



AMERICAN SOCIETY OF ANESTHESIOLOGISTS

Office of Governmental Affairs

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May 24, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Via e-mail

Re: **File Code CMS-3122-P**

Medicare and Medicaid Programs; Hospital Conditions of Participation; Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations
(70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

The American Society of Anesthesiologists (ASA) would like to commend CMS for proposing to change two provisions of the Hospital Conditions of Participation that have been of much concern to our members: securing medications and postanesthesia evaluations. We urge you to finalize the changes as you have proposed them.

Securing Medications

The requirement that carts containing anesthesia medications be locked whenever they are not directly monitored by an individual with legal access to the medications, even within a secure operating room suite, was never published until the State Operations Manual was revised in May, 2004. Nevertheless, numerous hospital surveyors have followed this interpretation and have warned or cited institutions for noncompliance. At least one state, California, took the interpretation so seriously that its Department of Health Services issued a memorandum on medication security stating explicitly that “anesthesia carts and anesthetic machines may remain unlocked during and in between consecutive surgical cases in a given operating room, as long as there are surgical service personnel in the immediate vicinity.” This statement is a paraphrase of ASA policy and would follow the CMS proposed position.

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There has never been any question that controlled drugs must be under lock. Locking up the non-controlled medication on top of or in anesthesia carts between cases in a busy operating room, on the other hand, is a threat to patient safety: if the patient suddenly needs a life saving drug on the cart while the anesthesiologist is accompanying him or her to post-anesthesia recovery, delayed access could be lethal. Accounts of broken locks, forgotten combinations or security codes and other failures or shortcomings of the equipment used to lock up the anesthesia medications are not rare. Moreover, the cost to hospitals of purchasing or leasing and maintaining special locking devices or systems is very substantial – and has not been shown to prevent any contamination or diversion of the anesthesia drugs, which appear not to have been problems in the first place.

ASA is extremely pleased, therefore, with CMS' proposal to revise § 462.25(b)(2) to require that ***“all drugs and biologicals be kept in a secure area, and locked when appropriate.”*** This formulation is consistent with the ASA Position Statement on Security of Medications in the Operating Room that we were also pleased to see referenced in the notice published in the Federal Register on March 25, 2005.

The Federal Register notice cited several examples of areas that would be deemed secure under the new standard, e.g., private offices and procedure rooms. It did not, however, mention operating suites and anesthesia carts. Because a paragraph in the Interpretive Guidelines on § 462.25(b)(2) specifically provides that if an anesthesia cart, nursing or other “cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart,” we would ask that CMS list operating suites among the examples of secure areas, or otherwise make absolutely unequivocal that the proposed rule does not require direct monitoring of an unlocked anesthesia cart in an operating suite that is in use. Areas restricted to authorized personnel would generally be considered “secure” under the revised standard; ASA recommends, and revised §462.25(b)(2)(iii) would require, that access to operating room suites be strictly limited to authorized persons. We also agree with CMS that if there are medication security problems, the hospital must at that time assess and if appropriate modify its systems and processes.

Completion and Documentation of the Postanesthesia Evaluation

ASA appreciates CMS' response to our concerns about the current requirement in §482.52(b)(3) that the practitioner who performs the anesthetic personally write a follow-up report within 48 hours after surgery. The proposed regulation would allow any individual who is qualified to administer anesthesia to complete and document the postanesthesia evaluation. This is a change that ASA has been seeking for some time, as have individual anesthesiologists and the American Medical Association (AMA).

American Society of Anesthesiologists
Comments on 70 Fed. Reg. 15266, March 25, 2005

In making the postanesthesia evaluation standard a mirror image of the preanesthesia evaluation rule at §482.52(b)(1), CMS has greatly simplified the regulation. This will give hospitals and anesthesiology departments much needed flexibility to deploy anesthesiologists, anesthesiologist assistants and nurse anesthetists so as to ensure the highest quality and timeliness of postoperative anesthesia care.

On behalf of our many members and their patients who will benefit from ensuring the ready availability of critical anesthesia medications in busy, secure operating rooms and from the ability to schedule anesthesia practitioners to perform postoperative evaluations in a way that is best for patient and practitioner, we thank you for proposing to change the hospital Conditions of Participation regulations. If you have any questions, please do not hesitate to contact us through Karin Bierstein, JD, MPH at (202) 289-2222 or k.bierstein@asawash.org.

Sincerely,

Eugene P. Sinclair, MD
President