

## Report on Medicare Compliance Volume 33, Number 30. August 19, 2024 CMS Proposes New OB CoP, Would Revise Three Others With OB Links

## By Nina Youngstrom

Partly with an eye to easing the maternal health crisis, CMS has proposed a new condition of participation (CoP) for obstetrical services and updated other CoPs that tie into obstetrical services, including for emergency services. The new and revised CoPs, which affect hospitals and critical access hospitals (CAHs), are in the proposed 2025 outpatient prospective payment system (OPPS) regulation published in the *Federal Register* July 22.[1]

The obstetrical services CoP would only apply to hospitals that offer obstetrical (OB) services, said attorney Rachel Carey with Whiteford in Richmond, Va. "But they also updated the emergency services CoP and emergency departments must be able to handle obstetric emergencies," she said. Even if a hospital or CAH eliminated OB services, they'd have to demonstrate they're equipped to provide emergency OB services.

CMS also proposed revisions to the CoP on quality assurance and performance improvement (QAPI) to include obstetrics-related services and the CoP on discharge planning.

"These are CoPs primarily related to health and safety, and organizations must satisfy the CoPs to maintain their Medicare certification agreement," said Martie Ross, a principal with PYA. State surveyors review compliance with CoPs, and hospitals must address deficiencies or they risk losing their Medicare certification. "CoPs carry a great deal of weight to hospitals and their compliance activities," she noted.

The obstetrical services CoP is designed to create national standards around the operation of hospital OB units, Ross said. This CoP is referred to as optional because hospitals and CAHs aren't required to provide OB services outside the emergency room, "but if you do, you provide the services in compliance with the CoP." She noted that 5,797 hospitals and 513 CAHs provide OB services beyond the emergency room.

There are three core requirements in the proposed OB services CoP:

- 1. **Organization and staffing:** OB services must be supervised by an experienced registered nurse, nurse practitioner or physician. "As part of medical staff privileges, you must delineate specific OB privileges based on demonstrated competence," Ross explained.
- 2. **Delivery of services:** Hospitals and CAHs would be required to have sufficient provisions and protocols consistent with nationally recognized, evidence-based guidelines. "It sounds like generic language, and we tend to read past generic guidelines," but CMS's expectation is that hospitals providing OB services will identify the nationally recognized, evidence-based guidelines they're following—"and reference them in policies and procedures as well as processes for updating them," Ross said. Also, labor and delivery rooms and post-partum rooms would require appropriate equipment to respond to patient needs. For example, labor and delivery rooms must have a call-in system, a cardiac monitor and a fetal doppler or monitor.
- 3. **Staff training:** The hospital/CAH governing body must identify and document the types of staff members who are required to complete annual training on best practices and areas ripe for advanced training that

have been identified by the QAPI program. "Hospitals must be able to demonstrate to surveyors that staff has knowledge" on training topics (i.e., specific issues identified in your organization), Ross said. "It's not enough to do online training and certify you attended it. You must have a way to show that folks heard and understand the information and gained appropriate knowledge, whether it's post-training testing or some other sort of acknowledgement." (CMS noted in a 2023 memo that "QAPI CoP deficiencies are the third most frequently cited of the 24 CoPs for Medicare-certified hospitals.")<sup>[2]</sup>

The proposed OPPS rule would also revise the QAPI CoP for hospitals and CAHs. Although CMS made major changes to the QAPI CoP for CAHs in 2020, it hasn't released interpretive guidelines on them, which affect enforcement, Ross said. "Regardless, CMS is now proposing to amend them to add requirements around OB services." They only apply to hospitals and CAHs offering OB services outside the emergency room.

CMS is proposing to require OB leadership to employ QAPI to evaluate and improve health outcomes and reduce disparities among OB patients, she said. That includes measuring, analyzing and tracking health equity data and quality indicators. CMS drilled down into the inequality of the maternal health crisis. For example, rural, minority and disabled populations "experience complications more frequently," she said. Hospitals and CAHs would be required to track their performance across identified outcomes "to ensure performance improvement is sustained," and do at least one OB performance improvement project every year.

The updated discharge planning CoP applies only to hospitals, not CAHs. Hospitals would be required to keep written policies and procedures for transferring patients to the appropriate level of care to meet their specific needs. "This isn't specific to OB transfers," Ross noted. "It's a broad requirement for transfer protocols but it's around the discussion of when it's appropriate to transfer a patient who requires a higher level of care and that includes OB patients." Hospitals also would be required to train staff on the policies and procedures.

## **Emergency Services CoP May Have Most Impact**

The proposed changes to the emergency services CoP will have the most impact because it applies to all hospitals and CAHs, with and without OB programs, Ross said. The revised CoP would require hospitals and CAHs "to maintain protocols consistent with nationally recognized, evidence-based guidelines for patients with emergency conditions," she said. That includes patients with OB emergencies, complications and immediate post-delivery care needs. CMS expects hospitals and CAHs to cite the protocols they rely on and have adequate provisions to treat emergencies, including equipment, supplies, drugs and biologics typically used in life-saving procedures. Although CMS doesn't specify what they are, "you need to demonstrate why you chose what you chose," Ross explained. And emergency treatment areas must have a call-in system for every patient.

"Where the rubber meets the road" is the requirement for annual staff training on emergency protocols and provisions, she said. The governing body would identify who must be trained, and the QAPI program would inform the training. "As you evaluate emergency conditions, what are you learning about challenges and outcomes, and how are you incorporating that into your training?" Hospitals and CAHs also must be able to prove staff knowledge on training areas. Especially for CAHs, "there's an expectation you have some capacity within the organization to respond to an OB emergency," Ross noted. "Simply packing the mom into a car and shipping her off to another hospital won't be adequate."

The new and proposed revisions to CoPs don't apply to rural emergency hospitals, Carey noted.

Carey predicts CMS will finalize the new and revised CoPs because of the legwork it has done. "They already put out an RFI about the possibility of enhancing these CoPs" in the proposed 2025 inpatient prospective payment system rule, she noted. It was a surprise they turned up in the proposed OPPS rule, which indicates CMS is fast-tracking the CoPs, Ross said.

Carey added that the new and revised CoPs seem to speak to the crackdown on abortion in many states. Providers continue to be "in a sticky situation in terms of" the conflict between state limits on obstetric care in the realm of abortion and what's "considered obstetrics and emergency care in the current administration," she said. CMS is "trying to get the point across that they will use what they can to secure access for women who need it."

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<u>1</u> 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, 89 Fed. Reg. 59186 (July 22, 2024), <a href="https://bit.ly/46MOrDf">https://bit.ly/46MOrDf</a>.

<u>2</u> Centers for Medicare & Medicaid Services, "Revision to State Operations Manual (SOM), Hospital Appendix A – Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program," March 9, 2023, <a href="https://go.cms.gov/3yIMoUj">https://go.cms.gov/3yIMoUj</a>.

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