Issue Brief:

Obstetrical Services and Obstetrical Emergency Services[1]

In November 2024, CMS issued a final rule titled "Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals" along with detailed responses to initial feedback provided on the proposed rule during the summer of 2024. The new Conditions of Participation (CoP) include requirements for the organization of obstetrical services, protocols, and provisions for delivery of care, and staff training requirements.

Note that CMS has indicated that sub-regulatory and interpretative guidance will be forthcoming in many of the areas highlighted below. Also note that per the final rule, if a surveyor identifies deficiencies pertaining to any of the areas below during their survey, the initial step is for the hospital to develop a Plan of Correction to remedy the deficiency prior to any other punitive actions.

Emergency Services Readiness

(42 C.F.R. §§ 482.55(c) and 485.618(e))

Effective July 1, 2025

Applies to all acute care and critical access hospitals (CAHs) that provide emergency services and not those with only obstetrical services.

- All acute care hospitals and CAHs, regardless of whether they offer obstetrical care, will have a new readiness standard under the existing Emergency Services CoP.
  - Acute care hospitals will have new requirements for equipment, supplies, and medication that are aligned with existing equipment and supply standards for CAHs.
- Acute care hospitals and CAHs must have protocols in place to treat patients with emergency conditions, consistent with nationally recognized evidence-based guidelines. These protocols must include standards for the treatment of obstetrical emergencies, complications, and immediate post-delivery needs.
- Applicable staff, as determined by the acute care hospital or CAH, must receive annual training on these protocols and provisions required under the new readiness standard.
  - This annual training must be informed by the acute care hospital or CAH's Quality Assurance and Performance Improvement (QAPI) Program.
- The new readiness standard also requires certain equipment, supplies, and medications to be kept at the hospital and readily available to treat emergency patients. These include drugs, blood and blood products, biologicals, equipment, and supplies that are commonly used in life-saving procedures.
  - Hospitals are responsible for determining the specific equipment, supplies, and medications needed to provide comprehensive emergency care based on the needs of their patients.
- Each emergency services treatment area must have a call-in system for each patient.

Transfer Protocols

(42 C.F.R. § 482.43(c))

Effective, July 1, 2025

Applies to all hospitals and not those with only obstetrical services.

- All hospitals must have written policies and procedures for transferring patients within the same hospital or to a different facility.
  - Relevant staff, as determined by the hospital, must receive annual training on these policies and procedures.
  - The rule does not explicitly require that hospitals have written policies and procedures for accepting transfers. However, CMS states that hospitals are encouraged to do so.
- At this time, the new transfer requirements as written in the rule do not apply to CAHs, however CMS notes that CAHs are already required to transfer patients with all necessary medical information pertaining to the patient's condition.

[1] Adapted in part from the American Hospital Association Regulatory Advisory, Nov. 21, 2024

Organization and Supervision of Services

(42 C.F.R. §§ 482.59(a) and 485.649(a))

Effective Jan. 1, 2026

Applies to all acute care hospitals and CAHs with obstetrical service lines

- Obstetrical services must be "well organized and provided in accordance with nationally recognized standards of practice" for physical and behavioral health and integrated with the rest of an acute care hospital's or CAH's departments.
  - Obstetrical services include labor and delivery, prenatal and post-partum care, and care for newborn infants. This includes services provided in obstetrical units, inpatient units, emergency departments, and hospital outpatient departments.
  - "Well-organized" is defined in the State Operation Manual (SOM). In the final rule, CMS states "obstetrical services should be organized and staffed in such a manner to ensure the health and safety of patients. Additionally, similar to the interpretive guidance provided in the SOM, acceptable standards of practice for obstetrical services would also include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing obstetrical services or obstetrical service locations, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations." CMS has committed to providing additional interpretive guidance in the SOM in the future.
  - "Integration" is defined such "that the facility can make available the full extent of its patient care resources, such as laboratory, surgery, or anesthesia, to assess and render appropriate care for a patient receiving obstetrical services, particularly in emergency situations."
- Obstetrical services must be supervised by an "experienced" registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or physician.
  - Each facility will determine its own requirements for an "experienced" practitioner based on the scope and complexity of the services offered, although CMS notes such requirements might include standards for education and experience or specialized training in obstetrical services or management of obstetrical services operations.
  - Supervision does not mean physical presence 24/7 in a facility. However, existing CAH CoPs do require CAHs to establish procedures for a physician to be available for tele-consultation 24/7 for emergent situations.
- Privileges must be delineated for each obstetrical services provider, although acute care hospitals and CAHs will not be required to maintain a separate roster of providers as originally proposed.

Delivery of Care

(42 C.F.R. §§ 482.59(b) and 485.649(b))

Effective Jan. 1, 2026

Applies to all acute care hospitals and CAHs with obstetrical service lines

- The obstetrical services offered by an acute care hospital or CAH must correspond with the needs and resources of the facility, and policies for providing these services should be designed in a manner that ensures patient safety and delivery of high-quality care.
- Acute care hospitals and CAHs must maintain adequate provisions and protocols to address obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified by the acute care hospital or CAH's QAPI program.
- Each acute care hospital and CAH offering obstetrical services must keep at the hospital, and make readily available, call-in-systems, cardiac monitors, and fetal dopplers or monitors, in accordance with the scope, volume, and complexity of services offered.
  - CMS defines "readily available" as meaning equipment is either on the obstetrical unit or in close proximity and easily accessible to the unit's staff.
  - CMS defines a "call-in system" as a "mechanism by which a patient and/or caregiver can alert staff of any emergencies or concerns. Examples may include a call-bell, alarm, or other notification device."
  - Per CMS "a large-volume high-acuity OB unit may have this equipment in every L&D room, while a rural hospital with a low-volume of births may have this equipment readily available within the hospital."

- Additional equipment, supplies, and medication used in treating emergencies must also be kept at the hospital and readily available. This could include "crash carts," obstetrical hemorrhage carts, or other types of emergency kits.
  - There are no mandates on specific equipment or medications. All equipment and medications should be based on nationally recognized and evidence-based guidelines as well as the facilities' scope, volume, and complexity of services.
  - Examples of equipment cited by CMS include resuscitator, defibrillator, aspirator, and airways, endotracheal tubes, Ambu bag/valve/mask, oxygen, tourniquets, nasogastric tubes, IV therapy supplies, suction machine, and defibrillator.
  - Examples of emergency medications cited by CMS include analgesics, local anesthetics, anti-arrhythmic, cardiac glycosides, antihypertensives, antiepileptics, uterotonics, anticoagulants, antifibrinolytics, electrolytes and replacement solutions.

Staff Training

(42 C.F.R. §§ 482.59(c) and 485.649(c))

Effective Jan. 1, 2027

Applies to all acute care hospitals and CAHs with obstetrical service lines

- Staff training must occur at least once every two years. In addition, new staff must receive initial training. All training must be documented.
  - The staff roles responsible for training, and which training they complete, must be designated by the hospital's governing body.
  - CMS has not mandated what modalities can be used for training (in person, online, etc.)
- Training must be informed by the acute care hospital or CAH's QAPI program and include facility-identified evidence-based best practices.
  - Training must be high-quality, consistent with and tailored to the individual staff member's expected role, with the goal of improving the delivery of OB care.
  - CMS provided training in substance use disorders and providing culturally and linguistically appropriate care as examples, assuming these trainings were consistent with hospitals' QAPI program findings.
  - CMS expects that hospitals will evaluate trainings and their alignment with the QAPI program regularly and on a continuous and ongoing basis.

Quality Assessment Performance Improvement

(42 C.F.R. §§ 482.21 and 485.641)

Effective Jan. 1, 2027

Applies to all acute care hospitals and CAHs with obstetrical service lines

- Acute care hospitals and CAHs offering obstetrical services must utilize their QAPI programs to identify disparities in care, services and operations, and improve outcomes among obstetrical patients.
- Acute care hospitals and CAHs, including their obstetrical services leadership, must collect, track, and analyze data on an ongoing basis to improve identified disparities and ensure sustained progress among diverse populations.
  - Obstetrical leadership is defined as facility leadership, obstetrical services leadership, or their designee.
  - CMS is not requiring specific data analysis or methods, nor is CMS defining "diverse populations" or time periods being used for analysis. CMS is also not requiring that electronic health data be utilized.
- At least one measurable performance improvement project focused on improving disparities and outcomes of the acute care hospital or CAH's obstetrical patients is required each year.
  - The project can be continuous from year to year. Hospitals are not required to participate in a new project each year.
- For acute care hospitals and CAHs located in a state, tribal area, or local jurisdiction with a maternal mortality review committee (MMRC), the hospital must have in place a process to incorporate publicly available data from the MMRC into their QAPI program.
- Participation in "external" quality improvement efforts, including those led by designated perinatal quality collaboratives, may satisfy these requirements.

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