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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

November 20, 2024

Key Takeaways

On November 1, the Centers for Medicare & Medicaid Services (CMS) issued the annual final rule to update the Calendar Year (CY) 2025 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS) (hereinafter, "Final Rule"). The Final Rule includes changes to payment policies and payment rates at hospital outpatient departments (OPDs) and ambulatory surgical centers (ASCs), in addition to updating requirements for several quality reporting programs, including the Hospital Outpatient Quality Reporting (OQR) Program. The Final Rule also updates and adds Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) to help advance maternal health and safety. This summary focuses primarily on policies related to hospital OPDs.

A CMS fact sheet is available here.

Most policies provided in the Final Rule go into effect on January 1, 2025.

Major Finalized Proposals and Key Changes from the Proposed Rule

OPPS Payment Updates

For CY 2025, CMS finalized policy to apply an OPD fee schedule increase factor of 2.9 percent, except for those hospitals not meeting certain quality reporting requirements, which would be subject to a 2-percentage point reduction in payments. The Proposed Rule had a fee schedule increase of 2.6 percent, so the Final Rule contains a 0.3 percent increase from the Proposed Rule. The fee schedule increase factor was driven by the final inpatient hospital market basket percentage increase of 3.4 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a final productivity adjustment of 0.5 percentage point.[1]. CMS estimates that total CY 2025 payments to OPPS providers will be approximately $87.7 billion, which will be an increase of about $4.7 billion compared to estimated CY 2024 OPPS payments. CMS approximates that, for CY 2025, the cumulative effect of all finalized changes will increase payments by 3.0 percent for all providers and 3.2 percent for all hospitals, as shown in Table 1.

[1] The Proposed Rule's productivity adjustment reduced the OPDCMS fee schedule increase by 0.5 percentage point.

Table 1. Estimated Impact of the Final 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	3562	0.0	0.1	3.0	3.0
All hospitals	3460	0.1	0.2	3.2	3.2
Urban hospitals	2775	0.1	0.1	3.2	3.2
Rural hospitals	685	-0.4	0.9	3.3	3.2
Non-teaching status hospitals	2125	0.1	0.3	3.3	3.3
Minor teaching status hospitals	893	0.2	0.5	3.7	3.5
Major teaching status hospitals	442	-0.1	-0.3	2.5	2.7

* Column 1 shows total hospitals and/or CMHCs. These 3,562 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
Column (2) includes all final CY 2025 OPPS policies and compares those to the CY 2024 OPPS.
** Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2025 hospital inpatient wage index, including the low wage index hospital policy. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the final 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 final 2.9 percent OPD fee schedule update factor (3.4 percent reduced by 0.5 percentage point for the productivity adjustment).
**** Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but CMS moved the frontier adjustment to Column 3 in this table.

Final Updates Affecting OPPS Payments

Final Recalibration of Ambulatory Payment Classification (APC) Relative Payment Weights

For the CY 2025 OPPS, CMS finalized the proposed recalibration of the APC relative payment weights for services furnished on or after January 1, 2025, and before January 1, 2026, using CY 2023 claims data.

Calculation of Single Procedure APC Criteria-Based Costs

CMS finalized the proposed CY 2025 payment rates for blood and blood products and brachytherapy sources. See Addendum B of the Final Rule for the payment rates for blood and blood products (generally identified with status indicator "R") and brachytherapy sources (generally identified with status indicator "U"). In the Final Rule, CMS stated that they will continue to invite, on an ongoing basis, interested parties to submit recommendations for new codes to describe new brachytherapy sources because the agency plans to add new brachytherapy source codes and descriptors to their payment systems on a quarterly basis.

Comprehensive APCs (C-APCs) for CY 2025

In the Proposed Rule, CMS considered expanding the list of exclusions from the C-APC policy to add cell and gene therapies for one year and asked for comments on the potential need for a different, modified or expanded changes to the C-APC packaging policy for future rulemaking. For CY 2025 and subsequent years, CMS finalized a policy not to package payment for cell and gene therapies into C-APCs, when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service. For new cell and gene therapy products, CMS will continue to add their product-specific HCPCS codes to the C-APC exclusion list, if eligible.[2]

Also, considering future cell and gene therapy payment policy, in the Final Rule, CMS indicated it is not, at this time, considering the creation of a new C-APC, similar packaged payment policy, or modified outliers policy, for services to administer cell and gene therapies.

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

CMS finalized the proposed policy to exclude the non-opioid treatments for pain relief from the C-APC policy to ensure payment is not packaged into any C-APC and that separate payment is made.

C-APCs for CY 2025

Each year CMS reviews and revises the services within each APC group and the APC assignments under the OPPS. For CY 2025, CMS did not propose to convert any standard APCs to C-APCs. The Final Rule states that the number of C-APCs for CY 2025 would be the same as the number for CY 2024, which is 72 C-APCs. Table 5 of the Final Rule (pg. 85-87) lists the final C-APCs for CY 2025.

Composite APC for Mental Health

In the Proposed Rule, CMS indicated it aimed to continue the current policy for CY 2025 and subsequent years regarding a composite APC for mental health. In the Final Rule, CMS finalized the proposal, without modification, that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for four partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), those specified mental health services would be paid through composite APC 8010 for CY 2025. Also finalized was CMS's proposal to continue to set the payment rate for composite APC 8010 at the same payment rate that was proposed for APC 5864, which is a partial hospitalization per diem payment rate for 4 partial hospitalization services furnished in a day by a hospital.

Multiple Imaging Composite APCs

For CY 2025, CMS proposed 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. CMS did not receive any comments on this proposal, which was finalized in the Final Rule without modification.

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[2] Table 4 of the Final Rule (pg. 81-82) list the cell and gene therapies finalized for exclusion from C-APC packaging for CY 2025.

Proposed Payment for Diagnostic Radiopharmaceuticals

CMS finalized the proposal to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630; any diagnostic radiopharmaceutical with a per day cost below that threshold would continue to be policy packaged. Table 7 in the Final Rule (pg. 107) illustrates how CMS calculated the $630 threshold. While CMS received stakeholder comments regarding alternative potential thresholds, the agency did not modify the policy, reiterating the agency's initial belief that diagnostic radiopharmaceuticals are distinct from therapeutic drugs and biologics to so warrant a different threshold, and that alternative thresholds would be inconsistent with the agency's OPPS two-times rule.[3]

In addition, CMS finalized policy starting in CY 2026 to annually update the threshold amount of $630 by the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription) (from IHS Global, Inc (IGI)).

Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m) Derived from Domestically Produced Mo-99

Technetium-99m (Tc-99m), the radioisotope used in most diagnostic imaging services, is produced through the radioactive decay of molybdenum-99 (Mo-99). The CY 2024 OPPS final rule established that CY 2025 will be the final year of the $10 add-on payment for Tc-99m derived from non-highly enriched uranium (HEU) sources. In this Final Rule, CMS finalized that for CY 2026, they will replace the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.[4] For CY 2026, the new add-on payment will be $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

Invoice Drug Pricing

To provide appropriate payment rates for drugs and biologicals without pricing data (e.g., ASP, WAC, AWP and mean unit cost information), CMS finalized as proposed a temporary policy that will be in effect for CY 2025 and another policy that will begin in CY 2026. For CY 2025, CMS provides that the affected drugs and biologicals would continue to be assigned a non-payable status indicator until CMS implements the invoice pricing policy. For CY 2026, CMS will allow Medicare Administrative Contractors (MACs) to use the provider invoice amount to set a payment rate for a separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available. HCPCS codes with a missing payment rate in Addendum B for a separately payable drug, biological, or radiopharmaceutical will indicate to MACs that CMS does not have pricing information for a product, and MACs would then calculate the payment for the product based on provider invoices. Although CMS acknowledged various stakeholder concerns, including those regarding 340B drug acquisition cost data, the agency indicates that the aim of the policy is not to collect 340B drug acquisition cost data and that invoice-based payment will result in collection of drug acquisition

[3] The two-times rule utilizes a two times multiplier to determine APC levels, where a significant service that has a cost greater than two times the lowest cost significant service in an APC is generally moved to a higher-level APC in the series. The lower thresholds suggested by commenters to the Final Rule, according to CMS, would not follow this principle, and therefore, would not exclusively identify diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment.

[4] CMS stated in the Final Rule that for 2026 and subsequent years the Department of Energy National Nuclear Security Administration (DOE/NNSA) is establishing the criteria to certify whether the Tc-99m radiopharmaceutical dose is domestically produced and eligible for the addon payment and those criteria will be included in the CY 2026 OPPS/ASC proposed rule. CMS will consider in CY 2026 rulemaking any additional requirements for Medicare providers to document that the Tc-99m radiopharmaceutical used in a procedure was domestically produced and can qualify to receive the add-on payment based on the criteria developed by DOE/NNSA.

cost data for only a few drugs for only a short period of time, and only if the provider wants to submit the invoice in order to receive payment for the drug. CMS also noted that the agency does not disclose proprietary data and discloses summarized population drug payment data in mean unit cost for ratesetting purposes.

Request for Comment on Cardiac CT Services, CPT Codes 75572, 75573, and 75574 (APC 5572)

In the Proposed Rule, CMS asked specific questions to gather information on hospitals' billing practices for cardiac CT services with the goal being to use the comments received and the information from claims with dates of service between January 1 and December 31, 2023 to help the agency identify whether the current OPPS payment is appropriate for the cardiac CT codes, or whether the agency should revise the payment methodology for the CY 2025 OPPS.

In the Final Rule, CMS stated they received many comments from providers who bill these codes indicating that they would prefer to bill them with the cardiology revenue code but have not been able to do so due to the prior revenue code edit[5] and other procedural hurdles. Based on stakeholder comments and the agency's analysis of this issue, for CY 2025 and subsequent years, CMS finalized policy to use an alternative methodology to calculate the payment for the cardiac CT. Specifically, CMS finalized a temporary reassignment of the cardiac CT codes (CPT code 75572 through 75574) to APC 5572 (Level 2 Imaging with Contrast). Table 68 of the Final Rule (pg. 331) shows the final APC assignments for CPT codes 75572 through 75574. The agency anticipates it may take 3 to 4 years to see an impact on changes in billing practices from providers based on the comments received on this topic. If CMS does not see a significant change in the geometric mean costs after several years, the agency will return payment for these services to the standard OPPS payment methodology and assign the cardiac CT codes to appropriate APCs based on their geometric mean costs.

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

The CY 2023 OPPS final rule finalized a requirement that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely. In addition, there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. The Consolidated Appropriations Act (CAA) of 2023 extended policy to delay implementing the in-person visit requirements for mental health services furnished remotely, for professionals billing for mental health services via Medicare telehealth, until January 1, 2025 (e.g., billing under the PFS). In the CY 2024 OPPS final rule, CMS finalized delaying the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025 to better align with PFS policy, which was based on the CAA, 2023.

In the Final Rule, CMS continues to emphasize the importance of aligning payment policy for remotely furnished mental health services across the OPPS and PFS payment systems. Accordingly, the in-person visit requirements that will apply under the CY 2025 PFS will also apply

[5] Regarding the revenue code edit and procedural hurdles, CMS provided that if there had not been a systems edit in place preventing providers from choosing the cardiology revenue code (048X) and cardiology cost center (03140) and 50 percent or more of HOPDs had billed these services with the cardiology revenue code, the mean cost for these codes would have increased and would have resulted in a revised APC assignment from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast).

for mental health services furnished remotely by hospital staff to beneficiaries in their homes through communications technology beginning January 1, 2025. CMS stated the agency may consider modifications to this policy through future rulemaking but did not give a specific timeframe for these possible changes.

Payment Adjustments under the IPPS and OPPS for Domestic Personal Protective Equipment (PPE)

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. The CY 2025 OPPS Proposed Rule requested feedback on potential changes to the payment adjustment to help reduce reporting burden and achieve the policy goal of maintaining a baseline domestic production capacity of PPE. The Proposed Rule also asked for comment on other types of PPE and medical devices that could be appropriate for a similar payment adjustment. In the Final Rule, CMS agreed with recommendations calling for improvements to and expansion of these payment adjustments and stated the agency intends to propose a new payment methodology in 2026 rulemaking that does not rely exclusively on hospital-specific data. CMS also stated that, in future rulemaking, the agency will propose to expand the payment adjustments to domestic non-surgical N95 respirators and domestic nitrile gloves, explore expansion of the payment adjustments to include other types of domestically made PPE and other medical products and study the feasibility of creating a list of qualifying surgical N95 respirators that are domestically made PPE.

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

In February 2024, CMS issued the Advancing Interoperability and Improving Prior Authorization Processes Final Rule, requiring certain payers to send prior authorization decisions as quickly as the enrollee's or beneficiary's health condition requires but no later than 72 hours for expedited (urgent) requests and 7 calendar days for standard (non-urgent) requests. The Proposed Rule sought to align the current OPD prior authorization review timeframe in Medicare FFS with the Advancing Interoperability Final Rule's requirements by changing the current review timeframe for standard review requests from 10 business days to 7 calendar days. CMS finalized the OPD prior authorization request timeframe as proposed.

Although CMS did not propose adopting the expedited request timeframe with the 72-hour expedited request timeframe finalized in the CMS Advancing Interoperability and Improving Prior Authorization Final Rule, in the Final Rule, the agency indicated that it is still considering the impact of such alignment. For example, CMS indicated that it may take longer for OPD providers to receive a decision using the 72-hour timeframe than the current expedited timeframe of 2 business days. The agency may address this issue in future rulemaking.

Final Changes to the List of ASC Covered Surgical Procedures (CPL) for CY 2025

In the Final Rule, CMS updated the ASC CPL list by adding 21 medical and dental surgical procedures to the list for CY 2025. For a full list of the added ASC CPL codes for CY 2025, see Table 154 of the Final Rule (pg. 1019-1020).

Highlights Related to Quality Programs

Health Equity Measures Under the Hospital Outpatient Quality Reporting (OQR) Program

Hospital Commitment to Health Equity (HCHE) Measure

The HCHE measure assesses[6] a hospital or facility's commitment to health equity by using five equity-focused organizational domains aimed at advancing health equity for all patients, including, but not limited to, those in racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. This measure was proposed for adoption for the CY 2025 reporting period/CY 2027 payment or program determination, with a submission deadline of May 15, 2026. CMS finalized adoption of this measure as proposed.

Screening for Social Drivers of Health (SDOH) Measure

This measure assesses the total number of patients, who were 18 years or older on the date of service, screened for social risk factors [specifically, the five-health related social needs (HRSNs) of food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety]. This was proposed for adoption with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting for the CY 2026 reporting period/CY 2028 payment or program determination. CMS finalized adoption of this measure as proposed.

Screen Positive Rate for Social Drivers of Health (SDOH) Measure

This measure provides information on the percentage of patients receiving care, who were 18 years or older on the date of service, who were screened for all five HRSNs described above, and who screened positive for one or more of those HRSNs. This measure was proposed for adoption 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. CMS finalized adoption of this measure as proposed.

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 (IQR) Program

For both hybrid measures, which are in the Hospital IQR Program, hospitals were required to submit data for the mandatory reporting period impacting the FY 2026 payment determination, based on performance data from July 1, 2023 through June 30, 2024. But based on hospital performance data during the most recent voluntary reporting period, it appeared to CMS that hospitals are unprepared for mandatory reporting of these measures.[7] As a result, in the Proposed Rule, CMS proposed that the submission of core clinical data elements (CCDEs) and linking variables would remain voluntary for the FY 2026 payment determination, but would become mandatory for the FY 2027 payment determination and subsequent years. Commenters stated that they needed additional years of voluntary reporting because of challenges they identified with the current measure reporting requirements. As a result, CMS finalized this proposal with modifications to

[6] Table 159 on Pages 1104-1105 of the Final Rule describe the five attestation domains and their elements for the HCHE measure.
[7] CMS stated that data indicated that 75 percent of the participating hospitals would not have met the reporting thresholds for the core clinical data elements and linking variables if the reporting requirement had been mandatory. CMS also received feedback from hospitals raising various issues with reporting including issues related to CCDE collection timing and clinical workflow, issues with the types of units required for CCDE values, and achievability of the data submission requirement thresholds.

certain required CCDE data elements and allowing the submission of CCDEs and linking variables to be voluntary for the FY 2027 payment determination. The agency also will continue to evaluate potential changes to the reporting requirements related to CCDEs and linking variables.

Request for Information (RFI): Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Measure Group

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information reported through CMS's hospital quality measurement programs by assigning hospitals between one and five stars for ease of patient understanding. Although not proposed, to inform future potential rulemaking, CMS requested input on three options to modify the Overall Hospital Quality Star Rating methodology: reweighting the Safety of Care Measure Group; applying a one-star reduction for all hospitals in the lowest quartile of Safety of Care; and reweighting the Safety of Care measure group combined with a policy-based 4-star rating maximum on a Star Rating of any hospital in the lowest quartile of Safety of Care. In the Final Rule, CMS indicated it plans to take stakeholder feedback into consideration, as appropriate, in future potential rulemaking.

Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

To help address the current maternal health crisis, CMS finalized, largely as proposed with exceptions, a new obstetrical (OB) services Conditions of Participation (CoP) and related changes to existing CoPs.

CoP: Obstetrical Services

New Standards: Organization and Staffing; Delivery of Service; and Staff Training

Regarding the standards for organization and staffing and delivery of service, CMS finalized requirements for a hospital or a CAH that offers obstetrical services:

- the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for physical and behavioral health care of pregnant, birthing, and postpartum patients (inclusive of both mental health and substance use disorders).
- the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
- the organization of the OB services should be appropriate to the scope of services offered by the facility and integrated with other departments of the facility.
- OB patient care must be supervised by an individual with the necessary education and training.
- OB privileges must be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner, and consistent with established credentialing agreements.[8]
- OB services must be consistent with the needs and resources of the facility and that policies governing OB care be designed to ensure the achievement and maintenance of high standards of medical practice and patient care and safety.

[8] In the Final Rule, CMS modified this requirement to reference existing regulations, specifically 42 CFR §485.616 CMS Condition of participation: Agreements, (b) Standard: Agreements for credentialing and quality assurance. Available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-F/section-485.616

- labor and delivery room suites and services must have certain basic equipment and personnel readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor for emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program.
    - In the Final Rule and in response to stakeholder concerns about challenges in meeting the equipment requirements, particularly for smaller or rural hospitals and CAHs, CMS clarified that basic equipment requirements for treating OB patients must be kept at the facility and be readily available to meet the needs of OB patients in accordance with the scope, volume and complexity of services offered at the facility.

The new requirements for organization, staffing and delivery of services for hospitals and CAHs must be implemented by January 1, 2026.

CMS finalized the following staff training requirements for OB staff at hospitals and CAHs with OB services:

- develop policies and procedures that would ensure that relevant OB staff are trained on and demonstrate knowledge of select topics that 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.
- have any additions, revisions, or updates to topics be informed by the hospital and CAH's QAPI program findings.
- have the governing body to identify and document which staff must complete annual training that must be documented in the staff personnel records that the training was successfully completed.
- provide relevant staff with initial training upon hiring.
- the governing body identify and document which staff must complete initial training and the subsequent biannual training.
- document in the staff personnel records that the training was successfully completed.
- demonstrate staff knowledge on the topics identified the staff training portion of the CoP.

The new staff training requirements for hospitals and CAHs must be implemented by January 1, 2027.

CoP: Quality Assessment and Performance Improvement (QAPI) Program

CMS finalized the requirements as proposed that a hospital or CAH that offers OB services would be required to:

- use its QAPI program to assess and improve health outcomes and disparities among OB patients on an ongoing basis.
- engage facility leadership, obstetrical services leadership, or their designate(s) in the facility's QAPI activities.
- have a process for incorporating Maternal Mortality Review Committees' (MMRC) data and recommendations into the facility's QAPI program.
- evaluate how these proposals would impact maternal health and safety, how facilities currently use their QAPI programs to address maternal health, best practices for data analysis and stratification in QAPI programs, and best practices for sharing QAPI findings with impacted communities.

The new QAPI requirements for hospitals and CAHs must be implemented by January 1, 2027. In addition, CMS stated in the Final Rule that the agency will issue sub-regulatory guidance in the future on how compliance with the best practices for QAPI data analysis and stratification requirements will be assessed. The agency also stated in the Final Rule that they are considering

the feedback received on the best practices for sharing QAPI findings with impacted communities for possible future rulemaking.

CoP: Emergency Services - New Emergency Services Readiness Standard

CMS finalized a new standard entitled "Emergency Services Readiness" within the existing Emergency Services CoP for all hospitals and CAHs offering emergency services, whether or not a hospital/CAH offers an additional specialty service line (such as OB services). Specifically, these facilities would be required to:

- have adequate provisions and protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions to meet the emergency needs of patients in accordance with the complexity and scope of services offered. These CoPs do not require adherence to a specific organization's guidelines or recommendations.
- have provisions that include equipment, supplies, and medication used in treating emergency cases.
- have emergency services personnel, as determined by the facility, trained on these protocols and provisions annually.

The new emergency services readiness requirements for hospitals and CAHs must be implemented by July 1, 2025.

CoP: Discharge Planning

CMS finalized revisions to the hospital discharge planning regulations to include requirements for transfer protocols. Specifically, hospitals must:

- have written policies and procedures for transferring patients under their care (inclusive of hospital inpatients), such as transfers from the emergency department to inpatient admission, transfers between inpatient units in the same hospital, and transfers between inpatient units at different hospitals.
- require the hospital to provide training for relevant staff, as determined by the facility. regarding the hospital policies and procedures for transferring patients under its care.
- require acute care hospitals to provide annual training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under their care.

The new discharge planning requirements must be implemented by July 1, 2025.

Implementation Timeline for the CoPs

In the Final Rule, due to stakeholder concerns regarding the implementation resource demands and cost, CMS finalized an alternative, phased-in implementation timeline, as shown in Table 2.

Table 2. Implementation Timeframe for Hospitals and CAHs

Regulatory Section	Implementation Date
Emergency Services Readiness for Hospitals (§482.55) and CAHs (§ 485.618)	July 1, 2025
Discharge Planning (§482.43)	July 1, 2025
Organization, Staffing, and Delivery of Services for Hospitals (§482.59(a) and (b)) and CAHs (§485.649(a) and (b))	January 1, 2026
QAPI Program for OB Services in Hospitals (§ 482.21) and CAHs (§ 485.641)	January 1, 2027
Training for OB Staff in Hospitals (§482.59(c)) and CAHs (§485.649(c))	January 1, 2027

Medicaid Clinic Services Four Walls Exceptions

States may decide to offer certain Medicaid benefits to categorically needy and medically needy Medicaid beneficiaries. Clinic services are one of these optional benefit categories. CMS provides that clinic services include services furnished at the clinic (referred to as the "four walls" requirement) by or under the direction of a physician or dentist and services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who is unhoused.

In the Final Rule, CMS finalized, without modification, the following changes to the four walls requirement:

- adding an exception for clinic services furnished by Indian Health Service/Tribal clinics as a mandatory component of the clinic benefit for States electing to cover that benefit.
- adding 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 and substance use disorders as an optional clinic benefit for States electing to cover that benefit.
- adding an exception for clinic services furnished by a clinic located in a rural area as an optional clinic benefit for States electing to cover that benefit.

In the Final Rule, CMS stated that the agency will determine whether possible future rulemaking on additional exceptions to the four walls requirement is warranted. The agency also stated that they will contemplate issuing sub-regulatory guidance regarding their interpretation of how the four walls requirement applies when Medicaid clinic services are delivered via telehealth.

What's Next?

Most provisions of the Final Rule go into effect January 1, 2025, with a few exceptions, such as those related to new Conditions of Participation.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Final Rule. Please direct your feedback to Jenna Stern, AVP, Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.