Anesthesiologists Targeted in CMS' Review of Existing Rules

Neda Mirafzali, Esq.
The Health Law Partners, PC, Southfield, MI

On August 22, 2011, as a result of a directive from President Obama, the US Department of Health and Human Services ("HHS") issued its *Plan for Retrospective Review of Existing Rules* ("Plan"). The Plan includes a review from all HHS operating and staff divisions (*e.g.*, the Centers for Medicare and Medicaid Services ("CMS")) that establish, administer and/or enforce regulation. HHS' Plan aims to review "existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined." While, on its face, a review of unnecessary regulations appears to be beneficial, looking below the surface reveals that the review may create fundamental changes in medical and anesthesia practice. CMS is contemplating reviewing the conditions of participation ("CoPs") for anesthesia services (42 CFR 482.52) to eliminate the certified registered nurse anesthetist ("CRNA") supervision requirement, which could significantly impact anesthesiologists, CRNAs, their practices and their patients.

Current Hospital CoPs for Anesthesia Services

As a preliminary matter, it should be noted that for the purposes of the hospital CoPs for anesthesia services, CMS considers the areas where anesthesia services are furnished and may include operating room suite(s), both inpatient and outpatient; obstetrical suite(s); radiology departments; clinics; emergency departments; psychiatry departments; outpatient surgery areas and special procedure areas (*e.g.*, endoscopy suites, pain management clinics, etc.). Moreover, administering anesthesia must only be by:

i. A qualified anesthesiologist;

ii. A non-anesthesiologist MD or DO;

iii. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

iv. A CRNA who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

v. An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed.

These requirements concerning who may administer anesthesia do not apply to the administration of topical or local anesthetics, minimal sedation, or moderate sedation.

The CRNA supervision requirement (number (iv), above) applies in States that have not opted out of the requirement. States may opt out of the CRNA supervision requirement by sending a letter, signed by the State's governor, to CMS concluding that it is in the best interest of the State's citizens to opt out

of the physician supervision requirement (42 CFR 482.52(c)).[1] According to CMS, as of October 2010, sixteen (16) states have chosen to opt out: California, Iowa, Nebraska, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, South Dakota, Wisconsin, Montana and Colorado. Notably, this rule does not require hospitals to allow CRNAs to practice unsupervised; this rule merely exempts those States that have opted out from requiring supervision of CRNAs as a condition to Medicare reimbursement.

For those remaining thirty-four (34) states that have not opted out, the requirement that the operating practitioner or anesthesiologist be "immediately available" is satisfied if the operating practitioner or anesthesiologist is "physically located within the same area as the CRNA, *e.g.*, in the same operative/procedural suite, or in the same labor and delivery unit, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed." This supervision requirement is intended to ensure the safety of the patients while also allowing the anesthesiologists to simultaneously tend to multiple patients, thus providing for more efficient delivery of care.

HHS' *Plan for Retrospective Review of Existing Rules* Targets Anesthesia

However, these rules may change with HHS' and CMS' upcoming review. As part of its Plan, HHS agencies identified regulations that that will be reviewed over the next two years. One of CMS' areas of review includes the hospital CoPs. Specifically, CMS will be reviewing the CoPs for anesthesia services (42 CFR 482.52) in response to the following comment:

> *Many regulations requiring a "physician" to perform procedures or at least supervise them are called unnecessary by commenters because oftentimes the work can be done just as easily by Certified Registered Nurse Anesthetists (CRNAs) and other Advanced Practice Registered Nurses (APRNs).*
>
> *Similarly, this commenter wrote that current regulations, 42 CFR part 482.52(a)(4) require unnecessary supervision by an "operating practitioner or an anesthesiologist" upping costs by increasing staff members but not safety. This commenter summed up these particular concerns by, "suggest[ing] that all regulations and interpretive guidelines issued by CMS be reviewed with the intent of removing restrictions concerning anesthesia services provided by nurse anesthetists."*

CMS argues that the purpose of reviewing the hospital CoPs would be to "remove or revise multiple requirements that are inconsistent with other requirements or impose unnecessary burdens to increase flexibility." CMS indicates that the review of the hospital CoPs would result in an estimated $600 million in savings, annually.

According to the American Society of Anesthesiologists ("ASA"), while CRNAs are certainly valuable, they are only qualified to perform *some* anesthesia services and are not qualified to perform *all* anesthesia services. In other words, a CRNA does not equal an anesthesiologist. The ASA contends that CRNAs should *supplement* an anesthesiologist's practice by performing services under that anesthesiologist's supervision, pursuant to the current regulations. The AANA categorically disagrees.

The ASA also takes the position that when anesthesiologists are involved in procedures, the anesthesiologist plays the role of the perioperative physician in which s/he is solely responsible for providing comprehensive care to the patient during the entirety of the procedure. Moreover, the ASA states that it is because of the anesthesiologist's over twelve (12) years of formal training that s/he is knowledgeable enough to evaluate all aspects of a patient's condition, taking

Continued on page 14

[1] The CoPs for ambulatory surgery centers ("ASCs") (42 CFR 416.42) and critical access hospital ("CAHs") (42 CFR 485.639) provide that CRNAs can administer anesthesia services when under the supervision of an operating physician. These CoPs likewise allow States to opt out of this requirement.

Anesthesiologists Targeted in CMS' Review of Existing Rules

Continued from page 13

into account all of the potential risks. A 2000 study published in *Anesthesiology* found that death and failure-to-rescue deaths were greater when care was not directed by anesthesiologists.

Last year, however, an article appeared in *Health Affairs* that marshaled data to show that there were no differences in outcomes between anesthesiologists and CRNAs.

As stated above, lifting the requirement that CRNAs be supervised when performing anesthesia services would affect Medicare Part B payment policies, but lifting the requirement does not necessarily imply that CRNAs will immediately begin providing services independently. CRNAs can only perform services independently if the hospital in which they perform those services embraces a supervision-free environment. The ASA urges anesthesiologists to continue working with their local and national anesthesia associations and lobbying organizations to encourage CMS to reject the commenter's suggestion. The American Association of Nurse Anesthetists has worked long and hard to eliminate the supervision requirement, and it will also urge its members to use the HHS-CMS review of the CoPs to further its professional goals. No one can predict the outcome, but everyone who wishes will have a chance to be heard, directly or indirectly.

Ms. Mirafzali is an associate attorney with the Health Law Partners, PC and practices in all areas of health care law, assisting clients with transactional and corporate matters; representing providers and suppliers in health care litigation matters; providing counsel regarding compliance and reimbursement matters; and representing providers and suppliers in third party payor audit appeals. She can be reached at (248) 996-8510 or at nmirafzali@thehlp.com.

The Institute for Safety in Office-Based Surgery (ISOBS)

Continued from page 8

and physicians to ensure safe care. Perhaps most important, the checklist is fully customizable to a variety of office-based settings, from elective plastic surgery to ophthalmology. ISOBS recently completed a retrospective chart review using the checklist, and is now proceeding to the prospective phase of checklist deployment. In addition, ISOBS is developing web-based educational modules for practitioners on using the checklist.

The need for leadership in office-based procedure performance is clear. Without tools to aid patient safety, neither practitioners nor patients will have the security they deserve. Using a comprehensive safety checklist as well as associated educational modules, ISOBS aims to fill this void and supply practitioners with innovative yet common sense tools to protect their patients.

For further information, see Shapiro FE, Durman RD. Office-Based Anesthesia and Surgery: Creating a Culture of Safety. ASA Newsl. 2011; 75(8);10-12. ISOBS also publishes a complimentary electronic newsletter to which you may subscribe through the organization's website, www.ISOBS.org.

ISOBS will host a reception at the ASA Annual Meeting in Chicago on Friday, Oct. 14, 2011 honoring Atul Gawande, MD and Mark Warner, MD, for their contributions to the field of patient safety.

Fred E. Shapiro, DO, is Assistant Professor of Anesthesia, Harvard Medical School, Beth Israel Deaconess Medical Center Department of Anesthesia Critical Care and Pain Medicine, Boston, MA. He is Co-Founder of The Institute for Safety in Office-Based Surgery (ISOBS), Immediate Past President of the Massachusetts Society of Anesthesiologists and member of ASA Committees on Patient Safety and Education, Quality Management and Departmental Administration (QMDA), Governmental Affairs, and Ambulatory Surgical Services. He can be reached at fshapiro@bidmc.harvard.edu.