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

Office of Policy Planning
Bureau of Economics
Bureau of Competition

April 19, 2013

Hon. Heather A. Steans
Illinois State Senate
Room M120 – State Capitol Building
Springfield, IL 62706

Dear Senator Steans:

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 Illinois Senate Bill 1662 ("SB1662" or "the Bill").[2] The Bill provides that only physicians may treat chronic pain through use of injections around the spine or spinal cord. SB1662 may 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 Illinois law.[3]

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.[4] 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."[5] 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."[6]

Legislative testimony indicates that SB1662 would prohibit CRNAs from providing treatments that they currently provide to patients.[7] In some areas of Illinois, no alternative providers, such as anesthesiologists or board-certified physician pain specialists, appear to be available. Shortages of physicians in Illinois exist now and are projected to increase.[8] By restricting the provision of services by CRNAs, the Bill may impede price and non-price competition among providers of pain management services and increase costs to Illinois citizens, the State of Illinois, and other third-party payers. It may also exacerbate problems of access to care, especially for rural and other underserved populations.

For these reasons, we recommend that the Illinois Senate carefully examine whether the broad prohibition in SB1662 is necessary for patient safety. We recognize that patient health and safety concerns are of critical importance when states regulate the scope of practice of health

care professionals, and FTC staff express no opinion on the ultimate health and safety standards or scope of practice restrictions that the Illinois legislature may choose to establish. We do, however, 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 health and safety concerns based on those demonstrated harms. Given the Bill's potential negative effects, avoiding unwarranted restrictions on CRNA practice can offer significant benefits to the provision of health care in Illinois.

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.[9] Competition is at the core of America's economy,[10] 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,[11] research,[12] and advocacy.[13] Recently, FTC staff has analyzed the likely competitive effects of proposed regulations relating to CRNA and advanced practice registered nurse ("APRN") practice in other states.[14]

II. Senate Bill 1662

SB1662 would prohibit CRNAs from providing patients with interventional chronic pain management, with or without the aid of imaging technology. The Bill generally prohibits anyone from using interventional procedures to either diagnose or treat chronic pain in Illinois "unless the person is a physician licensed to practice medicine in all its branches."[15] Although the Bill would permit APRNs – including CRNAs – to assist physicians, it would prohibit attending physicians from delegating any of the prohibited interventional pain procedures to licensed CRNAs.[16]

The Bill's list of prohibited treatments appears to encompass a broad range of services, including some currently provided by CRNAs, consistent with their training and national certification.[17] Stakeholders have expressed concern, for example, that prohibited procedures would include commonly used types of epidural injections in any region of the spine, "with or without imaging guidance."[18] The Bill would categorically prohibit CRNAs from administering such treatments for chronic pain, regardless of the CRNA's training, licensure, and experience, and regardless of physician participation in other aspects of a patient's diagnosis or treatment. Indeed, by imposing a blanket prohibition on the provision of these services by CRNAs, the Bill appears to eliminate the ability of physicians, other care team members to make patient-specific decisions regarding the optimal allocation of responsibilities and tasks.

III. Likely Costs and Benefits of SB1662

We recognize that certain professional licensure requirements are necessary to protect patients.[19] In particular, special practice requirements or other restrictions may be recommended

or required for certain chronic 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 SB1662.

a. The Bill Raises Significant Competitive Concerns

The breadth of the limitations in SB1662 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. An IOM report on pain and pain treatment observes that under-treatment of chronic pain is widespread, and that "undertreatment generates enormous costs to the [health care] system and to the nation's economy."[20] The same report notes that, "chronic pain rates are likely to continue to rise,"[21] and suggests that the general population of primary care physicians, as well as some specialist physicians, may be undertrained and inexperienced in best pain management practices.[22] Access problems may be particularly acute in rural areas, where alternative providers of pain management services appear to be in short supply.[23] As noted above, many areas in Illinois already are subject to shortages of both primary care and specialist physicians,[24] and CRNA practices disproportionately serve rural patients.[25]

The Bill's effects would likely be felt most acutely by Illinois' most vulnerable populations – the elderly, the disadvantaged, and rural citizens. As the IOM pain report notes, "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."[26] The same report notes that, nationally, rural areas face particular shortages of pain care specialists,[27] even though aspects of rural life may increase the likelihood of injuries requiring pain treatment.[28] Based on recent reports, numerous Illinois counties appear to have zero specialized providers of anesthesia or pain care, and in more than two dozen counties CRNAs are the only such licensed providers.[29]

In addition, SB1662 may reduce competition on price, convenience, and quality among remaining providers. By limiting the ability of CRNAs to provide chronic 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 Illinois 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."[30]

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. For example, under SB1662, attending or supervisory physicians could not delegate the administration of a restricted procedure to a non-physician professional.[31] The Bill's restrictions also may impede CRNA access to training opportunities, especially as standards of care for chronic 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 SB1662 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 chronic pain treatment practice in Illinois and consider available empirical and other evidence that may bear on patient safety issues, including relevant IOM reports.[32]

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.[33] In this circumstance, the legislature may wish to consider a more flexible regulatory approach, rather than the categorical statutory limits proposed in SB1662. 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 particular risks.[34]

Conclusion

In our view, SB1662 threatens to raise costs, limit access, and reduce choices for Illinois patients. We therefore recommend that the Senate 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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Richard A. Feinstein, Director
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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 Hon. Heather A. Steans, Illinois Senate, to Andrew I. Gavil, Director, FTC Office of Policy Planning (Feb. 25, 2013).

[3] Ill. Comp. Stat. Art. 65 § 65-5(b), (b-5).

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

[5] *Id*. at 4.

[6] 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].

[7] Staff have received input regarding CRNA practice and training in Illinois from, e.g., Draft Testimony of Rev. Jeremiah Loch, CRNA, Illinois Association of Nurse Anesthetists Before the Senate Licensed Activities & Pensions Committee RE: Senate Bill 1662 (Apr. 2013).

[8] *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.

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

[10] *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.").

[11] *See generally, e.g.*, Fed. Trade Comm'n, An Overview of FTC Antitrust Actions In Health Care Services and Products (March. 2013), *available at* t http://www.ftc.gov/bc/healthcare/antitrust/hcupdate.pdf; *see also* FTC, Competition in the Health Care Marketplace: Formal Commission Actions, *available at* http://www.ftc.gov/bc/healthcare/antitrust/commissionactions.htm.

[12] *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].

[13] 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 11.

[14] *See* FTC Staff Letter to the Hon. Jeanne Kirkton, Missouri House of Representatives, Concerning Missouri House Bill 1399 and the Regulation of Certified Registered Nurse Anesthetists (March 2012), *available at* http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf; 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 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; 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.

[15] SB1662, Ill. 98th Gen. Assembly, § 10.

[16] *Id.*

[17] 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, 120th National Certification Examination (NCE) Candidate Handbook (2013), *available at* http://www.nbcrna.com/certification/Documents/2013%20NCE%20Candidate%20Handbook%20v3.pdf; IOM NURSING REPORT, *supra* note 4, at 41 (CRNAs "[a]dminister anesthesia and provide related care before and after surgical, therapeutic, diagnostic, and obstetrical procedures, as well as pain management.").

[18] SB1662, Ill. 98th Gen. Assembly, § 5(4). Regarding CRNA practice and training in Illinois, see *supra* note 7; Interview with Paul Darr, Southern Illinois Univ. School of Nursing (Apr. 9, 2013).

[19] 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.

[20] IOM PAIN REPORT, *supra* note 6, at 153. For a more detailed discussion of the scope of the problem and its associated costs, see generally *id.* at C.2, 55-103..

[21] *Id.* at 62.

[22] *Id.* at 154-6.

[23] *See, e.g.*, IOM NURSING REPORT, *supra* note 4, at 107-09, 112 (regarding physician shortages in rural and other underserved areas).

[24] *See supra* note 8 and accompanying text. Although FTC staff have not surveyed pain specialist distribution in Illinois county-by-county, we note that testimony regarding a neighboring state, Missouri, indicated that CRNAs were the only licensed specialist providers of anesthesia services in 31 of the state's counties. FTC Staff Letter to the Hon. Jeanne Kirkton, Missouri House of Representatives, Concerning Missouri House Bill 1399 and the Regulation of Certified Registered Nurse Anesthetists, note 23 and accompanying text (Mar. 2012), *available at* http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf.

[25] *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).

[26] IOM PAIN REPORT, *supra* note 6, at 48.

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

[28] *Id.* at 80.

[29] Am. Ass'n of Nurse Anesthetists, Distribution of Illinois Anesthesia Providers (Oct. 2011) (map and county-level table based on AMA master file and reporting to U.S. Dep't Health and Human Servs., HRSA).

[30] 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.

[31] SB1662, Ill. 98th Gen. Assembly, § 10.

[32] *See, e.g.*, IOM NURSING REPORT, *supra* note 4, at 111 (citing diverse evidence, including Dulisse & Cromwell, *supra* note 25, in concluding that CRNAs provide high-quality care, with no evidence of patient harm, with respect to anesthesia and acute services).

[33] *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.").

[34] 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.