Fact Sheets

CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1809-P)

Jul 10, 2024 Medicaid & CHIP, Policy

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On July 10, 2024, the Centers for Medicare & Medicaid Services (CMS) proposed Medicare payment rates for hospital outpatient and Ambulatory Surgical Center (ASC) services. The Calendar Year (CY) 2025 Hospital Outpatient Prospective Payment System (OPPS) and ASC Payment System Proposed Rule is published annually and will have a 60-day comment period, which will end on September 9, 2024. The final rule will be issued in early November.

In addition to proposing payment rates, this year's rule includes proposed policies that align with several key goals of the Administration, including addressing health disparities, expanding access to behavioral health care, improving transparency in the health system, and promoting safe, effective, and patient-centered care. The proposed rule advances the Agency's commitment to strengthening Medicare and uses the lessons learned from the COVID-19 PHE to inform the approach to quality measurement, focusing on changes that would help address health inequities.

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These proposed payment policies would affect approximately 3,500 hospitals and approximately 6,100 ASCs. As with other rules, CMS is publishing this proposed rule to meet the legal requirements to update Medicare payment policies for OPPS hospitals and ASCs annually. This fact sheet discusses the major provisions of the proposed rule (CMS-1809-P), which can be downloaded at: https://www.federalregister.gov/documents/current.

Updates to OPPS and ASC payment rates

In accordance with Medicare law, CMS proposes updating OPPS payment rates for hospitals that meet applicable quality reporting requirements by 2.6%. This update is based on the projected hospital market basket percentage increase of 3.0%, reduced by a 0.4 percentage point productivity adjustment.

In the CY 2019 OPPS/ASC final rule with comment period, CMS finalized a proposal to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of five years (CY 2019 through CY 2023). The CY 2024 OPPS/ASC final rule with comment period extended the interim period for an additional two years, that is, through CY 2024 and CY 2025. Accordingly, using the hospital market basket update, CMS proposes an update factor to the ASC rates for CY 2025 of 2.6%. The update applies to ASCs meeting relevant quality reporting requirements. This update is based on the proposed IPPS market basket percentage increase of 3.0%, reduced by 0.4 percentage point for the productivity adjustment.

Intensive Outpatient Program

Intensive Outpatient Program (IOP) Rate Setting
The CY 2025 OPPS/ASC proposed rule would update Medicare payment rates for intensive outpatient program services furnished in hospital outpatient departments and CMHCs. The IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness or substance use disorder, consisting of a specified group of behavioral health services paid on a per diem basis for a minimum of 9 hours of IOP services per week under the OPPS, or another applicable payment system when furnished in hospital outpatient departments, Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs),

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and Rural Health Clinics (RHCs). IOP services may also be furnished in Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD).

Update to IOP Payment Rates in Hospital Outpatient Departments and CMHCs

CMS is proposing to maintain the existing rate structure, with two IOP APCs for each provider type: one for days with three services per day and one for days with four or more services per day. Consistent with the OPPS, for this CY 2025 rate setting, CMS is proposing to use the CY 2023 claims data and the latest available cost information from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking.

For CY 2025, CMS is proposing to maintain the calculation of both hospital outpatient and CMHC IOP payment rates for three services per day and four or more services per day based on cost per day using OPPS data that includes PHP and non-PHP days. CMS believes continuing to use the OPPS data set will allow CMS to capture data from hospital claims that are not identified as PHP but that include the service codes and intensity required for a PHP day.

Partial Hospitalization Program

Partial Hospitalization Program (PHP) Rate Setting

The CY 2025 OPPS/ASC proposed rule would update Medicare payment rates for partial hospitalization program services furnished in hospital outpatient departments and CMHCs. The PHP is an intensive, structured outpatient program provided as an alternative to psychiatric hospitalization, consisting of a specified group of mental health services paid on a per diem basis for a minimum of 20 hours of PHP services per week under the OPPS, based on PHP per diem costs.

Update to PHP Per Diem Rates

CMS is proposing to maintain the existing rate structure, with two PHP APCs for each provider type: one for days with three services per day and one for days with four or more services per day. Consistent with the OPPS, for this CY 2025 rate setting, CMS is proposing to use the CY 2023 claims data and the latest available cost information from

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cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking.

For CY 2025, CMS is proposing to maintain the calculation of both hospital outpatient and CMHC PHP payment rates for three services per day and four or more services per day based on cost per day using OPPS data that includes PHP and non-PHP days. CMS believes continuing to use the OPPS data set will allow CMS to capture data from hospital claims that are not identified as PHP but that include the service codes and intensity required for a PHP day.

Access to Non-Opioid Treatments for Pain Relief

CMS is proposing to implement Section 4135 of the Consolidated Appropriations Act (CAA), 2023, which provides temporary additional payments for certain non-opioid treatments for pain relief in the hospital outpatient department (HOPD) and ASC settings from January 1, 2025, through December 31, 2027. This proposal would implement several statutory provisions including evidence requirements for medical devices and the FDA-approved indications that meet the statutory requirements. To implement the statutory payment limitation under which the additional payment must not exceed the estimated average of 18% of the OPPS payment for OPPS service or group of services with which the non-opioid treatment for pain relief is furnished, CMS is proposing to utilize the top five OPPS procedures by volume for each nonopioid drug or device to calculate the payment limitation. Finally, CMS is proposing to initially assign a payment offset of zero dollars for the qualifying non-opioid products, as maintaining the non-opioid portion of the procedure payment rate better aligns with the overall intent of the non-opioid policy to ensure access is not hindered by Medicare payment policies.

We are proposing that seven drugs and one device qualify as non-opioid treatments for pain relief, and we propose these products be paid separately in both the HOPD and ASC settings starting in CY 2025. We are soliciting comment and supporting documentation from interested parties on additional products that may qualify for separate payment under this provision starting in CY 2025.

OPPS Payment for Remote Services

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CMS is proposing to clarify that for OPPS payment for services furnished remotely by hospital staff to individuals in their homes, including remotely furnished outpatient therapy services, Diabetes Self-Management Training and Medical Nutrition Therapy services, and mental health services, that we would anticipate aligning our requirements with those associated with Medicare telehealth and billed under the PFS.

All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Hospitals

Under current regulations, IHS and tribal hospitals are excluded from payment under the OPPS. Instead, IHS and tribal outpatient departments are paid the Medicare outpatient hospital AIR for each encounter that provides outpatient services. On an annual basis, IHS calculates and publishes, in the Federal Register, calendar year reimbursement rates. These rates are often referred to as the AIR, which is updated annually based on a review of yearly cost reports. For CY 2024, the outpatient AIR is $667 in the lower 48 states. IHS and tribal hospitals have continued to expand the breadth of services that they provide to their communities. Increasingly, this has meant providing higher-cost drugs along with more complex and expensive services, such as cancer-related services. There are hospitals providing specialty services where the AIR might not be an adequate representation of the hospital's costs to provide services to people with Medicare. To improve the payments to IHS and tribal hospitals and better account for the costs of high-cost drugs furnished to people with Medicare seeking care at these facilities, we propose to pay an add-on to the AIR for certain high-cost drugs for people with Medicare who receive care at IHS or tribal hospitals.

Request for Information: Paying all IHS and Tribally Operated Clinics the IHS Medicare Outpatient AIR

In response to the CMS Tribal Technical Advisory Group (TTAG) request that CMS amend its Medicare regulations to make all IHS and tribal hospitals eligible for payment at the IHS Medicare outpatient AIR, we are requesting information on the types of clinics and costs of services in these settings. This is a follow-up to a similar request for information in the CY 2022 PFS proposed rule, and CMS looks forward to reviewing responses.

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OPPS Proposal to Improve Payment for Specialized Diagnostic Radiopharmaceuticals

Under the OPPS, the costs associated with diagnostic radiopharmaceuticals are packaged into the payment for the nuclear medicine tests they are used with. While this payment approach generally works appropriately to support efficient care, we recognize that in some specific circumstances, the payment amount for the nuclear medicine tests may not adequately account for the cost of certain specialized diagnostic radiopharmaceuticals, even when those agents may be the most clinically appropriate. Consequently, we are proposing refinements to the existing packaging policy to improve the accuracy of the overall payment amounts by paying separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 and removing their costs from the payment amounts for the nuclear medicine tests. Any diagnostic radiopharmaceutical with a per-day cost equal to or below that threshold would continue to be policy-packaged, with costs incorporated into the payment rates for the nuclear medicine tests. This update should address challenges for patients in accessing these prescribed nuclear medicine tests with higher-cost radiopharmaceuticals.

Add-on Payment for Domestically Produced Technetium-99m (Tc-99m)

Radioisotopes are widely used in modern medical imaging. Technetium-99m (Tc-99m), the radioisotope used in most diagnostic imaging services, is historically derived from legacy reactors outside of the United States using highly enriched uranium (HEU). Beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost of Tc-99m produced by non-HEU sources.

CY 2025 is the final year of the add-on payment for Tc-99m when the Tc-99m is produced without the use of HEU, as the Secretaries of Energy and Health and Human Services have issued a certification that there is sufficient global supply of Tc-99m without the use of HEU available to meet the needs of patients in the United States.

However, the Department of Energy and other interested parties have identified another issue affecting the domestic supply chain for molybdenum-99 (Mo-99), the source material for Tc-99m, that could

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cause payment inequity among outpatient hospital providers. Foreign Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, foreign government-subsidized prices have created a disincentive for domestic investments in Mo-99 production infrastructure and a barrier to entry for new producers. We propose to address this payment inequity in this rule by establishing a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026. We believe the $10 add-on payment for domestically produced Tc-99m would ensure equitable payments by paying providers who use domestically produced Tc-99m radiopharmaceuticals when available, an amount that reflects the anticipated higher cost of these products. The $10 add-on payment will help to preserve provider and individual access to domestically produced Tc-99m radiopharmaceuticals by addressing the additional cost of domestically produced Tc-99m radiopharmaceuticals.

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

In the CY 2023 OPPS final rule with comment period, we finalized a policy to make a single blended payment for devices and services in Category B Investigational Device Exemptions (IDE) studies in order to preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient had been assigned. We are also proposing to extend our coding and payment policy to trials for drugs and devices that meet CAG's coverage and evidence development (CED) requirement, for which the trial includes a treatment and control arm.

Individuals Formerly in the Custody of Penal Authorities

To support individuals returning to the community from incarceration, CMS is proposing to narrow the definition of "custody" in Medicare's payment exclusion rule and to revise the Medicare special enrollment period (SEP) for formerly incarcerated individuals. These modifications would remove real or perceived barriers to Medicare access by

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individuals who have recently been released from incarceration or are on parole, probation, or home detention.

Medicare is prohibited by statute from paying for an item or service if the individual receiving the item or service has no legal obligation to pay for it. Under Medicare regulations, an individual who is in custody of penal authorities (e.g., in prison or jail) is presumed to have no legal obligation to pay for his or her health care, and therefore, Medicare is presumed to be prohibited from paying for health care items or services furnished to such individuals. Currently, the definition of "custody" is very broad, including not only individuals who are physically detained in prison or in jail but also potentially individuals who are not physically confined in jail or prison, such as individuals on parole, probation, or home detention. Thus, applying the current definition of "custody," there is a presumption that Medicare will not pay for health care items or services furnished to individuals who are on parole, probation, or home detention.

CMS is proposing to narrow the definition of "custody" to no longer include individuals who are on parole, probation, and home detention. The proposal, if finalized, would remove the presumption that Medicare is prohibited from paying for health care items or services furnished to individuals on parole, probation, or home detention, thus facilitating access to Medicare payment. To facilitate access to Medicare coverage, CMS is also proposing to revise the eligibility criteria for the special enrollment period for formerly incarcerated individuals to include individuals who have been released from incarceration or on parole, probation, or home detention and align more closely with the Social Security Administration's criteria for determining incarceration status. CMS is also seeking comment on how these policies should apply to individuals who are required to reside in halfway houses.

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Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a pay-for-reporting quality program that reduces payments to hospitals that do not meet program requirements. Hospitals that do not submit quality data or do not meet all Hospital IQR Program requirements are subject to a one-fourth reduction in their Annual Payment Update under the IPPS.

In the CY 2025 OPPS proposed rule, CMS is proposing to continue voluntary reporting of the core clinical data elements (CCDEs) and linking variables for both the Hybrid Hospital-Wide Readmission (HWR) and Hybrid Hospital-Wide Standardized Mortality (HWM) measures for the performance period of July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program.

Hospital Outpatient Quality Reporting (OQR) Program

The Hospital OQR Program is a pay-for-reporting quality program for hospital outpatient departments that requires hospitals to meet quality reporting requirements or receive a reduction of two percentage points in their annual payment update if these requirements are not met.

For the Hospital OQR Program, CMS is proposing to adopt: (1) the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In addition, CMS is proposing the adoption of Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance measure (Information Transfer PRO-PM) beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, to provide specific insight into the communication of recovery information and enable hospital outpatient departments to improve patient understanding of such information.

CMS is also proposing to remove: (1) the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2025 reporting period/CY 2027 payment determination, as recent studies have found that performance or improvement on the measure did not result in better patient outcomes; and (2) the Cardiac Imaging for Preoperative

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Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination, because the wide range of cases per hospital outpatient department and lack of statistically distinguishable variation in performance indicates the measure does not provide sufficiently meaningful data to result in better patient outcomes.

Furthermore, CMS is proposing to modify the Hospital OQR Program's immediate measure removal policy, applicable when continued use of a measure raises patient safety concerns, to an immediate measure suspension policy. In the event of an immediate suspension, CMS would address the suspension and propose to retain, modify, or remove the measure in the next feasible rulemaking cycle. CMS is proposing this change to align measure suspension policies across the REH, HOPD, and ASC quality reporting programs. Additionally, our goal is to increase transparency and the public's voice in decision-making through the rulemaking process before potentially removing a measure.

Lastly, CMS is proposing to require that Electronic Health Record (EHR) technology be certified to all eCQMs available to report in the Hospital OQR Program measure set to ensure that hospitals are able to accurately capture and report data for all eCQMs in the measure set. CMS is also proposing that the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure - Psychiatric/Mental Health Patients strata be publicly reported on Care Compare. This data is already reported on data.medicare.gov in downloadable data files. By displaying data on Care Compare, our goal is to provide information that is useful for patients when choosing a care location, as well as researchers and hospital staff as they attempt to address health disparities and improve the timeliness of care for mental health patients.

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Rural Emergency Hospital Quality Reporting (REHQR) Program

Section 125 of Division CC of the CAA, 2021 added section 1861(kkk) to the Social Security Act (the Act), which established a new Medicare provider type, Rural Emergency Hospitals (REHs). An REH is a facility that, in relevant part as of December 27, 2020, was a Critical Access Hospital (CAH) or a subsection (d) hospital with not more than 50 beds located in a county (or equivalent unit of local government) that is in a

rural area (defined at section 1886(d)(2)(D) of the Act) or was a subsection (d) hospital with not more than 50 beds that was treated as being in a rural area (pursuant to section 1886(d)(8)(E) of the Act). An REH must submit quality measure data to the Secretary, and the Secretary shall establish procedures to make the data available to the public on a CMS website (section 1861(kkk)(7)(B) and (D) of the Act).

For the REHQR Program, CMS is proposing to adopt: (1) the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and (3) the Screen Positive Rate for Social Drivers of Health (SDOH) measure beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

CMS is also proposing to extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from one year to two years, beginning with the CY 2025 reporting period/CY 2027 program determination.

In addition, CMS is proposing to establish when, after conversion to REH status, REHs would be required to report data under the REHQR Program. CMS is proposing that an REH would begin submitting data to the REHQR Program on the first day of the quarter following the date that a hospital has been designated as converted to an REH in accordance with the process outlined in section 1861(kkk) of the Act.

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Ambulatory Surgical Center Quality Reporting (ASCQR) Program

The ASCQR Program is a quality reporting program implemented by CMS. For this program, participating ASCs must report data on certain quality measures as specified by CMS. These quality measures reflect CMS priorities, including safety and readmissions, and align with National Quality Strategy and CMS Quality Strategy priorities. Under the ASCQR Program, ASCs must report on quality measures in accordance with the program's requirements; failure to do so may result in the ASC receiving a two percentage point payment penalty to

their annual payment rate update. These requirements include allowing the public display of data submitted under the program.

As discussed above, for the ASCQR Program, CMS is proposing to adopt: (1) the Facility Commitment to Health Equity (FCHE) measure beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, and (3) the Screen Positive Rate for Social Drivers of Health (SDOH) measure beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Furthermore, CMS is proposing to modify the immediate measure removal policy for measures adopted in the ASCQR Program to an immediate measure suspension policy. Currently, the policy provides that CMS may immediately remove a measure where CMS believes the continued use of a measure as specified raises patient safety concerns. CMS proposes to modify this policy to provide that CMS will immediately suspend, instead of removing, the measure if CMS determines that collection and reporting activities related to the measure raise patient safety concerns. CMS would then address the suspension and propose to retain, modify, or remove the measure in the next feasible rulemaking cycle. CMS is proposing this modification to its policy to align measure removal and suspension policies across the REH, HOPD, and ASC quality reporting programs. Additionally, CMS' goal is to increase transparency and the public's voice in decision-making through the rulemaking process before potentially removing a measure. CMS would notify the healthcare facility (HOPDs or ASCs, as applicable) and the public of the decision to suspend the measure and then address the suspension and propose policies regarding any such suspended measure in the next feasible rulemaking cycle.

Lastly, CMS is seeking comment on a Request for Information regarding Development of a Specialty Focused Reporting and Minimum Case Number for Required Reporting framework. Under this potential framework, we are considering revising the data reporting requirements for the ASCQR Program to only require that ASCs report

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data to CMS on quality measures that are generally applicable to all ASCQR Program individuals and relate to the conditions they treat or procedures they perform or can be abstracted from claims. We are seeking comment on a potential future reporting framework that would achieve the following outcomes: (1) the addition of case minimums for measure reporting for specialty measures, defined as measures related to clinical procedures performed only by a subset of ASCs; (2) the removal of the zero case attestation requirement for specialty measures to decrease reporting burden; and (3) the verification of case counts using claims data to determine which specialty measures would be required for reporting for individual ASCs.

Overall Hospital Quality Star Rating

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information on Medicare.gov based on publicly available quality measure results reported through CMS' hospital quality measurement programs by assigning hospitals between one and five stars in a way that is simple and easy for patients to understand. 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 conceptually coherent 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).

As part of the national commitment to improving patient safety, we seek feedback on whether hospitals that performed in the bottom quartile (lowest-performing 25%) in the Safety of Care measure group should be eligible to receive the highest 5-star rating. We are considering modifying the Overall Hospital Quality Star Rating methodology, specifically the Safety of Care measure group, to reinforce our dedication to emphasizing patient safety across CMS.

We are currently seeking comments on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology. We are requesting input from interested parties on the following options: (1) reweighting the Safety of Care measure group; (2) applying a policy-based adjustment that reduces the Star

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Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measures in the group) by one star; (3) reweighting the Safety of Care measure group combined with a policy-based 4-star rating maximum on Star Rating of any hospital in the lowest quartile of Safety of Care.

Proposed Obstetrical Services Conditions of Participation

The United States is currently facing a maternal health crisis, which has not only led to a maternal mortality rate that is among the highest in high-income countries but also disproportionately affects racial and ethnic minorities. Native Hawaiian and Pacific Islander women, Black women, and American Indian/Alaska Native (AI/AN) women are two to three times more likely to suffer a pregnancy-related death than non-Hispanic White women. Moreover, over 80% of pregnancy-related deaths are preventable. CMS has broad statutory authority to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of pregnant, postpartum, and birthing women. However, there are currently no baseline requirements for maternal health regarding organization, staffing, training, maternal health-focused quality assessment and performance improvement (QAPI), and delivery of obstetrical (OB) services in hospitals and Critical Access Hospitals (CAHs). CMS believes that proposing revisions to the current Conditions of Participation for OB services ensures that all Medicare and Medicaid participating hospitals and CAHs offering these services are held to a consistent standard of high-quality maternity care that protects the health and safety of patients.

Specifically, CMS is proposing new Conditions of Participation (CoPs) for hospitals and CAHs for obstetrical services, including new requirements for maternal quality assessment and performance improvement (QAPI), baseline standards for the organization, staffing, and delivery of care within obstetrical units, and staff training on evidence-based maternal health practices on an annual basis. CMS is further proposing revisions to the emergency services CoP related to emergency readiness for hospitals and CAHs that provide emergency services. Lastly, CMS is proposing revisions to the Discharge Planning CoP for all hospitals and CAHs related to transfer protocols. These proposals were informed by available evidence, stakeholder input, and requests for information in the FY 2023 IPPS/LTCH PPS and FY 2025

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IPPS proposed rules. Lastly, CMS is soliciting comments on whether these proposed requirements should also apply to rural emergency hospitals (REHs).

Proposed Provisions for OB Services CoP

Organization and Staffing

CMS is proposing a new standard that requires that for hospitals and CAHs providing OB services outside of an emergency department, such services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, and postpartum patients. This proposed requirement mirrors other hospital and CAH optional services CoPs (such as surgical services) and is foundational to ensuring high-quality, safe care. Additionally, we are proposing that the organization of the OB services be appropriate to the scope of services offered by the facility and be integrated with other departments in the facility. For example, in order to provide high-quality and safe care, a labor and delivery unit must ensure good communication and collaboration with services such as laboratory, surgical, and anesthesia services when applicable. CMS is also proposing that OB patient care units be supervised by an individual with necessary education and training, such as an experienced registered nurse (RN), certified midwife, nurse practitioner, physician assistant, or doctor of medicine or osteopathy. Lastly, CMS is proposing that OB privileges be delineated for all practitioners providing OB care, and a roster of practitioners specifying the privileges of each practitioner must be maintained. This process is important to ensure that practitioners have the necessary education, training, and experience to provide safe, effective care and to safely perform specific procedures.

Delivery of service

CMS is proposing a new standard that requires OB services to be consistent with the needs and resources of the facility. Additionally, the policies governing OB care must assure high standards of medical practice and patient care and safety. CMS believes that a basic set of equipment should be in place in hospitals and CAHs providing OB services to ensure efficient, effective delivery of care as well as a

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timely response to emergency situations. Therefore, we are proposing that labor and delivery rooms have certain basic resuscitation equipment readily available, including a call-in system, cardiac monitor, and fetal doppler or monitor. Lastly, CMS is proposing that the facility ensure that it has adequate, readily available provisions and protocols consistent with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. Although we are not requiring specific items, examples of provisions would include equipment, supplies, and blood used in treating emergency cases.

Staff Training

CMS is proposing a new standard that requires hospitals and CAHs that offer OB services outside of the emergency department to develop policies and procedures to ensure that relevant staff are trained on certain topics aimed at improving the delivery of maternal care. CMS proposes that these training topics 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. Additionally, CMS is proposing that hospitals and CAHs use findings from their QAPI programs to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis. Lastly, we are proposing that the hospitals and CAHs providing OB services identify which staff must complete the trainings, document in staff personnel records that training was successfully completed, and be able to demonstrate staff knowledge on the training topics identified.

Quality Assessment and Performance Improvement (QAPI) Program

CMS is proposing to revise the existing QAPI CoP for hospitals and CAHs that offer OB services to promote safe and high-quality care for all pregnant, birthing, and postpartum patients. We are proposing that a hospital or CAH with OB services be required to use its QAPI program to assess and improve health outcomes and disparities among OB patients on an ongoing basis. Specifically, at a minimum, the facility would have to:

1. analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the facility

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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 obstetrical 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 obstetrical patients;
4. conduct at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

Additionally, we are proposing to require that each OB facility's leadership be involved in the facility's QAPI activities. Lastly, per existing state statutes as applicable, facilities are already required to report data to maternal mortality review committee/s (MMRC/s). Therefore, CMS is proposing that if a MMRC is available at the state or local jurisdiction in which the facility is located, hospitals and CAHs that offer OB services must have a process for incorporating information and data from the MMRC into the hospital QAPI program.

Emergency Services Readiness

Medicare-participating hospitals and CAHs with emergency departments must be continually prepared to provide appropriate medical screenings and offer stabilizing treatment to a patient in the emergency department with an emergency condition or when needed, transfer such patients to receive stabilizing care that the originating hospital cannot provide. Such readiness is essential to the health and safety of emergency services patients and relies on adequate staff training, provisions, protocols, and supplies.

Therefore, CMS is proposing a revised Emergency Services CoP to improve facility readiness in caring for emergency services patients, including pregnant, birthing, and postpartum women. It is important to note that these proposed emergency services requirements would apply to all hospitals and CAHs offering emergency services, regardless of whether they provide specialty services, such as OB

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services. CMS is proposing that hospitals and CAHs with emergency services be required to have adequate provisions and protocols to meet the emergency needs of patients. Hospitals and CAHs must have protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions. Additionally, for hospitals and CAHs with emergency services, we are proposing that applicable staff would need to be trained on these protocols and provisions annually, and documentation would be expected to show those staff have successfully completed such facility-identified training and knowledge on these topics.

Lastly, CMS is proposing, for hospitals only, that provisions include equipment, supplies, and medication used in treating emergency cases. Although we are not requiring specific items, the available provisions must include the following:

1. drugs, blood and blood products, and biologicals commonly used in lifesaving procedures;
2. equipment and supplies commonly used in lifesaving procedures;
3. a call-in system for each patient in each emergency services treatment area.

Transfer Protocols

CMS is proposing to require hospitals to have written policies and procedures for transferring patients under its care, which would be inclusive of hospital inpatients (e.g., transfer from one unit to another in the same hospital) to the appropriate level of care as needed to meet the patients' needs. This would also include transferring the patient to another hospital if deemed necessary. Lastly, we are proposing that hospitals provide training to the relevant staff regarding the hospital policies and procedures for transferring patients under its care.

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Medicaid and CHIP Continuous Eligibility

Section 5112 of the Consolidated Appropriations Act, 2023 (CAA, 2023) amended section 1902(e)(12) of the Act and added a new paragraph (K) to section 2107(e)(1) of the Act to make the previously optional continuous eligibility policy a requirement under the state plan

or a waiver of the state plan for children enrolled in Medicaid and CHIP. In this proposed rule, CMS proposes updates to the Medicaid and CHIP regulations to codify the requirements of the CAA, 2023. Specifically, CMS proposes to require 12-months of continuous eligibility for children under the age of 19 enrolled in Medicaid and CHIP. CMS proposes to remove the previous options of applying continuous eligibility to a subgroup of enrollees or limiting continuing eligibility to a time period of less than 12 months. For CHIP, CMS also proposes to remove failure to pay premiums as an optional exception to continuous eligibility.

Medicaid Clinic Services Four Walls Exceptions

CMS is proposing to amend the Medicaid clinic services regulation to authorize federal reimbursement for services furnished outside the "four walls" of a freestanding clinic by IHS/Tribal clinics. In addition, at state option, federal reimbursement would also be available for services provided by behavioral health clinics and services provided by clinics located in rural areas. For clinics located in rural areas, CMS is not proposing a specific definition of rural but is seeking public comment on different alternative definitions for consideration in final rulemaking.

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Biden-Harris Administration Expands Access to Mental Health and Substance Use Services with Addition of 10 New States to CCBHC Medicaid Demonstration Program

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CMS Statement on Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (MDRP) Proposed Rule (CMS-2434-P)

May 15, 2024

Biden-Harris Administration Finalizes Policies to Increase Access to Health Coverage for DACA Recipients

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Biden-Harris Administration Takes Historic Action to Increase Access to Quality Care, and Support to Families and Care Workers

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