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Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (RIN 0938-AU43)

August 9, 2021

Background & Summary

On July 19, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2022 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). The CY 2022 OPPS Proposed Rule includes changes to payment policies, payment rates and quality provisions for Medicare patients who receive care at hospital outpatient departments (HOPDs) or receive care at ambulatory surgical centers (ASCs).

The Proposed Rule also updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. Additionally, the agency proposes to update Hospital Price Transparency requirements and penalties. Among other proposed policies, CMS intends to continue site-neutral payment policies between different Medicare sites of services, but the agency halts elimination of the inpatient only (IPO) list. In addition, the agency intends to continue to pay for drugs acquired under the 340B program at a rate of average sales price (ASP) minus 22.5 percent. The agency also seeks comment on the impact of temporary policies implemented to address the COVID-19 public health emergency (PHE).

Comments are due **September 17, 2021,** and the final rule is expected to be released on or around November 1, 2021. Most provisions will go into effect January 1, 2022. Vizient looks forward to working with members to help inform our letter to the agency.

OPPS Payment Update

CMS proposes to apply a fee schedule increase factor of 2.3 percent for CY 2022 (except for hospitals not meeting certain quality reporting requirements which would be subject to a 2 percent reduction, resulting in a fee schedule increase factor of 0.3 percent). The proposed increase factor of 2.3 percent is based on the proposed hospital inpatient market basket percentage increase of 2.5 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.2 percentage points.

For CY 2022, CMS estimates that the total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization and case-mix) would be approximately $82.704 billion, approximately $10.757 billion more compared to estimated CY 2021 payments.

As a result of the OPPS fee schedule increase factor (2.3 percent) and other budget neutrality adjustments, the combined impact of the changes and update to the conversion factor is reflected in Column 4 in the table below. CMS estimates that, based on the budget neutral changes, both urban and rural hospitals would experience an increase (approximately 2.3 percent for urban hospitals and rural hospitals). When classifying hospitals by teaching status, CMS estimates non-teaching hospitals would experience an increase of 2.5 percent, minor teaching hospitals would experience an increase of 2.3 percent and major teaching hospitals would experience an increase of 2.2 percent. Column 5 shows the full impact of the proposed CY 2022 policies on providers and

hospitals by including the effect of all changes for CY 2022 and comparing them to total spending in CY 2021. CMS estimates that, for CY 2022, the cumulative effect of all proposed changes will increase payments by 1.8 percent for all providers and 1.8 percent for all hospitals.

Estimated Impact of the Proposed CY 2022 Changes for the Hospital OPPS

	Number of Hospitals (1)	Proposed Ambulatory Payment Classification (APC) Recalibration (All Proposed Changes) (2)	New Wage Index and Provider Adjustments (3)	All budget neutral changes (combined cols 2-3) with Market Basket Update (4)	All Proposed Changes (5)
All providers*	3,662	0.0	0.0	2.3	1.8
All hospitals	3,555	0.0	0.0	2.3	1.8
Urban hospitals	2,803	0.0	0.0	2.3	1.8
Rural hospitals	752	0.1	0.0	2.3	1.8
Non-teaching status hospitals	2,388	0.1	0.0	2.5	2.0
Minor teaching status hospitals	792	0.0	-0.1	2.3	1.8
Major teaching status hospitals	375	-0.1	0.0	2.2	1.7

*Excludes hospitals permanently held harmless and Community Mental Health Centers

Proposed Updates Affecting OPPS Payments

Use of CY 2019 Claims Data for CY 2022 Ratesetting

In OPPS rate setting, the agency typically uses claims data and cost report data from 2 years prior to the calendar year that is the subject of the rulemaking. In the Proposed Rule, CMS notes concerns with CY 2020 data due to the impact of the COVID-19 PHE. As a result, the agency proposes to generally use CY 2019 claims data and the same set of cost reports used for 2021 OPPS rate-setting purposes for CY 2022 OPPS and ASC ratesetting.

Along those lines, CMS proposes to recalibrate the Ambulatory Payment Classification (APC) relative payment weights for services furnished during CY 2022, using the same basic methodology as previous year but using the service volume in CY 2019 claims data.

Comprehensive APCs for CY 2022

A comprehensive Ambulatory Payment Classification (C-APC) is a classification for a primary service and all adjunctive services provided to support delivery of the primary service. A single prospective payment is made for the comprehensive service. In addition, certain combinations of comprehensive services are eligible for higher payment through complexity adjustments. CMS packages payments for add-on codes into the comprehensive C-APC payment rate. CMS designates a service described by a Healthcare Common Procedure Coding System (HCPCS) code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator "J1". Addendum J of the Proposed Rule (available on the CMS website) lists the complexity adjustments for "J1" and add-on code combinations for CY 2022, along with all of the other proposed complexity adjustments.

Based on CMS's annual review of the services of the APC assignments under the OPPS, the agency is not proposing to convert any standard APCs to C-APCs in CY 2022. Therefore, for CY 2022, CMS proposes that there will continue to be 69 C-APCs.

Proposed Wage Index Changes

CMS continues to propose changes to the OPPS wage indexes that are in line with the Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) rule. Under current law, CMS delineates hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). As done in the FY 2022 IPPS/LTCH Final Rule, CMS proposes to adopt OMB Bulletin No. 20-01 even though the agency determined the Bulletin-encompassed changes would not affect the wage index for IPPS (FY 2022) or OPPS (CY 2022).

Consistent with previous years, CMS proposes to adopt the related IPPS wage index to calculate the CY 2022 OPPS wage indexes, including the imputed floor policy.[1] Thus, the adjustments for the FY 2022 IPPS post-reclassified wage index, including policies in the IPPS final rule to address wage index disparities between low and high wage index value hospitals – would be reflected in the final CY 2022 OPPS wage index beginning on January 1, 2021. CMS believes that it is logical to use the IPPS wage index as the source of the adjustment factor for the OPPS since HOPDs are inseparable from the overall hospital itself.

For hospitals paid under OPPS but not IPPS, CMS proposes to continue its policy of assigning a wage index. As a result, for CY 2022, CMS would apply the wage index to non-IPPS hospitals paid under the OPPS as if those hospitals were paid under IPPS. The wage index that would apply to non-IPPS hospitals paid under the OPPS would include any adjustments CMS may finalize for the FY 2022 IPPS post-reclassified wage index.

CMS has posted on their website the hospital-specific estimated payments for CY 2022 – both the hospital-specific file layout and the hospital-specific file. CMS was able to provide hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 71 (pg. 807). However, the agency does not provide data for hospitals whose claims they were unable to use. For hospitals paid under the OPPS, for CY 2022, CMS estimates the proposed rule wage indexes would result in no change for urban hospitals or rural hospitals.

Proposed Hospital Outpatient Outlier Payments

OPPS provides outlier payments (added to the APC amount) to help mitigate financial risks associated with high-cost and complex procedures that could present a hospital with significant financial loss. In CY 2021, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $5,300 (the fixed-dollar amount threshold). For CY 2022, CMS proposes to increase the fixed-dollar amount threshold by $800 to $6,100 plus the APC payment amount. The CY 2022 multiplier threshold remains at 1.75 times the payment amount. When the cost of a hospital outpatient service is above these thresholds, the hospital would receive an outlier payment.

Proposed Site-neutral Payment Policies for Off-campus Provider-based Departments

In the Proposed Rule, CMS addresses site-neutral payment policies for off-campus provider-based departments (PBDs). In prior rulemaking, CMS adopted a policy to utilize a Physician Fee Schedule (PFS)-equivalent payment rate for hospital outpatient clinic visit services when furnished in excepted

[1] In the FY 2022 IPPS/LTCH proposed rule, due to the enactment of the Consolidated Appropriations Act, 2021, CMS reinstated the "imputed floor" policy. Under this policy, 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 using previously established methodology.

off-campus PBD. For CY 2022, CMS does not propose changes to this site-neutral payment policy. Specifically, CMS proposes that excepted off-campus PBDs will be paid approximately 40 percent of the OPPS rate (i.e., 100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2022) for the clinic visit service in CY 2022. CMS notes it will continue to monitor for the effect of this Medicare payment policy, including the volume of these types of outpatient department (OPD) services. In addition, for CY 2022, CMS proposes to continue to utilize the PFS payment system for non-excepted services and will set payment for such services at 40 percent of the OPPS rate.

CY 2022 OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS final rule, CMS finalized its proposal to pay for separately payable, nonpass-through drugs and biologicals (other than vaccines but including biosimilars) purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5 percent, rather than the prior rate of ASP plus 6 percent.

Since CY 2018, a district court ruled that the Secretary of Health and Human Services (HHS) lacks authority to align the default rate with the average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. The agency appealed this decision and a U.S. Court of Appeals reversed the district court's judgment. Although the appellees' (e.g., hospitals and hospital associations) petition for a rehearing was denied in October 2020, on July 2, 2021, the Supreme Court indicated it would hear the parties argue whether the petitioners' suit challenging HHS's 340B drugs payment adjustment is precluded under law.

Although in the Proposed Rule CMS acknowledged these legal developments, the agency indicates its belief that the Secretary has discretion to propose a payment rate for 340B drugs based on 2018 survey results. The agency also emphasized the importance of providing consistency and reliable payment for these drugs, including for the remainder of the PHE and after its conclusion. Therefore, for CY 2022, CMS proposes to continue the payment rate of ASP minus 22.5 percent.

Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

Current statute provides for temporary additional payments – "transitional pass-through payments" – for certain drugs and biologicals. Under the OPPS, the ASP methodology uses several sources of data as a basis for payment – including the ASP, the wholesale acquisition cost (WAC) and the average wholesale price (AWP). For pass-through payment purposes, radiopharmaceuticals are included as "drugs".

Proposed Drugs and Biologics with Expiring Pass-Through Payment Status

CMS provides that there are 26 drugs and biologicals whose pass-through payment status will expire during CY 2022, as listed in Table 28 (pgs. 270-272). With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status, CMS's standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost, and compare it with the OPPS drug packaging threshold for that calendar year. For CY 2022, CMS proposes an OPPS drug packaging threshold of $130. CMS is also proposing that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, the agency would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, CMS is proposing to provide separate payment at the applicable relative ASP-based payment amount – which for CY 2022, is proposed at ASP plus 6 percent.

The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of the Proposed Rule (available on the CMS website). Also, as described below, CMS proposes separate payment under certain circumstances due to the PHE.

Proposed Drugs, Biologicals and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2022

For CY 2022, CMS proposes to continue pass-through payment status for 46 drugs and biologicals. These drugs and biologicals are listed in Table 29 (pg. 274-276), and their pass-through payment status will expire after CY 2022. For 2023, CMS proposes to continue to pay for pass-through drugs and biologics at ASP plus 6 percent, equivalent to the rate these products would receive in the physician's office setting in CY 2022.

Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packages into APC Groups

Nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure or surgical procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents and other diagnostic drugs. CMS provides a payment offset to provide an appropriate transitional pass-through payment to ensure no duplicate payment is made. For CY 2022, consistent with CY 2021, CMS proposes to continue to apply the same policy-packaged offset policy to payment for passthrough diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents and pass-through skin substitutes. Table 30 (pg. 277-278) provides proposed APCs to white a policy-packaged drug or radiopharmaceutical offset may be applicable in CY 2022.

Packaging Policy for "Threshold-packaged" and "Policy-packaged" Drugs, Biologicals and Radiopharmaceuticals

As noted above, CMS proposes a packaging threshold of $130. CMS proposes to package items with a per day cost of less than or equal to $130, and to identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged.[2] Therefore, products with a cost greater than $130 would be paid separately through their own APC.

Proposed Payment for Drug without Pass-through Status that are not Packaged

For CY 2022, CMS proposes to continue its policy to pay for separately payable drugs and biologicals (except for 340B-acquired drugs) at ASP plus 6 percent. For drugs and biologicals where data on the prices for sales are not sufficiently available from the manufacturer, CMS proposes to continue to base payments on WAC with a 3 percent add-on.

CY 2022 Evaluation of Payments for Opioids and Non-Opioid Alternatives for Pain Management and Comment Solicitation on Extending the Policy to OPPS

For the past several years, CMS has reviewed non-opioid alternatives and evaluated the impact of packaging policies on access to these products. Based on this review, CMS previously decided to provide separate payments for two drugs (Exparel and Omidaria) when furnished in an ASC. CMS proposes to continue separate payments for both drugs but **seeks comments as to whether it**

[2] "Policy-packaged" drugs, biologicals, and radiopharmaceuticals includes Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4)); Intraoperative items and services (§ 419.2(b)(14)); Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

should expand its current policy that only applies in the ASC setting (i.e., pay separately at ASP plus 6 percent for certain non-opioid pain management drugs).

For CY 2022, CMS proposes that non-opioid pain management drugs and biologicals would be required to meet the following criteria to be eligible for separate payment under the ASC payment system: FDA approval and indication for pain management or analgesia; and cost of the product. The proposed per-day drug packaging threshold for CY 2022 is $130. CMS also provides a more detailed comment solicitation in the Proposed Rule regarding additional policy modifications or criteria and barriers to access non-opioid pain management products that exist, and to what extent the agency's policies under the OPPS or ASC payment system could be modified to address these barriers. CMS notes that some of the topics discussed in the comment solicitation could be included in the final rule.

Proposed OPPS Payment for Devices – Pass-Through Payment for Devices

CMS is evaluating eight applications for device pass-through payment for CY 2022 and seeks feedback on whether these applications meet the criteria for device pass-through payment status. CMS preliminarily approved one device. Under current statute[3], the period for which a device category is eligible for transitional pass-through payments under the OPPS is at least 2 years but not more than 3 years.

CMS notes there are 11 device categories currently eligible for pass-through payment. CMS details the expiration dates of the pass-through payments for each device category.

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

In the CY 2021 OPPS/ASC proposed rule, CMS requested comment on whether it should 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 the period of time that utilization for the devices was reduced due to the PHE. In the CY 2021 OPPS/ASC final rule, the agency did not finalize a policy and indicated any rulemaking on this issue would be included in the CY 2022 OPPS/ASC proposed rule.

In the Proposed Rule, CMS notes that based on stakeholder feedback and CMS's belief that CY 2020 claims data may not be the best available data for ratesetting purposes, the agency proposes a one-time equitable adjustment[4] 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. CMS also proposes that separately payable drugs and biologicals that are eligible for this adjustment would not be paid at the proposed reduced amount of ASP minus 22.5 percent when they are acquired under the 340B program and would generally continue to be paid ASP plus 6 percent for the duration of the time period during which the adjustment applies. Table 38 (pg. 425-426) lists pass-through drugs, biologicals and device categories with expiring pass-through status that would receive separate payment for up to four quarters in CY 2022. **CMS seeks comment on this proposal.**

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[3] Section 1833(t)(6) and Section 1833(t)(6)(B) of the SSA

[4] CMS's equitable adjustment authority is based on Section 1833(t)(2)(E) of the Social Security Act, states the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

Payment for Partial Hospitalization Services

A partial hospitalization program (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 (e.g., depression, schizophrenia, and substance use disorders). For CY 2022, due to the PHE, CMS proposes a cost floor that maintains the CY 2021 per diem costs. As a result, the proposed CY 2022 PHP per diem cost for Community Mental Health Centers (CMHCs) is $136.14 and $253.76 for hospital-based PHPs, which is used to determine the proposed payment rates for CMHCs ($143.42) and hospital-based PHPs ($267.31).

Services That Will Be Paid Only as Inpatient Services

The inpatient only (IPO) list identifies services for which Medicare will only make payments when the services are furnished in the inpatient hospital setting because of the nature of the procedure, the underlying physical condition of the patient or the need for at least 24 hours of postoperative recovery time or monitoring period before discharge. Prior to CY 2021, CMS traditionally used five criteria to determine whether a procedure should be removed from the IPO list. In the CY 2021 OPPS Final Rule, the agency finalized a policy to eliminate the IPO list over three years. Beginning in CY 2021, CMS removed 298 codes from the IPO list; these procedures were not assessed against the agency's criteria for removal as the agency had eased its criteria for removal.

In the Proposed Rule, CMS proposes to halt the elimination of the IPO list for various reasons, including stakeholder safety and quality concerns related to the procedures removed from the IPO list. Also, the agency indicates the timeframe for finalization would not be sufficient to assess whether a procedure should be payable in the HOPD setting.

Proposal to Return the Procedures Removed from CY 2021 to the IPO List for CY 2022

CMS reviewed each of the services removed from the IPO list in CY 2021 against the agency's prior, long-standing criteria for removal from the list. The agency also provides an overview of its review, including that for many of the removed services, CMS did not find information or data to support their removal. Based on this review, the agency proposes to add all 298 of these services back to the IPO list beginning in CY 2022. Table 35 (pg. 363 – 378) provides the proposed additions to the IPO list. CMS also proposes to codify in regulation its prior five, longstanding criteria for determining whether a service or procedure should be removed from the IPO list.

CMS seeks comment on whether there are services that were removed from the IPO list in CY 2021 that meet the longstanding criteria for removing services from the IPO list and should continue to be payable in the outpatient setting in CY 2022. If so, the agency suggests that commenters submit corresponding evidence (e.g., case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets and patient selection protocol).

In addition, the agency is interested in feedback on whether CMS should maintain the longer-term objective of eliminating the IPO list or if CMS should maintain the IPO list but continue to systematically scale the list back to so that inpatient only designations are consistent with current standards of practice. The agency provides additional, more specific questions in the Proposed Rule (pg. 378 -379).

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

In relation the agency's CY 2021 OPPS decision to progressively eliminate the IPO list, the agency also finalized a policy to exempt procedures that have been removed from the IPO list from certain

medical review activities. For those services and procedures removed on or after January 1, 2021, this exemption was supposed to last until the Secretary determined that the service or procedure is more commonly performed in the outpatient setting.

However, since CMS proposes returning procedures to the IPO list for CY 2022, the agency also proposes changes to its prior policy to exempt procedures removed from the IPO list from medical review activities. Specifically, CMS proposes to rescind the indefinite exemption and instead revert to its prior two-year exemption policy from certain medical review activities for services removed from the IPO list on or after January 1, 2021. **CMS seeks comment on whether a 2-year period is appropriate, or if a longer or shorter period may be more warranted**.

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

In the Proposed Rule, CMS notes that the agency, due to the COVID-19 PHE, issued waivers and implemented various temporary policies to prevent the spread of infection and support the diagnosis of COVID-19. Since these waivers are currently set to expire at the conclusion of the PHE, CMS seeks comment on the extent to which stakeholders utilized flexibilities under these waivers.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries at Home

In the Proposed Rule, CMS acknowledges that the Consolidated Appropriations Act (CAA) included a section that expanded the circumstances in which Medicare makes payments for telehealth services under the Physician Fee Schedule, after the PHE. More specifically, the CAA removed the geographic or originating site restrictions and added the home of the individual as a permissible originating site for Medicare telehealth services when furnished for the purposes of diagnosis, evaluation or treatment of a mental health disorder. CMS also notes that in many cases, hospitals provide outpatient mental health services, education and training services (e.g., psychotherapy, diabetes self-management training and medical nutrition therapy). However, with limited exceptions, Medicare does not have a benefit category that would allow these types of professionals (e.g., mental health counselors, registered nurses) to bill Medicare directly for their services.

During the PHE, hospital staff have had the flexibility to provide these kinds of services to beneficiaries in their homes through communications technology; however, this flexibility is tied to waivers and other temporary policies that expire at the end of the PHE. CMS clarifies that if a beneficiary is receiving mental health services from a hospital clinical staff member who cannot bill Medicare independently for their professional service, then the beneficiary would need to physically travel to the hospital to continue receiving the services post-PHE. CMS is concerned this could have a negative impact on access. **CMS seeks comment on the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE, and whether they would anticipate continuing demand following the conclusion of the PHE.**

CMS also seeks comment on whether, during the PHE, hospitals have seen a dramatic increase in telehealth for mental health services, including when hospital staff provide such services to patients in their home. CMS also seeks comment on whether there are changes commenters believe CMS should make to account for shifting patterns of practice that rely on communications technology to provide mental health services to beneficiaries in their homes.

Direct Supervision by Interactive Communications Technology

During the PHE, CMS has allowed direct supervision for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services to be provided through virtual presence. CMS believes more information on the issues involved with direct supervision through virtual presence is needed before implementing this policy permanently.

CMS seeks comment on whether it should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, for some period of time after the conclusion of the PHE or beyond December 31, 2021. CMS is also seeking comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

Payment for COVID-19 Specimen Collection in Hospital Outpatient Departments

During the PHE, CMS created a new E/M code (HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source) to support COVID-19 testing during the PHE. In addition, CMS assigned HCPCS code C9803 to APC 5731-Level I Minor Procedures for the duration of the COVID-19 PHE, and assigned a status indicator "Q1" to HCPCS code C9803 to indicate the OPPS will package services billed under HCPCS code C9803 when billed with a separately payable primary service in the same encounter.

CMS seeks comments on whether it should keep HCPCS code C9803 active beyond the conclusion of the COVID-19 PHE. CMS also asks whether it should extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the COVID-19 PHE ends, including why it would be necessary to continue to provide OPPS payment for this service.

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

In the CY 2020 Hospital Price Transparency rule, CMS required public release of hospital standard charge information as a first step in ensuring transparency in health care prices for consumers. The Hospital Price Transparency rule required hospitals to make certain information publicly available on January 1, 2021. In the Proposed Rule, CMS proposes to change several hospital price transparency policies to ensure compliance with the Hospital Price Transparency rule's disclosure requirements and seeks stakeholder input on a variety of issues.

Increasing the Civil Monetary Penalty 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 provide a written warning notice to the hospital, request a correction action plan or impose a civil monetary penalty (CMP) of up to $300 per day and publicize the penalty on a CMS website under certain circumstances. Based on CMS's initial experiences with enforcing the hospital price transparency requirements, CMS proposes enhancing penalties. Specifically, proposes to use a scaling factor based on the number of beds available for use by patients to determine the CMP amount for noncompliance. The table below shows CMS's proposed application of CMP daily amounts for hospital noncompliance for CMPs assessed in CY 2022 and subsequent years.

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for Full Calendar Year of Noncompliance
30 or fewer	$300 per hospital	$109,500 per hospital
31 – 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

CMS seeks comment on its proposal to use a sliding scale approach, based on the hospital's number of beds, to determine the CMP amount. In particular, the agency seeks comment on specifying a minimum penalty amount of $300, consistent with the existing CMP amount, for hospitals with 30 beds or fewer, and whether 30 beds is an appropriate number to delineate for this part of the scale. CMS also notes that as an alternative, it considered using hospital revenue as a scaling factor, instead of, or in addition to, hospital bed count. Table 64 (pg. 744) details the proposed alternative application of the CMP daily amounts. **CMS seeks feedback on the proposed and alternative approach and seeks comment on additional factors that would be feasible for scaling a CMP amount, along with potential data sources.**

Prohibiting Additional Barriers to Accessing Machine-readable File

In the Hospital Price Transparency rule, CMS provided that a hospital would have discretion to choose the Internet location it uses to post its file containing the list of standard charges, so long as the comprehensive machine-readable file is displayed on a publicly-available webpage, it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data is easily accessible, without barriers, and can be digitally searched. In the Proposed Rule, CMS provides various concerns related to access. The agency proposes to clearly specify that although the hospital has flexibility in how it ensures the standard charge information is "easily accessible" it clarifies the steps a hospital should take in determining whether the information is easily accessible based on access barriers the agency has learned of during compliance reviews (e.g., ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website). **CMS seeks comment on whether there are additional barriers that the agency should prohibit. Also, the agency seeks comment on whether there is specific criteria CMS should consider when evaluating whether a hospital has displayed the machine-readable file in a "prominent manner."**

Clarification of the Price Estimator Tool Option and Considerations for Future Price Estimator Tool Policies

CMS previously finalized requirements for hospitals to make public payer-specific negotiated charges, discounted cash prices, the de-identified minimum negotiated charge and the de-identified maximum negotiated charge for 300 "shoppable" services that are displayed and packaged in a consumer-friendly manner. CMS also finalized a policy that hospitals offering an internet-based price estimator tool that meets certain requirements would be deemed to have met the requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner.

In the Proposed Rule, the agency indicates it is considering whether to add requirements for the use of an online price estimator tool. **The agency seeks stakeholder input for future consideration related to the price estimator tool policies, including identifying best practices, common features, and solutions to overcoming common technical barriers.**

Definition of 'Plain Language'

In prior rulemaking, CMS finalized certain required data elements a hospital must include when displaying its standard charges for its list of shoppable services, the first of which is a 'plain-language' description of each shoppable service. Based on CMS's compliance reviews, CMS indicates not all hospitals 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 plain language standards should be.**

Identifying and Highlighting Hospital Exemplars

CMS seeks comment on potential ways it could highlight fully compliant hospitals that are "embracing and exemplifying the spirit of consumer price transparency" (e.g., through

education and outreach material, CMS websites, publicizing results of comprehensive compliance reviews, collaborating with consumer organizations, integrating price transparency patient surveys into hospital quality measurement and value-based purchasing initiatives).

Improving Standardization of the Machine-Readable File

In the Proposed Rule CMS notes that various stakeholders indicated that more standardization of the machine-readable file may be necessary to meet the goal of permitting comparisons of standard charges from one hospital to the next. **CMS seeks comment on various issues related to standardization, such as best practices for formatting data, additional data elements that should be required in the future to ensure data is comparable across hospitals, other policies CMS should consider to ensure data posted by hospitals is complete and accurate and policies or incentives to improve standardization.**

Request for Information on Rural Emergency Hospitals

In the Proposed Rule, CMS notes that in the Consolidated Appropriations Act (CAA) of 2021, Congress stablished a new Medicare provider type: Rural Emergency Hospitals (REHs)[5]. Critical Access Hospitals (CAHs) and small rural hospitals that convert to REHs may furnish rural emergency hospital services for Medicare payment beginning in 2023. The Secretary is required to establish quality measurement reporting requirements for REHs, which may include claims-based measures and/or patient experience surveys. An REH is required to submit quality measure data to the Secretary, and the Secretary shall establish procedures to make the data available to the public on the CMS website. **CMS seeks comment regarding the type and scope of services REHs offer, health and safety standards (including licensure and conditions of participation), health equity, care coordination, quality measurement, payment provisions and the enrollment process.** A complete list of questions is available in the Proposed Rule (pgs. 669-679).

Radiation Oncology Model

The Radiation Oncology (RO) Model is a mandatory model that is designed to test whether prospective episode-based payments for radiotherapy (RT) services will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. Under the RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for service (FFS) beneficiaries diagnosed with certain cancer types. In addition, the RO Model is to include 30 percent of all eligible Medicare fee-for-service RO episodes nationally. Although CMS engaged in prior rulemaking on the RO model[6], due to the COVID-19 PHE, the agency delayed the start of the RO model. In addition, the CAA, which passed in December 2021, prohibited implementation of the RO Model until January 1, 2022, at the earliest.

In the Proposed Rule, CMS proposes to begin the RO Model on January 1, 2022 and end the model on December 31, 2026, maintaining a five-year duration. In addition, the agency clarifies each performance year (PY) would be a 12-month period beginning on January 1 and ending on

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[5] Section 125 of the CAA, 2021, Division CC, defines an REH as a facility that: is enrolled in the Medicare program 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 emergency department; meets staff training and certification requirements established by the Secretary; and meets certain conditions of participation (CoPs) applicable to hospital emergency departments and critical access hospitals (CAHs) with respect to emergency services.

[6] *See* Centers for Medicare & Medicaid Services, Radiation Oncology Model at: https://innovation.cms.gov/innovation-models/radiation-oncology-model, last accessed: August 6, 2021.

December 31 (unless the initial model performance period starts mid-year, in which case PY 1 will begin on that date and end on December 31 of that year). In addition, given the model timeline was delayed due to the COVID-19 PHE and CAA, CMS proposes revised definitions related to the RO Model (e.g., baseline period, model performance period, performance year and stop-loss reconciliation amount) and modification to its low volume opt-out policy.

In addition, CMS proposes changes that would modify the scope of the RO model. For example, CMS proposes slight changes to the participants that are excluded from the RO Model and changes the criteria for included cancer types (which would remove liver cancer from the included cancer types). Also, CMS proposes to remove brachytherapy from the list of RT services f in the RO model. The proposed list of included RT services is included in Table 56 (pg. 691-692). **CMS invites comments on these proposals, including if brachytherapy is removed from the RO Model, how payments for multi-modality care might be handled in the future.** Notably, CMS does not intend to respond to these comments in the CY 2022 OPPS/ASC final rule but plans on using the comments to inform future potential rulemaking.

The Proposed Rule also addresses RO model pricing methodology, the reconciliation process, quality reporting requirements and the RO Model as an Advanced Alternative Payment Model (Advanced APM) and Merit-Based Incentive Payment System APM (MIPS APM). **CMS also seeks comments on these proposals.**

Additional Hospital Inpatient Quality Reporting Program and Medicare Promoting Interoperability Program Policies

In the Proposed Rule, CMS includes an RFI regarding potential future measure updates of the Safe Use of Opioids eCQM and required reporting and submission requirements for the Safe Use of Opioids eCQM (e.g., the appropriate of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from the agency's finalized set of eCQMs). **CMS seeks comments considering these measures for both the Hospital Inpatient Quality Reporting (IQR) Program and Medicare Promoting Interoperability Program.**

Requirements for the Hospital Outpatient Quality Reporting Program

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the Hospital Inpatient Quality Reporting Program (IQR Program). Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the outpatient department (OPD) fee schedule increase factor.

In the Proposed Rule, CMS proposes to adopt the following three new measures for the Hospital OQR Program measure set:

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. ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (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. Notably, CMS would use this single measure in place of two chart-abstracted measures (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP-2); and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3)).

In addition, CMS proposes modifications to previously adopted measures. CMS notes it previously adopted the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) measures to assess patient experience with care following a

procedure or surgery in a HOPD. In the CY 2018 OPPS/ASC final rule the agency delayed implementation of the measure due to lack of sufficient operational and implementation data. In the Proposed Rule, CMS proposes to restart the OP-37a-e measure by 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 seeks feedback on this proposal.**

Also, 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. Although CMS excluded the measure in prior rulemaking, the agency now believes hospitals are familiar with the measure and that the measure addresses a high-impact condition that is not otherwise adequately addressed in the agency's current measure set. **CMS invites comments on this proposal.**

Hospital OQR Program Measures and Topics for Future Consideration

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

In the Proposed Rule, CMS indicates it is seeking to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the hospital outpatient setting. Although CMS is proposing to halt the elimination of the IPO list, the agency anticipates that as technology and surgical techniques advance, services will continue to transition off the IPO list and become payable in the outpatient setting. **As a result, the agency seeks comment on potential future adoption of measures that address care quality in the hospital outpatient setting given the transition of procedures from inpatient settings to outpatient settings of care.**

In addition, CMS requests comment on the potential future adoption of a modified version of a patient-reported outcome-based performance measure (PRO-PM) for elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) both of which were removed from the IPO list in recent years. CMS notes that it will continue to monitor the number of THA and TKA procedures in the outpatient setting and when it believes there is a sufficient number of such procedures performed in these settings to reliably measure a meaningful number of facilities, it may expand the PRO-PM to these settings. CMS seeks specific feedback regarding the mechanism of PRO data collection and submission, usefulness of having an aligned set of PRO-PMs across settings where THA/TKA are performed and considerations unique to THA/TKAs performed in the hospital outpatient setting (e.g., volume of procedure performed, measure cohort or risk adjustment approach).

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

In the Proposed Rule, **CMS seeks comment on expanding its efforts to apply disparity methods to stratify performance results by dual eligibility and confidentially provide such information to promote health equity and improve healthcare quality.** The agency has identified the following six 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);
- Admission and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35); and
- Hospital Visits after Hospital Outpatient Surgery (OP-36).

CMS also seeks comment on future confidential reporting of the above six measures, stratified by dual eligibility status. In addition, the agency seeks comment on the potential benefits and challenges associated with measuring facility equity using indirect estimation. CMS aims to use indirect estimation in this context to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

Lastly, CMS seeks comments on improving demographic data collection. The agency is interested in learning current data collection practices by facilities to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language and disability status) and challenges facing facility collection on the day of service, of a minimum set of demographic data elements in alignment with national data collection standards and standards for interoperable exchange.

A complete list of questions in the RFI is available in the Proposed Rule (pg. 576-577).

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

In the Proposed Rule, CMS provides the clinical data submission deadline for the CY 2024 payment determination which are also provided in the below table. CMS does not propose changes the submission deadlines.

CY 2024 Payment Determination	
Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 – June 30)	11/1/2022
Q3 2022 (July 1 – September 30)	2/1/2023
Q4 2022 (October 1 – December 31)	5/1/2023
Q1 2023 (January 1 – March 31)	8/1/2023

As noted above, CMS proposes to change the data submission requirement for the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey. In the Proposed Rule, CMS also proposes requirements related to survey administration, vendors and oversight activities. Notably, CMS clarifies that if data collection and reporting becomes mandatory beginning with the CY 2024 reporting period, all locations that offer outpatient services at each eligible Medicare participating hospital would be required to participate in the OAS CAHPS Survey, unless an exception applies. Also, CMS proposes that survey vendors acting on behalf of a hospital must submit data by the specified deadlines and strongly encourages hospitals to be fully apprised of vendors' compliance with the OAS CAHPS Survey administration protocols. CMS invites comment on these proposals.

In the Proposed Rule, CMS requires certain previously adopted quality measure data to be submitted via a CMS web-based tool for the CY 2022 reporting period/CY 2023 payment determination and subsequent years.

In addition, although CMS does not propose changes to submission via the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) website, it does propose policies specific to the proposed COVID-19 Vaccination Coverage Among HCP measure, which would be submitted via the CDC NHSN website.

Proposed eCQM Reporting and Submission Deadlines

In the Proposed Rule, the agency proposes a progressive increase in the number of quarters for which hospitals report eCQM data, as outlined in the below table. CMS invites comments on this proposal. In addition, 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. CMS also aims to align eCQM data submission deadlines across quality reporting programs and therefore proposes to require eCQM data submission by February 29, 2024, for the CY 2023 reporting period/CY 2025 payment determination.

Calendar Year Period	Calendar Quarters of Reporting	Reporting
CY 2023 Reporting Period (RP)/CY 2025 Payment Determination (PD)	Any quarter(s)	Voluntary
CY 2024 RP/CY 2026 PD	One self-selected quarter	Mandatory
CY 2025 RP/CY 2027 PD	Two self-selected quarters	Mandatory
CY 2026 RP/CY 2028 PD	Three self-selected quarters	Mandatory
CY 2027 RP/CY 2029 PD and Subsequent Years	Four quarters (one CY)	Mandatory

Hospital OQR Program Validation Requirements

Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation, or they may submit copies of medical records for validation by securely transmitting electronic versions of medical information. Submission of electronic versions can either entail downloading or copying the digital image of the medical record onto Compact Disc (CD), Digital Video Disc (DVD) or flash drive, or submission of Portable Document Format (PDF) using a secure file transmission process. CMS notes its belief that requiring electronic file submissions can be a more effective and efficient process for hospitals selected for validation.

As such, CMS proposes to discontinue the option for hospitals to send paper copies or actual CDs, DVDs or flash drives containing medical records for validation affecting the CY 2024 payment determination. Under this proposal, hospitals would be required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process. CMS is also proposing to revise the time period given to hospitals to submit medical records to the CMS Clinical Data Abstraction Center (CDAC) contractor from 45 calendar days to 30 calendar days. CMS clarifies this would begin with medical record submission for encounters in Q1 of CY 2022/validations affecting the CY 2024 payment determination and for subsequent years. **CMS invites comment on this proposal.**

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

As part of CMS's proposals to include eCQMs into the Hospital OQR Program, the agency is also proposing to expand its established Extraordinary Circumstances Exceptions (ECE) 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. CMS notes it may also consider being a newly participating hospital as undergoing a hardship. CMS proposes that a hospital must submit its exception request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred (e.g., if an extraordinary circumstance occurred on or before Dec. 31, 2024, the ECE request must be submitted by April 1, 2025). Specific requirements for submission of a request for an exception would be available on the QualityNet website. **CMS invites comment on this proposal.**

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

In the Proposed Rule, CMS indicates its aim to move fully to digital quality measurement in the Centers for Medicare & Medicaid Services (CMS) quality reporting and value-based purchasing (VBP) programs by 2025. As part of this modernization effort, the agency includes an RFI in the

proposed rule to gain public input solely for planning purposes for its transition to digital quality measurement. To advance digital quality measurement, CMS notes it seeks to refine the definition of digital quality measures and identifies four potential actions areas it is considering:

1. Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs;
2. Redesign CMS quality measure to be self-contained tools;
3. Build a pathway to data aggregation in support of quality measurement; and
4. Potential future alignment of measures across reporting programs, federal and state agencies and the private sector.

CMS seeks comment on these potential actions and a complete list of questions is available in the Proposed Rule (pg. 518-520). CMS notes any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate notice and comment rulemaking, as necessary.

Updates to the Ambulatory Surgical Center Payment System

Using the hospital market-basket methodology, for CY 2022, CMS is proposing to increase payment rates under the ASC payment system by 2.3 percent for ASCs that meet the ASC quality reporting program requirements. This proposed increase is based on the hospital market-basket percentage increase of 2.5 percent minus a multifactor productivity (MFP) adjustment of 0.2 percentage points. Under the ASC Quality Reporting (ASCQR) Program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet ASCQR requirements. For CY 2022, CMS is proposing to apply a 0.3 percent MFP-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs not meeting ASCQR requirements. For CY 2022, the proposed updated ASC payment rates for covered surgical procedures and covered ancillary services are displayed in Addenda AA and BB, respectively (available on the CMS website).

Key Changes to the List of ASC Covered Surgical Procedures

CMS evaluates the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list and changes to the list are often made in response to stakeholder concerns. From CY 2008 to CY 2020, CMS applied specific exclusion criteria to evaluate whether a procedure could be added to the ASC CPL.[7] In the CY 2021 OPPS/ASC Final Rule, CMS eased the criteria to add procedures to the ASCCPL and added 267 surgical procedures to the ASC CPL.

In the Proposed Rule, CMS indicates it reexamined its ASC CPL policy and prior public comments. As a result, the agency proposes to revise the criteria and process for adding procedures to the ASC CPL by reinstating the ASC CPL policy and regulatory text that were in place in CY 2020.

Also, CMS addresses procedures that were added to the ASC CPL in CY 2021 that would not meet the proposed revised CY 2022 criteria. Specifically, based on the agency's review, it proposes to remove 258 procedures (see Table 45 (pg. 465-478) for a complete listing) from the ASC CPL for CY 2022 that were added to the list in CY 2021. **CMS seeks input on whether any of procedures added to the ASC CPL in CY 2021 should remain on the ASC CPL.**

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

In addition, for CY 2022, CMS proposes to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. Specifically, external parties (e.g., medical specialty societies, members of the public) could nominate procedures to be added to the ASC CPL. For 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 to be considered in that rulemaking. Therefore, CMS would address nominated procedures beginning with the CY 2023 rulemaking cycle. **CMS seeks feedback on this proposal and how CMS should prioritize nominations.**

Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

For the ASCQR Program, CMS proposes numerous changes, including adopting the COVID-19 Vaccination Coverage Amount HCP measure beginning with the CY 2024 payment determination and resuming data collection for four measures[8] beginning with the CY 2025 payment determination. In addition, CMS proposes data submission requirements for the OAS CAHPS Survey-based measures and the COVID-19 Vaccination Coverage Among HCP measure. Table 52 and Table 53 (pg. 635) provide previously finalized and proposed ASCQR program measure set for the CY 2022 reporting period/CY 2024 payment determination and the CY 2023 reporting period/CY 2025 payment determination.

The agency also requests stakeholder comment on the potential future development and inclusion of a patient-reported outcomes measure following elective THA/TKA; potential measurement approaches or social risk factors that influence health disparities in the ASC setting; and the future inclusion of a measure to assess pain management surgical procedures performed in ASCs. Also, consistent with other requests in the Proposed Rule, CMS seeks comment on potential action and priority areas that would enable the continued transformation of the agency's quality measurement toward greater digital capture of data and use of the FHIR standard.

What's Next?

The OPPS tables for this CY 2022 Proposed Rule are available on the CMS website. CMS is anticipated to publish the final OPPS regulation on or before November 1, 2021 and the changes are effective at the beginning of the calendar year (January 1, 2022). The comment period closes on September 17, 2021.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.

[8] The four measures are: ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission.