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Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction (CMS-1786-P)

July 28, 2023

Background & Summary

On July 13, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2024 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 (OPDs) or receive care at ambulatory surgical centers (ASCs). This summary focuses primarily on policies related to hospital OPDs.

The Proposed Rule also updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital (REH) Quality Reporting (REHQR) Program. Additionally, the agency provides insights regarding reimbursement for medications acquired through the 340B program, seeks information regarding additional payment for providers access to buffer inventories of essential medicines and implements several policies related to mental health, including access to intensive outpatient services. CMS also proposes to except biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid and proposes several changes related to hospital price transparency requirements.

Comments are due **September 11, 2023**, and the final rule is expected to be released by early November. Most provisions will go into effect January 1, 2024. Vizient looks forward to working with members to help inform our letter to the agency.

OPPS Payment Update

For CY 2024, CMS proposes to apply an outpatient department (OPD) fee schedule increase factor of 2.8 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 0.8 percent. The proposed increase factor of 2.8 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 productivity adjustment of 0.2 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 2024 OPPS conversion factor. As a result, all budget neutrality changes combined with the market basket update are reflected in Column 4 of Table 1 below. Also, column 5 shows the additional adjustments to the conversion factor resulting

from a change in the pass-through estimate[1] and adding estimated outlier payments as compared to CY 2023.

CMS estimates that based on changes for budget neutrality, both urban and rural hospitals would experience an increase (approximately 2.8 percent for urban hospitals and 4.4 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 3.0 percent and major teaching hospitals would experience an increase of 2.4 percent.

CMS estimates that, for CY 2024, the cumulative effect of all proposed changes will increase payments by 3.0 percent for all providers and 2.9 percent for all hospitals. Also, CMS proposes a CY 2024 conversion factor (CF) of $87.488 for hospitals that meet the Hospital Outpatient Quality Reporting (OQR) Program requirements.

CMS estimates total payments to OPPS providers for CY 2024 would be approximately $88.6 billion, which is an increase of approximately $6 billion, compared to CY 2023 OPPS payments.

Table 1. Estimated Impact of the Proposed CY 2024 Changes for the Hospital OPPS

	Number of Hospitals (1)	Proposed Ambulatory Payment Classification Recalibration Changes (2)	New Wage Index and Provider Adjustments (3)**	All budget neutral changes (combined cols 2-3) with Market Basket Update (4)***	All Proposed Changes (5)
All providers	3567	0.0	0.1	2.9	2.9
All hospitals*	3472	0.1	0.2	3.0	3.0
Urban hospitals	2761	0.0	0.0	2.8	2.8
Rural hospitals	711	0.4	1.4	4.7	4.4
Non-teaching status hospitals	2186	0.4	0.4	3.6	3.5
Minor teaching status hospitals	872	0.1	0.3	3.2	3.0
Major teaching status hospitals	414	-0.3	-0.2	2.2	2.4

*Excludes hospitals held harmless and Community Mental Health Centers
**In previous years, Column 5 included the frontier adjustment. However, for the Proposed Rule, the frontier adjustment is included in Column 3
***Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.8 percent OPD fee schedule update factor (3.0 percent reduced by 0.2 percentage point for the productivity adjustment).

Proposed Updates Affecting OPPS Payments

Recalibration of Ambulatory Payments Classifications Relative Payment Weights

As least once annually, CMS must revise the relative payment weights for Ambulatory Payment Classifications (APCs) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Consistent with

[1] CMS estimates that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2024 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2024 would be approximately $234.1 million (approximately $134.1 million for device categories and approximately $100 million for drugs and biologicals) which represents 0.26 percent of total projected OPPS payments for CY 2024 (approximately $88.6 billion)

CY 2023, for CY 2024, CMS proposes to recalibrate the APC relative payment weights for each APC based on claims and cost report data for hospital OPD services to construct a database for calculating APC group weights. For CY 2024 APC recalibration, CMS started with claims for hospital OPD services furnished on or after January 1, 2022, and before January 1, 2023, and then applied methodological adjustments resulting in fewer claims being included in the APC recalibration process.

For CY 2024 APC recalibration, CMS proposes to continue to use the hospital-specific overall ancillary and departmental cost-to-charge (CCRs) to convert charges to estimated costs through the application of a revenue code-to-cost center crosswalk. For this step, CMS used CY 2022 claims data. To ensure completeness of the code-to-cost center crosswalk, CMS reviewed changes to the CY 2022 list of revenue cost and updates to the National Uniform Billing Committee (NUBC) 2022 Data Specifications Manual. Among other changes for CY 2024, CMS proposes to revise the revenue code-to-cost center crosswalk to better align with the NUBC definitions and to improve the accuracy of cost data for OPPS ratesetting with respect to chimeric antigen receptor therapy (CAR-T) administration services. More specifically regarding CAR-T administration, CMS proposes the following changes to the revenue code-to-cost center crosswalk and seeks comment on these proposals[2]:

- Revising revenue codes 0870 (Cell/Gene Therapy General Classification) and 0871 (Cell Collection) to be mapped to a primary cost center of 9000 (Clinic);
- Revising revenue codes 0872 (Specialized Biologic Processing and Storage - Prior to Transport) and 0873 (Storage and Processing After Receipt of Cells from Manufacturer) to be mapped to a primary cost center of 3350 (Hematology);
- Revising revenue codes 0874 (Infusion of Modified Cells) and 0875 (Injection of Modified Cells) to be mapped to a primary cost center of 6400 (Intravenous Therapy), and;
- Revising revenue codes 0891 (Special Processed Drugs - FDA Approved Cell Therapy) and 0892 (Special Processed Drugs - FDA Approved Gene Therapy) to be mapped to a primary cost center of 7300 (Drugs Charged to Patients).

Although CMS notes that some hospitals report nonstandard cost centers on cost report lines that do not correspond to the cost center number, the agency indicates that it will continue excluding the nonstandard cost centers reported in this way in the OPPS ratesetting database construction.

Proposed Calculation of Single Procedure APC Criteria-Based Costs

CMS has consistently made separate payment for certain products, such as blood and blood products and brachytherapy sources[3], through APCs rather than packaging payment for them into payment for procedures in which they are administered.

While CMS proposes to continue establishing payment rates for blood and blood products using its blood-specific CCR methodology, the agency does proposes changes related to brachytherapy. For example, CMS proposes to designate five brachytherapy APCs as Low Volume APCs to mitigate wide variation in payment rates. The proposed CY 2024 payment rates for brachytherapy sources

[2] In the Proposed Rule, CMS notes that after reviewing the impact of these crosswalk revisions on the proposed CY 2024 OPPS APC geometric mean costs, CMS only observed an increase in the geometric mean cost of CPT code 0540T (Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous) – from $148.31 to $294.17 for Proposed Rule – as a result of the revenue code for CPT code 0540T being assigned to a new cost center and the new corresponding cost-to-charge ratio.

[3] Statute requires CMS to create additional groups of covered OPD services that classify devices of brachytherapy – cancer treatment through solid source radioactive implants – consisting of a seed or seeds (or radioactive source) (“brachytherapy sources”) separately from other services or groups of services.

are included on Addendum B of the Proposed Rule and identified with status indicator "U". **Also, CMS invites recommendations for new codes to describe new brachytherapy sources which CMS may add on a quarterly basis.**

Comprehensive APCs (C-APCs) for CY 2024

CMS defines a C-APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under the agency's C-APC policy, a service described by a HCPCS code is assigned to a C-APC as the primacy service when the service has the OPPS status indicator "J1". With some exceptions[4], CMS will make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (collectively referred to as "adjunctive services") and representing components of a comprehensive service. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Addendum J of the Proposed Rule includes a list of CY 2024 C-APC payment policy exclusions, among other information. Table 1 (pg. 59) of the Proposed Rule lists the proposed C-APCs for CY 2024. The following two new C-APCs are proposed: C-APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures) and C-APC 5496 (Level 6 Intraocular Procedures).

Composite APCs

For CY 2008, CMS developed composite APCs to provide single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Under the OPPS, CMS has composite policies for mental health services and multiple imaging services.

For CY 2024, consistent with prior years, CMS proposes that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the per diem payment rate for three partial hospitalization program (PHP) services provided in a day by a hospital, those specified mental health services would be paid through APC 8010 (Mental Health Services Composite). In addition, CMS proposes to set the payment rate for composite APC 8010 at the same payment rate proposed for APC 5863 (a partial hospitalization per diem payment rate for three PHP services furnished in a day by a hospital). Notably, for CY 2024 CMS proposes APC 5864 which is for four hospital-based PHP services per day. **CMS seeks comment on whether it would be appropriate to use proposed APC 5864, which is for four hospital-based PHP services per day, as the daily mental health cap for composite APC 8010 (as opposed to APC 5863 which is for three services per day).**

For CY 2024, CMS proposes to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. Table 2 (pg. 66-70) of the Proposed Rule lists the proposed HCPCS codes

[4] Services excluded from the C-APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. A list of services excluded from the C-APC policy is included in Addendum J of the Proposed Rule. If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

that would be subject to the multiple imaging composite APC policy and approximate composite APC proposed geometric mean costs for CY 2024.

Proposed Changes to 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 2024, CMS examined the HCPCS code definitions (including CPT code descriptors) and hospital OPD billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. **While CMS does not propose changes to the overall packaging policy, the agency seeks comment on potential modifications to the packaging policy for certain non-opioid treatments for pain relief and diagnostic radiopharmaceuticals.**

Non-Opioid Treatments for Pain Relief

CMS notes that the Consolidated Appropriations Act of 2023 (CAA, 2023) provides temporary additional payments for non-opioid treatments for pain relief. Specifically, non-opioid treatments furnished from January 1, 2025 and before January 1, 2028 for pain relief are not to be packaged and CMS is required to make an additional payment. To prepare to implement this change, CMS seeks comment on a range of question as provided in the Proposed Rule (pg. 529-535) to inform policy that would take effect in CY 2025. For example, CMS seeks comment on potential qualifying drugs, biologicals and devices, and appropriate codes and descriptors if no HCPCS codes currently exist for the product. CMS notes that it expects this policy to operate similarly in the ASC and hospital OPD settings but welcomes comment on whether there are any specific hospital OPD payment issues the agency should take into consideration.

Diagnostic Radiopharmaceuticals

CMS notes that under the OPPS it packages several categories of nonpass-through drugs, biologicals and radiopharmaceuticals, regardless of the cost of the products. A diagnostic product (e.g., contrast agents, stress agents and other products) is a type of product where the cost is “policy packaged” for purposes of determining the costs of the associated procedures in the APC. Although CMS believes that packaging policies are inherent to the principles of the OPPS, the agency also aims to ensure beneficiary access to diagnostic radiopharmaceuticals and to new and innovative diagnostic tools. **CMS requests comments related to diagnostic radiopharmaceuticals and notes that it may adopt a final alternative payment mechanism for radiopharmaceuticals for CY 2024, depending on the comments received. CMS seeks feedback on a range of topics (pg. 75-79) in the Proposed Rule, including clinical scenarios that warrant the use of higher-cost radiopharmaceuticals, differences in outcomes (both financial and patient-focused) based on the radiopharmaceutical used and five potential alternative payment approaches.** The five alternative payment approaches listed by CMS are noted below:

1. Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140;
2. Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold;
3. Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals;

4. Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and
5. Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

Proposed Wage Index Changes

By law, CMS must determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. 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. CMS proposes to continue setting the OPPS labor-related share at 60 percent of the national OPPS payment.

For CY 2024, 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) if the otherwise applicable wage index is less than 1.00. CMS also notes that the proposed Fiscal Year (FY) 2024 IPPS wage index continues to provide adjustments including a proposal related to the reclassification of hospitals to different geographic areas. However, CMS also notes policy proposals provided in the FY 2024 IPPS proposed rule where the agency would include certain reclassifying hospitals (e.g., §412.103 reclassification) with geographically rural hospitals in all rural wage index calculations and exclude "dual reclass" hospitals (simultaneous §412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassification) impacted by a statutory hold harmless provision. CMS also proposes to continue the low wage index hospital policy. CMS proposes to use the FY 2024 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for the OPPS payment rate and copayment for CY 2024.

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. For CY 2024, CMS proposes to decrease the fixed-dollar amount threshold to $8,350 plus the APC payment amount. The CY 2024 multiplier threshold remains at 1.75 times the APC payment amount. When the cost of a hospital outpatient service is above these thresholds (i.e., 1.75 is multiplied by the total line-item APC payment to decide eligibility for outlier payments and the estimated cost of a service must be greater than the APC payment amount plus the fixed-dollar amount threshold), the hospital would receive an outlier payment.

Proposed Beneficiary Copayments

In the Proposed Rule, CMS proposes to implement provisions of the Inflation Reduction Act that impact beneficiary copayments. For example, CMS proposes to codify the OPPS program payment and cost sharing amounts for Part B rebatable drugs. In addition, CMS proposes changes to the regulatory text to align with the agency's policy for calculating Medicare program payment and cost sharing amount for separately payable drugs and biologics.

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2024 are shown in Addenda A and B. CMS notes that statute limits the amount of beneficiary payment 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

Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically HCPCS codes, that are reported on hospital OPD claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The proposed status indicator, APC assignment and payment rate for each HCPCS code can be found in Addendum B. **CMS seeks comments on the proposed APC and status indicator assignments for the codes listed in Tables 6 and 7.** Table 8 (pg. 136) of the Proposed Rule clarifies when an OPPS quarterly update change request would be effective and which rulemaking cycle would be relevant for purposes of public comment. For example, April 2023 OPPS quarterly updates for CPT codes that are effective April 1, 2023, would be part of the CY 2024 OPPS proposed rule and potentially finalized in the CY 2024 OPPS final rule.

Application of the 2 Times Rule

CMS notes that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to resource use if the highest cost for an item or service in the group is more than two times greater than the lowest cost for an item or service within the same groups (known as the "2 Times Rule"). However, CMS may provide exceptions to the 2 Times Rule in unusual cases (e.g., low-volume items and services).

For the proposed CY 2024 OPPS update, CMS identifies APCs that violate the 2 Times Rule and proposed change to the procedure codes assigned to these APC (with some exceptions) in Addendum B of the Proposed Rule. To eliminate a violation of the 2 Times Rule and improve clinical and resource homogeneity in the APCs for which CMS is not proposing a 2 Times Rule exception[5], CMS proposes to reassign these procedure codes to new APCs that contain services that are similar considering both their clinical and resource characteristics.

Proposed New Technology APCs

In prior rulemaking, CMS established criteria for assigning a complete or comprehensive service to a New Technology APC (e.g., the service must be new; not eligible for transitional pass-through payments; and the service must be considered reasonable and necessary and fall within the scope of Medicare benefits under section 1832(a) of the Social Security Act). For CY 2024, CMS included the proposed payment rates for New Technology APCs 1491-1599 and 1901-1908 in Addendum A.

In the Proposed Rule (pgs. 146-185), CMS proposes to retain various services within the New Technology APC groups until the agency obtains sufficient claims data to justify reassignment of the service to an appropriate clinical APC.

[5] Table 9 (pg. 141) of the Proposed Rule lists the 21 APCs for which CMS proposes to make an exception under the 2 Times Rule for CY 2024.

Proposed OPPS Payment for Devices

Proposed OPPS Pass-Through Payment for Devices

The purpose of transitional device pass-through payment is to facilitate access for beneficiaries to the advantages of new and innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the codes for the device into the procedure APC rate.

CMS notes that the CAA, 2023, extended the device pass-through status for a one-year period beginning January 1, 2023, for device categories whose period of pass-through status would have ended on December 31, 2022. Table 28 (pg. 187) of the Proposed Rule lists the five device categories for which pass-through status has been extended until December 31, 2023 (pass-through status for these devices began January 1, 2020) and devices with pass-through status expiring in the fourth quarter of 2023, 2024 or 2025.

Regarding applications for device pass-through status for CY 2024, CMS received six complete applications by the March 1, 2023, quarterly deadline. For each application, CMS provides additional information (pgs.193-262) and welcomes comment on whether the pass-through payment criteria have been met.

Also, CMS provides the full listing of proposed CY 2024 device-intensive procedures in Addendum P.

Proposed OPPS Payment 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.[6] Under the OPPS, the Average Sales Price (ASP) methodology uses several sources of data as a basis for payment – including the ASP, the wholesale acquisition cost (WAC) and the average wholesale price (AWP). Proposed CY 2024 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B.

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

CMS provides that there are 43 drugs and biologicals whose pass-through payment status will expire by December 31, 2023, as listed in Table 35 (pg. 279-282) of the Proposed Rule. 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

[6] As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. "Current" refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented. Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as a hospital OPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs."

the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year. For CY 2024, CMS proposes an OPPS drug packaging threshold of $140.

As in prior years, 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 proposes to provide separate payment at the applicable relative ASP-based payment amount – which for CY 2024 is generally ASP plus 6 percent.

Drugs, Biologicals and Radiopharmaceuticals with Pass-Through Payment Expiring in CY 2024

For CY 2024, CMS proposes to end pass-through payment status for 25 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2021 – January 1, 2022, are listed in Table 36 (pg. 284-287) of the Proposed Rule. For CY 2024 and subsequent years, CMS proposes to continue to pay for pass-through drugs and biologics using the ASP methodology, which is generally at ASP plus 6 percent; this is equivalent to the rate these products would receive in the physician's office setting in CY 2024.

For policy-packaged drugs (e.g., anesthesia drugs, drugs, biologicals, and radiopharmaceuticals) that function as supplies when used in a diagnostic test or procedure as well as drugs and biologicals that function as supplies when used in a surgical procedure, CMS proposes their pass-through payment amount would be equal to the payment rate calculated using the ASP methodology. This rate would generally be ASP plus 6 percent for CY 2024 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 2024 if later quarter ASP submissions (or more recent WAC or AWP information) indicates that adjustment to the payment rates are necessary.

Also, 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.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing in CY 2024

CMS proposes to continue pass-through payment status in CY 2024 for 42 drugs and biologicals which had pass-through payment status begin between April 1, 2022 – April 1, 2023; these drugs and biologicals are listed in Table 37 of the Proposed Rule (pgs. 289-293).

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 2024, consistent with prior years, 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 38 (pg. 294) of the Proposed Rule provides proposed APCs to which a policy-packaged drug or radiopharmaceutical offset may be applicable. CMS proposes to continue

to post annually on the 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.

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

Proposed Packaging Threshold

Since CY 2007, CMS has updated the threshold for establishing separate APCs for payment for drugs and biologicals, using a four-quarter moving average Producer Price Index (PPI) level for Pharmaceutical Preparations (Prescription) and rounding the resulting dollar amount to the nearest $5 increment. For CY 2024, CMS proposes a packaging threshold of $140.

Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

For CY 2024, CMS is not proposing any changes to policies for payment for separately payable drugs and biologicals; the agency is continuing the payment policy that has been in effect since CY 2013. However, CMS notes that is proposing to amend the regulation text to reflect the agency's policies for calculating the Medicare program payment and copayment amounts for separately payable drugs and biologics.

Biosimilar Biological Products

The Inflation Reduction Act (IRA), which was signed into law in August 2022, includes two provisions[7] regarding payment limits for biosimilars. One section requires that a qualifying biosimilar be paid at ASP plus 8% of the reference biological's ASP rather than 6 percent during the applicable 5-year period. Consistent with statutory requirements and previous guidance, CMS proposes regulatory changes to specify that OPPS payment for biosimilars also be subject to the temporary payment increase. More information regarding this policy can be found in the CY 2024 Physician Fee Schedule proposed rule as the proposed regulations cross-references this regulatory text.

In addition, CMS describes its concerns that packaging biosimilars when the reference biological or other marketed biosimilars are separately paid may create financial incentives for providers to select more expensive, but clinically similar, products. Although a biosimilar is likely to have pass-through status or be separately payable, CMS notes that there have been instances where biosimilars are packaged. For example, CMS indicates that payment for HCPCS code Q5101 (Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram) is packaged because its per day cost fell below the agency's packaging threshold of $135 for CY 2023. To promote use of biosimilars, CMS proposes to except biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid.

Also, CMS clarifies that under the proposal, if a reference product's per day cost falls below the threshold packaging policy, then all biosimilars related to the reference product would similarly be packaged regardless of whether their per-day costs are above this threshold.

[7] Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available. Section 11403 of the IRA makes changes to the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years.

CMS seeks comment on a variety of topics related to biologic and biosimilar reimbursement, such as a potential policy that would result in packaged payment for a biologic if the reference biologic or any of its biosimilars have per day costs below the drug packaging threshold. In addition, CMS seeks comment on other ways to structure payment for biologicals and biosimilars that would encourage efficiency while maintaining beneficiary access.

Proposed OPPS Payment Methodology for 340B Purchased Drugs and Biologicals

In the CY 2023 OPPS final rule and due to litigation, CMS finalized a policy to revert to the default payment rate, which is generally ASP plus 6%, for 340B acquired drugs and biologicals. In July 2023, CMS published a proposed rule ("remedy proposed rule") to address the reduced payment amounts to 340B hospitals under the reimbursement rates in the final OPPS rules for CYs 2018-2022 and to comply with the statutory requirements to maintain budget neutrality. CMS makes clear that the remedy proposed rule does not necessitate changes to the Proposed Rule, including the CY 2024 conversion factor. For CY 2024, CMS proposes to continue the statutory default rate, which is generally ASP plus 6%, for 340B acquired drugs and biologicals.

In the CY 2023 OPPS final rule, CMS maintained the requirement that 340B hospitals report the "JG" (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) modifiers to identify drugs and biologicals acquired through the 340B program for informational purposes. In addition, in the CMS guidance, "Part B Inflation Rebate Guidance: Use of 340B Modifiers," CMS requires all 340B covered entities, including hospital-based and non-hospital-based entities, to report the applicable modifier for separately payable drugs and biologicals acquired through the 340B program since products acquired under the 340B program are not to be included among those products that have a Part B inflation rebate liability.

However, in the Proposed Rule, CMS is reconsidering the need to have two modifiers. As a result, CMS proposes to require hospitals to report a single modifier. Specifically, CMS proposes that all 340B covered entity hospitals paid under the OPPS report the "TB" modifier effective January 1, 2025, even if the hospital previously reported the "JG" modifier. CMS further clarifies that the "JG" modifier would remain effective through December 31, 2024, but hospitals could choose to use the "TB" modifier during this period. Should CMS finalize this proposal, the agency also indicates it will update Part B Inflation Rebate Guidance to align with this policy. **CMS seeks comments on this proposal.**

Requirement in Physician Fee Schedule Proposed Rule to Require Hospital OPDs 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. CMS encourages parties to refer to the CY 2024 Physician Fee Schedule (PFS) proposed rule for a full description of proposed policies. CMS also notes that comments related to this policy will be addressed in the CY 2024 PFS final rule.

OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2024, 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. CMS reiterates previously finalized policy where CMS utilizes a PFS-equivalent payment

rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2023 and beyond.

Additionally, for CY 2024, CMS proposes to continue to exempt 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, from the site neutral clinical visit payment policy (i.e., applying PFS-equivalent payment rates for the clinic visit service). CMS notes it will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

Payment for Partial Hospitalization Services and Intensive Outpatient Services

Since 2000, Medicare has covered partial hospitalization program and policies under the OPPS. Among other changes, the CAA, 2023 included changes related to partial hospitalization services that go into effect January 1, 2024, which CMS aims to implement in the Proposed Rule. Also, beginning in CY 2024 (per the CAA, 2023), Medicare will also cover intensive outpatient (IOP) services furnished by hospital OPDs, community mental health centers (CMHCs), federally qualified health centers (FQHCs) and rural health clinics (RHCs).

Partial Hospitalization

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 furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour daily care, in a location other than an individual's home or inpatient or residential setting. Partial hospitalization services are further defined in statute.[8]

In the CAA, 2023, Congress added to the current definition of partial hospitalization services to note that such services are "for an individual determined (not less frequently than monthly) by a physician to have a need for such services for a minimum of 20 hours per week." To implement the law, CMS proposes revisions to PHP certification requirements to require the physician certification for PHP services to include a certification that the patient requires such services for a minimum of 20 hours per week (current regulation requires an initial recertification after 18 days, with subsequent recertification of PHP service no less frequently than every 30 days).

In addition, CMS proposes to change its methodology for calculating PHP payment rates by establishing separate payment rates for 3-service and 4-service days. **CMS seeks comment on whether it would be appropriate to apply a different methodology for calculating the PHP and intensive outpatient program (IOP) rates for nonexcepted off-campus hospital outpatient departments. CMS seeks comment on alternative methodologies commenters believe would be appropriate.** For example, CMS is considering whether it would be appropriate to apply the PFS Relativity Adjuster of 40 percent, which applies to most other nonexcepted OPPS services furnished by a nonexcepted off-campus hospital OPDs. Depending on the comments CMS receives, the agency notes that it may finalize an alternative methodology such as the PFS Relativity Adjuster.

[8] Section 1861(ff)(1) of the Social Security Act

CMS clarifies that if it were to adopt such a methodology, CMS would apply it to both PHP and IOP services.

Additional policy related to the PHP, including policies that overlap with newly proposed IOP regulations, are provided in the following section.

Intensive Outpatient Program Services

The CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. Although similar to PHPs, CMS notes that an IOP is thought to be less intensive than a PHP, which the agency believes is reflected in the statutory definition of IOP services (e.g., IOP services are prescribed for a minimum of 9 hours per week; patients of an IOP would not require inpatient psychiatric care in the absence of such services). Also, as provided in the CAA, 2023, an IOP is a program furnished by a hospital to its outpatients, or by a CMHC, FQHC or RHC, as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting.[9]

The Proposed Rule includes policies to establish payment and program requirements for the IOP benefit in various settings, including by a hospital. In addition, the Proposed Rule details the proposed scope of benefits for IOP services, proposed physician certification requirements, coding and billing for both PHP and IOP services under the OPPS beginning in CY 2024 and the proposed payment methodology (pg. 351-389 of the Proposed Rule). For example, CMS proposes two IOP APCs for each provider type that aligns with PHP proposals that are based on 3-service days and 4-service days.

Table 43 (pg. 365-367) of the Proposed Rule provides the proposed HCPCS applicable for PHPs and IOPs. CMS proposes to use the list of HCPCS in Table 43 to determine the number of services per PHP and IOP per day, which would be used to determine the APC per diem payment amount for each day. CMS also proposes that to qualify for payment for the IOP APC (5851, 5852, 5861 or 5862) or the PHP APC (5853, 5854, 5863, or 5864) one service must be from the Partial Hospitalization and Intensive Outpatient Primary list.

Notably, CMS proposes to add CPT code 90853 (group psychotherapy) to the list of service codes recognized for the PHP and IOP even though the agency believes there could be overlap between this code and existing codes for PHP group psychotherapy (G0410 and G0411). **CMS seeks comment on whether it would be appropriate to remove G0410 and G0411 from the list of recognized service codes for the PHP and IOP and retain only CPT code 90853.**

In addition, CMS proposes to include IOP services furnished by Opioid Treatment Programs in the definition of Opioid Use Disorder (OUD) treatment services (pg. 409-421). Also, as noted above, CMS seeks comment on applying the PFS Relativity Adjuster of 40 percent to IOP rates for nonexcepted off-campus hospital OPDs.

[9] Special payment rules for IOP services furnished in FQHCs and RHCs are provided in the CAA, 2023 and the Proposed Rule, but are not included in this summary.

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.[10] For CY 2024, although CMS received requests to remove some procedures from the IPO list, the agency did not find sufficient evidence to warrant removal. Therefore, CMS is not proposing to remove any services from the IPO list for CY 2024 but does **seek comment on whether services described by four CPT codes (43775, 43644,43645 and 44304) which relate to laparoscopy surgery, are appropriate to remove from the IPO list. CMS seeks evidence that these services can be performed safely on the Medicare population in the outpatient setting.**

As provided in Table 2, CMS proposes to add several services to the IPO list for codes that were newly created by the AMA CPT panel for CY 2024.

Table 2. Proposed Additions to the IPO List for CY 2024

CY 2024 CPT Code	CY 2024 Long Descriptor
X114T	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed
2X002	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
2X003	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments
2X004	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
619X1	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)
7X000	Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic
7X001	Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report
7X002	Placement, manipulation of transducer, and image acquisition only
7X003	Interpretation and report only
0646T	Transcatheter tricuspid valve implantation (ttvi)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed

Note: All proposed additions to the IPO list for CY 2024 would also be assigned status indicator “C”

[10] 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.

Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, and Pulmonary Rehabilitation Services

Supervision by Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists of Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, and Pulmonary Rehabilitation Services Furnished to Hospital Outpatients

A section of the Bipartisan Budget Act of 2018 (BBA of 2018) revised the definitions of cardiac rehabilitation (CR) program and intensive cardiac rehabilitation (ICR) program, respectively, to provide that services these programs furnish can be under the supervision of a physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). In addition, similar changes were made to the definition of a pulmonary rehabilitation (PR) program to provide that PR services can be furnished under the supervision of these same types of practitioners. However, these changes do not go into effect until January 1, 2024. CMS proposes various regulatory amendments to implement these statutory provisions to provide that supervision of pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services can be provided by a physician, PA, NP or CNS.

During the COVID-19 public health emergency (PHE), CMS allowed the presence of the physician for purposes of the direct supervision requirement to include virtual presence through audio/video real-time communications. In the CY 2023 OPPS final rule, CMS extended the revised definition of direct supervision to include the presence of the supervising practitioner through two-way, audio/video telecommunications technology until December 31, 2023 and in the Proposed Rule, CMS extends this policy through 2024.

To maintain similar policies for direct supervision of PR, CR and ICR under the OPPS and PFS, CMS proposes to allow for the direct supervision requirement for these programs to include virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and extend this policy to the nonphysician practitioners, including NPs, PAs and CNSs. **CMS is soliciting comments on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the current or proposed extensions and what policies CMS could adopt to address those concerns if the policy were extended beyond 2023. For a complete discussion of the proposed revisions, CMS refers readers to the CY 2024 PFS proposed rule.**

Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital

The Bipartisan Budget Act of 2015 provided that applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services for purposes of payment under the OPPS and are instead paid “under the applicable payment system” under Medicare Part B if the requirements for such payment are otherwise met. In prior rulemaking, CMS implemented this statutory change by establishing a PFS Relativity Adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted, off-campus PBD in order to calculate payment rates under the PFS. Nonexcepted items and services furnished by nonexcepted, off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (that is, 60 percent less than the OPPS rate).

However, CMS notes that ICR services (i.e., HCPCS codes G0422 and G0423) provided in the physician’s office have been paid at 100 percent of the OPPS rate for CR services. Yet, since 2017, ICR services provided by an off-campus, non-excepted PBD of a hospital have been paid at the PFS-equivalent rate through application of the PFS Relativity Adjuster. Table 3 shows a

reimbursement disparity between the two sites of service. For CY 2024, CMS proposes to pay for ICR services provided by an off-campus, non-excepted and provider-based department of a hospital at 100 percent of the OPPS rate for CR services (which is also 100 percent of the PFS rate) rather than at 40 percent of the OPPS rate. **CMS seeks comment on whether there are other services for which the OPPS rate is unconditionally used under the PFS, as the agency believes these services should be treated similarly for purposes of payment to off-campus, non-excepted provider-based departments of hospitals.**

Table 3. Reimbursement for HCPCS Codes G0422 and G0423 Under the OPPS On-Campus Rate, OPPS Non-Excepted Rate and PFS Rate

HCPCS Code	2023 OPPS On-Campus Rate	2023 OPPS Non-Excepted Rate	2023 Medicare PFS Payment Rate
G0422 (intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session)	$120.47	$48.03	$120.47
G0423 (intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session)	$120.47	$48.03	$120.47

OPPS Payment for Specimen Collection for COVID-19 Tests

During the COVID-19 PHE, 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]), any specimen source) to meet the need of the COVID-19 PHE and indicated that the agency expected to retire it at the conclusion of the COVID-19 PHE. Given the COVID-19 PHE has ended, CMS proposes to delete HCPCS code C9803 effective January 1, 2024 (the code will remain active for the remainder of CY 2023). **CMS seeks comment on the proposal to delete the code for CY 2024.**

Remote Services

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 makes payment for a discrete set of Medicare telehealth services. While most services are ordinarily furnished in-person, many of these services can also be provided by using interactive, real-time telecommunications technology. Generally, the Medicare statute limits 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 and Congress 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 beneficiaries who are not physically located in the hospital. However, CMS does pay for certain services that do not require the beneficiary's physical presence in the hospital.

In the CY 2023 OPPS final rule, CMS finalized creation of three HCPCS C-codes (C7900[11], C7901[12], C7902[13]) to describe mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. CMS intentionally did not specify whether these codes should be used for individual or group services. Also, since these policies have been implemented, CMS has gained stakeholder feedback regarding their use.

In the Proposed Rule, CMS notes that stakeholders have commented that it is administratively burdensome to report and document each unit of time using the recently finalized HCPCS C-codes. As a result, CMS proposes to create a new, untimed, HCPCS C-code (C79XX[14]) describing group therapy. CMS proposes to assign the code to an APC based on the facility payment amount for a similar service (CPT code 90853 Group Psychotherapy (other than of a multiple-family group)) under the PFS. If finalized as proposed, CMS indicates that it would need to refine the code descriptors for HCPCS codes C7900-C7902 to stipulate that they are solely for services furnished to an individual beneficiary.

CMS seeks comment on whether HCPCS code C79XX sufficiently describes group psychotherapy to the extent that group psychotherapy would no longer be reported with HCPCS codes C7900-C7902. In addition, CMS seeks comment on whether or there are circumstances where it would be appropriate to bill for group services using HCPCS codes C7900-C7902.

Also, related to the CY 2023 finalized HCPCS C7900 and C7901 descriptors, CMS heard from stakeholders that the word "initial" is preventing billing for remote behavioral health services furnished after either the first 15 to 29 minutes or 30 to 60 minutes. To facilitate accurate billing, regardless of whether the remote mental health service is being furnished as an initial or subsequent service, CMS proposes to revise the code descriptors for C7900 and C7901 to remove "initial" and C7902 to being in addition to C7901.

Periodic In-Person Visits

In the CY 2023 OPPS final rule, CMS finalized a requirement that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within the 6 month period before the first time the hospital clinical staff provides the mental health services remotely; there must also be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. Notably, these requirements were not to go into effect until the 152nd day after the end of the COVID-19 PHE to align with similar policies under the PFS and for RHCs/FQHCs.

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[11] C7900: 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.
[12] C7901: 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.
[13] C7902: Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 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 (List separately in addition to code for primary service).
[14] C79XX: Group psychotherapy service for diagnosis, evaluation, or treatment of a mental health or substance use disorder 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.

The CAA, 2023, extended the delay in implementing the in-person visit requirements until January 1, 2025, for both professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. To maintain consistency across payment systems, CMS proposes to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025.

Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy when Furnished by Hospital Staff to Beneficiaries in Their Homes Through Communication Technology

The CAA, 2023, extended the telehealth flexibility which allowed physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists (SLPs) to serve as telehealth distant site practitioners through the end of CY 2024. In the CY 2024 PFS proposed rule, CMS proposes to continue to make payment for outpatient physical therapy, occupational therapy, speech-language pathology services, Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) when furnished via telehealth by qualified employed staff of institutional providers through the end of CY 2024. In the Proposed Rule, CMS makes clear that this proposal includes outpatient therapy, DSMT and MNT services furnished via telehealth by staff of hospital outpatient departments. For further discussion, CMS refers to the CY 2024 PFS proposed rule.

OPPS Payment for Dental Services

Although the Social Security Act (SSA) precludes payment under Medicare Parts A or B for many dental services, in the CY 2023 PFS final rule, CMS finalized a policy to support access to certain dental services inextricably linked to certain Medicare-covered services (e.g., organ transplant, cardiac valve replacement, treatment of head and neck cancers). The CY 2023 PFS final rule specified that Medicare payment for these dental services may be made regardless of whether the services are furnished in an inpatient or outpatient setting. In addition, beginning CY 2023, CMS established a process where the agency would be able to review additional dental services that are inextricably linked to other covered medical services.

In the Proposed Rule, CMS notes that the current dental codes assigned to APCs for CY 2023 do not fully describe the dental services that may be inextricably linked to covered medical services and payable under Medicare Part B. As a result, CMS proposes to assign 229 HCPSC codes related to dental services to clinical APCs to enable them to be paid for under OPPS when payment and coverage requirements are met. CMS clarifies that the dental services for which APC assignments are proposed are those dental services described in the CY 2023 PFS final rule for which Medicare Part B payment can be made when they are inextricably linked to other covered services. Table 53 (pg. 448-453) of the Proposed Rule lists the dental codes proposed for assignment to clinical APCs in CY 2024; **CMS requests comment on the additional dental codes added and the proposed APC assignments for the dental codes for CY 2024.** CMS also notes that Addendum B includes the proposed CY 2024 APC assignment and associated payment rates for the dental codes.

For CY 2024, CMS proposes packaging payment for dental services by assigning the dental codes to packaged status indicators. **CMS requests comment on this proposal.**

Use of Claims Data for CY 2024 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 conducted to determine which data would be the best available data for purposes of CY 2024 ratesetting since the HCRIS extracted in December 2022 contains cost reports ending in FY 2020 and 2021. Despite observing some differences at the aggregate and service level volumes in the CY 2022 claims data relative to the pre-PHE period, CMS believes the CY 2022 claims data are appropriate for setting CY 2024 OPPS rates. In addition, CMS proposes to resume its typical cost report update process of including the most recently available cost report data (primarily including cost reports with cost reporting periods including CY 2021).

Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities

In the Proposed Rule, CMS notes concerns that if payments under the All-Inclusive Rate (AIR), which is relied on for payment to Indian Health Service (IHS) and tribally-owned facilities, is inadequate for high-cost drugs, then it may threaten access to care, including specialty services. **As a result, CMS seeks comment on potential policies to address IHS and tribally-owned facilities for high-cost drugs and services, including whether Medicare should pay separately for high-cost drugs provided by IHS and tribally-owned facilities.** A complete list of questions is provided in the Proposed Rule (pg. 463-464).

Proposed CY 2024 OPPS Payment Status and Comment Indicators

Payment status indicators (SIs) that CMS assigns to HCPCS codes and APCs indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS policies apply to the code. For CY 2024, CMS proposes to change the definition of status indicator "P" from "Partial Hospitalization" to "Partial Hospitalization or Intensive Outpatient Program" in order to account for the proposed payment of intensive outpatient services beginning January 1, 2024. The complete list of proposed CY 2024 payment status indicators and their definitions is displayed in Addendum D1. The proposed CY 2024 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B.

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 for CY 2024 is $85.782, which is $1.706 less than hospitals who meet the reporting requirements.

In the Proposed Rule, CMS considers retention, removal, replacement or suspension of quality measures from the hospital OQR program measure set, and proposes the following:

- Removal of the left without being seen measure beginning with the CY 2024 hospital OQR reporting period.
- Modification of the COVID-19 vaccination coverage among health care personnel (HCP) measure beginning with CY 2024 to address "up to date" in the HCP vaccination definition (more information on the term "up to date" from the Centers for Disease Control and Prevention (CDC)) and to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines; CMS also clarifies the measure is a process measure.
- Modification of survey instrument used for the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract surgery beginning with the voluntary CY 2024 reporting period.

- Modification of the appropriate follow-up interval for normal colonoscopy in average risk patients measure denominator change to align with current clinical guidelines beginning with the CY 2024 reporting period.
- Re-adoption of the original Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures with modification (instead of collecting and displaying data for eight broad categories, CMS would collect and display data reported for the top five most frequently performed procedures among hospital OPDs within each category), beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. CMS also proposes that hospital OPDs submit these data to CMS during January 1 – May 15 in the year prior to the affected payment determination year.
- Adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the hospital OPD Setting (THA/TKA PRO–PM), beginning with the voluntary CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period. Table 72 (pg. 624) of the Proposed Rule provides the pre-operative and post-operative periods for THA/TKA PRO-PM voluntary reporting and Table 73 (pg. 625-626) of the Proposed Rule details the period for mandatory reporting.
- Adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults measure, beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. Table 71 (pg. 620) of the Proposed Rule provides the proposed progressive increase in eCQM reporting beginning with the CY 2025 reporting period and for subsequent years.

Tables 66 (pg. 598-599) and 67 (pg. 599-600) of the Proposed Rule include the proposed hospital OQR measure set for the CY 2026 and CY 2027 payment determinations.

Also, regarding public reporting, beginning with CY 2024, CMS proposes to post data on the Care Compare website (downloadable files found at data.cms.gov) for the following two chart-abstracted measure strata: Median Time for Discharged ED Patients-Transfer Patients and the Median Time for Discharged ED Patients-Overall Rate which contains data for all patients. **CMS invites comments on these proposals.**

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

In the CY 2023 OPPS final rule, CMS finalized alignment of the patient encounter quarters for chart-abstracted measures beginning with the CY 2024 reporting period/CY 2026 payment determination. To facilitate this process, CMS finalized transitioning to the new timeframe for the CY 2026 payment determination and subsequent years. However, for the CY 2025 payment determination, CMS will use only three quarters of data for chart-abstracted measures, as shown in Tables 68 (pg. 614), 69 (pg. 614), and 70 (pg. 614-615) of the Proposed Rule. CMS does not propose changes to this transition.

Hospital OQR Program Quality Measure Topics for Potential Future Consideration

In the Proposed Rule, **CMS requests comment on innovative measurement approaches and data sources for use in quality measurement**. CMS identified the following three potential quality measurement topics for the Hospital OQR program: promoting safety (patient and workforce); behavioral health and telehealth. In addition, CMS seeks public comments that address: quality measurement gaps in the hospital OPD setting, including the ED; changes in outpatient care (such as shifts in volume, technology use, and case complexity); growth of concerns around workforce

and patient safety; the transition to digital quality measurement; and interest in patient-reported outcomes.

Some specific questions CMS poses are noted below, and additional questions are available in the Proposed Rule (pg. 606-612):

- Whether the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500330) (the Sepsis measure) would be appropriate and feasible for use in the Hospital OQR Program, as well as whether CMS should consider adopting an alternative measure that assesses the quality of sepsis care in the hospital outpatient setting.
- What are interested parties' highest priority outcomes for ensuring safety in the outpatient setting?
- What outcomes should be measured across all settings within the Hospital OQR Program?
- What aspects of workforce safety are important for us to consider for the Hospital OQR Program?
- Access is one of the biggest challenges around improving behavioral health outcomes. What measurement approaches could be used to drive improvements in access to services?
- Should CMS consider a measure related to universal suicide risk in the ED? Are there other interventions or measurement approaches targeted at suicide prevention that CMS should consider?
- What do commenters believe are the most relevant clinical issues addressable through telehealth in outpatient settings, and gaps in care that telehealth can address?
- Which existing outpatient quality measures should be stratified by telehealth as the mode of delivery?

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

For CYs 2019-2023, CMS adopted a new policy to update the ASC payment using a market basket update. Due to the impact of the COVID-19 PHE on healthcare, CMS proposes to extend the policy to use the market basket update for CY 2024 and 2025. Using the hospital market-basket methodology for CY 2024, CMS proposes to increase payment rates under the ASC payment system by 2.8 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 productivity adjustment of 0.2 percentage points. Based on various proposals, CMS estimates that total payments to ASCs would increase by approximately $170 million compared to CY 2023 Medicare payments.

In Table 56 (pg. 476-477) of the Proposed Rule, CMS outlines its process for updating codes through the ASC quarterly update change requests, public comment opportunities and finalizing the treatment of new codes under the ASC payment system. CMS seeks comment on the proposed CY 2024 payment indicators (which are listed in Addendum AA and Addendum BB) for the new Category I and III CPT codes that will be effective January 1, 2024.

In the Proposed Rule, CMS outlines a policy for proposed payment for ASC add-on procedures eligible for complexity adjustments under the OPPS. For CY 2024, CMS proposes to continue the special payment policy and methodology for OPPS complexity-adjusted C-APCs that was finalized in the CY 2023 OPPS final rule. However, CMS notes this process may change for CY 2025 rulemaking as the agency has more claims data for packaged codes in the ASC setting. The full list of the proposed ASC complexity adjustment codes for CY 2024 can be found in the ASC addenda and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions, and is published on the CMS website.

In addition, as listed in Table 58 (pg. 499) of the Proposed Rule, CMS proposes two ASC covered surgical procedures to be newly designated as permanently office-based for CY 2024 and to

designate three new CY 2024 CPT codes for ASC covered procedures as temporarily office-based (CPT placeholder code 6X000[15], 64XX4[16] and X170T[17]). Further, as outlined in Table 59 (pg. 500) of the Proposed Rule, CMS proposes to no longer designate four of nine surgical procedures that, in CY 2023, were temporarily assigned an office-based payment indicator.

Regarding the ASC covered procedure list (CPL, for CY 2024, CMS proposes to add 26 surgical procedures related to dental care to the ASC CPL, as noted in Table 61 (pg. 515) of the Proposed Rule.

ASC Quality Reporting (ASCQR) Program

Under the ASCQR Program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet ASCQR requirements. Table 75 (pg. 677-678) of the Proposed Rule provides the proposed ASCQR program measure set for the CY 2024 reporting period/2026 payment determination and Table 76 (pg. 678-679) of the Proposed Rule provides the proposed ASCQR program measure set for the CY 2025 reporting period/CY 2027 payment determination. CMS also proposes modifications to two previously adopted measures, including the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure. In addition, CMS proposes mandatory reporting in future years, as outlined in Table 78 (pg. 689-690) of the Proposed Rule, for the pre-operative and post-operative period for THA/TKA PRO-PM.

Rural Emergency Hospitals (REHs)

Proposal Regarding Payment for REHs

CMS notes that some tribal and IHS hospitals have expressed interest in converting to an REH but have concerns about doing so due to having to transition from their existing payment methodology under the AIR to the REH payment methodology. CMS proposes that IHS-REHs be paid for hospital outpatient services under the same rate (the applicable AIR that is established and published annually by the IHS) that would otherwise apply if these services were performed by an IHS or tribal hospital. Also, CMS proposes IHS-REHs would receive the REH monthly facility payment consistent with how this payment is made to REHs that are not tribally or IHS operated.

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

The CAA, 2021, effectively requires CMS to establish quality measurement reporting requirements for REHs and that REHs must submit quality measure data, which will be made available to the public on a CMS website. However, the law did not require the Secretary to provide incentives or impose penalties related to submitting data under the REHQR. CMS proposes to implement a quality reporting program requiring REHs to submit data on measures in the form, manner, and at a time specified by the Secretary. **CMS invites comment on this proposal.**

CMS proposes to adopt the following four measures for the REHQR Program measure set: (1) Abdomen Computed Tomography (CT) - Use of Contrast Material; (2) Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy; and (4) Risk-Standardized

[15] 6X000: Suprachoroidal space injection of pharmacologic agent (separate procedure)
[16] 64XX4: Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
[17] X170T: Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy

Hospital Visits Within 7 Days After Hospital Outpatient Surgery. CMS notes that based on its analysis, a relatively high percentage of hospitals eligible to convert to REH status has reported aggregated measure data in sufficient number for disclosure per CMS privacy policy for the initial REHQR Program measure set. In addition, CMS proposes that once adopted into the REHQR Program measure set, such measures are retained for use until CMS proposes to remove (including potential immediate removal if a measure raises potential safety concerns), suspend or replace the measure.

Regarding public display, CMS proposes to make publicly reported data under the REHQR Program available to the public both on the Care Compare website and in downloadable data files located in the Provider Data Catalog (PDC), found at http://data.cms.gov. CMS intends to display these data publicly beginning with measure data submitted relevant to services provided in CY 2024.

CMS also requests comment on program measures and topics for future consideration. **For example, CMS seeks feedback regarding eCQMs for reporting quality data under the REHQR program, including any specific eCQM measures the agency should consider for inclusion in the measure set, such as the Excessive Radiation eCQM. CMS also welcomes comment on care coordination measures and a potential multi-tiered approach for quality measures and reporting requirements to incentivize REH reporting.**

Changes to Community Mental Health Center (CMHC) Conditions of Participation (CoPs)

The CAA, 2023 established coverage of intensive outpatient (IOP) services in community mental health centers (CMHCs). In addition, per the CAA, 2023, Medicare coverage of IOP services furnished by a CMHC is available beginning January 1, 2024, allowing coverage of both partial hospitalization services and IOP services furnished by CMHCs. CMS proposes several modifications to the requirements for the CMHC to include IOP services through the CoPs. For example, CMS proposes to revise the personnel qualifications of Mental Health Counselors (MHCs) and add personnel qualifications of Marriage and Family Therapists (MFTs) to the CMHC CoPs (though CMHCs are not required to employ MHCs or MFTs). **CMS requests additional comments from CMHC stakeholders on a range of questions (pg. 750-751 of the Proposed Rule), including whether CMHCs expect the total number of clients served to increased with the addition of IOP, whether CMHCs expect outpatient treatment clients, such as those receiving office-based therapy, to step up to the IOP program and whether offering IOP would impact CMHC eligibility requirements.**

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

In the CY 2020 Hospital Price Transparency (HPT) final rule, CMS adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF) and (2) in a consumer-friendly format. CMS notes that in the HPT final rule and subsequent rules, the agency aims to address barriers that limit price transparency with a goal of increasing competition among healthcare providers. In the CY 2022 OPPS final rule, CMS strengthened the HPT enforcement policies by increasing the penalty amount for noncompliance using a scaling factor based on hospital bed count and prohibiting hospitals from coding their MRF in way that made it inaccessible to automated searches and direct downloads. In the Proposed Rule, CMS proposes several changes to the HPT requirements to improve the agency's monitoring and enforcement capabilities.

Proposal to Modify the Requirements for Making Public Hospital Standard Charges

In the CY 2020 HPT final rule, CMS finalized specific requirements for hospitals to meet for purposes of making public a comprehensive list of standard charges for the items and services they provide. The requirements also govern the format, data elements, location and accessibility of the list, and frequency in which the list is updated.

Define New Terms

CMS proposes to add the following definitions and to make several technical and conforming revisions to ensure the consistency of the use of the new terms in regulation:

- "CMS Template" means a CSV format or JSON schema that CMS makes available for purposes of compliance with the hospital price transparency regulations.
- "Consumer-friendly expected allowed amount" means the average dollar amount that the hospital estimates it will be paid by a third-party payer for an item or service.
- "Encode" means to enter data items into the fields of the CMS template.
- "Machine-readable file" means a single digital file that is in a machine-readable format.

Require hospitals to affirm the accuracy and completeness of their standard charge information displayed in the MRF

CMS notes that since the HPT regulations have been implemented, the public and CMS has questioned the accuracy of the standard charge information hospitals display. For example, CMS notes that MRFs may include "blanks" without indicating whether this was intentional (e.g., if a hospital has not established any discounted case prices for any item or service). As a result, CMS proposes to require that each hospital affirm directly in its MRF (using a CMS template) that it has included all applicable standard charge information in its MRF as of the date in the MRF. **CMS seeks comment on this proposal.**

Improve Standardization of Hospital MRF Formats and Data Elements

In the CY 2020 HPT final rule, CMS expressed concern that lack of uniformity in the way that hospitals display their standard charges will leave the public unable to meaningfully use, understand and compare standard charge information across hospitals. As a result, CMS established an initial set of rules for making public all standard charges in an MRF. However, since the regulation has been implemented (January 2021), CMS has received feedback that more standardization is needed considering both the template and additional contextual data elements. In November 2022, CMS made available "sample formats" and a supplemental data dictionary that provides technical instructions to hospitals on how to conform to the sample formats and encode standard charge information. The sample formats and data dictionary can be found on the HPT website. The agency proposes to require hospitals to encode all data items for additional data elements in their MRF. CMS encourages commenters to review the sample templates and data dictionary to inform their comments to the agency. Table 84 (pg. 780-781) of the Proposed Rule summarizes and compares the existing sample format data elements with the proposed data elements.

To improve standardization, CMS proposes the following and seeks comments on the proposed revisions:

- *Indicate that each hospital must encode, as applicable, all standard charge information corresponding to each required data element in the MRF*.
    - CMS notes that this would differentiate the standard charge information, or data values, that must be encoded in the MRF from the "data elements," or categories of data as the basis for the CMS template.
- *Revise and expand the required data elements.*

    - CMS indicates many of the proposed data elements are incorporated in the CMS "sample formats" currently available for voluntary use by hospitals. CMS proposes general data elements (i.e., Hospital name(s), license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges apply) and data elements related to the types of standard charges (i.e., consolidate into a single data element the standard charges and continue to require the payer-specific negotiated charge be displayed by name of the third party payer and plan(s) or by plan categories, such as all PPO plans).
    - CMS also proposes to require that hospitals indicate the contracting method they used to establish the payer-specific negotiated charge. **CMS seeks comment on the contracting type that CMS should consider as allowed values in the CMS template, should this data element be finalized.**
- *Indicate whether the payer-specific standard charge listed should be interpreted by the user as a dollar amount, percentage, or, if an algorithm determines the dollar amount of the item or service.*
- *Consumer-friendly data element called the "expected allowed amount" that hospitals would be required to display in situations where the payer-specific negotiated charge cannot be expressed as a dollar figure.*
    - This amount is generally considered to be analogous to the 'allowed amount' that is established in the contract the hospital has with the third- party payer, and that appears on a patient's explanation of benefits. CMS proposes that when a hospital has established a payer-specific negotiated charge that can only be expressed as a percentage or algorithm, it must display alongside that percentage or algorithm a consumer-friendly expected allowed amount in dollars (this is likely to represent reimbursement for an average patient, rather than an exact amount).
- *Additional data elements related to hospital items and services (e.g., whether the standard charge is for an item or service provided in connection with an inpatient admission or an outpatient department visit and that hospitals indicate the drug unit and type of measurement as separate data elements).*

Proposals for Data Elements Related to an Item or Service Billing

CMS proposes to specify data elements related to item or service billing, including relevant modifier(s) to describe the standard charge and the code type(s) (e.g., whether the code is based on HCPCS, CPT, APC, DRG, NDC, revenue center, or other type of code).

Proposal to Specify Formatting Requirements for Display of Standard Charge Information Using a CMS Template

To improve automated aggregation of standard charge information, CMS proposes to require each hospital to conform to the CMS template layout, data specifications, data dictionary, and to meet any other specifications related to the encoding of the hospital's standard charge information in its MRF. CMS also believes this proposal will help streamline the agency's enforcement authorities.

For purposes of this requirement, CMS proposes to make available a CMS template in CSV and JSON formats and in three different layouts: (1) JSON schema (plain format), (2) CSV ("wide" format), and (3) CSV ("tall" format). In the Proposed Rule, CMS clarifies that hospitals that do not conform to the CMS template layout, data specifications, and data dictionary would be determined to be noncompliant and could be subject to a compliance action. **CMS seeks comment on whether hospitals would find a validator tool that could be used to check compliance with formatting requirements helpful, and, if so, what technical specifications such a validator ought to assess.**

Enforcement Timeline and Enhancements

If finalized, CMS proposes a 60-day enforcement grace period for adopting and confirmation to the new CMS template layout and encoding of standard charge information of the new proposed data elements. CMS clarifies that this proposal would be solely related to enforcement actions based on the new (if finalized) CMS template display requirements at revised § 180.50(b) and (c); it would in no way affect already-initiated compliance actions or actions for noncompliance with other requirements as they are currently being implemented. Additionally, this proposal would not apply to other proposals which would become effective and enforced on January 1, 2024, including proposals related to inclusion of an affirmation statement in the hospital's MRF. **CMS seeks comment on this proposal, particularly, whether and why an enforcement grace period should or should not be applied.**

In the Proposed Rule, CMS also proposes policy to improve assessment of hospital compliance (e.g., CMS's comprehensive compliance review of a hospital's standard charges information posted on a publicly available website) and requiring an authorized hospital official to submit to CMS a certification to the accuracy and completeness of the standard charges information posted in the MRF at any stage of the monitoring, assessment or compliance phase. In addition, CMS proposes to require submission of additional documentation (e.g., contracting documentation, hospital's license number) as necessary to assess hospital compliance. CMS also proposes to require hospitals to acknowledge receipt of a warning notice.

In addition, CMS proposes new actions to address noncompliance within hospital systems. For example, CMS proposes to have express authority to notify health system officials of a compliance action that CMS has taken against one or more hospitals within their system. CMS believes that working directly with them, where appropriate, to educate health system leadership and aid them in bringing all hospitals in the system into compliance, could aid in streamlining hospital compliance and their enforcement process. **CMS seeks comment on these proposals, including on whether there are additional data sources that CMS could access for purposes of identifying health system affiliation and leadership contact information.**

Lastly, CMS proposes to publicize compliance actions and outcomes by including information on the CMS website information related to CMS' assessment of a hospital's compliance, any compliance actions taken against a hospital, the status of such compliance action(s), and the outcome of such compliance action(s). CMS also notes that it proposes to publicize on its website information related to notifications that CMS may send to health system leadership if other elements of the Proposed Rule are finalized.

Proposal to Improve the Accessibility of Hospital MRFs

CMS indicates that it believes current policies are sufficient for purposes of manual search but may not be sufficient for automated searches. As a result, CMS proposes to require that a hospital ensure that the public website on which it chooses to host the MRF establishes and maintains automated access to the MRF in the following two ways:

- Ensure the public website includes a .txt file in the root folder that includes a standardized set of fields including the hospital location name that corresponds to the MRF, the source page URL that hosts the MRF, a direct link to the MRF (the MRF URL), and hospital point of contact information; and
- Ensure the public website includes a link in the footer on its website, including but not limited to the homepage, that is labeled "Hospital Price Transparency" and links directly to the publicly available webpage that hosts the link to the MRF.

CMS seeks comment on whether there: may be better or more efficient ways of improving access to MRFs or the direct links to the MRFs; are additional benefits or challenges that CMS should alternatively consider; might be any challenges for automation tools to find MRFs when they are hosted by a publicly available website other than a website hosted by the hospital, and ways that would make those automated searches more easily accessible; and, might be any challenges for hospitals to meet the proposed requirements when the publicly available website hosting the MRF is not under direct control of the hospital.

Seeking Comment on Consumer-Friendly Displays and Alignment with Transparency in Coverage and No Surprises Act

In the Proposed Rule, CMS outlines various consumer friendly requirements that are in the process of becoming fully realized, such as requirements from the No Surprises Act and Transparency in Coverage regulations. CMS seeks feedback regarding how the HPT requirements can best support and complement the consumer-friendly requirements found in other transparency initiatives. A complete list of questions is available in the Proposed Rule (pg. 807-808).

Request for Public Comments on Potential Payment under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines

In the Proposed Rule, CMS outlines various Federal government supply chain announcements and initiatives, including those related to pharmaceuticals and active pharmaceutical ingredients. Also, CMS indicates it believes it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency. As a result, CMS seeks comment on potential separate payment for establishing and maintaining access to a buffer stock of essential medicines. Essential medicines for the potential IPPS separate payment would be the 86 essential medicines prioritized in the report, Essential Medicines Supply Chain and Manufacturing Resilience Assessment. CMS notes that an adjustment under OPPS could be considered for future years.

Notably, for IPPS, this separate payment would not be budget neutral and could be effective for cost reporting periods beginning on or after January 1, 2024. CMS also notes an adjustment under OPPS could be considered for future years.

Potential Separate Payment Under the IPPS and OPPS for Establishing and Maintaining Access to a Buffer Stock of Essential Medicines

Payment Amount

Given policy goals related to a more resilient supply chain, CMS believes it may be appropriate to pay separately for the additional resource costs associated with establishing and maintaining access, including through contractual arrangements, to a buffer stock of essential medicines. In the Proposed Rule, CMS clarifies that these potential separate payments would be in addition to payment for the essential medicines themselves (e.g., bundled with other items or services or separately paid) and would help account for the additional resource costs associated with establishing and maintaining access, including through contractual arrangements, to a buffer stock of these essential medicines.

While CMS expects that the resources required to establish and maintain access to a buffer stock of essential medicines will generally be greater than the resources required to establish and maintain access to these medicines without such a buffer stock, the agency indicates that based on currently available information, it is challenging to quantify these additional resource costs. As a result, CMS notes that it could initially base the IPPS payment on the IPPS share of the additional reasonable

costs of a hospital to establish and maintain access to its buffer stock.[18] These costs, which could include costs to hold essential medicines directly at the hospital, arrange contractually for a distributor to hold or arrange contractually with a wholesaler for a manufacturer to hold, could be reported to CMS by a hospital in aggregate on its cost report. This reported information, along with existing information already collected on the cost report, could be used to calculate a Medicare payment for the estimated cost, specific to each hospital, incurred to establish and maintain access to its buffer stock of these essential medicines.

Also, CMS provides that payments for the IPPS shares of establishing and maintaining access to a buffer stock of essential medicines could be provided biweekly as interim lump-sum payments (a provider could make a request for these payments) to the hospital and would be reconciled at cost report settlement. CMS notes that the payment amount would be determined by Medicare Administrative Contractors (MACs). CMS indicates that it will separately seek comment on a potential supplemental cost reporting form that could be used for this purpose. In future years, the MACs could determine the interim biweekly lump-sum payments utilizing information from the prior year's cost report, which may be adjusted based on the most current data available.

CMS seeks comment on all aspects of this potential payment policy. In addition, CMS poses a series of questions to related to the potential payment policy, as listed in the Proposed Rule (pg. 826-829).

Devices

CMS provides that it may consider expanding the policy to include critical medical devices once the Food and Drug Administration's Critical Medical Device List becomes available, which is expected to be released by the end of 2023.

What's Next?

The OPPS tables for this CY 2024 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 at the beginning of the calendar year (January 1, 2024). The comment period closes on September 11, 2023.

Vizient's Office of Public Policy and Government Relations looks forward to hearing 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.

[18] As noted in the Proposed Rule, the use of IPPS shares in this payment adjustment would be consistent with the use of these shares for the payment adjustment for domestic NIOSH approved surgical N95 respirators