

CMS Regulatory Reduction Rule Adds New Regulatory Burdens in Florida

Florida ambulatory surgical centers will not gain much regulatory relief under the new CMS Regulatory Burden Reduction Rule (Rule). State of Florida rules corresponding to the CMS requirements are now more stringent and therefore supersede the CMS changes, keeping many requirements in place. In addition, current accrediting organization standards are also more stringent than the new CMS rules and will need to be followed to maintain accreditation. Ironically, the new rule also adds several requirements that ASCs are burdened to comply with.

Below we discuss the State of Florida rules in comparison to the CMS changes. You may also want to review your accreditation organization's standards if you are considering making any changes as a result of the CMS rule.

§ 416.41 Condition for coverage—Governing body and management

CMS is removing the requirement at §416.41(b)(3), that ASCs must have a written transfer agreement with a hospital or ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital.

They are adding the requirement that ASCs must periodically provide a local hospital with “written notice of its operation and patient population served”.

Note: Florida regulation 59A-5.005(k) continues to require that ASCs have written center transfer agreements with one or more acute care general hospital and (j) that medical staff maintain admitting privileges at an acute care general hospital or have an agreement in place with a physician who has admitting privileges.

NEW REQUIREMENT: *The written notice of operating hours and patient population is a new requirement that takes effect November 29th, 2019 although the specifics of what will be required are not yet known. CMS is expected to release updated Interpretive Guidelines so that ASCs will know how to meet compliance with the new requirement.*

§ 416.47 Condition for coverage—Medical records

CMS is revising the medical records requirement at § 416.47(b)(2), to state “Significant medical history and results of physical examination, as applicable.”

This permits at the Federal level that an ASC may determine (see below) that an H&P is not necessary for a patient and therefore the results would not appear in the medical record.

§ 416.52 Condition for coverage—Patient admission, assessment and discharge

1. CMS is eliminating the requirement at § 416.52(a) for each patient to have a medical history and physical assessment completed by a physician not more than 30 days before the scheduled surgery, and replaces it with the requirement for ASCs to develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery.

Note: Florida regulation 59A-5.0085(d) continues to require that ASCs provide a history and physical examination prior to the administration of anesthesia for every patient.

2. CMS is slightly revising § 416.52(a)(1)(iii) to assure that the ASC policy on patient history and physical assessment will be based on nationally recognized standards of practice and guidelines, and applicable State and local health and safety laws. This language is similar to what is currently in place, but differs in the emphasis on “nationally recognized standards of practice and guidelines”.

NEW REQUIREMENT: *The documentation that H&P policies must be based on nationally recognized standards of practice and guidelines and applicable State and local health and safety laws is a new requirement that takes effect November 29th, 2019. CMS is expected to release updated Interpretive Guidelines so that ASCs will know how to meet compliance with the new requirement.*

§ 416.54 Condition for coverage--Emergency preparedness

These changes affect the CMS Emergency Preparedness Plan.

Existing State law continues to govern an ASC’s state Comprehensive Emergency Management Plan (CEMP)(see below).

1. CMS is lengthening the timeframe to review an emergency preparedness plan from once a year to every two years (biennially).

2. CMS is lengthening the timeframe to provide staff emergency preparedness training from once a year to every two years (biennially).

3. CMS is lowering the required number of testing exercises from twice to once per year.

4. CMS is eliminating the requirement that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and facilities’ participation in collaborative and cooperative planning efforts. It is leaving in place the requirement that ASCs participate in a community-based full-scale exercise every other year, if available.

§ Florida Comprehensive Emergency Management Plan (CEMP)

Florida law maintains different requirements for the CEMP. To the extent that your ASC's two emergency management plans coincide, you will want to keep the more stringent requirements of Florida law rather than those of CMS.

1. Florida regulation 59A-5.018(3) continues to require that the center's emergency preparedness plan be submitted to the county emergency management agency on an annual basis.
2. Florida regulation 59A-5.018(4) continues to require that ASCs test their emergency preparedness plan twice each year (semi-annually).
3. Florida law requires that all staff be trained on emergency preparedness but does not set a requirement regarding how often. ASCs should determine how to train new staff if they move to the CMS' biennial training standard.

FSASC will work with AHCA as they begin to survey under the "regulatory reduction" rules. This will be some time after the November 29th, 2019 effective date of the Rule. We encourage members to share what they are doing in response to the new rules on our forum or to contact FSASC directly if you have concerns.