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Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals (RIN 0938-AU12)

August 14, 2020

Background & Summary

On Tuesday, August 4, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2021 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). The CY 2021 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).

This 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 is proposing changes to the Overall Hospital Quality Star Rating Methodology in CY 2021 and subsequent years. Among other proposed policies, CMS intends to continue site-neutral payment policies between different Medicare sites of services, proposes to eliminate the inpatient only (IPO) list over the course of three calendar years and intends to pay for drugs acquired under the 340B program at a new payment rate of average sales price (ASP) minus 34.7 percent, plus 6 percent add-on of the product's ASP, for a net payment rate of ASP minus 28.7 percent..

Comments are due **October 5, 2020**. Due to COVID-19, CMS indicates that there will likely be a 30-day delay in the publication of the final rule, with the effective date still expected to be January 1, 2021. 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 2.6 percent for CY 2021 (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 .6 percent). The proposed increase factor of 2.6 percent is based on the proposed hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus

the proposed multifactor productivity (MFP) adjustment of 0.4 percentage point. For CY 2021, 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 $83.9 billion, an increase of approximately $7.5 billion compared to estimated CY 2020 OPPS payments."

As a result of the OPPS fee schedule increase factor (2.6 percent) and other budget neutrality adjustments noted in the below table, the combined impact of the changes and update to the conversion factor is reflected in Column 5 in the table below. CMS estimates that both urban and rural hospitals would experience an increase (approximately 2.8 percent for urban hospitals and 3.6 percent for rural hospitals). When classifying hospitals by teaching status, CMS estimates non-teaching hospitals would experience an increase of 3.5 percent, minor teaching hospitals would experience an increase of 3.2 percent and major teaching hospitals would experience an increase of 1.6 percent. Column 6 shows the full impact of the proposed CY 2021 policies on providers and hospitals by including the effect of all changes for CY 2021 and comparing them to total spending in CY 2020. CMS estimates the cumulative effective of all proposed changes will increase payments by 2.5 percent in CY 2021 for all providers and 2.6 percent for all hospitals.

Estimated Impact of the Proposed CY 2021 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)	340B Adjustment (4)	All budget neutral changes (combined cols 2-4) with Market Basket Update (5)	All Proposed Changes (6)
All providers*	3,628	0.0	0.2	0.0	2.8	2.5
All hospitals	3,523	0.1	0.2	0.0	2.9	2.6
Urban hospitals	2,772	0.0	0.2	-0.1	2.8	2.5
Rural hospitals	751	0.1	0.4	0.4	3.6	3.2
Non-teaching status hospitals	2,367	0.3	0.2	0.3	3.5	3.2
Minor teaching status hospitals	778	0.2	0.4	0.1	3.2	2.8
Major teaching status hospitals	377	-0.4	0.0	-0.6	1.6	1.4

*Excludes hospitals permanently held harmless and Community Mental Health Centers

Comprehensive APCs (C-APCs) for CY 2021

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 payment 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 2021, along with all of the other proposed complexity adjustments.

For CY 2021, CMS is proposing to create two new C-APCs under the existing payment policy: 1) proposed C-APC 5378 (Level 8 Urology and Related Services); and 2) proposed C–APC 545 (Level 5 Neurostimulator and Related Procedures). Adding these APCs would increase the total number of C-APCs to 69.

Proposed Updates Affecting OPPS Payments

Proposed Wage Index Changes

CMS continues to propose changes to the OPPS wage indexes that are line with the Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) FY 2021 rulemaking. Under current law, CMS delineates hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). Like the FY 2021 IPPS/LTCH PPS Proposed Rule, CMS proposes to adopt updated OMB delineations (OMB Bulletin No. 18-04). While the new OMB delineations are not based on new census data, CMS indicates the update includes "some material changes to the OMB statistical area delineations."

Consistent with previous years, CMS proposes to adopt the related IPPS wage index to calculate the CY 2021 OPPS wage indexes. Thus, any adjustments for the FY 2021 IPPS post-reclassified wage index – including, but not limited to, any proposed policies finalized under the IPPS to address wage index disparities between low and high wage index value hospitals – would be reflected in the final CY 2021 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.

Hospitals that are not paid under the IPPS but are paid under the OPPS do not have an assigned hospital wage index. As a result, for CY 2021, 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 2021 IPPS post-reclassified wage index, including those related to the adoption of the revised OMB delineations.

CMS has posted on their website the hospital-specific estimated payments for CY 2021 – 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 57 (pg. 725). However, the agency does not provide data for hospitals whose claims they were unable to use. For hospitals paid under the OPPS, CMS estimates that the proposed update of the wage indexes would result in an estimated increase of 0.2 percent for urban hospitals and an estimated increase of 0.4 percent for rural hospitals.

OPPS Payment for Devices

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

The aim of the transitional device pass-through payment is to support access to new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate. The period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Current statute[1] provides for pass-through payments for devices and requires CMS to use categories when determining the eligibility of these devices for pass-through payments.

In response to stakeholder concerns regarding reduced utilization of procedures that include pass-through devices during the COVID-19 public health emergency (PHE), CMS is specifically requesting public comment on whether CMS should utilize its equitable adjustment authority[2] to provide separate payment for some period of time after pass-through status ends for these devices in order to account for the period of time that utilization for the devices was reduced due to the PHE. Any rulemaking on this issue would be included in the CY 2022 OPPS/ASC Proposed Rule and in the Proposed Rule, CMS indicates it will consider the impact of the PHE on devices with OPPS device pass-through payment status during the PHE.

Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

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

Current statute provides for temporary additional payments – transitional pass-through payments – for certain drugs and biologicals that were not paid for as a hospital outpatient department service, and whose cost is not insignificant in relation to the payment for the procedures or services associated with it.[3] For pass-through payment purposes, radiopharmaceuticals are included as “drugs”. Transitional pass-through

[1] Section 1833(t)(6) and Section 1833(t)(6)(B) of the SSA
[2] *See* Section 1833(t)(2)(E) of the SSA
[3] Section 1833(t)(6) of the SSA

payments can be made for 2 to 3 years after the payment was first made for the product as a hospital outpatient service under Medicare Part B.

For CY 2021, CMS proposes to continue to pay for pass-through drugs and biologicals at average sales price (ASP) plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2021. In addition, CMS proposes to continue pass-through payment status for 46 drugs and biologicals, which were approved for pass-through payment status beginning between April 1, 2019 and April 1, 2020. These drugs and biologicals are listed in Table 23 (pg. 273).

CMS also proposes to end pass-through payment status for 26 drugs and biologicals, which are listed in Table 22 (pgs. 269 -271). These drugs and biologicals' pass-through payment status will expire between March 31, 2021 and December 31, 2021.

Consistent with prior rulemaking, for CY 2021, CMS proposes that the pass-through payment amount for policy-packaged drugs (e.g., anesthesia; medical and surgical supplies and equipment; surgical dressings; devices used for external reduction of fractures and dislocations; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure) would be equal to ASP plus 6 percent, minus a payment offset for any predecessor drug products contributing to the pass-through payment.

Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2020

There are 28 drugs and biologicals whose pass-through payment status will expire during the remainder of CY 2020, as listed in Table 21 (pgs. 265-267). With the exception of those groups of drugs and biologicals where payment is packaged into payment for other services when they do not have pass-through payment status, CMS applies a standard methodology to determine payment for the upcoming calendar year. First, CMS determines the product's estimated per day cost and compares it with the OPPS drug packaging threshold for that calendar year. 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 packages 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 provides a separate payment at the applicable relative ASP-based payment amount – which for CY 2021, is proposed at ASP plus 6 percent. For CY 2021, the proposed OPPS drug packaging threshold is $130. The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this Proposed Rule (available on the CMS website).

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

For CY 2021, CMS proposes to continue its policy to pay for separately payable drugs and biologicals (except for 340B-acquired drugs), at ASP plus 6 percent. Consistent with previous policy, 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 wholesale acquisition cost (WAC) and utilize a 3-percent add-on. For separately payable nonpass-through drugs acquired with a 340B discount, CMS proposes to pay a net rate of ASP minus 28.7 percent, as described in more detail in the CY 2021 OPPS Payment Methodology for 340B Purchased Drugs section of this summary.

Under the OPPS, CMS packages several categories of nonpass-through drugs, biologicals, radiopharmaceuticals (also known as policy-packaged drugs), regardless of the cost of the products. In the Proposed Rule, CMS describes their packaging methodology to determine the threshold for establishing separate APCs. Table 25 (pgs. 284-285) includes the proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2021.

For biosimilar biological products, for CY 2021, CMS proposes to continue making all biosimilar biological products eligible for pass-through payment. For other products' payment policy (e.g., therapeutic radiopharmaceuticals; blood clotting factors, nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS claims data), CMS proposes to continue to use previous payment policy.

CY 2021 OPPS Payment Methodology for 340B Purchased Drugs

In CY 2018 rulemaking, 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 what was the current rate of ASP plus 6 percent. These policy changes have not applied to drugs on pass-through payment status, which are required to be based on the ASP methodology – or vaccines, which are excluded from the 340B Program. For CY 2021 and subsequent years, CMS proposes to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP. According to CMS, under this payment methodology, each drug would receive the same add-on payment regardless of whether it is paid at the reduced 340B rate or not. Notably, CMS alternatively proposes that the agency could continue the current Medicare payment policy (ASP minus 22.5 percent) for CY 2021 and subsequent years.

CMS identified 34.7 percent by utilizing data from the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs and assessing a number of factors including: multiple measures of central tendencies; the effect of including penny priced drugs; mapping of multi-source National Drug Codes to a single HCPCS code; weighted values by volume/utilization; and applying certain methodologies to remove anomalous or outlier data. CMS administered the survey to 1,422 340B entities between April 24 and May 15, 2020 and requested average acquisition cost data for each specified covered outpatient drug (SCOD) purchased during the fourth quarter of CY 2018 and/or the first quarter of 2019. CMS allowed a quick survey option where the hospital indicated its preference that CMS utilize the 340B ceiling prices obtained from HRSA as reflective of their hospital acquisition costs. Of the survey hospitals 7

percent completed a detailed survey, 55 percent affirmatively responded via the Quick Survey option and 38 percent did not respond (CMS applied the ceiling price for non-respondents). Additional detail regarding the survey and the agency's methodology to calculate the ASP reduction amount based on the survey data is included in the Proposed Rule.

Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals have been excluded from this payment adjustment since CY 2018 – and Critical Access Hospitals (CAHs) are not reimbursed under OPPS, so this policy does not apply to them. For CY 2021 and subsequent years, CMS proposes that rural SCHs, children's hospitals, and PPS-exempt cancer hospitals would continue to be excepted from the 340B payment adjustment, continue to report informational modifier "TB" for 340B-acquired drugs, and continue to be paid ASP plus 6 percent. However, CMS also indicated that in future rulemaking it may revisit the policy to exempt rural sole community hospitals, as well as other hospital designations for exemption from the 340B drug payment reduction.

Finally, CMS indicates in the Proposed Rule that it is exercising its authority to vary the amount of payment for the group of hospitals that is enrolled in the 340B program because their drug acquisition costs vary significantly from those not enrolled in that program.

OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2021, CMS proposes to continue current payment policies for clinic and emergency department (ED) hospital outpatient visits and critical care services. CMS seeks comment on any changes to codes that CMS should consider for future rulemaking cycles and encourages commenters to provide related data and analysis to justify suggested changes.

Regarding site neutrality, in the CY 2019 OPPS/ASC final rule, CMS adopted a method to control increases in the volume of covered outpatient department services by utilizing a PFS-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments (PBDs). CY 2020 was the second year of the 2-year transition of this site-neutral payment policy, and, beginning in CY 2020, these departments were paid the site-specific PFS rate for the clinic visit service.

In 2019, a district court entered an order in opposition to CMS's site-neutral payment policy and in 2019, CMS stated it was working to ensure affected 2019 claims for clinical visits are paid consistent with the court's order. However, as indicated in the Proposed Rule, on July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, holding that the regulation was a reasonable interpretation of the agency's statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. For CY 2021, CMS does not propose changes to their site-neutral payment policy.

Services That Will Be Paid Only as Inpatient Services

Services that are typically provided only in an inpatient setting and, and therefore will not be paid by Medicare under the OPPS are included on an inpatient only (IPO) list. There are currently 1,740 services on the IPO list. The complete list of codes for IPO services is included as Addendum E to this CY 2021 OPPS/ASC Proposed Rule (available on the CMS website). Most notably, in the Proposed Rule, CMS proposes to eliminate the entire IPO list over a 3-year transitional period. As a first step towards eliminating the IPO list, for CY 2021, CMS proposes to remove all 266 musculoskeletal services from the IPO list.

CMS is requesting comments on whether 3 years is an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term given known technological and other advances in care, and the order of removal of additional clinical families and/or specific services for each of the CY 2022 and CY 2023 rulemaking years, until the IPO list is completely eliminated. Additionally, CMS seeks comment on whether the agency should restructure or create any new APCs to allow for OPPS payment for services that are removed from the IPO list. CMS is also soliciting public comments on whether any of the musculoskeletal codes proposed for removal from the IPO list for CY 2021 may meet the criteria to be added to the ASC Covered Procedures List.

CMS believes physicians should use their clinical knowledge and judgment, together with consideration of the patient's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the patient, subject to the general coverage rules requiring that any procedure be reasonable and necessary. CMS is requesting commenters submit evidence on what effect, if any, they believe eliminating the IPO list may have on the quality of care.

In the CY 2020 OPPS/ASC final rule CMS finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities for 2 calendar years following their removal from the IPO list. In other words, procedures that have been removed from the IPO list would not be eligible for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule after they have been removed from the list. For CY 2021 and subsequent years, CMS proposes to continue this 2-year exemption from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIO) referrals to RACs, and RAC reviews for "patient status" for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. CMS is seeking comment on whether a 2-year exemption continues to be appropriate, or if a longer or shorter period may be more warranted.

Proposed Nonrecurring Policy Changes

Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

In an interim final rule (IFC) issued March 31, 2020, CMS adopted a policy to reduce, on an interim basis for the duration of the COVID-19 PHE, the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which CMS had previously required direct supervision. CMS also specified in the March IFC that, for the duration of the COVID-19 PHE, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. For CY 2021 and beyond, CMS proposes to permanently adopt these policies.

Specifically, CMS proposes to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. This would be consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. CMS seeks comments on this proposal.

In addition, for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, CMS proposes to specify that, beginning on or after January 1, 2021, direct supervision for these services includes virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. CMS also clarifies that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. CMS also noted that it does not believe that it can change the detail level of supervision for these services to general supervision under current law. CMS seeks public comments on this proposal.

OPPS Payment for Specimen Collection for COVID-19 Tests

During the PHE, through an IFC, CMS created HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source). This code was established in response to the significant increase in specimen collection and testing for COVID-19 in HOPDs during the PHE.

Given that the PHE is still active at this time and that it may need to be extended into 2021, for CY 2021, CMS proposes to continue to assign HCPCS code C9803 to APC 5731 (level 1 minor procedures) with a status indicator of “Q1”. CMS also presumes that this code will be deleted when PHE ends.

In this Proposed Rule, CMS accepts public comments on the proposed APC and status indicator assignment for HCPCS code C9803 for CY 2021 (and reminds commenters that the code is only active for the duration of the COVID-19 PHE under the IFC). CMS is also soliciting public comments on whether it should keep HCPCS code C9803 active beyond the PHE and whether it should extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the PHE ends, including the reasoning for continuing to provide OPPS payment for this service as well as the timeframe for extending payment for this code.

In the event CMS keeps HCPCS code C9803 active after the PHE concludes, CMS is seeking public input on whether it should continue to assign HCPCS code C9803 to APC 5731 - Level 1 Minor Procedures with a proposed status indicator of "Q1".

Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

Hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Reporting (OQR) Program would continue to be subject to a further reduction of 2.0 percentage points from the OPPS fee schedule increase factor.

For the CY 2023 payment determination for the Hospital OQR Program (i.e. beginning with October 2021 encounters), CMS is not proposing any changes to the previously finalized measure set. Table 43 (pgs. 536) summarizes the previously finalized hospital OQR program measure set for the CY 2023 payment determination and subsequent years.

CMS also proposes to expand the agency's review and corrections policy to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years. Hospitals would have a review and corrections period for web-based measures, which would run concurrently with the data submission period. CMS believes the expansion of the existing policy for chart-abstracted measures to data submitted via the CMS web-based tool would accommodate a growing diversity of measure types in the Hospital OQR Program. CMS seeks comment on this proposal.

Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

According to CMS, the goal of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make more informed decisions about their healthcare.

For the Overall Star Rating beginning in CY 2021 and subsequent years, CMS proposes a methodology which includes elements of the current methodology, as well as updates that aim to increase simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings

among hospitals. CMS also proposes to include Veterans Health Administration (VHA) hospitals and continue to include CAHs in the Overall Star Rating.

Due to CMS's production timeline to calculate and distribute Overall Star Rating results in time for hospitals to preview the ratings in advance of public release, CMS uses this CY 2021 OPPS/ASC Proposed Rule to propose the revised methodology for the Overall Star Rating even though it typically proposes changes to the Overall Star Rating in the Inpatient Prospective Payment System (IPPS) rule. In the Proposed Rule, CMS indicates it plans to reference policies for the Overall Star Rating in the FY 2022 IPPS rule.

Proposal to Continue to Include Critical Access Hospitals in the Overall Star Rating

For the Overall Star Rating beginning in CY 2021 and subsequent years, CMS proposes to continue to include voluntary measure data from CAHs for the purpose of calculating Overall Star Rating. CAHs that do not elect to participate or that elect to withhold their data from public reporting will not be included in the Overall Star Rating calculation. Since CAHs voluntarily report measures, CAHs may have their Overall Star Rating withheld from public release provided they submit a timely request.

Veterans Health Administration Hospitals in the Overall Star Rating

CMS proposes to include VHA hospitals in the Overall Star Rating beginning in CY 2023, which allows CMS to establish the methodology through this Proposed Rule and host confidential reporting of the Overall Star Rating for VHA hospitals prior to public release of VHA star ratings. In order to be eligible to receive a star rating, VHA data would be subject to the same reporting threshold as subsection (d) hospitals[4] and CAHs included in the Overall Star Rating (proposed as three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each measure group).

CMS anticipates the inclusion of VHA hospitals would be apparent in three places of the Overall Star Rating Methodology: standardization of individual measure scores; standardization of measure group scores, and in the calculation of star ratings using k-means clustering. CMS intends to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule. CMS invites public comment on the proposal to include VHA hospitals in the Overall Star Rating beginning with CY 2023.

Current and Proposed Overall Star Rating Methodology

For public release of the Overall Star Rating beginning CY 2021 and subsequent years, CMS proposes to both retain and update certain aspects of the current Overall Star Rating six step methodology.

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[4] As defined under section 1886(d)(1)(B) of the Social Security Act

Current Star Rating Methodology	
Step 1	The measures are selected from among those reported on Hospital Compare to include as much information as possible while considering whether the measures are suitable for combination within the Overall Star Rating. The measure scores are also standardized to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude.
Step 2	The measures are grouped into one of seven measure groups.
Step 3	For each group, a statistical model, called a latent variable model (LVM), is used to determine a group score for each hospital reporting on measures in that group.
Step 4	A weight is applied to each measure group score and all available measure groups are averaged to calculate the hospital summary score.
Step 5	Hospitals that provide acute inpatient and outpatient care reporting too few measures and measure groups are excluded.
Step 6	Hospital summary scores are organized into five categories, representing the five star ratings, using an algorithm process called k-means clustering. K-means clustering is a method to cluster data so that observations within one cluster are more similar to each other than observations in another cluster.

CMS proposes to retain several aspects of its current methodology and process, such as the inclusion of measures publicly reported on Hospital Compare that meet specific inclusion and exclusion criteria and standardization of measure score within the first step of the methodology (selection and standardization of measures for inclusion in the overall star rating). However, CMS does propose removing one of the exclusion criteria (measures with statistically significant negative loadings estimated by the latent variable modeling) that rely on LVM. CMS indicates this change is because the agency is proposing to calculate measure group scores using a simple average of measure scores, instead of LVM. However, should that proposal not be finalized, CMS would continue using LVM to calculate measure group scores and exclude measures with statistically significant loadings. CMS invites comment the measure exclusion proposals.

For step 2 (assignment of measures to groups), CMS proposes to consolidate the three process measure groups – Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging – into one process measure group: Timely and Effective Care. In making this consolidation proposal, CMS notes that 12 measures were removed from CMS quality programs and public reporting ultimately resulted in two of the previously used measure groups, Timeliness of Care and Efficient Use of Medical Imaging, being comprised each of only three measures, which would not produce robust or predictable measure group scores. CMS believes this new consolidated group would reflect the principles of measure reduction under the Meaningful Measures Initiative and is necessary to ensure that a sufficient number of measures exist in this group.

For step 3 (calculation of measure group scores), CMS proposes to replace LVM, which has been used to calculate measure group scores, with a simple average of measure group scores. CMS believes this change will increase the simplicity of the methodology and predictability of measure weights within the methodology. Under the proposed replacement for LVM, CMS would average the measure scores a hospital reports within a given measure group, which have been standardized, to calculate the measure group scores. In the Proposed Rule, CMS provides additional detail regarding its proposed process to standardize measure group score.

In addition, related to step 3, CMS notes that in the past it has not stratified or adjusted any of the measures, measure groups, summary scores, or star ratings by social risk factor variables within the Overall Star Rating methodology. However, for CY 2021 and subsequent years, CMS proposes to specifically stratify only the Readmission measure group based on hospitals' proportion of dual-eligible hospital discharges. CMS indicates the agency is proposing this change to be responsive to stakeholder concerns that some hospitals providing acute inpatient and outpatient care face unique challenges preventing readmissions among patients with complex social risk factors, and to align with the payment adjustment recently implemented for Hospital Readmissions Reduction Program payment determination.

For step 4 (calculation of hospital summary scores as a weighted average of group scores), CMS describes its previous practice of calculating hospital summary scores as a weighted average of measure group scores and indicates stakeholders believed outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. As a result, CMS proposes to weight each of the outcome and patient experience measure groups – Mortality, Safety of Care, Readmission, and Patient Experience – at 22 percent, and the proposed combined process measure group, Timely and Effective Care, at 12 percent. CMS also propose that hospital summary scores would then be calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summed. CMS invites public comment on the proposals to regarding the hospital summary score calculation and weighting of measure groups.

Also, regarding step 4, CMS proposes to continue to reweight measure group scores when a hospital did not report or have sufficient measures for a given measure group. However, since CMS proposes a new measure group (Timely and Effective Care) and measure group weighting, the agency proposes to re-distribute measure group weights for measure groups when a hospital does not have sufficient measures within the Overall Star Rating methodology. Once a hospital meets the reporting threshold to receive a star rating (at least three measure groups each with at least three measures), any additional measures and measure groups would contribute to their star rating. CMS proposes to re-distribute the weights for measure groups which are not reported proportionally across the remaining measure groups.

For step 5 (application of minimum thresholds for receiving a star rating), CMS proposes a modification to the minimum threshold policy. Specifically, CMS proposes that hospitals must report at least three measures for three measures groups,

however, one of the groups must specifically be the Mortality or Safety of Care outcome groups.

Currently, CMS does not group hospitals by peers within the Overall Star Rating methodology. However, in the Proposed Rule, CMS proposes that hospitals that provide acute inpatient and outpatient care would be grouped by the number of measure groups (three measure groups, four measure groups and five measure groups) for which they have at least three measures. Once grouped, k-means clustering would be applied within each peer group to assign hospital summary scores to star ratings. CMS believes grouping hospitals by measure group reporting will capture key differences among hospitals, such as different in size, patient volume, case mix, and services provided. According to CMS, the proposal is dependent on a sufficient number of hospitals that provide acute inpatient and outpatient care reporting sufficient measures to be included in the three, four and five measure groups to form the three peer groups. In the Proposed Rule, CMS indicated it simulated the effects of the proposed grouping policy using January 2020 data and vetted the group sizes (348 hospitals reporting at least 3 measures in 3 groups; 583 reported 4 groups and 2,509 reported all 5 groups) with a technical expert panel and workgroups. CMS also notes this proposal is contingent on the participation of CAHs since CAHs make up approximately half of the hospitals in the three measure group peer group. Should CMS not finalize the proposals to include CAHs, it will not peer group the Overall Starr Rating by number of measure groups.

For step 6 (Application of Clustering Algorithm to Obtain a Star Rating), CMS used an approach called k-means clustering (with a statistical method called complete convergence) to group hospitals into the five star rating categories. CMS proposes to continue to use k-means clustering (with complete convergence) to group hospitals into five clusters to assign star ratings.

Time Frame

Regarding the timeframe, CMS proposes to continue an annual publication cycle. However, instead of using data from the same quarter as or the quarter prior to the publication of the Overall Star Rating, CMS proposes to use publicly available measure results on Hospital Compare from a quarter within the prior year. In other words, CMS proposes to use data from the January, April, July or October Hospital Compare refreshes to calculate the Overall Star Rating. As an example, CMS indicates for a January 2021 Overall Star Rating release, CMS could use data refreshed on *Hospital Compare* in July or October of 2020.

Preview Period

In the past, hospitals providing acute inpatient and outpatient care that are included in the Overall Star Rating had the opportunity to review certain information relevant to their rating. Currently, CMS provides hospitals at least 30 days to preview their results and ask CMS questions prior to CMS releasing the Overall Star Rating. During this preview period, hospitals receive a confidential hospital-specific report (HSR), which details their measure performance and measure group scores with comparisons to the national average, as well as their summary score and star rating. In the Proposed

Rule, for Overall Star Rating beginning with the CY 2021 and subsequent years, a few months prior to public release of the Overall Star Rating, CMS proposes to continue to provide a preview period where CMS would issue a confidential HSR, which would detail measure and measure group scores, their summary score and star rating, and allow for hospitals to ask questions about their results – although hospitals would still have only 30 days to provide feedback to the agency. CMS invites public comment on the proposal to establish a 30-day confidential preview period.

Overall Star Ratings Suppressions

For the Overall Star Rating beginning in CY 2021 and subsequent years, CMS proposes separate suppression policies for subsection (d) hospitals[5] and CAHs given that subsection (d) hospitals are subject to CMS quality programs and CAHs voluntarily submit measure data. Specifically, CMS proposes to consider suppressing Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issues) as determined by CMS or when CMS is at fault, including but not limited to when:

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation; or
- A Public Health Emergency substantially affects the underlying measure data.

CMS makes clear that, consistent with past practices, it does not propose to suppress an individual hospital's Overall Star Rating because the hospital or one of its agents (for example, authorized vendors, representatives, or contractors) submitted inaccurate data to CMS, including inaccurate underlying measure data and claims records. CMS invites comments on these proposals.

For CAHs, for Overall Star Rating beginning in CY 2021 and subsequent years, CMS proposes to continue to allow CAHs to withhold their Overall Star Rating. Specifically, CMS proposes that CAHs may request to withhold their Overall Star Rating from public release on Hospital Compare or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on Hospital Compare or its successor website through completion of the "Request Form for Withholding/Footnoting Data for Public Reporting" form, all of their measures scores will be withheld from the Overall Star Rating calculation. However, individual measure scores would still be included in the public input file. In addition, CMS proposes that CAHs may request to have their Overall Star Rating withheld from public release on Hospital Compare or its successor website, as well as their data from the public input file, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the

[5] As defined under section 1886(d)(1)(B) of the Social Security Act

Hospital Compare refresh used to calculate the Overall Star Ratings. CMS invites comment on these proposals.

Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule, CMS established a prior authorization process for certain hospital OPD services (regulations at 42 CFR part 419, subpart I). The regulations include definitions associated with the prior authorization process, provide that prior authorization must be obtained as a condition of payment for the listed service categories, and include the process by which hospitals must obtain prior authorization.

For CY 2021, CMS proposes to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. CMS proposes that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. In making this decision, CMS notes its determination that there has been an unnecessary increase in the volume of these services.

Updates to the Ambulatory Surgical Center Payment System

Using the hospital market-basket methodology, for CY 2021, CMS is proposing to increase payment rates under the ASC payment system by 2.6 percent for ASCs that meet the ASC quality reporting program requirements. This proposed increase is based on the hospital market-basket percentage increase of 3.0 percent minus a multifactor productivity (MFP) adjustment of 0.4 percentage point. 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 2021, CMS is proposing to apply a 0.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs not meeting ASCQR requirements. For CY 2021, 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). Table 45 (pgs. 555-556) summarizes the proposed ASCQR Program measure set for the CY 2024 payment determination and subsequent years.

Additions to the List of ASC Covered Surgical Procedures

At least every two years, CMS must specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but can be safely performed in an ASC, CAH, or an HOPD. Based on this work, CMS reviews and updates the ASC covered surgical procedures list (ASC-CPL). CMS also evaluates the ASC-CPL each year to determine whether procedures should be added or removed. CMS also indicates it seeks to continue to promote site neutrality between the hospital outpatient department and ASC settings, and believes expanding the ASC-CPL to include more procedures (as reasonably possible) will advance the agency's goal.

For CY 2021, CMS proposes to apply current policies and criteria for updates the ASC-CPL. Based on CMS's review, the agency proposes to update the list of ASC covered surgical procedures by adding eleven procedures, including total hip arthroplasty (THA), to the list for CY 2021, as shown in Table 40 (pg. 489). CMS seeks comments these proposals, particularly as related to the inclusion of THA.

In addition, since CMS proposes to eliminate the IPO list in the Proposed Rule, the agency proposes changes to the general exclusion criteria to conform to changes to the IPO list. CMS indicates that it is retaining certain exclusion criteria to exclude procedures designated as requiring inpatient care as of December 31, 2020. CMS believes this change will ensure procedure performed on an inpatient basis and cannot be safely performed on an ambulatory basis will not be added to the CPL prematurely.

Alternative Proposals under Consideration for CY 2021

CMS notes that the PHE has highlighted the need for more healthcare access points. As a result, CMS believes allowing greater flexibility for physicians and patients to choose ASCs as the site of care would help to support access to elective procedures and emergency care. CMS proposes two alternative options (both of which are anticipated to expand the ASC-CPL) that would change the way surgical procedures are added to the ASC-CPL: (1) a nomination process for adding new procedures to the ASC-CPL, and (2) revising regulations to eliminate five of the general exclusion criteria. In the Proposed Rule, CMS indicates it proposes to finalize only one of these alternative proposals in the final rule.

Under the first alternative option, CMS proposes certain parameters (e.g., risk of life-threatening complications, need for specialized resource not generally available in an ASC, average length of time for patients to be stabilized, resources and providers available at nearby facilities for intervention) as guidelines and would solicit recommendations from external stakeholders, like medical specialty societies and other members of the public, for procedures that may be suitable candidates to add to the ASC-CPL. CMS proposes to establish the nomination process in the CY 2021 final rule for surgical procedures that could be added to the ASC-CPL beginning CY 2022. CMS also indicates, since it proposes to eliminate the IPO list, that it would not accept nominations for procedures to add to the ASC-CPL if the procedure is on the CY 2020 IPO list. CMS also proposes other modifications to existing general exclusion criteria. CMS seeks comment on this proposal.

Under the second alternative option, CMS proposes to remove five of the current general exclusion criteria and keep the remaining general standard criteria[6]. Under

[6] 42 CFR §416.166 (b), "Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the Federal Register and/or via the Internet on the CMS Web site that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an

this less-stringent revised criteria, CMS proposes to add approximately 270 potential surgery or surgery-like codes (found on Table 41, beginning on page 489) that are not on the CY 2020 IPO list. CMS seeks stakeholder comments on various potential revisions to the ASC conditions of coverage if alternative two is adopted.

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

In the Proposed Rule, CMS is not proposing to remove any existing measures or to adopt any new measures for the CY 2023 payment determination. Table 45 (pgs. 555-556) summarizes the previously finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years.

In addition, for future consideration, the agency seeks measures that would facilitate meaningful comparisons between ASCs and hospitals. CMS invites public comment on new measures that address care quality in the ASC settings as well as on additional measures that could facilitate comparison of care provided in ASCs and hospitals.

Like the proposed changes to the Hospital OQR Program submission deadline and review and correction policy, CMS proposes similar changes for the ASCQR program. Specifically, CMS proposes that all deadlines falling on a nonwork date be moved forward, such that all deadlines occurring nonwork days for federal employees by statute or Executive order would be extended to the first workday for federal employees. CMS also proposes to implement a review and correction period which would run concurrently with the data submission period beginning with the effective date of this rule, which is expected to be January 1, 2021.

Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy

Generally, the date of service (DOS) for clinical laboratory services is the date the specimen was collected. Currently, there are three exceptions to the general date of service rule (e.g., tests/services performed on stored specimens, chemotherapy sensitivity tests/services performed on live tissue, and advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests). For ADLTs and molecular pathology, CMS has twice extended the enforcement discretion period for implementation of the laboratory DOS policy. The most recent enforcement discretion period was in effect until January 2, 2020. CMS continues to gauge the industry's preparedness to implement the laboratory DOS exception. A list of the specific laboratory tests currently subject to the laboratory DOS exception is available on the CMS website.

ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure."

In the Proposed Rule, CMS indicates it believes certain Multianalyte Assays with Algorithmic Analyses (MAAAs), specifically, cancer-related protein-based MAAAs have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine posthospital care. As a result, CMS proposes to create an exception to the laboratory DOS rule for cancer-related protein-based MAAAs. In another section of the Proposed Rule, CMS proposes to exclude these MAAAs from the OPPS packaging policy. If these proposals are finalized, it would mean that Medicare would pay for cancer-related protein-based MAAAs under the Clinical Laboratory Fee Schedule instead of the OPPS and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements.

Physician-owned Hospitals

The physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The law also provides specific exceptions and grants the Secretary of Health and Human Services the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. In the Proposed Rule, CMS proposes to remove regulatory restrictions on the expansion of physician-owned hospitals that qualify as “high Medicaid facilities”.

A “high Medicaid facility” means a hospital that: (1) is not the sole hospital in a county; (2) with respect to each of the 3 most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. CMS proposes to permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. If that permitted expansion meets certain requirements regarding capacity and location. CMS is also considering removing the requirement for community input in the review process with respect to high Medicaid facilities.

In addition, in 2010, CMS clarified in a Frequently Asked Questions publication that it defers to state law with respect to the determination of whether a bed is licensed as related to physician self-referral law exemptions. CMS proposes to revise the regulatory definition of “baseline number of operating rooms, procedure rooms, and beds” to include a statement that, for purposes of determining the number of beds in a hospital’s baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital

by the State. CMS seeks comments on this proposal and is specifically interest in learning whether the inclusion of this language is necessary or could be perceived as inadvertently limiting the definition of “baseline number of operating rooms, procedure rooms, and beds.”

What’s Next?

The OPPS tables for this CY 2021 Proposed Rule are available on the CMS website. CMS is anticipated to publish the final OPPS regulation on or before December 1, 2020 and the changes are effective at the beginning of the calendar year (January 1, 2021). The comment period closes on October 5, 2020.

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.