial nerve
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous
0614T	Removal and replacement of substernal implantable defibrillator pulse generator
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris ansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

i. Elimination of Low-Volume Device-Intensive Procedures Payment Policy

Under current policy, CMS establishes 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 using the median cost instead of geometric cost. Currently, CPT code 0308T is the only code subject to the low-volume device-intensive policy.

CMS proposes to eliminate its payment policy for low-volume device-intensive procedures for CY 2022 and subsequent years. As discussed further in section VIII.c, 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 ratesetting (using CY 2019 claims data for CY 2022 rates). CMS proposes to establish a payment rate using the highest of median cost, arithmetic mean cost, or the geometric cost. Given that the proposed universal low volume APC policy would utilize a greater number of claims and provide additional cost metric alternatives for ratesetting than the existing low-volume device-intensive policy, CMS believes that any codes subject to the existing low-volume device-intensive policy would be appropriately addressed under its broader universal low-volume APC proposal.

CMS seeks comment on its proposal to eliminate the low-volume device-intensive procedure payment policy.

IV. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

a. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

Section 1833(t)(6) of the SSA mandates transitional pass-through payments for certain drugs and biological products for two to three years after initial payment as a hospital outpatient service under Part B at the payment rate established under section 1847A of the SSA—generally, ASP plus six percent. Specifically, a pass-through payment is the amount by which the ASP-based payment under 1847A exceeds the otherwise applicable Medicare OPD fee schedule associated with the drug or biological product. Effectively, this means that the pass-through payment for most drugs and biologicals is $0 because there is no difference between the ASP plus six percent authorized under section 1847A and the portion of the otherwise applicable OPD fee schedule. In the case of policy-packaged drugs and biological products (e.g., anesthesia drugs, diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes), the payment is ASP plus six percent minus a payment offset for the portion of the APC payment associated with predecessor products.

CMS both accepts pass-through applications and expires pass-through status on a quarterly basis in order to afford a pass-through payment period as close to a full three years as possible.

b. Proposal to Provide Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals with Transitional Pass-Through Payment Status Expiring between December 31, 2021 and September 30, 2022

CMS solicited comments in the CY 2021 OPPS/ASC proposed rule regarding whether it should utilize its equitable adjustment authority under section 1833(t)(2)(E) of the SSA to provide separate payment for some period of time after pass-through status ends for devices with expiring pass-through status in order to account for time that utilization of the devices was reduced due to the PHE. CMS only solicited comments with respect to devices, but received comments urging that CMS use this authority to provide an adjustment to extend pass-through payments for drugs, biologicals, and biosimilar biological products as well.

Because CMS is proposing to use CY 2019 claims data to establish the CY 2022 OPPS rates, and recognizing that CY 2020 claims data may not be the best available data for ratesetting for devices, drugs, and biologicals for which pass-through status expires between December 31, 2021 and September 30, 2022, CMS is proposing a one-time equitable adjustment under section 1833(t)(2)(E) to continue separate payment for the remainder of CY 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022. Devices, drugs, and biologicals subject to this adjustment would continue to receive separate payment through December 31, 2022. Drugs and biologicals subject to this adjustment would continue to be paid at ASP plus 6 percent, even if the drug or biological product is purchased through the 340B Drug Discount Program.

See below for a table of drugs and biological products with applicable pass-through periods, including notation where the pass-through period would be extended through the proposed equitable adjustment:[13]

Drugs and Biologicals with Pass-Through Payment Status Expiring in CY 2021						
CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date	Proposed Adj. Equiv. to Ext. of Pass-Through Status (# of quarters)

[13] Note also that one device category, C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads) is also receiving 4 quarters of adjustment equivalent to an extension of pass-through status.

Drugs and Biologicals with Pass-Through Payment Status Expiring in CY 2021						
C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021	-
J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021	-
J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021	-
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021	-
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021	-
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021	-
J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021	-
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	03/31/2021	-
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	03/31/2021	-
Q5104	Injection, infliximab- abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021	-
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021	-
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021	-
J7170	Injection, emicizumab- kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021	-
J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021	-
Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021	-
Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/01/2018	06/30/2021	-
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021	-
Q5105	Injection, epoetin alfa- epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021	-
Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021	-
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021	4
J0222	Injection, Patisiran, 0.1mg	G	9180	01/01/2019	12/31/2021	4
J0291	Injection, plazomicin, 5mg	G	9183	01/01/2019	12/31/2021	4
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021	4
J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021	4
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021	4

Drugs and Biologicals with Pass-Through Payment Status Expiring in CY 2022							
CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date	Proposed Adj. Equiv. to Ext. of Pass-Through Status (# of quarters)

Drugs and Biologicals with Pass-Through Payment Status Expiring in CY 2022							
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022	3
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022	3
J0642	J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	G	9334	04/01/2019	03/31/2022	3
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022	3
J3031	J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022	3
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022	3
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022	3
J9119	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022	3
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022	3
Q5108	Q5108	Injection, pegfilgrastimjmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022	3
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022	3
Q5111	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022	3
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022	2
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022	2
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022	2
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022	2
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022	2
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022	2
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022	2
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022	1
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022	1
C9054	J0691	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022	-
C9055	J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022	-
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022	-
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022	-
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022	-

Drugs and Biologicals with Pass-Through Payment Status Expiring After CY 2022						
CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass- Through Payment Effective Date	Pass-Through Payment End Date

Drugs and Biologicals with Pass-Through Payment Status Expiring After CY 2022						
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
C9056	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
C9053	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
C9122	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023

c. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

At the expiration of pass-through status, CMS provides separate payment at the applicable relative ASP-based amount (generally, ASP plus six percent) for drugs and biological products with an estimated per day cost above the proposed CY 2022 packaging threshold of $130, unless such drug or biological product is always packaged as a matter of policy. CMS proposes to continue its longstanding policy to package (without regard to whether the drug is above the $130 threshold) certain drugs and biological products, including anesthesia drugs, diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, as set forth in 42 CFR 419.2(b).

CMS proposes to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP plus six percent in accordance with section 1833(t)(14)(A)(iii)(II) of the SSA. CMS proposes to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described further below). CMS proposes to continue to pay Wholesale Acquisition Cost (WAC) plus three percent for separately payable drugs and biologicals when ASP data are not sufficiently available (WAC minus 22.5 percent for such drugs acquired with a 340B discount).

With respect to biosimilar biological products, CMS proposes to continue current policies to reimburse such biosimilars at ASP plus six percent of the reference product's ASP during the pass-through period. After the pass-through period, biosimilars would continue to be paid at ASP plus six percent of the reference product's ASP, except that nonpass-through biosimilars acquired under the 340B program would be paid at ASP minus 22.5 percent of the biosimilar's ASP in accordance with the 340B payment reduction as described further below.

CMS proposes to continue to pay for blood clotting factors at ASP plus six percent, plus an additional payment for the furnishing fee. The furnishing fee, which was $0.238 per unit in CY 2021, is increased with inflation and will be announced through applicable program instructions when the underlying data become available.

d. Proposed Payment Methodology for 340B Purchased Drugs

Payment rates for drugs under the OPPS are typically based on average acquisition cost and governed by section 1847A of the SSA, which generally sets a default rate of ASP plus six percent for certain drugs subject to adjustment by the Secretary. The Secretary utilized this adjustment authority to set the payment rate for 340B-acquired drugs to ASP minus 22.5 percent to approximate a minimum average discount for such drugs beginning in CY 2018.

CMS proposes to continue its current payment policy for 340B-acquired drugs. Specifically, CMS proposes to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent. Where ASP data are not available, CMS would pay WAC minus 22.5 percent for such drugs. Nonpass-through biosimilars acquired under the 340B program would be paid at ASP minus 22.5 percent of the biosimilar's ASP. CMS proposes to continue to exempt children's hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals from the 340B payment reduction.

This payment reduction has been the subject of protracted litigation, including a ruling by the U.S. District Court for the District of Columbia that such adjustment is beyond the authority of the Secretary unless the Secretary obtains survey data from hospitals on their acquisition costs.[14] On July 31, 2020, the U.S. Court of Appeals for the D.C. Circuit reversed the district court's ruling, holding that the payment reduction was a reasonable interpretation of the Medicare statute and within the Secretary's authority.[15] On July 2, 2021, the U.S. Supreme Court agreed to take up the case. Notably, the Supreme Court directed the parties to argue whether the suit challenging HHS's 340B drug payment adjustment is precluded by section 1833(t)(12) of the SSA.[16]

e. Proposed Payment for Packaged Skin Substitutes

CMS proposes 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. The proposed CY 2022 MUC threshold is $48 per cm^2 (rounded to the nearest $1). The proposed CY 2022 PDC threshold is $949 (rounded to the nearest $1).

CMS proposes to continue its payment policy for packaged skin substitutes. Specifically, CMS proposes to continue to assign each skin substitute that exceeds either the MUC or PDC threshold to the high cost group, and those that do not to the low cost group. Consistent with current policy, CMS proposes that any skin substitute product that was assigned to the high cost group in CY 2021 would remain in the high cost group for CY 2022, regardless of whether it exceeds or falls below the CY 2022 MUC or PDC threshold. CMS proposes to continue its policy to assign skin substitutes with pass-through payment status to the high cost category. Synthetic products would continue to be included in the description of skin substitutes, in addition to biological products. If a skin substitute has pricing data but no claims data, the high/low cost category assignment would continue to be based on the product's ASP plus 6 percent as compared to the MUC threshold. If ASP is not available, WAC plus 3 percent would be used; if neither ASP nor WAC are available, 95 percent of average wholesale price (AWP) would be used. Finally, if no pricing data are available, the product would be assigned to the low cost category until pricing information is available to

[14] *Am. Hosp. Ass'n v. Azar*, 348 F.Supp.3d 62 (D.D.C. Dec. 27, 2018).

[15] *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818 (D.C. Cir. July 31, 2020).

[16] *See* https://www.supremecourt.gov/docket/docketfiles/html/public/20-1114.html.

compare to the CY 2022 MUC and PDC thresholds. See Table 32 of the proposed rule for skin substitute assignments to high/low cost groups for CY 2022.

In recent years, CMS has sought comment on potential refinements to the payment methodology for skin substitutes.[17] Two policy ideas were presented for more extensive comments in the CY 2020 rulemaking cycle:

1. Establish a payment episode between 4 to 12 weeks where a lump-sum payment would be made to cover all of the care services needed to treat the wound. There would be options for either a complexity adjustment or outlier payments for wounds that require a large amount of resources to treat.
2. Eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products.

CMS continues to consider the comments it received in response to the CY 2019 and CY 2020 comment solicitations.

i. Human Cell, Tissue, or Cellular or Tissue-Based Products (HCT/Ps)

While context is not provided in the proposed rule, CMS included a clarification concerning FDA regulation of skin substitutes. Regulations implementing section 361 of the Public Health Service Act (PHSA) include a set of criteria that, if met, exempt an HCT/P from premarket review and approval processes. HCT/Ps that do not meet these criteria may be subject to the more stringent requirements of section 351 of the PHSA (usually requiring a Biologics License Application (BLA) or investigational new drug application (IND)). FDA implemented an enforcement discretion period to give HCT/P manufacturers time to file an IND or marketing application with the FDA, if required. The enforcement discretion period ended May 31, 2021.[18]

CMS notes in the proposed rule that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHSA and the FDA regulations in 21 CFR part 1271. CMS states that manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHSA and the regulations in 21 CFR part 1271.

f. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

Section 1833(t)(6)(E) of the SSA limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an "applicable percentage," currently not to exceed two percent of total OPPS payments for that year.

CMS proposes estimates as follows:

- $472.4 million for drugs and biologicals
- $552.3 million for device categories

[17] Refer to the CY 2019 OPPS/ASC final rule (83 Fed. Reg. 58818 at 58967 (Nov. 21, 2018)) and the CY 2020 OPPS/ASC final rule (84 Fed. Reg. 61142 at 61328 (Nov. 12, 2019)) for a detailed summary and discussion.

[18] *See* FDA, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*, July 2020, available at https://www.fda.gov/media/109176/download.

- $1,024.7 million total for drugs, biologicals, and devices

This figure represents 1.24 percent of total projected OPPS payments for CY 2022 (approximately $83 billion), which does not exceed 2 percent of total OPPS payments.

V. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2022, CMS proposes to continue its current clinic and emergency department (ED) hospital outpatient visits payment policies. Note that this would include the continued reimbursement for hospital outpatient clinic visits (HCPCS code G0463) at 40 percent of the normal OPPS rate for CY 2022. In addition, CMS proposes to continue its payment policy for critical care services (CPT codes 99291 and 99292). **CMS seeks comment on any changes to these codes that should be considered for future rulemaking cycles.** CMS states that it will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of outpatient department services.

VI. Payment for Partial Hospitalization Program (PHP) Services

A PHP is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Specifically, a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Such services must be prescribed by a physician and provided under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

a. PHP APC Update for CY 2022

PHP services are paid using one of two single tiered APC structures: CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)).

Under this proposed rule, CMS would use the latest available CY 2019 claims and cost data from the CY 2021 OPPS/ASC final rule to determine CY 2022 geometric mean per diem costs in this proposed rule, and, if the final CY 2022 cost for CMHCs or hospital-based PHPs is calculated to be above the proposed floor, CMS would use the final calculated cost instead of the floor. This approach would rely on claims data and cost information from prior to the COVID-19 PHE. Note that for CY 2022 and future years, CMS proposes to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF).

For CY 2022 only, CMS proposes to use the CY 2022 CMHC geometric mean per diem cost calculated in accordance with CMS's existing methodology, but with a cost floor equal to the per diem cost for CMHCs ($136.14) as calculated for CY 2021 ratesetting, as the basis for developing the CY 2022 CMHC APC per diem rate. After applying the data preparation steps (e.g., trims, exclusions, adjustments), and after using the CMHC CCRs calculated based on HCRIS information, the CY 2022 geometric per diem cost for all CMHCs for providing three or more services per day (CMS APC 5853) was calculated to be $130.41, a decrease from the $136.14 calculated for CY 2021. Because this would potentially result in a disruption to

CMHC payments, and in accordance with the proposed cost floor for CY 2022 only, CMS instead proposes the CY 2022 geometric mean per diem to be the CY 2021 amount of $136.14.

CMS also proposes, for CY 2022 only, to use this approach for the CY 2022 hospital-based geometric mean per diem cost (floor equal to per diem cost of hospital-based providers of $253.76, as calculated for CY 2021 ratesetting). Like the CMHC geometric mean per diem cost calculated, CMS calculated a CY 2022 hospital-based PHP APC geometric mean per diem cost to be slightly lower than that of CY 2021 ($253.08 instead of $253.76). While CMS does not believe a decrease of this magnitude would be unexpected due to normal variations in cost and claims data, CMS reiterates its concerns that a decrease may result in a disruption in payments. Therefore, CMS proposes for CY 2022 only that the CY 2021 calculated amount of $253.76 would serve as the cost floor.

b. Outlier Policy for CMHCs

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 according to previously established policies. CMS proposes the following for CY 2022:

CMHC outlier percentage	Approximately less than 0.01 percent of the estimated one percent hospital outpatient outlier threshold for CMHCs
Cutoff point and percentage payment amount	50 percent payment for costs that exceed 3.4 times the payment rate for CMHC APC 5853
Outlier reconciliation	Providers whose outlier payments meet a specified threshold (currently $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 are subject to outlier reconciliation
Outlier payment cap	Eight percent CMHC outlier payment cap to CMHC's total per diem payments
Fixed-dollar threshold	No threshold set for CMHC outlier payments

VII. Changes to the Inpatient Only (IPO) List

In a reversal from the CY 2021 OPPS/ASC final rule, CMS proposes to halt the elimination of the IPO list[19] and, after clinical review of the services removed from the IPO list in CY 2021, CMS proposes to add the removed services back to the IPO list beginning in CY 2022. CMS proposes to amend its regulation to remove the reference to the elimination of the IPO and reinstitute the criteria for determining whether a service or procedure should be removed from the IPO list (new 42 CFR 419.23).[20]

[19] In the CY 2021 OPPS/ASC final rule, CMS finalized a 3-year transition that would eliminate the IPO list by January 1, 2024.

[20] The five criteria include: (1) most outpatient departments are equipped to provide the services to the Medicare population; (2) the simplest procedure described by the code may be furnished in most outpatient departments; (3) the procedure is related to codes that CMS already removed from the IPO list; (4) a determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis; and (5) a determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by CMS for addition to the ASC list.

a. Halting the Elimination of the IPO List in CY 2022

CMS states that after further consideration, it continues to believe the IPO list is a valuable tool to ensure that the OPPS only pays for services that can safely be performed in the hospital outpatient setting. CMS states that this proposal will allow for greater consideration of the impact removing services from the list has on beneficiary safety and will allow providers impacted by the COVID-19 PHE additional time to prepare to furnished appropriate services safely and efficiently, before CMS removes large numbers of services from the IPO list.

CMS seeks comment on whether it should maintain the longer-term objective of eliminating the IPO list and if so, suggestions for a reasonable timeline for doing so and the method that should be employed to evaluate procedure removal. CMS requests evidence on what effect, if any, eliminating or scaling back the IPO list will have on beneficiary quality of care and provider behavior, incentives, or innovation. CMS also seeks feedback on the clinical, financial, and administrative impact of removing services from the IPO list. Finally, CMS seeks comment on refining the approach to inpatient only code evaluation to keep pace with advances in technology and surgical techniques.

b. Returning Procedures Removed in CY 2021 to the IPO List for CY 2022

With respect to the procedures 298 services[21] removed from the IPO list for CY 2021, CMS states that the removed procedures were not assessed against the longstanding criteria (new 42 CFR 419.23) because CMS proposed to eliminate the IPO list entirely. After a clinical review of each of the procedures removed, CMS now believes that these services do not currently meet CMS's longstanding removal criteria and, therefore, CMS proposes to add them back to the IPO list for CY 2022.

CMS seeks comment on whether there are other services removed from the IPO list in CY 2021 that stakeholders believe do meet the longstanding criteria for removing services from the IPO list. CMS requests the corresponding evidence (e.g., case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols) supporting this position. CMS also seeks comment on whether any of the 298 services should remain off the IPO list.[22]

i. Topics and Questions for Public Comment

Overall, **CMS seeks comments in response to the following:**

- 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 streamline the list of services included on the list and, if so, suggestions for ways to systematically scale the list back to allow for the removal of 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?

[21] The list of 298 services CMS proposes to add back to the IPO list is available in Table 35 of the proposed rule. The complete proposed IPO list for CY 2022 is included as Addendum E to the proposed rule.

[22] CMS recognizes that there may be a subset of Medicare beneficiaries who, on a case-by-case basis, may be appropriately treated in the outpatient setting.

- 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?
- Are there services that were removed from the IPO list in CY 2021 that stakeholders believe meet the longstanding criteria for removal from the IPO list and should continue to be payable in the outpatient setting in CY 2022? If so, what evidence supports the conclusion that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the Medicare population in the outpatient setting?

VIII. Nonrecurring Policy Changes

a. Proposed Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2022 and Subsequent Years

In the CY 2021 OPPS/ASC final rule, CMS finalized a policy to indefinitely exempt procedures removed from the IPO list on or after January 1, 2021 from certain medical review activities due to the significant number of procedures (298) removed from the list in CY 2021. The indefinite exemption was meant to last until CMS had Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting.

Because CMS proposes in the CY 2022 proposed rule to halt the elimination of the IPO list, CMS proposes to return to the 2-year exemption from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIO) referrals to Recovery Audit Contractors (RACs), and RAC reviews for "patient status" (i.e., site-of-service) for procedures that are removed from the IPO list under the OPPS on January 1, 2021 or later. Services removed beginning on January 1, 2021 would receive the same 2-year exemption from the 2-midnight medical review activities as they currently apply to services removed between January 1 and December 30, 2020, and not the indefinite exemption finalized in the CY 2021 OPPS/ASC final rule. CMS notes that this is not an exemption from the 2-midnight rule in general, but of certain medical review procedures and site-of-service claim denials.

While CMS proposes to halt the elimination of the IPO list (as described above), **CMS seeks comment on whether a 2-year time period is appropriate, or if a longer or shorter period is warranted.** If CMS does not finalize its proposal to halt the elimination of the IPO list, it may continue with the indefinite exemption previously finalized.

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

Section 122 of Division CC of the Consolidated Appropriations Act of 2021 (CAA) established a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code billed for the establishment of a diagnosis as a result of the test or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal screening test. The reduced coinsurance will be phased-in beginning in January 1, 2022. Currently, any procedure beyond the planned colorectal cancer screening test results in the beneficiary paying coinsurance. The coinsurance percentage is 20 or 25 percent depending upon the setting where the

procedure is performed. Under the CAA's special coinsurance rule, the coinsurance will be successively reduced such that for services furnished on or after January 1, 2030, the coinsurance will be zero.

To implement section 122, CMS proposes to modify its regulations at 42 CFR 410.37 such that for services furnished on or after January 1, 2022, a flexible sigmoidoscopy or a colonoscopy can be considered a screening test even if an additional procedure is furnished to remove tissue or other matter. CMS notes that only flexible screening sigmoidoscopies and screening colonoscopies are currently recognized colorectal cancer screening tests that might involve removal of tissue or other matter. CMS also proposes to modify its regulations at 42 CFR 410.152(l)(5) to reflect the phased-in increase of Medicare payment (and corresponding decrease in beneficiary coinsurance) for such instances as follows:

- 80 percent payment for services furnished during CY 2022 (20 percent coinsurance);
- 85 percent payment for services furnished during CY 2023 through 2026 (15 percent coinsurance);
- 90 percent payment for services furnished during CY 2027 through 2929 (10 percent coinsurance); and
- 100 percent payment for services furnished during CY 2030 and future years (0 percent coinsurance)

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

CMS has historically used its equitable adjustment authority at section 1833(t)(2)(E) of the SSA on a case-by-case basis to adjust the determination of costs for certain low-volume services. CMS has applied this in two settings: the low-volume device-intensive procedure payment policy and the New Technology APCs.

CMS calculates the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 single claims for all procedures in the APC using the median cost rather than the geometric mean cost, reasoning that the geometric mean cost is more impacted by extreme observations.

CMS calculates payment rates for low-volume procedures with fewer than 100 claims per year that are assigned to a New Technology APC by using up to 4 years of claims data to calculate the geometric mean, the median, and the arithmetic mean. CMS includes the result of each statistical methodology in annual rulemaking, and solicits comment on which methodology should be used to establish the payment rate. Once CMS identifies a payment rate for a low-volume service, it assigns the service to the New Technology APC with the cost band that includes its payment rate.

These policies are intended to address the same concerns—low utilization leads to volatility in year-to-year payment rates, which can reduce access to these new technologies and limits CMS's ability to assign the service to an appropriate APC. CMS believes it would be beneficial to apply this methodology to other APCs with low claims volume.

As such, CMS proposes to designate clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year (the CY 2019 claims year for this CY 2022 proposed rule) as low volume APCs. CMS proposes to use up to 4 years of claims data to establish a payment rate for each item or service. Given CMS's concerns regarding CY 2020 claims data due to the PHE, the 4 years of claims data would be based on claims from CY 2016 to CY 2019. Further, CMS proposes to use the greatest of the median, arithmetic mean, or geometric mean cost to approximate the cost of items and services assigned to a low volume APC. As discussed in section III.b of this summary, CMS proposes to eliminate the low-volume device-intensive procedure payment policy, and subsume the ratesetting for HCPCS code 0308T (the only procedure that has been subject to this policy) within the newly proposed broader low-volume APC proposal.

CMS notes that New Technology APCs are different from clinical APCs in that they contain procedures that may not be clinically similar to other procedures assigned to the same New Technology APC based on cost and are only assigned to a New Technology APC because there are not sufficient data to assign these procedures to a clinical APC. To account for this difference, CMS proposes to apply the proposed methodology at the procedure level for New Technology APCs.

CMS proposes to not apply this low volume APC policy to partial hospitalization program (PHP) APCs (specifically 5853 and 5863) due to the different nature of policies affecting the PHP. CMS also proposes not to apply this low volume APC policy to 2698 (Brachytx, stranded, nos) or APC 2699 (Brachytx, non-stranded, nos), as CMS believes its current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

CMS solicits comment on its proposal to establish a Low Volume APC policy for clinical APCs, brachytherapy APCs, and New Technology APCs, including (1) the proposed criterion for low-volume designation of less than 100 single claims in the APC, (2) the use of the highest of the geometric mean, median, and arithmetic mean to determine the payment rate for clinical and brachytherapy APCs, as well as individual services assigned to New Technology APCs, and (3) CMS's use of CYs 2016-2019 claims data.

Proposed Low Volume APCs for CY 2022						
APC	APC Description	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	CY 2022 Proposed APC Cost
1562	New Technology – Level 25 ($3,501 - $4,000)	$2,692.69	$3,707.76	$3,085.64	$2,692.69	$3,750.50
1908	New Technology – Level 52 ($145,001 - $160,000)	$155,412.90	$150,363.60	$154,321.70	$148,778.00	$152,500.50
2632	Iodine I-125 sodium iodide	$26.04	$30.24	$38.52	$34.16	$38.52
2635	Brachytx, non-str, HA, P-103	$44.37	$34.04	$43.53	$36.72	$43.53
2636	Brachy linear, non-str, P-103	$30.59	$24.78	$50.16	$36.43	$50.16
2645	Brachytx, non-str, Gold-198	$280.90	$61.85	$588.31	$131.86	$588.31
2647	Brachytx, NS, Non-HDRIr-192	$275.13	$145.36	$196.38	$94.24	$196.38
5244	Level 4 Blood Product Exchange and Related Services	$31,015.17	$34,287.01	$39,444.97	$34,399.17	$39,444.97
5494	Level 4 Intraocular Procedures	$14,621.42	$16,155.58	$14,951.58	$11,490.23	$16,155.58

d. Comment Solicitation on Temporary Policies to Address the COVID-19 PHE

CMS notes that the various waivers issued and emergency rulemaking to implement a number of temporary policies to address the COVID-19 PHE will expire at the end of the PHE. **CMS seeks comment on the extent to which stakeholders utilized the flexibilities available, as well as whether certain of these**

temporary policies should be made permanent (to the extent possible within CMS's existing authority). Specifically, CMS seeks comment on the following:

- Mental health services furnished remotely by hospital staff to beneficiaries in their homes (as described in the CY 2022 PFS proposed rule).
- Direct supervision by interactive communications technology (as described in the CY 2022 PFS proposed rule).
- Payment for COVID-19 specimen collection in HOPDs. Specifically, CMS seeks comment on whether it should keep HCPCS code C9803 (hospital outpatient clinic visit specimen collection for COVID-19, any specimen source) active beyond the conclusion of the COVID-19 PHE and whether CMS should extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the PHE ends. CMS seeks comment on why it would be necessary to continue to provide OPPS payment for this service ($24.67 for CY 2021), and how long payment should be extended.

e. Use of CY 2019 Claims Data for CY 2022 OPPS and ASC Payment System Ratesetting Due to the PHE

CMS notes that ordinarily, the best available claims data for updating the OPPS payment rates is the set of data from two years prior to the calendar year that is the subject of rulemaking (i.e., 2020 data for CY 2022 OPPS/ASC rule). The data sources are typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file (i.e., cost report data from HCRIS extracted in December 2020, which would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period).

Given concerns due to the impact and changing environment with regards to COVID-19, CMS proposes to use FY 2019 data as part of the FY 2022 IPPS proposed rule, instead of FY 2020 data. CMS notes that it has observed a number changes, likely as a result of the COVID-19 PHE, in the CY 2020 OPPS claims data that it would ordinarily use for ratesetting. The most significant difference is the decrease in the overall volume of outpatient hospital claims – approximately 20 percent fewer claims usable for ratesetting purposes compared to 2019. In addition, the decrease in outpatient claims volume applied to a majority of the clinical APCs in the OPPS. For example, CMS observed an approximately 30 percent decrease in volume for hospital emergency department and clinic visit APCs. Conversely, CMS saw a significant increase in the use of HCPCS code Q3014 (telehealth originating site facility fee) in the hospital outpatient claims (increasing from 35,000 services in 2019 to 1.8 million services in 2020). Two other notable exceptions to the general decrease in services furnished include APC 5731 (level 1 minor procedures) and APC 5801 (ventilation initiation and management).

With respect to APC 5731, HCPCS code C9803 (described above) had more than 1 million single claims available for cost modeling, representing approximately 93 percent of claims used to model the APC cost. While this would, in some cases, be appropriate in establishing the APC cost, CMS generally does not expect the same volume of this procedure in 2022 because it anticipates that the specimen collection for COVID-19 testing will be significantly lower than it was in 2020. With respect to APC 5801, the estimated increase in the geometric mean cost based on 2020 claims data may not be predictive of 2022 costs if there is less use of this service in 2022.

As a result of the COVID-19 PHE-related factors, including changes in services potentially related to the PHE, the significant decrease in volume (suggesting patients may have been deferring elective care during 2020), the changes in APC relative weights for services, and the increasing number of Medicare beneficiaries vaccinated against COVID-19, CMS believes that 2020 data are not the best overall approximation of expected outpatient hospital services in CY 2022. Instead, CMS believes that CY 2019

data, as the most recent complete calendar year of data prior to the COVID-19 PHE are a better approximation of expected 2022 hospital outpatient services. CMS acknowledges that 2022 data are unlikely to look exactly like either 2019 or 2020 data, but believes they will be more similar to a standard year (i.e., without the effects of the COVID-19 PHE), as pandemic-related issues decline and more of the population is vaccinated against COVID-19.

In addition to CMS's proposal to use 2019 claims data to establish the 2022 OPPS rates, CMS also proposes to use cost report data from the same set of cost reports originally used in the CY 2021 OPPS/ASC final rule. While CMS proposes to generally use 2019 claims data and the data components related to them in establishing 2022 rates, there are specific cases where CMS is using updated information (e.g., ASP data used in determining drug packaging and separately payable status, as described above in section IV).

CMS also considered the alternative of continuing with its standard process of using the most updated claims and cost report data available. **CMS seeks comment on this alternative and has made available the cost statistics and addenda utilizing the 2020 data it would ordinarily have provided in conjunction with this proposed rule.** Specifically, CMS provides a file comparing the budget neutrality and certain other ratesetting adjustments calculated under this proposal and under the alternative approach. CMS also is making available other proposed rule supporting data files based on the use of 2020 data, including: the OPPS Impact File; cost statistics files; addenda; and budget neutrality factors.

IX. OPPS Payment Status and Comment Indicators

For CY 2022, CMS is not proposing to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2021 OPPS/ASC final rule with comment period. However, CMS is requesting public comments on the proposed definitions of the OPPS status indicators for CY 2022.[23, 24]

Additionally, for the CY 2022 OPPS, CMS proposes to continue using the four following comment indicators:

- "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 current calendar year for which we requested 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 current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

[23] The complete list of the proposed payment status indicators and their definitions that would apply for CY 2022 is displayed in Addendum D1 to this proposed rule, which is available here: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p.

[24] The proposed CY 2022 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available here: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p.

- "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 current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

X. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the SSA in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. CMS would like to make stakeholders aware of the following MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2021 report.[25]

Proposed OPPS Payment Rates Update

MedPAC recommended that Congress update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the "Hospital Value Incentive Program (HVIP)."

Proposed ASC Conversion Factor Update

MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate. As a result, for CY 2022, MedPAC stated that payments to ASCs are adequate and recommended that in the absence of cost report data no payment update should be given for CY 2022 (that is, the update factor would be zero percent).

ASC Cost Data

MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that 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 but should make cost reporting a condition of ASC participation in the Medicare program.

CMS is interested in public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs.

XI. Updates to the Ambulatory Surgical Center (ASC) Payment System

a. ASC Treatment of New and Revised Codes

[25] The March 2021 MedPAC report is available here: http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf.

Since 2007, CMS annually evaluates new and revised Category I[26] and Category III[27] CPT codes and Level II HCPCS[28] codes that describe surgical procedures and makes preliminary determinations during the OPPS/ASC rulemaking process on whether they meet criteria for payment in the ASC setting. CMS also identifies new and revised codes as ASC covered ancillary services and provides quarterly updates for covered ACS services.

For the April 2021 update, CMS added 11 new Level II HCPCS codes to the list of ASC covered surgical procedures and the list of covered ancillary services assigned to an interim APC (denoted by the "NP" comment indicator in Addendum BB), with varying effective dates. The proposed comment indicators, payment indicators, and payment rates, where applicable, for these April codes can be found in Addendum BB.[29] The new codes that were effective April 1, 2021, are listed in Table 39 of the proposed rule (displayed below).[30]

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie	NP	K2
C9074*	Injection, lumasiran, 0.5 mg	NP	K2
C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	NP	N1
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)	NP	N1
J1427	Injection, viltolarsen, 10 mg	NP	K2
J1554	Injection, immune globulin (asceniv), 500 mg	NP	K2
J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms	NP	K2
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	NP	K2
J9349	Injection, tafasitamab-cxix, 2 mg	NP	K2

*HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 (Injection, lumasiran, 0.5mg) effective July 1, 2021.

CMS invites comments on the proposed payment indicators for these ancillary services.

For the July 2021 update, CMS added numerous separately payable CPT and Level II HCPCS codes to the list of covered surgical and ancillary services. The proposed comment indicators and payment indicators as

[26] Codes describing surgical procedures, diagnostic, therapeutic, and vaccine codes.

[27] Codes describing new and emerging technologies, services, and procedures.

[28] Codes primarily used to identify drugs, devices, supplies, temporary procedures, and services not described by the CPT codes.

[29] Addendum BB can be accessed here: https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1753-p.

[30] Note that of the 11 new Level II HCPCS codes added, seven were established effective April 1, 2021, as reflected in the table. In addition, HCPCS codes C9776 and C9777 were added through a separate April 2021 update to the OPPS and have been included in this table.

well as payment rates can be found in Addendum AA and Addendum BB.[31] Descriptions of the ASC payment indicators and corresponding definitions can be found in DD1 and the list of definitions used under the ASC payment system can be found in Addendum DD2.[31] These codes are also assigned to an interim APC. Table 40 of the proposed rule includes the new services. **CMS is inviting comment on the new services.**

CMS also proposes to establish ASC payment for 11 new Category III CPT codes as covered ancillary services, effective July 1, 2021. The CY 2022 proposed payment rates for these codes can be found in Addendum BB and payment indicators and comment indicators are in Addendum DD1 and Addendum DD2, respectively.[31] **CMS is inviting public comment on the new changes.** The new Category III CPT codes for ancillary services are included in Table 41 of the proposed rule (displayed below).

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
0493T	Contact near-infrared spectroscopy studies of lower extremity wounds (eg, for oxyhemoglobin measurement)	CH	N1
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	NP	J8
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	NP	J8
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	NP	Z2
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NP	N1
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	NP	J8
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	NP	J8
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	NP	J8
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	NP	J8
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	NP	G2
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)	NP	N1

[31] Addenda AA, BB, DD1, and DD2 may be accessed here: https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1753-p.

For CY 2022, CMS is proposing that the Level II HCPCS codes effective October 1, 2021 would be flagged with the "NI" comment indicators in Addendum B to the CY 2022 OPPS/ASC final rule to indicate that CMS has assigned the codes an interim OPPS payment status for CY 2022.[32] **CMS is inviting public comments on the interim payment indicators, which would ultimately be finalized in the CY 2023 OPPS/ASC final rule.**

January 2022 HCPCS Codes

CMS incorporates new Level II HCPCS codes that are effective in January 2022 in the OPPS/ASC annual final rule, thereby updating the ASC payment system for the calendar year. However, most Level II HCPCS codes are not released until November to be effective in January. Since they are not available yet, CMS cannot include them in this proposed rule. Therefore, CMS will release these codes in the CY 2022 OPPS/ASC final rule. Additionally, CMS is proposing to assign comment indicator "NI" in Addendum AA and Addendum BB to the final rule to indicate that CMS is assigning them an interim payment indicator and are subject to public comment. **CMS will invite public comments in the CY 2022 OPPS final rule.**

Codes for Public Comment Within this Rule

For the new and revised CPT codes that were received in time to be included in this proposed rule, CMS is proposing the appropriate payment indicator assignments, and soliciting public comments on the ASC payment assignments. CMS will accept comments and finalize the payment indicators in the CY 2022 OPPS/ASC final rule. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, CMS may either make interim final assignments in the final rule with comment period or use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until CMS can propose APC and status indicator assignments in the following year's rulemaking cycle.

CMS is soliciting public comments on the CY 2022 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2022. The codes and short descriptions are available in Addendum AA and Addendum BB while Addendum O contains the long descriptors. CMS is proposing to finalize the payment indicator for these codes in the final rule (which also can be found in Addenda AA and BB). The new CPT codes will be assigned to comment indicator "NP" in Addendum AA and Addendum BB to indicate they are assigned to an interim payment indicator and that comments will be accepted on their interim status. Comment indicators and definitions are available in Addendum DD2. Table 42 summarizes the process for updating codes through ASC quarterly updates, the public comments period, and the treatment of the new codes under the ASC.

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

[32] Addendum B is accessible here: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p.

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

b. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

In 2007, CMS finalized its policy to designate "office-based" procedures as those that are added to the ASC Covered Procedures List (CPL) in CY 2008 and later. CMS reviews whether such services are predominantly furnished in physicians' offices based on volume and utilization data for each procedure and, if appropriate, the characteristics, utilization, and volume of related codes. Procedures that were added to the CPL list beginning 2008 were office-based along with specific payment indicators (e.g., "P2," "P3," or "R2") depending on whether the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the Physician Fee Schedule non-facility PE RVU-based amount. CMS then identifies covered services as either temporarily office-based, permanently office-based, or non-office-based.

CMS has reviewed procedures that were assigned "G2" (non-office based surgical procedure; payment based on OPPS relative payment weight) as well as the original office-based indicators P2, P3, and R2. However, given CMS's concerns with CY 2020 claims data as a result of the PHE, CMS is not proposing to review the most recent claims volume and utilization data from CY 2020 claims and instead they are proposing not to assign permanent office-based designations for CY 2022 to any covered surgical procedure currently assigned a payment indicator of "G2" (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight). Similarly, 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 procedures as temporarily office-based for CY 2022 (see Table 43 of the proposed rule).

In the absence of claims-based data, CMS will review other sources (e.g., specialty societies, clinical advisors, etc.) submitted by commenters to determine whether a code should be office-based. For CY 2022, CMS proposes to designate two new CPT codes as temporarily office based. Based on their review of 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) and CPT code 31505 (Laryngoscopy, indirect; diagnostic (separate procedure), CMS proposes to add these services to the list of temporarily office-based covered surgical procedures.

i. ASC Covered Surgical Procedures Designated as Device-Intensive

CMS previously adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. CMS also has updated its device-

intensive criteria in previous rulemakings. Based on the criteria, for CY 2022, CMS is proposing to update the ASC CPL to indicate procedures that are eligible for payment according to their device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2019 OPPS claims and cost report data available for the CY 2022 OPPS/ASC proposed rule. The proposed procedures would be assigned J8 payment indicator and are included in Addendum AA. The CPT code, short descriptor and proposed CY 2022 ASC payment indicator, and indication of whether the full/partial credit adjustment policy would apply as a device-intensive procedure are also included in Addendum AA.

In past rulemaking, CMS has stated that the device-intensive methodology for ASCs should align with the device-intensive policies under the OPPS. Further, CMS does not believe that procedures are device-intensive in one setting and not in another setting. CMS believes that the different ratesetting methodologies used under the OPPS and ASC payment system can create conflicts when determining device-intensive status. Therefore, for CY 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.

Additionally, CMS believes that in situations where a procedure is designated as device-intensive under the OPPS but the procedure's device offset percentage is below the device-intensive threshold under the standard ASC ratesetting methodology, deference should be given to the OPPS designation to address this conflict in status. Therefore, for CY 2022, CMS 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 is soliciting comments on these proposed changes related to designating surgical procedures as device-intensive under the ASC payment system.

ii. Adjustment to No Cost/Full Credit and Partial Credit Device Payments

Established policy provides a reduction in payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. However, CMS inadvertently omitted language clarifying these types of payments would apply in CY 2019 and *subsequent years* for the partial credit payment. Therefore, CMS is proposing to apply the partial payment policy in CY 2021 and subsequent years. CMS is not proposing any other changes related to no cost/full credit or partial credit devices for CY 2022.

iii. Additions to the List of ASC Covered Surgical Procedures

CMS reviews and updates the CPL each year to determine whether procedures should be added to or removed from the list. CMS consults with medical societies in their decision-making process and follows certain safety requirements in federal regulation when determining whether a procedure should be included or excluded from the CPL, among other longstanding policies.

CMS believes that as technology and the practice of medicine has advanced, ASCs are able to perform procedures that were once considered inpatient only (e.g., total knee arthroplasty (TKA) and certain coronary interventions). Furthermore, outpatient hospital services are now performed safely in ASCs. CMS also noted that the COVID-19 pandemic has highlighted the need for additional health care access points,

including ASCs. As a result, in the CY 2021 OPPS/ASC Final Rule, CMS significantly revised their policy for adding surgical procedures to the ASC CPL.

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

Since the CY 2021 OPPS/ASC final rule was published, CMS has reexamined their ASC CPL policy and the public comments they received in response to the CY 2021 OPPS/ASC proposed rule, considered the concerns they received from stakeholders since the final rule was published, and conducted an internal clinical review of the 267 procedures they added to the ASC CPL under their revised policy beginning in CY 2021. CMS now believes that the policy may not appropriately assess the safety of performing surgical procedures on a typical Medicare beneficiary in an ASC, and that the 258 surgical procedures added to the ASC CPL beginning in CY 2021 may not be appropriate to be performed on a typical beneficiary in the ASC setting.

One issue CMS identified with their revised policy is that many of the procedures added in CY 2021 would only be appropriate for Medicare beneficiaries who are healthier and have less complex medical conditions than the typical beneficiary. Upon further review, CMS believes the subset of Medicare beneficiaries who may be suitable candidates to receive these procedures in an ASC setting do not necessarily represent the average Medicare 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.

In light of these concerns, for CY 2022, CMS proposes to revise the criteria and process for adding procedures to the ASC CPL by reinstating the ASC CPL policy and regulation text that were in place in CY 2020. Therefore, CMS is proposing to remove 258 procedures from the ASC CPL for CY 2022 that were added to the ASC CPL in 2021 that CMS believes do not meet the proposed revised CY 2022 ASC CPL criteria.

CMS seeks input from commenters who believe any of the 258 procedures added to the ASC CPL in CY 2021 meet the proposed revised CY 2022 criteria and, if those revised criteria are finalized, should remain on the ASC CPL for CY 2022.

Additionally, for CY 2022, CMS proposes to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. CMS proposes that external parties—for example, medical specialty societies or other members of the public—could nominate procedures to be added to the ASC CPL. Specifically, for the OPPS/ASC rulemaking for a calendar year, CMS would request stakeholder nominations by March 1 of the year prior to the calendar year for the next applicable rulemaking cycle in order to be included in that rulemaking cycle. For example, stakeholders would need to send in nominations by March 1, 2022, to be considered for the CY 2023 rulemaking cycle and potentially have their nomination effective by January 1, 2023. CMS proposes to address nominated procedures beginning in the CY 2023 rulemaking cycle.

CMS is seeking comments on how they might prioritize their review of nominated procedures if they receive an unexpectedly or extraordinarily large volume of nominations for which CMS has insufficient resources to address in the annual rulemaking.

(2) Covered Ancillary Services

CMS proposes to continue their existing policies relating to covered ancillary services with a proposed revision to their policy related to payment for non-opioid pain management drugs and biologicals. For CY 2022, CMS proposes to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS.

c. Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

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

Section 122 of the CAA amends section 1833(a) of the SSA to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. The reduced coinsurance will be phased-in beginning January 1, 2022.

ii. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2022

CMS proposes to update CY 2022 ASC payment rates using the existing methodologies at 42 CFR 416.171 and using the CMS definition of device-intensive procedures. CMS proposes to continue to use the ASC standard rate setting methodology for procedures assigned A2 and G2. The office-based procedure (P2, P3, and R2) rates would be set according to established policies as well. CMS also proposes to continue its policy for device removal procedures for CY 2021.

iii. Proposed Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

For CY 2022, CMS is proposing a low volume APC policy for CY 2022 and subsequent calendar years. Under the 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. CMS proposes to use up to four years of claims data to establish a payment rate for each item or service as they currently do 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. Because CMS is proposing to adopt a low volume APC policy, they are also proposing to eliminate their low volume device-intensive procedure policy and subsume the ratesetting issues associated with HCPCS code 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens) within their broader low volume APC proposal.

CMS seeks comments on their proposal to limit the ASC payment rate for services assigned to low volume APCs to the payment rate for the OPPS.

iv. Ancillary Services

Generally speaking, CMS provides separate ASC payment for certain ancillary items and services related to the provision of covered surgical services that are paid separately under the OPPS and provides packaged payment for other ancillary items and services under OPPS. CMS typically provides separate payment for drugs and biologicals at OPPS rates.

However, as discussed above, for CY 2022, CMS is proposing 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.

For CY 2022, CMS proposes to update ASC rates and to change payment indicators as necessary to maintain consistency with the OPPS. Furthermore, CMS proposes to continue to set the CY 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 CY 2022 and subsequent year payment rates. All proposed CY 2022 ancillary services and payment indicators are listed in Addendum BB[33] of the proposed rule.

d. New Technology Intraocular Lenses (NTIOLs)

NTIOLs are lenses that replace a patient's natural lens that has been removed in cataract surgery and that meet certain regulatory requirements. CMS has a process to establish new classes of NTIOLs that is detailed in the proposed rule. CMS has not received any requests for new NTIOL classes and CMS is not proposing to revise CY 2022 payment adjustments.

e. ASC Payment and Comment Indicators

Over the years, CMS has developed Addendum DD1 to define ASC payment indicators that CMS uses in Addenda AA and BB to provide payment information regarding covered surgical and ancillary procedures, respectively. CMS also created Addendum DD2 which lists ASC comment indicators that are included in Addenda AA and BB to identify the status of HCPCS codes and its payment indicator with respect to when comments will be accepted. CMS is not proposing to add any new ASC payment indicators for CY 2022. **However, CMS will respond to public comments on ASC payment and comment indicators**.

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

CMS used their existing policies to calculate the ASC conversion factor for purposes of payment rates. However, CMS notes that given their concerns with CY 2020 claims data as a result of the PHE, they are using the CY 2019 claims data to be consistent with the OPPS claims data for the CY 2022 OPPS/ASC proposed rule.

For CY 2022, CMS proposes to use the 2.5 percent hospital market basket update (as proposed in the CY 2022 IPPS proposed rule) minus the proposed 0.2 percent multifactor productivity (MFP) adjustment. Therefore, CMS is proposing to apply a 2.3 percent MFP-adjusted hospital market basket update to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 ASC payment amounts. CMS also proposes to utilize the hospital market basket update of 2.5 percent reduced by two percent for ASCs that do not meet ASCQR reporting requirements and then to subtract the 0.2 percent MFP adjustment.

CMS proposes to adjust the 2021 ASC conversion factor ($48.952) by the proposed wage index budget neutrality factor of .9993 in addition to the MFP-adjusted hospital market basket update of 2.3 percent, which results in a proposed CY 2022 ASC conversion factor of $50.043 for ASCs meeting the quality reporting requirements. For ASCs not meeting quality reporting programs, the proposed conversion factor for CY 2022 is $49.064.

[33] Accessible here: https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1753-p.

For purposes of displaying the rates online, CMS notes all proposed rates are available in the proposed rule's Addenda.

XII. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs – Request for Information

CMS aims to move fully to digital quality measurement in the CMS quality reporting and value-based purchasing (VBP) programs by 2025. As part of this modernization effort, CMS is issuing a request for information (RFI) to gather broad public input solely for planning purposes for the Agency's transition to digital quality measurement. Specifically, CMS is seeking comments on:

- The potential definition of digital quality measures;
- Standardizing data required for quality measures for collection via Fast Healthcare Interoperability Resources (FHIR®)-based Application Programming Interfaces (APIs);
- Leveraging technological opportunities to facilitate digital quality measurement;
- Better supporting data aggregation;
- Developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.

XIII. Quality Reporting Programs

a. Hospital Outpatient Quality Reporting (OQR) Program

CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) program, formerly known as the Hospital Outpatient Quality Data Reporting Program. The Hospital OQR Program measure set (as previously finalized and newly proposed) for the CY 2023, CY 2024, CY 2025, and CY 2026 payment determinations are included in Table 46, Table 47, Table 48, and Table 49 of the proposed rule, respectively.

Overall, CMS proposes a clarification the administrative requirements that failing to maintain an active QualityNet security official will not result in a finding that the hospital did not successfully participate in the Hospital OQR Program. The majority of proposed changes relate to the OQR Program quality measures and the form, manner, and timing of data submitted. Additionally, CMS is seeking input on ideas to revise the Hospital OQR Program to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for facilities, providers, and patients.

i. Hospital OQR Program Quality Measures

For the CY 2023 reporting period (CY 2025 payment determination), CMS proposes to remove two chart-abstracted measures under removal Factor 4 (the availability of a more broadly applicable (across settings, population, or conditions) measure): (1) Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (OP-2); and (2) Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3). Instead, CMS proposes to adopt the ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) into the Hospital OQR Program measure set, which would replace these two measures.

CMS also proposes to adopt three new measures: (1) COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period; (2) Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; and (3) STEMI eCQM, beginning as a

voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period.

COVID-19 Vaccination Coverage Among HCP Measure

This process measure, which would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID-19, has been proposed in other annual payment rules. If finalized in this proposed rule, non-long-term care facilities, including outpatient hospitals would be required to report data quarterly for the January 2022 through December 2022 reporting period (i.e., impacting the CY 2024 payment determination). The denominator is the number of HCP eligible to work in the hospital for at least one day during the self-selected week, excluding persons with contraindications to COVID-19 vaccination. The numerator is the cumulative number of HCP eligible to work in the hospital for at least one day during the self-selected week and who received a complete COVID-19 vaccination course.[34]

Acute care facilities would count HCP working in all inpatient or outpatient units that are physically attached to the inpatient acute care facility site and share the same CMS certification number (CCN), regardless of the size or type of unit. Facilities also would count HCP working in inpatient and outpatient departments that are affiliated with the specific acute care facility (e.g., sharing medical privileges or patients), regardless of the distance from the acute care facility. The decision to include or exclude HCP from the facility's vaccination counts would be based on whether the individuals meet the specified National Healthcare Safety Network (NHSN) criteria *and* are physically working in a location that is considered any part of the on-site acute care facility that is being monitored.

As noted in the FY 2022 IPPS proposed rule, the Measure Applications Partnership (MAP) offered only conditional support for rulemaking on this measure contingent on CMS bringing the measure back to the MAP once the specifications are further refined, specifically stating that "the incomplete specifications require immediate mitigation and further development should continue."[35] CMS notes that while it values input from the MAP, the agency believes it is important to propose the measure as quickly as possible to address the urgency of the COVID-19 PHE and its impact on vulnerable populations. CMS continues to engage with the MAP to mitigate concerns. CMS also notes that this measure is not National Quality Forum (NQF)-endorsed and has not been submitted to NQF for endorsement consideration.

CMS invites public comment on this proposed measure.

Breast Screening Recall Rates Measure

CMS proposes to adopt this claims-based measure, which is intended to address the health and clinical risks associated with too many or too few breast screening recalls, beginning with the CY 2023 payment determination, using a data collection period of July 1, 2020, to June 30, 2021, and then data collection periods from July 1 through June 30 of the following year starting 3 years before the applicable payment calendar year for subsequent years. CMS notes that evidence from clinical literature suggests appropriate recall rates should fall between 5 to 12 percent, and this measure is intended to move facilities toward this range. While this measure, as currently specified, would not provide data on outcomes, results could be

[34] The proposed specifications for this measure are available on the National Quality Forum Website: https://www.cdc.gov/nhsn/nqf/index.html.

[35] Measure Applications Partnership. 2020-2021 MAP Final Recommendations. Available at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

used to identify opportunities for improving the efficiency and quality of care provided and would be added to a measure set focused on imaging efficiency.

The Breast Screening Recall Rates measure would calculate the percentage of Medicare fee-for-service (FFS) beneficiaries for whom a traditional mammography or digital breast tomosynthesis (DBT) screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or MRI of the breast in an outpatient or office setting on the same day or within 45 calendar days of the index image. Specifically, the measure denominator includes Medicare FFS beneficiaries who received a screening mammography or DBT study at a facility paid under the OPPS. The numerator consists of individuals from the denominator who had a diagnostic mammography study, DBT, ultrasound of the breast, or MRI of the breast following a screening mammography or DBT study on the same day or within 45 days of the screening study. The measure does not have any exclusions and is not risk adjusted.

In January 2021, MAP reviewed the measure and voted to conditionally support the measure, pending NQF endorsement. The measure has not yet been submitted for NQF endorsement; however, CMS is proposing to adopt this measure for use in the Hospital OQR Program because of its importance to women's health and its ability to fill a gap in CMS's Meaningful Measure portfolio.

CMS invites public comment on this proposed measure.

STEMI eCQM

As noted above, for CY 2022, CMS proposes to adopt the STEMI eCQM process measure into the Hospital OQR Program measure set, to replace Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (OP-2); and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3). CMS believes the use of the STEMI eCQM measure, in lieu of the OP-2 and OP-3 measures, would eliminate the need for manual chart-abstraction. It would also broaden the group of measured STEMI patients, including patients who present to and receive primary PCI at a PCI-capable facility, which is the vast majority of STEMI patients, instead of only including patients presenting to non-PCI-capable facilities and receiving either fibrinolytics or being transferred to a PCI-capable facility. In alignment with the Meaningful Measures quality priority of promoting effective prevention and treatment of chronic disease, CMS believes this STEMI eCQM encourages timely, effective and appropriate treatment using clinical data available in certified electronic health record technology (CEHRT) and that this measure has the potential to reduce adverse health outcomes.

The STEMI eCQM measures the percentage of ED patients with a diagnosis of STEMI who received timely delivery of guideline-based reperfusion therapies appropriate for the care setting and delivered in the absence of contraindications. The denominator includes all ED patients 18 years or older diagnosed with STEMI who do not have contraindications to fibrinolytic, antithrombotic, and anticoagulation therapies.The numerator includes: (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 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. CMS proposes to implement the STEMI eCQM starting with voluntary reporting beginning with the CY 2023 reporting period and then with mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years.

In January 2021, MAP reviewed the measure and voted to conditionally support the measure, pending NQF endorsement. The measure was submitted to NQF in January 2021 and is under review.

CMS invites public comment on this proposed measure.

Modifications to Previously Adopted Measures

For CY 2022, CMS proposes the following modifications:

- CMS proposes to restart the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures by requiring the measure in the Hospital OQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, for the Hospital OQR Program, CMS is proposing voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.
- CMS proposes to require hospitals to report on OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2023 reporting period/CY 2025 payment determination.

Hospital OQR Program Measures and Topics for Future Considerations

Request for Comment on Potential Adoption of Future Measures for the Hospital OQR Program

In the CY 2021 OPPS/ASC final rule, CMS finalized the elimination of the Inpatient Only (IPO) list over a 3-year transitional period, beginning with the removal of approximately 300 primarily musculoskeletal-related services, with the list to be completely phased out by CY 2024. After further consideration and review of the additional feedback from stakeholders, CMS is proposing to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. However, as technology and surgical techniques advance, services will continue to transition off of the IPO list, becoming payable in the outpatient setting. CMS recognizes that there may be a need for more measures that inform decision-making regarding care and for quality improvement efforts, particularly focused on the behaviors of services that become newly eligible for payment in the outpatient setting. **CMS therefore seeks comment on potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and become eligible for payment in the outpatient setting**.

Request for Comment on Potential Future Adoption and Inclusion of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

CMS is also requesting comments on the potential future adoption of a respecified version of a patient-reported outcome-based performance measure (PRO-PM) for two procedures— elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)—which were removed from the IPO list effective CY 2020 and CY 2018, respectively. **Specifically, CMS invites public comment on the following:**

- Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO-PMs across settings where elective THA/TKA are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a hospital that performs both inpatient and outpatient elective THA/TKAs.

- Considerations unique to THA/TKAs performed in the hospital outpatient setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach.

Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program

CMS notes that they are committed to achieving equity in health care outcomes for their beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care inequities. In the FY 2022 IPPS proposed rule, CMS summarizes their existing initiatives aimed at closing the equity gap in outcomes for Medicare beneficiaries, including the CMS Disparity Methods. As described in the FY 2022 IPPS proposed rule, CMS is considering further expanding the confidential reporting to include measurement of racial and ethnic disparities for one measure in the Hospital IQR Program, the Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789).

CMS is seeking comments on expanding their efforts to provide results of the CMS Disparity Methods to promote health equity and improve healthcare quality. Specifically, CMS seeks comments on the idea of stratifying the performance results in the hospital outpatient setting. CMS has identified six priority measures included in the Hospital OQR Program as candidate measures for 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).

Additionally, CMS is seeking comments on several aspects of their approach to demographic data collection. Specifically, CMS seeks comments on the following:

- The potential future application to the Hospital OQR Program measures of the two disparity methods currently used to confidentially report stratified measures in HRRP.
- The possibility of reporting stratified results confidentially in Facility-Specific Reports (FSRs) 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 facility collection, on the day of service, of a minimum set of demographic data using standardized and interoperable electronic health record standards.

Maintenance of Technical Specifications for Quality Measures

CMS is proposing the adoption of eCQMs into the Hospital OQR Program measure set beginning with the CY 2023 reporting period. Therefore, CMS is also proposing the manner to update the technical specifications for eCQMs. CMS proposes that the technical specifications for eCQMs used in the Hospital OQR Program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs

(Annual Update).[36] Hospitals would be required to register and submit quality data through the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal).

Additionally, CMS notes that they previously indicated that hospitals would be required to maintain a current QualityNet security administrator (now referred to as a security official) for as long as the hospital participates in the Program. For CY 2022, CMS is clarifying that failing to maintain an active QualityNet security official once a hospital has successfully registered to participate in the Hospital OQR Program will not result in a finding that the hospital did not successfully participate in the Hospital OQR Program.

ii. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

CMS is proposing several updates to the policies related to the form, manner, and timing of data submitted for the Hospital OQR Program. Specifically, CMS proposes updates to the following:

- CMS proposes several changes to the data submission requirements for the e OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2024 reporting period/CY 2026 payment determination and subsequent years.
- CMS proposes several policies specific to data submission for the proposed COVID-19 Vaccination Coverage Among HCP Measure for the CY 2022 reporting period/CY 2024 payment determination.
- CMS proposes updates to the eCQM reporting and submission requirements, including a progressive increase in the number of quarters for which hospitals report eCQM data.
- CMS proposes to require hospitals to utilize certified technology updated consistent with the 2015 Edition Cures Update for the CY 2023 reporting period/CY 2025 payment determination and subsequent years, which includes both the voluntary period and required submissions.
- CMS proposes several updates to the file format for EHR data, zero denominator declarations, and case threshold exemptions.
- CMS is also proposing to require eCQM data submission by the end of 2 months following the close of the calendar year for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years.
- CMS proposes that hospitals would have a review and corrections period for eCQM data submitted to the Hospital OQR Program which would run concurrently with the data submission period.
- CMS proposes to discontinue the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the CY 2024 payment determination (that is, beginning with data submission for Q1 of CY 2022). CMS is proposing to require hospitals to instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the CY 2024 payment determination (that is, Q1 of CY 2022) and for subsequent years.
- CMS also proposes to change the time period given to hospitals to submit medical records to the Clinical Data Abstraction Center (CDAC) contractor from 45 calendar days to 30 calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022/validations affecting the CY 2024 payment determination and for subsequent years.
- Additionally, CMS previously codified that they select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals for validation purposes based on the following criteria: (1) the hospital fails the validation requirement that applies to the previous year's payment determination; or (2) the hospital has an outlier value for a measure based on the data it submits. Beginning with validations affecting the CY 2022 reporting period/CY 2024 payment

[36] The Annual Update and implementation guidance documents are available here: https://ecqi.healthit.gov/.

determination and subsequent years, CMS is proposing to add to the two established targeting criteria used to select the 50 additional hospitals. Specifically, CMS proposes to add the following criteria: (1) any hospital that has not been randomly selected for validation in any of the previous 3 years; and (2) Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

Extraordinary Circumstances Exception (ECE) Process for the CY 2022 Payment Determination and Subsequent Years

Beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, CMS is proposing to expand their established Extraordinary Circumstances Exceptions policy to allow hospitals to request an exception from the Hospital OQR Program's eCQM reporting requirements based on hardships preventing hospitals from electronically reporting. Under this proposal, applicable hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification). In addition, under the Hospital OQR Program, CMS may consider being a newly participating hospital as undergoing hardship such that newly participating hospitals can apply for an exemption for the applicable program year. Hospitals participating in the Hospital OQR Program that wish to request an exception must submit their requests to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred.

iii. Payment Reduction for Hospitals that Fail to Meet the Hospital OQR Program Requirements for the CY 2022 Payment Determination

Under current law, hospitals that fail to report required data on measures, in the form and manner, and at a time, specified by HHS, such hospitals will incur a two percent reduction to their OPD fee schedule increase factor (i.e., annual payment update factor). The reduction only applies to the payment year involved and is not considered in computing the OPD fee schedule the next year. CMS has a technical formula based on the OPPS conversation factor to determine a "reporting ratio." This reporting ratio is used for hospitals that did not meet their OQR reporting requirements. CMS also has an established policy that effectively allows beneficiaries and other secondary payers to share in the reduction of payments to these hospitals

CMS is proposing to continue its policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio. The proposed CY 2022 reporting ratio is 0.9805, which when multiplied by the proposed OPPS conversation factor of $84.457 equals a proposed conversion factor for hospitals that do not meet their OQR requirements of $82.810. CMS will continue to apply the reporting ratio to all services calculated using the OPPS conversion factor and will continue to apply the reporting ratio for certain HCPCS codes with a specific status indicator.[37]

b. Ambulatory Surgical Center Quality Reporting (ASCQR) Program

i. ASCQR Program Quality Measures

CMS is not proposing any changes to the priorities used to consider ASCQR measure selection and is not proposing any changes to the policy related to the retention of adopted ASCQR measures. The Agency also

[37] Those status indicators include status indicator assignments of "J1", "J2", "P", "Q1", "Q2", "Q3", "R", "S", "T", "V", and "U" (other than new technology APCs to which CMS has proposed status indicator assignment of "S" and "T").

is not proposing any changes to the measure removal factors and is not proposing to remove any existing measures.

CMS is proposing to adopt one new measure: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2022 reporting period/2024 payment determination. For that payment year, ASCs would be required to report data quarterly on the measure for the January 2022 through December 2022 reporting period. The measure would assess the proportion of an ASC's health care workforce that has been vaccinated against COVID-19. Please refer to the Hospital OQR Program section above for additional details on this proposes measure.

If this proposal is finalized, ASCs would collect the numerator and denominator for the COVID-19 HCP vaccination measure for at least one, self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet ASCQR Program requirements. Each quarter, CMS is proposing that the CDC would calculate a single quarterly COVID-19 HCP vaccination coverage rate for each ASC, which would be calculated by taking the average of the data from the three submission periods submitted by the ASC for that quarter. If finalized, CMS would publicly report each quarterly COVID-19 HCP vaccination coverage rate as calculated by the CDC.

Additionally, CMS is proposing to resume requiring data submission for the following measures: ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC-4: All-Cause Hospital Transfer/Admission; ASC–11: Cataracts—Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery; and ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems. CMS now believes that previous concerns related to the data submission method previously utilized for these measures can be addressed. CMS is proposing to require reporting on this measures beginning with the CY 2023 reporting period/CY 2025 payment determination.

Table 52 of the proposed rule summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2022 reporting period/CY 2024 payment determination. Table 53 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2023 reporting period/CY 2025 payment determination. Table 54 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2024 reporting period/CY 2026 payment determination and subsequent years.

CMS invites public comment on this proposal.

ASCQR Program Measures and Topics for Future Considerations

Request for Comment on Potential Adoption of Future Measures for the ASCQR Program

Similar to the Hospital OQR proposal for CY 2022, CMS is soliciting comments potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and become eligible for payment in the outpatient setting.

Request for Comment on Potential Future Adoption and Inclusion of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

Similar to the Hospital OQR proposal for CY 2022, CMS is also requesting comments on the potential future adoption of a respecified version of a patient-reported outcome-based performance measure (PRO-

PM) for two procedures— elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)—which were removed from the IPO list effective CY 2020 and CY 2018, respectively.

Request for Comment on Potential Future Efforts to Address Health Equity in the ASCQR Program

Similar to the Hospital OQR proposal for CY 2022, CMS is soliciting comments on their efforts to address health equity in the ASCQR program. CMS notes that to date, they have not expanded disparities reporting to the ASC setting. Internally testing the two disparities methods (Within- and Across-Hospital Disparity Methods) on ASCQR Program quality measures calculated using Medicare FFS claims revealed several unique challenges to measuring disparities for dually eligible individuals in the ASC setting, principally, relatively low volumes of dual eligible patients in many facilities, and large diversity in the types and patient mix between ASCs as these facilities tend to specialize. CMS is therefore considering social risk factors, including neighborhood-level social determinants of health, such as the poverty, education, and housing quality, which can adversely influence health outcomes, contributing to health inequities, in order to report more information regarding equity gaps in the care provided in the ASC setting.

CMS seeks comment on the possibility of providing equity reporting in the ASCQR Program in a way that maximally supports facilities in improving the quality of care for all Medicare beneficiaries, regardless of their socioeconomic status or other risk factors. CMS is particularly interested in learning about measurement approaches or social risk factors which may permit illuminating social-based disparities in facilities which have relatively few individuals who possess social risk factors. Specifically, CMS seeks comments 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 factor.
- The utility of neighborhood-level socioeconomic factors toward measuring disparities in quality-of-care outcomes for ASCs.
- Ways social risk factors influence the access to care, quality of care and outcomes for ASC patients in general or for specific ASC services.

Request for Comment on the Future Development and Inclusion of a Pain Management Measure

CMS notes that with advances in techniques and growing recognition by providers that pain is a treatable condition, pain management services have seen rapid growth as a form of early intervention and more such procedures are being performed in ASCs. CMS sees pain management surgical procedures as a significant portion of procedures performed in the ASC setting and that an applicable measure would provide important quality of care information for a specialty not included in the current ASCQR Program measure set. CMS requests public comment on the development and future inclusion of such a measure.

ii. Form, Manner, and Timing of Data Submitted for the ASCQR Program

Generally, CMS is not proposing any updates or changes to the policies that set the requirements for the form, manner, and timing of data submitted for the ASCQR program. However, CMS is proposing some policy-specific changes to the proposed form, manner, and timing for reporting the COVID-19 Vaccination Coverage Among HCP Measure and for reporting the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures.

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

Under the ASCQR, any annual increase to this payment update will be reduced by two percent for ASCs that fail to meet ASCQR reporting requirements.

In order to implement this reduction, CMS had finalized a policy to calculate two conversion factors: (1) a full update conversion factor; and (2) an ASCQR Program reduced update conversion factor. CMS finalized the proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements.

The ASC conversion factor is used to calculate the ASC payment rate for services with certain payment indicators.[38] CMS previously finalized the proposal that payment for all services assigned these payment indicators will be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR reduced update conversation factor when the ASC did not meet reporting requirements.

For ASCs that fail to meet ASCQR reporting requirements, CMS believes it is appropriate that a reduction in payment for a service remain proportionate for the reduced coinsurance for a beneficiary. CMS has previously finalized a policy that the beneficiary's national unadjusted coinsurance for a service would reflect the lower payment.

CMS has also finalized a policy that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program. The following standard adjustments apply to the reduced national unadjusted payment rates: wage index; multiple procedure adjustment; interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost. CMS believes these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR program requirements.

CMS proposes to continue all these policies for CY 2022.

XIV. Request for Information on Rural Emergency Hospitals

Section 125 of Division CC of the CAA established the Rural Emergency Hospital (REH) program. In general, the REH program is a new, voluntary Medicare hospital designation for REHs. Under section 125, REH is defined as a facility that: is enrolled in Medicare on or after January 1, 2023; does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements to be a staffed ED; meets staff training and certification requirements (as established by HHS); and meets certain conditions of participation (CoPs) applicable to hospital EDs and critical access hospitals (CAHs) with respect to emergency services. CAHs and small rural hospitals that convert to REHs may furnish rural emergency hospital services for Medicare payment beginning in 2023.

Pursuant to section 125:

- HHS is required to establish quality measurement reporting requirements, which may include claims-based measures and/or patient experience surveys.
- REHs are required to submit quality measure data to HHS, and HHS must establish procedures to make that data publicly available on the CMS website.

[38] Indicators include "A2", "G2", "P2", "R2" and "Z2" as well as the service portion of device-intensive procedures identified by "J8."

- Quality Improvement Organization requirements will apply to REHs in the same manner they apply to hospitals and CAHs.
- Requirements for hospitals and CAHs to be surveyed in compliance with CoPs will apply to REHs as they apply to other hospitals and CAHs.
- REHs must provide ED and observation services, and, at the election of the REH, other medical and health services furnished on an outpatient basis (as specified by HHS).
- REHs must have a staffed emergency department 24 hours a day, 7 days a week, with staffing requirements similar to those for CAHs.

To become an REH, a provider must, as of December 27, 2020 (the date of enactment of the CAA), either already be a CAH or a rural subsection (d) hospital with not more than 50 beds. In addition, the REH must meet other requirements, including, but not limited to:

- Annual per patient average of 24 hours or less in the REH;
- Staff training and certification requirements (established by HHS);
- Emergency services CoPs applicable to CAHs;
- Hospital ED CoPs (determined applicable by HHS);
- Applicable SNF requirements (if the REH includes a distinct part SNF);
- A transfer agreement with a level I or level II trauma center; and
- Other requirements HHS finds necessary in the interest of the health and safety of individuals furnished REH services.

Beginning January 1, 2023, a REH that provides rural emergency hospital services will receive a Medicare payment for those services that reflects a 5 percent increase over the normal OPPS payment rate. Any co-payments for these services will be calculated based on the standard OPPS rate (i.e., excluding the 5 percent increase). REHs also will receive an additional facility payment in twelve monthly installments. The additional facility payment will be determined based on the excess (if any) of the total amount that was paid to all CAHs in 2019 over the estimated total amount that Medicare would have paid to CAHs in 2019 for inpatient, outpatient, and SNF services during the year. The excess amount is then divided by the total number of CAHs in 2019 to determine the REH Medicare subsidy amount. Additional facility payments following 2023 will increase by the hospital market basket percentage increase. REHs will be required to maintain detailed information as to how they have used these payments.[39]

CMS seeks comment on: (1) the type and scope of services offered; (2) health and safety standards, including licensure and CoPs; (3) health equity concerns; (4) collaboration and care coordination; (5) quality measurement; (6) payment provisions; and (7) the enrollment process. Specifically, CMS seeks comments in response to the following 29 questions:

Type and Scope of Services Offered

1. What are the barriers and challenges to delivering emergency department services customarily provided by hospitals and CAHs in rural and underserved communities that may require different or additional CoPs for REHs (for example, staffing shortages, transportation, and sufficient resources)?
2. An REH must provide emergency and observation services and may elect to provide additional services as determined appropriate by the Secretary. What other outpatient medical and health services, including behavioral health services, should the Secretary consider as additional eligible

[39] Section 125 of the CAA specifically describes the following examples: telehealth services; ambulance services; and use of payments to operate the facility and maintain the ED to provide covered services.

services? In particular, what other services may otherwise have a lack of access for Medicare beneficiaries if an REH does not provide them?

3. What, if any, virtual or telehealth services would be appropriate for REHs to provide, and what role could virtual care play in REHs?
4. Should REHs include Opioid Treatment Programs, clinics for buprenorphine induction, or clinics for treating stimulant addiction in their scope of services? Please discuss the barriers that could prevent inclusion of each of these types of services.
5. What, if any, maternal health services would be appropriate for REHs to provide and how can REHs address the maternal health needs in rural communities? What unique challenges or concerns will the providing of care to the maternal health population present for an REH?

Health and Safety Standards, Including Licensure and Conditions of Participation

6. The statute requires that REHs meet the requirements for emergency services (set forth at § 485.618) that apply to CAHs. Which hospital emergency department requirements (set forth at § 482.55) should or should not be mandated for REHs and why or why not? Are there additional health and safety standards that should be considered? What are they, why are they important, and are there data that speak to the need for a particular standard?
7. The REH must meet staff training and certification requirements established by the Secretary. Should these be the same as, or similar to, CAH requirements (Personnel qualifications, §485.604 and Staffing and staff responsibilities, §485.631)? Are there additional or different staff training and certification requirements that should be considered for REHs and why? Are there any staffing concerns that the existing CAH requirements would not address?
8. What additional considerations should CMS be aware of as it evaluates the establishment of CoPs for REHs? Are there data and/or research of which CMS should particularly be aware?
9. What, if any, lessons have been learned as they relate to rural emergency services during the COVID-19 pandemic that might be pertinent to consider for policy implementation after the Public Health Emergency?
10. Are there state licensure concerns for hospitals and CAHs that wish to become REHs? What issues with respect to existing or potential state licensure requirements should CMS consider when developing the CoPs for this new provider type? What supports and timelines should be in place for States to establish licensing rules?

Health Equity

11. How can REHs address the social needs arising in rural areas from challenging social determinants of health, which are the conditions in which people are born, live, learn, work, play, worship, and age, and which can have a profound impact on patients' health, ensuring that REHs are held accountable for health equity?
12. With respect to questions 1 through 11 above, are there additional factors CMS should consider for specific populations including, but not limited to, elderly and pediatric patients; homeless persons; racial, ethnic, sexual, or gender minorities; veterans; and persons with physical, behavioral (for example, mental health conditions and substance use disorders), and/or intellectual and developmental disabilities?
13. How can the CoPs ensure that an REH's executive leadership (that is, its governance, or persons legally responsible for the REH) is fully invested in and held accountable for implementing policies that will reduce health disparities within the facility and the community that it serves? In addition, with regards to governance and leadership, how can the CoPs:
    a. Encourage a REH's executive leadership to utilize diversity and inclusion strategies to establish a diverse workforce that is reflective of the community that it serves;

b. Ensure that health equity is embedded into a facility's strategic planning and quality improvement efforts; and
c. Ensure that executive leadership is held accountable for reducing health disparities?

14. An important first step in addressing health disparities and improving health outcomes is to begin considering a patient's post-discharge needs and social determinants of health prior to discharge from a facility. How can health equity be advanced through the care planning and discharge planning process? How can the CoPs address the need for REHs to partner with community-based organizations in order to improve a patient's care and outcomes after discharge?
15. In order to ensure that health care workers understand and incorporate health equity concepts as they provide culturally competent care to patients, and in order to mitigate potential implicit and explicit bias that may exist in healthcare, what types of staff training or other efforts would be helpful?
16. Finally, how can the CoPs ensure that providers offer fully accessible services for their patients in terms of physical, communication, and language access with the resources they have available to them?

Collaboration and Care Coordination

17. How can CMS and other Federal agencies best encourage and incentivize collaboration and coordination between an REH and the healthcare providers, entities, or organizations with which an REH routinely works (for example, requirements related to the Emergency Medical Treatment and Active Labor Act (EMTALA), transfer agreements, and participation in EMS protocols), to help the REH successfully fulfill its role in its community? Healthcare providers, entities, and organizations with which an REH might typically work and interact might include, for example, federally qualified health centers, rural health clinics, state and local public health departments, Veterans Administration and Indian Health Service facilities, primary care and oral health providers, transportation, education, employment and housing providers, faith-based entities, and others.

Quality Measurement

18. What existing quality measures that reflect the care provided in rural emergency department settings can be recommended? What existing quality measures from other quality reporting programs, such as the Hospital Inpatient Quality Reporting and Hospital Outpatient Quality Reporting Programs, are relevant to the services that are likely to be furnished in REHs and should be considered for adoption in the REH context? What measures, specific to REHs, should be developed?
19. Based on experiences in quality reporting by small rural hospitals and CAHs, what barriers and challenges to quality reporting are REHs likely to encounter? What quality reporting strategies should CMS consider to mitigate those barriers?
20. For CAHs, what are the barriers and challenges to electronic submission of quality measures, and will those barriers likely apply to REHs? What similar barriers and challenges could CAHs and REHs experience for chart abstracted measures?
21. What factors should be considered for the baseline measure set and how should CMS assess expanding quality measures for REHs? How could quality measures support survey and certification for REHs?
22. What additional incentives and disincentives for quality reporting unrelated to payment would be appropriate for REHs? Are there limitations or lower limits based on case volume/mix or geographic distance that would be appropriate for CMS to consider when assessing the quality performance of REHs?

23. The inclusion of CAHs within the Overall Hospital Quality Star Ratings provides patients with greater transparency on the performance of CAHs that provide acute inpatient and outpatient care in their area. What factors should CMS consider in determining how to publicly report REH quality measure data?

Payment Provisions

24. Under the law, only existing CAHs or subsection (d) hospitals with not more than 50 beds that are located in a rural area are eligible to convert to an REH. While REHs will receive the applicable OPPS rate that would otherwise apply under section 1833(t)(1) of the SSA and with an increase of 5 percent under section 1834(x)(1) of the SSA as well as an additional facility payment to be made on a monthly basis under section 1834(x)(2) of the SSA, CMS notes that rural sole community hospitals (SCHs) currently receive an additional 7.1 percent payment for all services paid through the OPPS. CMS is seeking comment on the likelihood of rural SCHs deciding to seek to become REHs.
25. In order to calculate the additional annual facility payment for rural emergency hospitals required by section 1834(x)(2) of the SSA, CMS will need to compare all CY 2019 payments to CAHs with an estimate of the total amount of payment that would have been made to CAHs in CY 2019 if CAHs were paid through the inpatient, outpatient, and SNF prospective payment systems (PPSs), rather than receiving Medicare payment at 101 percent of the reasonable costs of these services. Are there any claims or other payment reporting issues that CMS should consider when calculating the hypothetical estimated payment under the prospective payment systems for services furnished by CAHs in CY 2019?
26. CMS also is seeking comment on whether the claims forms used by CAHs to report inpatient hospital services, outpatient hospital services, and skilled nursing services contain all of the necessary information in order that the claims could be processed by the applicable CMS PPS. CMS is seeking this information because section 1834(x)(2)(C) of the SSA requires as a part of the calculation to determine the additional facility payment for CY 2023 for CMS to estimate what CAHs would have received for payment of inpatient hospital services, outpatient hospital services, and SNF services if those services were paid through their respective PPS. CMS wants to know what barriers, if any, CMS may face when attempting to use CAH claims to perform this calculation. If the CAH claims are missing information that would be required to process the claims through a PPS, what challenges could CAHs face in collecting the missing information and submitting it to CMS for processing?
27. The statute requires that a facility seeking to enroll as an REH must provide information regarding how the facility intends to use the additional facility payment provided under section 1834(x)(2) of the SSA, including a detailed description of the services that the additional facility payment would be supporting, such as furnishing of telehealth and ambulance services, including operating the facility and maintaining the emergency department to provide covered services. What challenges will providers face to maintain and submit what will likely be similar detailed information about how their facility has spent the additional facility payment for rural emergency hospitals as required by section 1834(x)(2)(D) of the SSA? What assistance or guidance should HHS consider providing to facilities to meet this reporting requirement? Enrollment Process
28. The statute requires that an eligible facility must submit an application to enroll as an REH in a form determined by the Secretary. In accordance with the requirements of the CAA, the application for enrollment must include 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. What suggestions do facilities who are considering enrolling as REHs want us to take into account in developing the enrollment requirements?

29. What considerations should be taken into account regarding the steps and timing for conversion to an REH?

XV. Radiation Oncology (RO) Model

The RO Model is designed to test whether prospective episode-based payments for radiotherapy (RT) services (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. Under the RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare FFS beneficiaries diagnosed with certain cancer types. The RO Model will include 30 percent of all eligible RO episodes (that occur in 204 eligible Core-Based Statistical Areas (CBSAs) in 48 states and the District of Columbia). CMS finalized in the "Specialty Care Models to Improve Quality of Care and Reduce Expenditures" final rule (Specialty Care Models Rule)[40] that the base payment amounts for RT services would be the same for HOPDs and freestanding RT centers. The proposed list of included RT services as identified by HCPCS codes are in Table 56 of the proposed rule. Further, the RO model would be 5 performance years (PYs), beginning July 1, 2021[41] (ending December 31, 2025), with a final data submission of clinical data elements and quality measures in 2026. Section 133 of the CAA further delayed the start of the RO Model to no earlier than January 1, 2022. Despite the delay, CMS expects the RO Model will meet the criteria to be both an Advanced Alternative Payment Model (APM) and a Merit-based Incentive Payment System (MIPS) APM in PY 1 and all subsequent PYs.

In this proposed rule, CMS proposes provisions related to the delayed implementation due to the CAA, as well as modifications to certain RO Model policies not related to the delay. Specifically, CMS proposes:

- To begin implementation of the RO Model on January 1, 2022 and to modify the model performance period to end on December 31, 2026, such that each PY will be a 12-month period beginning on January 1 and ending on December 31 of each year. This also would retain the 5-year model performance period.
- To add and modify several definitions, including:
    - Add a definition for "extreme and uncontrollable circumstances" (EUC) to correspond with the proposed EUC policy (described in more detail below).
    - Add definitions for "legacy CMS Certification Numbers (CCNs)" and "legacy Tax Identification Numbers (TINs)" to describe how such changes are treated under the RO Model.
    - Clarifying how RO Model requirements align with the Quality Payment Program (QPP).
    - Add a definition for "baseline period" to mean the three CY period that begins on January 1 no fewer than 5 years (but no more than 6 years) prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments for the model performance period, and the participant-specific professional and technical case mix adjustments for PY1. Under this definition, the baseline period would be January 1, 2017 through December 31, 2019 (unless the RO Model is delayed further).

[40] 85 Fed. Reg. 61114 (Sept. 29, 2020).

[41] The RO Model was originally supposed to start on January 1, 2021. However, due to impacts of the COVID-19 PHE, CMS, in the CY 2021 OPPS/ASC final rule, delayed the performance period to begin on July 1, 2021. CMS did not extend the end date of December 31, 2025.

  - Modify the definition of the "model performance period" to mean the 5 PYs during which RO episodes must initiate and terminate (proposed to be January 1, 2022 to December 31, 2026).
  - Modify the definition of "PY" to mean each 12-month period beginning on January 1 and ending on December 31 of each year. If the RO Model begins on a date other than January 1, the first PY would begin on that date and end on December 31 of the same year.
  - Modify the definition of "stop-loss reconciliation amount" to mean the amount owed by CMS for the loss incurred under the RO Model to 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.
- To modify RO Model Participant exclusions as follows:
  - Exclude from the RO Model only the HOPDs that are participating in the Pennsylvania Rural Health Model (PARHM), as opposed to excluding both HOPDs participating in PARHM and those that have been identified by CMS as eligible to participate in PARHM.[42]
  - 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. This exclusion is intended to avoid double payment for the same services.[43] However, for the CHART Accountable Care Organization (ACO) Transformation Track, CMS will follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs.[44]
  - Clarifying the dates of the data used to determine eligibility for the "low volume opt-out"[45] in accordance with section 133 of the CAA's required delay of the RO Model. Specifically, 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 PY 2. If PY 1 begins on January 1, RO episodes will be used to determine the eligibility of the low volume opt-out for PY 3. If PY 1 begins on any date other than January 1, both RO episodes of PY 1 and episodes occurring in the CY of PY 1 (but prior to the start of PY 1 in that year) will be used to determine the eligibility of the low volume opt-out for PY 3. RO episodes of PY 2 and PY 3 will be used to determine eligibility for this opt out for PY 4 and PY 5, respectively.
  - For the low volume opt-out, CMS also proposes to include episodes and RO episodes (as applicable) associated with the RO participant's current CCN or TIN and to the RO participant's legacy CCN(s) or legacy TIN(s). CMS proposes that a legacy CCN would be a CCN that an RO participant that is a HOPD, or its predecessor(s), previously used to bill Medicare for included RT services, but no longer uses to bill Medicare for included RT services. CMS proposes that a legacy TIN would be a TIN that an RO participant that is a physician group practice (PGP), a freestanding RT center, or its predecessor(s), previously

[42] CMS would continue to use the PARHM list available here: https://innovation.cms.gov/innovation-models/pa-rural-health-model.

[43] Participating hospitals listed here: https://innovation.cms.gov/innovation-models/chart-model.

[44] Finalized in the Specialty Care Models Rule, 85 Fed. Reg. 61114 at 61260 (Sept. 29, 2020).

[45] A physician group practice, freestanding RT center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt-out for a given PY if it has fewer than 20 episodes or RO episodes, as applicable, depending on the PY, across all CBSAs selected for participation in the most recent year with claims data available (2 years prior to the applicable 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.

used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

- To modify the list of RO Model episodes as follows:
  - Revise the cancer removal such that a cancer type that does not meet all three inclusion criteria,[46] or for which CMS discovers a 10 percent or greater error in established national base rates, shall be removed.
  - Remove from the RO Model liver cancer as CMS does not believe it is commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines.
  - Remove from the RO Model brachytherapy from included RT services. If finalized, CMS would continue to monitor utilization of brachytherapy (both as a single modality and multimodality among RO participants compared to non-participants and consider whether there is an opportunity to adjust pricing for multimodality episodes without disrupting the RO Model design.).
  - Remove intraoperative RT (IORT) because the evidence base for IORT is limited to certain cancer types and therefore does not meet the qualifications for inclusion.

CMS also proposes multiple changes and clarifications to the pricing methodology,[47] quality (form, manner, and timing for quality reporting),[48] and reconciliation process.

With respect to the proposed EUC policy, CMS proposes to define an 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. Should CMS declare an EUC for a geographic region, CMS proposes that it may: (1) amend the model performance period; (2) eliminate or delay certain reporting requirements for RO participants; and (3) amend the RO Model's pricing methodology. CMS proposes to apply the EUC policy only if the magnitude of the event requires this intervention. CMS states it would not use a "bright-line test" to assess all types of public health emergencies, disasters, or other extraordinary circumstances. Instead, the application of the policy would be tailored to the specific circumstance and to the affected geographic area(s). To identify RO participants experiencing an EUC, 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 SSA.
- 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.

[46] These criteria include: (1) the cancer type must be commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; (2) associated with current ICD-10 codes that have demonstrated pricing stability (determined by analyzing the interquartile ranges of the episode prices across cancer types as described in the Specialty Care Model Rule; and (3) HHS has not determined that the cancer type is not suitable for inclusion in the RO Model.

[47] *See* Table 62 of the proposed rule for an example that 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.

[48] In particular, CMS proposes that for PY 1, Professional and Dual participants would be required to submit data for three pay-for-performance measures: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. These participants also would be required to submit data on a pay-for-reporting measure – Treatment Summary Communication—Radiation Oncology – beginning in PY 1. CMS proposes that this pay-for-reporting data submitted in PY 1 would serve as the baseline for PY 3, and the measure would be re-specified as a pay-for-performance measure beginning in PY 3.

- Whether a state of emergency has been declared in the relevant geographic area.

If an EUC is nationwide and impacts the model performance period start date, CMS proposes that it may delay the performance period by up to one CY. This would impact other aspects of the RO Model, such as its status as an Advanced APM and the years that would be included in the baseline. CMS proposes to include a notification on the RO Model website no later than 30 days prior to the original start date.

If an EUC is regional, CMS proposes not to delay the performance period, but instead only delay or exempt requirements for those RO participants in an impacted region.

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 them optional, and/or extend the time for impacted RO participants to report data to CMS. CMS also proposes that it may waive compliance with or adjust the requirements related to engaging with patient safety organizations and providing peer review (audit and feedback) on treatment plans.

If CMS decides to remove (not extend) quality and clinical data submission requirements, CMS proposes that it could choose to repay the quality withhold during the next reconciliation and award all possible points in the subsequent "Aggregate Quality Score" calculation for affected RO participants (this would potentially increase episode payments during this time). Further, if RO participants nationwide experience significant, aggregate-level disruptions to their service utilization (i.e., 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 corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY), CMS proposes that it may modify the trend factor calculation for the professional component (PC) and/or technical component (TC) of an included cancer type.

XVI. Updates to Hospital Price Transparency Requirements

CMS proposes to amend several of hospital price transparency policies (45 CFR part 180) to improve compliance. Specifically, CMS proposes:

- Increase the amount of penalties for noncompliance through the use of a scaling factor based on hospital bed count;
- Deem state forensic hospitals that meet certain requirements to be in compliance with the hospital price transparency requirements; and
- Prohibit certain conduct that CMS has concluded are barriers to accessing standard charge information.

CMS also clarifies the expected output of hospital online price estimator tools. CMS notes that an issue occurs with respect to a hospital that chooses to use an online price estimator tool in lieu of posting its standard charges for the required shoppable services in a consumer-friendly format. CMS also seeks comment on several issues that it may consider to improve standardization of the data that hospitals disclose.

a. Increasing the Civil Monetary Penalty (CMP) Amounts Using a Scaling Factor

Currently, should CMS conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions, which generally, but not necessarily occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s).
- Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Impose a CMP on the hospital not to exceed $300 per day and publicize the penalty on a CMS website if the hospital fails to respond to CMS's request to submit a corrective action plan or comply with the requirements of the corrective action plan.

CMS notes that it previously considered using a scalable factor across all institutions that meet the definition of "hospital" as defined for purposes of price transparency.[49] Initially, CMS believed it would be challenging to find a reliable source of data that provides for a scalable factor across all hospitals. Now, however, CMS is concerned by the potential trend towards a high rate of hospital noncompliance (based on CMS sampling and reviews) and the reported initial high rate of hospital noncompliance. To address these concerns, CMS considered two general approaches for increasing the CMP amount: (1) use a flat increase in the amount that would be applied uniformly across all hospitals (e.g., increasing the maximum CMP from $300 per to $1,000 per day); or (2) establish a minimum penalty amount and apply a scaling factor (e.g., bed count, hospital revenue) to increase the penalty in manner tailored to the noncompliant hospital. CMS propose to use the scaling factor (option 2).

CMS notes that the proposed scaling factor would allow CMS to penalize a hospital on a sliding scale that generally correlates to the hospital's characteristics (e.g., number of beds as a proxy for the size of the patient population served). Further, CMS notes that other Federal programs use scaling factors to determine a CMP amount. CMS also considered whether to use hospital bed count and hospital revenue as the scaling factor. CMS proposes to use number of beds (or bed count) as specified in hospital cost report data submitted to CMS as the scaling factor to establish CMP amounts.

CMS believes the hospital cost report data would be an appropriate data source because it is routinely submitted by Medicare-enrolled hospitals, is certified by a hospital official, and is reviewed by a Medicare Administrative Contractor (MAC) to determine acceptability. One of the facility characteristics in the cost report is "number of beds," defined as the number of beds available for use by patients at the end of the cost reporting period. A "bed" means an adult bed, pediatric bed, portion of inpatient labor/delivery/postpartum (LDP) room (i.e., birthing room) bed when used for services other than labor and delivery, or newborn intensive care unit (ICU) bed (excluding bassinets) maintained in a patient care area for lodging patients in acute, long-term, or domiciliary areas of the hospital. Beds in post-anesthesia, post-operative recovery rooms, outpatient areas, emergency rooms, ancillary departments (other than for labor and delivery department), nurses' and other staff residences, and other areas regularly maintained and utilized for only a portion of a patient's stay (e.g., special procedures or not for inpatient lodging) are **not** considered a bed for hospital cost report purposes.

For Medicare-enrolled hospitals, CMS proposes to determine the CMP amount using the number of beds for the noncompliant hospital, as specified on the most recently available, finalized cost report data. CMS anticipates this would be the number of beds as indicated in Healthcare Provider Cost Reporting Information Systems (HCRIS) for those hospital cost reports with a status of: settled without audit; settled with audit; reopened; or amended. Note that this would exclude hospital cost reports with an "as submitted"

[49] 45 CFR 180.20. A hospital, for the purposes of the price transparency requirements, means an institution in any state or in which state or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such law or is approved by the agency of such state or locality responsible for licensing hospitals as meeting the standards established for such licensing. Note that at 45 CFR 180.50, the requirements for making this information public applies to each hospital location operating under a single hospital license or approval that has a different set of standard charges. This requirement does not apply to ambulatory surgical centers.

status. The approach to scaling the CMP amount based on the bed count, which would begin in CY 2022 if finalized, is as follows:

Number of Beds	Penalty Applied Per Day	Maximum Penalty Amount per Calendar Year of Noncompliance
30 or less	$300 per hospital	$109,500 per hospital
31 up to 550	$310 - $5,500 per hospital (number of beds times $10)	$113,150 - $2,007,500 per hospital
>550	$5,500 per hospital	$2,007,500 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).[50]

CMS states that it has reviewed CMP amounts for other HHS programs that require reporting information and believes the sliding scale between $300 and $5,500 per day per hospital is commensurate with the level of severity of the potential violation. As an example, CMS states that the maximum $2,007,500 CMP per year generally aligns with the Health Insurance Portability and Accountability Act (HIPAA)-related CMP (penalties are statutorily capped at $1.5 million per year).

If the number of beds for the hospital cannot be determined according to the most recently available finalized Medicare cost report data in HCRIS, CMS proposes to use documentation provided by the hospital to determine the bed count for purposes of calculating the CMP. CMS notes that this approach would be necessary for non-Medicare-enrolled hospital. CMS also believes there may be circumstances where there is a discrepancy or obvious error in the finalized cost report data, and additional documentation would be needed to accurately determine the CMP amount.

Should CMS require additional documentation to determine the CMP amount, CMS proposes to require that the hospital provide CMS with documentation of its bed count in a form and manner and by the deadline prescribed by CMS. This would be provided to the hospital in a written notice. If a hospital fails to comply, CMS proposes that it would impose the highest maximum CMP per day (i.e., $5,500 per day).

CMS proposes that this scaling approach, if finalized, would be effective January 1, 2022. CMS notes that the CMP must be adjusted annually (pursuant to 45 CFR 180.90(c)(3)) and that CMS would apply the adjustment beginning in CY 2023 and in subsequent years. For CY 2021, the current regulation specifying a maximum $300 per day per hospital CMP would remain in place.

CMS seeks comment on the sliding scale approach based on bed count. Specifically, CMS seeks comment on delineation of penalty by number of beds and whether the threshold bed counts and corresponding penalty amounts are appropriate. CMS also seeks comment on whether hospital cost report data in the HCRIS is appropriate or if other validated data sources or files should be considered. In particular, CMS seeks information on other available data sources that would encompass relevant scaling data for all hospitals, including those not Medicare-enrolled.

As an alternative, CMS considered using hospital revenue as the scaling factor, instead of or in addition to hospital bed count as follows:

Proposed Alternative Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years

[50] According to 45 CFR 180.90(c)(3), the CMP amount will be adjusted annually using the multiplier determined by the Office of Management and Budget for annually adjusting CMP amounts under 45 CFR part 102. This is based on the Consumer Price Index for All Urban Consumers (CPI-U), not seasonally adjusted.

Net Patient Revenues	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
$109,500,000 or less	$300 per hospital	$109,500 per hospital
>$109,500,000 up to $2,000,000,000	$300 - $5,479 per hospital (0.1% of revenue prorated by day)	$109,500 - $1,999,835 per hospital
>$2,000,000,000	$5,480 per hospital	$2,000,200 per hospital

CMS expressed concern that a scaling factor based on revenue may not be as effective as a scaling factor based on bed count. CMS notes that noncompliance appears to be "fairly high" among larger hospitals and therefore hospital bed count can serve as a more reliable proxy than net patient revenues. Conversely, CMS states that a penalty based on revenues would increase the penalty for better resourced hospitals compared to those that might have fewer resources, which could be more effective at deterring noncompliance among better resourced hospitals that choose not to comply with the price transparency requirements when there is a relatively low CMP amount.

CMS also considered using additional scaling factor, including:

- Gross, inpatient, or outpatient revenue.
- The nature, scope, severity, and duration of noncompliance.
- The hospital's reason for noncompliance.

CMS states that there are advantages to using multiple scaling factors (e.g., tailoring the CMP amount for unique circumstances, assessing a greater CMP amount for egregious noncompliance). However, CMS is not proposing this approach because it would need additional time and input to ensure other scaling factors could be applied in a consistent manner.

CMS seeks comment on the following:

- What additional factors would be feasible for scaling a CMP amount?
- What data sources for the criteria could be used to ensure consistency in application of the criteria (e.g., hospital revenue, gross income, net income, net patient revenue) across all hospitals subject to these regulations?
- How should nature, scope, and severity of noncompliance be determined and applied for purposes of assessing CMPs?
- How should a hospital's reason for noncompliance be determined? What factors should be considered when evaluating reason for noncompliance? Are there bases for imposing lower CMPs, such as resource limitations or extreme or unusual circumstances? If yes, how could resource limitations or circumstances contributing to noncompliance be demonstrated and should that be treated differently than documented statements of intent to not comply with the requirements?
- If multiple factors are used to scale the CMP amount, should there be a priority applied to specific factors? Should some factors be weighted more when determining the CMP amount? If yes, which one(s)?

b. Deeming Certain State Forensic Hospitals as Having Met Requirements

The price transparency requirements do not apply to federally-owned or operated hospitals including those operated by an Indian Health Program, the Department of Veterans Affairs, and Department of Defense (45 CFR 180.30(b)). CMS states that these facilities do not provide services to the general public and their established payment rates for services are not subject to negotiation. Further, they impose little or no cost-sharing and are authorized to provide services to specific populations that meet specific eligibility criteria.

While it is possible that they provide emergency services, these are not shoppable services as defined under the price transparency regulations.

CMS believes that deeming state forensic hospitals as having met the price transparency requirements is reasonable for similar reasons federally-owned or operated hospitals also are excluded and, therefore, CMS proposes to add such hospitals to those excepted from the price transparency requirements. Under this proposal, "state forensic hospital" would be defined as a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities. To be deemed as having met the requirements, the state forensic hospital would be required to provide treatment exclusively for individuals who are in the custody of penal authorities (e.g., offenders incompetent to stand trial, offenders with mental health disorders, mentally ill prisoners transferred from prison, offenders found not guilty by reason of insanity, post-incarcerated civilly committed individuals). As an example, a state psychiatric hospital with a forensic wing would not meet the necessary criteria to be deemed compliant with the requirements. **CMS welcomes comments on this proposal.**

c. Prohibiting Additional Barriers to Accessing the Machine-Readable File

Currently, hospitals are required under 45 CFR 180.50 to make standard charge information public in a single machine-readable file. Hospitals have discretion to choose a website for making this information public, but must also meet certain accessibility requirements (e.g., must be displayed prominently, must be easily accessible without barriers, digital file and information must be digitally searchable). CMS states that while standard charge data has been made available online, some hospitals have, intentionally or unintentionally, placed barriers to make it more challenging for the public to find and access the file and its contents.

In light of this, CMS proposes to amend its regulations 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. CMS believes this requirement would prohibit some the practices CMS encountered in its compliance reviews, such as lack of a link for downloading a single machine-readable file, using "blocking codes" (that hide files from search engine results) or CAPTCHA (which prevents direct access to the file), and requiring the user agree to terms and conditions or submit other information prior to access. CMS notes these are examples and not an exhaustive list. Should CMS identify other barriers that prevent automated searches or direct downloads, CMS may prohibit them via guidance or future rulemaking.

CMS seeks comment on additional barriers that CMS should prohibit. CMS also seeks comment on whether there are specific criteria it should consider when evaluating whether a hospital has displayed the machine-readable file in a "prominent manner." For example, CMS is considering establishing a more standardized approach (as opposed to the current flexibility) for how hospitals would be required to make the machine-readable file public. CMS states one method would be to require hospitals to post their machine-readable file(s) using a CMS-specified URL. Another approach could be to require a standardized location for hospitals to post a link to the file from the hospital's homepage.

d. Clarifications and Requests for Comment

i. Price Estimator Tool Option and Considerations for Future Price Estimator Tool Policies

Currently, hospitals may meet the shoppable services requirement by offering an online price estimator tool that: (1) provides estimates for as many of the 70 CMS-specified shoppable services provided by the hospital and as many additional hospital-selected shoppable services as is necessary to combine for at least 300 shoppable services; (2) allows consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for a shoppable service; and (3) is prominently displayed on the hospital's website and be accessible without charge and without having to register or establish a user account or password (45 CFR 180.60(a)(2)). CMS clarified in the CY 2020 Hospital Price Transparency final rule that the price estimator tool must be "tailored to individuals' circumstances (whether an individual is paying out of pocket or using insurance) and provide real-time individualized out of pocket estimates that combines hospital standard charge information with the individual's benefit information directly from the insurer, or provide the self-pay amount."[51]

CMS states that based on review of hospital compliance, some hospital price estimator tools do not tailor a single estimated amount based on the individual's circumstance. Instead, some price estimator tools provide estimated average amounts or ranges based on a broad population of patients (including outliers), do not appear to combine standard charges with the individual's benefit information and instead appear to use information from prior reimbursements or require the user to input benefit information, or indicate that the price is not what the hospital anticipates the individual would be obligated to pay. Therefore, CMS states that these price estimator tools fail to satisfy its requirements.

Beyond the current requirements, CMS is considering whether to add requirements for the use of an online price estimator tool as an alternative to making the shoppable services list available in a consumer-friendly format. **CMS seeks comment for future consideration related to the price estimator tool policies, including the following:**

- 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?

ii. Request for Comment on the Definition of "Plain Language"

One of the requirements for displaying shoppable services in a consumer-friendly manner is that data elements must include a "plain-language" description of each shoppable service. CMS recommended, but did not require, that hospitals review and use the Federal plain language guidelines.[52] CMS notes that some hospitals do not appear to be using what could reasonably be considered "plain language" to describe shoppable services. **CMS seeks comment on whether it should require specific plain language standards, and if so, what those standards should be.**

iii. Request for Comment on Identifying and Highlighting Hospital Exemplars

CMS seeks comment on potential ways it could highlight best practices. CMS is considering approaches that include:

- Opportunities to highlight hospitals that are in compliance with various aspects of the price transparency regulations through education and outreach materials.

[51] 84 Fed. Reg. 65524 at 65578 (Nov. 27, 2019).
[52] Available here: https://www.plainlanguage.gov/guidelines/.

- Opportunities to highlight exemplar hospitals on existing CMS websites, for example, the Hospital Price Transparency website, Care Compare, or other CMS websites.
- Publicizing the results of comprehensive compliance reviews on CMS's website.
- Opportunities to collaborate with consumer organizations, health policy organizations, hospital accrediting organizations or others to develop a price transparency certification. Depending on how such a certification process would be structured, CMS may consider proposing future regulatory action to deem certified hospitals as being in compliance with these regulations.
- Opportunities for integrating price transparency questions into patient experience of care assessments and surveys or other methods for integrating into hospital quality measurement and value-based purchasing initiatives.

CMS also seeks comment in response to the following:

- Should hospitals be recognized for patient-centered price transparency efforts? If yes, how should such hospitals be identified and by whom? What criteria should be used for assessing patient-centered price transparency efforts?
- What method or methods for highlighting exemplar hospitals would be most beneficial to consumers?
- Of the methods described above, what are the relative advantages or disadvantages of each?

iv. Request for Comment on Improving Standardization of the Machine-Readable File

In the CY 2020 Hospital Price Transparency final rule, CMS expressed concern that lack of uniformity in how hospitals display their standard charges may result in the public being unable to meaningfully use, understand, and compare standard charge information across hospitals.[53] CMS finalized certain requirements, such as the data elements and final formats that would be standardized across hospitals (45 CFR 180.50(b)). CMS declined to be more prescriptive regarding the standardization requirements.

CMS states that early feedback from stakeholders, particularly from IT specialists, researchers, and others who seek to use the public information, indicates that more standardization of the machine-readable file may be necessary to meet the goal of permitting comparisons of standard charges across hospitals. **CMS seeks comment in response to the following:**

- 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? What one(s)? Is such data readily found in hospital systems? In what ways would inclusion of such data impact hospital burden?
- Are there any specific examples of hospital disclosures that represent best practice for meeting the requirements and goals of the CY 2020 Hospital Price Transparency final rule?
- 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, for example, ensuring that hospitals post all payer-specific negotiated charges for all payers and plans with which the hospital has a contract, as required by the regulations?

XVII. Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

[53] 85 Fed. Reg. 65524 at 65556 (Nov. 27, 2019).

a. Safe Use of Opioids – Concurrent Prescribing eCQM (NQF # 3316e) and eCQM Reporting Requirements in the Hospital IQR Program – Request for Information

CMS is seeking input regarding the Safe Use of Opioids — Concurrent Prescribing eCQM (NQF # 3316e) (Safe Use of Opioids eCQM) as well as the previously finalized policy of requiring hospitals to report on the Safe Use of Opioids eCQM beginning with the CY 2022 reporting period/FY 2024 payment determination.[54]

For the CY 2022 reporting period/FY 2024 payment determination, hospitals will be required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. For the CY 2023 reporting period/FY 2025 payment determination and subsequent years hospitals will be required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 for re-endorsement consideration as part of the measure maintenance process. The purpose of this RFI is to gather public input for potential measure updates as CMS prepares for NQF re-endorsement of the endorsed Safe Use of Opioids – Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure.

Specially, CMS is soliciting comments on (1) additional information or considerations to inform future measure updates to the Safe Use of Opioids eCQM; and (2) comments on the appropriateness of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from CMS's finalized set of eCQMs.

XVIII. Additional Medicare Promoting Interoperability Program Policies

a. Safe Use of Opioids – Concurrent Prescribing eCQM (NQF # 3316e) and eCQM Reporting Requirements in the Medicare Promoting Interoperability Program– Request for Information

Similarly, to maintain alignment with the Hospital Inpatient Quality Reporting Program, CMS is seeking input regarding the Safe Use of Opioids eCQM as it relates to the Medicare Promoting Interoperability Program. As described above, CMS is soliciting comments on (1) additional information or considerations to inform future measure updates to the Safe Use of Opioids eCQM; and (2) comments on the appropriateness of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from CMS's finalized set of eCQMs.

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We hope this summary was helpful to you. Please do not hesitate to contact us if you have any questions.

[54] 84 Fed. Reg. 42044 at 42503 (Aug. 16, 2019).