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Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

July 26, 2024

Background & Summary

On July 10, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2025 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 proposes updates to the Conditions of Participation (CoPs) for hospitals and critical access hospitals with the aim of advancing the health and safety of pregnant, birthing and postpartum patients.

Comments are due **September 9, 2024**, and the final rule is expected to be released by early November. Most provisions will go into effect January 1, 2025. Vizient looks forward to working with members to help inform our letter to the agency.

OPPS Payment Update

For CY 2025, CMS proposes to apply an outpatient department (OPD) fee schedule increase factor of 2.6 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 0.6 percent. The proposed increase factor of 2.6 percent is based on the proposed hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital Inpatient Prospective Payment System (IPPS), minus the proposed productivity adjustment of 0.4 percentage points.

As done in prior years, CMS proposes to use the OPD fee schedule increase factor and other budget neutrality adjustments to calculate the CY 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 on the following page. 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 2024.

CMS estimates that based on changes for budget neutrality, both urban and rural hospitals would experience an increase (approximately 2.4 percent for urban hospitals and 2.8 percent for rural hospitals). When classifying hospitals by teaching status, CMS estimates non-teaching hospitals would experience an increase of 2.5 percent, minor teaching hospitals would experience an increase of 2.7 percent and major teaching hospitals would experience an increase of 2.1 percent.

CMS estimates that, for CY 2025, the cumulative effect of all proposed changes will increase payments by 2.3 percent for all providers and 2.4 percent for all hospitals. Also, CMS proposes a CY 2025 conversion factor (CF) of $89.379 for hospitals that meet the Hospital OQR Program requirements.

CMS estimates total payments to OPPS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for CY 2025 would be approximately $88.2 billion, which is an increase of approximately $5.2 billion, compared to estimated CY 2024 OPPS payments.

Table 1. Estimated Impact of the Proposed CY 2025 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	3511	0.0	0.1	2.7	2.3
All hospitals*	3413	0.1	0.2	2.9	2.4
Urban hospitals	2722	0.1	0.1	2.8	2.4
Rural hospitals	691	-0.1	1.0	3.5	2.8
Non-teaching status hospitals	2093	0.2	0.2	3.0	2.5
Minor teaching status hospitals	882	0.1	0.5	3.2	2.7
Major teaching status hospitals	438	-0.1	-0.2	2.3	2.1

*Excludes hospitals held harmless and Community Mental Health Centers (CMHCs)
** Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2025 hospital inpatient wage index. The final rural SCH adjustment would continue the CMS policy of 7.1 percent, so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0006 because the proposed CY 2025 target payment-to-cost ratio is less than the CY 2024 PCR target.
***Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage point for the productivity adjustment).

[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)

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 this 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 2025, CMS proposes to continue implementing various provisions affecting the wage index, such as reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), the low wage index hospital policy and the permanent 5 percent cap on any decrease to a hospital's wage index from its wage index in a prior FY.

In addition, CMS notes that the proposed changes to the IPPS wage index based on the newest Core Based Statistical Area (CBSA) delineations (Office of Management and Budget Bulletin No. 23-01) are available in the FY 2025 IPPS proposed rule. CMS proposes that corresponding changes from the FY 2025 IPPS final rule would be adopted in the OPPS, which uses the IPPS wage index (proposed FY 2025 hospital wage index files).

Proposed Hospital Outpatient Outlier Payments

OPPS provides outlier payments (added to the Ambulatory Payment Classification (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 2025, CMS proposes an $8,000 fixed-dollar amount threshold plus the APC payment amount. The CY 2025 multiplier threshold would remain 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 Updates Affecting OPPS Payments

Recalibration of Ambulatory Payments Classifications Relative Payment Weights

At least once annually, CMS must revise the relative payment weights for APCs to consider changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Consistent with CY 2024, for CY 2025, 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 2025 APC recalibration, CMS proposes to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios to convert charges to estimated costs through the application of a revenue code-to-cost center crosswalk. CY 2025 recalibration uses CY 2023 claims data.

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[2], through APCs rather than packaging payment for them into payment for procedures in which they are administered. The proposed CY 2025 payment rates for blood and blood products (generally identified with status indicator "R") and brachytherapy sources (generally identified with status indicator "U") are included on Addendum B of the Proposed Rule. **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 2025

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 comprehensive C-APC policy, a service described by a HCPCS code is assigned to a C-APC as the primary service when the service has the OPPS status indicator "J1". Historically, items packaged for payment provided in conjunction with the primary C-APC service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as supplies. Also, with some exceptions[3], 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.

For CY 2025, CMS does not propose to convert any standard APCs to C-APCs and therefore, the number of C-APCs for CY 2025 would remain stable at 72 C-APCs. Table 2 of the Proposed Rule (Pg. 65) lists the Proposed CY 2025 C-APCs.

Addendum J of the Proposed Rule includes a list of CY 2025 C-APC payment policy exclusions, among other information. Additional detail regarding two exclusion proposals (Cell and Gene Therapies and Non-Opioid Treatment for Pain Relief) are described below.

C-APC Policy Exclusions for Cell and Gene Therapies

In the Proposed Rule, CMS considers expanding the list of exclusions from the C-APC policy to add cell and gene therapies. CMS notes that there are rare instances where the cell and gene therapies listed in Table 1 of the Proposed Rule (pg. 61-62) (i.e., Yescarta, Kymriah, Provenge, Tecartus, Breyanzi, Abecma, Carvytki, Luxturna, Zolgensma), which are usually separately payable under the OPPS, appear on the same claim as a primary C-APC service and therefore, have their payment packaged with payment for the primary C-APC service. In addition, CMS believes that the cell and gene therapies listed in Table 1 of the Proposed Rule serve as independent therapies and are not assisting in the delivery of any primary procedure currently assigned to a C-APC. As a result, for CY 2025 only, CMS proposes not to package payment for the cell and gene therapies listed in Table 1 of the Proposed Rule into the payment for the primary C-APC service when they appear on the same claim as primary C-APCs service. CMS indicates that the proposal is for one year only to

[2] 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.

[3] 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.

gather more information from interested parties as to whether this proposed policy appropriately captures all of the unique therapies that function as primary treatments and do not support C-APC primary services. **CMS welcomes comments on this proposal and the potential need for a different, modified, expanded, or supplemental policy for future rulemaking. CMS also seeks comment on whether there are any additional cell and gene therapies that may be appropriate to exclude from C-APC packaging for CY 2025.**

CMS also seeks comment on the following questions:

- **How could the agency structure a new C-APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such by creating as a Chimeric Antigen Receptor (CAR) T-cell therapy administration C-APC, with which the CAR-T or gene therapy would be integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service?**
- **What integral, ancillary, supportive, dependent, or adjunctive items and services are routinely provided as part of the administration of cell and gene therapies or in conjunction with cell and gene therapies generally?**

C-APC Policy Exclusions for Non-Opioid Treatment for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328), included a section that prohibits the packaging of payment for non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and requires that an additional payment be made for the non-opioid treatment for pain relief. Accordingly, CMS proposes to exclude the non-opioid treatments for pain relief from the C-APC policy. A list of products for which CMS proposes would qualify for payment under the new payment policy for non-opioid drugs, biologicals, and devices for pain relief is available in Tables 84 and 85 of the Proposed Rule (pg. 592-594). Also, among other changes to implement this section of the CAA, 2023, CMS proposes to create new status indicators for non-opioid drugs and devices and payment limitations. Under the OPPS, non-opioid drugs and biologicals included in this exclusion policy would be assigned a status indicator of K1, while non-opioid devices would be assigned a status indicator of H1.

Composite APCs

Since CY 2008, CMS has developed composite APCs to provide a 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 2025 and subsequent years, CMS proposes to continue policy finalized in CY 2024 regarding payment through composite APC 8010. Specifically, payment through composite APC 8010 is provided when the aggregate payment for specified mental health services is 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, and exceeds the per diem payment rate for 4 partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864). In addition, CMS proposes to continue to set the payment rate for composite APC 8010 at the same payment rate that CMS proposes for APC 5864, which is a partial hospitalization per diem payment rate for 4 partial hospitalization services furnished in a day by a hospital.

For CY 2025, 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 3 (pg. 72-76) of the Proposed Rule lists the proposed HCPCS codes

that would be subject to the multiple imaging composite APC policy and approximate composite APC proposed geometric mean costs for CY 2025.

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 2025, 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. **CMS does not propose changes to the overall packaging policy, but does provide payment proposals related to diagnostic radiopharmaceuticals and non-opioid treatments for pain relief.**

Proposed Payment for 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.

In the CY 2024 OPPS proposed rule, CMS requested feedback on how the OPPS packaging policy for diagnostic radiopharmaceuticals has impacted beneficiary access and potential new payment approaches that would improve access. Based on this feedback, CMS proposes to change the current policy that packages diagnostic radiopharmaceuticals regardless of their cost.

Specifically, CMS proposes to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630. CMS reaches $630 by proposing to use two as the multiplier for the volume weighted average amount of the offset, as further detailed in the Proposed Rule (pg. 82-87). **However, the agency seeks comment regarding the use of 1.75 times as the multiplier threshold, rather than 2. Also, CMS seeks comment on the alternative of using the standard drug packaging threshold, which is proposed to be $140 for CY 2025, as the threshold for separate payment for diagnostic radiopharmaceuticals.** CMS also proposes that only radiopharmaceutical HCPCS codes that are identified as separately payable in the final rule with comment period would be subject to quarterly updates. As a result, the packaging status of some HCPCS codes for diagnostic radiopharmaceuticals in the OPPS/ASC proposed rule may differ from the same HCPCS codes' packaging status determined based on the data used for the final rule with comment period.

The agency clarifies that any diagnostic radiopharmaceutical with a per day cost below that threshold would continue to be policy packaged. CMS also clarifies that if the proposal to unpackage certain diagnostic radiopharmaceuticals (i.e., radiopharmaceuticals listed in Table 5 of the Proposed Rule (pg. 102-103)) is finalized then it would change the APC geometric mean unit costs (MUCs) as well as the offset percentages for nuclear medicine APCs.

Also, starting in CY 2026 and in subsequent years, CMS proposes to update the proposed threshold amount of $630 by the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI).

Regarding the amount of the separate payment for diagnostic radiopharmaceuticals, CMS proposes to assign a given radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD). Although CMS typically uses an Average Sales Price (ASP) methodology for payment purposes, the agency notes that radiopharmaceuticals are not required to report ASP. As a result, the agency has limited ASP data and the values that the agency does have generally do not align with the ASP that CMS would expect based on the cost and mean unit cost (MUC) data submitted to CMS by hospitals. CMS encourages manufacturers to submit ASP information for diagnostic radiopharmaceuticals which could be used in the future in paying for diagnostic radiopharmaceuticals. **CMS seeks comment on whether it should require payment for diagnostic radiopharmaceuticals on ASP in the future, such as in CY 2026 rulemaking.** More information regarding reporting of this ASP data is in the Proposed Rule (pg. 92-96). In CY 2025, CMS proposes to use MUC to pay for separately payable diagnostic radiopharmaceuticals.

CMS also seeks comment on unique situations in which it may be appropriate for CMS to use ASP information to assess per days costs and payment amounts for diagnostic radiopharmaceuticals for CY 2025 (e.g., continuing the use of ASP for a particular HCPCS code once its pass-through status has ended). CMS clarifies that under the current proposal, payment for a diagnostic radiopharmaceutical would be based on MUC once its pass-through status ends. **CMS also seeks comment on the use of the agency's equitable adjustment authority to make limited ASP data reported for diagnostic radiopharmaceuticals usable for purposes of setting payment rates for qualifying products.**

Proposed Payment for Non-Opioid Treatments for Pain Relief

As noted above, the CAA, 2023 provides temporary additional payments for non-opioid treatments for pain relief furnished from January 1, 2025 and before January 1, 2028.

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. Also, OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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 2025 OPPS update, CMS identified 23 APCs that violate the 2 Times Rule and for which CMS proposes to make an exception for CY 2025. Table 13 of the Proposed Rule (pg. 168-169) lists the proposed exceptions.

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 2025, CMS included the proposed payment rates for New Technology APCs 1491-1599 and 1901-1908 in Addendum A.

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 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. Table 42 (pg. 235) of the Proposed Rule lists the devices with pass-through status expiring in 2024, 2025, 2025 or 2027.

Regarding applications for device pass-through status for CY 2025, CMS received 14 complete applications by the March 1, 2024 quarterly deadline which is the last quarterly deadlines for application to be included in the Proposed Rule. CMS received 10 alternative pathway device pass-through applications (i.e., devices that received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation). More information regarding the applications is available in the Proposed Rule (pg. 241-377). **CMS welcomes comments on these applications.**

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.[4] 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 2025 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B.

Drugs, Biologicals and Radiopharmaceuticals with Pass-Through Payment Expiring in CY 2025

For CY 2025, CMS proposes to end pass-through payment status for 28 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2022 – January 1, 2023, are listed in Table 63 (pg. 400-402) of the Proposed Rule. For CY 2025, CMS proposes to continue to pay for pass-through drugs and biologics using the ASP methodology, which is generally ASP plus 6 percent.

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

[4] 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."

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. CMS also notes that if ASP data is not available for a radiopharmaceutical, CMS would continue to provide pass-through payment at WAC plus 3 percent which is the equivalent payment provided for pass-through drugs and biologicals without ASP information.

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 2025

CMS proposes to continue pass-through payment status in CY 2025 for 57 drugs and biologicals which had pass-through payment status begin between April 1, 2023 – April 1, 2024; these drugs and biologicals are listed in Table 64 of the Proposed Rule (pgs. 404-409).

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 for drugs, biologicals and therapeutic radiopharmaceuticals.

As noted above, CMS proposes a packaging threshold of $630 for CY 2025 for diagnostic radiopharmaceuticals.

Biosimilar Biological Products

CMS notes that in recent years, the agency observed that there has been an increasing number of drug and biological HCPCS codes for which ASP, WAC, AWP, and mean unit cost information (MUC) is not available. These are often HCPCS codes for new drugs or biologicals that have been approved for marketing, but for which the manufacturer does not have sales data, and WAC, AWP, and MUC information is not available. As a result, CMS is unable to assign a payable status indicator to these drugs or biologicals due to of a lack of payment data.

To provide appropriate payment rates for these drugs and biologicals without pricing data, CMS proposes to adopt an invoice pricing policy beginning in CY 2026. More specifically, Medicare Administrative Contractors (MACs) would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, CMS proposes that MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. CMS generally would expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP. Also, CMS provides that for drug products that are not required to report ASP, invoice pricing may be used longer term until a MUC can be calculated. To implement

this policy, CMS indicates that it would need to make technical updates to outpatient hospital claims to allow the hospitals to report drug invoice pricing.

For CY 2025, CMS clarifies that the affected drugs and biologicals would continue to be assigned a non-payable status indicator until CMS implements the invoice pricing policy, if adopted.

Radioisotopes Derived from Non-Highly Enriched Uranium (non-HEU) Sources

Technetium-99m (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced through the radioactive decay of molybdenum-99 (Mo-99). Historically, most of the Mo-99 used in the United States was produced outside of the United States using highly enriched uranium (HEU). However, the United States government has been working to minimize reliance on HEU sources and encouraged non-HEU sources in response to supply concerns. In prior rulemaking, CMS finalized policy to provide an additional $10 payment for Tc-99m derived from non-HEU sources given increased costs associated with such sources.[5]

As noted in the Proposed Rule, in January 2022, the Secretary of Energy stated that there was a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. In the CY 2023 OPPS final rule, CMS indicated that in CY 2025, the agency believed there would no longer be a need for the additional $10 payment.

In the Proposed Rule, CMS indicates that U.S. companies have made significant progress towards establishing the infrastructure needed for large-scale Mo-99 production. However, U.S. companies have experienced challenges in competing with foreign producers for customers and currently, there is no domestic production of Mo-99. CMS anticipates that once U.S. companies initiate or resume Mo-99 production, domestically produced Mo-99 will be more expensive than imported Mo-99. Using its equitable adjustment authority and starting January 1, 2026, CMS proposes to provide a $10 add-on payment for domestically produced Tc-99m radiopharmaceuticals. CMS clarifies that Department of Energy (DOE)/National Nuclear Security Administration (NNSA) would establish the criteria to certify whether the Tc-99m radiopharmaceutical dose is domestically produced and eligible for the add-on payment, which would be included in the CY 2026 OPPS proposed rule. Also, the CY 2026 OPPS proposed rule would include additional details on how providers would bill for this add-on payment in CY 2026.

Requirement in the CY 2025 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 2025 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 2025 PFS final rule.

[5] Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources.

Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments

In the Proposed Rule, CMS notes that on July 12, 2023, CMS proposed to cover Pre-Exposure Prophylaxis (PrEP) to prevent Human Immunodeficiency Virus (HIV) under Medicare Part B. If finalized as proposed, all of the components would be covered as an additional preventive service without Part B cost-sharing (i.e., deductibles or co-pays). The final National Coverage Determination (NCD) has not been issued as of the issuance of the Proposed Rule. For CY 2025, CMS proposes to pay for HIV PrEP drugs and related services as additional preventive services under the OPPS, if covered in the final NCD.

Table 72 of the Proposed Rule (pg. 512-513) provides the HCPCS coding and long descriptors for HIV PrEP drugs and services. CMS proposes to pay for the HCPCS codes listing in Table 72 that are furnished in HOPDs in a similar manner as when the codes are furnished in the physician office. The proposed CY 2025 payment rates can be found in Addendum B.

To determine the OPPS payment amount for HIV PrEP drugs, CMS proposes to utilize the ASP methodology. If ASP data for HIV PrEP is not available, CMS proposes to determine the payment amount for the applicable billing and payment code using the most recently published amount for the drug in Medicaid's National Average Drug Acquisition Cost (NADAC) survey. NADAC data is publicly available, reflects prices paid by retail community pharmacies, and it can be accessed at https://data.medicaid.gov/nadac. CMS propose to use Federal Supply Schedule (FSS) data when ASP and NADAC data are not available; more information on this pricing methodology for the physician office setting is available in the CY 2025 PFS proposed rule.

CMS notes that the PFS proposal includes a final step of invoice pricing; however, invoice pricing is not currently available under the OPPS, so CMS is not proposing to adopt that portion of the PFS proposal. Instead, for OPPS, CMS proposes that if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, CMS will generally use WAC plus 6 percent, or 3 percent, in certain circumstances. In the Proposed Rule, CMS acknowledges that this would result in different pricing between the OPPS and PFS if ASP, NADAC, and FSS pricing are not available, but CMS believes it is appropriate because invoice pricing is not an option under the OPPS and this pricing metric should only apply to a small subset of drugs covered as additional preventive services until one of the other pricing metrics becomes available. CMS also proposes to treat other drugs covered as an additional preventive service under this same methodology. CMS proposes to assign drugs covered as an additional preventive service to status indicator K to operationalize separate payment.

Lastly, CMS notes that HCPCS code J0799 may be used to describe an HIV PrEP drug that is approved by the Food and Drug Administration (FDA) but not otherwise classified. For these products, CMS proposes to pay 95 percent of AWP for HCPCS codes J0799, consistent with how unlisted drugs and biologicals are paid under the OPPS when reporting with HCPCS codes C9399 (Unclassified drugs or biologicals).

Payment Policy for Devices in Category B Investigational Device Exemption (IDE) Clinical Trials Policy and Drugs/Devices with a Medicare Coverage with Evidence Development (CED) Designation

CMS proposes to develop alternative methods of payment under Medicare Part B for drugs and devices being studied in clinical trials under a CED NCD. Such methods of payment aim to be similar to the agency's policy on devices in Category B IDE trials. These CED NCDs will be listed on the CMS CED website. For CY 2025, CMS proposes to make a single blended payment rate that would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control where the investigational device is not

used. Also, CMS proposes to base the payment amount for the study drug, or active comparator drug, on the ASP methodology, that is ASP plus 6 percent if ASP data is available.[6]

In the Proposed Rule, CMS also proposes to codify policy related to Category B IDE clinical trials with control arms.

Request for Comment on Payment Adjustments under the IPPS and OPPS for Domestic Personal Protective Equipment

The CY 2023 OPPS final rule implemented payment adjustments under the OPPS and IPPS to support a resilient and reliable supply of surgical N95 respirators. CMS notes that although the payment adjustments for domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 respirators under the OPPS and IPPS have applied to cost reporting periods beginning on or after January 1, 2023, use of the payment adjustments has been limited. **CMS is interested in feedback on potential modifications to the payment adjustment in order to reduce reporting burden and achieve the policy goal to maintain a baseline domestic production capacity of PPE.**

In the Proposed Rule, CMS provides specific questions regarding payment adjustment methodology (pg. 504-505), payment adjustment eligibility (pg. 505-506) and types of N95 respirators (pg. 507). In addition, CMS is considering expanding the payment adjustment policy to include nitrile gloves. Since nitrile gloves are not covered by the Berry Amendment[7], CMS believe the Make PPE in America domestic content requirements outlined in Section 70953 of the Infrastructure Investment and Jobs Act is the most appropriate framework for determining if a nitrile glove is wholly made in the U.S. Also, based on available data, the agency's best estimate of the difference in the average unit cost of domestic and non-domestic nitrile gloves is $0.13 per glove. More specific questions for feedback are provided in the Proposed Rule (pg. 511-512). **Lastly, CMS seeks comment on other PPE types and medical devices that could be appropriate for a similar payment adjustment.**

OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2025, 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 (Hospital outpatient clinic visit for assessment and management of a patient) when it is furnished by these departments.

For CY 2025, CMS proposes to continue to exempt excepted off-campus provider-based departments (PBDs) of rural sole community hospitals (SCHs) from the clinic visit payment policy. CMS indicates it will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

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[6] If ASP data is not available, then CMS proposes to pay the wholesale acquisition cost (WAC). During an initial sales period, we propose to base the payment on WAC plus 3 percent, otherwise, we propose to base payment on WAC plus 6 percent. If WAC is not available, then we propose to pay 95 percent of average wholesale price (AWP). This payment hierarchy is consistent with CMS payment for non-passthrough separately payable drugs in the OPPS as discussed in section V.B. of this proposed rule.

[7] The Berry Amendment is a statutory requirement that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States.

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.[8] For CY 2025, 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 2025.

As provided in Table 2, CMS proposes to add three services to the IPO list for codes that were newly created by the AMA CPT Editorial Panel for CY 2025. CMS proposes to assign these services to status indicator ‘‘C’’ (Inpatient Only) for CY 2025.

Table 2. Proposed Additions to the IPO List for CY 2025

CY 2025 CPT Code	CY 2025 Long Descriptor
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary)
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)

Proposed Changes to the Ambulatory Surgical Center (ASC)-Covered Procedures List (CPL)

For CY 2025, CMS proposes to add 20 medical and dental surgical procedures to the ASC CPL based upon existing criteria. Table 82 of the Proposed Rule (pg. 574-575) lists these additions.

Remote Services

Periodic In-Person Visits for Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

The Consolidated Appropriations Act (CAA), 2023 provided that an in-person visit within six months of an initial behavioral/mental telehealth service, and annually thereafter, is not required for Medicare patients. In the CY 2024 OPPS final rule, CMS reiterated the agency’s aim to maintain consistent requirements for telehealth policies across payment systems. As a result, in the CY 2024 OPPS final rule, CMS finalized delaying the in-person visit requirement for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025. As such,

[8] 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.

under OPPS, the in-person visit requirements are currently set to take effect for services furnished on or after January 1, 2025.

In the Proposed Rule, CMS notes that to the extent that these in-person visit requirements are delayed in the future for professionals billing for mental health services via Medicare telehealth, CMS anticipates that it would align the requirements for mental health services furnished remotely to beneficiaries in their homes through communications technology with mental health services furnished via Medicare telehealth in future rulemaking.

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

The CAA, 2023, temporarily extended several telehealth flexibilities that were available for Medicare telehealth services during the COVID-19 Public Health Emergency (PHE). In the CY 2024 PFS Final Rule, CMS finalized policy to continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have done during the PHE for COVID–19 through the end of CY 2024. Without subsequent legislation to extend certain PHE-related flexibilities, these flexibilities will no longer be available beginning January 1, 2025 (e.g., access to telehealth services in any geographic area in the United States, rather than only rural areas; allowing patients to stay in their homes for telehealth visits rather than traveling to a health care facility; scope of practitioners who can provide telehealth services).

While CMS provides greater detail regarding Medicare telehealth services through PFS rulemaking, in OPPS, the agency describes its aim to align payment policies for outpatient therapy, DSMT, and MNT services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services provided under PFS. As a result, CMS provides that to the extent that therapists and DSMT and MNT practitioners continue to be distant site practitioners for purposes of Medicare telehealth services, CMS anticipates aligning OPPS policy for these services with policies under the PFS and continuing to make payment to the hospital for these services when furnished by hospital staff.

Proposed HOPD Payment for Telemedicine Evaluation and Management (E/M) Services

In 2014, CMS established HCPCS code G0463 to describe the service associated with a hospital outpatient clinic visit for assessment and management of a patient. Also, the CPT codes describing office/outpatient E/M visits are not recognized under OPPS and instead hospitals report HCPCS code G0463 when billing for the facility costs associated with an outpatient E/M visit.

More recently, the CPT Editorial Panel created 17 new codes describing audio/video and audio-only telemedicine E/M services. Additional information regarding these 17 new codes and CMS' related proposals is included in the CY 2025 PFS proposed rule. In the Proposed Rule, CMS proposes not to recognize the new telemedicine E/M code set under OPPS. **However, CMS seeks comment on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for HCPCS code G0463. CMS is also seeking comment, should CMS finalize separate payment for these telemedicine E/M codes under the PFS, on the resource costs that would be associated with these services for hospitals and whether the agency should develop separate coding to describe the resource costs associated with a telemedicine E/M service.**

Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients

In the CY 2024 OPPS final rule, CMS continued to allow for the direct supervision requirement for CR, ICR, and PR to include the virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and to extend this policy to the nonphysician practitioners, that is Nurse Practitioners (NPs), Physician Assistants (PAs), and Clinical Nurse Specialists (CNSs), who were eligible to supervise these services beginning in CY 2024. CMS provided similar extensions to permit virtual supervision of diagnostic services furnished to hospital outpatients in prior rulemaking.

In the CY 2025 PFS proposed rule, CMS proposes to revise the definition of direct supervision to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025. To maintain consistency between the PFS and OPPS, CMS proposes to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025.

Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

The recently finalized CMS Interoperability and Prior Authorization rule requires certain impacted payers to send prior authorization (PA) decisions as expeditiously as the enrollee's health condition requires and no later than 72 hours for expedited (that is, urgent) requests or 7 calendar days for standard (that is, non-urgent) requests. While Medicare fee-for-service (FFS) is not an impacted payer under the CMS Interoperability and Prior Authorization rule, CMS proposes to align the current review timeframe in Medicare FFS to with the aforementioned final rule's requirements. Specifically, CMS proposes to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for these services from 10 business days to 7 calendar days.

However, CMS notes that it is still considering the impact of aligning the expedited review decision timeframe in the CMS Interoperability and Prior Authorization final rule. CMS indicates that, depending on when the expedited request is submitted, it may take longer for OPD provider to receive a decision using the 72-hour timeframe than the agency's current expedited timeframe of 2 business days.

Coverage Changes for Colorectal Cancer (CRC) Screening Services

For CY 2025, based on public input and consultation with specialty societies, and as discussed in the CY 2025 PFS proposed rule, CMS proposes to expand coverage for CRC screening. Table 71 of the Proposed Rule (pg. 502) includes the proposed CY 2025 OPPS status indicator and APC assignment for certain colorectal cancer screening-related codes.

Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

In the Proposed Rule, CMS provides an overview of the agency's commitment to health equity, particularly the interest in a uniform approach for gathering, reporting, and analyzing health equity data across CMS quality programs. As a result, for the Hospital OQR Program, CMS proposes to adopt the Hospital Commitment to Health Equity (HCHE) Measure for the Hospital Outpatient Quality Reporting, in addition to the Rural Emergency Hospital Quality Reporting (REHQR)

Programs beginning with the CY 2025 reporting period/CY 2027 payment determination or program determination.[9] Table 86 of the Proposed Rule (pg. 617-618) provides more information regarding the HCHE attestation measure domains. CMS notes that the HCHE measure is currently used in the Hospital Inpatient Quality Reporting (IQR) Program.

In addition, CMS proposes to adopt the Screening for Social Drivers of Health (SDOH) Measure for the Hospital OQR, REHQR, and ASCQR Programs. Voluntary reporting would begin for the CY 2025 reporting period followed by mandatory reporting for the CY 2026 reporting period/CY 2028 payment or program determination.

CMS also proposes to adopt the Screen Positive Rate for SDOH Measure for the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination.

In addition, CMS proposes to modify the immediate measure removal policy for the Hospital OQR and ASCQR programs beginning with CY 2025. Under this proposed immediate measure suspension policy in the Hospital OQR or ASCQR Programs, in cases where CMS determines there is evidence that the collection and reporting of a measure raises potential patient safety concerns, CMS would suspend the measure from the program (as applicable) until potential removal can be proposed through the rulemaking process. CMS will notify the healthcare facility (HOPDs or ASCs, as applicable) and the public of the decision to suspend the measure through standard communication channels, including, but not limited to, program-specific listservs and program guidance currently housed on a CMS-designated website. CMS would then address the suspension and propose policies regarding any such suspended measure in the next feasible rulemaking cycle. **CMS invites comments on these proposals.**

Requirements for the Hospital Outpatient Quality Reporting Program

The Hospital OQR Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency and ensure accountability of hospital OPDs. Certain hospitals[10] that do not submit data required for measures selected with respect to such a year will incur a 2.0 percentage point reduction to their annual OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, CMS proposes that the reduced conversion factor would be $87.636.

As noted above, CMS proposes to adopt three health equity measures in the Hospital OQR Program. CMS also proposes to remove the cardiac imaging for preoperative risk assessment for non-cardiac, low-risk surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination. **CMS welcomes comment on this proposal, including other potential measures that may better address unnecessary imaging.**

In addition, beginning with voluntary reporting for the CY 2026 reporting period, CMS proposes to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure

[9] CMS makes a similar proposal for the Facility Commitment to Health Equity (FCHE) Measure for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
[10] Subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act)

(Information Transfer PRO–PM). CMS proposes that this measure would be mandatory to report for the CY 2027 reporting period/ CY 2029 payment determination.

Information regarding the proposed updated Hospital OQR Program measure set beginning with the CY 2027 payment determination is available in Table 3. In addition, Table 91 of the Proposed Rule (pg. 659) includes the proposed updated Hospital OQR program measure set beginning with the CY 2031 payment determination.

Table 3. Proposed Updated Hospital OQR Program Measure Set Beginning with the CY 2027 Payment Determination

CBE #	Measure Name
None	Abdomen CT – Use of Contrast Material
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None^	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among HCP
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None	Hospital Commitment to Health Equity***
None^	Left Without Being Seen
None^	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OAS CAHPS • About Facilities and Staff • Communication About Procedure • Preparation for Discharge and Recovery • Overall Rating of Facility • Recommendation of Facility
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	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 HOPD Setting (THA/TKA PRO–PM)****
None	Screening for Social Drivers of Health*****
None	Screen Positive Rate for Social Drivers of Health*****
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

^Measure no long endorsed by the consensus based entity (CBE) but was endorsed previously.
*The measure is voluntary
** This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.
***In the Proposed Rule, CMS proposes to adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination.
****This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination.
*****In the Proposed Rule, CMS proposes to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

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

In prior rulemaking, CMS established general data submission policies and is not proposing any changes to these policies.

For the proposed health equity measures, CMS proposes that HOPDs would be required to submit all of the data required to calculate these measures annually using a CMS-approved, web-based, data collection tool. CMS also outlines the data submissions period in the Proposed Rule. For

example, for the CY 2025 reporting period/2027 payment determination, the data submission period would be January 1, 2026, through and including May 15, 2026, covering the performance period of January 1, 2025, through and including December 31, 2025. During this timeframe, HOPDs would be able to enter, review, and correct data submitted for these measures. **CMS invites comment on this proposal.**

Building from prior policy in the Hospital IQR Program and the Medicare Promoting Interoperability Program, CMS proposes that beginning with the CY 2025 reporting period/CY 2027 payment determination, a HOPD using EHR technology certified to the Office of the National Coordinator (ONC) Health Information Technology (IT) certification criteria would be required to have its electronic health record (HER) technology certified to all electronic clinical quality measures (eCQMs) that are available to report under the Hospital OQR Program to meet reporting requirements for the Hospital OQR Program. Also, CMS further proposes that for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, HOPDs would additionally be required to use the most recent version of the eCQM electronic measure specifications for the designated reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: https://ecqi.healthit.gov/. **CMS welcomes comment on these proposals.**

Regarding data submission for PRO-PM, CMS proposes to require the use of the HQR system for submissions to all PRO-PM, including the Information Transfer PRO-PM which will be voluntary for the CY 2026 reporting period and mandatory for the CY 2027 reporting period. CMS clarifies that HOPDs may choose to: (1) directly submit their PRO–PM data to CMS using the HQR system; or (2) utilize a third-party entity, such as a vendor or registry, to submit their data using the Hospital Quality Reporting (HQR) system. **CMS welcomes public comment on this proposal.**

More information regarding reporting requirements specific to the Information Transfer PRO-PM is available in the Proposed Rule (pg. 666-667).

Public Reporting of Measure Data

CMS notes that in the CY 2024 OPPS final rule, CMS finalized that data for three measure strata (i.e., Overall Rate, Reporting Measure and Transfer Patients) would be publicly reported on both data.medicare.gov and on the Care Compare website. Data for Psychiatric/Mental Health Patients stratum are not reported on the Care Compare website but are published on data.medicare.gov. Beginning in CY 2025, CMS proposes to make data for the Psychiatric/Mental Health Patients stratification available on Care Compare. **CMS invites comments on this proposal.**

Modification to the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measures in the Hospital Inpatient Quality Reporting Program

Within the Hospital Inpatient Quality Reporting Program, the Hybrid Hospital-Wide Readmission (HWR) measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. Also, the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure is an outcome measure that captures the hospital-level, risk-standardized mortality rate (RSMR) of unplanned, all-cause mortality within 30 days of hospital admission for any eligible condition. CMS previously finalized policy that it would begin public reporting of both hybrid measures' results, beginning with data collected from July 1, 2023 – June 30, 2024 reporting period, impacting the FY 2026 payment determination.

However, CMS indicates that based on hospital performance during the most recent voluntary reporting period, it appears that hospitals are unprepared for mandatory reporting of the Hybrid

HWR and Hybrid HWM measures. As a result, CMS proposes the for the FY 2026 payment determination, the submission of core clinical data elements (CCDEs) and linking variables would remain voluntary. Also, CMS proposes that for the FY 2027 payment determination and subsequent years, the submission of CCDEs and linking variables would become mandatory. CMS clarifies that under the proposal, a hospital's annual payment determination for FY 2026 would not be affected by the voluntary reporting of CCDEs and linking variables, although CMS would still evaluate and assess the claims data portion of these measures. **CMS welcomes comment on the proposal to continue voluntary reporting of the CCDEs and linking variable for both the Hybrid HWR and Hybrid HWM measures for the FY 2026 payment determination for the Hospital IQR Program. CMS seeks specific feedback regarding the difficulties hospitals have in meeting the thresholds and any recommendations hospitals may have based on their experiences reporting on hybrid measures.**

Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Summary

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS' hospital quality measurement programs, by assigning hospitals between one and five stars. Measures reported on the provider comparison tool on Medicare.gov (https://www.medicare.gov/care-compare/) that meet the criteria for inclusion in the Overall Hospital Quality Star Rating are organized into five measure groups: Safety of Care, Mortality, Readmission, and Patient Experience (all of which include outcome measures), and Timely and Effective Care (which includes a selection of process measures). The current methodology places the highest emphasis on the Safety of Care and Mortality measure groups (i.e., each weighed at 22% and hospitals must report at least three measures in each of at least three measure groups, one of which must specifically be Safety of Care or Mortality).

CMS notes the government's commitment to the improvement of patient safety and acknowledges the decline in patient safety measure scores during the COVID-19 Public Health Emergency (PHE). Also, CMS provides that under the current Overall Hospital Star Rating methodology, a hospital could score very low in the Safety of Care measure group but still receive a high Star Rating due to their performance in other measure groups. **As part of the national commitment to improving patient safety, CMS seeks feedback on whether hospitals that performed in the bottom quartile (lowest-performing 25 percent) in the Safety of Care measure group should be eligible to receive the highest 5-star rating.**

In addition, CMS is considering three options to modify the Overall Hospital Quality Star Rating methodology: reweighting the safety of care measure group[11]; policy-based 1-star reduction for poor performance on Safety of Care; or reweighting the Safety of Care measure group combing with a Policy-based Star Rating Cap[12]. CMS notes that any modification to the Overall Hospital Quality Star Rating methodology would be addressed through future notice-and-comment rulemaking.

[11] Under this option, the Safety of Care groups weight would increase from 22% to 30%. The Mortality, Readmission and Patient Experience weight would decrease from 22% to 19.7% and the Timely and Effective Care group would decrease from 12% to 10.8%.
[12] Under this option, CMS would increase the weight of the Safety of Care measure group to 30% (and proportionally reducing the weights assigned to the other measure groups, as described in the first option) while also applying a policy that would limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of four stars out of five.

CMS welcomes input from interested parties on these options. Specifically, CMS requests comment on the following:

- **Do you support re-weighting the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care as described in option 1? Do you agree with the potential new weights for each measure group?**
- **Do you support reducing the Star Rating for hospitals with a low Safety of Care score as described in option 2? Do you agree with the potential policy to apply a 1-star reduction to all hospitals in the lowest quartile of Safety of Care?**
- **Do you support a combination of reweighting the Safety of Care measure group with a 4-star maximum on Star Rating as described in option 3?**
- **Do you have feedback or preference towards an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2?**
- **What are other methodological approaches that could be used to emphasize the Safety of Care measure group?**
- **With respect to the potential changes to the Overall Hospital Quality Star Rating methodology, are there any special considerations for small, rural or safety net hospitals (including Critical Access hospitals)?**

Health and Safety Standards for Obstetrical Services in Hospitals and CAHs

Under the Social Security Act, a hospital participating in the Medicare program must meet certain requirements, including those that the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. As a result of this authority, regulatory requirements, known as Conditions of Participation (CoPs) for Hospitals, have been established. To receive Medicaid payments from states, hospitals must also meet the Medicare CoPs.

In the Proposed Rule, CMS provides an overview of various steps the agency has taken to address maternal health, including the issuance of a Request for Information (RFI) on obstetrical service standards for hospitals, CAHs and REHs in the FY 2025 IPPS proposed rule. Based on issues regarding delivery and maternity care, CMS proposes a new obstetrical (OB) services CoP, including proposing requirements for the organization, staffing, and delivery of OB services and staff training. Also, CMS proposes revisions to the current hospital and CAH Quality Assurance and Performance Improvement (QAPI), hospital and CAH emergency services requirements and hospital discharge planning requirements specific to OB services.

Organization, Staffing, and Delivery of Services

The Hospital CoPs include requirements for optional services that hospitals are not required by law to provide but may elect to offer to their patients. If a hospital provides an optional service to its patients, the hospital must comply with the requirements of the CoP specific to that service. While some states have laws and regulations regarding OB services' organizational standards, among others, CMS aims to provide a consistent set of requirements and CMS proposes CoPs specific to obstetrical services for hospital and CAHs CoPs.

Specifically, CMS proposes the following new CoPs for hospitals and CAHs offering obstetrical services outside of an ED. More specifically, CMS proposes:

- Obstetrical services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for physician and behavioral (inclusive of both mental health and substance use disorder) health care of pregnant, birthing, and postpartum patients.

    - In the Proposed Rule, CMS notes that it expects that facilities would be able to articulate their standards and the source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources.
- Obstetrical services must be consistent in quality with inpatient care in accordance with the complexity of services offered. Nationally recognized acceptable standards of practice may be based on medical professional society and/or accrediting organization standards.
- The organization of the obstetrical services is appropriate to the scope of services offered by the facility and integrated with other departments of the facility.
    - For example, a labor and delivery unit would need to ensure good communication and collaboration with services such as laboratory, surgical services, and anesthesia services as applicable.
- The OB patient care units (that is, labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate) are supervised by an individual with the necessary education and training, and specify that that person should be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy.
- Obstetrical privileges be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service must maintain a roster of practitioners specifying the privileges of each practitioner. CMS notes that this CoP provides additional specificity for obstetrics services in contrast to existing CoPs. Also, CMS clarifies that if not otherwise prohibited by State law, a hospital may elect to include these practitioners (such as advanced practice providers, including advanced practice registered nurses, clinical nurse specialists, physician assistants, and nurse midwives) as part of their medical staff.
- Requiring that OB services be consistent with the needs and resources of the facility. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.
- Labor and delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. **CMS welcomes comment on what is an appropriate minimum set of equipment for all hospitals offering obstetric services.**
- Ensure that it has protocols, consistent with evidence-based, nationally recognized guidelines, as well as readily available provisions (that is, necessary supplies and equipment on the unit or in close proximity and easily accessed by unit personnel) for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program. While this requirement does not require any specific items, CMS indicates it would expect provisions to include equipment, in addition to the equipment required under other parts of the CoPs, supplies, blood, and medication used in treating emergency cases.
- **CMS welcomes comments on these proposals, including whether these proposed requirements should be applicable to REHs.**

Regarding training for obstetrical staff, CMS proposes:

- Hospitals and CAHs with OB services would be required to develop policies and procedures that would ensure that relevant obstetrical services staff would be trained on select topics for improving the delivery of maternal care.
- Training topics would have to reflect the scope and complexity of services offered, including, but not limited to, facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility.
- Hospitals and CAHs that provide OB services must use findings from their QAPI programs to inform obstetrical staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

- A governing body must identify and document which staff must complete annual training on certain topics identified in regulation.[13]
- The hospital and CAH must document in the staff personnel records that the training was successfully completed.
- The hospital and CAH must be able to demonstrate staff knowledge on the topics identified in regulations[14]. CMS is not proposing to require the specific manner or method in which the facility would be required to demonstrate that their staff is knowledgeable.
- **CMS welcomes comment on these proposals, including whether these proposed staff training requirements should be applicable to REHs. CMS also seeks public comment on whether CMS should require specific training on person-centered care, trauma-informed care, cultural competency, and/or other topics as part of the evidence-based training.**

Quality Assessment and Performance Improvement Program

Medicare-participating hospitals and CAHs are required by CMS regulations to engage in quality activities to improve patient care and outcomes and to facilitate efficient and effective operations under the QAPI program standards. CMS proposes to revise existing QAPI standards for hospitals and CAHs that offer obstetrical services. CMS proposes that a facility would, at a minimum, have to: (1) analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the facility among OB patients; (2) measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among OB patients; (3) analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among OB patients; and (4) conduct at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of OB patients annually.

Also, CMS proposes a new standard for Maternal Health QAPI activities for hospitals and CAHs. Specifically, CMS proposes that for those hospitals and CAHs offering OB services, leadership must be engaged in the facility's QAPI activities. CMS clarifies that for this provision, leadership is defined as facility leadership, obstetrical services leadership or their designate.

CMS welcome public comments on the enhancements to the existing QAPI standards for hospitals and CAHs that offer obstetrical services proposed above. CMS also welcomes comment on:

- **How effectively would these proposals achieve CMS' central goal of improving the health and safety of all pregnant, birthing, and postpartum patients in Medicare-participating hospitals and CAHs, including reducing worsened health outcomes among vulnerable subpopulations?**
- **To what extent do facilities already stratify, measure, analyze, and track quality data and indicators over time by diverse subpopulations or conduct performance improvement projects focused on reducing maternal health disparities as part of their QAPI activities? What are examples and outcomes of such work to date? What challenges do facilities (including those in rural areas or geographically isolated**

[13] §482.59(c)(1) and §485.649(c)(1)
[14] §482.59(c)(1) and §485.649(c)(1)

areas) face in performing such data stratification (for example, administrative recordkeeping processes, information systems, patient willingness to disclose information, and staff time/expertise) and implementing maternal health equity related QAPI projects? How can such challenges be overcome? What is needed for facilities to collect and stratify data by diverse sub-populations?

- **What types of data stratifications/subgroups/categories are key to ensuring the health and safety of all pregnant, birthing, and postpartum patient subgroups? How can facilities best ensure their subgroup data collection and analysis reflects the diverse subpopulations served? What is the benefit versus possible unintended consequences of CMS defining and requiring a minimum set of data stratifications/subgroup/categories in facilities' maternal health QAPI program analyses? For example, should facilities be required to, at minimum, collect and stratify data by the subgroups included in MMRIA? How can facilities meaningfully acquire and disseminate subpopulation data in a way that avoids disclosure (that is, protecting individual privacy and confidentiality of their data), which can lead to increased vulnerability for underserved populations? How should facilities address stratifying small populations?**
- **How can facilities best involve and/or share the results of the facilities' maternal health equity focused QAPI efforts with patients, their families/caregivers, and community members? What are examples and outcomes of such efforts to date? What gaps and challenges exist?**
- **Should any of these proposals apply to other types of Medicare-participating facilities besides hospitals and CAHs that offer OB services? For example, should similar requirements apply to REHs? What could be the benefits, challenges, or potential unintended consequences of such policies? How could CMS minimize the burden of any such requirements?**

Emergency Services Readiness

In the Proposed Rule, CMS notes that while the hospital Emergency Services CoP already requires that "there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility", CMS believes clearer expectations surrounding "qualified in emergency care" and maintenance of qualifications (that is, training) would improve facilities' readiness to care for patients with emergency conditions, enhancing patient health and safety. As a result, CMS proposes the following for facilities that offer emergency services:

- Facilities would be required to have adequate provisions and protocols to meet the emergency needs of patients in accordance with the complexity and scope of services offered. For protocols, hospitals must have protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions.
    - CMS also clarifies that for these hospitals and CAHs, applicable emergency personnel would need to be trained on these protocols and provisions annually.
- Facilities must keep certain provisions at the hospital and readily available for treating emergency cases. The available provisions must include: (1) drugs, blood and blood products, and biologicals commonly used in life-saving procedures; (2) equipment and supplies commonly used in life-saving procedures; and (3) a call-in-system for each patient in each emergency services treatment area. Also, CMS clarifies that each facility would be expected to tailor their equipment and supplies to meet the needs of their patient populations, consistent with the needs, services, and resources of the facility. CMS notes it is not proposing new emergency services equipment, supplies or medication requirements for CAHs or REHs.

- A call-in-system for each patient in each emergency services treatment area. CMS notes this is in line with the surgical services CoP[15].

CMS welcomes comments on these proposals and also poses the following questions:

- **While REHs do have existing equipment, supply, and medication standards, should the above proposals related to provisions, protocols, and staff training apply to REHs as well?**
- **What would be the benefits versus burden of such an approach? How could any burdens be mitigated?**

Transfer Protocols

The discharge planning CoP for hospitals currently requires facilities to have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) in the process. The discharge planning CoP include standards for the discharge planning process, the provision and transmission of the patient's necessary medical information, and discharge to post-acute services. However, as noted in the Proposed Rule, the hospital Discharge Planning CoP does not currently include baseline requirements related to patient transfers. As a result, CMS proposes revisions to the hospital discharge planning regulations to include requirements for transfer protocols.

Specifically, CMS proposes the following:

- Require the hospital to have written policies and procedures for transferring patients under their care. CMS clarifies this would be inclusive of hospital inpatients (e.g., transfers from the emergency department to inpatient admission, transfers between inpatient united within the same hospital, transfers between inpatient units at different hospitals).
- Require the hospital to provide training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care.

CMS welcomes comments regarding the following questions:

- **How often should staff be trained in transfer protocols?**
- **What definitions or criteria exist to determine if a transfer is carried out "promptly and without undue delay"?**
- **Should hospitals be required to have written policies and procedures outlining their standards and conditions for accepting transfers?**
- **Should all hospitals (inclusive of CAHs and REHs) be required to have a documented partnership with another hospital that both provide OB services, as well as have a Medical Fetal Medicine (MFM) specialist available for consultations in urgent situations, if such service(s) are already offered directly by the hospital? What would be the benefits versus burden of such a policy? How could any burden be mitigated?**

Individuals Currently or Formerly in the Custody of Penal Authorities

Under the statutory no legal obligation to pay payment exclusion[16] and subsequent rulemaking, Medicare is prohibited from paying for services furnished to individuals in the custody of penal

[15] 482.51(b)(3)

[16] Section 1862(a)(2) of the Act prohibits Medicare payment under Part A or Part B for any expenses incurred for items or services for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's

authorities with limited exceptions. In the Proposed Rule, CMS outlines various regulatory changes that would help support access to care for individuals returning to the community from incarceration (e.g., narrow the definition of "custody" to no longer include individuals who are on parole, probation and home detention in Medicare's payment exclusion rule, revise the Medicare special enrollment period (SEP) for formerly incarcerated individuals). **CMS welcomes comment on these proposals and seeks comment on how these policies should apply to individuals who are enrolled in halfway houses.**

Medicaid Clinic Services Four Wall Exceptions

Under statutory authority, states may offer certain, optional Medicaid benefits. Clinic services[17] are one of these optional benefit categories. Regulations to implement Medicaid law include certain conditions and limitation on Medicaid coverage of clinic services. Specifically, current regulations provide that clinic services include two types of services furnished to outpatients. The first type of these services is services furnished at the clinic (hereinafter the "four walls" requirement) by or under the direction of a physician or dentist. The second type of clinic services are those furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who is unhoused. CMS proposes to add the following three exceptions to the four walls requirement: (1) an exception for clinic services furnished by IHS/Tribal clinics; (2) an exception for clinic services furnished by a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health disorders and substance use disorders; and (3) an exception for clinic services furnished by a clinic located in a rural area (and that is not an RHC, which could already provide services covered under a separate Medicaid benefit).[18] CMS proposes to make the exception for clinic services furnished by IHS/Tribal clinics a mandatory component of the clinic benefit and to make the exceptions for clinic services furnished by behavioral health clinics and clinics located in rural areas optional for States.

In making this proposal, CMS notes that it is reinterpreting statute to permit additional exceptions to the four walls requirements for populations served by clinics if those populations have similar health care access issues to individuals who are unhoused. The four criteria that CMS provides to determine whether individuals have similar health care access issues to individuals who are unhoused are:

- The population experiences high rates of behavioral health diagnoses or difficulty accessing behavioral health services;
- The population experiences issues accessing services due to lack of transportation;
- The population experiences a historical mistrust of the health care system; and
- The population experiences high rates of poor health outcomes and mortality.

Table 141 of the Proposed Rule (pg. 921-922) demonstrates the agency's estimates for total impact of these proposals for five years. **CMS invites comments on whether the proposals might create any burdens for States, beneficiaries, providers or other interested parties. Also, CMS invites comment on whether there are additional populations that are likely to meet the four criteria described in this proposed rule and that have no alternative access to services**

membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services. CMS refers to this payment exclusion as the "no legal obligation to pay" payment exclusion.

[17] Under statutes, clinic services as services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address

[18] CMS notes that instead of specifying a uniform definition of rural nationwide for this exception then the state would choose any definition of rural that can be linked to the four walls criteria noted in the Proposed Rule and if certain other requirements are met.

through Medicaid benefits not subject to a four walls requirement under Federal Medicaid law, and on whether there are additional types of clinics that might serve as a proxy for such a population.

What's Next?

The OPPS tables for this CY 2025 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, 2025). The comment period closes on September 9, 2024.

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 in Vizient's Washington, D.C. office.