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Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (CMS-1772-P)

August 5, 2022

Background & Summary

On July 15, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2023 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS) (Proposed Rule). The 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, while establishing the Rural Emergency Hospital (REH) Quality Reporting (REHQR) Program. Additionally, CMS provides insights regarding future reimbursement for medications acquired through the 340B program, seeks feedback to inform the agency's organ acquisition payment policy and requests comments on the use of CMS data to drive competition in health care marketplaces. CMS also proposes adding a new service category for the hospital outpatient department prior authorization process, updating requirements for the Overall Hospital Quality Star Ratings, and providing a positive payment adjustment for NIOSH-approved domestic surgical N95 respirators.

Comments are due **September 13, 2022,** and the final rule is expected to be released in early November. Most provisions will go into effect January 1, 2023. Vizient looks forward to working with members to help inform our letter to the agency.

OPPS Payment Update

For CY 2023, CMS proposes to apply an outpatient department (OPD) fee schedule increase factor of 2.7 percent, except for those hospitals not meeting certain quality reporting requirements, which would be subject to a 2 percent reduction resulting in a fee schedule increase factor of 0.7 percent. The proposed increase factor of 2.7 percent is based on the proposed hospital inpatient market basket percentage increase of 3.1 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.4 percentage points.

As done in prior years, CMS proposes to use the OPD fee schedule increase factor and other budget neutrality adjustments to calculate the CY 2023 OPPS conversion factor. As a result, all budget neutrality changes combined with the market basket update are reflected in Column 4 in the following table. Column 5 displays estimated changes in payment related to the agency's proposal to apply an exception to the site neutral payment policy for off-campus provider-based departments (PBDs) for sole community hospitals, which are non-budget neutral. Column 6 shows the full impact of the proposed CY 2023 policies on providers and hospitals by including the effect of all changes for CY 2023 and comparing them to total spending in CY 2022. For example, CMS estimates both urban and rural hospitals would experience an increase in payments (approximately 2.9 percent for urban hospitals and 3.2 percent for rural hospitals). When classifying hospitals by teaching status,

CMS estimates non-teaching hospitals would experience an increase of 3.3 percent, minor teaching hospitals would experience an increase of 3.0 percent and major teaching hospitals would experience an increase of 2.6 percent. CMS estimates that, for CY 2023, the cumulative effect of all proposed changes will increase payments by 2.9 percent for all providers and 3.0 percent for all hospitals. Also, CMS proposes a CY 2023 conversion factor (CF) of $86.785.

For CY 2023, 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 $86.2 billion, approximately $6.2 billion more compared to estimated CY 2022 payments.

Notably, the below table and proposed conversion factor does not reflect changes related to 340B reimbursement, which are expected in the final rule. In the Proposed Rule, CMS indicates that should these 340B changes be considered, the revised CF would be approximately $83.279, as there would be an offset of $1.96 billion that would decrease the CF.

Estimated Impact of the Proposed CY 2023 Changes for the Hospital OPPS

	Number of Hospitals (1)	Proposed 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)	Proposed Rural Sole Community Hospital Exception to Off Campus PBDs Visits Policy (5)	All Proposed Changes (6)
All providers	3502	0.0	0.1	2.9	0.1	2.9
All hospitals*	3411	0.1	0.2	2.9	0.1	3.0
Urban hospitals	2686	0.1	0.2	3.0	0.0	2.9
Rural hospitals	725	-0.1	0.0	2.6	0.7	3.2
Non-teaching status hospitals	2200	0.4	0.1	3.2	0.1	3.3
Minor teaching status hospitals	819	0.1	0.1	3.0	0.1	3.0
Major teaching status hospitals	398	-0.4	0.3	2.6	0.1	2.6

*Excludes hospitals held harmless and Community Mental Health Centers

Additional Proposed Updates Affecting OPPS Payments

Proposed Recalibration of APC Relative Payment Weights

CMS primarily uses claims data and cost report data in OPPS ratesetting, including when recalibrating Ambulatory Payment Classification (APC) relative payment weights. Also, the agency generally relies on a full year of claims data from the 2-years prior to the calendar year that is the subject of rulemaking.

CMS notes that unlike CY 2020 data, the agency does not have significant concerns with CY 2021 claims data due to the COVID-19 public health emergency (PHE). Therefore, CMS proposes to use CY 2021 claims data and the data components related to it in establishing the CY 2023 OPPS. Also, CMS proposes to use cost report data from the June 2020 Healthcare Cost Report Information System (HCRIS) data set (including only cost report data through CY 2019 for the Proposed Rule and final rule ratesetting purposes). In addition, in the Proposed Rule, CMS discusses various other changes related to the recalibration of APC relative payment weights, including the calculation and use of cost-to-charge ratios, calculation of single procedure APC criteria-based costs (e.g., blood and blood products, brachytherapy services) and ongoing application of the comprehensive APC (C-APCs) payment policy methodology and proposed C-APCs and composite APCs (i.e., mental health services composite APC and multiple imaging composite APCs).

Proposal and Comment Solicitation on Packaged Items and Services

The OPPS packages payments for multiple interrelated items and services into a single payment that is designed to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. For CY 2023, CMS examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate.

While CMS does not propose changes to the overall packaging policy, for CY 2023, the agency proposes to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where CMS believes that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Also, CMS requests comments on data regarding whether to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the HOPD setting.

Proposed Wage Index Changes

By law, CMS must determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to geographic differences in labor and labor-related costs. This wage adjustment must be done in a budget neutral manner and the portion of the OPPS payment rate is called the labor-related share. The labor-related share is 60 percent of the national OPPS payment.

For CY 2023, CMS proposes to continue implementing various provisions affecting the wage index, such as the Frontier State wage index floor of 1.00 (not applied in a budget neutral manner) and the out-migration adjustment policy. Also, CMS indicates policies and adjustment from the FY 2023 IPPS final rule would be reflected in the final CY 2023 OPPS wage index beginning CY 2023. In the FY 2023 IPPS Final Rule, CMS finalized a policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. CMS also proposes to use the FY 2023 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2023.

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 2022, 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 $6,175 (the fixed-dollar amount threshold). For CY 2023, CMS proposes to increase the fixed-dollar amount threshold $8,350 plus the APC payment amount. The CY 2023 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.

Although there is a substantial increase in the proposed fixed-dollar threshold compared to CY 2022, CMS proposes to continue to allocate 1.0 percent of aggregated total OPPS payments to outlier payments. Also, for modeling estimated outlier payments, CMS indicates that the April 2022 Outpatient Provider Specific File (OPSF) contains cost data primarily from CY 2021 and CY 2022 and is the basis for current CY 2022 OPPS outlier payments. As a result, CMS proposes to use the April 2022 OPSF to determe the cost-to-charge ratios (CCRs) that will be applied to CY 2023 hospital outpatient claims.

Proposed Beneficiary Copayments

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2023 are shown in Addenda A and B to the Proposed Rule (available on the CMS website). CMS

notes that statute limits the amount of beneficiary payments that may be collected for a procedure in a year to the amount of the inpatient hospital deductible for that year.

Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

COVID-19 Vaccine and Monoclonal Antibody Administration Services

CMS proposes to use the agency's equitable adjustment authority to maintain the payment rate of $40 for each COVID-19 vaccine administration (APCs 9397 and 9398). CMS also proposes to continue the in-home add-on HCPCS code (M0201) at an additional $35.50 when the COVID-19 vaccine is provided in certain circumstances in the patient's home. CMS believes maintaining the current, site neutral payment rate is necessary to ensure equitable payments during the PHE and at least through CY 2023. Table 29 of the Proposed Rule (pgs. 175-176) includes proposed payment rates for COVID-19-related administration services. CMS requests comment on whether it should continue a site-neutral payment policy for COVID-19 vaccine administration for CY 2023, as rates are generally consistent between outpatient and ambulatory settings. In addition, CMS seeks comments on what alternative approaches may be appropriate to update the OPPS payment rates for COVID-19 vaccine administration HCPCS codes, including the in-home add-on HCPCS code (M0201), while continuing to ensure site neutral payment for these services. CMS also requests comments on whether the agency should instead use the rate finalized through the Physician Fee Schedule (PFS) rulemaking that generally applies under the preventive vaccine benefit.

However, CMS clarifies unlike COVID-19 vaccine administration, the OPPS payment rates for administration of COVID-19 monoclonal antibody products under the Part B preventive vaccine benefit are set at the midpoint of the cost bands for the New Technology APCs to which the monoclonal antibody administration services are assigned under the OPPS. CMS assigned COVID-19 monoclonal antibody administration services to New Technology APCs based on estimated costs for these services.

Comment Solicitation on the Appropriate Payment Methodology for Administration of Preventive Vaccines Post PHE

Under the OPPS, the codes describing the administration of the influenza, pneumococcal, and Hepatitis B vaccines are assigned to APC 5691 (Level 1 Drug Administration), with a payment rate of approximately $40. However, there is also a statutory benefit for preventive vaccines and related services, such as influenza, pneumococcal and COVID-19, and their administration under Medicare Part B for physicians, non-physician practitioners, mass immunizers and certain other providers and suppliers. CMS seeks comments on the appropriate payment methodology for the administration of Part B preventive vaccines, including the COVID-19 vaccine, post PHE, when furnished by HOPDs.

COVID-19 Monoclonal Antibody Products and Their Administration Services Under OPPS

When monoclonal antibody products for COVID-19 treatment were granted emergency use authorizations (EUAs) during the PHE for COVID-19, CMS made the determination to cover and pay for them under the Part B vaccine benefit. Consistent with payment for COVID-19 vaccine products and their administration, under the OPPS, CMS pays separately for COVID-19 monoclonal antibodies and their administration. Except when the provider receives the COVID-19 monoclonal antibody product for free, providers are paid for these products at a reasonable cost. For CY 2023, CMS proposes to use equitable adjustment authority to maintain the CY 2022 New Technology APC Assignment (i.e., 1503-1507 and 1509) and corresponding payment rates for each of the COVID-19 monoclonal antibody product administration HCPCS codes for as long as these product are considered to be covered and paid under the Part B benefit; so that when the PHE ends, the benefit category and payment methodology under the OPPS will remain site-neutral.

CMS clarifies that once these products are no longer considered to be covered and paid under the Medicare Part B vaccine benefit, CMS expects the COVID-19 monoclonal antibody product

administration services to be paid similar to monoclonal antibody products (i.e., as biologicals), as long as such products have market authorization.

Proposed OPPS Pass-Through Payment for Devices

The purpose of transitional device pass-through payment is to facilitate access for beneficiaries to new and innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to develop the procedure APC rate. Table 30 of the Proposed Rule (pgs. 181-182) details the expiration dates of pass-through payment status for each of the 11 devices currently receiving device pass-through payment. CMS notes that although it extended pass-through payment for some devices in the CY 2022 OPPS final rule, the agency is not proposing to provide any additional quarters of separate payment for any device whose pass-through payment status will expire between December 31, 2022 and September 30, 2023. CMS seeks comment on how the circumstances for CY 2023 are similar to those in CY 2022, when the agency adopted a policy to effectively continue pass-through status for drugs, biologicals and devices with pass-through status expiring between December 31, 2021 – September 30, 2023.

Regarding applications for device pass-through status for CY 2023, CMS received nine complete applications by the March 1, 2022, quarterly deadline (the last deadline to be included in the CY 2023 OPPS proposed rule). For each application, CMS provides additional information and welcomes comment on whether the pass-through payment criteria has been met.

To improve transparency, promote stakeholder engagement and streamline the evaluation process, CMS proposes that, beginning January 1, 2023, it will post online the completed OPPS device pass-through application form and related materials received from applicants. Such information would be publicly posted at the same time the proposed rule is issued. However, CMS indicates it would not summarize in significant detail each OPPS device pass-through application as done in the past. Should CMS adopt this proposal in the final rule, the agency indicates it would begin referring to publicly posted applications in CY 2023 rulemaking cycle, depending on when they are received. However, CMS does solicit comment on whether it should consider an alternative implementation date of March 1, 2023, such that all OPPS pass-through applications discussed in the CY 2024 OPPS proposed and final rules would follow the current process and would appear in the rule as a full write-up. Under this approach, CMS would begin publicly posting all OPPS device pass-through applications and summaries and cross-reference the applications beginning in the CY 2025 proposed and final rules.

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 average sales price (ASP) methodology uses several sources of data as a basis for payment – including manufacturer-reported data). For pass-through payment purposes, radiopharmaceuticals are included as “drugs”.

Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2022

CMS notes that there are 31 drugs and biologicals whose pass-through payment status will expire on December 31, 2022, as listed in Table 39 of the Proposed Rule (pgs. 314-316). 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 2023, CMS proposes an OPPS drug packaging threshold of $135. 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 2023, 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).

Drugs, Biologicals and Radiopharmaceuticals with Pass-Through Payment Expiring in CY 2023

For CY 2023, CMS proposes to end pass-through payment status for 43 drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2020 – January 1, 2021. They are listed in Table 40 of the Proposed Rule (pgs. 318-322). 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 2023.

For policy-packaged drugs (e.g., anesthesia drugs, 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, CMS proposes their pass-through payment amount would be equal to ASP plus 6 percent for CY 2023 minus a payment offset for the portion of the otherwise applicable OPD fee schedule.

CMS proposes to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2023 if later quarter ASP submissions (or more recent WAC or AWP information) indicates that adjustment to the payment rates are necessary.

Also, consistent with CMS's 2022 policy for diagnostic and therapeutic radiopharmaceuticals, CMS proposes to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. If ASP data is not available for radiopharmaceuticals, CMS proposes to provide pass-through payment at WAC plus 3 percent, which is the equivalent payment provided for pass-through drugs and biologicals without ASP information. If WAC information is not available, CMS proposes to provide pass-through payment at 95 percent of its most recent AWP.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing in CY 2023

CMS proposes to continue pass-through payment status in CY 2023 for 32 drugs and biologicals which had pass-through payment status begin between April 1, 2021 – April 1, 2022 and these drugs and biologicals are listed in Table 41 of the Proposed Rule (pgs. 325-327).

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 2023, consistent with CY 2022, CMS proposes to continue to apply the same policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents and pass-through skin substitutes. Table 42 of the Proposed Rule (pgs. 328-329) provides proposed APCs to which a policy-packaged drug or radiopharmaceutical offset may be applicable in CY 2023. CMS proposes to continue to post annually on a CMS website the APC offset amounts and percentages of APC

payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

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

As noted above, CMS proposes a packaging threshold of $135. CMS proposes to package items with a per day cost of less than or equal to $135, and to identify items with a per day cost greater than $135 as separately payable unless they are policy-packaged.[1] Therefore, products with a cost greater than $135 would be paid separately through their own APC.

Proposed Payment for Drugs, Biologicals and Radiopharmaceuticals without Pass-through Status

For CY 2023, 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.

Proposed Payment for Drugs and Biologicals without Pass-Through Status that are Not Packaged

A "specified covered outpatient drug" (SCOD) is a covered outpatient drug for which a separate APC has been established that is either a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002. The statutory default rate of reimbursement for SCODs is ASP plus 6 percent. For CY 2023, CMS proposes to continue the payment policy that has been in effect since 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP plus 6 percent.

As noted elsewhere in the Proposed Rule, while CMS proposes to pay for separately payable non pass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent, the agency intends to finalize a payment policy for such drugs at ASP plus 6 percent. However, CMS also indicates that for SCOD products that would otherwise be acquired under the 340B program and where WAC-based pricing would apply, the agency proposes that the payment amount for these drugs (i.e., WAC minus 22.5 percent) would continue to apply.

For CY 2023 and subsequent years, CMS proposes to continue to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC. Similarly, CMS proposes to apply this policy to non-SCOD separately payable drugs.

Separately payable drug and biological payment rates are listed in Addenda A and B which is available on the CMS website.

Additional Product Types

In the Proposed Rule, CMS also proposes policies and payment rates for biosimilar biological products, therapeutic radiopharmaceuticals, blood clotting factors and skin substitutes. Notably, CMS provides greater detail regarding skin substitutes including details regarding the agency's goal

[1] "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)).

of a consistent payment approach across the physician office and hospital outpatient department setting, using a uniform benefit category across products (e.g., synthetic, comprised of human or animal-based material), and a potential phased approach over the next 1-5 years to avoid unnecessary unintended impacts involving the use of these products.

Proposal in Physician Fee Schedule Proposed Rule to Require HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

The Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. In the Proposed Rule, CMS provides policies to implement this section of the law, including a proposal that HOPDs and ASCs would be required to report the JW modifier to identify discarded amounts of refundable single-dose containers or single-use package drugs that are separately payable under the OPPS or ASC payment system. Also, CMS references the CY 2023 PFS proposed rule, which also proposes to require that HOPDs and ASCs use a separate modifier (JZ) in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts. CMS clarifies comments on this topic should be submitted in response to the CY 2023 PFS proposed rule.

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, CMS has continued to implement a payment rate of ASP minus 22.5 percent, despite ongoing litigation and calls that the agency revert to the pre-2018 policy of ASP plus 6 percent.

On June 15, 2022, the Supreme Court of the United States released a decision[2] in favor of the plaintiffs, which included national hospital associations, indicating that CMS lacked authority to reduce the reimbursement as it had done because CMS did not obtain necessary survey data from hospitals. While the Supreme Court's decision focused on payment rates for CY 2018 and 2019, CMS acknowledges it has implications for CY 2023 payment rates. However, CMS also notes that given the timing of the Supreme Court decision, the agency lacked the necessary time to incorporate the adjustment to the proposed payment rates and budget neutrality calculations to account for the decision before issuing the Proposed Rule. As a result, it is important to be aware that the payment rates, tables, and addenda in the Proposed Rule reflect a payment rate of ASP minus 22.5 percent for drugs and biologicals acquired through the 340B program for CY 2023, consistent with the agency's 2018 policy which the Supreme Court found to be unlawful.

However, on the CMS website that agency provides "Alternative 340B Proposal Related Files" which include information regarding the anticipated effects of reversing the 340B program payment policy for CY 2023. CMS indicates that it fully anticipates applying a rate of ASP plus 6 percent to such drugs and biologicals in the final rule for CY 2023, in light of the Supreme Court's decision.

In addition, CMS indicates it is still evaluating how to apply the Supreme Court's recent decision to craft an appropriate remedy for CYs 2018-22. While the Supreme Court did not address potential

[2] American Hospital Association v. Becerra, No. 20-1114, 2022 WL 2135490

remedies, CMS is interested in public comments on the best way to craft any potential remedies affecting CYs 2018-2022, as the issue remains unresolved.

For CY 2023, based on CMS's analysis, it anticipates that the estimated payment differential of ASP minus 22.5 percent and ASP plus 6 percent would be an increase of approximately $1.96 billion in OPPS drug payments. To ensure budget neutrality, CMS would apply the $1.96 billion offset to decrease the OPPS conversion factor, which would result in an estimated, reduced conversion factor of $83.279. As a result, non-340B hospitals may be more significantly impacted as they would have a reduced conversion factor and would not be eligible for the increased 340B reimbursement rates. CMS indicates that comments on the budget neutrality adjustment are welcome and will be carefully considered.

Also, for CY 2023, CMS proposes to continue 340B payment for WAC-priced drugs, which is WAC minus 22.5 percent. The 340B-acquired drugs that are priced using AWP would continue to be paid an adjusted amount of 69.46 percent of AWP. Also, CMS proposes to continue to require hospitals to use modifiers to identify 340B-acquired drugs.

Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2023, CMS proposes to continue current clinical and emergency department (ED) hospital and outpatient visit payment policies, and previously established payment policy for critical care services.

Additionally, for CY 2023, CMS proposes that excepted off-campus provider-based departments (PBDs) (departments that bill the "PO" modifier on claims) of rural Sole Community Hospitals (SCH) and designated as rural for Medicare payment purposes, would be exempt from the site neutral clinical visit payment policy (i.e., applying PFS-equivalent payment rates for the clinic visit service). As a result of this proposal, if finalized, an excepted off-campus PBD of a rural SCH would continue to bill HCPCS code G0463 with the "PO" modifier in CY 2023, but the payment rate for these services would now be the full OPPS payment rate. This would cost beneficiaries an average of an additional $16 per visit. CMS notes it will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services.

Proposed 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). A PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering fewer than 24-hour daily care, in a location other than an individual's home or inpatient or residential setting.

In the Proposed Rule, CMS outlines various changes, several related the impact of COVID-19 on the best available data, that were made to develop the proposed PHP APC geometric mean per diem costs. The proposed CY 2023 PHP geometric mean per diem costs are shown in Table 45 of the Proposed Rule (pg. 396) and are used to derive the proposed CY 2023 PHP APC per diem rates for CMHCs and hospital-based PHPs.

In addition, CMS addresses outpatient non-PHP mental health services furnished remotely to partial hospitalization patients after the COVID-19 PHE. For the duration of the PHE, hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling and educational services (including certain PHP services) incident to a physician's services to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of

participation and provider-based rules to the extent not waived. Also, such services can be furnished using telecommunication services to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. While CMS proposes that payment is made under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital, CMS makes clear it is not proposing to recognize these proposed OPPS remote services as PHP services. CMS clarifies that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital if that proposal is finalized.

In the Proposed Rule, CMS also provides a Request for Information (RFI) regarding remote PHP services furnished by hospital outpatient departments and CMHCs during the COVID-19 PHE (pgs. 401-404 of the Proposed Rule).

Proposed 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. CMS uses five specific criteria for assessing procedures for removal from the IPO list.[3]

Using the five criteria, for CY 2023, CMS proposes to remove 10 services[4] from the IPO list. In addition, CMS proposes to add eight services that were newly created by the American Medical Association CPT Panel to the IPO list. Table 46 of the Proposed Rule (pg. 414) also lists these services, along with their proposed status indicator and proposed APC assignment.

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

The Medicare statute specifies the payment amounts and circumstances under which Medicare reimburses for a discrete set of Medicare telehealth services. Generally, the Medicare statute limits both the types of health care providers who can provide telehealth services and the originating sites to medical care settings in rural areas. During the PHE, CMS relaxed these requirements to expand access to telehealth services by reconsidering the types of practitioners who may furnish services, the geographic and originating site restrictions and permitting certain telehealth services to be furnished via audio-only communication. However, for services that are not paid under the PFS, there is no statutory provision that addresses payment for services furnished by hospitals to

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

[4] The 10 services CMS proposes to remove are: CPT code 16036 (Escharotomy; each additional incision (list separately in addition to code for primary procedure)); CPT code 22632 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)); CPT code 21141 (Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft); CPT code 21142 (Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft); CPT code 21143 (Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft); CPT code 21194 (Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)); CPT code 21196 (Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation); CPT code 21347 (Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches); CPT code 21366 (Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)); and CPT code 21422 (Open treatment of palatal or maxillary fracture (lefort i type);)

beneficiaries who are not physically located in the hospital. CMS does have a history, before the PHE, of paying for certain services that do not require the beneficiary's physical presence in the hospital.

The Consolidated Appropriation Act, 2021 (CAA, 2021) made permanent several of telehealth flexibilities after the PHE for mental health services. The CY 2022 PFS final rule implemented the section of the CAA, 2021 regarding mental health telehealth services. Often, hospitals provide outpatient mental health services that are furnished by a hospital-employed counselor or other licensed professionals (e.g. marriage and family therapists or licensed professional counselors), but the Medicare statute does not have a benefit category that allows these professionals to bill independently for their services.

However, these services can be covered when furnished by providers such as hospitals and paid under the OPPS. During the PHE, CMS permitted the beneficiary's home and any other temporary expansion location operated by the hospital during the PHE to be a provider-based department (PBD) of the hospital, so long as the Conditions of Participation (CoP) are met (to the extent the CoPs are not waived). In addition, in May 2020, CMS made clear that when a hospital's clinical staff is furnishing hospital outpatient mental health services, education, and training services to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, the agency considers regulatory requirements related to incident-to services as being met.

Unless regulatory changes are made, CMS acknowledges that after the PHE ends, the beneficiary would need to physically travel to the hospital to continue receiving these outpatient hospital services from hospital clinical staff. To promote access to care and prevent disruptions, for CY 2023, CMS proposes to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services that are among the "covered OPD services". To implement this policy, CMS also proposes OPPS-specific coding to describe these services. The proposed code descriptors specify that the beneficiary must be in their home and that there is no associated professional service billed under the PFS. CMS also proposes that the hospital clinical staff be physically located in the hospital outpatient department when furnishing services remotely using communications technology, and that staff be licensed to furnish the services in accordance with applicable state law.

CMS seeks comment on whether requiring the hospital clinical staff to be located in the hospital when furnishing the mental health service remotely to the beneficiary in their home would be overly burdensome or disruptive to existing models of care delivery developed during the PHE, and whether CMS should revise the regulatory text in the provisions cited above to remove references to the practitioner being "in" the hospital outpatient department.

In addition, CMS proposes to assign HCPCS codes[5] to APCs based on the PFS facility payment rates for CPT codes 96159 (Health behavior intervention, individual, face-to-face; each additional 15

[5] HCPCS codes are: CXX78: Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service; CXX79: Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service; and CXX80: Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely

minutes (List separately in addition to code for primary service)) and 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes), respectively. Table 48 of the Proposed Rule (pg.425-426) provides the proposed status indicator (SI), APC assignment and geometric mean cost for the proposed HCPCS codes. CMS seeks comment on the designation of mental health services furnished remotely to beneficiaries in their homes as covered OPD services payable under the OPPS, and on these proposed codes, descriptors, HCPCS codes and PFS facility rates as proxies for hospital costs, and the proposed APC assignments for the proposed codes.

Periodic In-Person Visits

The CAA, 2021 prohibits payment for a Medicare mental health telehealth service furnished in the patient's home unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within six months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as CMS determines appropriate (PFS CY 2022 provided timing of within 12 months of each mental health telehealth service, with limited exceptions). To maintain consistency, CMS proposes similar requirements when RHCs and FQHCs furnish telehealth services, including any exceptions. Notably, the Consolidated Appropriations Act, 2022, delayed the 6-month in-person visit requirement, as a result, CMS proposes a similar delay for RHCs and FQHCs.

Audio-only Communication Technology

For purposes of telehealth services, the term "telecommunications system" which is used in statute regarding telehealth services, is further defined by CMS via regulation. During the PHE, CMS used waiver authority to permit certain services to be furnished using audio-only communications technology if certain requirements are met, such as the patient not being capable of using telecommunications technology that includes audio and video or the patient did not consent to such use. Similarly, CMS proposes that hospital clinical staff must have the capability to furnish two-way, audio/video services, but may use audio-only communications technology given an individual patient's technological limitations, abilities, or preferences.

Comment Solicitation on Intensive Outpatient Mental Health Treatment, including Substance Use Disorder (SUD) Treatment Furnished by Intensive Outpatient Programs (IOPs)

In the Proposed Rule, CMS notes that there are a range of services that can be described by existing coding under the PFS and OPPS that can be billed for treatment of mental health conditions. In the CY 2020 PFS final rule, CMS provided coverage for bundled payments for episodes of care for the treatment of opioid use disorder (OUD) furnished by opioid treatment program (OTPs). PHPs are structured to provide intensive psychiatric care through active treatment using a combination of clinically recognized items and services, such that PHPs closely resemble a structured, short-term hospital inpatient program and are a level more intensive than outpatient day treatment. CMS notes that in some cases, people who do not require a level of care for PHP services may require intensive services on an outpatient basis. As such, CMS seeks comments on whether there are gaps in existing CPT codes paid under OPPS that may be limiting access to needed levels of care for treatment of mental health disorders or substance use disorders (SUDs). CMS is also interested in additional information about intensive outpatient program (IOP) services, such as the range of services typically offered and setting of care.

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by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service).

Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology

In the Proposed Rule, CMS outlines various policy updates regarding direct supervision of certain cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) services by interactive communications technology that were provided in the CY 2022 Physician Fee Schedule Final Rule. In the Proposed Rule, CMS clarifies that these services will not be able to be furnished as Medicare telehealth services to beneficiaries in their homes after the PHE ends due to statutory requirements related to originating sites. However, these services do appear on the Medicare Telehealth Services List through the end of CY 2023. As a result, payment for these services will continue until the end of CY 2023, so long as the geographic and originating site requirements are met. To implement a similar policy under OPPS to beneficiaries in hospitals, CMS seeks comment on whether to continue to allow direct physician supervision for these services to include presence of the supervising practitioner physician via two-way, audio/video communication technology through the end of CY 2023. CMS also seeks 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.

Use of Claims Data for CY 2023 OPPS and ASC Payment System Ratesetting Due to the PHE

When updating the OPPS payment rates and system for each rulemaking cycle, CMS primarily uses outpatient Medicare claims data (Outpatient Standard Analytic File) and Healthcare Cost Report Information System (HCRIS) cost report data. Ordinarily, the best available claims data are the data from 2 years prior to the calendar year that is the subject of rulemaking. In the Proposed Rule, CMS describes several factors and the analysis it considered to determine which data would be the best available data for purposes of CY 2023 ratesetting. Based on this information, CMS proposes to use cost report data for the Proposed Rule from the same set of cost reports CMS originally used in the CY 2021 OPPS/ASC final rule for ratesetting, which in most cases included cost reporting periods beginning in CY 2018.

CMS notes it is also considering using the most updated claims and cost report data available. To facilitate comment on this alternative option, CMS makes available the cost statistics and addenda utilizing the CY 2021 claims and updated cost report data that CMS would ordinarily have provided in conjunction with the CY 2023 OPPS/ASC proposed rule. CMS notes that the primary change associated with the alternative proposed methodology would be in the scaled weights, which are displayed in the addenda on the CMS website.

Proposed Update to the Ambulatory Surgical Center (ASC) Payment System

Using the hospital market-basket methodology, for CY 2023, CMS is proposing to increase payment rates under the ASC payment system by 2.7 percent for ASCs that meet the ASC quality reporting program requirements. This proposed increase is based on the hospital market-basket percentage increase of 3.1 percent, minus a productivity adjustment of 0.4 percentage points. Based on various proposals, CMS estimates that total payments to ASCs would increase by approximately $130 million compared to CY 2022. For CY 2023, the proposed updated ASC payment rates for covered surgical procedures and covered ancillary services are available on the CMS website.

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 2023, CMS proposes to apply a 0.4 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs not meeting ASCQR requirements. Table 71 of the Proposed Rule (pg. 601) provides the proposed ASCQR program measure set for the CY 2025 reporting period/2027 payment determination and subsequent years.

CMS also requests comments on a range of topics for future consideration, such as a potential future specialty centered approach for the ASCQR program and potential reimplementation of ASC facility volume data on selected ASC surgical procedure measures, or another volume indicator.

Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

Prior to the PHE, only physicians were permitted to supervise the performance of diagnostic tests (e.g., diagnostic x-ray tests, diagnostic laboratory tests) and payment was made under the PFS. During the PHE, CMS has allowed certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwifes, certified registered nurse anesthetists) to supervise the performance of diagnostic tests to the extent they were authorized to do so under their scope of practice and applicable State law. Regarding diagnostic services furnished to outpatients, CMS proposes to revise existing supervision requirements to extend this flexibility that has been provided during the PHE, such that nonphysician practitioners may provide general, direct and personal supervision of outpatient diagnostic services furnished to the extent they are authorized to do so under their scope of practice and applicable State law. CMS proposes similar changes regarding supervision requirements for therapeutic outpatient hospital and CAH services, which also rely on definitions of general and personal supervision.

OPPS Payment for Software as a Service

In the Proposed Rule, CMS notes that new clinical software (e.g., clinical decision support software, clinical risk modeling, and computer aided detection) are increasingly available to providers and that providers typically pay to use such software either as a subscription or on a per-use basis (Software as a Service (SaaS)). For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the main diagnostic/image procedure (i.e., the primary service). In other circumstances, more recently, CMS has begun paying for other SaaS procedures.

Also, CMS notes that the AMA has established several codes that describe SaaS procedures using two codes: a primary code that describes the standalone clinical software service and an add-on code that describes a clinical software service that is adjunctive to and billed concurrent with a diagnostic imaging service. However, CMS raises concerns with the definition of the add-on costs and, for CY 2023, proposes not to recognize certain CPT add-on codes that describe SaaS procedures under the OPPS. Instead, CMS proposes to establish HCPCS codes (C-codes) to describe the add-on codes as standalone services that would be billed with the associated imaging service.

CMS proposes that the C-code be assigned to identical APCs and have the same status indicator assignments[6] as their standalone codes. Proposed payment rates for newly established C codes can be found in Addendum B on the CMS website.

Lastly, CMS requests comments on a payment approach that would broadly apply to SaaS procedures, such as how to identify services that should be separately recognized from the underlying imaging test to the professional service and how to identify costs associated with these

[6] The status indicator (SI) under the OPPS identifies which services will or will not be paid under OPPS.

kinds of services, among other questions. CMS also requests feedback on alternative payment approaches (e.g., expanding composite APCs or assigning a code that describes combined services to the New Technology APC). In addition, CMS seeks comment on how it could encourage software developers and other vendors to prevent and mitigate bias in their algorithms and predictive modeling.

Proposed Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators

CMS notes that in the FY 2023 IPPS proposed rule, the agency requested public comment on potential IPPS and OPPS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators. In the Proposed Rule, CMS proposes a payment adjustment under the OPPS and IPPS for additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. Under the IPPS, CMS proposes to make the payment adjustment using its exceptions authority. But for the OPPS, CMS proposes to make the payment adjustment in a budget neutral manner.

For purposes of this policy, CMS proposes to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: 1) Domestic NIOSH-approved surgical N95 respirators; and 2) Non-domestic NIOSH-approved surgical N95 respirators. CMS proposes to rely on the Berry Amendment[7] to define a NIOSH-approved surgical N95 respirator as domestic if the respirator and all of its components are grown, reprocessed, reused, or produced in the United States. For purposes of this policy, all other NIOSH-approved surgical N95 respirators would be non-domestic.

Recognizing that hospitals cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases meets the definition of domestic, CMS proposes that a hospital may rely on a written statement[8] from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under the agency's proposed definition. Also, CMS clarifies the written statement, or a copy of the statement, could be obtained by the hospital directly from the manufacturer, obtained through the supplier or Group Purchasing Organization (GPO), or obtained by the hospital because it was included with or printed on the packaging by the manufacturer.

Regarding the payment adjustment, CMS proposes to initially base the payment adjustments on the IPPS and OPPS shares of the estimated difference in the reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators. These payments would be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. Any provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period; however, the payment amounts would be determined by the Medicare Administrative Contractor (MAC).

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[7] The Berry Amendment is a statutory requirement that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States. Berry Amendment restrictions are implemented by the DoD Federal Acquisition Regulation Supplement (DFARS) 252.225-7002, and State DOD cannot acquire specified "items, either as end products or components, unless the items have been grown, reprocessed, reused, or produced in the United States."

[8] CMS provides that the written statement must have been certified by one of the following: (i) the manufacturer's Chief Executive Officer (CEO); (ii) the manufacturer's Chief Operating Officer (COO); or (iii) an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. CMS also indicates that the written statement may be required to substantiate data included in the supplemental cost report.

To facilitate this process, CMS also provides that an N95 supplemental cost reporting form, in addition to the cost report, will be used by MACs to determine the lump sum payment. As a result, Medicare would make payments for the estimated cost differential, specific to each hospital, as noted above. CMS provides that as it gains more experience with this policy, it may revisit the approach of payments based on the reasonable cost of each hospital.

In the Proposed Rule, CMS further details a proposed five-step process to calculate the OPPS and IPPS payment adjustments on the cost report. Also, Table 50 of the Proposed Rule (pgs. 472-473) is a mock N95 supplemental cost reporting form, which helps clarify the additional data that CMS anticipates the hospital would report.

CMS notes that, for budget neutrality purposes, it is hard to estimate the percentage of domestically manufactured NIOSH-approved surgical N95 respirators that will be used in the treatment of OPPS patients in CY 2023. As a result, considering the supply of products the meet the definition of domestic NIOSH-approved surgical N95 respirators, CMS anticipates that 40 percent of respirators used in the treatment of OPPS patients in CY 2023 will be impacted by this policy. In estimating the cost of the policy, CMS includes a value of $0.20 for each claim, with a total cost of $8.3 million (103.4 million claims * $0.20 * 40 percent). CMS notes that in future years, it may refine this approach or expand this policy to other forms of personal protective equipment used in a PHE, such as elastomeric respirators, surgical/procedural masks, gloves and medical gowns.

Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the Hospital Inpatient Quality Reporting (IQR) Program. CMS proposes that the reduced conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program is $85.093, whereas the proposed whole conversion factor is $86.785.

In the Proposed Rule, CMS considers modifications to previously adopted measures. Specifically, CMS proposes to change the Cataracts: Improvement in Patient's Visual Function within 90 Days following Cataract Surgery (OP-31) measure from mandatory to voluntary beginning with the CY 2027 payment determination. CMS indicates that this shift is in response to stakeholder concerns that the reporting requirement for this measure would be burdensome due to COVID-19 related changes, such as changes in patient case volume and national staffing and medical supply shortages. CMS clarifies that while a hospital would not be subject to a payment reduction for failing to support this measure, the agency encourages hospitals to gain experience with the measure as the agency plans to continue to evaluate this policy moving forward. Table 62 of the Proposed Rule (pg. 568) lists the hospital OQR program measure set, including policies provided in the Proposed Rule, for the CY 2025 payment determination.

Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) Measure or Adoptions of Another Volume Indicator

In the Proposed Rule, CMS provides an overview of research which indicates the volume in outpatient departments is expected to grow significantly in the coming years. Also, CMS notes that the Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did previously (i.e., Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure (OP–26) beginning with the CY 2012 reporting period/CY 2014 payment determination). However, in the CY 2018 OPPS final rule, CMS removed this measure based on the belief that there is a lack of evidence to support the measure's link to improved clinical quality. However, CMS notes that it is considering reimplementing OP-26 or another volume measure because of the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures. CMS welcomes comments on the potential future inclusion of the OP-26 measure and information regarding what volume data

hospitals currently collect, and if it is feasible to submit this data to the Hospital OQR Program to minimize potential reporting burden. Also, CMS seeks information regarding the usefulness of including a volume indicator in the Hospital OQR Program measure set and publicly reporting volume data. Also, CMS welcomes insights regarding the design of a volume indicator and potential reporting by volume type.

Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

Consistent with the CY 2023 IPPS Proposed Rule, CMS provides an RFI regarding key considerations that CMS should take into account across all CMS quality programs, including the Hospital OQR Program, when advancing the use of measure stratification to address healthcare disparities and advance health equity. CMS encourages stakeholders to review the CY 2023 IPPS Proposed Rule for additional information and welcomes feedback on the application of those principles to the hospital OQR program. A Vizient-prepared summary of the RFI, as shown in the FY 2023 IPPS proposed rule, is available here (pg. 26).

Proposal to Align Hospital OQR Program Patient Encounter Quarters for Chart-abstracted Measures to the Calendar Year for Annual Payment Update (APU) Determinations

In the Proposed Rule, CMS notes that as finalized in the CY 2016 OPPS final rule, the patient encounter quarters for chart-abstracted measures data submitted to the Hospital OQR Program are not aligned with the January through December calendar year. Since these quarters are not aligned with the calendar year, CMS understands that this misalignment has resulted in confusion among some hospitals regarding submission deadlines and data reporting quarters. Beginning with the CY 2024 reporting period/CY 2026 payment determination, CMS proposes to align the patient encounter quarters for chart-abstracted measures with the calendar year. If finalized, CMS clarifies all four quarters of patient encounter data for chart-abstracted measures would be based on the calendar year two years prior to the payment determination year. To facilitate this transition, CMS proposes new timeframes for the CY 2025 and 2026 payment determinations and subsequent years. Notably, for the proposed CY 2025 payment transition period, only quarters 2-4 of data for chart-abstracted measures would be used. CMS seeks comments on this proposal.

Rural Emergency Hospitals (REHs)

In the Consolidated Appropriations Act (CAA), 2021, Congress established a new Medicare provider type: Rural Emergency Hospitals (REHs). REHs will furnish emergency department and observation care and may provide other specified outpatient medical and health services under certain circumstances. Hospitals may convert to REHs if they were CAHs or rural hospitals with not more than 50 beds participating in Medicare as of the date of enactment of the CAA. Also, REHs must meet several other statutory requirements, such as having an annual per patient average of 24 hours or fewer in the REH and meeting certain conditions of participation and staffing and certification requirements. Starting January 1, 2023, an REH that provides rural emergency hospital services will be eligible for Medicare payment that is equal to the OPPS rate plus 5 percent. The beneficiary co-payments for these services will be calculated the same way as under the OPPS for the service, excluding the 5 percent payment increase.

Also, REHs are to receive a monthly facility payment from the Federal Hospital Insurance Trust Fund. In the Proposed Rule, for CY 2023, CMS details the methodology it will apply and finds that the monthly facility payment for REHs would be $268,294. CMS also provides that for 2024 and subsequent years, the monthly facility payment will be the amount of the monthly facility payment for the previous year increased by the hospital market basket percentage increase. CMS welcomes comment regarding its methodology to calculate the monthly REH facility payment for CY 2023.

In the Proposed Rule, CMS proposes to further define “REH services” (it is defined in statute) such that all services paid under the OPPS when furnished in an OPPS hospital (except for acute inpatient services) would be REH services when furnished in an REH. CMS seeks comment regarding whether it should adopt a narrower definition of REH services. Also, in the proposed rule, CMS further clarifies payment policy regarding ambulance services and post-hospital extended care services that are furnished by an REH.

Also, CMS proposes that site neutral payment requirements would not apply for off-campus PBDs of an REH. In the Proposed Rule, CMS further details its thinking on this issue, including that the alternative option of imposing a site neural payment policy appears to be contrary to Congressional intent for creating the new provider type. CMS welcomes comment on the issue.

In a separate proposed rule, CMS proposed Conditions of Participation (CoPs) for REHs. CMS clarifies that all of the final health and safety, payment, quality measures, and enrollment policies will be published in the CY 2023 OPPS/ASC final rule with comment period.

Regarding REH provider enrollment, in the Proposed Rule, CMS addresses the requirements that providers and suppliers must meet to maintain Medicare billing privileges. REHs must enroll in Medicare using Form CMS 855A, but the REH would not have to pay an application fee since CMS views the enrollment as a conversion from a CAH or hospital to an REH, and not an initial enrollment. CMS notes that this conversion is unique to REHs, since other enrollment policies require that existing enrollment be terminated, and enrollment occurs as a new provider or supplier type.

CMS requests information regarding the potential need for REHs to notify beneficiaries of their status as outpatient, the implications of such status and whether the Medicare Outpatient Observation Notice (MOON) would be the appropriate notice for communicating this information.

Notably, in the Proposed Rule, CMS also addresses application of the physician self-referral law to rural emergency hospitals. For example, CMS clarifies that once an entity is enrolled in Medicare as an REH, the physician self-referral law would prohibit a physician from making a referral for designated health services to the REH if the physician (or immediate family member of the physician) has a financial relationship with the REH, unless an exception to the law’s referral and bulling prohibitions applies and all its requirements are satisfied. However, CMS doses propose an REH exception and related definition and examples for purposes of the physician self-referral law and welcomes comments.

Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

The CAA, 2021, effectively requires CMS to establish quality measurement reporting requirements for REHs, which must submit quality measure data that will be made public.

In the Proposed Rule, CMS aims to establish the REHQR Program but does note some potential barriers, such as uncertainty regarding how many hospitals, particularly CAHs, would be likely to convert to REH status. As a result, the agency has various measurement concerns related to a potentially low volume of REHs and welcomes comment on recommendations for addressing these low volume issues for performance measurement of rural providers.

In the Proposed Rule, CMS provides a request for comment on potential measures for an REHQR program. CMS notes that it considered reporting requirements from other quality programs and recommendations from the National Advisory Committee on Rural Health and Human Services, among other sources, when proposing measures for the REHQR Program. CMS seeks comment regarding the following measures as the agency selects REHQR measures that focus on REH areas of care, especially emergency department care: OP-2: Fibrinolytic Therapy Received Within

30 Minutes of ED Arrival; OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention; OP-4: Aspirin on Arrival; OP-18: Median Time from ED Arrival to ED departure for Discharged ED Patients; OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and OP-22: Left Without Being Seen. In addition, the National Advisory Committee on Rural Health and Human Services also recommended the Medicare Beneficiary Quality Improvement Project (MBQIP) measure, which is a quality improvement activity under the Medicare Rural Hospital Flexibility program, and the Emergency Department Transfer Communications (EDTC) measure. CMS welcomes comment on these measures.

Also, CMS requests feedback on the following claims-based hospital OQR quality measures for potential application to REHs: OP-10: Abdomen Computed Tomography (CT) - Use of Contrast Material and OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. CMS also welcomes comments on potential other topics that may be applicable to an REH quality reporting program, including telehealth, maternal health, mental health, emergency department services and health equity. Finally, CMS also proposes a policy regarding administrative requirements for quality reporting and registration on QualityNet and Security Official.

Organ Acquisition Payment Policy

In the Proposed Rule, CMS notes that the Medicare program supports organ transplantation by, among other factors, providing payment under reasonable cost to account for patient differences and to ensure providers are paid appropriately for their share of organ acquisition costs. For example, Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant, and separately reimburses transplant hospitals (THs) for their organ acquisition costs under reasonable cost principles based on the TH's ratio of Medicare usable organs to total usable organs. Also, Medicare authorizes payment to designated independent organ procurement organizations (IOPOs) for kidney acquisition costs, under reasonable cost principles based on the IOPOs ration of Medicare usable kidneys to total usable kidneys. THs and IOPOs annually complete a Medicare cost report.

In the FY 2022 IPPS proposed rule, CMS proposed to change the counting policy for Medicare usable organs for purposes of calculating Medicare's share of organ acquisition costs. Specifically, CMS proposed to count only organs transplanted into Medicare beneficiaries such that Medicare would not share in the costs to procure organs used for research, and the agency proposed to require donor community hospitals to bill organ procurement organizations (OPOs) their customary charges reduced to costs for services provided to deceased organ donors. However, in the FY 2022 IPPS final rule, CMS did not finalize several of these proposals, including how Medicare usable organs would be counted and the counting of organs for research purposes.

As provided in the FY 2022 IPPS final rule, CMS indicated that for Medicare payment purposes, Medicare generally does not include the costs to procure an organ for research in Medicare's share of organ acquisition costs. However, CMS did not finalize a proposal regarding how OPOs and THs count certain organs that are eventually donated for research. In this year's Proposed Rule, CMS proposes to require that THs and OPOs exclude organs used for research from the numerator (Medicare usable organs) and the denominator (total usable organs) of the calculation used to determine Medicare's share of organ acquisition costs on the Medicare cost report.

In addition, regarding deceased donors, CMS proposes that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors. Under this proposal, hospitals would bill the OPO for certain services (e.g., evaluating an organ for transplant viability and preparing the donor for donation), and the OPO would record those billed amounts as organ acquisition costs on its Medicare cost report. CMS clarifies that the donor patient's health insurance

would not be billed for the organ acquisition costs, and the patient or patient's family would not be responsible for those amounts.

Lastly, CMS provides an RFI on an alternative methodology to counting organs for Medicare's share of organ acquisition costs. For example, under the alternative methodology, TH/HOPOs would include as Medicare usable organs only organs transplanted within their TH into Medicare beneficiaries. Under this circumstance, CMS would exclude organs that a TH furnishes to other THs or OPOs from its Medicare share fraction, in both the numerator (Medicare usable organs) and denominator (total usable organs) and require revenue offsets against total organ acquisition costs for these organs. CMS indicates the alternative methodology would not require TH/HOPOs to track organs they furnish to other THs and OPOs. Also, for OPOs, CMS is considering counting all organs and calculating Medicare's share of organ acquisition costs using a ratio of Medicare usable organs to total usable organs. OPOs would include in Medicare usable organs only organs transplanted into Medicare beneficiaries, using recipient payor data provided to OPOs by the Organ Procurement Transplantation Network (OPTN). Under such a methodology, OPOs would need to offset total organ acquisition costs with revenue received for Medicare usable organs. CMS clarifies that IOPOs would not be required to track organs they furnish to other OPOs or THs to determine whether the organ recipient is a Medicare beneficiary.

CMS anticipates such a methodology would result in an apportionment of costs and redistribution of reasonable organ acquisition costs to only organs transplanted into Medicare beneficiaries. CMS seeks additional information, including other payers' practices for organ transplants, IOPO kidney standard acquisition charges, the role of clinical decision-making for organ allocation and transplantation and the extent to which THs, OPOs, and other interested parties would be impacted under these alternative organ counting methodologies.

Request for Information on Use of CMS Data to Drive Competition in Healthcare Marketplaces

In the Proposed Rule, CMS provides an overview of recent actions, such as Executive Orders, that aim to promote competition in the American economy. Also, CMS references a 2018 Medicare Payment and Advisory Commission report that noted, "Because the literature is mixed, we cannot make a definitive conclusion about the effect of mergers on the quality of care other than to say the effect is not large enough to result in consistent findings across studies." In addition, CMS notes that it is publicly releasing data files outlining hospital and nursing facilities' mergers, acquisitions, consolidations, and changes in ownership that were reported to the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) from 2016 to 2022, to promote transparency of these mergers, acquisitions, consolidations, and changes in ownership.

CMS notes that it is now seeking information from the public on how various data sources that CMS collects could be used to promote competition across the health care system or protect the public from harmful effects of consolidation within healthcare.

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

In the CY 2020 OPPS final rule, CS established a prior authorization process for certain hospital OPD services. In the CY 2021 OPPS final rule, CMS added additional service categories to the prior authorization process. In the Proposed Rule, CMS proposes to require prior authorization for a new service category (Facet Joint Intervention), which CMS proposes would be effective for dates of service on or after March 1, 2023. The list of the additional services in the Facet Joint Interventions service category impacted by the proposal are found in Table 79 of the Proposed Rule (pg. 779).

In the Proposed Rule, CMS also outlines the basis for this proposal, including the agency's responsibility to protect the Medicare Trust Fund, the review of approximately 1 billion claims, including increased rates of claims submitted, and an HHS Office of the Inspector General (OIG) report that indicate questionable billing practices, improper Medicare payments, and questionable utilization of facet joint interventions. As such, CMS believes prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expects that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. CMS requests comments on the addition of this service category, including any unintended clinical consequences from the addition of this service category.

Overall Hospital Quality Star Rating

As outlined by CMS, the Overall Hospital Quality Star Ratings provide a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars. The Overall Hospital Quality Star Rating was first introduced and reported on the agency's Hospital Compare Website in July 2016 and has been refreshed multiple times. In the Proposed Rule, CMS provides that the most recent refresh is planned for July 2022 and the methodology was most recently updated in the CY 2021 OPPS final rule, which, among other changes, provided a policy to include Veterans Health Administration (VHA) hospitals' quality measure data in the Overall Hospital Quality Star Ratings beginning with the 2023 refresh. On July 27, 2022, CMS updated the Overall Hospital Quality Star Ratings.

VHA Hospitals

In the Proposed Rule, CMS indicates that since the CY 2021 final rule's publication, the agency conducted an internal analysis from February 28, 2022, through March 30, 2022, with measure data from all VHA hospitals in the calculation of the Overall Hospital Quality Star Ratings methodology. Using this information, CMS compared 2021 Overall Hospital Quality Star Ratings scores for non-VHA hospitals before and after adding VHA hospitals to Overall Hospital Quality Star Ratings and 119 out of 171 VHA hospitals met the requirements to receive a Star Rating. As a result, the total number of hospitals receiving a star rating increased to 3,474. The distribution of Star Ratings was nearly identical for VHA and non-VHA hospitals and CMS indicates peer group assignments were similar across VHA and non-VHA hospitals. Based on this analysis, CMS found that 3,119 (93 percent) non-VHA hospitals maintained the same number of stars after adding VHA hospitals to 2021 Overall Hospital Quality Star Rating, and for the 236 non-VHA hospitals with a different star rating, 23 gained a star and 213 lost a star. CMS notes that as previously finalized, the agency intends to include VHA hospitals in future Overall Hospital Quality Star Ratings.[9]

Frequency of Publication and Data Used

In the CY 2021 OPPS final rule with comment period, CMS stated that "we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior year" to refresh Overall Hospital Quality Star Ratings. Since finalizing this policy, CMS heard stakeholder feedback that the language, as finalized, is confusing.

In the Proposed Rule, CMS proposes to amend its policy to clarify the data periods that may be used to refresh the Overall Hospital Quality Star Ratings. Specifically, CMS proposes to state, "The Overall Star Rating are published once annually using data publicly reported on Hospital Compare

[9] Information regarding the July 2022 Care Compare release is available at: https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/resources#tab3, last accessed August 1, 2022.

or its successor website from a quarter within the previous 12 months." Also, In the Proposed Rule, CMS provides an example for the July 2024 Overall Hospital Star Ratings, where any Care Compare refreshes from the previous 12 months would be used (i.e., July 2023, April 2023, January 2022, October 2022 or July 2022). CMS welcomes comments on this proposal.

Overall Hospital Quality Star Ratings Suppression

In the Proposed Rule, CMS notes that the Overall Hospital Quality Star Ratings aggregate performance on underlying measures adopted under certain CMS quality programs, so any changes or updates to the measures from those programs are already included. CMS recognizes that there may be concerns with publishing the Overall Hospital Quality Star Ratings if the underlying measure reflects some aspect of extenuating circumstances (e.g., skewed performance related to treating patients with COVID-19). Yet, CMS also indicates it wants to provide quality information to Medicare beneficiaries and the public.

Regarding refreshes, CMS notes that the Overall Hospital Star Ratings will have been refreshed twice since the emergence of COVID-19 and almost all measures included in those refreshes used pre-COVID-19 data to calculate 2021 and 2022 Overall Star Ratings, as CMS's Extraordinary Circumstance Exception (ECE) for hospitals and other facilities was applicable to CMS quality reporting and value-based purchasing programs during the COVID-19 PHE.[10] However, CMS notes that even if measures were suppressed, if the measure is considered valid and reliable enough to be reported on Care Compare then it meets the criteria to be included in the Overall Hospital Quality Star Ratings calculations.

In the CY 2021 OPPS final rule, CMS finalized a policy that the agency would consider suppressing the Overall Star rating only under extenuating circumstances that affect numerous hospitals as determined by CMS or certain other circumstances, including a public health emergency that substantially affects the underlying measure data. CMS notes that while it intends to publish the Overall Hospital Quality Star Ratings in 2023, the agency may exercise its authority should the COVID-19 PHE substantially affect the underlying measure data.

What's Next?

The OPPS tables for this CY 2023 Proposed Rule are available on the CMS website. CMS is anticipated to publish the final OPPS regulation around early November and the changes are effective January 1, 2023 (CY 2023). The comment period closes on September 13, 2022.

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, Associate Vice President, Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.

[10] Among other changes, the ECE exempted data reporting requirements for Q1 and Q2 2020 data. Any subsequent measure data collected from these programs would be incorporated into the Overall Hospital Quality Star Ratings, even if measurement periods are partially or fully concurrent with the PHE.