

December 21, 2010

Mark Chassin, MD, MPP, MPH  
President  
The Joint Commission  
One Renaissance Blvd.  
Oakbrook Terrace, IL 60181

Re: Medication Management and Anesthesia Practice

Dear Dr. Chassin,

The American Society of Anesthesiologists (ASA), representing over 44,000 members, the American Association of Nurse Anesthetists (AANA), representing more than 40,000 members, the American Academy of Anesthesiologist Assistants (AAAA), representing 900 members, and the Anesthesia Patient Safety Foundation (APSF) are pleased to submit this joint letter to summarize our collective and unified thoughts on relevant medication management issues that continue to persist.

Our societies and members take very seriously medication management issues, especially as they relate to patient safety. We also recognize that such issues and their respective standards and regulations should be evidence-based, when possible, and feasible for all anesthesia providers to efficiently and effectively perform their job and deliver high quality, safe patient care. We are pleased to know that The Joint Commission agrees that standards should be evidence-based and is working to eliminate those that fail to achieve this goal.

### **Labeling of Syringes and Containers**

Our members support the need for labeling medications appropriately and are working to promote the most effective means of eliminating medical errors in the operating room, both on and off the sterile field. However, we still have outstanding concerns with respect to the following issues:

- Prohibition on pre-labeled syringes
- Labeling of spinal and epidural anesthetics and analgesics
- Label verification requirements when two individuals are involved

We disagree with the continued prohibition of pre-labeled syringes in NPSG.03.04.01 EP 2 and The Joint Commission's Frequently Asked Question on this topic. The key safety factor is reading the label on the syringe when drawing up the medication. There is no evidence to show benefit from attaching the label and drawing up the medication at the same time. This action would not prevent drawing up the wrong medication and provides a false sense of security where none should exist. Pre-labeled syringes are often prepared in advance to improve efficiency for locations with emergency situations such as trauma rooms, obstetric suites and operating rooms.

Further, we believe that use of pre-labeled syringes actually decreases medication management errors. Pre-labeled syringes allow the anesthesia professional to compare the label on the original container with the label on the syringe while the medication is being extracted from its original container. In fact, Jensen, et al, recommends that the primary means to avoid errors in drug administration, as endorsed by incident data analysis, is to carefully read a syringe or ampule label before a drug is drawn or injected (Jensen LF, Merry AF, Webster CS, et al, *Evidence-based strategies for preventing drug administration errors during anesthesia,* Anaesthesia 2004; 59:493-504).

We also have concerns with The Joint Commission's position on labeling of spinal or epidural anesthetics (MM 05.01.09 EP1; NPSG.03.04.01, EPs 1 and 5). We request written confirmation from the Joint Commission that medications and solutions prepared for epidural and spinal procedures need not be labeled during the time of initial epidural or spinal insertion. When the anesthesia professional is performing a spinal or an epidural anesthetic under sterile conditions without any break in the process, the medications are immediately administered and never out of the sight and control of that individual. We believe that syringes for epidural and spinal injections should fall under The Joint Commission's labeling exception for immediate use. The ASA currently guides its members in this fashion, following its House of Delegates-approved Statement on Standard Practice for Avoidance of Medication Errors in Neuraxial Anesthesia (attached). The possibility of a syringe swap of one of the two syringes on a spinal or epidural tray is immeasurably small, given the distinctive difference in size. A focused review of the ASA Closed Claim Database (data search of 8,954 claims through December 2008) revealed no cases of the wrong medication being placed into a sterile syringe during administration of a spinal or epidural anesthetic. Further, if a label were mandated, meeting the labeling expectation to include the drug name, strength (concentration), and amount, potentially imposes additional patient safety risks, e.g., labeling of syringes for spinal or epidural injection could result in a break in the sterile field, contamination of the drugs or needles, and/or undue delay in the completion of such procedure in emergent situations. Adverse reactions, such as arachnoiditis arising from allergy or inflammation associated with contact of the spinal or epidural medications with dyes in the ink used for the label could occur and cause substantial injury. If some kind of label is mandated to distinguish the two syringes on a spinal or epidural tray, at most, sterile labels that designate one syringe containing medication for "spinal or epidural anesthesia" and another for "local infiltration" could be applied, if these were supplied in the sterile kit by the manufacturer.

Our third area of concern related to labeling is with The Joint Commission requirement that both anesthesia professionals verify medication labels in situations where one person prepares and another administers the medication (NPSG.03.04.01 EP 4). It is common practice in both educational and anesthesia care team settings for one anesthesia professional to prepare the necessary medications for a particular procedure and another anesthesia professional to administer them. Because the contents of the syringe cannot be verified except by reading its

label, this requirement, as written, has no added value for patient safety. Medication errors are no different in their genesis from other human errors: some result from poor knowledge or defective plans, and some from the unavoidable slips and lapses that are inevitable dangers in routine acts. Reading the label is the primary strategy to intercept medication errors. There is insufficient evidence to suggest that routine verification by multiple anesthesia professionals increases patient safety or is anything more than a ritual.

### **Medications for Patients in Transport to Recovery Areas**

We ask that The Joint Commission provide written confirmation that its standards do not prohibit anesthesia professionals from carrying medications on their person when indicated and/or necessary for patient safety and in accordance with institutional policy. Anesthesia professionals typically transport patients to designated recovery areas, or intensive care units, where they transfer the care of their patients to the appropriate personnel. Depending on the hospital, the transport distance and time to reach these recovery areas can be extensive. Since postoperative patients can experience medical conditions requiring emergency interventions en route, anesthesia professionals carry on their person various medications to treat the patient's urgent medical problems, as needed. Our members have received conflicting information from surveyors and The Joint Commission's Standards Interpretation Group on this topic, particularly as to whether medications are incorrectly stored when carried on the person of the anesthesia professional in a shirt pocket or "fanny pack." We believe that when taken to its extreme, standard MM.03.01.01, EP 4 could detrimentally impact patient safety by limiting access to emergency medications during patient transport. Thus, we seek guidance from The Joint Commission as to how anesthesia professionals can safely transport patients with appropriate medications while balancing the safety concerns related to storage, disposal and return of medications.

### **Medication Security and Locked Carts**

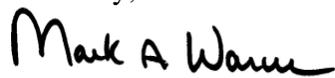
We understand that The Joint Commission, in line with the Centers for Medicare & Medicaid Services Conditions of Participation for Hospitals, requires uncontrolled medications to be kept in a secure area and controlled substances to be locked and kept in a secure area (MM. 03.01.01 EP 3). It is our understanding that Joint Commission standards allow placement of uncontrolled medications on top of an anesthesia cart in a secure operating room before and in between cases. Anesthesia professionals maintain this practice as a means to increase efficiency and have quick access to necessary medications should patient conditions require them. There have been considerable inconsistencies in field surveys with regard to this practice. Some members have indicated that surveyors are informing them that controlled medications are not deemed secure under The Joint Commission standards even when they are securely locked in the medication drawer of the anesthesia cart in a secure operating room. Some members are being told that leaving uncontrolled medications on top of the anesthesia cart between cases in a secure operating room is not permissible. We urge The Joint Commission to issue additional guidance clearly stating that this practice is permissible under MM 03.01.01 EP 3.

### **Informed Consent**

We understand and welcome efforts of The Joint Commission to rectify informed consent issues related to medication administration. MM. 06.01.01 EP 9 requires providers to inform the patient or family about any potential clinically significant adverse drug reactions or other concerns regarding administration of a new medication. This standard appears to be directed at medications ordered to treat conditions (e.g., new onset hypertension) and is not practical as applied to anesthesia professionals. It is nearly impossible to predict all of the anesthesia medications a patient might need to receive during a procedure. Fully explaining the potential adverse effects of dozens of medications to patients and their family members increases anxiety levels for all and adds little value to the patient experience. In addition, once anesthesia begins, it is impossible to obtain informed consent for a medication not discussed with the patient but determined during the course of the procedure to be needed. We see this issue as similar to surgical consents whereby the patient consents to "all other indicated procedures." We would appreciate an exemption from this requirement for anesthesia professionals as previously expressed during our January 14, 2009, meeting.

We appreciate The Joint Commission's consideration of our comments and issues raised in this letter. We propose the formation of an expert panel to review the difficulty that anesthesia professionals have in complying with many of the medication management standards when applied to operative settings. Perhaps many of the issues we raise can be addressed satisfactorily through Joint Commission's FAQs for standards interpretation. We would also be happy to assist the Joint Commission in preparing its surveyor guidance documents to better ensure consistency in surveyor interpretation and application of Joint Commission standards relating to anesthesia practices. The ASA, AANA, AAAA and APSF look forward to working with The Joint Commission on these and other issues in the hopes of optimizing patient safety.

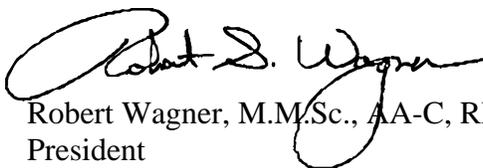
Sincerely,



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cc: Robert A. Wise, M.D.