UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

November 3, 2010

Patricia E. Shaner, Office of General Counsel
Alabama State Board of Medical Examiners
Post Office Box 946
848 Washington Avenue (36104)
Montgomery, Alabama 36101-0946

Dear Ms. Shaner:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition[1] appreciate this opportunity to comment on the proposed regulation of interventional pain management services (Proposed Rule) issued by the Alabama State Board of Medical Examiners.[2] The Proposed Rule restricts the "interventional treatment of pain" to "qualified, licensed medical doctors and doctors of osteopathy,"[3] who "may not delegate to non-physician personnel the authority to utilize such procedures to diagnosis [sic], manage or treat chronic pain patients."[4] The rule appears to prohibit certified registered nurse anesthetists (CRNAs) from performing, under the supervision of a physician, pain management procedures that the Board of Nursing considers within the scope of CRNA practice.[5] Absent evidence that the proposed restrictions are necessary to protect the public, there appears to be no reason to sacrifice the benefits of CRNA pain management services as currently available under Alabama law.

Unnecessary restrictions on the ability of physicians to provide pain management services in collaboration with CRNAs are likely to reduce the availability, and raise the prices, of pain management services in Alabama. In particular, the Proposed Rule may burden cancer

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[1] This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission ("Commission") or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

[2] *See* Alabama State Board of Medical Examiners, Proposed Rule 540-X-15, Interventional Pain Management, *available at* http://www.ala-crna.org/download/ALANA-Call-to-action-BMEP-rule.pdf [hereinafter Proposed Rule].

[3] *Id.* at 540-X-15-.01, 540-x-.05.

[4] *Id.* at 540-x-.04.

[5] *See, e.g.*, In re Steve Sykes, MD, Petition for Declaratory Ruling Before the Alabama Board of Nursing, 4-6 (Mar. 19, 2010), *available at* http://www.abn.state.al.us/UltimateEditorInclude/UserFiles/docs/Declaratory-Ruling/AP-Steve-Sykes.pdf (enumerating various interventional pain management procedures currently within the scope of CRNA practice).

patients and others with chronic pain, rural Alabamans and others whose access to health care, or ability to pay for it, is limited, and hospice patients.

We therefore urge the Board to consider carefully the impact of the Proposed Rule and to avoid adopting provisions that would limit the role of CRNAs in pain management more strictly than patient protection requires. The Proposed Rule provides no evidence that the current practice has harmed patients. Further, studies that have examined CRNA provision of anesthesia services have not found safety or quality defects in CRNA practice.[6]

Interest and Experience of the Federal Trade Commission

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[7] Competition is at the core of America's economy,[8] and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, more choices, and greater innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key target of FTC law enforcement,[9] research,[10] and advocacy, such as this letter.[11] Recently, FTC staff have urged several states to reject or narrow restrictions that limit health care access and raise prices to consumers by limiting competition among health care providers and professionals.[12]

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[6] *See, e.g.*, A.F. Smith, et al., *Comparative Effectiveness and Safety of Physician and Nurse Anaesthetists: A Narrative Systematic Review*, 93 BRIT. J. ANAESTHESIA 540, 544 (2004) (review article examining U.S. and foreign studies finding "no recent, high-level evidence that there are significant differences in safety between different anaesthesia providers"); Paul F. Hogan et al., *Cost Effectiveness Analysis of Anesthesia Providers*, 28 NURSING ECON. 159, 161 (2010) ("there are no studies that show a significant difference between CRNAs and anesthesiologists in patient outcomes.").

[7] Federal Trade Commission Act, 15 U.S.C. § 45.

[8] *See National Society of Professional Engineers v. United States*, 435 U.S. 679, 695 (1978) ("The heart of our national economy long has been faith in the value of competition.").

[9] *See generally, e.g.,* FEDERAL TRADE COMMISSION (FTC), FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Mar. 2008), *available at* http://www.ftc.gov/bc/0608hcupdate.pdf ; *see also* Competition in the Health Care Marketplace: Formal Commission Actions, *available at* http://www.ftc.gov/bc/healthcare/antitrust/commissionactions.htm.

[10] *See, e.g.*, FTC & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 7 (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[11] FTC and staff advocacy may comprise letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.*, Letter from FTC Staff to Hon. Timothy Burns, Louisiana Legislature, (May 1, 2009) (regarding proposed restrictions on mobile dentistry); *available at* http://www.ftc.gov/os/2009/05/V090009 louisianadentistry.pdf; FTC and Department of Justice Written Testimony before the Illinois Task Force on Health Planning Reform Concerning Illinois Certificate of Need Laws (Sept. 2008), *available at* http://www.ftc.gov/os/2008/09/V080018illconlaws.pdf; FTC Amicus Curiae Brief in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* Concerning Drug Patent Settlements Before the Court of Appeals for the Federal Circuit (Case No. 2008-1097) (Jan. 2008), *available at* http://www.ftc.gov/os/2008/01/080129cipro.pdf; FEDERAL TRADE COMMISSION AND THE DEPARTMENT OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (July 2004), *available at* http://www.usdoj.gov/atr/public/health_care/204694.htm.

[12] *See, e.g.,* Letter from FTC Staff to Hon. Timothy Burns, *supra* note 11; Letter from FTC Staff to Elain Nekritz, Illinois Legislature (May 29, 2008) (regarding proposed LSC regulations); *available at*

I. Background

A. Brief Background on CRNAs

In Alabama, CRNAs are licensed under the Alabama Code[13] and Alabama Board of Nursing regulations.[14] In general, "[p]ractice as a certified registered nurse anesthetist (CRNA) means the performance of or the assistance in any act involving the determination, preparation, administration, or monitoring of any drug used to render an individual insensible to pain for surgical and other therapeutic or diagnostic procedures. . . . [by the CRNA] under the direction of a physician licensed to practice medicine, or a dentist, who is immediately available."[15]

Under Board of Nursing regulations, CRNAs are required to have:

(a) An active Alabama registered nurse license. . . .
(b) Met all requirements for completion of or graduation from an organized program of study and clinical experience beyond the basic educational preparation as a registered nurse that prepares nurse anesthetists and is accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs/Schools . . . and recognized by the Board of Nursing.
(c) Earned at least a master's degree, or post-master's certificate in advanced practice nursing . . . [and]
(d) Current certification as a registered nurse anesthetist . . . .[16]

B. The Proposed Rule

As noted above, the Proposed Rule restricts the "interventional treatment of pain" to "qualified, licensed medical doctors and doctors of osteopathy,"[17] who "may not delegate to non-physician personnel the authority to utilize such procedures to diagnosis [sic], manage or treat chronic pain patients."[18] "Interventional pain management"[19] is defined broadly as "the

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http://www.ftc.gov/os/2008/06/V080013letter.pdf; Letter from FTC Staff to Massachusetts Dep't of Health (September 27, 2007) (regarding proposed LSC regulations); *available at* http://www.ftc.gov/os/2007/10/v070015massclinic.pdf. Many of these advocacy efforts have been successful in preserving competition. For example, following the above referenced advocacy letters, the Louisiana and Illinois legislatures rejected the proposed restrictions on competition, and Massachusetts followed FTC Staff recommendations in adopting its final LSC regulations.

[13] Code of Ala. §§ 34-21-81, 34-21-90 (2010) (definitions and certification, respectively, for advance practice nurses, including CRNAs).

[14] Ala. Admin. Code r. 610-X-9-.01 (2010) (Qualifications For Approval To Practice As A Certified Registered Nurse Anesthetist). Statutory authority to adopt standards of nursing practice is assigned to the Alabama Board of Nursing by statute. Code of Ala. § 34-21-2(j) (2010).

[15] Code of Ala. § 34-21-81(4)(c) (2010).

[16] Ala. Admin. Code r. 610-X-9-.01 (2010)

[17] *Id.* at 540-X-15-.01, 540-x-.04.

[18] *Id.* at 540-x-.04.

diagnosis and treatment of pain-related disorders with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain."[20] The Proposed Rule also includes examples of "interventional techniques," which

> often involve injection of steroids, analgesics, and anesthetics and include: lumbar, thoracic, and cervical spine injections, intra-articular injections, intrathecal injections, epidural injections (both regular and transforaminal), facet injections, discography, nerve destruction, occipital nerve blocks, lumbar sympathetic blocks and vertebroplasty, and kyphoplasty.[21]

The Proposed Rule also provides a non-exhaustive list of several dozen specific interventions.[22]

Because the proposed rule effectively prohibits non-physicians from providing interventional pain treatment, and physicians from delegating authority to provide such treatment to other licensed health care professionals, the Proposed Rule appears to prevent CRNAs from performing many of the pain management procedures that the Board of Nursing considers to be within the scope of CRNA practice in Alabama, subject to physician supervision.[23] For example, the scope of CRNA practice includes "intradermal, subcutaneous, or intramuscular administration of a local anesthetic agent in a specified amount designated by order of a licensed physician or dentist," and "the monitoring and adjustment of local anesthetic agent(s) and analgesic agent(s) infusing via an epidural, brachial plexus, or femoral catheter placed by a qualified [CRNA] or qualified licensed physician may be performed by a registered nurse . . . as ordered by a licensed prescriber."[24]

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[19] It is not clear from the plain language of the Proposed Rule whether "interventional treatment of pain" is meant to be co-extensive with "interventional pain management" or a broader concept that includes it.

[20] Proposed Rule at 540-X-15-.02.

[21] *Id.*

[22] Specific interventions include SI joint injections; spinal punctures; epidural blood patches; epidural injections; epidural/spinal injections; lumbar injections; epidural/subarachnoid catheters; occipital nerve blocks; axillary nerve blocks; intercostal nerve blocks; multiple intercostal nerve blocks; ilioinguinal nerve blocks; peripheral nerve blocks; facet joint injections; cervical/thoracic facet joint injections; lumbar facet injections; multiple lumbar facet injections; transforaminal epidural steroid injections; transforaminal cervical steroid injections; sphenopalatine ganglion blocks; paravertebral sympathetic blocks; neurolysis of the lumbar facet nerve; neurolysis of the cervical facet nerve; and destruction of the peripheral nerve. Proposed Rule at 540-X-15-.02.

[23] *See, e.g.*, In re Steve Sykes, MD, *supra* note 5 (enumerating various interventional pain management procedures within the scope of CRNA practice).

[24] *Supra* note 5, at 4. The Board of Nursing reports that, when it recently invited public comment regarding revisions to the pertinent standards of practice, the Board of Medical Examiners did not question CRNA qualification to perform such procedures. *Id.* at 5 (regarding November 2009 letter submitted by Board of Medical Examiners Executive Director, Larry Dixon).

II. Consumer Protection Concerns and the Scope of Practice

Patient safety or consumer protection concerns can justify licensure requirements and scope of practice restrictions.[25] FTC staff recognize that particular pain management procedures may require the specific training and experience of a board certified anesthesiologist and that other particular interventions may require the special skills of a certified surgical sub-specialist. Staff notes, however, that the Proposed Rule applies broadly and does not identify such particular procedures.[26]

Available evidence indicates that CRNAs operating within the scope of their licensure provide pain management services safely.[27] Published data tend to indicate that the baseline risk of anesthesia is extremely low across all providers, and provider settings, with several studies indicating that recent decades have seen "a remarkably abrupt decrease in anesthetic related death rates, morbidity, and risk of perioperative deaths."[28] In publishing its final rule regarding the provision of hospital anesthesia services under the Medicare and Medicaid programs, the U.S. Department of Health and Human Services (HHS) concluded that, "the anesthesia-related death rate is extremely low, and that the administration of anesthesia in the United States is safe relative to surgical risk."[29] Moreover, HHS found no "need for Federal intervention in State professional practice laws governing CRNA practice. . . . [and] no reason to require a Federal rule in these conditions of participation mandating that physicians supervise the practice of [state-licensed CRNAs]."[30]

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[25] In competition terms, licensure requirements or scope of practice restrictions may sometimes offer an efficient response to certain types of market failure that can occur in professional services markets. *See* CAROLYN COX & SUSAN FOSTER, FEDERAL TRADE COMMISSION, BUREAU OF ECONOMICS, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION, 5-6 (1990), *available at* http://www.ftc.gov/be/consumerbehavior/docs/reports/CoxFoster90.pdf.

[26] In addition, the Proposed Rule does not appear to restrict the scope of any pain management practices to any particular physician specialists, instead referring generally to "qualified, licensed medical doctors and doctors of osteopathy." *Id.* at 540-X-15-.01, 540-x-.04.

[27] *See supra* note 6; *cf.* Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians*, 29 HEALTH AFFAIRS 1469, 1469 (2010) ("adverse events related to anesthesia are rare regardless of the provider."). Much of the public data appears to regard the provision of anesthesia generally, without distinguishing profession-related risks particularly related to chronic or acute pain management. FTC staff notes a general question regarding the scope of Proposed Rule's intended limitation to chronic pain management settings, in addition to the question whether there is evidence of consumer harms associated with CRNA practice in particular chronic care contexts.

[28] J.P. Abenstein & Mark A. Warner, *Anesthesia Providers, Patient Outcomes, and Costs*, 82 ANESTHESIA & ANALGESIA 1273, 1277 (1996) (citing, e.g., Mark A. Warner, et al., *Major Morbidity and Mortality Within 1 Month of Ambulatory Surgery and Anesthesia*, 270 JAMA 1437 (1993)); *see also* Dulisse & Cromwell, *supra* note 27, at 1469 ("adverse events related to anesthesia are rare regardless of the provider.").

[29] Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA), Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 CFR Parts 416, 482, and 485, Final Rule, 66 Fed. Reg. 4674, 4675 (Jan. 18, 2001).

[30] *Id.* at 4674.

The Proposed Rule appears to provide no countervailing evidence that CRNAs operating within their established scope of practice impose substantial risks on Alabama health care consumers in chronic care settings or otherwise.[31]

III. Likely Effects on Alabama Health Care Consumers

The Proposed Rule's restrictions on the ability of physicians to direct and supervise CRNA provision of interventional pain treatments to chronic pain patients practice may increase prices for pain management services and decrease access to such services. By limiting the number of health care professionals licensed to provide pain management services, the Proposed Rule would reduce price competition.[32] Further, prices may rise to the extent that physician services are substituted for lower-cost CRNA services.[33] Finally, the Proposed Rule may thwart innovation in health care delivery by limiting the ability of health care providers to develop, test, and implement the most efficient teams of pain management professionals.[34]

Moreover, the burdens imposed by the Proposed Rule may be felt especially by some of the most vulnerable citizens of Alabama. For example, CRNA practices disproportionately serve

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[31] A study by the Lewin Group notes directly that "there are no studies that show a significant difference between CRNAs and anesthesiologists in patient outcomes." Paul F. Hogan et al., *supra note* 6, at 161 (reviewing literature on safety and efficiency of anesthesia). FTC staff recognize that the published evidence regarding aggregate or comparative risks of anesthesia are complex, and staff do not wish to suggest that some particular anesthesia staffing model is optimal. *See, e.g.*, Abenstein & Warner, *supra* note 28, at 1276 (comorbidities and other difficulties in attributing adverse events to anesthesia); *cf.* Smith et al., *supra* note 6, at 541 (studies too dissimilar to admit formal meta-analysis). Still, published data generally indicate that CRNAs, working under physician supervision or separately, provide pain management services safely –*see supra* notes 6, 27 - 30, and accompanying text – and there does not appear to be countervailing evidence that CRNAs generally, or in particular chronic care contexts, are unsafe. In addition, there are studies that compare various anesthesia workforce models. *See, e.g.*, Laurent G. Glance, *The Cost Effectiveness of Anesthesia Workforce Models: A Simulation Approach Using Decision Analysis Modeling*, 90 ANESTHESIA & ANALGESIA 584 (2000). FTC staff could find no evidence comparing the relative safety, efficacy, or efficiency of CRNA pain management services with those provided by the larger population of physicians and doctors of osteopathy. There is, however, some evidence that the risk of "failure to rescue" is substantially higher in hospitals in which relatively few of the anesthesiologists are board-certified. *Id.* at 587 (2.5 times higher when 0-33% anesthesiologists board-certified than those where 66-99% of anesthesiologists are board certified). Such studies could raise questions about when or whether it is safe to substitute physicians and osteopaths who are not board-certified anesthesiologists for those who are.

[32] *Compare* ALISON J. TERRY, ALABAMA BOARD OF NURSING, BIANNUAL ANALYSIS OF ALABAMA'S REGISTERED NURSE WORKFORCE: 2008, p. 9, Table 4 (April 2009), *available at* http://www.abn.state.al.us/UltimateEditorInclude/UserFiles/docs/research/VIII%20E%202%20Report%20of%202008%20RN%20Renewal%20Workforce%20Survey.pdf (indicating 1,378 CRNAs in Alabama) *with* Alabama Department of Industrial Relations, Occupational Employment Projections in Alabama for Anesthesiologists for a base year of 2006 and a projected year of 2016, *available at* http://216.226.191.114/vlmi/analyzer/qsoccproj.asp?quicksearch=True&setvar=True&cat=OCC&session=OCCPROJ&subsession=99&areaname= (estimating 760 Alabama anesthesiologists in 2006 and projecting 950 for 2016), last checked 10/18/10.

[33] *See, e.g.*, Editorial, *Who Should Provide Anesthesia Care?*, N.Y. TIMES, Sept. 6, 2010 (relative costs of physician and nurse provided care).

[34] Glance, *supra* note 31, at 588-91 (regarding cost-effective models of anesthesia care for low, intermediate, and high risk cases, and concluding that, "the *physician-intensive* model, in which physicians working alone anesthetize all patients, is also not cost effective.")

smaller, rural hospitals.[35] In addition, hospice providers and patients may face both increased prices and reduced access to care if only physicians can provide palliative care for chronic pain.

It is possible that the Proposed Rule may, on balance, reduce patient safety. As noted, economic or geographic access problems may place some Alabamans at risk of inadequate care. Also, if CRNA pain management specialists are sometimes replaced not by board certified anesthesiologists, but by physicians and osteopaths who do not specialize in pain management, the average quality of interventional pain management in Alabama, or certain parts of Alabama, could be reduced.

Conclusion

If particular interventional pain treatment services demonstrably require more specialized training and experience than CRNAs working under physician supervision posses, then the Board should tailor the rule to address those particular services. To the extent that there is no evidence that CRNA practice harms patients, staff recommend that the Board reject the Proposed Rule outright.

We appreciate your consideration of these issues.

Respectfully submitted,

Susan S. DeSanti, Director
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Joseph Farrell, Director
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Richard A. Feinstein, Director
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[35] *See, e.g.*, Dulisse & Cromwell, *supra* note 27, at 1469 (CRNAs "provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals."); *cf.* Abenstein & Warner, *supra* note 28, at 1279 (nurse anesthetist only practices found predominantly in smaller, rural hospitals).