



February 8, 2010

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Frizzera,

We are writing on behalf of the Society for Pediatric Sedation in relation to the recently released “Revised Hospital Anesthesia Services Interpretive Guidelines.” The SPS shares CMS’s interest related to improving sedation safety and appreciate your interest in standardizing this care. As a society, we would also like to offer our expertise in aiding your efforts related to improving sedation, and request further clarifications be made to the surveyors on acceptable standards.

As background, in 2006, the Society for Pediatric Sedation (SPS) was founded by a multi-specialty group of sedation providers who believed that through collaboration, research and education, sedation practices and outcomes could be improved. The basis of this collaboration arose from participation in the Pediatric Sedation Research Consortium (PSRC). Formed in 2000, the PSRC is the largest data-sharing pediatric sedation quality improvement and research initiative. Its collaborators include physicians, nurses and other sedation providers from specialties including Anesthesiology, Pediatric Emergency Medicine, Pediatric Critical Care and Pediatric Hospitalist Medicines. Information gathered through the PSRC helps the SPS form data-driven recommendations for training, credentialing, and standardization of sedation practice.¹⁻⁴ The SPS’s unique independent, collaborative and multidisciplinary makeup enables us to advocate for sedation care based on evidence-based best practices.

Our collective experience and research make us concerned about possible interpretations of this document as written, which may in our opinion, detract from patient care. We have noted several areas that appear to be internally inconsistent with current standards including; the variable inclusion of provider types, the variable allocation of moderate and deep sedation, the specification for oversight by a single physician or Anesthesia Department, and issues with the privileging of providers. These points are expanded upon below.

We applaud the continued inclusion of non-anesthesiologist’s ability to provide “anesthesia care.” As a clarification, in the algorithm on page 7 titled “Hospital Anesthesia Services”, however, non-anesthesiologist physicians have been omitted from the left-sided “oval” which states “To be given by anesthesiologist, CRNA or anesthesia assistant within scope of practice”. This inclusion would be consistent with the remainder of the document and section CFR 482.52 a(2). Data from the PSRC support continued inclusion of this provision, and demonstrate that skilled and trained non-anesthesiologists can safely deliver this care when done as part of a structured sedation service.^{4,5}

We are additionally concerned about the ambiguity potentially created by excluding “moderate sedation” from these Guidelines. The 2006 Joint Commission Accreditation Manual recognizes and gives particular guidelines for “Operative or other High-Risk Procedures and/or the Administration of Moderate or Deep

Sedation or Anesthesia.”⁶ Current JCAHO requirements include monitoring and evaluation for both moderate and deep sedation. In fact, pre-evaluation of patients, prior to the delivery of sedation medications, is a very important part of all sedation practice, both to determine the depth of sedation required for procedure completion as well as identify risks and determine appropriate monitoring. Since sedation occurs along a continuum and patients can easily slip from one level to a deeper one, rescue from an unintended sedation depth may be required.⁷ The inclusion of moderate and deep sedation in the Interpretive guidelines would clarify this ambiguity by maintaining consistency between guidelines, and avoid potential loopholes opened by the current language. We are concerned that providers may say they intend “moderate” sedation in order to avoid some of the perceived restrictions these regulations denote during deep sedation. This is especially relevant in children, for whom most procedures require deep sedation. The inclusion of both moderate and deep sedation in the Interpretive Guidelines would also continue to facilitate the efforts of many organizations to emphasize that sedation safety depends on providers having the proper training, monitoring, equipment, and skills to rescue a patient for all levels of sedation.⁷

Based on the experience and collaborative nature of the SPS, we have concern with the implications of placing oversight for all sedation and analgesia under one single physician or one anesthesia department within a hospital. The reality is that a wide variety of providers have the skills and currently provide and oversee sedation practice. In fact, in a growing number of hospitals, dedicated sedation services, of various types of expert anesthesia and non-anesthesia providers, oversee and deliver nearly all of the sedation.^{2, 8-10} We feel that clarification related to “responsibility” and acceptable structures for this oversight responsibility could be appropriately broadened to include sedation committees, which bring together the sedation expertise of multiple provider types. Such committees currently function well in many institutions across the United States. Rather than a single person or specialty potentially controlling all pediatric sedation practice, multidisciplinary committees foster a collaborative approach to the oversight of medications, quality improvement, and privileging for sedation providers throughout the hospital. By allowing collaboration, these committees lessen the burden on any one person or department in overseeing this complex and expanding area of practice. We understand the need to specify responsibility for sedation oversight, and standardization across the hospital. The SPS feels this committee system is an optimal method to ensure access to and provision of safe sedation. We strongly encourage you to include this option as an example of an acceptable standard for sedation oversight.

Finally, we agree that “The medical staff bylaws *or rules and regulations* must include criteria for determining the *anesthesia service* privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges”. The role of the advanced practice nurse and registered nurses needs clarification and inclusion. Since these providers are not mentioned, the guidelines could be interpreted as disallowing participation of these providers in sedation practice. Again, we would emphasize, that within a structured sedation service as previously mentioned and cited, that non-physician providers play a key role in improving sedation safety. For example, assessment of patient status is certainly well within the scope of practice of a registered nurse as defined by multiple State Nursing Boards. By specifically limiting pre- and post-anesthesia screening and discharge services to only personnel credentialed to provide anesthesia services, nurses and advanced practice nurses appear to be excluded. We would like to make you aware that some hospitals utilize advanced practice nurses within their structured sedation services. These sedation services, have been appropriately sanctioned and credentialed by hospital medical staffs and State Nursing Boards when performed within the scope of sedation or anesthesia services, with appropriate physician oversight. SPS does not advocate for nurses and advanced practice nurses providing sedation independently. However, we are concerned, that without clarification, the Interpretive Guidelines may exclude nurses and advanced practice nurses within structured sedation services. In our opinion, this change would not be in the best interest of sedation safety and practice.

Our pediatric research demonstrates that the establishment of specialized services dedicated solely to procedural sedation, has greatly enhanced children's access to consistent, safe, and cost effective sedation. These services are currently staffed and supervised by multiple models comprising different specialties. These services have demonstrated safety in more than 130,000 cases in the PSRC database. If these guidelines were interpreted in such a way to eliminate or prohibit these practices this would limit access to an equivalent number of children and jeopardize the safe sedation care which we are all working to achieve.

As a collaborative group, with a multi-specialty board of providers, the Society for Pediatric Sedation would be delighted to assist the CMS with areas related to the sedation continuum. As a society, we could provide i) extensive data on our multispecialty experience, ii) examples of sedation systems that are models of success and, iii) a broad experience of expertise. Representatives from the SPS Board of Directors would be delighted to engage with you if you feel we could be of assistance. We appreciate you considering our viewpoint and look forward to your response to our requests.

Thank you,



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