American Society of Anesthesiologists

1501 M Street, N.W. • Suite 300 • Washington, D.C. 20005 • (202) 289-2222 • Fax: (202) 371-0384 • mail@ASAwash.org

September 4, 2012

Ms. Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1590-P, RIN 0938-AR11, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, etc.

Dear Ms. Tavenner:

On behalf of the over 48,000 members of the American Society of Anesthesiologists (ASA), I appreciate the opportunity to comment on the Physician Fee Schedule Proposed Rule (CMS-1590-P) that was published in the *Federal Register* on July 30, 2012.[1] In this letter, we focus our comments on the issue of nurse anesthetists (CRNAs) and chronic pain management. We also provide comment on the undervaluation of anesthesia services; resource-based practice expense (PE) relative value units (RVUs); spinal cord stimulation for trial procedures in the non-facility setting; the physician quality reporting system (PQRS); and the physician value-based payment modifier (VBM).

Certified Registered Nurse Anesthetists and Chronic Pain Management Services

As the medical specialty representing the largest number of practicing pain medicine physicians and the recognized leaders in patient safety, ASA is extremely disappointed with the Centers for Medicare & Medicaid Services' (CMS) proposal to create a new national policy to pay for chronic pain services delivered by CRNAs or nurse anesthetists. **We urge CMS in the strongest possible terms to withdraw this proposed policy for the following reasons: anesthesia and related care does not include chronic pain care; the training and education of nurse anesthetists is inadequate for safe, effective and appropriate chronic pain care; the exceedingly low number of times nurse anesthetists bill for this care does not support an**

[1] 76 *Fed. Reg*. 44721 (July 30, 2012), available at http://www.gpo.gov/fdsys/pkg/FR-2012-07-30/pdf/2012-16814.pdf.

access issue; the increased risk of fraud and abuse; the potential for misuse, abuse and diversion of controlled substances; and the sometimes ambiguous state scope of practice rules for nurse anesthetists.

1. "Anesthesia and related care" does not include chronic pain care

In the proposed rule, CMS proposes that the determination of whether chronic pain is included within "anesthesia and related care" should be resolved by state scope of practice. **We strongly disagree that chronic pain care is a subset of anesthesia or of care related to the provision of anesthesia.** This is illustrated by the fact that anesthesiologists are not the only physicians that specialize in chronic pain. Chronic pain is multidisciplinary; to be board certified in pain medicine, a physician must complete a fellowship training program and pass a board certification examination created by a multidisciplinary committee with representatives from the fields of anesthesiology, physiatry (PM&R), neurology, and psychiatry. In addition, orthopedic surgeons, family physicians, neurosurgeons, oncologists and others provide chronic pain management services. This multi-disciplinary approach to chronic pain treatment is known to improve outcomes and is reflected in the professional societies that represent pain care medicine. For example, the membership of the American Academy of Pain Medicine (AAPM), the North American Spine Society (NASS) and the International Spine Intervention Society (ISIS) include not only anesthesiologists, but also physicians across a broad range of medical specialties. **Taking the premise that "anesthesia and related care" includes chronic pain medicine to its ultimate conclusion, one would construe that non-anesthesiologists practicing pain medicine would be qualified to deliver anesthesia; nothing could be further from the truth.**

Furthermore, the nurse anesthetists Standards for Accreditation do not support an assertion that chronic pain is related to anesthesia. As recently as 2012, the Council on Accreditation of Nurse Anesthesia Educational Programs in the *Standards for Accreditation of Nurse Anesthesia Education Programs* did not define chronic pain management as being within the scope of practice of graduates.[2] As stated in the document,

> **Full scope of practice** - Preparation of graduates who can administer anesthesia and anesthesia related care in four general categories: (1) preanesthetic preparation and evaluation; (2) anesthesia induction, maintenance and emergence: (3) post-anesthesia care; and (4) perianesthetic and clinical support functions.

[2] Standard for Accreditation of Nurse Anesthesia Educational Programs, Council on Accreditation of Nurse Anesthesia Educational Programs, Revised 2012, Page 27.

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That same document also provides its definition of perianesthetic management,[3]

> **Perianesthetic management** - Anesthesia care and management of patients, including preoperative, intraoperative, and postoperative care. Preoperative care includes the evaluation of patients through interview, physical assessment, and a review of records. Intraoperative care includes administration of anesthetics, decision-making, and recordkeeping. Postanesthesia care includes evaluation, monitoring of physiological functions, and appropriate intervention when a patient is emerging from anesthesia and surgery.

All of the above standards for nurse anesthetists are related to providing anesthesia in the surgical setting and none of them relate in any way to chronic pain management.

The procedural aspects of treating chronic pain are also unique. For example, placement of an epidural for labor pain is not the same as an 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 and the training and experience for one does not equate to being sufficient for the other. To elaborate, in providing an epidural for labor or surgical pain relief, one avoids areas with pathological changes and the target size for a successful outcome is much larger. In chronic pain interventions, the target is specific, usually limited in size, and in most cases, requires image guidance for procedural success, and often involves areas with significant anatomical abnormalities. What is a contraindication for acute pain management is often the very reason for the intervention in chronic pain.

Moreover, there are significant risks involved with interventional chronic pain procedures, and nurse anesthetists' training does not prepare them to respond to medical complications. Even in the hands of specially trained physicians, chronic pain procedures are inherently dangerous due to the anatomy and delicate structure of the spine and nerves upon which chronic pain interventions are performed. Specifically, many chronic pain procedures are administered in and near the spinal column, and, as mentioned above, involve anatomically abnormal structures. This substantially increases risks to patients. Potential complications include allergic reactions, infections, bleeding, nerve damage, spinal cord injuries (e.g., paralysis), and brain stem tissue damage – all of which can require extensive and costly medical interventions to address. Delayed diagnosis and intervention may worsen the injury, and in some cases, irreversibly.

[3] Standard for Accreditation of Nurse Anesthesia Educational Programs, Council on Accreditation of Nurse Anesthesia Educational Programs, Revised 2012, Page 29.

2. Nurse anesthetists do not have the education and training necessary to perform chronic pain management services

While nurse anesthetists receive education and training to provide anesthesia in the acute perioperative setting, their curriculum does not require any education or training in diagnosing and treating chronic pain conditions as exemplified above. There are significant risks involved in interventional procedures for chronic pain, and nurse anesthetists are not prepared to respond to medical complications that may arise. In contrast to CMS' proposal, other stakeholders and federal agencies are calling for more health care professional education in pain care. The proposal is detrimental to patient safety and disregards sister agencies' calls for additional education and training of professionals who treat patients with chronic pain. Education must come first and it must be sufficient to assure safe, appropriate and effective care for our citizens.

a. Nurse anesthetists are not required to receive any clinical experience with chronic pain management

Becoming a nurse anesthetist does not require education and training in chronic pain management. Nurse anesthetists 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 an approximately 30-month anesthesia training program. In the training program, nurse anesthetists are not required to receive any clinical experience with chronic pain management. **The American Association of Nurse Anesthetists' (AANA's) own "Standards for Accreditation of Nurse Anesthesia Education Programs," specifically cite that no clinical experience with "Pain management (acute/chronic)" is required as part of nurse anesthesia training."**[4]

Chronic pain management is not merely a technical skill; it is a combination of medical diagnosis, medical decision-making, multidisciplinary training, and technical skills including imaging, combined with the technical skills of performing the procedures. The diagnosis and treatment of chronic pain differs from the medical approach used to diagnose and treat acute pain. 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. Successful diagnosis involves exquisite skill in history taking, physical examination and understanding the presentation of various disease states. This will guide appropriate diagnostic tests, including imaging and diagnostic interventions. To provide long-term relief from chronic pain, various types of therapies are needed because often

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

more than one appropriate therapy exists. However, the education and training of nurse anesthetists do not provide them with the necessary training to diagnose and the knowledge to develop appropriate treatment plans. Compared to physicians, they do not receive necessary training in diagnostic assessment, anatomy in normal or abnormal states, disease presentation, in prescribing treatment or in the techniques of chronic pain interventions.

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.

The AANA has admitted that it has no existing methods to determine whether nurse anesthetists are qualified to perform interventional pain procedures. During the 2008 litigation in Louisiana regarding whether nurse anesthetists could perform interventional pain procedures, the president-elect of the 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).[5] Ultimately, the court concluded that the practice of interventional pain management is <u>not</u> within the scope of practice of a nurse anesthetist, and is solely the practice of medicine.

In comparison to nurse anesthetists, physicians who choose to practice anesthesiology complete 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 then begin their specialty residency training. In the case of anesthesiology, this is a three-year program. 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 chronic pain-related disorders during their residency program.

Anesthesiologists or other physicians choosing to specialize in pain medicine must then complete a minimum one-year multidisciplinary pain fellowship. They then apply to enter the examination process for board certification in pain medicine upon successful completion of medical school and their primary specialty residency. The requirement for multidisciplinary pain

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

medicine fellowship training is recognized by the ACGME, which oversees and accredits pain medicine programs.

b. The American Academy of Pain Management credentialing process is not rigorous and does not ensure that applicants are prepared to perform all chronic pain management services

It is ASA's opinion that American Academy of Pain Management certification of nurse anesthetists or other providers is not sufficient in and of itself for ensuring appropriate training for the treatment of chronic pain. The Academy, founded in 1988, is a nonprofit professional organization representing a broad array of disciplines that treat people with pain. According to the American Academy of Pain Management, its mission is to "advance the field of pain management using an integrative model of patient-centered care by providing evidence-based education for pain practitioners, as well as credentialing and advocacy for its members."[6] The American Academy of Pain Management offers its members credentialing, an e-newsletter, publications, continuing education, and an annual clinical meeting.[7] Notably, the American Academy of Pain Management states its credentialing "is not, and cannot be used as, Board Certification."[8]

Applicants for credentialing must sit for an examination, but the examination is extremely short and potentially asks few, if any, questions on interventional pain procedures, as discussed further below. The examination also does not contain any content on potential medical complications from these procedures. It is clear to ASA that the American Academy of Pain Management's credentialing process does not meet the high standards that CMS should demand of health care professionals who provide advanced care to patients with chronic pain, such as procedural interventions or prescription of controlled substances.

The American Academy of Pain Management's *Credentialing* brochure details the requirements to become credentialed.[9] First, the practitioner must be in good standing with regulatory agencies and professional associations, be a general member of the American Academy of Pain Management, meet entry-level requirements, and complete an application form. To meet the

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[6] American Academy of Pain Management, *Academy Vision*, http://www.aapainmanage.org/aboutus/Mission.php.

[7] American Academy of Pain Management, http://www.aapainmanage.org/aboutus/Professionals.php.

[8] American Academy of Pain Management, *Credentialing*, page 5, http://www.aapainmanage.org/literature/Forms/CredentialingBrochure.pdf.

[9] American Academy of Pain Management, *Credentialing*, http://www.aapainmanage.org/literature/Forms/CredentialingBrochure.pdf.

entry-level requirements, a practitioner is only required to have "a Bachelor's degree (or its equivalent) in a related health care field and two years of clinical experience working with people in pain or practicing pain management," and the clinical experience must be after education or training.[10] Current credentialed members' professions include massage therapy, oriental medicine, social work, and veterinary medicine.[11]

Second, the practitioner must pay a specified fee and be approved to sit for and pass an exam. Every discipline takes the same examination. The examination is only two hours and contains 120 questions, with 40 questions on assessment, 40 questions on treatment, and 20 questions on ethical, professional, legal, and business issues. Twenty questions are not scored.

Of the 40 questions on treatment modalities, 13 of the questions are on implementing 26 specific categories of treatment modalities. These treatments include: "physical activities, conditions, and activities of daily living, vocational rehabilitation counseling, work hardening, job placement, education of patient and others (family, employer third involvement party, etc.), family, recreational therapy, manual/manipulative therapy, and hot/cold therapy."[12] Since there are only 13 questions covering 26 treatment modalities, it is possible that the exam does not even cover interventional techniques, let alone ask more than one question on these important treatment options. The exam does not include content on addressing medical complications during treatment.

It is important to note that the American Academy of Pain Management is an entirely different organization than the American Academy of Pain Medicine. The American Academy of Pain Medicine is an organization for physicians practicing pain medicine in the United States, and "[m]embers represent a variety of origins, including anesthesiology, internal medicine, neurology, neurosurgery, orthopedic surgery, physiatry, and psychiatry."[13] Its core purpose is "[t]o optimize the health of patients in pain and eliminate the major public health

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[10] American Academy of Pain Management, *Credentialing*, page 5, http://www.aapainmanage.org/literature/Forms/CredentialingBrochure.pdf.

[11] American Academy of Pain Management, https://members.aapainmanage.org/aapmssa/censsacustlkup.query_page (queried credentialed member and profession).

[12] American Academy of Pain Management, *Credentialing*, page 8, http://www.aapainmanage.org/literature/Forms/CredentialingBrochure.pdf.

[13] American Academy of Pain Medicine, *AAPM: The Physician's Voice in Pain Medicine*, http://www.painmed.org/MemberCenter/About.aspx.

problem of pain by advancing the practice and the specialty of pain medicine."[14] The American Academy of Pain Medicine, and not the American Academy of Pain Management, is one of the organizations that represent the pain medicine specialty in the American Medical Association (AMA) House of Delegates.

c. The proposal is contrary to other stakeholders' and federal agencies' calls for increased health care professional education in pain care

Medicare contractors and private payers understand the significant differences between nurse anesthetists' and physicians' education and training, and require health care professionals to have advanced education in pain care in order to be paid for chronic pain management services. Two major Medicare contractors, Noridian Administrative Services and Wisconsin Physician Services (WPS), which serve 19 states, declined to use Medicare funds to pay for nurse anesthetists providing chronic pain services. The contractors concluded that the assessment skills required for the evaluation of chronic pain and development of a plan of care were "not part of the CRNA training curricula."[15] [16] The contractors' determination is in line with Blue Cross Blue Shield of North Carolina's stance on this issue, which only provides payment to physicians with a fellowship in pain medicine for pain management services.[17]

The federal government has also acknowledged the need for additional health care professional education in pain care. The IOM Report entitled, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, found that health care professionals have insufficient education and training in pain care, and ultimately recommended that,

> Health professions education and training programs, professional associations, and other groups that sponsor continuing education for health professionals should develop and provide educational opportunities for primary care practitioners and other providers to

[14] American Academy of Pain Medicine, *AAPM: The Physician's Voice in Pain Medicine,* http://www.painmed.org/MemberCenter/About.aspx.

[15]Noridian Administrative Services, LLC. CRNA Practice and Chronic Pain Management Revised. Medicare Part B News Issue 273. October 6, 2011, 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.

[16] WPS Medicare Certified Registered Nurse Anesthetist (CRNA) Practice and Chronic Pain Management August 16, 2012. http://www.wpsmedicare.com/j5macparta/resources/provider_types/crna-pain-management.shtml.

[17] Blue Cross Blue Shield of North Carolina. BCBSNC Pain Management Education Criteria http://www.bcbsnc.com/assets/providers/public/pdfs/PainManagementCriteria.pdf.

> improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing.[18]

The IOM Report found that CMS has a role to play in advancing pain care education, stating, "The Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, accrediting organizations, and undergraduate and graduate health professions training programs should improve pain education curricula for health care professionals."[19] Specifically, CMS "should provide financial support for advanced training in pain management."[20]

Importantly, the IOM Report recommends that the Secretary of HHS develop a strategy to improve pain care, and this strategy should include a plan for reimbursement. The recommendation specifically states that the Secretary should "develop a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and research that includes specific goals, actions, time frames and resources."[21] The proposed rule preempts this strategy. CMS should wait for the Secretary to outline such a comprehensive approach that will improve pain care. Allowing those without necessary education and training to provide advanced pain care is the complete opposite of the IOM proposal.

Finally, ASA is concerned that nurse anesthetists may believe they are competent to perform chronic pain management services when, in fact, they are not. The IOM report cited a study that concluded:

> Reorganization of graduate medical training programs to increase patient contact might improve residents' readiness to care for common pain conditions. However, physicians' beliefs about their ability to manage pain do not always match their actual competence, and physicians may not recognize deficits in their pain care knowledge … [There is] no correlation between physicians' confidence in their knowledge and abilities to manage pain and their ability to make good treatment decisions. Educators and policy-makers need to develop effective tools for self-assessment and creative ways of using these tools to helping [sic] physicians understand and remediate their knowledge and skill deficits.[22]

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[18] IOM Report, page 9 (recommendation 3-3).

[19] IOM Report, page 210 (recommendation 4-2).

[20] IOM Report, page 210 (recommendation 4-2).

[21] IOM Report, page 7 (recommendation 2-2).

[22] IOM Report, page 197.

If this is true for physicians who do receive training in managing chronic pain, it is even truer for those without such training. This is an example where a health care professional may think they can manage pain, despite not having the training to do so.

CMS, in the proposed rule, acknowledges that nurse anesthetists might not be adequately trained to provide chronic pain management services.[23] Given the above study's findings, ASA is extremely concerned that nurse anesthetists will incorrectly assume they have the education and training to provide chronic pain management services. Allowing this to happen will place patients at risk.

3. <u>The proposal will not improve access</u>

Physicians provide the overwhelming majority of chronic pain services, and adopting a national policy to include nurse anesthetists will not improve access. A variety of physicians with specialty training in chronic pain management – anesthesiologists, physiatrists, psychiatrists, neurologists, neurosurgeons, orthopedic surgeons and other medical specialists – appropriately deliver chronic pain services throughout the country. Medicare's own data shows that nurse anesthetists provide few, if any chronic pain services, and, in particular, do not provide these services in rural areas. **In fact, Medicare's data shows that physicians are the overwhelming providers of pain services, even in underserved areas, delivering over 99.8% of all services.**

A review of national Medicare claims data from 2010 shows that of the nearly 2.4 million Medicare claims for the most commonly billed chronic pain procedures, only 4,000 – less than one-quarter of 1% (0.17%) – were billed by nurse anesthetists. Similarly, in reviewing data associated with rural and underserved areas, the 2010 Medicare claims data from Health Professional Shortage Areas (HPSAs) for all procedures for acute and chronic pain showed only 27 (0.2%) claims from nurse anesthetists. Almost all of these procedures appear to be for acute pain management, specifically peripheral nerve injections. The same data shows that physicians billed for approximately 120,361 procedures in HPSAs during that same period of time. **In other words, only 1 in 4,000 patients in underserved areas received any pain treatment from a nurse anesthetist. This data shows patients are not seeking these services from nurse anesthetists, and this data reflects practice prior to the actions by Noridian and WPS.**

[23] "Simply because the State allows a certain type of health care professional to furnish certain services does not mean that all members of that profession are adequately trained to provide the service…As with all practitioners who furnish services to Medicare beneficiaries, CRNAs practicing in States that allow them to furnish chronic pain management services are responsible for obtaining the necessary training for any and all services furnished to Medicare beneficiaries."

Physicians referring for pain care did not refer to nurse anesthetists in rural areas before Noridian and WPS announced their payment policies, and they probably will not if CMS finalizes its proposal. Nurse anesthetists have not provided more than a minuscule amount of pain care in rural areas and this will not change. However, if CMS still believes there is an access issue in rural communities (despite evidence to the contrary), CMS should support sending pain care physicians to clinics in outlying areas. For example, hospital systems in rural states often send specialists to clinics in outlying areas and CMS should support sending physician pain specialists to rural areas to ensure that patients receive the highest quality chronic pain care. This could be part of the Secretary's comprehensive plan for improving pain care. As stated earlier in this letter, nurse anesthetists do not have the education and training to perform chronic pain management services. If this proposal is finalized it would result in inferior care for patients in both urban and rural areas.

4. **The proposal carries significant risk of fraud and abuse and will likely increase costs**

The Health and Human Services' Office of Inspector General (OIG) has found that common interventional pain procedures resulted in improper payments by Medicare. It is unclear why CMS would allow payment to another group of health care professionals such as nurse anesthetists who perform a low volume of services because low volume service providers had the highest error rates including demonstrating medical necessity. CMS should explain why they contend the proposal will not increase costs to the Medicare program. There is significant potential for a higher number of unnecessary procedures and other reasons for improper payments resulting from the proposal's attempt to increase the number of health care professionals available to perform interventional pain procedures. In addition, in 2010, all pain procedures reported by nurse anesthetists in HPSAs occurred outside the office setting. This is a more expensive setting than the office where much of physician-delivered interventional pain care takes place.

The OIG's September 2008 report, *Medicare Payments for Facet Joint Injection Services,* found that "Sixty-three percent of facet joint injection services allowed by Medicare in 2006 did not meet Medicare program requirements, resulting in approximately $96 million in improper payments."[24] Specifically, 38% of facet joint injection services had a documentation error, 31% had a coding error, and 8% had a medical necessity error.

Finally, the proposal will increase costs because it permits nurse anesthetists to bill directly – not "incident to" – for the service and receive 100% of the allowed amount under the Physician Fee Schedule. Pursuant to the Physician Fee Schedule, a physician can bill for a nurse practitioner's

[24] Department of Health and Human Service, Office of Inspector General. Medicare Payments for Facet Joint Injection Services. September 2008. http://oig.hhs.gov/oei/reports/oei-05-07-00200.pdf

(NP) services if those services are billed "incident to" the physician's services, as long as the physician meets certain requirements. If the service is billed "incident to," the practice receives 100% of the allowed amount for the service. If the service is not billed "incident to" and the NP bills directly for that service, the NP receives 85% of the allowed amount. Under the proposed rule, nurse anesthetists will bill directly for the service and will receive 100% – not 85% – of the allowed amount. This would further increase costs to the Medicare program. Also, we have previously described that chronic pain care is not part of "anesthesia and related services." The law allows 100% payment for anesthesia care to CRNAs under specified circumstances. If CMS finalizes this proposal, we do not see a statutory basis for paying these non-anesthesia services at a higher rate than other non-physicians would receive.

5. **The proposal is detrimental to efforts to curb prescription drug abuse, misuse, and diversion**

Chronic pain services include complex prescription medication regimens, often involving opioids. Specialized physician training is necessary to prevent potentially lethal side effects and medication dependency. In spite of widespread agreement across federal agencies that health care professionals need additional education on pain care and proper opioid prescribing, CMS is proposing a national policy that will encourage nurse anesthetists to prescribe opioids even though they are not required to have *any* clinical experience with chronic pain management as part of their training. CMS should reject the proposal on chronic pain care services and work with its sister agencies to adopt payment policies that will help – not hinder – efforts to improve pain care and reduce prescription drug abuse.

The White House Office of National Drug Control Policy (ONDCP) has identified prescription drug abuse as the country's fastest-growing drug problem. According to the Centers for Disease Control and Prevention (CDC), nearly 15,000 people in the United States died from opioid-based pain reliever overdoses in 2008. The CDC also found that the misuse and abuse of opioid pain relievers resulted in more than 475,000 visits to the emergency department in 2009, a number that has almost doubled in five years.

According to ONDCP's 2011 Prescription Drug Abuse Prevention Plan, most prescribers receive insufficient education and training on proper opioid prescribing:

> In addition, prescribers and dispensers, including physicians, physicians assistants, nurse practitioners, pharmacists, nurses, prescribing psychologists, and dentists, all have a role to play in reducing prescription drug misuse and abuse. Most receive little training on the importance of appropriate prescribing and dispensing of opioids to prevent adverse effects, diversion, and addiction. Outside of specialty addiction treatment programs, most healthcare providers have received minimal training in how to recognize substance abuse

> in their patients. Most medical, dental, pharmacy, and other health professional schools do not provide in-depth training on substance abuse; often, substance abuse education is limited to classroom or clinical electives. Moreover, students in these schools may only receive limited training on treating pain.[25]

In response to the Prescription Drug Abuse Prevention Plan, the Food and Drug Administration (FDA) announced that it would issue a Risk Evaluation and Mitigation Strategy (REMS) for long-acting and extended-release opioids (LA/ER). According to the FDA, REMS is a "risk management plan that FDA can require a drug company to develop and implement to manage serious risks associated with a drug." The central component of the REMS is a voluntary prescriber education program that will include drug information on LA/ER opioids; information on assessing patients for treatment; initiating therapy, modifying dosing, and discontinuing use of LA/ER opioids; managing therapy; and counseling patients and caregivers about the safe use of these drugs. Additionally, prescribers will learn how to recognize evidence of and potential for opioid misuse, abuse, and addiction.

Like FDA, HHS' Substance Abuse and Mental Health Services Administration (SAMSHA) provides training to physicians on prescription drug abuse online and in person, and "since 2007, 49 courses have been offered in 31 states with particularly high rates of opioid dispensing."[26] National Institutes of Health (NIH) Centers of Excellence in Pain Education (CoEPE) will also encourage prescriber education on opioids. According to NIH, CoEPEs will "act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools to enhance and improve how health care professionals are taught about pain and its treatment."[27] With regard to opioids, "[t]hese new CoEPEs can help prevent negative outcomes by designing curricula that promote appropriate screening and management of chronic pain patients, along with education about the risks of prescription drug abuse."[28]

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[25] Executive Office of the President of the United States. Epidemic: Responding to America's Prescription Drug Abuse Crisis. 2011. http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf.

[26] Statement of Director Kerlikowske before the Senate Caucus on International Narcotics Control: "Responding to the Prescription Drug Abuse Epidemic," http://www.whitehouse.gov/ondcp/news-releases-remarks/senate-intl-narcotics-caucus-statement-rx-drug-abuse

[27] National Institutes of Health Pain Consortium, *NIH Pain Consortium Centers of Excellence in Pain Education (CoEPEs)*, http://painconsortium.nih.gov/centers-of-excellence-in-pain-education.html.

[28] National Institutes of Health, *NIH Selects 11 Centers of Excellence in Pain Education*, http://www.nih.gov/news/health/may2012/nih-21.htm.

Ultimately, the proposal may also have the unintended consequence of encouraging the development of "pill mills." Some states may permit nurse anesthetists to prescribe controlled substances, but prohibit them from performing interventional pain services. For example, in Washington, D.C., nurse anesthetists are permitted to prescribe controlled substances,[29] but it is not within their scope of practice to perform interventional pain procedures.[30] These clinics may offer a prescription for controlled substances, but will not offer the full scope of pain medicine interventions that are necessary to treat patients with chronic pain.

6. Some state laws are silent as to whether chronic pain management is within nurse anesthetists' scope of practice

As the largest payer of claims, CMS is allowing the states to determine whether nurse anesthetists may provide chronic pain management services. Many states have not yet decided whether these services are within nurse anesthetists' scope of practice. Most states do not explicitly permit nurse anesthetists to perform chronic pain management services or they parrot the "anesthesia and related service" phrase that is subject to misinterpretation. It is unclear who will ultimately interpret state law and determine whether chronic pain management is within nurse anesthetists' scope of practice. Will it be the Board of Nursing or the Board of Medicine, each of which may have conflicts of interest when it comes to scope of practice? Will this require specific legislative language? Particularly in cases of conflict, it is also unclear whether making the determination will be a transparent process that is open for public input or whether providers can independently determine whether they "feel like" they are competent to perform this care. The vagueness of this proposal, if implemented, will undoubtedly create a chaotic environment in many states including, if history is any guide, costly litigation for financially strapped states. This is a huge distraction from our attempts to improve our healthcare system.

ASA reiterates that **chronic pain management is the practice of medicine**, and properly trained physicians provide essentially all interventional pain services in the United States, including in rural areas. CMS' proposal to use scarce Medicare dollars to expand coverage allowing nurse anesthetists to provide chronic pain services is fraught with risk to patients with no identifiable benefit to the Medicare program or to the patients served by the program. **The proposal should be rejected.**

Summary of Cost and Benefits

In the Summary of Cost and Benefits in the Executive Summary of the Proposed Rule, CMS raises concerns about improving payment for primary care services; primary care is not the only specialty that is undervalued. In July 2007, a Government Accountability Office (GAO) report

[29] 17 D.C. MUN. REGS. tit. 17, §§ 5709 (prescriptive authority) and 5710 (prescribing controlled substances)

[30] 17 D.C. MUN. REGS. tit. 17, § 5708

confirmed for the public and the Congress what anesthesiologists have known and struggled with for years: Medicare payments for anesthesia services are drastically low.[31] According to the GAO, Medicare payments for anesthesia services represent only 33% of the prevailing commercial insurance payment rates for the same service. In contrast, the Medicare Payment Advisory Commission (MedPAC) consistently reports Medicare's payments for other physician services represent approximately 80% of commercial rates when averaged across all physician services and geographic areas. Further, the anesthesia payment differential continues and may be expanding. Based on ASA's annual survey data, the 2011 Medicare anesthesia conversion factor was only 31% of even the lowest average commercial conversion factor for anesthesia.[32] The 33% problem will be exacerbated by the budget neutrality implications of efforts to address primary care payments in the rule.

As noted in the proposed rule, "Section 1848(b)(2)(B) of the Acts specifies that the RVUs for anesthesia services are based on RVUs from a uniform relative value guide, with appropriate adjustment of the conversion factor (CF), in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value." **We encourage CMS to take into account the established under-valuation of anesthesia under the Medicare Fee Schedule and extend appropriate protections to ensure that the fee schedule adheres to relevant requirements stated in the Social Security Act so that anesthesia payments are in fact consistent with other comparable services.**

Resource-Based Practice Expense (PE) Relative Value Units

When determining volume and time data to use in the calculations to determine indirect practice expense indices, CMS will make data adjustments based on payment policies and use of modifiers that impact payment. CMS states, "For anesthesia services, we do not apply adjustments to volume since the average allowed charge is used when simulating RVUs and therefore includes all discounts. A time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only occasion where time units are duplicative." **We do not agree that CMS should adjust time for a medically directed case when determining the indirect PE indices.**

Even if a reduction were indicated, ASA does not believe that the arbitrary choice of a 33% reduction accurately portrays the manner in which anesthesia services are provided in the care team mode. Claims for services that include the modifier QK represent medical direction of 2, 3 or 4 concurrent cases. **We strongly urge CMS to obtain data that would establish the**

[31] U.S. Government Accountability Office. *Medicare and Private Payment Differences for Anesthesia Services*, GAO-07-463, Washington, DC: Government Accountability Office, 2007.

[32] Byrd, Jason R. Loveleen Singh. *ASA Survey Results for Commercial Fees Paid for Anesthesia Services*, 2011. American Society of Anesthesiologists *NEWSLETTER*. October 2011. Vol. 75. Number 10: 38-41.

'typical' physician to nurse anesthetist/anesthesiologist assistant (AA) ratio. We would not necessarily agree that 1:3 is typical. We are confident that CMS is as eager as we are to make sure that payments are determined using the most accurate and current information available and we would welcome the opportunity to work with CMS to resolve this important issue.

CMS is operating under flawed assumptions about practice expense and anesthesia care and is not considering that:

1. Practice expense is not evenly divided across the time of the anesthesia service; and
2. Practice expense is not evenly divided between the anesthesiologist and the medically directed nurse anesthetists or AA.

When anesthesia care is provided in the care team mode with an anesthesiologist medically directing nurse anesthetists or anesthesiologist assistants, the anesthesiologist must:

- Perform a pre-anesthetic examination and evaluation;
- Prescribe the anesthesia plan;
- Personally participate in the most demanding procedures in the anesthesia plan, including if applicable, induction and emergence;
- Ensure that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified anesthetist;
- Monitor the course of anesthesia administration at frequent intervals;
- Remain physically present and available for immediate diagnosis and treatment of emergencies; and
- Provide indicated-post-anesthesia care.

These activities are performed by the anesthesiologist – not by the medically directed nurse anesthetists or AA – and do not represent duplicative services. Furthermore, most of these services are performed outside the parameters of reported anesthesia time. Each activity is done in a consecutive series of events for each case and there is no overlap in the time spent on each event between each patient. **Since the expense is borne by the anesthesiologist, the time for these activities are, for the most part, outside of anesthesia time, and they are without overlap from patient to patient, reducing the indirect PE based on an assumed medical direction concurrency rate of 1:3 gravely overstates any reduction that may be necessary in removing duplicative indirect PE. The proposed methodology should not be applied.**

If CMS remains concerned that the indirect practice expense indices for anesthesia do not accurately reflect the resources required to provide anesthesia care for a medically directed case, we suggest that the agency consider alternative methods to address that concern. For instance, perhaps CMS should consider whether the current payment structure for medically directed anesthesia cases – the full allowed amount is evenly divided between the anesthesiologist and the medically directed nurse anesthetists – needs to be re-evaluated. The medically directing anesthesiologist will carry the practice expense costs associated with the care. As such, perhaps the payment split should be 50% of the full allowed amount to the anesthesiologist and an appropriate figure that may be <50% of the full amount to the nurse anesthetist. This would correspond to some degree with the methodology used to determine payment for anesthesia care team cases when the anesthesiologist medically supervises the case as described with modifier AD.

Spinal Cord Stimulation Trial Procedures in the Nonfacility Setting

CMS requests the AMA/Specialty Society RVS Update Committee (the RUC) review the work and the practice expense for CPT® code 63650. This request is subsequent to a meeting between CMS and specific stakeholders to address those stakeholders' concerns about payment for the leads when this service is provided in a non-facility setting. ASA believes that since the work value for this code has recently been subjected to an intensive, multi-year review by the RUC and CMS, there is no need to again review the work value because the work has not changed since then. However, the direct practice expense inputs have not been developed for those instances where this service is performed in the office setting, and **we recommend that CMS revise its request to the RUC to limit the review of 63650 to assess only direct PE inputs in the office setting.**

Physician Payment, Efficacy and Quality Improvements –Physician Quality Reporting System

We appreciate CMS' efforts to align all the various quality programs to make processes more efficient for both providers and CMS. However, we ask that CMS be mindful of problems that could spread across these programs. For example, CMS recently granted a hardship exemption for anesthesiologists under the Electronic Health Record (EHR) Incentive Program because many anesthesiologists' practice patterns did not conform to a requirement that more than 90% of services provided are provided in an in-patient setting. This situation developed despite clear Congressional intent in the American Recovery and Reinvestment Act to classify anesthesiologists as hospital-based. CMS will need to show similar consideration when developing the definition of hospital-based for the purposes of the PQRS and VBM.

Because successful reporting of PQRS for value based payment modifier purposes is predicated on reporting at the group level, CMS must make certain that appropriate group reporting options

are universally available for 2013 PQRS (the base reporting period for the 2015 value based payment modifier). As proposed, groups with more than 99 eligible providers (EPs) are limited to two reporting options: web based Group Practice Reporting Option (GPRO) and Administrative Claims. These two options are specific to measures and metrics for chronic disease and preventative care; these measures are not germane to non-primary care, single specialty large groups like some anesthesiology groups. We believe that CMS has recognized that it will need to offer more flexible PQRS reporting options for these large groups. CMS could either make all options available to them (the two listed plus claims based, registry and EHRs) or CMS could link relevant measures to specialties reporting via the two proposed methods. While we are not clear as to why all options were not offered in the proposed rule, **we ask that CMS offer all group reporting options to all groups- without limitation to the number of EPs.** Group reporting may be new to many providers for 2013 if they have been successfully reporting PQRS as individual providers. **CMS should finalize the registration process (a step that is not part of reporting as an individual EP) as quickly as possible so that there is ample time for outreach to make certain that all interested groups understand how to register and to confirm that they have correctly done so.**

Group size could change throughout a reporting period. There may be some churn meaning that at some point in the year, a group's size could change and result in it being less than 25 EPs or more than 99 EPs or some other shift where its status in the group reporting methodology is impacted. CMS needs to be able to accommodate this situation or at very least, be very exact as to how it will handle them. CMS proposes in the rule that the size and composition of the group at the time it goes into a GPRO would carry throughout the year even if there were changes to the group within the reporting period. **All efforts should be made to make it possible for all groups to successfully report on applicable measures – for either PQRS or for VBM purposes.**

Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

For the VBM, CMS proposes to divide groups of 25 or more eligible professionals (EPs) into two groups: those that successfully reported PQRS (as defined by VBM not PQRS) and those that did not. CMS has asked for input as to whether those that did not successfully report should be differentiated between those who tried and were not successful and those who did not report at all. **There should be a distinction between a group that worked to report PQRS measures and one that did not.** CMS is launching a very complicated and complex program. All involved may encounter technical issues in this initial period and the program needs to allow for flexibility.

If a group successfully reports 2013 PQRS, it may elect to enter into quality/cost scoring. The method CMS will use to determine patient attribution will be a key element in implementing the VBM. CMS notes a "plurality of care" determination will not be applicable to single specialty

groups that do not report evaluation and management services. While we are pleased that CMS has recognized this concern, we do not agree that a "degree of involvement" determination is necessarily workable. **We request the opportunity to work with the agency to identify ways in which anesthesiologists may help achieve the goals of the VBM and to be recognized for that contribution.**

Other Considerations for the Selection of Proposed PQRS Quality Measures for 2013 and Beyond

While we understand the importance of National Quality Forum (NQF) endorsement of proposed measures, we also agree that CMS should work directly with specialties to ensure that each specialty is adequately represented by clinically relevant measures. CMS indicates that "we may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the [NQF]." The pace of implementation of programs like PQRS and the VBM means that physicians who provide more specialized types of care for which there is not yet a sufficiently robust set of established measure will face penalties under PQRS and other programs that are aligning with the PQRS measure set. CMS also instructs stakeholders developing measures to consider "measures groups that reflect the services furnished to beneficiaries by a particular specialty." We believe this consideration should be given equal weight to the other considerations CMS is requesting stakeholders take into account.

ASA has been working to establish additional quality metrics applicable to anesthesia care. On October 7, 2011 ASA proposed quality measures for potential inclusion in the 2013 PQRS program. These measures are not listed in the measures under consideration for 2013 as presented in the proposed rule**. Given the link between the 2013 PQRS program and implementation of the VBM, ASA asks that CMS reconsider and include the measures we previously submitted in the 2013 program.** At the very least we urge you to include these measures for PQRS in 2014. We have already re-submitted them in an August 1, 2012 communication and are happy to answer any questions the agency may have as it continues its review and ultimately renders a final determination.

Perioperative Temperature Management Measure (PQRS #193)

ASA submitted a revision of this measure to CMS that would have made it more oriented toward outcome rather than process. As part of this effort, we requested that the Category II CPT codes be updated to match the revision to the measure. Since CMS has not indicated that it intends to adopt this revision for 2013 PQRS, we have the situation in which the coding no longer corresponds to the measure. **If CMS does not include this revision in 2013 PQRS, we request that CMS remedy the coding misalignment by establishing a G-code to replace deleted CPT Category II code 4250F – Active warming used intraoperatively for the purpose of**

maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.

Proposed Measure #0493

ASA strongly encourages inclusion of NQF measure #493 "Participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed quality measures" as a PQRS measure. Multi-center registries of anesthesia care are now available to all anesthesiologists in the United States, enabling participants to compare their own outcomes to national and peer group benchmarks. ASA believes that participation in such a registry is an important component of ongoing quality improvement in anesthesiology.

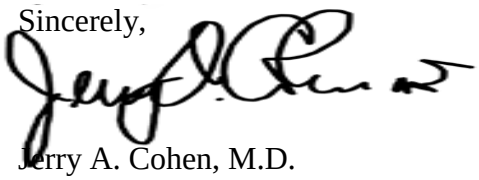
Conclusion

We firmly oppose CMS' proposal to create a new national policy to pay for chronic pain service delivered by providers who have no formal education in chronic pain medicine. **We urge you in the strongest possible terms to not adopt this proposed policy.**

If you have questions regarding the Certified Registered Nurse Anesthetists and Chronic Pain Management Services section of this letter, please contact Lisa Pearlstein, J.D. (l.pearlstein@asawash.org) Pain Medicine and Regulatory Lobbyist at (202) 289-2222.

If you have questions about any other section of this letter, please contact Grant Couch (g.couch@asawash.org) Federal Affairs Associate or Sharon Merrick, M.S. CCS-P (s.merrick@asawash.org) Director of Payment and Practice Management at (202) 289-2222.

Sincerely,



Jerry A. Cohen, M.D.
President
American Society of Anesthesiologists

Attachments