ASIPP®
American Society of Interventional Pain Physicians
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Re: Certified registered nurse anesthetist (CRNA) Scope of Practice and AANA letter date March 24, 2015 to Dr. Capehart

Dear Dr. Capehart:

On behalf of the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP), 50 state societies, and the Puerto Rico Society of Interventional Pain Physicians, we would like to comment on certified registered nurse anesthetists (CRNAs) claim that they have the ability to perform interventional pain procedures. These procedures are often extremely complex and involve a high amount of risk.

ASIPP is a not-for-profit professional organization founded in 1998 which now comprises over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP also has affiliated state societies in all 50 states and Puerto Rico.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain-related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment.[1]

Interventional pain management techniques are minimally invasive procedures, including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps, and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain.[2]

ASIPP has strongly opposed and continues to oppose allowing CRNAs to perform chronic pain management services. This expansion of services is deleterious to the American health care system and its survival, resulting in unnecessary procedures, duplication of services, and potentially major disasters.

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[1] The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf

[2] Medicare Payment Advisory Commission. 2001. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001. http://www.medpac.gov/documents/reports/december-2001-report-to-the-congress-paying-for-interventional-pain-services-in-ambulatory-settings.pdf?sfvrsn=0

In fact, we have requested a survey by the US Government Accountability Office (GAO) through Congressman Ed Whitfield and Senators David Vitter and Richard Colburn requesting a study on "the training and qualification of nurse anesthetists to perform interventional pain management procedures." Instead, GAO sidestepped the issue and performed a study on how nurse anesthetists billed for a few chronic pain procedures, which was extremely disappointing. The GAO report was based on inaccurate information from the Institute of Medicine (IOM)[3] which had conducted a flawed analysis of chronic pain data. The data were based on the IOM report and an article by Gaskin and Richard[4] from Johns Hopkins who estimated the cost of chronic pain to be $560 to $630 billion; however, unfortunately they defined chronic pain, not only as those who experienced pain, but also those who were diagnosed with joint pain or arthritis and had a disability that limited their ability to work, including functional disability from stroke and other ailments. In reality, moderate and severe pain constitutes approximately 44 million individuals instead of 100 million as reported. Joint pain, arthritis, and functional disability are not related to chronic noncancer pain and the expenses involved are totally different, sometimes exceeding $30,000 per case. Even spinal surgery is not included in chronic pain generally; even then, including surgical interventions, etc, chronic spinal care costs have been estimated to be $100 billion.[5]

These procedures have seen an explosive increase. Access is not an issue. Even considering ASIPP members only, which probably constitutes 60% of qualified interventional pain physicians, there is a physician located at least every 40 to 50 miles.

Anesthesia and Related Care

1. "Anesthesia services and related care" does not include interventional pain management. Where and under what circumstances does it state this?} It would be a major stretch to include chronic pain management as related care. Chronic pain management is not just an epidural injection. It requires skills beyond anesthesia, physical medicine and rehabilitation, and neurology. That is why interventional pain physicians have fellowship training.

2. In the early years, pain management was performed by anesthesiologists utilizing blind spinal injections. However, since then, much has changed. The surveys from the Office of the Inspector General (OIG) of the Centers for Medicare and Medicaid Services (CMS) have reported that fraud and abuse issues related to interventional pain management mainly come from untrained physicians and other health practitioners, including nurse anesthetists.

3. The opioid epidemic continues to worsen. Evaluations show that prescriptions written by nurse practitioners, physician assistants (PA's), and nurse anesthetists are increasing. Consequently, for all practical purposes, multiple states have enacted pill mill legislation. Neither education nor certification is available for CRNAs to perform E/M services and prescribe drugs. There are no outcomes in reference to CRNAs managing chronic pain patients. Some argue that IPM procedures should not even be performed by well-trained physicians due to an alleged lack of effectiveness (Chou and Huffman, Carragee).

4. The Louisiana State Supreme Court ruled that IPM is the practice of medicine and that CRNAs should not be practicing interventional pain management. Other states have imposed many restrictions. In fact, in Tennessee, no physicians other than anesthesiologists, physiatrists, and neurologists can perform these procedures unless they have fellowship training. They are also not entitled to supervise nurse anesthetists.

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[3] Institute of Medicine (IOM). *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* The National Academies Press, Washington, DC, June 29, 2011. http://www.iom.edu/~/media/Files/Report%20Files/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research/Pain%20Research%202011%20Report%20Brief.pdf

[4] Gaskin DJ, Richard P. The economic costs of pain in the United States. *J Pain* 2012; 13:715-724.

[5] Martin BI, Turner JA, Mirza SK, Lee MJ, Comstock BA, Deyo RA. Trends in health care expenditures, utilization, and health status among US adults with spine problems, 1997-2006. *Spine (Phila Pa 1976)* 2009; 34:2077-2084.

5. The nurse anesthetists' standards for accreditation do not support an assertion that chronic pain is related to anesthesia. The full scope of practice includes preparation of graduates who can administer anesthesia and anesthesia-related care in 4 general categories:

- Preanesthetic preparation and evaluation
- Anesthetic injection, maintenance and emergence
- Postanesthesia care
- Perianesthetic and clinical support functions.

Consequently, none of these provide any information on training for evaluation and management services, assessment of the patient, and performance of chronic pain management procedures, which are different from managing acute pain.

IPM is a specialized field of medicine, included within the broader medical field of chronic pain management that involves a clinically based approach to improve function and quality of life for a patient who suffers from a chronic disease state. IPM is not the delivery of anesthetics. Most IPM practices are referral based, i.e., patients are sent for specialist consultation by other physicians for care that is beyond the scope of the referring physician's medical practice. A consultation requires a thorough musculoskeletal, neurological, physiological, and psychological examination and evaluation. Diagnostic studies must be ordered and interpreted when determined to be medically necessary. The treating physician often must prescribe complex medication management and coordinate long-term physical therapy, oncology, rehabilitation, surgical consultations and psychology services. Complex procedures and surgeries are often performed. Complication management and follow-up care are required. All of these services must be provided and represent the quintessential definition of the practice of medicine. All aspects of this care lie fully outside the scope of perioperative "anesthesia-related care" as defined in the Social Security Act and as acknowledged by the society representing CRNAs.

MedPAC has defined interventional pain management techniques as including percutaneous precision needle placement, with placement of drugs in targeted areas or destruction of targeted nerves; and also surgical techniques, such as laser or endoscopic discectomy, percutaneous lumbar decompression, and surgically implanted devices such as intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent, or intractable pain. Interventional pain management is a minimally invasive specialty with maximum risks, even when practiced by qualified and experienced hands.

CRNAs are now seeking an unprecedented expansion of their scope of practice to diagnose complex medical conditions, independently order and interpret expensive diagnostic studies, provide unsupervised treatments, and perform complicated and dangerous procedures and surgeries for which they have had no formal training or certification.

Assessing the Need: Fallacy of Access and Cost Savings

The CRNA groups requesting independent medical privileges to diagnose and treat these complex disease states frame their argument in terms of patient access and reduction in costs. Both arguments are patently specious. Payers, including Medicare and Medicaid, pay CRNAs in most practice settings *precisely the same amount as doctors*. No cost savings are possible and overutilization in this group of providers appears to be rampant. Further, well-trained, certified physicians are abundant.

CRNA advocacy groups quote recent findings of the IOM to support access issues. This is a gross misstatement of the findings and inconsistent with all available data. While chronic pain is a pervasive and costly societal burden, access to spinal injections and complex interventional procedures is not lacking. The need, as articulated by the IOM, is for patient education and conservative management.[3] The report states:

The plan should:

- *heighten awareness about pain and its health consequences;*
- *emphasize the prevention of pain;*
- *improve pain assessment and management in the delivery of health care and financing programs of the federal government;*
- *use public health communication strategies to inform patients on how to manage their own pain; and*
- *address disparities in the experience of pain among subgroups of Americans.*

We agree with this approach. In fact, while CRNA's have no training in clinically based medicine, other advanced nurse practitioners do and we support their earnest and admirable efforts to relieve suffering consistent with the fundamental and historical goals of nursing. Primary care education for practitioners to identify and refer patients to tertiary centers for complex procedures is a well-studied and effective model of health care delivery. Proliferation of procedure-driven centers does not accomplish this goal and exacerbates the problems of overutilization. Moreover, the opportunity to provide clinically based evaluative and management care to suffering patients by nurse practitioners is already an acknowledged and covered service and is reimbursed identically as for physicians within most payer systems and practice arrangements.

Education, Certification and Outcomes: Privileges by Legislation without Education

CRNA curricula do not include training in chronic pain management. In fact, unlike other fields of advanced nurse training, clinically based chronic patient care is not required or even offered.

The AANA's own "Standards for Accreditation of Nurse Anesthesia Education Programs" specifically states that no clinical experience with "pain management (acute/chronic)" is required as part of nurse anesthesia training.[6]

Some CRNAs receive instruction in "blind" regional anesthetic techniques such as obstetric epidurals. **This is unrelated to procedures for chronic pain**. CRNAs receive no training on indications, pathophysiology, physical examination, psychological and medical management, rehabilitation, vocational management, anatomical and radiographic diagnosis, MRI interpretation, CT, ultrasound and fluoroscopic guidance - all of which are required to practice Chronic Pain Medicine and are an integral part of all interventional pain fellowships and board examinations.

Unlike physicians, there are no required board certifications or accreditation programs in IPM for nurse anesthetists and other non-physicians. Many boards of nursing have taken the position that if a CRNA wants to start practicing IPM and perform these procedures, then it is OK to do so and it is the responsibility of the CRNA to determine his or her own competency. Virtually all experience and documentation of competency is gained through participation in for-profit workshops and on-the-job observation and proctoring.

In this context, it is useful to examine a typical interventional pain procedure such as spinal cord stimulation (SCS). This is a procedure that involves almost exactly the same level of diagnostic skills, medical judgment, and surgical acumen as exercised by an interventional cardiologist or cardiovascular surgeon performing pacemaker implantation. First, the physician must diagnose the condition based on careful history taking and physical examination. Complex diagnostic studies must be performed and interpreted. Alternative therapies must be investigated and offered. Medication trials are usually pursued and evaluated for efficacy prior to moving towards surgery. Psychological factors are evaluated and treated. Once surgical implantation has been decided, the patient is brought to an operating room and placed under anesthesia by an anesthesia provider. Leads are placed directly into the spinal column through a surgical incision and introducer under fluoroscopic guidance to avoid severe neurological damage of the spinal cord. Just as a cardiovascular surgeon would place cardiac leads, precise positioning is critical. Likewise, testing is performed similar to testing a pacemaker's function. Subsequently, a surgical pocket is fashioned in the operating room under an anesthetic then leads are

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[6] Standard for Accreditation of Nurse Anesthesia Educational Programs, Council on Accreditation of Nurse Anesthesia Educational Programs, Revised 2012, Page 23.

tunneled from one part of the body to another and connected to a generator and retested. Hemostasis is achieved using electrocautery, incisions are then closed surgically, and the patient is managed postoperatively for complications.

There is no aspect of the above vignette, although typical in daily practice for an IPM doctor that is consistent with a CRNA's scope of practice - any more than is placing a pacemaker or defibrillator.

The art of medicine is defined by two pillars of clinical practice:

1. Diagnosis: figuring out what is wrong with the patient, and
2. Treatment: deciding what to do for the patient, and then carrying out the plan.

Medical school curriculum and nurse anesthesia curriculums are very different and not transferable. Medical school involves 4 years of post graduate training in gross anatomy cadaver dissection, patho-physiology, pharmacology, etc. For credentialing in pain management, primary residencies upon completion of medical school in Anesthesiology, PM&R and neurology require further fellowship training for sub certification by the ABMS with 10 year required re-certification exams. Further training in interventional pain medicine is also offered by the ABIPP. The purpose of this extensive certification is demonstrate *as a benchmark to the public* - that extensive training with certification has been undertaken to ensure public safety and to ensure the integrity of the Medicare program. Along these lines we continue to implore MC to credential based on training and not politics. The desire of the nurse anesthetist to shortcut this training pathway for economic benefit is dangerous and destabilizes medical education.

Bachelor of Nursing curriculum followed by two years of vocational anesthesia operating room training has no exposure to the evaluation and treatment of complex pain and medical disorders. Blind-guided spinal block for surgical purposes or blind epidural injections for labor is not akin to performing complex neuro-axial interventions under fluoroscopic guidance in complex spine disease. The analogy is this: No federal agency would allow an individual with only a private pilot license to fly commercial jets- for this same reason, no one should let a nurse anesthetist perform complex spine interventions without extensive medical training and certification.

While legal definitions vary somewhat from state to state, correctly diagnosing what is wrong with a given patient then providing only necessary and appropriate treatment is the *sine qua non* of practicing medicine. The Federation of State Medical Boards (FSMB) recommends that every state's Medical Practice Act provide a definition of the "Practice of Medicine" and that the definition includes "rendering a determination of medical necessity or appropriateness of proposed treatment."[7]

The American Medical Association rightly introduced at the November 2006 House of Delegates meeting language included in Resolution 902 that, "state medical boards have full authority to regulate the practice of medicine by all persons within a state, notwithstanding claims to the contrary by boards of nursing, mid-level practitioners or other entities."

Public safety requires that interventional pain management in statute and regulation is clearly recognized as the practice of medicine and that the interventional treatment of pain is provided only by well-qualified and well-trained physicians. Due to the complexities involved in the treatment of pain, pain medicine is recognized as a separate medical subspecialty by the American Board of Medical Specialties.

In fact, we oppose many untrained physicians performing interventional pain management or practicing pain medicine.

Further, as promulgated in multiple LCDs at the present time which was initiated by Noridian, CRNAs do not meet the definition of required training to perform any interventional procedures.

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[7] Federation of State Medical Boards of the United States. *A Guide to the Essentials of a Modern Medical*

Provider Qualifications

The CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1 (http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf) states that "reasonable and necessary" services are "ordered and/or furnished by qualified personnel." Services will be considered medically reasonable and necessary only if performed by appropriately trained providers.

Patient safety and quality of care mandate that healthcare professionals who perform epidural steroid injections are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting. (At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure and utilization of the required associated imaging modalities).

Creation of Profit Centers

This approach will facilitate creation of profit centers for orthopedic surgeons, neurosurgeons, and even other types of physicians rather than providing comprehensive care. This technique is already used by chiropractors.

The regulations from Ohio, Kentucky, Florida, and multiple other states clearly show that even to provide opioids, physicians must be board certified in pain medicine or interventional pain management. Whereas for doing interventional procedures, which are associated with high risk, CMS is proposing that nurse anesthetists, who lack basic training (the only training they have is blind epidural injections in obstetrics sometimes) be permitted to perform these complex procedures.

Case Precedence

The inclusion of interventional pain management procedures in CRNAs' scope of practice was successfully challenged in Louisiana and affirmed by the courts. The appellate court affirmed the trial court's grant of a permanent injunction that limited the scope of practice for CRNAs by restricting them from performing IPM procedures.[8] During the lengthy process these issues were fully examined after numerous national experts testified at trial and amicus briefs were filed by several entities from across the nation.

After reviewing all the evidence, the Louisiana Supreme Court upheld the trial court's decision that ensured pain management patients in Louisiana would receive the highest quality of care from licensed medical physicians. The ruling shows that the scope of practice issue and public health and welfare issues are inseparable.

Additionally, Noridian Administrative Services, the Medicare Contractor for most of the Western United States, issued an opinion on March 17, 2011,[9] that CRNAs cannot practice IPM. Noridian determined that CRNAs are not trained in curricula that teach assessment skills for evaluation of chronic pain states and thus do not have the skills to manage such patients. Wisconsin Physician Services (WPS) came to the same conclusion.[10]

Position of ASIPP and State Organizations

The paramount responsibility of medical regulation is to ensure safety and efficacy for patients who seek care but may not understand the vast differences in training and skill among health care providers and medical treatments. The US medical education system and credentialing process seeks to ensure that even the least of physician providers possesses an acceptable level of competency and safety through an arduous course of extensive medical training, broad-based patient care responsibilities, mentored specialty training, critical oral,

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[8] Spine Diagnostic Center of Baton Rouge, Inc. versus Louisiana State Board of Nursing, Appellate Court Decision (2008). Page 16.

[9] http://bbnor.noridian.com/Bulletins/Medicare_Part_B/Medicare_B_News/Medicare_B_News_Issue_273_October_6_2011_/CRNA_Practice_and_Chronic_Pain_Management_-_Revised___.htm

[10] http://www.wpsmedicare.com/j8macparta/resources/provider_types/crna-practice-chronic-pain-management.shtml

written and hands-on specialty board certification, as well as ongoing medical education and specialty re-certification.

Current requests by CRNAs to enter into the practice of medicine, specifically the complex field of chronic pain medicine, without any formal education, training, or certification, circumvents the goal of medical education and the responsibility of regulatory agencies such as CMS to provide for the safe and effective delivery of health care services.

CRNAs are not, in fact, requesting that advanced practice nurses be allowed to provide independent medical management of chronic pain; that role of primary care - as advocated by the IOM - is currently reimbursed by CMS for advanced nurse practitioners. The requested coverage language is specifically crafted to allow payment for complex procedures in facility and non-facility settings.

ASIPP, our Puerto Rican society, and all state societies strongly object to any consideration of CRNAs' request to practice outside the field of anesthesia services, specifically in the specialized field of interventional pain management.

Thank you again. If you need further information, please contact us.

Sincerely,

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