American Society of Anesthesiologists®

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April 8, 2013

Marilyn B. Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Re: CMS-3267-P Medicare and Medicaid Programs; Part II—Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction.

Dear Ms. Tavenner:

On behalf of the over 50,000 members of the American Society of Anesthesiologists (ASA), I would like to thank CMS for the opportunity to comment on the Medicare and Medicaid Programs; Part II—Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction Proposed Rule that was published in the *Federal Register* on February 7, 2013. **We greatly appreciate that CMS maintained the physician supervision safety standard** for anesthesia care, which is a very important contributor to patient safety and quality of care. We also appreciate that CMS requires each hospital to have an organized, individual medical staff that is distinct to each hospital. However, we are concerned that CMS proposes to rescind the current requirement that a hospital's governing body include a medical staff member and we are also troubled by the proposal to revise the bi-weekly physician presence requirement for critical access hospitals.

Physician Supervision Safety Standard for Anesthesia Services

ASA commends CMS for maintaining the current federal physician supervision safety standard for anesthesia services even as some have suggested removing Medicare's anesthesia supervision safety standard. Substituting nurses for doctors would significantly decrease patient safety and quality of care. Further, such a substitution provides the Medicare program and taxpayers with no additional cost savings since Medicare pays the same for anesthesia services whether they are furnished by nurse anesthetists or highly-trained anesthesiologists. We urge CMS not to lose sight of the fact that giving and receiving anesthesia is dangerous, life-threatening and should only be safely undertaken under the direct administration and/or supervision of a physician who has the extensive and necessary educational training and experience.

Anesthesiologists have improved anesthesia safety and delivery for the benefit of their patients, but significant risks still remain. An anesthesiologist applies advanced medical knowledge to diagnose patient conditions and to prevent factors that contribute to patient complications. While nurse anesthetists are competent to perform some of the technical aspects of the administration of anesthesia, they do not have the education, skills or training to fully manage patients or respond to medical complications that occur in the perioperative period. Close physician supervision is needed in real time to prevent adverse events.

Indeed, ASA's comprehensive patient safety efforts over the past three decades were denominated a "gold standard" for medical specialties in the Institute of Medicine's report on patient safety, *To Err is Human – Building a Safer Health System*. There has been a decrease in anesthesia-related deaths over the past three decades.[1] From the 1950s through the 1970s, there were approximately two deaths per 10,000 anesthetics. Today, there is approximately one death per 200,000 to 300,000 anesthetics.

Anesthesiologists have designed safer anesthetic medicines, devices and techniques, resulting in the decline in preventable mishaps. All of this progress has occurred with anesthesiologists either administering anesthesia services or supervising their administration. We recognize that more work needs to be done in improving surgical and anesthesia safety, and we believe anesthesiologists must be allowed to continue innovating so more progress in safety may be realized. We believe the current physician supervision standard in the hospital Conditions of Participation (CoPs) provides significant flexibility to hospitals to ensure compliance, maintain appropriate patient access to care and maximize patient safety. The standard provides that a physician oversee nurse anesthetists during the administration of anesthesia.

In the absence of an anesthesiologist, the operating physician is present to supervise the nurse anesthetist. Recent changes to CMS' Interpretive Guidelines have significantly added flexibility to all hospitals, but particularly rural hospitals. Hospitals now have autonomy to "establish policies and procedures, based on nationally recognized guidelines that address whether specific clinical situations involve anesthesia versus analgesia."

ASA further believes that removing or weakening the physician supervision safety standard would seriously decrease quality. Nurse anesthetists have used the opt-out to expand their scope of practice to include the performance of interventional pain management procedures. For instance, in Iowa, a current opt-out state, a lawsuit is pending that alleges independent practice nurses have harmed patients, provided excessive and unnecessary treatment and fraudulently billed. Details of that case also involve inappropriate expansion by nurses into interventional pain management.

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[1] Source: Committee on Quality of Healthcare in America, IOM: To err is human, building a safer health system. Edited by Kohn L., Corrigan J, Donaldson M, Washington Academy National Press, 1999, p 32.

For these reasons, ASA commends CMS for maintaining the current federal physician supervision safety standard for anesthesia services and strongly urges that CMS maintain this important patient safety standard.

Distinct and Individual Medical Staff

We support CMS' proposal that each hospital should have its own separate and individual medical staff. The medical staff is familiar with and understands the unique needs of the hospital, physicians and other health care professionals. The medical staff can nimbly respond to health and safety issues that arise with respect to their patients and that hospital. Medical staff self-governance is a basic requirement for The Joint Commission accreditation[2] and is a requirement in some states[3]. **We urge CMS to maintain and finalize the distinct and individual medical staff proposal.**

Medical Staff on Governing Body

ASA is concerned with the CMS proposal to rescind the requirement that a medical staff member be on a hospital's governing body. Inclusion of a medical staff member on a hospital governing body is absolutely essential to ensure patient health and safety. While non-clinicians who sit on the governing body often bring relevant experience to provide overall management, as non-clinicians they are not equipped to evaluate and guide patient care at a facility. In order to properly address patient safety and health concerns at the hospital level, it is essential to have a medical staff member who understands clinical concerns within the hospital's governing body. **We strongly oppose this proposal and urge CMS to retain the current requirement that a member of the medical staff be on a hospitals governing body.**

Physician Presence at Critical Access Hospitals (CAHs)

We believe that having physicians physically present at critical access hospitals is optimal. While telehealth can serve as a way to connect patients with physicians, especially in rural areas it is not appropriate in all circumstances, especially the surgical setting. CMS acknowledges that the majority of CAH's can and do meet the current bi-weekly standard and that, "for CAHs that offer a wide range of complex services, have more than one physician on staff, and have busy emergency departments and/or extensive outpatient services, a visit by a physician only once

[2] Joint Commission Standard LD 01.01.01. Element of Performance 2 states, "(t)he organized medical staff is self-governing."

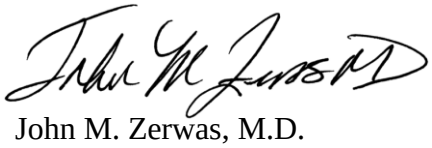
[3] For example, under Oregon Revised Statutes §441.055, "[t]he physicians organized into a medical staff pursuant to[Oregon law] shall propose medical staff bylaws to govern the medical staff." Under Mississippi Hospitals, Minimum Standards of Operation Regulations, Title 15, Part III, Chapter 41 § 1 Q6.16, "the medical staff shall develop and adopt bylaws and rules and regulations to establish a framework for self-government and a means of accountability to the governing body, such bylaws and rules and regulations to be approved by the governing body." Georgia Regulation 290-9-7-11 (c) states, "The medical staff of the hospital shall adopt and enforce bylaws and rules and regulations which provide for the self-governance of medical staff activities and accountability to the governing body for the quality of care provided to all patients." California law also has codified medical staff self-governance within Business and Professions Code §2282.5 (S.B. 1325).

every 2 weeks could well be grossly inadequate." We believe that more review and analysis is necessary before revising or eliminating this requirement.

A recent article in *The Journal of the American Medical Association* is particularly of note. Joynt et al found that "among Medicare beneficiaries with acute myocardial infarction, congestive health failure, or pneumonia, 30-day mortality rates for those admitted to CAHs, compared to those admitted to other acute care hospitals, increased from 2002 to 2010."[4] The authors go on to point out that while the patient population being seen at CAH is getting sicker, the percentage of patients being transferred out to other facilities is actually decreasing. This is certainly an unexpected finding and, as they discuss, may be related to inappropriate triage of patients who require transfer. These findings reinforce our belief that having physicians present at these hospitals is imperative. CMS should carefully consider the impact on patient safety before revising standards for critical access hospitals. We believe that, as it relates to the work performed by anesthesiologists, physician presence is needed at critical access hospitals. In fact, ASA has been advocating that rural health pass thru payments be extended to anesthesiologists to facilitate anesthesiologist practice in these settings.

Again, thank you for the opportunity to comment on this proposed rule and for maintaining the high levels of patient safety and quality through the physician supervision safety standard. If you have any questions with respect to our comments please feel free to contact Grant Couch (g.couch@asawash.org), Federal Affairs Associate, Sharon Merrick (s.merrick@asawash.org), M.S. CCS-P, Director of Payment and Practice Management or Maureen Amos (m.amos@asawash.org) Director of Quality and Regulatory Affairs at (202) 289-2222.

Sincerely,



John M. Zerwas, M.D.
President
American Society of Anesthesiologists

[4]Joynt KE, Orav E, Jha AK. Mortality Rates for Medicare Beneficiaries Admitted to Critical Access and Non–Critical Access Hospitals, 2002-2010. JAMA. 2013; 309(13):1379-1387. doi:10.1001/jama.2013.2366.