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

Office of Policy Planning
Bureau of Economics
Bureau of Competition

March 27, 2012

Hon. Jeanne Kirkton
Missouri House of Representatives
State Capitol – Room 135BC
Jefferson City, MO 65101-6806

Dear Representative Kirkton:

The staffs of the Federal Trade Commission Office of Policy Planning, Bureau of Economics, and Bureau of Competition[1] appreciate the opportunity to respond to your invitation for comments on Missouri House Bill 1399.[2] The Bill provides that only physicians may treat pain through use of injections around the spine or spinal cord guided by imaging technology. HB 1399 appears to have significant implications for the provision of services by certified registered nurse anesthetists (CRNAs), a type of advanced practice registered nurse with specialized training in anesthesia and pain management and recognized under Missouri law.

Recent reports by the Institute of Medicine (IOM) have identified a key role for advanced practice nurses – including CRNAs – in improving the delivery of health care.[3] The IOM, established in 1970 as the health arm of the National Academy of Sciences, provides expert advice to policy makers and the public and has conducted an intensive examination of issues surrounding advanced nursing practice. Among other things, the IOM found that "[r]estrictions on scope of practice. . . have undermined [nurses'] ability to provide and improve both general and advanced care."[4] In a separate study examining pain as a public health problem, the IOM found that regulatory barriers "limit the availability of pain care and contribute to disparities found among some groups."[5]

As is discussed below, legislative testimony indicates that HB 1399 would prohibit CRNAs from providing treatments that they currently provide to patients. In some areas of Missouri, no alternative providers, such as anesthesiologists or board-certified physician pain specialists, appear to be available. Shortages of physicians in Missouri exist now and are projected to increase.[6] By restricting the provision of services by CRNAs, the Bill could exacerbate problems of access to care, especially for rural and other underserved populations. It may also impede price and non-price competition among providers of pain management services and increase costs to Missouri citizens.

For these reasons, we recommend that the Missouri House of Representatives carefully examine whether the broad prohibition in HB 1399 is necessary for patient safety. Patient health and safety concerns are paramount when states regulate the scope of practice of health care

providers. FTC staff are not experts in patient care or safety, and we do not offer advice on such matters. But we recommend that in considering the Bill, you seek to ensure that any limits on CRNAs are no stricter than patient protection requires. In particular, we recommend that you investigate whether there is evidence that current CRNA practice is harmful to patients and, if so, whether the Bill is tailored to address those health and safety concerns. Given the Bill's potential negative effects, avoiding unwarranted restrictions on CRNA practice can offer significant benefits to the provision of health care in Missouri.

I. 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.[11] Recently, FTC staff has analyzed the likely competitive effects of proposed regulations relating to CRNA and APRN practice in other states.[12]

II. House Bill 1399

HB 1399 would prohibit CRNAs from providing patients with interventional pain management with the aid of imaging technology. The Bill covers "the injection of therapeutic substances around the spine or spinal cord for the treatment of acute and chronic pain syndromes" when guided by "fluoroscopic, computerized axial tomography (CAT) scan, magnetic resonance imaging (MRI), or ultrasound."

The Bill's application to treatment of both acute and chronic pain appears to encompass a broad range of services provided by CRNAs, including services for which CRNAs have been nationally certified.[13] Stakeholders have expressed concern that the Bill's restriction of injections "around the spine or spinal cord" could be applied to a wide range of common procedures, including epidural injections administered to manage pain during labor and delivery or in post-surgical pain management.[14] Some Missouri hospitals have stated that they depend on CRNAs to safely provide certain pain management treatments associated with labor and delivery, and with certain surgical procedures, with the aid of imaging technology.[15] Missouri CRNAs have stated that their use of ultrasound technology, in particular, is integral to their treatment of both acute and chronic pain.[16]

Imaging technology is used in connection with injections near the spine to enhance the quality of care provided to patients.[17] The Bill would categorically prohibit CRNAs from administering treatment for either acute or chronic pain with the aid of commonly recommended imaging technology, regardless of the CRNA's training, licensure, and experience.

III. Likely Costs and Benefits of HB 1399

We recognize that certain professional licensure requirements are necessary to protect patients.[18] In particular, special practice requirements or other restrictions may be recommended or required for certain chronic or acute pain indications or treatments that may present heightened consumer risks. In light of concerns about the Bill's likely competitive impact, however, we urge careful scrutiny of the need for HB 1399.

a. The Bill Raises Significant Competitive Concerns

The broad limitation in HB 1399 threatens a variety of competitive harms. First, by limiting the supply of health care professionals who can provide the covered pain treatments, it appears likely to exacerbate health care access problems, particularly in rural areas, where alternative providers of pain management services appear to be in short supply.[19] Indeed, Missouri's Department of Health and Senior Services reports that both hospitals and full-time physicians "are relatively scarce in Missouri's rural areas,"[20] and that rural facilities often lack specialists.[21] Staff notes that CRNA practices disproportionately serve rural patients,[22] and the Missouri Association of Nurse Anesthetists has testified that CRNAs are the only licensed providers of anesthesia services in 31 Missouri counties.[23] Consistent with these general observations of rural shortages, testimony from two Missouri hospitals states, "Our two communities are not served by anesthesiologists, and without CRNA services, we could not provide the range of important medical services we now provide to our respective towns and the rural areas surrounding our facilities."[24]

The Bill's effects would likely be felt most acutely by Missouri's most vulnerable populations – the elderly, the disadvantaged, and rural citizens. An IOM report on pain and pain treatment notes that "pain is more prevalent and less likely to be adequately treated in certain population groups, including the elderly, women, children, and racial and ethnic minorities."[25] The same report notes that, nationally, rural areas face particular shortages of pain care specialists,[26] even though aspects of rural life may increase the likelihood of injuries requiring pain treatment.[27]

In addition, HB 1399 may reduce competition on price, convenience, and quality among remaining providers. By limiting the ability of CRNAs to provide pain management services, the Bill likely will reduce the competitive pressures – and constraints – on practitioners and facilities that remain able to offer pain treatment. Higher out-of-pocket prices, more limited hours, and reduced distribution of services throughout the state all may tend to reduce access to pain treatment. Higher prices, in particular, may force difficult choices on some Missouri health care consumers who rely on relief from chronic pain to go about their daily lives. As an article in *Health Affairs* noted, "when costs are high, people who cannot afford something find substitutes or do without."[28]

Finally, the Bill may reduce innovation in health care delivery. Restrictions on CRNAs may limit not only physician-CRNA collaborations, but also the ability of health care providers to develop, test, and implement the most efficient teams of pain management professionals. The

Bill's restrictions also may impede CRNA access to training opportunities, especially as standards of care for image-guided pain treatments evolve.

b. Legislative Consideration of Health and Safety Issues

FTC staff urge legislators to carefully consider whether there is evidence to justify the broad restriction on CRNA practice that HB 1399 would impose. We urge the legislature to consult with experts in nursing and medicine and to rely upon other pertinent information to clarify various technical matters. We also encourage the legislature to consider the nature of current pain treatment practice in Missouri and consider available empirical and other evidence that may bear on patient safety issues, including relevant IOM reports.[29]

If the legislature finds that regulation is warranted—for example, with respect to particular procedures or indications—we recommend that the legislature consider how best to tailor provisions and restrict CRNA practice only to the extent required to ensure patient safety.[30] In this circumstance, the legislature may wish to consider a more flexible regulatory approach, rather than the categorical statutory limits proposed in HB 1399. Appropriate regulations may more readily be recalibrated over time, as the scientific understanding of chronic pain and pain therapy progresses, and may more readily take into account such developments and more easily target specific particular risks.[31]

Conclusion

In our view, HB 1399 threatens to raise costs, limit access, and reduce choices for Missouri patients. We therefore recommend that the House carefully investigate patient safety issues and ensure that any statutory limits on CRNAs are no stricter than patient safety requires.

We appreciate your consideration of these issues.

Respectfully submitted,

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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] Letter from Letter from Hon. Jeanne Kirkton, Missouri House of Representatives, to Susan S. DeSanti, Director, FTC Office of Policy Planning (Jan. 23, 2012).

[3] *See generally* INSTITUTE OF MEDICINE, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH (2011) [hereinafter IOM NURSING REPORT] (especially Summary, 1-15).

[4] *Id.* at 4.

[5] INSTITUTE OF MEDICINE, COMMITTEE ON ADVANCING PAIN RESEARCH, CARE, AND EDUCATION, RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 2, 80, 157 (2011) [hereinafter IOM PAIN REPORT].

[6] *See, e.g.*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH RESOURCES AND SERVICES ADMINISTRATION BUREAU OF HEALTH PROFESSIONS, THE PHYSICIAN WORKFORCE: PROJECTIONS AND RESEARCH INTO CURRENT ISSUES AFFECTING SUPPLY AND DEMAND, 70 (2008) [hereinafter HRSA PHYSICIAN WORKFORCE REPORT]; *id.* at 70-72, exhibits 51-52; *infra* notes 19-24 and accompanying text (regarding present and projected shortages in Missouri and nationally).

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

[8] *Standard Oil Co. v. Federal Trade Commission*, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.")

[9] *See generally, e.g.*, FTC, An Overview of FTC Antitrust Actions In Health Care Services and Products (Sept. 2010), *available at* http://www.ftc.gov/bc/110120hcupdate.pdf; *see also* FTC, 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 ("DOJ"), IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf [hereinafter FTC & DOJ, IMPROVING HEALTH CARE].

[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/V090009louisianadentistry.pdf; FTC and DOJ 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; FTC & DOJ, IMPROVING HEALTH CARE, *supra* note 10.

[12] *See* FTC Staff Letter to the Honorable Gary Odom, Tennessee House of Representatives, Concerning Tennessee House Bill 1896 (H.B. 1896) and the Regulation of Providers of Interventional Pain Management Services (Sept. 2011), *available at* http://www.ftc.gov/os/2011/10/V11001tennesseebill.pdf; FTC Staff Comment Before the Alabama State Board of Medical Examiners Concerning the Proposed Regulation of Interventional Pain Management Services (Nov. 2010), *available at* http://www.ftc.gov/os/2010/11/101109alabamabrdme.pdf; FTC Staff Letter to the Hon. Rodney Ellis and the Hon. Royce West, the Senate of the State of Texas, Concerning Texas Senate Bills 1260 and 1339 and the Regulation of Advanced Practice Registered Nurses (May 2011), *available at* http://www.ftc.gov/os/2011/05/V110007texasaprn.pdf; FTC Staff Letter To The Hon. Daphne Campbell, Florida House of Representatives, Concerning Florida House Bill 4103 and the Regulation of Advanced Registered Nurse Practitioners (Mar. 2011), *available at* http://www.ftc.gov/os/2011/03/V110004campbell-florida.pdf.

[13] National certification of CRNAs is administered by the National Board on Certification and Recertification of Nurse Anesthetists (NBCRNA), which determines eligibility requirements for the certification exam, and formulates and administers the National Certification Exam for CRNAs. *See, e.g.*, National Board on Certification and Recertification of Nurse Anesthetists, Certification, *available at* http://www.nbcrna.com/cert/Pages/default.aspx; *see also* NBCRNA, NBCRNA Candidate Handbook for the 119th National Certification Examination (2012), *available at* http://www.nbcrna.com/Documents/08_NBCRNA_%202012_Candidate%20Handbook_119th_%20NCE.pdf; IOM NURSING REPORT, *supra* note 3, at 41 (CRNAs "[a]dminister anesthesia and provide related care before and after surgical, therapeutic, diagnostic, and obstetrical procedures, as well as pain management.").

[14] *See* Matt Wenzel, Hendrick Medical Center, Testimony Before the Missouri S. Comm. on Health, Mental Health, Seniors and Families on SB682 (Feb. 14, 2012) (Bill's definitions "so broad in scope that we believe it will be applied to the OB and surgical procedures for which we use CRNA anesthesia."); Gary Jordan, Wright Memorial Hospital, Testimony Before the Missouri H. Comm. on Licensure and Professional Registration, on HB1399 (Feb. 15, 2012) (same); Vicki Coopmans, CRNA, Ph.D., Missouri Ass'n Nurse Anesthetists, Testimony Before the Missouri S. Comm. on Health, Mental Health, Seniors and Families on SB682 (Feb. 14, 2012) (expressing concerns

about the Bill's impact on the ability of CRNAs ability of CRNAs "to perform many procedures to treat or prevent acute pain, such as epidurals for women in labor or certain nerve blocks after surgery.")

[15] Matt Wenzel, Hendrick Medical Center, *supra* note 14; Gary Jordan, Wright Memorial Hospital, *supra* note 14.

[16] *See* Joe Dietrick, CRNA, M.A., Testimony Before the Missouri H. Comm. on Professional Registration and Licensing (Febr. 15, 2012) ("Ultrasound, particularly, is a commonly used and extremely safe form of imaging used not just by physicians, but also by CRNAs, and even Registered Nurses. This device can help us with difficult epidural or spinal placement for surgery or obstetrical patients. Although clearly within our Scope of Practice, our plans for acute post-operative pain techniques using ultrasound guidance for patients of our Orthopedic Surgeon may be impeded. It is also used for placement of central venous catheters."); Vicki Coopmans Testimony, *supra* note 14 (noting that the language of the Bill could be interpreted to prevent CRNAs from providing chronic and acute pain treatments).

[17] The Supreme Court of Missouri has observed that fluoroscopy is used to "aid in pain management. . . . improving the safety and accuracy" of pain management injections. Missouri Ass'n of Nurse Anesthetists v. State Board of Registration for the Healing Arts, 343 S.W.3d 348, 351 n. 6 (Mo. S.Ct. 2011) (citing Brief for the American Ass'n of Nurse Anesthetists as Amici Curia Supporting Appellants); *see also* note 16, *supra* (testimony regarding use of imaging guidance in Missouri to enhance patient safety).

[18] For example, licensure requirements or scope of practice restrictions may sometimes offer an efficient response to certain types of market failure arising 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.govibe/consumerbehavior/docs/reports/CoxFoster90.pdf.

[19] *See, e.g.*, IOM NURSING REPORT, *supra* note 3, at 107-09, 112 (regarding physician shortages in rural and other underserved areas).

[20] MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES, OFFICE OF PRIMARY CARE AND RURAL HEALTH, MISSOURI RURAL HEALTH BIENNIAL REPORT, 2010-2011, 3 (2011) *available at* http://health.mo.gov/living/families/ruralhealth/pdf/biennial2011.pdf.

[21] *Id.* at 34. This is consistent with national projections of a "growing shortage of specialists" across medical specialties. HEALTH RESOURCES AND SERVICES ADMIN. BUREAU OF HEALTH PROF., THE PHYSICIAN WORKFORCE: PROJECTIONS AND RESEARCH INTO CURRENT ISSUES AFFECTING SUPPLY AND DEMAND, *supra* note 6, at 70; *id.* at 70-72, exhibits 51-52.

[22] *See, e.g.,* Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians,* 29 HEALTH AFFAIRS 1469, 1469 (2010) (CRNAs "provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals."); *cf.* J.P. Abenstein & Mark A Warner, *Anesthesia Providers, Patient Outcomes, and Costs,* 82 ANESTHESIA & ANALGESIA 1273, 1279 (1996) (nurse anesthetist-only practices found predominantly in smaller, rural hospitals).

[23] Vicki Coopmans Testimony, *supra* note 14. Some pain management services may be provided by non-anesthesiologist physicians in those counties, although there are corresponding shortages of other types of specialists and primary care physicians in rural counties. *See supra* notes 19 - 22, and accompanying text.

[24] Matt Wenzel, Hendrick Medical Center, *supra* note 14; Gary Jordan, Wright Memorial Hospital, *supra* note 14.

[25] IOM PAIN REPORT, *supra* note 5, at 48.

[26] *Id.* at 80, 157.

[27] *Id.* at 80.

[28] William Sage, David A. Hyman & Warren Greenburg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (Mar./Apr. 2003). Although estimates of the elasticity of demand for health insurance coverage vary, the empirical evidence is clear that higher costs result in less coverage. *See* DAVID M. CUTLER, HEALTH CARE AND THE PUBLIC SECTOR, National Bureau of Economic Research Working Paper W8802, Table 5 (Feb. 2002), *available at* http://papers.nber.org/papers/W8802.

[29] *See, e.g.,* IOM NURSING REPORT, *supra* note 3, at 111 (citing diverse evidence, including Dulisse & Cromwell, *supra* note 22, in concluding that CRNAs provide high-quality care, with no evidence of patient harm, with respect to anesthesia and acute services).

[30] *See, e.g. id.* (with respect to CRNA provision of anesthesia and acute services, Dulisse & Cromwell "found no increase in patient mortality or complications in states that opted out of the [Centers for Medicare and Medicaid Services] requirement that an anesthesiologist or surgeon oversee the administration of anesthesia by a CRNA.").

[31] Another potential advantage of a regulatory approach is that the regulatory process would facilitate full participation by all stakeholders with an interest in the safe, effective, and efficient delivery of pain management services, including physicians, CRNAs, hospitals, and others.