Legal Aspects of Conscious Sedation & Patient Release

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The black cloud of medical malpractice is always a concern. *EndoNurse* takes a look at the many legal twists and turns surrounding conscious sedation and patient release, and offers tips on how to keep you and your center out of the courts.

FIRST OF ALL, "Conscious sedation is fast becoming an outdated term," according to Deborah A. Krohn, RN, JD, partner of Siegel & Krohn, P.C., located in Towson, Md., and staff nurse in the endoscopy unit of Johns Hopkins Hospital in Baltimore, Md.

Now termed "continuum of depth of sedation," conscious sedation, or moderate sedation/analgesia, is the use of appropriate medication to produce a controlled state of depressed consciousness.[1] The primary goal of conscious sedation is to achieve a minimally sedated patient with intact protective airway reflexes.

Everyone Has Something to Say . . . And It All Varies

Mixed signals abound all across the country on just who may or may not administer sedation. For example, the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) supports the position that registered nurses trained and experienced in gastroenterology nursing and endoscopy can administer and maintain moderate sedation and analgesia (conscious sedation) by the order of a physician, and the gastroenterology registered nurse can be given responsibility for the administration of reversal agents prescribed by the physician.

However, the regulations for ambulatory surgery centers (ASCs) set forth by the Centers for Medicare and Medicaid Services (CMS) specify that even certified registered nurse anesthetists (CRNAs) must be supervised by the operating physician when administering anesthesia.[2]

In all cases, care must be provided in adherence to locally defined or state-mandated nursing scope of practice.[3]

Each endoscopy unit must have policies regarding the use of sedation, according to the joint statement, "Role of GI Registered Nurses in the Management of Patients Undergoing Sedated Procedures," issued by the American Society for Gastrointestinal Endoscopy (ASGE) and SGNA. The policies should specify the responsibilities of each member of the sedation team, the guidelines read, and the endoscopy unit must also provide continuing education with ongoing competencies for administering and monitoring all levels of sedation.

According to the Association of periOperative Registered Nurses (AORN), all centers should develop written protocols and policies. Written policies must include the provisions, if any, as prescribed by each state's board of nursing.[4] The provisions of other state boards of nursing could be considered for possible inclusion, and professional association position statements, such as those issued by the ANA and the American Association for Nurse Anesthetists (AANA), also should be consulted.

Another important factor to keep in mind is that it is the responsibility of the physician to determine the suitability of the patient for sedation. An appropriate pre-anesthesia evaluation and examination should be conducted by an anesthesiologist prior to anesthesia and surgery, according to the American Society of Anesthesiologists' (ASA) "Guidelines for Ambulatory Anesthesia and Surgery." In the event that non-

physician personnel are used in this process, the anesthesiologist must verify the information and repeat and record essential key elements of the evaluation.

The key point in policymaking and adherence is to thoroughly examine your state's board of nursing policies and ensure absolute adherence to its rules. Every state varies.

What's Going On in Jersey?

Last year, the New Jersey Association of Nurse Anesthetists (NJANA) was smacked with proposed new in-office anesthesia regulation that included anesthesiologist supervision requirements. The attempted regulation comes from the New Jersey State Board of Medical Examiners (BME). The BME regulation sets forth new standards for the administration of anesthesia in physicians' offices during surgeries and procedures.

The regulation mandates that a physician who provides conscious sedation in his office must be privileged by a hospital in conscious sedation or obtain alternative privileges from the BME in order to supervise a CRNA. If the physician does not obtain those privileges, he must hire an anesthesiologist to provide the anesthesia.

By Feb. 1, 2005, any physician who wishes to continue providing conscious sedation with a CRNA must have submitted an application to the BME for alternate privileges or replace the CRNA with an anesthesiologist, the rules read.

According to an article written by Alma L. Saravia, in the winter 2004 issue of *Health Law Report,* a newsletter produced by Flaster Greenberg, New Jersey is the only state in the nation to mandate that CRNAs must work under the supervision of an anesthesiologist or a physician with anesthesia privileges in an office setting. The New Jersey Nurse Practice Act does not require nurses to be supervised by a physician.

NJANA appealed the decision to the New Jersey Supreme Court, and on May 3, 2005 the Supreme Court conducted oral argument. NJANA informed the court that anesthesia is safe whether it is administered by a CRNA or an anesthesiologist. "In fact, CRNAs and anesthesiologists are comparable in numbers and each profession administers all types of anesthesia," NJANA officials told the court. "CRNAs provide 65 percent of all anesthetics administered, they are the sole anesthesia providers in some hospitals, and they work closely with all physicians."

NAPS

The Nurse Administered Propofol Sedation (NAPS) debate is gaining more recognition with each passing day. According to Krohn, in 2003, approximately 13 state nursing boards "expressly disallowed" NAPS. She found the topic intriguing and conducted her own survey of the state boards this year, and found the number topping off at a current 23.

"That's a pretty dramatic trend in only a two-year period," Krohn points out. During her surveying, she found Oregon and Oklahoma also are currently looking at the issue of NAPS and may soon become "no" states, she says. "It's on the agenda of many nursing boards in the country," she warns. "The NAPS debate is evolving and continuing. It is getting a lot of attention and it's a matter of staying tuned to changes," she says.

According to the April 14, 2004, joint statement from the AANA and ASA, "Propofol should be administered only by persons trained in the administration of general anesthesia who are not simultaneously involved in the surgical or diagnostic procedure."

"This distinction is critical," advises Krohn. "There is no concern with propofol being administered by a CRNA. A CRNA has the necessary advanced training in the provision of anesthesia — and airway management — to safely administer the drug. The concern centers on registered nurses (RNs) without any advanced training in anesthesia giving the drug for procedural sedation."

Krohn points out centers may prefer RNs to CRNAs administering sedation due to the simple aspect of the salary requirements of the two. The savings involved with using an RN to administer sedation can become quite impressive over the course of a year. However, Krohn advises nurses, doctors, and centers to think

carefully of the pros and cons of such penny pinching.

"Physicians who are using nurses to give an anesthetic medication, I think they are at very high risk if there is any kind of problem with the procedure. That is my warning to nurses. If there is a misadventure with the propofol, and there is a lawsuit that results, the nurse [the RN] will be sued and be questioned in part on 'Why did you,' and 'Who are you, to disregard the package insert that warns expressly 'Warning; This is a drug that should be given by people trained in anesthesia ...'

"The practice of NAPS will come into play and be scrutinized," Krohn adds. "Nurses participating in NAPS may face licensure issues, specifically, if NAPS is deemed by their state board of nursing to be 'outside the scope of practice for a RN.' Physicians and nurses may be civilly liable, not only on malpractice/ negligence grounds, but physicians may be entertaining additional liability in the form of failure to obtain informed consent.

"In evaluating a malpractice NAPS case, the average person on a jury will have little difficulty understanding the inherent risks of NAPS (which may or may not be fully explained to patients pre-procedure), and will grasp the basics of the science, politics, and economics of the debate. And anesthesiologists will be lined up at the courthouse to provide any necessary testimony against the practice of NAPS," she warns.

The Case of Nurse Brown

In January 1999, Ernest Young received sedation for a colonoscopy performed at Gastro-Intestinal Center, Inc., located in Little Rock, Ark. Upon arrival, Young told the receptionist that following his procedure his friend Trundle Smith would drive him home to El Dorado, Ark.

Following the procedure, Trundle Smith had yet to arrive. Young's nurse, Diane Brown, RN, learned Young had every intention of driving himself home. Brown called Young's wife, Maggie, and was advised by Mrs. Young that no one was available to pick up Mr. Young.

Brown then attempted to persuade Young to wait at the center for the next several hours for the sedation to clear his system, or until someone was available to drive him home, but he refused. When it became apparent Young was going to leave on his own, Brown requested he sign a form indicating he understood he should not drive and that he was leaving against medical advice. Young signed the form and left the center. He then went to another medical appointment, underwent another medical procedure, and then began his drive home.

Young's attempted journey home resulted in a one-car accident, later proving fatal for Young. A suit was filed by Young's wife against Gastro-Intestinal Center, Inc., and Brown. According to court documents, Mrs. Young argued that the center and Brown breached three distinct duties to Mr. Young:

- not to sedate a patient without a driver;
- not to discharge a patient from the recovery room; and
- not to discharge a sedated patient to drive himself home.

"This case was about duty," says Krohn. "Anyone suing a healthcare provider for malpractice has to prove four things. The first thing they have to prove is duty, that a duty was owed.

"The nurse's duty in this case was to warn the patient not to drive. It is undisputed she did it over and over and over again. She wasn't required to take the man's keys away, she wasn't required to hide his clothes for eight hours, and she wasn't required to call a cab."

Those actions would have been false imprisonment, Krohn says. She also pointed out that a call to local police to warn of an impaired driver also isn't a safe option due to law infringement of HIPAA (the Health Insurance Portability and Accountability Act of 1996).

"Nobody has the duty to force a patient to follow medical advice," says Krohn. "Her duty was to warn him not to drive. The duty to warn, not the duty to control. She fulfilled her duty and so the Arkansas court did not

enlarge upon that duty or expand it in any other way."

But is it enough for nurses to rely on what the patient says, or should it become regular practice to phone the patient's driver and receive verification of a safe ride?

Cathy Dykes, MS, RN, CCRC, CGRN, testified in the case through affidavit. She and Fred Sutton, MD, testified on behalf of the plaintiff that "all healthcare providers who sedate patients must confirm the existence of someone to take the patient home, and that this means more than writing down a name on a piece of paper; it means actually speaking with the driver to make sure they exist and know when to come pick the patient up."

"What I've always done in the past," says Dykes, is "if a driver is not there and we can't be reasonably sure one is coming, we do not sedate the patient. We offer to either do it without sedation or to reschedule," she says.

"I would try to do anything I could," advises Dykes. "I think that we need to just take our time to do the right thing."

Eventually, the ruling in the case of Brown and her center came in on their side — five years after it all began. "The court reasoned: 'Nobody has the duty to force a patient to follow medical advice,'" says Krohn. "Nurses have the duty to warn, that's it. But [now] having a conscious sedation law on the books, other states may look at it for guidance and reference. They may like the way the judges reasoned it and they may not, so we'll have to stay tuned."

OTHER HELPFUL INFORMATION ON SEDATION

The National Council of State Boards of Nursing (NCSBN) offers a comprehensive list of state-by-state regulations governing registered nurses in regard to administering sedation and analgesia.

Visit: www.ncsbn.org/news/stateupdates_state_sedation.asp

The "Pediatric Anesthesia Practice Recommendations" are available on the American Society of Anesthesiologists (ASA) Web site.

Visit: www.asahq.org/clinical/PediatricAnesthesia.pdf

Works Cited

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According to the American Association of Nurse Anesthetists (AANA) (www.aana.org), the basic qualifications for CRNAs applying for clinical privileges include:

- State licensure as a registered professional nurse.
- Compliance with state regulatory requirements in those states regulating advanced practice for nurse anesthesia.
- Graduation from a program of nurse anesthesia education accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs or its predecessor.
- Certification by the Council on Certification or recertification by the Council on Recertification or their respective predecessors or, if pending initial certification, evidence of graduation from an approved nurse anesthesia educational program.

Nurse anesthesia educational programs generally consist of 24 to 36 months of classroom and clinical experience, and offer a master's degree upon completion.

Tips to Keep in the Think Tank

TIMING CAN BE EVERYTHING:

The time for a patient with no driver to remain following a procedure goes by center policy, according to Krohn. She said it could generally run around eight hours, "But that's an anesthesiologist call," she says, depending upon the dose of medication, when the patient last received it, when it could be effectively considered cleared from the patient's system, etc.

THE AMA FORM — IS IT REALLY RELIABLE?

One thing to keep in mind, according to Krohn is, "The Against Medical Advice form is of little use because the patient is already compromised. They could argue later 'I didn't know what I was signing.' The AMA form, while it is something, it does not carry the day," she says. So when can a patient seek legal recourse? When there is "any finding of negligence — that's the short answer," advises Krohn. She says negligence is failing to conform to the standard of care. "What's the standard of care? It differs from state to state," she says. "Broadly speaking, the standard of care is what the reasonably prudent practitioner, nurse or doctor, in the same or similar circumstances" would exercise. "Any lawsuit in medical malpractice has to be based on either negligence, or lack of informed consent."

SEDATION-RELATED ERRORS

First of all, "It's important to know the correct dosages [of the sedative agent] and the correct time frames to give them in and not let the doctor hurry you too fast," says Cathy Dykes, MS, RN, CCRC, CGRN. Krohn offers other food for thought, adding that errors could include "a nurse overdosing the patient, a nurse failing to monitor the patient a nurse failing to communicate changes in the patient's condition — related to sedation — to the doctor," she says. "There are lots of things that could go wrong with administering medications: the wrong patient, wrong route, wrong dose, the wrong time, the nurse could give the sedation too quickly — there are lots of variations on giving the med wrong. Monitoring is big, and communicating the patient condition is big. Failing to protect the patient from injury such as failing to put the side rail up and the patient, in a sedated state, rolls off and breaks a hip. There's lots of ways you could link that to the sedation."

DYKES OFFERS OTHER TIPS:

- Assessment is imperative: "I think it's real important to get a good nursing history," she says. "Make sure the patient is not on blood thinners and has not had previous problems with anesthesia — no family history. Most nurse assessment forms have that on there."

- Teaching and time: "I think pre-op teaching is a big thing. For people to get discharge instructions, go over them with the patient and get the patient — and their significant other — to sign them *before* the procedure. Because if you sign them after the procedure, No. 1, they don't remember because of amnesia from the sedation, and No. 2, it's not legal. So I always try to impress on getting that signed and going over it with the patient and their significant other and have both of them date and sign it *before* the procedure. That's very important."
- Identify your state's board of nursing regulations — and adhere to them: For example, "In Texas, it is the physician's responsibility to give informed consent and get the required signature," according to Dykes. This is just one example of the types of steps that can be easily controlled and can make or break some legal cases. Always ensure your center complies with state laws.