July 5, 2013

TO: General Acute Care Hospitals (GACH)
Ambulatory Surgery Centers (ASC)
Surgical Clinics

SUBJECT: Procedural Sedation Policies and Procedures

AUTHORITY: Title 22 California Code of Regulations (CCR) Sections 70213, 70233, 70263, 70237(a)(3) (GACH)
42 Code of Federal Regulations (CFR) Sections: 416.42 (ASC), 482.52 (GACH)

This All Facilities Letter (AFL) is being issued to provide information on the state and federal requirements for safe administration of procedural sedation. The Centers for Medicare and Medicaid Services (CMS) has provided interpretative guidelines which specify that policies and procedures governing sedation practices must be based on nationally recognized guidelines. The guidance provided in this AFL draws from the CMS interpretative guidelines.

Central to any discussion of sedation is the recognition of the various levels of sedation, which exist along a continuum. Mild to moderate sedation (termed “conscious sedation”) involves a drug-induced depression of consciousness during which the patient will respond purposefully to verbal commands, either alone or with light tactile stimulation. In deep sedation (termed “monitored anesthesia care” or MAC), the patient has a drug-induced depression of consciousness and cannot be easily aroused but will respond purposefully following repeated or painful stimulation. A patient under general anesthesia loses the ability to respond purposefully or loses consciousness and may require interventional support to maintain normal functions.

Fundamentally, safe performance of any sedation procedure requires the ability to recognize when a patient has passed into a deeper level of sedation than intended, and the training and skills to immediately “rescue” the patient back to the intended level of sedation. A facility’s policies and procedures should ensure any physicians and nurses who may be assisting in the procedure will have this knowledge and capability; this usually involves additional training in sedation monitoring and advanced training.
consistent with Advanced Cardiac Life Support certification. The facility should additionally assure that these skills are kept current and that the individuals maintain their competency in sedation procedures.

Sedation policies should also include specific provisions to ensure the following:

- A qualified anesthesia provider (MD/DO anesthesiologist, or Certified Registered Nurse Anesthetist (CRNA)) may provide sedation-level services anywhere in the facility as part of anesthesia services.

- Administration of sedation practices may be conducted under the direction of a privileged practitioner (MD, DO, dentist, oral surgeon, or podiatrist) as an alternative to anesthesia services, as specified in 42 CFR 482.52(a) or 42 CFR 416.42(b, c).

- Conscious (or moderate) sedation may be administered by a privileged practitioner or a qualified Registered Nurse (RN) with training in both advanced cardiac care and sedation practices. The administration of conscious sedation must be pursuant to an order by a qualified and privileged practitioner when administered by someone other than the ordering practitioner. A qualified nurse or physician must monitor the patient’s airway, vital signs, and level of sedation continuously and may only do minor and interruptible tasks which do not compromise the patient’s monitoring.

- Deep sedation, due to the potential that it may inadvertently progress to general anesthesia, must be administered only by a properly privileged practitioner. An RN with appropriate training may monitor deep sedation and/or adjust it in order to begin a rescue only when supervised by a qualified practitioner.

- Practitioners may administer and/or monitor anesthesia consistent with the clinical privileges granted to them by the Governing Body of the specific facility. When a credentialed and privileged professional is both administering and monitoring, he or she may only perform those specific duties relating to the sedation practice and no other.

In general, the policies and procedures governing sedation practices should be specific to the unit of the facility in question, i.e. Emergency Room, Cardiac Catheterization Laboratory, or Surgical Suites and correspond to the appropriate nursing competency. While the policies and procedures may differ somewhat from unit to unit, all units where sedation is administered must comply with the state and federal regulations, be consistent with nationally recognized standards of practice, and be specific to that unit as well as to the anesthesia service requirements.

The guidance in this letter is intended to be informative to each facility, as an aid to developing appropriate policies and procedures which are compliant with existing federal and state laws and regulations. To be clear, this guidance only refers to procedural sedation and does not refer to rapid sequence induction (RSI) for emergency intubation or to sedation for ventilated or comatose patients.
Facilities are responsible for following all applicable laws. CDPH’s failure to expressly notify facilities of legislative or regulatory changes does not relieve them of this responsibility.

If you have any questions, please contact your local District Office.

Sincerely,

Original signed by Debby Rogers

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