Many ASA members have struggled to comply with the hospital requirement that anesthesia carts be locked between cases. Over the last several years, surveyors from the Joint Commission and from state health agencies have surprised quite a few departments by insisting on an extremely strict interpretation of the old Medicare regulation that provided, “Drugs and biologicals shall be kept in a locked storage area” (Conditions of Participation, 42 C.F.R. §462.25(b)).

As a result of a lengthy ASA campaign to change the so-called “locked cart rule,” the Centers for Medicare & Medicaid Services (CMS) revised the regulation effective January 26, 2007. The regulation now states that “All drugs and biologicals must be kept in a secure area, and locked when appropriate.”

It was the intention of CMS to give hospitals more flexibility in their policies on the storage of noncontrolled substances. Drug Enforcement Administration (DEA) Schedule II, III, IV and V drugs must continue to be kept locked even within a “secure area” such as an operating room (O.R.) suite. (Schedule V drugs are not used in anesthesia practice.) Only authorized personnel may have access to locked areas. As long as nonscheduled medications are in a “secure area” with access limited to authorized personnel, patients and supervised visitors, they do not need to be locked up in addition. Thus to cite the most obvious example, in an active O.R. suite it is not necessary to lock the anesthesia cart while the anesthesiologist is taking the patient to the recovery area.

In explaining its rationale for modifying the locked carts rule, CMS cited the Position Statement on Medication Security approved by ASA’s Executive Committee in October 2003, agreeing that it is critical for anesthesiologists to have access to resuscitation drugs and also acknowledging the need to set up anesthesia carts in preparation for use in the O.R. or labor and delivery unit. The position statement provides that “Anesthesia carts and anesthesia machines may remain unlocked, and non-controlled … medications may be left in or on top of unlocked anesthesia carts or anesthesia machines immediately prior to, during, and immediately following surgical cases in an operating room, so long as there are authorized operating room personnel in the O.R. suite.”

ASA members should consult the Position Statement on Medication Security, which is available at www.ASAhq.org/clinical/LockedCartPolicyFinalOct2003.pdf, in assisting their hospitals to update their own medication security policies.

Sample Policy Language

In the discussion accompanying the Federal Register notice regarding the revision to the regulation, CMS emphasized flexibility in allowing hospitals to determine their own medication security and storage policies. Thus there are several approaches, concepts and phrases that each hospital, in order to comply with the Medicare Conditions of Participation (CoP), must define in its own policies, including “secure area” and “authorized personnel.”

This particular CoP on “Pharmaceutical Services” imposes primary responsibility for local policies on hospital pharmacy units, but complementary policies also may be developed by anesthesiology, nursing, facilities and other hospital services. It is clear that they must be consistent with each other as well as with state and local law.

In order to help anesthesiologists work with their hospitals to update applicable policies, we offer sample language in Figure 1. James S. Hicks, M.D., Chair, Peter J. Dunbar, M.D., and Mark Singleton, M.D., of the Committee on Quality Management and Departmental Administration, contributed their time and expertise to the creation of this basic sample policy, which readers will need to customize. The sample policy assumes a teaching hospital in which access is generally restricted only to the O.R. suites and to some of the nonsurgical procedure units. The major items for customization include enumeration of controlled substances, determination of “secure areas” within the hospital, identification of procedures for controlling entrances to the secure areas, identification of the type of locking mechanism.
Preamble

Anesthesiologists use medications both to sedate or anesthetize patients and to relieve pain, most commonly with controlled substances from DEA Schedules II, III and IV. Anesthesiologists also administer medications to manage the neuromuscular system, cardiovascular system and pulmonary system: drugs used for these purposes must be immediately available at all times in any active anesthetizing location. Limiting access to these resuscitation drugs even for a few seconds could seriously compromise patient safety. Any protocols or procedures designed to prevent tampering with or diversion of anesthesia medications must permit immediate access to resuscitation drugs, consistent with federal regulations (42 C.F.R. §462.25(b) (2)) that were revised effective January 26, 2007.

Purpose

This policy provides that medications shall be stored securely to protect the safety of patients and the public health while allowing appropriate access by authorized personnel.

Pharmacy Policies

Pharmacy is ultimately responsible for the storage, dispensing and inventory control of all perioperative medications.

Coordination with Anesthesiology Policies

The Department of Anesthesiology is responsible for the safety of patients under its care. Pharmacy and Anesthesiology will together ensure that medication security policies proposed by either service (1) maintain patient safety, (2) do not conflict with each other and (3) comply with federal and state regulations.

Controlled and Noncontrolled Medications

Drugs used in anesthesiology are divided into controlled (DEA Schedules II, III and IV) and noncontrolled substances. (For the purpose of this policy on medication security, ephedrine and propofol are treated like controlled substances.)

Procedures and Definitions

1. All anesthesia medications will be kept in a secure area.
2. Controlled substances must be locked within a secure area.

"Secure Area"

A Suite or Unit is secure when it is locked, or when the Suite/Unit is in active use and access and egress is monitored and restricted to authorized personnel. Procedures to ensure that only authorized personnel (see below) and patients have access to secure areas are described in the Facilities Policies and Procedures.

A. All active operating room (O.R.) suites are considered secure areas when they are staffed and being used to provide patient care, as long as they are accessible only to authorized personnel (see below). When the entire O.R. Suite is closed and not staffed, it may be considered secure if it is locked.

B. The Procedure Units listed below are considered secure areas during regular hours when they are staffed and being used to provide patient care, as long as they are accessible only to authorized personnel. When the Units are closed, they will be considered secure only if they are locked.
   • Postanesthesia Care Unit
   • Labor and Delivery Unit

Surgical Intensive Care Unit
Radiology
Interventional Radiology
Cardiac Catheterization Lab
Endoscopy Unit

Security of NONCONTROLLED Medications

When the O.R. Suite or Procedure Unit is in use and access is restricted, NONCONTROLLED anesthesia medications may be left in or on top of unlocked anesthesia carts or anesthesia machines immediately prior to, during and immediately following surgical cases in an O.R. so long as there are authorized operating room personnel in the O.R. suite.

If access to any Unit is not restricted to authorized personnel, medications must be kept in a cart, cabinet or individual procedure room to which access is controlled or which is locked if not in

Continued on page 34
active use (i.e., awaiting a scheduled or emergency case, being used for a case, or during turnover or cleanup from a case).

The O.R. Suite is locked at all times when it is not in use. Anesthesia carts and/or individual O.R.s in a locked O.R. Suite may themselves be locked but are not required to be locked.

When the individual O.R. or procedure room in which medications are kept is not in active use, it is not considered secure even though the O.R. suite or the Procedural Unit is actively staffed and access restricted. Noncontrolled medications must be alternatively 1) locked in the anesthesia cart in the unused room, 2) secured by locking the individual room in which they are located or 3) moved to a secure room within the O.R. Suite or Procedure Unit.

**Security of CONTROLLED Substances**

CONTROLLED Substances are kept under lock and key in all locations at all times. The sole exception is for controlled substances under the direct control of the anesthesiologist or other clinician involved in the immediate administration of the drug.

**“Authorized Personnel”**

The following are considered “authorized personnel”:

- Members of the medical, clinical (including residents and medical students, anesthesia and O.R. nurses, anesthesia and O.R. technicians and student nurses) and pharmacy staff with patient care responsibilities in the secure area;
- Housekeeping, engineering and security staff and orderlies when needed to perform their assigned duties;
- Visitors (including technical consultants and drug and equipment manufacturer representatives) when under the supervision or in the presence of a medical or clinical staff member;
- Government and accreditation organization representatives when they are performing their regulatory responsibilities.

Impact on JCAHO Surveys

The federal standard now requires that medications be locked “when appropriate,” i.e., when they are on Schedules II, III, IV or V and when they are not otherwise in a “secure area.” What does this mean if a Joint Commission surveyor visiting your O.R. still insists that an unlocked anesthesia cart merits a citation?

The Joint Commission’s role is to ensure that accredited hospitals are in compliance with the Medicare CoPs. The Joint Commission may impose stricter standards than does Medicare, but there is no applicable Medication Management (MM) standard that stipulates locked anesthesia carts. The relevant standard (MM.2.20) provides only that “Medications are properly and safely stored,” and the closest Element of Performance (EP.5) prohibits “Unauthorized persons, in accordance with the hospital’s policy and law or regulation [from obtaining] access to medications.” Emergency medications must be “stored in sealed or in locked containers; in a locked room; or under constant supervision in accordance with law or regulation” (MM.2.30, EP.6).

Source Materials: