CMS Clarifies Interpretive Guidelines for Hospitals Providing Anesthesia Services

The Centers for Medicare and Medicaid Services (CMS) recently revised the interpretive guidelines for 42 C.F.R. § 482.52, which governs hospital conditions of participation (COPs) for anesthesia services. CMS revised the guidelines to clarify: (1) which anesthesia services fall under the § 482.52(a) rules that govern which practitioners may administer anesthesia; and (2) which anesthesia services require pre-, intra-, and post-operative anesthesia evaluations under § 482.52(b). This article summarizes the new interpretive guidelines for § 482.52 and explains how these guidelines affect the Medicare COPs for hospitals providing anesthesia services.

(1) Anesthesia Services Form a Continuum: Not All Services Fall Under § 482.52(a)

Section 482.52(a) specifies which practitioners may administer anesthesia services and also delineates which practitioners require supervision. The revised guidelines define various anesthesia services and place these definitions along a continuum ranging from true anesthesia to mere analgesia or sedation. Section 482.52(a) applies only to services that qualify as true anesthesia for regulatory purposes.2

(a) Anesthesia Services Subject to § 482.52(a) Administration Requirements

The revised guidelines clarify that the following anesthesia services qualify as true anesthesia for regulatory purposes and therefore fall under the § 482.52(a) requirements: (a) general anesthesia; (b) regional anesthesia; and (c) monitored anesthesia care (MAC). The guidelines define these services in detail.3 The guidelines define general anesthesia in part as “a drug-induced loss of consciousness during which patients are not arousable, even by pain-

1 The revised interpretive guidelines are available in the State Operations Manual (CMS Pub 100.7) Appendix A for 42 C.F.R. § 482.52 [hereinafter SOM, Appendix A].
2 Generally, the guidelines define anesthesia as a service that “involves the administration of a medication to produce a blunting or loss of pain perception; voluntary and involuntary movements; autonomic function; and memory and/or consciousness depending on where along the central neuraxial (brain and spinal cord) the medication is delivered.” By contrast, the guidelines define analgesia as “the use of medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system.” With analgesia, the “patient does not lose consciousness.” SOM, Appendix A, §482.52 Condition of Participation: Anesthesia Services.
3 The regulatory definitions generally follow the American Society of Anesthesiologists practice guidelines (Anesthesiology 2002; 96:1004-17).
Regional anesthesia is “the delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves.”5 Finally, the guidelines define MAC as “anesthesia care that includes the monitoring of the patient by an anesthesia professional.”6 Deep sedation – “a drug induced depression of consciousness during which patients cannot be easily aroused” – falls within the MAC definition.7

These true anesthesia services fall under § 482.52(a), which defines administration and supervision requirements for each service. Under section 482.52(a) only the following practitioners may administer anesthesia services without supervision: (a) qualified anesthesiologists; (b) doctors of medicine or osteopathy; or (c) dentists, oral surgeons, or podiatrists qualified to administer anesthesia under state law. Section 482.52(a) also allows certified registered nurse anesthetists (CRNAs) and anesthesiologist’s assistants to administer anesthesia as long as an operating practitioner or anesthesiologist is available to supervise.8

The § 482.52(a) administration rules apply in all cases where a hospital provides general anesthesia, regional anesthesia, or MAC. These rules create some complexity for hospitals that allow CRNAs to administer anesthesia. Such hospitals must create policies for operating practitioners and anesthesiologists who supervise CRNAs and these policies must conform to generally accepted standards of anesthesia. Also, such hospitals must ensure that operating practitioners and anesthesiologists who supervise CRNAs qualify as “immediately available” when a CRNA needs assistance. The revised guidelines state that an operating practitioner or anesthesiologist qualifies as immediately available “only if he/she is physically located in the same area as the CRNA . . . and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention.”9 Some hospitals may be able to avoid these complications if they are located in a state that has received special exemption from the rules that require CRNA supervision. Hospitals in exempted states may allow CRNAs to administer anesthesia services without a supervising physician.10 However, Georgia is not one of the fifteen exempted states.

(b) Anesthesia Services NOT Subject to § 482.52(a) Administration Requirements

The revised guidelines state that topical or local anesthetics, minimal sedation, and moderate sedation do not fall under the § 482.52(a) requirements. Thus, the strict guidelines governing which practitioners can administer anesthesia services, including the supervision requirements for CRNAs, do not apply to these services. An example is the provision of acute analgesia during labor and delivery (i.e., relief of pain, via an epidural or spinal route) is not considered “anesthesia,” and a CRNA administering these forms of anesthesia services does not require supervision by the operating practitioner or anesthesiologist. However, if the operating practitioner decides that an anesthesia effect (loss of voluntary and involuntary movement and total

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4 SOM, Appendix A, §482.52 Condition of Participation: Anesthesia Services.
5 Id.
6 Id.
7 Id.
8 42 C.F.R. § 482.52(a)
9 SOM, Appendix A, §482.52(a) Standard: Organization and Staffing. These guidelines defining immediate availability also apply to anesthesiologist’s assistants.
10 Id, § 482.52(c). States that have applied for the exemption are known as “opt-out” states. Click here for a list of opt-out states.
relief of pain) is necessary for a safe delivery of the infant, then the CRNA supervision requirements would apply.

Hospitals must still self-regulate these services to some extent. The guidelines explain that hospitals must enact policies and procedures consistent with state scope of practice laws to govern anesthesia services that do not fall under § 482.52(a). Additionally, hospitals must still ensure that these services “are provided in a safe, well-organized manner by qualified personnel” even though they do not fall under § 482.52(a).

(c) All Anesthesia Services Subject to Broader COPs

All anesthesia services, whether or not they fall under specific administration rules in § 482.52(a), are subject to the broader COP principles. Thus, hospitals must organize all anesthesia services into one service and appoint a qualified physician to supervise the overarching service. This overarching service must include all anesthesia services throughout all hospital departments, campuses, and off-site locations. Hospital medical staff must establish criteria in accordance with state law that will qualify a physician to act as director of anesthesia services. The director and his or her staff must take responsibility for developing policies and procedures that govern anesthesia services, including the minimum qualifications for practitioners who will administer services not covered under § 482.52(a).

(2) Continuum Governs Which Services Require Evaluations Under § 482.52(b)

Sections 482.52(b)(1) – (3) require pre-, intra-, and post-anesthesia evaluations for certain anesthesia services. The anesthesia services continuum governs which services fall under the § 482.52(b) evaluations requirements. As with the administration rules, general anesthesia, regional anesthesia, and MAC all trigger the rule; these anesthesia services require evaluations that meet the § 482.52(b) specifications. Moderate sedation and other less intensive services, such as minimal sedation and topical anesthetic, do not require § 482.52(b) evaluations. Most hospitals typically conduct evaluations before, during, and after moderate sedation; however, the revised guidelines note that the regulations do not require such evaluations because moderate sedation “is not considered to be ‘anesthesia’, and thus is not subject” to § 482.52(b).11

(a) Specific Rules for Pre-Anesthesia Evaluations Under § 482.52(b)(1)

The revised guidelines state that only practitioners qualified to administer anesthesia under § 482.52(a) may conduct pre-anesthesia evaluations. Qualified practitioners may not delegate evaluation responsibilities to other practitioners who are not qualified to administer anesthesia service under § 482.42(a). Additionally, hospitals must administer pre-anesthesia evaluations within 48 hours prior to any procedure requiring anesthesia services. The revised guidelines clarify that the 48-hour timeframe ends when the hospital delivers the first anesthesia medication dosage to the patient.

11 SOM, Appendix A, §482.52(b) Standard: Delivery of Services (emphasis in original).
The revised guidelines also list the minimum requirements for a proper pre-anesthesia evaluation. Such evaluations must include: (a) medical history review, including anesthesia, drug, and allergy history; (b) patient interview and examination; (c) anesthesia risk according to established practice standards; (d) potential anesthesia problems, particularly those that suggest complications or contraindications for the planned procedure; (e) any additional evaluations required by standard practice; and (f) a full plan for patient’s anesthesia care.

(b) Specific Rules for Intra-Anesthesia Evaluations Under § 482.52(b)(2)

The revised guidelines state that hospitals must create an intra-operative anesthesia record for each patient receiving an anesthesia service to subject the § 482.52(b) rules. At a minimum, this record must include: (a) patient name and hospital identification number; (b) names of practitioners administering anesthesia and names of any supervising practitioners; (c) name, dosage, route, and time of administration of drugs; (d) techniques used and patient positions; (e) name and amount of intravenous fluids; (f) time-based documentation of vital signs; and (g) any complications or adverse reactions.

(c) Specific Rules for Post-Anesthesia Evaluations Under § 482.52(b)(3)

Finally, the revised guidelines clarify the requirements for post-anesthesia evaluations. As with pre-anesthesia evaluations, only practitioners qualified to administer anesthesia under § 482.52(a) may conduct post-anesthesia evaluations and qualified practitioners may not delegate evaluation responsibilities to non-qualified practitioners. Hospitals must conduct such evaluations within 48 hours after the procedure requiring anesthesia. The revised guidelines clarify that the 48-hour timeframe begins at the point where the patient is moved into the recovery area; however the hospital may not begin the evaluation until the patient has sufficiently recovered from the anesthesia to participate in the evaluation. The guidelines advise hospitals to document post-anesthesia evaluations clearly and to conduct them according to current standards of anesthesia care. A typical evaluation would include: respiratory function, cardiovascular function, mental status, temperature, pain, nausea, and post-operative hydration.

Conclusion: Revised Guidelines Offer Some Clarity, But Questions Remain

The revised guidelines help hospitals comply with the COPs for anesthesia services by better defining these services and specifying which services qualify as true anesthesia for regulatory purposes. Hospitals now have some clarity about when the § 482.52(a) and (b) administration, supervision, and evaluation rules apply.

The continuum also raises new questions for services that fall close to the fuzzy border between anesthesia and mere analgesia. As the revised guidelines note, hospitals must be ready to rescue patients who enter deeper sedation levels than intended. This rescue requirement compels hospitals to make qualified practi-
tioners available even for services that do not fall under strict administration or supervision requirements.\textsuperscript{12} Additionally, the revised guidelines still require hospitals to develop administration and supervision policies for anesthesia services that do not fall under § 482.52(a). Hospitals must consider state law and prevailing practice standards to develop policies that are both practical and compliant.

\textsuperscript{12} SOM, Appendix A, §482.52 Condition of Participation: Anesthesia Services.