



January 19, 2011

Susan S. DeSanti, Director
Office of Policy Planning
Richard A. Feinstein, Director
Bureau of Competition
Joseph Farrell, Director
Bureau of Economics
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Ms. DeSanti and Messrs. Mr. Feinstein and Farrell:

On behalf of the American Society of Anesthesiologists (ASA), an association representing more than 45,000 members, I want to express concerns about your November 3, 2010 letter to the Alabama State Board of Medical Examiners (“Alabama Medical Board”). That letter discussed the medical board’s proposed regulations that would define interventional chronic pain management as the practice of medicine and prohibit a qualified, licensed physician from delegating to a non-physician the authority to utilize certain pain management procedures to diagnose, manage, or treat chronic pain patients. Your letter urges the medical board to “avoid adopting provisions that would limit the role of CRNAs in pain management more strictly than patient protection requires” and states that “absent evidence that the proposed restrictions are necessary to protect the public, there appears to be no reason to sacrifice the benefits of CRNA pain management services....”¹

We agree with your conclusion that the regulation should be no more restrictive than necessary to protect patients. However, we believe that the tone and effect of the letter from a primary enforcer of the antitrust laws will induce states to adopt regulations that do the opposite. Thus, we appreciate the opportunity to clarify why the proposal’s restrictions are necessary to protect chronic pain management patients and to articulate why the treatment of interventional pain requires the specialized training of an anesthesiologist or other physician who is specifically trained in interventional pain medicine.

As explained below, these restrictions are necessary because of the serious risks involved in treating chronic pain and the significant differences in education, training, and experience between an anesthesiologist and nurse anesthetist with respect to chronic pain management. As additional state medical boards and legislatures address this issue, we believe it is essential to educate state and federal policymakers on the risks involved in performing interventional pain management procedures to treat chronic pain in order to protect patients from needless injuries from treatment by unqualified providers.

¹ Federal Trade Commission comment letter to the Alabama State Board of Medical Examiners regarding proposed Rule No. 540-X-15, Interventional Pain Management.

Chronic Pain: Treatments and Risks

The ability to properly diagnose a patient's pain problem and to develop an appropriate treatment plan is critical in selecting and then providing the appropriate pain management therapy to effectively treat chronic pain. To provide long-term relief from chronic pain, various types of therapies are needed because there is often more than one appropriate therapy. Moreover, the treatment of chronic pain differs from the approach used to treat acute pain. For example, epidural injections of steroids may be an effective treatment to relieve acute leg pain after a herniated disc, but it may not be the appropriate treatment to relieve chronic low back pain. As we discuss below, the education and training of nurse anesthetists do not provide them with the expertise to diagnose and develop appropriate treatment plans or to provide the services that the treatment plan requires.

Examples of treatments to relieve chronic pain include nerve stimulation, nerve blocks, drug injections, and neurodestruction. The goal of nerve stimulation is to stimulate the nerves to mask the pain. It can be achieved by implanting a device surgically or applying external electric impulses to nerves endings below the skin. If implanted surgically, a small battery-operated generator sends an electrical current to trick the brain to turn off pain signals. Another potential treatment plan involves the use of devices or procedures to deliver drugs, such as nerve blocks, to the site of pain. As a temporary treatment plan, the goal of the blocks is to numb rather than destroy the nerves. Injection of drugs into or around an individual's joints or around nerves is a third type of treatment plan to relieve chronic pain. Scar tissue can be injected by drugs as a way to block any nerve endings that are causing pain. As a way to provide patients with long-term control of their pain, drug reservoirs can be inserted under the skin and used to supply drugs to the spine via catheters. Lastly, neurodestruction is a permanent or semi-permanent treatment plan that injects drugs into the nerve to destroy the nerve or group of nerves that contribute to pain. To properly diagnose and develop an appropriate plan requires detailed knowledge of the likely pathologic etiology, human anatomy, and risks associated with each plan.

Interventional pain management primarily involves minimally invasive procedures. However, these minimally invasive procedures carry substantial patient risk. As interventional chronic pain management procedures are frequently administered at high levels of the spinal column, the procedures involve significant risks. These risks include allergic reactions, infections, bleeding, nerve damage, spinal cord injuries (e.g., paraplegia or quadriplegia), brain stem infarctions, and even death. Injuries can result from improper performance of interventional pain procedures, including injection of drugs into vessels or neural tissue. Given the serious potential risks of interventional pain procedures, it is essential that the providers of these procedures perform them appropriately and perform them only when they are indicated or likely to offer benefit. **Anesthesiologists are trained to diagnose the pain processes, interpret the indications for various procedures, perform these invasive procedures, and treat potentially catastrophic complications. Nurse anesthetists are not.**

The drugs used for interventional pain procedures vary widely and can be associated with serious complications. In addition to commonly used sedative agents and local anesthetics, steroids and neurolytic agents not commonly used for any type of anesthetic care are used to treat chronic pain. Because of their complexity and serious potential side effects, these agents are included in the pharmacology programs of medical schools and anesthesia residency programs. The drugs are not only dangerous because of their specific pharmacology, but also due to the location of the injection and the specific complications associated with the injections. For example, drugs used as part of a neurodestructive treatment plan, such as absolute ethanol and phenol, are injected into the nerve to destroy the nerve or group of nerves that contribute to pain.

Complications that have been associated with use of neurolytic agents and particulate steroids include vasospasm and embolic phenomena, which can reduce blood flow and result in devastating complications, such as paraplegia, stroke and death.

Spinal cord stimulation involves surgically implanting a device in an individual's back to send an electrical current to the patient's spinal cord. A pulse generator sends electrical pulses to the spinal cord in order to interrupt the pain signals from reaching the brain. Risks associated with this type of nerve stimulation include epidural hemorrhage, hematoma, infection, spinal cord compression, paralysis, leakage of spinal fluid, infection, and numbness or pain below the level of implantation. In addition, this procedure has the general risks of surgery.

Placement of an epidural for labor pain is not the same as epidural steroid injection for chronic pain. The indications, procedures, and management of an epidural catheter placement for obstetrical analgesia are much different than those for chronic pain. The training and experience for one does not equate to being sufficient for the other. The risks involved with epidural steroid injection include infection, numbness of the bladder, bleeding, nerve damage, and complications from the steroid medication. Complications associated with injectable steroids can include ulcers, immunosuppression, cataracts, and arthritis.

One specific complication provides an example of the need for physicians to rapidly diagnose and treat problems as they occur. Pneumothorax is a complication associated with several of the interventional pain procedures. It occurs when a needle improperly damages lung tissue. Air escapes from the damaged tissue into the chest cavity and compresses the lungs. At times, this complication may acutely lead to an inability of a patient to breath and oxygenate. A person performing interventional pain procedures must be trained to identify this potentially lethal complication and qualified and able to insert a chest tube to allow the air to escape. In the absence of a proper, prompt diagnosis and treatment, the patient may die. Nurse anesthetists are not trained to insert chest tubes. Permitting nonqualified individuals to perform these interventional pain management procedures can seriously jeopardize patient safety.

Anesthesiologist and Nurse Anesthetist Training

a. Medical Training is an Essential Foundation to Treating Chronic Pain.

Caring for patients with chronic pain requires a broad understanding of diagnostic evaluation, interaction with consultants from many specialties, and familiarity with and use of a wide range of therapies. The practice of pain medicine extends far beyond the application of technical skills. Rather, it requires a detailed foundation in the fundamental knowledge and skills that can only be mastered as physicians who have extensive medical education and training. These would include the ability to elicit a history and perform a detailed physical examination, an understanding of the appropriate use of diagnostic testing and imaging, and selection of appropriate treatment from a broad range of useful modalities, including behavioral management, rehabilitation, pharmacologic therapy, and interventional pain treatment. Simply performing technical interventions to treat chronic pain exposes patients to unnecessary harm when performed incorrectly or unnecessarily, or without the necessary preliminary planning.

During the first year of medical school, medical students begin their in-depth study of anatomy through classroom lectures and cadaveric dissection and integration of advanced diagnostic imaging modalities, including plain x-ray, computed tomography, magnetic resonance imaging, and diagnostic ultrasound. The curriculum also includes cellular anatomy and abnormal pathology to understand anatomy in both healthy and diseased states. Medical students apply their knowledge of anatomy throughout their medical training to evaluate patients, diagnose their maladies, and choose the most appropriate therapies. The extensive didactic

and clinical coursework in anatomy and use of imaging techniques to diagnose and develop treatment plans, all of which are critical skills to treating interventional pain management, extends beyond medical school to a physician's internship and anesthesiology residency training.

b. Anesthesiology Residency

After successfully completing a bachelor's degree with a pre-medicine curriculum (four years), medical school (four years), and one additional year of hospital-based training in general medicine, pediatrics, surgery, or combination (internship year), physicians begin their anesthesiology residency programs. To assure clinical experience with interventional pain procedures, the Accreditation Council for Graduate Medical Education (ACGME) requires anesthesiology residents to treat no less than twenty patients who are evaluated for management of acute, chronic, or cancer-related pain disorders during a specific three-month period under the direction of faculty physicians with demonstrated expertise in pain medicine. Most residents treat many more than twenty patients with pain-related disorders during their residency program.

The goal is for residents to gain clinical experience with interventional pain procedures by demonstrating their understanding of the comprehensive patient evaluation and synthesis of evidence-based treatment plans that include a broad range of treatment modalities. This includes the appropriate selection of the procedure, assessment of the procedure's effects, and management of potential complications. The application and actual conduct of the interventions is a small part of the broader understanding of how to approach the evaluation and treatment of these patients' complex problem. The actual conduct of interventions in the pain clinic is largely an extension of the extensive training that anesthesiology residents gain during the course of residency training in the operating room and obstetric anesthesia settings. During their training in the pain clinic, anesthesiology residents also gain formal exposure to the radiographic anatomy required to perform image-guided intervention.

c. Board-Certification in Pain Medicine

Because of the complexities involved in the treatment of pain, pain medicine is recognized as a separate medical subspecialty by the American Board of Medical Specialties (ABMS). Anesthesiologists choosing to specialize in pain medicine must complete a one-year multidisciplinary pain fellowship and apply to enter the examination process for board-certification in Pain Medicine upon successful completion of medical school and their anesthesiology residency. The requirement for multidisciplinary pain medicine fellowship training is recognized by the ACGME, which oversees and accredits Pain Medicine programs.

The requirements for the pain management fellowship are on the ACGME web site at http://www.acgme.org/acWebsite/RRC_040/040_prIndex.asp. The required education primarily involves experiences and classes that increase medical knowledge of pain issues, assessment and treatment of acute and chronic pain, practice improvement, communication and professionalism, and system-based practice learning (pages 13-19 of the Pain Medicine program requirements). There also are specific requirements for interventional pain procedures and recognition and treatment of their complications (pages 12 through 14). Physicians who are board certified in Pain Medicine have undergone extensive training in the diagnosis and treatment of patients with chronic as well as acute pain problems.

d. Nurse Anesthetist Training

Conversely, nurse anesthetists complete nursing training, which does not adequately prepare them to practice pain medicine. They do not receive equivalent fundamental training in anatomy in normal or abnormal states

or in making diagnoses. Nor does their training prepare them to respond to medical complications. Nurse anesthetists who have trained in the past two decades have obtained a baccalaureate degree in nursing (four years), worked a minimum of one year in an intensive care setting, and then participated in a 30-month anesthesia training program. There are no boards or accreditation processes for nurse anesthetists seeking to perform chronic interventional pain techniques. In 2003, the Council on Accreditation of Nurse Anesthesia Educational Programs (COA) began developing standards for pain-management fellowships; however, the COA terminated its effort in 2004 and commented that there was a lack of existing accredited nurse anesthetist training programs offering pain management coursework.

Moreover, the Louisiana Court of Appeal, in a recent ruling upheld by the Louisiana Supreme Court, noted the lack of guidelines necessary to assess the competency, skill set, abilities, and training needed for nurse anesthetists to begin performing interventional pain management procedures. During the litigation, the president-elect of the American Association of Nurse Anesthetists (AANA) acknowledged that “there are no guidelines for assessing the competency, skill set, abilities, or training needed for CRNAs to begin performing interventional pain management procedures. Rather, she opined that a CRNA should be allowed to perform these procedures once the CRNA has had the ‘necessary education, training, and feels like they have the necessary skills.’” (emphasis added)² The court concluded that the practice of interventional pain management is not within the scope of practice of a nurse anesthetist, and is solely the practice of medicine.³

A limited number of the procedures that are listed in the Alabama Medical Board’s proposal as non-delegable to nonphysicians are included in the nurse anesthetist’s curriculum in the context of providing anesthesia or acute postoperative pain management. The procedures are not taught or used in the context of chronic pain management. Decisions on when to use these treatments and the technical application of the procedures are markedly different in patients with chronic pain versus patients treated in the perioperative (acute pain) setting. In contrast, many of the fundamental chronic pain procedures listed in the proposal are included in an anesthesia residency program.

Education on the use of other advanced interventional pain management techniques is incorporated into specialty fellowship training programs for pain medicine. Candidly, pain medicine has become sufficiently complicated and dangerous that fellowship programs are moving to two-year educational experiences in order to cover the necessary material. ABMS member boards (e.g., the American Board of Anesthesiology) have ensured that physicians who practice pain medicine have the formal training and have demonstrated the requisite knowledge and skills to practice pain medicine. Specifically, working with their national education associations, they have established ACGME-accredited residency and fellowship training programs. They also have developed board certification processes in pain medicine. Nurse anesthetists do not have the formal means to gain the requisite medical knowledge and technical skills required to practice the full scope of practice of medicine. It is this medical knowledge and the expanse of interventional technical skills that are required to care for patients with chronic pain.

We strongly urge you to consider that anesthesiologists have at least eight years of post-graduate education and training, while nurse anesthetists only have 30 months of required training. Policymakers must not fail to recognize the significant differences in education and experiential learning between the two groups. They must not conclude that there is equivalence among the two types of anesthesia providers, especially with regards to the differences in complex areas such as chronic pain management.

² *Spine Diagnostics of Baton Rouge, Inc. versus Louisiana State Board of Nursing*. (4 So.3d 854, 2008-08-13 (La.App. 1 Cir. 12/23/08)

³ *Id.*

Safety Studies Support Involvement of an Anesthesiologist

While there are no available data examining the outcomes associated with chronic pain care delivered by nurse anesthetists, safety studies demonstrate that anesthesiologists have a proven track record of improved outcomes when involved in the administration of anesthesia. Your letter to the Alabama Medical Board heavily relied on the 2010 AANA-funded Dulisse & Cromwell paper, *No Harm found when Nurse Anesthetists Work Without Supervision by Physicians* (“*Health Affairs* paper”), as evidence of patient safety equivalence. The letter states that “available evidence indicates that CRNAs operating within the scope of their licensure provide pain management services safely.” Most important, the paper does not address outcome data for nurse anesthetists performing *interventional* pain management procedures. ASA cautions policymakers against adopting policy on pain medicine that is not based on data that are applicable to interventional pain practice.

Since you based your comments on a study of provision of intraoperative anesthesia care and not interventional pain management, it is necessary to review additional information on intraoperative anesthesia care. According to the Institute of Medicine (IOM), there is one death per 200,000 to 300,000 anesthetics administered.⁴ The *Health Affairs* paper reflects the flaw of using billing data when assessing safety and quality. Billing data were not created for this purpose and do not distinguish between complications resulting from surgery or anesthesia; nor do they discriminate between conditions existing prior to surgery and those resulting from surgical or anesthetic care. Therefore, even had the *Health Affairs* paper focused on chronic pain management, any meaningful analysis of outcomes is impossible from billing codes alone. Using the anesthetic-related mortality frequency reported by the IOM, an analysis of 481,000 cases would have produced two deaths related to anesthesia, a number insufficient to support any conclusions about mortality. Moreover, the paper does not address the disturbing trend in the study’s own data. These data showed an increasing frequency of mortality and complications in patients who received nurse-administered anesthesia in the opt-out states as compared to improved outcomes in patients who had anesthesia provided by anesthesiologists or nurse anesthetists who worked with anesthesiologists.

Further, as acknowledged by the paper’s authors, anesthesiologists not only care for patients undergoing the most complex procedures, but also for sicker patients undergoing all procedures. Many studies have shown that a primary determinant of anesthesia outcome is the health of the patients. Healthier patients in all anesthesia settings have fewer complications than sicker patients. Therefore, the healthier patients who received anesthesia delivered by only nurse anesthetists should have experienced better outcomes than those sicker patients who received care from anesthesiologists or nurse anesthetists who worked with anesthesiologists. In fact, nurse anesthetist-only patients actually had higher mortality and complications. Even a finding of equivalent outcomes in healthier patients would be troubling.

The *Health Affairs* paper also contends that unsupervised nurse anesthesia is more cost effective than if anesthesia is administered under the supervision of a physician. However, anesthesiologists and nurse anesthetists are paid equally under Medicare and by many private insurers. Therefore, no cost-savings for patients or the government would result if the scope of nurse anesthetist practice was expanded to include other services. Given that anesthesiologists are better trained than nurse anesthetists and cost no more to government payers, patients and those who pay for their care benefit from the additional services that can be provided by anesthesiologists. The only exception is that nurse anesthetists can be eligible for a significant Medicare Part A bonus payment if they provide care in certain rural hospitals. Congress has thus far not taken

⁴ Committee on Quality of Healthcare in America, Institute of Medicine: *To Err is Human, Building a Safer Health System*. Edited by Kohn L, Corrigan J, Donaldson M. Washington, National Academy Press, 1999, p 241.

up legislation to extend this access opportunity to anesthesiologists to address access problems in some rural areas.

The *Health Affairs* paper is irrelevant to your commentary on pain medicine. However, since you noted it as a reason to question the action of the Alabama Medical Board, I will provide contrasting data on intraoperative anesthesia safety. The 2000 Silber study compared mortality and complication rates in patients who received anesthesia under the medical direction of anesthesiologists against patients who received anesthesia without anesthesiologist direction. The study was published in *Anesthesiology*, a peer-reviewed medical journal that is widely regarded as the premier scientific publication related to anesthesia. Jeffrey A. Silber, M.D., Ph.D. and colleagues at the University of Pennsylvania analyzed more than 200,000 Medicare cases involving general or orthopedic surgeries at Pennsylvania hospitals between 1991 and 1994. The authors found that there were 2.5 more deaths per 1,000 patients within 30 days of admission when an anesthesiologist was not involved. In those patients in whom post-operative complications occurred, there were 6.9 more deaths per 1,000 cases when an anesthesiologist was not involved. When extrapolated to the estimated 20 million Medicare surgical procedures of all types performed annually, the study results suggest hundreds of deaths per year could be prevented if anesthesiologists were always involved.⁵ This is supported by data from the Agency for Healthcare Research and Quality which found that anesthesiologists prevent more than six excess deaths per 1,000 cases in which an anesthesia or surgical complication occurs.

These findings are further supported by the AANA-funded Pine study, which studied the effect of type of anesthesia provider on mortality rates of Medicare patients undergoing eight different surgical procedures.⁶ The study examined only mortality of patients undergoing anesthesia and omitted any analysis of adverse outcomes of anesthesia care, including serious complications such as blindness, infection, seizure/stroke and brain injury. The authors found that there were 38 deaths per 10,000 patients in hospitals where all anesthetics were administered by an anesthesiologist or an anesthesiologist/nurse anesthetist care team, but 45 deaths per 10,000 patients when anesthesia was administered by nurse anesthetists who were supervised by non-anesthesiologist physicians. This finding equates to seven more patient deaths for every 10,000 cases where an anesthesiologist is not involved. Again, if extrapolated to the estimated 20 million Medicare surgical procedures performed annually, this finding suggests that 1,400 additional deaths could occur with nurse anesthetists supervised by non-anesthesiologist physicians or not supervised at all. The similarity between the findings of the Silber and Pine studies is striking.

As noted in your letter, the Centers for Medicare and Medicaid Services (CMS) concluded that “the anesthesia-related death rate is extremely low.” While this is accurate, CMS retained the federal requirement that a physician supervise the administration of anesthesia by a nurse anesthetist when it issued its final rule in 2001. Since then, 34 states have chosen to continue following the federal physician supervision requirement.

In Summary

There are many risks associated with treating patients who have chronic pain, especially when it involves interventional pain procedures. The additional training that an anesthesiologist receives to treat patients suffering from chronic pain has produced high quality outcomes and patient safety. Interventional pain management requires accurate medical diagnoses to ensure that the causes of symptoms are clearly identified

⁵ Silber JH, Kennedy SK, Even-Shoshan O, Chen W, Mosher RE, Showan AM, Longnecker DE: *Anesthesiologist Direction and Patient Outcomes*, *Anesthesiology* 2002; 93:152-63. Like the *Health Affairs* paper, this study did not focus on chronic pain management. We mention it here only because your letter suggests that more general studies comparing the services of anesthesiologists and CRNAs are relevant.

⁶ Pine M, Holt K, Lou YB: *Surgical Mortality and Type of Anesthesia Provider*, *AANA Journal* 2003; Vol 71, No 2.

among multiple possible etiologies and that any procedures performed are warranted based on sound clinical evidence and judgment. If interventional therapy is indicated, the specific choice of intervention must be made to maximize the likelihood of patient benefit and minimize risks. Treatments involving interventional pain procedures can be catastrophic to patients if they are improperly performed or if there are complications that are not immediately recognized and treated. Because of their extensive training and education, only physicians are able to properly diagnose, plan, and safely use interventional pain procedures to treat patient who have chronic pain.

Data examining the outcomes associated with chronic pain care delivered by nurse anesthetists are not available. However, the lack of data should not be used to drive policy decisions. It is inappropriate to ignore the significant, often catastrophic risks of treating chronic pain with interventional pain procedures. Nurse anesthetists do not have the education and training to diagnose and treat chronic pain and safely handle the devastating complications that can be associated with interventional pain procedures.

It is not relevant or appropriate to use studies on intraoperative anesthesia care to predict outcomes related to interventional pain management of chronic pain. In fact, studies of intraoperative anesthetic care, including those supported financially by the national nurse anesthesia society, show that patient safety is significantly enhanced (i.e., fewer deaths occur) when anesthesiologists are involved in the delivery of anesthetic care.

We fear that letters from federal antitrust officials may intimidate state medical boards into decisions that truly are not in the best interest of patient care. When all the facts are understood and considered, particularly the complexity of chronic pain management and the differences in education and knowledge between anesthesiologists and nurse anesthetists, the proposed Alabama Medical Board regulation should help ensure the highest quality patient care for pain management patients.

We hope that you might reconsider your commentary to the Alabama Medical Board after reviewing the information in this letter. Since it is not possible for my organization to discuss in full detail all the points raised here, I would welcome the opportunity to provide you with more information by telephone or, preferably, in person. Please feel free to contact me at (202) 289-2222. On behalf of ASA, I appreciate your consideration.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Warner". The signature is written in a cursive, slightly slanted style.

Mark A. Warner, M.D.

President

American Society of Anesthesiologists