April 30, 2014

Donald Clark, Secretary  
Federal Trade Commission  
Office of the Secretary  
Room H–113 (Annex X)  
600 Pennsylvania Avenue NW  
Washington, D.C. 20580

[Submitted online at: https://ftcpublic.commentworks.com/ftc/healthcareworkshop/]

Re:  Health Care Workshop, Project No. P131207

Dear Mr. Clark:

The American Society of Anesthesiologists® (ASA®) appreciates the opportunity to comment on the Federal Trade Commission’s (FTC) Notice of Public Workshop, “Examining Health Care Competition” published in the Federal Register on February 24, 2014 (79 FR 10153). The ASA is a 52,000 member educational, research, and advocacy organization dedicated to improving the medical care of our patients and raising standards in the science and art of anesthesiology. Since its founding in 1905, the ASA’s achievements have made it the leading voice and the foremost expert in American medicine on matters of patient safety in the perioperative environment and in pain medicine.

The ASA commends the FTC for its efforts to learn more about the importance of professional regulation and the possible impact of such provisions on competition. Our comments will address the importance of professional regulation of health providers in promoting competition that leads to high quality patient care and protects patient safety. We will particularly focus on the positive impact of professional regulation in anesthesiology and pain medicine and the need for FTC deference and application of the state action doctrine to professional regulation by state medical boards.

The ASA has been a leader in improving patient safety in the field of anesthesiology for more than a century. It has developed standards of practice for anesthesiology and pain medicine, and the work of physician anesthesiologists and their professional organizations have been identified by the Institute of Medicine as an example of systematic efforts to improve patient safety and quality of care.\(^1\) In part through these efforts, the mortality rate from anesthetics has dropped from 2 deaths out of every 10,000 during the early 1980s\(^2\) to 1 death per 200,000-300,000 anesthetics administered in the year 2000.\(^3\) These improvements in patient safety resulted in large part from the development of high-quality training programs for physician anesthesiologists, training that nurse anesthetists do not have.

Professional regulation and deference to the expertise of state medical boards in this area is essential to maintaining these high standards of practice so that the more complex anesthesiology and interventional pain medicine services continue to be provided by those with education, training, and experience in this field.

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3. To Err is Human, supra note 1 at 241.
1. Professional Regulation in the Field of Anesthesiology Is Necessary to Achieve the Appropriate Balance Between Competition and Patient Safety

The Supreme Court long ago established that regulation of the professions is within the province of the states. This is a critical component of the states’ authority to regulate public health and safety under their broad police powers. The FTC has recognized that professional regulation by its nature both displaces and enhances competition and that consumer interests in the benefits of competition must be balanced against the protection of the public’s health. In an FTC report on Competition and the Regulation of Advanced Practice Nurses, the FTC acknowledged that:

Licensure and scope of practice regulations can serve an especially important function in health care. Consumers face serious risks if they are treated by unqualified individuals, and laypersons may find it difficult (if not impossible) to adequately assess quality of care at the time of delivery. . . . Consumers might have difficulty distinguishing between professionals who possess certain basic or general competencies and those with more specialized training and experience, as may be appropriate for particular health needs.

Indeed, the Supreme Court has recognized that professional regulation by the states can actually promote competition by addressing market failures such as the inability of consumers to assess the quality of services available and by generally enhancing informed decision-making by patients. Likewise, the performance of medical procedures by unqualified practitioners can lead to patient injuries or deaths, the costs of which are not factored into the price of the low-cost services provided by such practitioners.

The pro-competitive benefits of professional regulation to consumers are particularly evident for the complex fields of anesthesiology and pain medicine. As the FTC has recognized, “particular pain management procedures may require the specific training and experience of a board-certified anesthesiologist and … other particular interventions may require the special skills of a certified surgical sub-specialist.” This is because many complex anesthesiology and pain medicine procedures fall exclusively in the scope of practice of physician anesthesiologists who have additional training and experience relative to their nurse anesthetist counterparts. Even for procedures that both nurse anesthetists and physicians are qualified to perform, it is clear from the research that physicians achieve better patient outcomes and lower mortality rates.

To prepare for the split second decision-making required to medically address life-and-death emergencies that occur during surgery, physicians undergo nearly a decade of formal post-graduate medical education and residency training. Policymakers who confuse the skill and training needed for primary care with that needed for surgical anesthesia put patient welfare and safety at risk.

Consumers of anesthesia services are not in a position to ascertain for themselves these important distinctions in quality without the assistance of state medical boards. In this respect, professional regulation of anesthesia services actually promotes competition by providing consumers with better information about their

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7 Fed. Trade Comm’n, Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses at 12-13 (March 2014) (citations omitted).
8 Id.
choices for anesthesia care and by saving them the time and effort of having to evaluate for themselves the qualifications of physician anesthesiologists versus nurse anesthetist providers.

a. **Many complex pain medicine and anesthesiology procedures are exclusively in the scope of practice of physicians**

Anesthesiology and pain medicine present unique challenges to practitioners, both as to diagnosis and administering treatment and drugs. First, diagnosing pain and developing a treatment plan can vary significantly with the type of pain and by patient health status. For chronic pain alone, a treatment plan can involve nerve stimulation, nerve blocks, drug injections, and neurodestruction.¹¹

Second, the procedures themselves are often complex. For example, while interventional pain medicine primarily involves minimally-invasive procedures, these procedures are often administered in the spinal column and can lead to complications including allergic reactions, infections, bleeding, nerve and spinal cord damage, such as paraplegia or quadriplegia, and death. These treatments also require a high-level understanding of the drugs used for pain medicine and their potential side-effects. For example, neurodestructive treatment involves the injection of neurolytic agents and particulate steroids into the nerve to destroy it. When not performed correctly, this treatment can result in reduced blood flow leading to paraplegia, stroke, or death.¹²

Physicians have training and capabilities that nurse anesthetists do not when it comes to diagnosing and treating patients for chronic pain. Physicians go through a minimum of twelve years of training after high school, including their bachelor’s degree, medical school, internship, and fellowship, and log between 12,000 and 16,000 patient care hours before they can become board certified.¹³ Nurse anesthetists, on the other hand, have approximately half the years of training after high school, including their bachelor’s degree and a 2-3 year master’s degree in a nurse anesthetist program,¹⁴ and complete only 1,650 patient-care hours during their training.¹⁵

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, neurology, and psychiatry. The curriculum for physician anesthesiologists is wholly different than that for nurse anesthetists. Not only do pain medicine physicians complete the same medical coursework as other physicians, but they engage in training in the complex diagnoses that are necessary to treat patients with chronic pain, a subject area that is not part of the nurse anesthetist curriculum. Pain medicine physicians also receive training in interventional pain medicine in addition to their other medical specialty course work that nurse anesthetists do not undertake. The differences in these two curriculums are so stark that when the Council on Accreditation of Nurse Anesthesia Educational Programs tried to create an accreditation process for nurse anesthetists performing complex interventional pain medicine procedures, it gave up after finding a lack of pain medicine coursework for nurse anesthetists.¹⁶ To date, the Council on Accreditation of Nurse Anesthesia’s “Standards for Accreditation of Nurse Anesthesia Education Programs” does not require clinical experience with “[p]ain management (acute/chronic)” as part of nurse anesthetist

¹² Id.
There can be no question that there are many complex procedures that are not within a nurse anesthetist’s scope of practice and can only be performed by physicians.

b. Even when performing the same procedures, physicians have better outcomes than nurse anesthetists and nurse anesthetists may require supervision

Even when performing the same services, research shows that physician anesthesiologists are likely to have better outcomes and lower patient mortality than their nurse anesthetist counterparts. This research strongly suggests that even for more basic anesthesiology procedures, nurse anesthetists should work within the supervision of a physician. For example, one study found that there are 2.5 more deaths per 1,000 anesthesiology patients when a physician anesthesiologist is not involved and 6.9 more deaths per 1,000 cases for patients with post-operative complications. In another study, the odds of an “unexpected disposition,” or the odds during low-risk outpatient surgery of having an outcome other than being discharged to go home the same day, were 80 percent higher when anesthesia was provided by nurse anesthetists alone compared to care provided by physician anesthesiologists. These findings are supported by a similar study conducted by some of the same authors. Not surprisingly, an additional result of these “unexpected dispositions” is that they required further treatment and care, leading to additional costs.

Some research has reached a different conclusion about the relative quality of care provided by nurse anesthetists and physician anesthesiologists. For example, a 2010 Health Affairs article found that there was “no harm when nurse anesthetists work without supervision by physicians.” This research, however, is methodologically flawed. The researchers used an inaccurate metric of identifying which cases were performed by nurse anesthetists alone, did not distinguish between deaths caused by anesthesia and those caused by other complications of surgery, and did not account for differences in case mix by patient health status across physicians and nurse anesthetists. The objectivity of the Health Affairs study is also somewhat suspect as it was sponsored and funded by the American Association of Nurse Anesthetists (AANA).

The sum of this research suggests that even where physician anesthesiologist and nurse anesthetist scopes of practice overlap, patients experience better outcomes when physician anesthesiologists are involved in their care. While nurse anesthetists continue to be important contributors to the anesthesia care team, there are valid patient-safety reasons for nurse anesthetist-provided anesthesiology procedures to be conducted with physician supervision.

c. Policymakers confusing surgical anesthesia and primary care puts patients at risk

Surgery is a complex medical procedure with many opportunities for medical or surgical complications and emergencies to arise. Physician anesthesiologists play a critical role in surgery. While the surgeon operates, the physician anesthesiologist serves as the patient’s medical doctor in the operating room and responds to medical emergencies when they arise. Often, these emergencies have nothing to do with anesthesia,

21 Id.
22 See Brian Dulisse and Jerry Cromwell No Harm Found when Nurse Anesthetists Work Without Supervision by Physicians, 29 HEALTH AFFAIRS 1469 (2010).
23 Id.
but with the patient’s underlying medical condition or an unforeseen medical complication. Physician anesthesiologists, who have 12,000 to 16,000 hours of clinical training, are best prepared to address emergency medical situations. The ASA believes that Advanced Practice Registered Nurses (APRNs) play a significant and important role in the delivery of primary care. That supportive position, however, should not be seen as a replacement for the higher level of training and experience that physician anesthesiologists offer during surgery. Patients should not be subjected to the complex and high-risk nature of surgical anesthesia without a physician’s overall management of their care. In a recent American Medical Association survey, 77 percent of consumer respondents said they believed only a physician should administer and monitor anesthesia levels before and after surgery.24

d. Professional regulation of the scope of practice of anesthesiology promotes competition by reducing health care costs and enhancing informed patient decision-making

Some of the primary goals of competition in health care are to protect consumer interests by reducing prices and improving informed decision-making by patients. Appropriate professional regulation of anesthesia services supports all of these objectives.

First, limiting nurse anesthetists from performing services and/or procedures that are beyond the scope of their education and training without physician supervision reduces costs to patients and the health care system by avoiding the “unexpected dispositions” and additional care discussed above.25

Second, physician anesthesiologist supervision of nurse anesthetists through pre-surgical assessment and preparation of patients for surgery often leads to lower rates of unnecessary testing and preventable cancellations of surgery. In one study, physician anesthesiologist supervision of anesthesia services reduced additional medical consultations by 75 percent. It also reduced cancellations by 88 percent and additional laboratory tests by 59 percent.26 These effects are critical to holding down health care costs generally and patient costs specifically (e.g., insurance premiums and out-of-pocket costs).

Third, there is generally no additional cost to consumers or payors when they receive the expertise of a physician anesthesiologist as Medicare, Medicaid, and most third-party insurers actually reimburse anesthesiology services provided by physicians and nurse anesthetists at the same rate.

Indeed, as noted above, limiting professional regulation can actually harm competition by depriving patients of the information and safeguards they need to make informed choices about their health care. By licensing and regulating health care professionals and defining scope of practice, states provide critical information to consumers about the qualifications of different types of practitioners who may be available to treat a particular type of condition. They also spare the consumers the extensive time it would take to evaluate the educational background and training of various practitioners and try to determine for themselves whether specific practitioners are capable of providing the needed treatment. Licensure provides a proxy for minimum qualifications in a particular field which allows the consumers to make better choices about who they choose for their treatment.27

This is particularly true in the field of anesthesiology where there are technical aspects of anesthesia administration that could be performed by a nurse anesthetist with physician supervision. Within those areas of

25 Memtsoudis, supra note 18.
potential overlapping practice, state licensure and scope of practice regulation allow patients to make a more informed decision about which type of practitioner to choose, while reducing the costs to patients and society of unexpected dispositions, injuries/deaths, and unnecessary treatment.

2. States Are in the Best Position to Make Policy Judgments Regarding Scope of Practice and Such Decisions Should Be Protected by the State Action Doctrine

All 50 states have established a policy of regulating the scope of medical practice through state medical boards comprised of practicing physicians with expertise in the fields they regulate. Professional regulation of medical practice generally, and in the fields of anesthesiology and pain medicine particularly, is necessary to protect patients and is within the traditional power of states to regulate public health and safety. The FTC’s current policies regarding state medical boards and professional regulation both violate the state action doctrine and discourage physicians on state medical boards from exercising their best medical judgment for fear of antitrust liability.

a. The FTC’s policy of bringing antitrust enforcement actions against state medical boards violates the state action doctrine and principles of federalism

FTC enforcement actions brought against state medical boards violate the state action doctrine and the principles of federalism that lie behind it. As first established in Parker v. Brown, state medical boards are state agencies and their actions are acts of government that fall outside the scope of federal antitrust laws. The Court in Parker reached this conclusion despite the fact that the California Agricultural Prorate Advisory Commission at issue was comprised of a majority of private actors with a financial interest in the market they were regulating. Apparently, the Court was satisfied by the fact that the prorate program supervised by the Commission “derived its authority and its efficacy from the legislative command of the state . . .” Where state medical boards are similarly comprised of state-appointed, practicing physicians, they are state actors and should receive the full protection from antitrust scrutiny afforded by Parker.

Even if state medical boards could be treated as quasi-governmental entities, they would still be exempt under the California Retail Liquor Dealers Association v. Midcal Aluminum, Inc. test under which the actions of private individuals can be treated as state action if they are (1) made pursuant to a clearly articulated state policy and (2) subject to active supervision from the state. Indeed, because they are, by definition, state agencies, medical boards would not even need to satisfy the active supervision requirement. In Town of Hallie v. City of Eau St. Clair, the Supreme Court stated that prong two of this test, the active supervision requirement, likely would not apply to state agencies. Many Circuit Courts have applied this holding to agencies similar to state medical boards. The FTC’s policy of subjecting state medical boards to the active supervision requirement, and the Fourth Circuit’s holding in North Carolina Board of Dental Examiners v. FTC supporting the FTC’s position, contradict this established case law.

In addition, while the FTC has indicated that a clearly articulated state policy requires more than a general grant of authority, and the Supreme Court has held that the regulations must be “the foreseeable

30 Parker, 317 U.S. at 350-52.
33 See Earles v. State Board of Certified Public Accounting, 139 F.3d 1033, 1041-42 (5th Cir. 1998) (exempting a board of certified public accounting from the state supervision prong of the Midcal test); Hass v. Oregon State Bar, 883 F.2d 1453, 1459-60 (9th Cir. 1989) (exempting a state Bar from the state supervision prong of the Midcal test).
34 North Carolina Board of Dental Examiners v. F.T.C., No. 12-1172 , slip op. at 17-18 (4th Cir. 2013).
35 In the Matter of South Carolina State Board of Dentistry, 138 F.T.C. at 253.
result” of the state mandate, most courts have adopted a more permissive interpretation of what this means. For example, in Earles v. State Board of Certified Public Accountants, the Fifth Circuit Court of Appeals held that an authorization to “[a]dopt and enforce all rules and regulations, bylaws, and rules of professional conduct as the Board may deem necessary and proper to regulate the practice of public accounting in the State of Louisiana” was a sufficiently clear articulation. The Supreme Court has also held that a state legislature need not explicitly state that a board or agency may displace competition to satisfy this requirement. By this metric, most state legislative directives to medical boards should be sufficient to satisfy the state action doctrine. So long as the board is then acting within its legislative mandate, which generally includes the licensing of physicians and the definition of the scope of the practice of medicine, it should be exempt from antitrust liability.

b. The FTC’s enforcement actions put physician members of state medical boards in the position of having to compromise their medical judgment in favor of FTC policy

When the FTC pursues antitrust enforcement actions against state medical boards that are protected by the state action doctrine or when it writes letters to states advising them to adopt policies that favor competition, it is inappropriately interfering with the ability of the physicians who serve on such boards to exercise their best professional judgment regarding licensure and scope of practice matters. State medical boards are primarily comprised of physicians for many of the same reasons that the scope of medical practice may be limited to these practitioners: physicians have more experience and training, and typically achieve better outcomes than their nurse anesthetist counterparts, placing them in the best position to define the scope of medical practice.

Under the FTC’s enforcement policies, however, physicians currently serving on medical boards will be more likely to allow their best medical judgment on scope of practice decisions to be influenced and inhibited by concerns about antitrust liability. The Alabama Board of Medicine, for example, retracted a proposed board policy limiting the practice of interventional pain medicine to licensed physicians. This retraction followed an FTC letter encouraging the board to reconsider its regulation in this area. FTC comments on board policies may therefore be pushing the physician members of these boards to abstain from limiting the scope of practice of interventional pain medicine to physicians, despite the high risk and complications of these treatments discussed previously, out of fear they will be subject to treble damages actions if they don’t comply.

The FTC’s actions will also make it increasingly difficult to persuade good physicians to sit on medical boards because of the fear of liability. In the context of state bar associations, the Supreme Court has stated “[t]here is no question that the threat of being sued for damages – particularly where the issue turns on subjective intent or motive – will deter “able citizens” from performing this essential public service.” The same principle would apply to state medical boards.

While these might be acceptable outcomes when dealing with private bodies that engage in professional self-regulation, it is completely inappropriate when it comes to state agencies that are making decisions pursuant to clearly articulated state policy. In essence, the FTC is interfering with the state’s fundamental right to exercise its police power free from federal interference.

37 Earles, 139 F.3d at 1043-44.
38 Id. at 1043 (quoting LA Rev. Stat. Ann. § 37.75(B)(2) (West 1988)).
39 See City of Columbia, 499 U.S. at 372.
40 Earles, 139 F.3d at 1041. In contrast, the Supreme Court in Goldfarb v. Virginia State Bar withheld antitrust immunity from the Virginia State Bar. 421 U.S. 773 (1975). The Bar had been enforcing minimum fee schedules that were outside of its legislative authority. Id. at 790. Where medical boards are instead acting pursuant to a legitimate grant of legislative authority to determine the scope of the practice of medicine, they are immune to antitrust enforcement under the state action doctrine.
41 Letter from Mark A. Warner, supra note 11.
42 Letter from Susan S. DeSanti, supra note 10.
These consequences are particularly inappropriate in the health care field generally and anesthesiology and pain medicine specifically. The FTC has no particular expertise in regulating health care and risks inflicting serious harm on patients by adopting enforcement policies that appear intended to promote competition over quality of treatment and patient safety. The risk is particularly high in the field of anesthesiology where, for many procedures, patients’ lives are at stake and only licensed physician anesthesiologists are capable of providing competent and safe treatment. In these circumstances, FTC interference with the long-established right of states to regulate scope of medical practice is not only contrary to established judicial guidance, but costly and dangerous to patients.

Conclusion

There are important patient safety reasons to limit the full practice of anesthesiology to physician anesthesiologists and to require physician supervision of nurse anesthetists. These regulations are actually pro-competitive in that they reduce costs to patients and society, and enhance informed patient decision-making. Thus, professional licensure and scope of practice regulation is a critical function of the states. In carrying out this function, the states rely on the expertise of licensed, practicing physicians who are in the best position to define the scope of practice of medicine.

The FTC’s recent increase in regulatory enforcement actions against state boards, its letters to state boards encouraging them to abstain from regulating, and its position that state boards should be composed of at least half lay persons are all in stark opposition to the state action doctrine and the principles of federalism and deference to state policy decisions that lie behind it. The agency’s actions can have tremendous negative effects on the ability of state medical boards to protect the safety and welfare of patients and to provide the pro-competitive benefits of professional regulation, particularly in the fields of anesthesiology and pain medicine. Accordingly, we would strongly encourage the FTC to modify its position on the application of the state action doctrine to state licensing authorities and its related enforcement policies against these bodies.

Thank you again for the opportunity to provide comments on this important issue. If you have any questions or need additional information, please contact Jason Hansen, M.S., J.D., director of state affairs, at j.hansen@asahq.org or by phone at 202-289-2222.

Respectfully yours,

Jane C.K. Fitch, M.D.
President

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45 See, e.g., Letter from Susan S. DeSanti, supra note 10.