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# CMS Proposal for Interventional Pain Management by Nurse Anesthetists: Evidence by Proclamation with Poor Prognosis

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The Office of Inspector General (OIG), Department of Health and Human Services (HHS), in a 2009 report, showed that unqualified nonphysicians performed 21% of the services. These nonphysicians did not possess the necessary licenses, certifications, credentials, or training to perform the services.

Since the time the medical profession was founded, advances in treatments and technology, as well as educational and training standards, have promoted a desire to go beyond the basic scope of practice. Many have sought to broaden the scope of practice through legislative efforts and proclamation rather than education and training.

In 2001, President Clinton signed into law a rule that permitted states to "opt out" of the Centers for Medicare and Medicaid Services' (CMS) requirement for nurse anesthetists to be supervised by any physician. Since then, 17 states have adopted this rule. While it was originally intended to help rural areas improve access to care, the opt out rule essentially supports any hospital or organization that seeks to make a profit or cut costs by allowing nurse anesthetists to function as physicians. With the implementation of sweeping health care regulations under the Affordable Care Act (ACA, also popularly known as Obamacare), the future of nurses and other professionals has been empowered. In fact, it has been proposed that medical training may be reduced by 30%, which will in their minds equalize training between nonphysicians and physicians. In 2010, the Federal Trade Commission (FTC) issued an opinion exerting their power to empower CRNAs with unlimited practice, with threats to opposing parties. In the 2013 proposed physician payment rule, CMS is proposing that CRNAs may perform interventional pain management services.

Interventional pain management is a medical discipline with defined interventional techniques to be performed by professionals who are well trained and qualified. Without considering the consequences of the lack of education and training qualifications for CRNAs to offer interventional techniques, the FTC issued their opinion and CMS proposed to expand these practice patterns with a policy of improved access and reduced cost. However, in reality, the opposite will happen and will increase fraud, reduce access due to inappropriate procedures, and increase complications, all as a result of privileges by legislation without education. The CMS proposal for interventional pain management by nurse anesthetists is a proclamation with a poor prognosis.

**Key words:** Interventional pain management, interventional techniques, certified registered nurse anesthetists, evidence-based medicine, fraud and abuse, education and training.

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The Office of Inspector General (OIG), Department of Health and Human Services (DHHS), in a 2009 published report (1) reported that in the first 3 months of 2007, unqualified nonphysicians performed 21% of the services. These nonphysicians did not possess the necessary licenses or certifications, had no verifiable credentials, and lacked the training to perform the services (1). Further, nonphysicians with inappropriate qualifications performed 7% of invasive services in 2007. Yet, in 2010, the Federal

Trade Commission (FTC), issued an opinion against the Alabama Board of Medical Licensure that defining interventional pain management as the practice of medicine will be considered as a restriction of trade (2). In 2012, with the administration mired in implementing Obamacare (3,4), IOM produced multiple documents (5) empowering the nursing profession. Advanced care practitioners celebrated Obamacare's expansion of the scope of practice regulations.

The Centers for Medicare and Medicaid Services (CMS), which is headed by what has been described as the Chief Nursing Officer (Marilyn Tavenner, acting CMS Administrator) proposed the independent practice of interventional pain management for certified registered nurse anesthetists (CRNAs) (6,7). Administration officials never bothered to listen to physicians, but promptly responded to the request by the American Association of Nurse Anesthetists to provide them full freedom to practice interventional pain management, despite multiple protests from various organizations, including the American Society of Interventional Pain Physicians (ASIPP) (8-13). In fact, CMS responded to ASIPP (14) with a letter enumerating what was written by the American Association of Nurse Anesthetists. The factors related to nurse anesthetists practicing interventional pain management that have become the major focus of contention are certification, education, and qualifications; nonexistent issues of patient access; and imaginary cost savings.

## Background

Since the time professions were first founded, some professionals have sought the authority to do what others do. This pursuit has certainly been true in the health professions, where advances in treatments and technology, as well as educational and training standards, have promoted a desire to go beyond the basic scope of practice (15). As Roberts and Sutton (15) described in 2001, unfortunately the quest to expand the scope of practice sometimes creates conflict between the professions, and perhaps, leads to reduced safety and quality standards when practitioners try to provide services for which they are inadequately trained.

Since the 1990s many nonphysician health care professionals have actively sought legislative expansion for their scope of practice. This broadening of the scope of practice has included such things as increased autonomy and independence in their practice, redefinition of their profession to encompass more services and responsibilities, or simply establishment of licensure requirements (15). However, in many cases these attempts to expand scope intruded on services traditionally provided by other health care professionals, which has created so-called turf wars, even though there is a vast difference between the training and education of physicians and nonphysicians. The main debate has been related to the practice of medicine when nonphysicians try to acquire the statutory authority to perform procedures and provide services that physicians and surgeons have been extensively trained to do. In general, the argument is access and cost effectiveness. These arguments, which started in the 1990s, may have been to some extent accurate. However, in the twenty-first-century reimbursements are equal and the costs of delivering health care are significantly higher.

## Nurse Anesthetist Scope of Practice: Déjà vu

In 2001, President Clinton (whose mother was a nurse anesthetist) signed into law a rule that permitted states to "opt out" of the Centers for Medicare and Medicaid Services (CMS) requirement for nurse anesthetists to be supervised by any physician which was initiated by President Clinton himself in 1994 (16). Since then, 17 states (Iowa, Nebraska, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, Montana, South Dakota, Wisconsin, California, Colorado, Kentucky) have adopted this rule. While it was originally intended to help rural areas improve access to care, the "opt out" rule supports any hospital that seeks to cut costs by allowing nurse anesthetists to work alone.

The staffs of the FTC Office of Policy Planning, Bureau of Economics, and Bureau of Competition, wrote to the Alabama Board of Medical Examiners (2) stating that the proposed rule to restrict interventional techniques to interventional pain physicians was unnecessary and anticompetitive. AANA has used this position to mean that they are permitted to proceed with interventional techniques and there should not be any restrictions at all.

The implementation of sweeping health care regulations and the enactment of the Patient Protection and Affordable Care Act (ACA) (3,4) has thrown the entire health care system into a state of mass confusion. The Institute of Medicine (IOM) Future of Nursing report (5) created a sense of urgency to remove barriers preventing advanced practice registered nurses from practicing to their full scope of practice (6,7). However, this report was mainly authored by nursing professionals and their

supporters. With the Chief Nursing Officer as the catalyst for change (Marilyn Tavenner), nurse practitioners have described their own collaborative models and processes that resulted in expanded clinical privileges for nurse practitioners in an integrated health care system (6). However, the major change appears to be instead of an integrated health care system, it is an independent nurse health care system.

Apart from numerous regulations created under ACA (3,4,9,17-26), CMS issued new rules concerning the conditions of participation in Medicare and Medicaid for hospitals and health care providers (12). It appears that the Obama administration wanted to reform the health care regulations considered as unnecessary in their view (27). In particular, the administration asserted that the "use of advanced practice nurse practitioners and physicians' assistants in lieu of higher-paid physicians could provide immediate savings to hospitals." Consequently, in the new rules CMS proposes to remove barriers to the work of physician extenders. One example is not making them seek out a physician supervision or co-signature or collaboration (12).

## CRNAs as Interventionalists

Midlevel providers on every team are essential to health care. When patients go to a physician's office, these providers are essential, whether in primary care or a specialty, to provide independent care in certain cases and assist physicians. However, their role is to work as part of a team, not as a replacement for the physician.

Many anesthesiologists, including Jane Fitch, the first vice-president of American Society of Anesthesiologists, and Stephen Pyles, a board certified interventional pain physician, started their career as nurse anesthetists. The majority of them were troubled by the limited knowledge they had compared to the physicians they worked with, and so went back for 8 more years of education – completing medical school, residency, and then a fellowship in their chosen speciality. All of them will state that when they were nurse anesthetists, they "didn't know how much they didn't know (27)." In his testimony before the Tennessee Senate Subcommittee on Welfare, Health, and Human Resources, Jerry Epps, who has been chairman of the Department of Anesthesiology for many years at the University of Tennessee, stated that even though he has trained many anesthesiologists, pain physicians, and nurse anesthetists, if he had to do interventional pain management he would require additional training (28). He did not recommend any anesthesiologist perform interventional techniques without additional training.

In contrast, nurse anesthetists with much less training than an anesthesiologist, and with no training at all in interventional pain management or chronic pain (anesthesiologists do have significant training in chronic pain management) have been lobbying to expand their scope of practice to perform interventional techniques and practice interventional pain management and pain medicine. Once any ruling is approved by CMS, in contrast to the belief that each state and insurer has to approve it, Section 2706 of Obamacare prohibits discrimination by insurance companies against health care providers so long as they are acting within the scope of their licenses (2,27). The most disturbing news is that the scope of practice was decided by the board of nursing, which consists to a great extent of registered nurses.

Even though this clause sounds innocuous, like many other clauses in ACA this nondiscrimination clause opens the door for nonphysicians – like nurse anesthetists or chiropractors – to open clinics without physician oversight and bill insurers directly for interventional pain management procedures, both simple and complex (27). It is a well known practice in many states that chiropractors are opening interventional pain management clinics with a rent-a-doctor model and practicing suboptimal interventional pain management, thus increasing health care expenses, reducing access, and creating an unsafe atmosphere for interventional pain management. Numerous complications have not been taken into account. This philosophy is also supported by the American Hospital Association (29) along with some surgical specialties who may benefit by creating such a model of practice to order nurse anesthetists to perform interventional techniques, without appropriate assessment for indications, medical necessity, or outcomes. If that is the case, many interventional pain physicians may be able to perform trigeminal decompressions and intracranial surgical procedures.

Interestingly enough, while nursing professionals tout acting CMS administrator Marilyn Tavenner as the Chief Nursing Officer and as a catalyst for change, a physician very familiar with Ms. Tavenner as a registered nurse describes her as a team player, a go-getter, and a pragmatist-in-chief rather than an officer with the responsibility to provide independence to the nursing profession at the expense of interventional pain management's destruction (29). It is also interesting to note that in President Obama's administration, no CMS administrator has received appropriate senate approv-

al. No such efforts have been made to obtain senate approval for Ms. Tavenner (30), whereas, Donald Berwick was a recess appointment (31). In addition, Obamacare has vastly expanded the powers of the secretary of Health and Human Services and the CMS administrator.

## Interventional Pain Management

Interventional pain management is a specialized field of medicine, and is included within the broader medical field of chronic pain management. It involves a clinic-based approach to improve function and quality of life for a patient who suffers from a chronic disease state. Interventional pain management is not the delivery of anesthetics. Most interventional pain management 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.

Interventional Pain Management is 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 treatments (32).

MedPAC has defined interventional pain management techniques (33) as including percutaneous precision needle placement, with placement of drugs in targeted areas or destruction of targeted nerves; 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.

Chronic pain management has become a field of immense complexity. Twenty years ago pain management was largely the province of anesthesiologists who performed simple "blind" spinal injections in the hospital as a sideline service while providing anesthetic services. More complicated interventional pain management procedures, such as spinal cord stimulation (a spinal implant to control pain) were usually performed by a select group of neurosurgeons. Opioid analgesics were used infrequently and with great caution. Board certification in pain management for physicians was not established.

Much has changed. In 2011 the CDC released a policy impact statement characterizing prescription painkiller overdose deaths as a growing, deadly epidemic (34). The report noted that overdose death rates in the US had more than tripled since 1990. Opioid pain relievers were present in 74% (14,800 of 20,044) of the prescription drug overdose deaths that occurred in 2008, more than cocaine and heroin combined (34) (Fig. 1). Prescription opioid analgesics have become among the most prescribed of all medications in the US and are now considered to be the leading public health problem in the country (34).

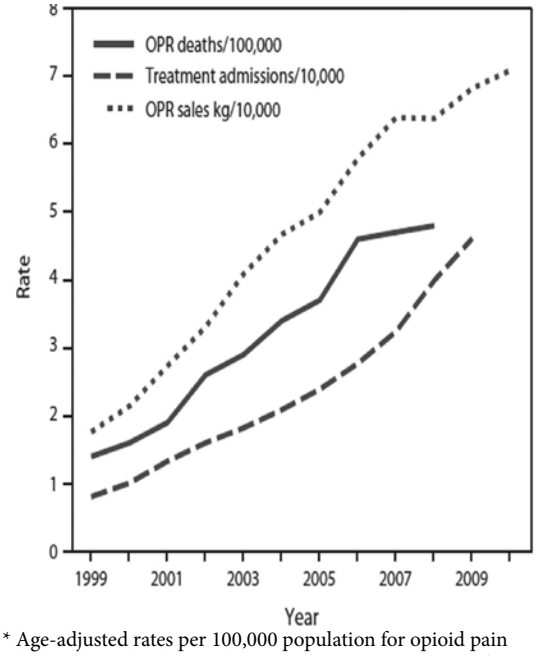
In response to its findings, the CDC issued recommendations aimed primarily at stricter state control of prescription drugs and health care provider accountability. For health care providers, education regarding appropriate prescribing for acute and chronic pain, and recognizing when to refer to a pain management physician, are recommended by the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA). Initiatives for formal Continuing Medical Education (CME) requirements for prescribing, even by physicians, are under consideration by legislative and regulatory bodies.

The Centers for Disease Control and Prevention (CDC) (35) also reported the percentage of prescription drug overdoses by risk group in the United States. They concluded that approximately 80% of prescribed low opioid doses, meaning less than 100 mg of morphine equivalent per day, were by a single practitioner, and accounted for an estimated 20% of all prescription overdoses (Fig. 2). In contrast, among the remaining 20% of patients, 10% were prescribed high opioid doses, meaning greater than 100 mg of morphine equivalent per day, (34-45) by a single prescriber accounted for an estimated 40% of the prescription opioid over-

dose fatalities (40,41). The remaining 10% of patients seeing multiple doctors, and typically involved in drug diversion, contributed to 40% of overdoses (42). This essentially translates to 60% of the deaths caused by opioid prescribing were caused by practitioners, whereas 40% were related to drug abuse. Further, multiple studies in the literature have reported an association between opioid prescribing and overall health status, with increased disability, medical costs, subsequent surgery, and continued or late opioid use (45).

Epidemiologic studies are less positive regarding improvement in function and quality of life when opioids are prescribed to chronic pain patients (45). In fact, an epidemiologic study from Denmark by Breivik et al (46) where opioids were prescribed liberally for chronic pain, demonstrated that in patients receiving opioids, pain was worse, health care utilization was higher, and activity levels were lower compared to a matched cohort of chronic pain patients not using opioids. In another study by Eriksen et al (47) these patients reported worse pain, higher health care utilization, and lower activity levels in the opioid-treated patients compared to a matched cohort of chronic pain patients not using opioids. In another study (48) evaluating the role of opioids, the odds of recovery from chronic pain were almost 4 times higher among individuals not using opioids compared with individuals using opioids.

Early opioid use, even in very low doses, functions as a gateway for future abuses and excessive uses. In fact, with only half the states permitting long-term opioid prescribing by advanced nurse practitioners, in-




* Age-adjusted rates per 100,000 population for opioid pain reliever(OPR) deaths, crude rates per 10,000 population for OPR abuse treatment admissions, and crude rates per 10,000 population for kilograms of OPR sold.

Fig. 1. *Rates of opioid pain reliever overdose death, opioid pain relief treatment admissions, and kilograms of opioid pain relievers sold – United States, 1999-2010.*

*Source: Centers for Disease Control and Prevention. Vital signs: Overdoses of prescription opioid pain relievers – United States, 1999-2008. MMWR Morb Mortal Wkly Rep 2011; 60:1487-1492 (34).*

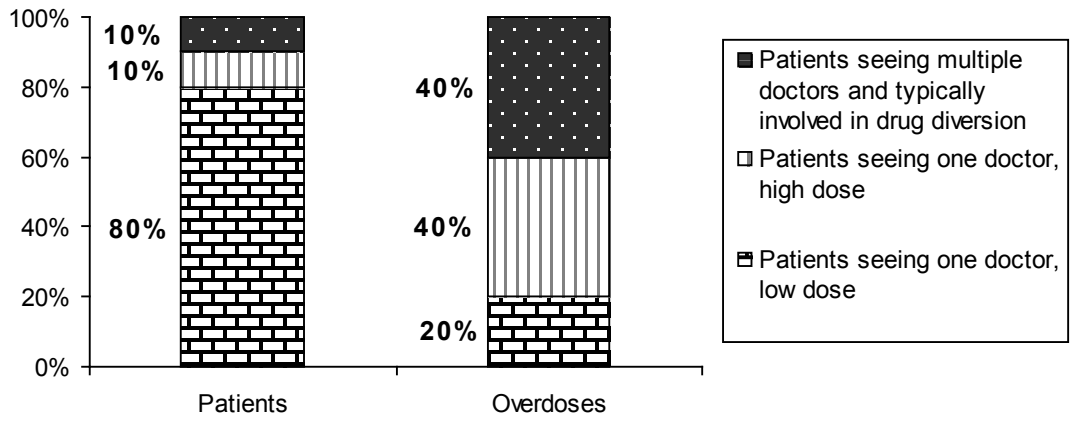



*Fig. 2. Percentage of patients and prescription drug overdoses, by risk group – United States.*
**Source:** *Centers for Disease Control and Prevention. CDC grand rounds: Prescription drug overdoses – a U.S. epidemic. MMWR Morb Mortal Wkly Rep 2012; 61:10-13 (35).*

cluding CRNAs, 7.5% of short-acting, immediate release opioids were prescribed by independent nurse practitioners and physician assistants. On the other hand, interventional pain medicine practioners, constituting anesthesiology and physical medicine and rehabilitation, who prescribe in all 50 states, prescribed less than 6% of these opioids (49-52). Further, as shown in Fig. 3, long-acting opioids were also prescribed to 10% of patients by independent nurse practitioners and physician assistants without including their practices in a team with physician supervisors. What is surprising is that the majority of the immediate release opioids and long-acting opioids were prescribed at primary care clinics where the majority of the nurse practitioners and physician assistants practice. In fact, CRNAs have published their experience in Washington State with having prescription authority. Approximately 30% of CRNAs held prescriptive authority to prescribe Schedule II through Schedule IV controlled substances (53).

Thus, 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, DC, nurse anesthetists are permitted to prescribe controlled substances (54), but it is not within their scope of practice to perform interventional pain procedures (55). These clinics may offer a prescription for controlled substances, but do not offer the full scope of pain medicine interventions that are necessary to treat patients with chronic pain. Thus, the entire spectrum of permitting nonphysician practitioners to manage chronic pain will lead to more fatalities, reduce access, and increase health care costs.

Even though there has been significant debate over the effectiveness of interventional techniques for managing chronic pain, the recent literature has provided substantial evidence that interventional techniques do manage chronic pain – however, all of the evidence has been produced by interventional pain physicians. Overall there is at least fair evidence for most interventional techniques when performed appropriately, thus it is not a panacea. The interventional pain management community and other physicians also have produced procedures and opioid guidelines (43-45,56-100).

## CMS Proposal

The CMS proposal, which is not a final rule, is part of the annual proposed rule that encompasses the suggested changes to Medicare's physician fee schedule (12). The final rule will be published in early November. The comment period has already closed by the time of

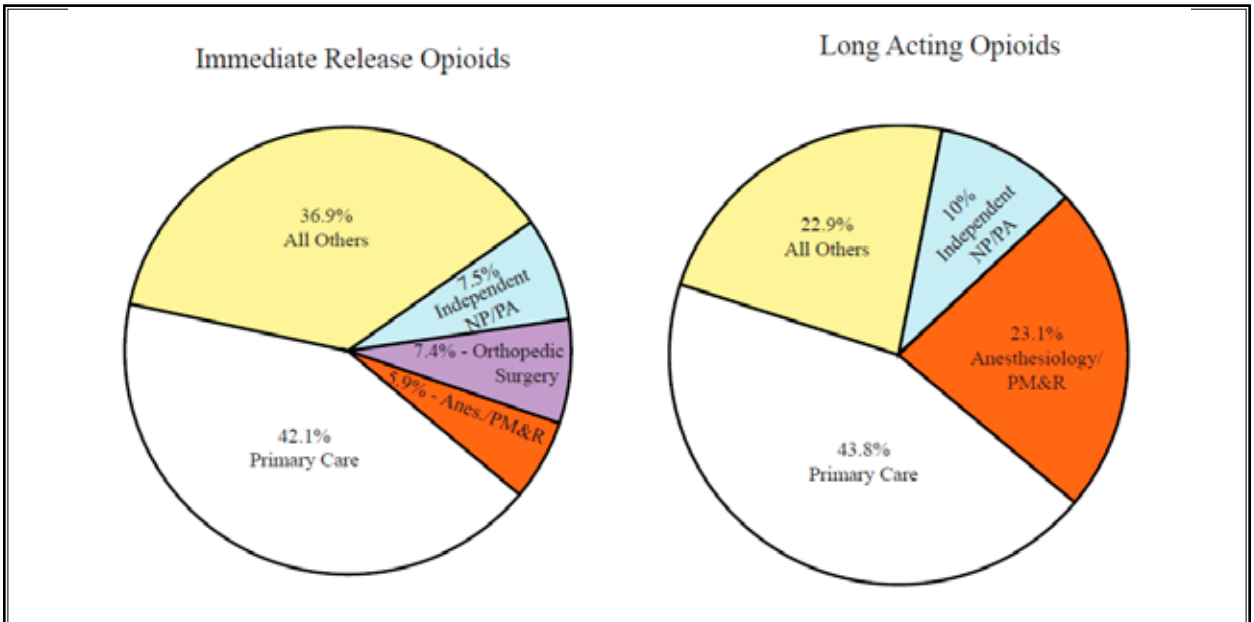



Fig. 3. *Total number of prescriptions dispensed in the U.S. by various specialties for IR and ER/LA opioids in 2009.*

this manuscript's publication. The proposal encompasses the following:

- It contains language as to what Medicare will pay regarding nonanesthesia services by CRNAs. It currently reads, "anesthesia and related care." The issue is what is "related care?" In the past, Medicare has limited payment to postoperative pain management. CMS has not been requested to clarify whether related care includes chronic pain. The CRNA organization has been lobbying to include chronic pain management and interventional techniques in their related care (12,101).
- Anesthesia and related care includes surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the state in which the services are furnished. The question arises how chronic pain management is related to anesthesia. CMS thinks chronic pain management is related to anesthesia, since the purpose of the amendment is to open the door to allow Medicare payments of chronic pain services by CRNAs if their state's scope of practice laws allow it (12,101).
- CMS acknowledges that although current federal regulations do not prohibit CRNAs from furnishing chronic pain services in those states that allow them to do so, Medicare regulations prohibit them from billing Medicare directly. In other words, currently CRNAs can provide chronic pain services if their states allow it, but they can't bill Medicare for those services as per the interpretation of CMS (12,101).
- A change in the language would allow CRNAs to invade the speciality of interventional pain management and bill Medicare directly, something they cannot legally do now, at least in some states. In those states that have opted out of Medicare, an argument could be made that CRNAs can open up their own chronic pain management practices, competing with board certified physicians. Further, we also have to take into consideration the provision in ACA, Section 2706, which prohibits discrimination by insurance companies against health care providers so long as they are acting within the scope of their license (2,12,27,101).
- Unfortunately, if the rule becomes final, the battleground will be fought in each state's legislature. However, this can also adversely affect CRNAs. They may also lose the battle of independently practicing anesthesia because of their request for independently practicing chronic pain management, even though the majority of CRNAs oppose practicing interventional pain management. In addition, this may also cause multiple problems to other advanced nurse practitioners who are attempting to increase their scopes of practice.

Based on the information obtained that CRNAs have been attempting to change the regulations (11), the American Society of Interventional Pain Physicians (ASIPP) contacted the Secretary of Health and Human Services, the Honorable Kathleen Sebelius, and expressed strong opposition (13). In response, Acting Administrator Marilyn Tavenner (14), a nurse at the helm of CMS, responded with the same language as used by CRNAs in their letter of request, essentially an advocacy position. The letter further stated that "under section 1861(bb)(1) of the Social Security Act, Medicare may cover and pay for "anesthesia services and related care furnished by a certified registered nurse anesthetist which the nurse anesthetist is legally authorized to perform as such by the state in which the services are furnished."

This letter clearly indicates a lack of research into the provision prior to embarking on proposing it, a lack of documentation of evidence of these nurses' training and ability to practice interventional pain management, issues related to access, and escalating health care expenses and lack of safety for the patients undergoing these procedures.

## Fraud and Abuse in Interventional Pain Management

As history repeats itself, interventional pain management has been heralded with claims of escalating use, fraud, and abuse (102-112). In general, overall the health care system has been criticized for exploding health care expenses for managing chronic pain (40-46,113-125). However, even an IOM report (125) provided a sobering view of managing chronic pain, calling for restricting opioids and interventional techniques, even when performed appropriately by physicians.

The Office of Inspector General of the Department of Health and Human Services has focused its attention on interventional techniques for several years (91,92,102-105). Medicare payments increased for facet joint injections from $141 million in 2003 to $307 million in 2006; payments for transforaminal epidural injections went from $57 million in 2003 to $141 million in 2007 (102). Of concern, 63% of facet joint injection

services and 34% of transforaminal epidural injections did not meet CMS' program requirements, resulting in improper payments of approximately $129 million for facet joints and $45 million for transforaminal epidural injections (103). An OIG study also showed that 21% of procedures were performed by nonphysicians without appropriate training (1).

To add fuel to this fire, at the same time a flood of practitioners has entered into the field of interventional pain management. It is this field and specifically the procedures associated with these services that the CRNA language is specifically designed to allow. Thus it is important to note that untrained practitioners have disproportionately contributed to an explosion in the utilization of interventional pain management procedures.

For example, the rate of increase for facet injections (2002 – 2006) performed in the Medicare population was reported at 100% annually for CRNAs (and nurse practitioners) (106). The use of fluoroscopy to guide these injections (a skill not taught in CRNA curricula but a mandatory requirement for safe and efficacious performance) was less than 19% in the general practitioner and nurse group while its use was nearly 90% in the interventional pain management group (106). At the same time, the OIG reported an error rate (procedures that did not meet Medicare reporting requirements) that was an astounding 100% for the nursing group but less than 12% for interventional pain management physicians (102). It should not be a surprise then that facet injections, imaging guidance, determination of medical necessity, and other interventional pain management practices are not part of CRNA anesthesia training.

For all of these reasons, many states have now enacted legislation that requires any pain management facility to be operated only by a physician and treatment rendered by physicians who are board certified in their primary specialty and also board certified in pain management (126-128). The usual 12 years or more of education and training is no longer adequate in these states – additional specific interventional pain management postresidency fellowship training and/or approved board certification requiring 1-3 years is necessary for physicians. No such training occurs in the 2 years of postgraduate education limited to anesthesia techniques received by CRNAs.

Many insurance companies also require that a physician be board certified in interventional pain management to be reimbursed for performing these procedures. As incongruous as this seems, CRNAs - with 2 years of nursing anesthesia training and no training at all in clinic-based medicine or interventional pain management procedures - are demanding to be paid precisely the same as board certified interventional pain management doctors for procedures that are disallowed by many national insurance companies even if performed by board certified anesthesiologists.

### Health Care Expenses

While overall health care expenses are increasing in the United States, the economic impact of chronic pain and various modalities of treatments provided to manage chronic pain are also skyrocketing (113-125). Gaskin and Richard (120) described the economic costs of pain in the United States. Their estimate is based on a 2008 medical expenditure panel survey and ranges from $560 to $635 billion in 2010 dollars. The additional health care costs due to pain ranged from $261 to $300 billion. Other reports evaluating spinal pain have shown these expenditures to range over $200 billion per year and they are escalating (117-124).

CMS has repeatedly utilized the explanation that cost savings from fraud and abuse alone will be sufficient to bend the curve of escalating health care costs. At the same time, in the guise of cost savings and increasing access, these proposed actions may contribute to fraud and abuse by empowering professionals without training to perform complex medical procedures, including interventional techniques.

## 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 a 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 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 (125).

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
- address disparities in the experience of pain among subgroups of Americans.

We agree with this approach. In fact, while CRNAs have no training in clinic-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. The proliferation of procedure-driven centers does not accomplish this goal and exacerbates the problems of overutilization. Moreover, the opportunity to provide clinic-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. However, these authorities, in an overzealous approach to empower nurses for services for which they are not trained, continue to create issues related to access. In fact, Kuehn (126) claims that if health care reform is to be a success, nurses must be allowed to play a greater role, both as caregivers and leaders, based on the study by the IOM. This report states that nurses have to be full partners with physicians and other health care providers in redesigning the health care system as per Donna E. Shalala, PhD, president of the University of Miami and chair of the panel that created the report. However, Shalala cautioned that the committee does not suggest that nurses substitute for other health professionals; rather, it seeks to ensure that nurses are used effectively and are fully represented "at the table." This has been translated to mean the independent practice of nurses and elimination of physicians.

The proposal will not improve access. 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 show 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 show 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 show 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. These data show patients are not seeking these services from nurse anesthetists, and these data reflect practice prior to the actions by Noridian and Wisconsin Physician Services (WPS).

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.

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 (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 would bill directly for the service and would receive 100% – not 85% – of the allowed amount. This would further increase costs to the Medicare program. The law allows 100% payment for anesthesia care to CRNAs under specific circumstances.

## Education, Training, Certification and Outcomes: Privileges by Legislation without Education

In the continuation of the theme of evidence by proclamation, privileges are provided by legislation without education, ignoring age old requirements. The twenty-first-century has witnessed numerous developments of interest to pain medicine. The unprecedented development and progress in managing chronic pain heralded the evolution of pain medicine. While there continues to be some debate on the role and differences between pain medicine, interventional pain management, and palliative care, they all share the common goal of relief of suffering (127). There has been a growing scientific interest in pain and various modalities, specifically interventional techniques, over the past several decades, even though opioid administration and biopsychosocial management have been the focus for a few decades.

The understanding of pain and interventional pain management has moved forward, occasionally with leaps and bounds, from Descartes' early conception of the pain pathway to Melzack and Wall's gate control theory (128,129), to evidence-based interventional pain management (56-100). Advances have been made by basic scientists and clinical researchers alike, representing numerous disciplines – including anesthesiology, surgery, rehabilitation, epidemiology, nursing, and psychology – now designated as specialists in pain medicine and interventional pain management. Thus, while nursing does occupy a part of interventional pain management, that is not the main profession for development and implementation of interventional techniques.

Interventional techniques date back to 1884 (130), with development of epidural injections in 1901 (133,134) and pioneering efforts for diagnostic interventional techniques (131,132) leading to the present state of the specialty. Over the years, interventional pain management, while marred by rapid developments and numerous issues, continued to grow. Pain medicine and interventional pain management have been represented by various groups, such as the formation of the International Association for the Study of Pain (IASP) in 1974 (135), largely as a result of the efforts of John Bonica; the establishment of the American Pain Society (APS) (www.ampainsoc.org/) in 1977 (136); the American Academy of Pain Medicine (AAPM) (www.painmed.org/) in 1983 (137); and finally, the American Society of Interventional Pain Physicians (ASIPP) (www.asipp.org) in 1998 (138).

The subspecialty of pain medicine was started in 1993, but only for board certified anesthesiologists with an accredited fellowship. Before 1993, training was frequently obtained in academic anesthesiology departments, mainly the program organized by Bonica. In the US, the American Board of Anesthesiology (ABA) developed an interest in certifying pain medicine training for obvious reasons, since pain medicine has its major origins and roots in anesthesiology. The first programs recognized by the Accreditation Council for Graduate Medical Education (ACGME) were accredited in 1993. The number of ACGME accredited programs and the number of trainees in accredited programs have grown steadily over the past decade, reaching almost 100 programs that train approximately 300 new pain specialists each year; there was, however a decline to 80 to 90 programs since 2006 due to stringent requirements. The ABA, working in parallel with the ACGME, developed a subspecialty certification examination in pain medicine (139). The same certification has been provided by the American Board of Physical Medicine and Rehabilitation (ABPMR) and the American Board of Neurology and Psychiatry (ABPN). Figure 4 illustrates the number of training programs accredited by ACGME in the United States. The ACGME accredited fellowships have provided a single curriculum for all programs. The ACGME curriculum for pain medicine (140) is extensive, as shown in Table 1.

Similarly, the content outline for the American

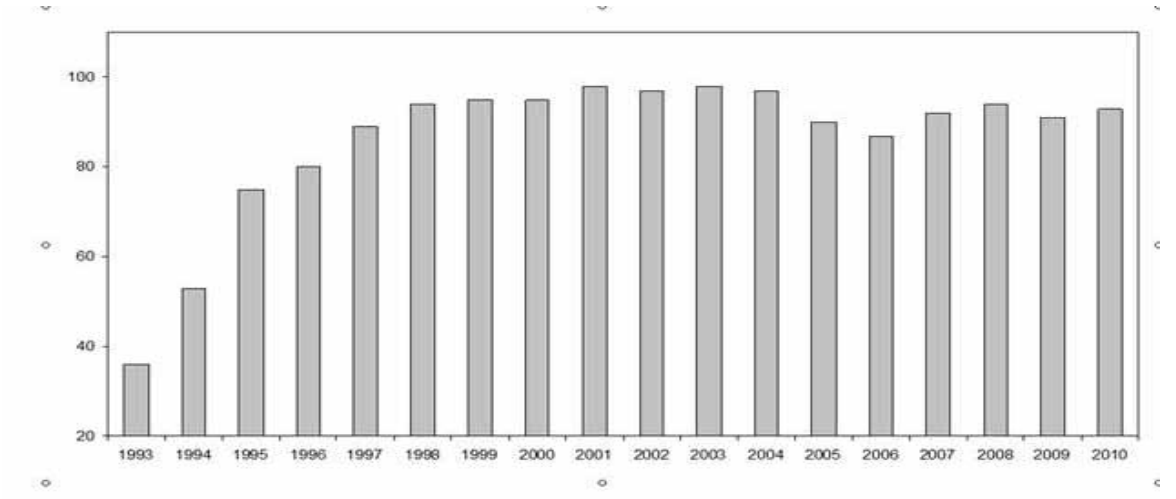



Fig. 4. *Illustration of the number of training programs accredited by the ACGME in the United States.*

Board of Medical Specialties (ABMS) pain medicine subspecialty examination is listed in Table 2. Since the inception of the pain medicine certification program in 1993, the ABA has issued 4,562 pain medicine certifications and 1,845 recertifications through 2011.

In addition, other groups providing certification, such as the American Board of Pain Medicine (ABPM) and the American Board of Interventional Pain Physicians (ABIPP) also have provided board certifications. These requirements are variable; however, all of them require primary certification by ABMS. Requirements for ABIPP certification are even more stringent than other examinations, as illustrated in Tables 3 and 4.

In contrast, there are no accredited or even nonaccredited programs for nurse anesthetists. Even if there were, they would have to be taught by physicians. In contrast, nurse anesthetists receive credentialing from the American Academy of Pain Management (AAPM). AAPM certification of nurse anesthetists or other providers is based on their ability to pay a fee without any training requirements (141). Founded in 1988, AAPM is a nonprofit professional organization representing a broad area of disciplines that treat people with pain. Their 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."

AAPM offers its members credentialing, an e-newsletter, publications, continuing education, and an annual clinical meeting. This examination or credentialing is not, and cannot, be used as board certification (141). Applicants for credentialing must sit for a nominal examination, which is extremely short and easy, attempting to accommodate all disciplines, including psychologists, nurses, chiropractors, and others with very few or no questions on interventional pain management. The examination also does not contain any content on potential medical complications from these procedures. This credentialing process does not meet any standards that CMS should demand of health care professionals who provide advanced care to patients with chronic pain, such as procedural interventions or the prescribing of controlled substances.

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

The AANA's own "Standards for Accreditation of Nurse Anesthesia Education Programs" specifically cites that no clinical experience with "pain management (acute/chronic)" is required as part of nurse anesthesia training (142).

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, com-

Table 1. *Accreditation Council for Graduate Medical Education (ACGME) recommended curriculum for pain medicine.*

| I. DIDACTIC CURRICULUM | II. CLINICAL CURRICULUM |
|---|---|
| A. Assessment of pain<br>1. Anatomy, physiology and pharmacology of pain transmission and modulation<br>2. General principles of pain evaluation and management including neurological exam, musculoskeletal exam, psychological assessment<br>3. Diagnostic studies: X-Rays, MRI, CT and clinical nerve function studies<br>4. Pain measurement in humans: experimental and clinical<br>5. Psychosocial aspects of pain, including cultural and cross-cultural considerations<br>6. Taxonomy of pain syndromes<br>7. Pain of spinal origin including radicular pain, zygapophysial joint disease, discogenic pain<br>8. Myofascial pain<br>9. Neuropathic pain<br>10. Headache and orofacial pain<br>11. Rheumatological aspects of pain<br>12. Complex regional pain syndromes<br>13. Visceral pain<br>14. Urogenital pain<br>15. Cancer pain, including palliative and hospice care<br>16. Acute pain<br>17. Assessment of pain in special populations: patients with ongoing substance abuse, the elderly, pediatric patients, pregnant women, the physically disabled, and the cognitively impaired; and<br>18. Functional and disability assessment<br>B. Treatment of pain<br>1. Drug Treatment I: opioids<br>2. Drug Treatment II: antipyretic analgesics<br>3. Drug Treatment III: antidepressants, anticonvulsants and miscellaneous drugs<br>4. Psychological and psychiatric approaches to treatment, including cognitive-behavioral therapy and treatment of psychiatric illness<br>5. Prescription drug detoxification concepts<br>6. Functional and vocational rehabilitation<br>7. Surgical approaches<br>8. Complementary and alternative treatments in pain management<br>9. Hospice and palliative care<br>10. Treatment of pain in pediatric patients<br>C. General topics<br>1. Epidemiology of pain<br>2. Gender issues in pain<br>3. Placebo response<br>4. Multidisciplinary pain medicine<br>5. Organization and management of a pain center<br>6. Continuing quality improvement, utilization review and program evaluation<br>7. Patient and provider safety<br>8. Designing, reporting and interpreting clinical trials of treatment for pain<br>9. Ethical standards in pain management and research<br>10. Animal models of pain, ethics of animal experimentation<br>D. Interventional pain treatment<br>1. Airway management skills<br>2. Sedation/analgesia<br>3. Fluoroscopic imaging and radiation safety<br>4. Pharmacology of local anesthetics and other injectable medications, including radiographic contrast agents and steroid preparations. This must include treatment of local anesthetic systemic toxicity<br>5. Trigger point injections<br>6. Peripheral and cranial nerve blocks and ablation<br>7. Spinal injections including epidural injections: interlaminar, transforaminal, nerve root sheath injections, and zygapophysial joint injections<br>8. Discography and intradiscal/percutaneous disc treatments<br>9. Joint and bursal injections, including sacroiliac, hip, knee and shoulder joint injections<br>10. Sympathetic ganglion blocks<br>11. Epidural and intrathecal medication management<br>12. Spinal cord stimulation<br>13. Intrathecal drug administration systems | A. The elements of pain medicine training from disciplines relevant to pain medicine:<br>1. Anesthesiology: the fellow will demonstrate competency in:<br>a. Obtaining intravenous access in a minimum of 15 patients<br>b. Basic airway management, including a minimum of mask ventilation in 15 patients and endotracheal intubation in 15 patients<br>c. Provider course in basic life support and advanced cardiac life support<br>d. Management of sedation, including direct administration of sedation to a minimum of 15 patients<br>e. Administration of neuraxial analgesia, including placement of a minimum of 15 thoracic or lumbar epidural injections using an interlaminar technique<br>2. Neurology: minimum of 5 observed patient examinations, 15 CT and/or MRI studies<br>3. Physical medicine and rehabilitation: experience hands-on experience in the musculoskeletal and neuromuscular assessment of 15 patients, and demonstrate proficiency in the clinical evaluation and rehabilitation plan development of a minimum of 5 patients<br>4. Psychiatry: conduct a complete mental status examination on a minimum of 15 patients, and must demonstrate this ability in 5 patients to a faculty observer<br>B. Core clinical curriculum<br>1. Outpatient (continuity clinic) pain experience: primary responsibility for 50 different patients followed over at least 2 months each must be documented<br>2. Inpatient chronic pain experience: minimum of 15 new patients<br>3. Acute pain inpatient experience: management of patients with acute pain, minimum of 50 new patients<br>4. Interventional experience: minimum of 25 patients who undergo interventional procedures<br>5. Cancer pain: longitudinal involvement with a minimum of 20 patients<br>6. Palliative care experience: longitudinal involvement with a minimum of 10 patients<br>7. Pediatric experience: strongly encouraged<br>8. Advanced education in interventional pain medicine<br>a. Image-guided spinal injection techniques cervical spine: 15 procedures<br>b. Image-guided spinal injection techniques lumbar spine: 25 procedures<br>c. Injection of motor joint or bursa: 10 procedures<br>d. Trigger point injection: 20 procedures<br>e. Sympathetic blockade: 10 procedures<br>f. Neurolytic techniques including chemical and radiofrequency treatment for pain: 5 procedures<br>g. Intradiscal procedures, including discography: 10 procedures<br>h. Placement of permanent spinal drug delivery system: 3 procedures |

From: ACGME Program requirements for fellowship education in pain medicine. Effective: July 1, 2007. www.acgme.org/acwebsite/downloads/rrc_progreq/sh_multipainPR707_tcc.pdf (140).

Table 2. *Content outline for ABMS pain medicine subspecialty examination.*

| | |
|---|---|
| **01. General** | |
| 01.01 | Anatomy and Physiology: Mechanisms of Nociceptive Transmission |
| 01.02 | Pharmacology of Pain Transmission and Modulation |
| 01.03 | Development of Pain Systems |
| 01.04 | Designing, Reporting, and Interpreting Clinical Research Studies about Treatments for Pain: Evidence-Based Medicine |
| 01.05 | Animal Models of Pain and Ethics of Animal Experimentation |
| 01.06 | Ethical Standards in Pain Management and Research |
| **02. Assessment and Psychology of Pain** | |
| 02.07 | Assessment and Psychology of Pain |
| 02.08 | Placebo and Pain |
| 02.09 | Clinical Nerve Function Studies and Imaging |
| 02.10 | Epidemiology |
| 02.11 | Psychosocial and Cultural Aspects of Pain |
| 02.12 | Sex and Gender Issues in Pain |
| **03. Treatment of Pain** | |
| A. Pharmacokinetics, Pharmacodynamics, Adverse Effects, Drug Interactions, And Indications/Contraindications | |
| 03.13 | Opioids |
| 03.14 | Antipyretic Analgesics: Nonsteroidals, Acetaminophen, and Phenazone Derivatives |
| 03.15 | Antidepressants and Anticonvulsants |
| 03.16 | Miscellaneous Agents: pharmacokinetics, pharmacodynamics, adverse effects, drug interactions, indications/contraindications |
| B. Other - Methods | |
| 03.17 | Psychological Treatments (Cognitive-Behavioral and Behavioral Interventions) |
| 03.18 | Psychiatric Treatment |
| 03.19 | Stimulation-Produced Analgesia |
| 03.20 | Interventional Pain Management Including Nerve Blocks and Lesioning |
| 03.21 | Surgical Pain Management |
| 03.22 | Physical Medicine and Rehabilitation |
| 03.23 | Work Rehabilitation |
| 03.24 | Complementary Therapies (CAM) |
| **04. Clinical States** | |
| A. Taxonomy | |
| 04.25 | Taxonomy of Pain Systems |
| B. Tissue Pain | |
| 04.26 | Acute Pain |
| 04.27 | Cancer Pain |
| 04.28 | Cervical Radicular Pain |
| 04.29 | Neck Pain |
| 04.30 | Lumbar Radicular Pain |
| 04.31 | Low Back Pain |
| 04.32 | Musculoskeletal Pain |
| 04.33 | Muscle and Myofascial Pain |
| C. Visceral Pain | |
| 04.34 | Visceral Pain |
| 04.35 | Chronic Urogenital Pain |
| 04.36 | Pain in Pregnancy and Labor |
| D. Headache And Facial Pain | |
| 04.37 | Headache |
| 04.38 | Orofacial pain |
| E. Nerve Damage | |
| 04.39 | Neuropathic Pain |
| 04.40 | Complex Regional Pain Syndromes |
| F. Special Cases | |
| 04.41 | Pain in Infants, Children, and Adolescents |
| 04.42 | Pain in older adults |
| 04.43 | Pain Issues in Individuals with Limited Ability to Communicate Due to Cognitive Impairment |
| 04.44 | Pain Relief in Substance Abusers |
| 04.45 | Pain Relief in Areas of Deprivation and Conflict |

Source: American Board of Anesthesiology: www.theaba.org/pdf/PMContentOutline.pdf

puted tomography, 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 interventional pain management for nurse anesthetists and other nonphysicians. Many boards of nursing have taken the position that if a CRNA wants to start practicing interventional pain management and perform these

Table 3. *Content for ABIPP Part I examination.*

| | |
|---|---|
| Anatomy and Physiology | 10% |
| Pharmacology | 10% |
| Psychology | 5% |
| Assessment of Pain | 5% |
| Diagnostic Testing | 5% |
| Pain Syndromes | 15% |
| Interventional Techniques | 15% |
| Non-Interventional Techniques of Pain Medicine | 10% |
| Coding, Compliance, and Practice Management | 10% |
| Controlled Substance Management | 10% |
| Ethics | 5% |

Table 4. *Most commonly used interventional pain management procedures.*

| | |
|---|---|
| 1. | Caudal epidural injections |
| 2. | Lumbar interlaminar epidural injections |
| 3. | Lumbar/sacral transforaminal epidural injections |
| 4. | Cervical epidural injections |
| 5. | Thoracic epidural injections |
| 6. | Lumbar/sacral medial branch and L5 dorsal ramus blocks |
| 7. | Cervical medial branch blocks |
| 8. | Thoracic medial branch blocks |
| 9. | Lumbar/sacral facet joint nerve radiofrequency neurolysis |
| 10. | Cervical medial branch radiofrequency neurolysis |
| 11. | Thoracic medial branch radiofrequency neurolysis |
| 12. | Sacroiliac joint injections |
| 13. | Cervical sympathetic blocks |
| 14. | Lumbar paravertebral sympathetic blocks |
| 15. | Intercostal nerve blocks |
| 16. | Lumbar discography |
| 17. | Celiac plexus blocks (not Splanchnic nerve blocks) |
| 18. | Percutaneous epidural adhesiolysis |
| 19. | Spinal cord stimulation lead placement |

procedures, then it is okay to do so and that 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. 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 a 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 toward 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, under an anesthetic a surgical pocket is fashioned in the operating room, then leads are 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 managed postoperatively for complications.

There is no aspect of the above vignette that is consistent with a CRNA's scope of practice - any more than placing a pacemaker or defibrillator. However, it accurately describes typical daily practice for an interventional pain management physician.

The art of medicine is defined by 2 pillars of clinical practice:

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

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 include "rendering a determination of medical necessity or appropriateness of proposed treatment (143)."

The American Medical Association at the November 2006 House of Delegates meeting rightly introduced 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 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 Ameri-

can Board of Medical Specialties.

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) (144). Ultimately, 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.

In fact, ASIPP opposes any untrained specialist physicians performing interventional pain management or practicing pain medicine.

In numerous letters to CMS and members of Congress, ASIPP has expressed their position and concerns in reference to various aspects, including training (13,145).

The American Society of Anesthesiologists (ASA) also produced an extensive document in reference to the ability of CRNAs to provide interventional pain management services (146). They urged 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 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."

ASA also elaborated on various aspects of this issue, including the following in reference to education, training, certification, and outcomes.

"Anesthesia and related care" does not include chronic pain care. In the proposed rule, CMS proposes that chronic pain should be included within "anesthesia and related care." However, chronic pain care is a subset of anesthesia or of care related to the provision of anesthesia along with other specialties. 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 AAPM, ASIPP 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 nonanesthesiologists 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 (147). It states:

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.

That same document also provides its definition of perianesthetic management (147).Thus, all of the standards for nurse anesthetists are related to providing anesthesia in the surgical setting; none of them relate in any way to chronic pain management.

The procedural aspects of treating chronic pain are also unique. For example, placing 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. Also, 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., It also 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 are irreversible.

Nurse anesthetists do not have the education and training necessary to perform chronic pain management services (146). 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. 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.

Becoming a nurse anesthetist does not require education and training in chronic pain management. Nurse anesthetists trained in the past 2 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. Nurse anesthetists are not required to receive any clinical experience with chronic pain management (146). In fact, 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 (147)."

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 more than one appropriate therapy exists. However, the education and training of nurse anesthetists do not provide them with the necessary training for diagnosing and the knowledge for developing 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.

In comparison to nurse anesthetists, physicians who choose to practice anesthesiology complete a bachelor's degree with a premedicine curriculum (four years), medical school (four years), and one additional year of hospital-based training in general medicine, pediatrics, surgery, or a combination (internship year). Physicians then begin their specialty residency training. In the case of anesthesiology, this is a 3-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 20 patients who are evaluated for management of acute, chronic, or cancer-related pain disorders during a specific 3-month period under the direction

of faculty physicians who have demonstrated expertise in pain medicine. Most residents treat many more than 20 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 medicine fellowship training is recognized by the ACGME, which oversees and accredits pain medicine programs.

The proposal is contrary to other stakeholders' and federal agencies' calls for increased health care professional education in pain care (147). 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 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" (148,149). 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 (150).

The federal government has also acknowledged the need for additional health care professional education in pain care. The IOM Report (125) titled, *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 improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing.

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" (125). Specifically, CMS "should provide financial support for advanced training in pain management" (125).

Importantly, the IOM report recommends that the secretary of HHS develop a strategy to improve pain care, and that 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" (125).

The IOM report cited a study that concluded: 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.

> 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 (125).

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 he 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.

## Creation of Profit Centers

This rule 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 in these settings.

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 (151-153). 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 sometimes have is blind epidural injections in obstetrics) be permitted to perform these complex interventional procedures.

Case Precedence

The inclusion of interventional pain management procedures in CRNA's 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 interventional pain management procedures (144). 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 (154), that CRNAs cannot practice interventional pain management. Noridian determined that CRNAs are not trained with curricula that teach assessment skills for evaluating chronic pain states and thus do not have the skills to manage such patients. WPS came to the same conclusion (155).

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 health care system.

Chronic pain management is the practice of medicine, and properly trained physicians provide essentially all interventional pain services in the US, including in rural areas. CMS' proposal to use scarce Medicare dollars to expand coverage by 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.

## Discussion

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

Current requests by CRNAs to enter into the practice of medicine, specifically the complex field of chronic pain medicine, without any formal education, train-

ing, 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 nonfacility settings.

It appears that CMS may be promoting a philosophy of empowering nurses and reducing physician education, thinking this will equalize the playing field, but it will equalize it only in their own mind. This philosophy may not be feasible considering that huge differences will still continue (156). The 30% reduction in medical training recommended by Emanuel and Fuchs (156) does not lower as much as to be equal to training for nurses. These policies will remove the role of the physician and the necessity for medical professions.

## Conclusion

In conclusion, CRNAs or other advanced practitioners have neither the education, training, nor qualification to perform interventional procedures safely. Allow CRNAs to perform them will increase health care costs, reduce access, and cause unnecessary suffering.

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## Disclosures

Dr. Caraway is a consultant for Medtronic, Inc., Spinal Modulation, Inc., and Vertos, Inc.

Dr. Falco is a consultant for St. Jude Medical Inc. and Joimax Inc.

Dr. Benyamin is a consultant with Bioness and Nevro, serves on the advisory boards of Vertos Medical and Nuvo Pharma, teaches/lectures for Vertos Medical, Boston Scientific, Neurotherm, and Bioness, and receives research/grants from Alfred Mann Foundation, Teknon Foundation, Spinal Restoration, Inc., Bioness, Boston Scientific, Vertos Medical, Medtronic, Kimberly Clarke, Epimed, BioDelivery Sciences International, Inc., Theravance, Mundipharma Research, Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP.

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