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

Office of Policy Planning
Bureau of Economics
Bureau of Competition

September 28, 2011

Hon. Gary Odom
Tennessee House of Representatives
18A Legislative Plaza
Nashville, Tennessee 37243-0167

Dear Representative Odom:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition[1] are pleased to respond to your invitation for comments on Tennessee House Bill 1896 ("H.B. 1896" or "the Bill"), which would regulate providers of interventional pain management services.[2] In health care facilities that are not licensed under Title 68, Chapter 11 of the Tennessee Code, the Bill would require a physician's direct, on-site supervision of any advanced practice nurse ("APN") administering any of a broad array of pain management services.[3] This supervision requirement would apply even to a certified registered nurse anesthetist ("CRNA"), an APN with specialized training in anesthesia and pain management. The Bill also would limit which physicians may supervise such services or provide them, outside certain licensed facilities. Because the Bill may do substantial competitive harm, it is important to scrutinize the need for its restrictions. The Bill may result in increased prices, reduced access, and reduced choice by consumers of health care in Tennessee, especially for the rural or underserved. We recommend that the House investigate the need for H.B. 1896, and the Bill's negative effects, before adopting any of its restrictions. Absent findings that the Bill's provisions are likely to ameliorate identifiable safety concerns, we recommend that it be rejected.

Many Tennessee patients benefit from APN/CRNA and physician pain management services under current Tennessee law. Indeed, the Bill itself implicitly acknowledges that physicians, CRNAs and other APNs, deliver pain management safely in many clinical settings.[4] Moreover, health care competition is an important way to address pressing issues of access and cost. A recent report by the Institute of Medicine ("IOM") identifies a key role for APNs in improving access to health care,[5] but cautions that "[r]estrictions on scope of practice . . . have undermined [nurses'] ability to provide and improve both general and advanced care."[6] Access to pain management services in Tennessee is likely to be compromised by unnecessary limits on the abilities of APNs, CRNAs, doctors, and other health care professionals to provide those services, with no demonstrable safety benefits. Access problems may be especially acute for elderly patients with chronic pain, as well as rural and low-income Tennesseans.

We recognize that safety concerns may justify the regulation of health care professionals or facilities. We are concerned, however, that H.B. 1896 may reduce patient access to, and

possibly increase the prices of, services that alleviate chronic pain and improve patients' quality of life, without evidence that these new restrictions are necessary to protect the public. We therefore urge the House study committee to investigate whether there are any demonstrated consumer risks or harms that would justify the proposed restrictions. If any specific risks or harms are identified, we encourage the study committee to consider whether they might be addressed through existing or pending regulations[7] that would protect patients without unduly or arbitrarily restricting the scope of practice of certain health care providers in certain types of facilities. Statutory limits on physicians, CNRAs, and other APNs should be no more strict than patient protection requires.

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.[8] Competition is at the core of America's economy,[9] 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,[10] research,[11] and advocacy.[12] 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.[13] In particular, staff have analyzed the likely competitive effects of CRNA and APN regulations in other states.[14]

II. Background: House Bill 1896 and Tennessee's New Pain Clinic Regulations

H.B. 1896 would impose new restrictions on the provision of interventional pain management services[15] in Tennessee. Specifically, H.B. 1896 requires the direct, on-site supervision of any APN – including a CRNA – administering any of a broad array of interventional pain management services in any facility that is not licensed under Title 68, Chapter 11 of the Tennessee Code.[16] A supervising physician must be one "who is actively practicing spinal injections and has current privileges to do so at a facility licensed pursuant to Title 68, Chapter 11,"[17] notwithstanding the physician's specialized training and practice outside Chapter 11 facilities.

H.B. 1896 also would restrict the types of physicians who can provide interventional pain management services outside Chapter 11 facilities. In particular, it would permit only physicians certified in certain specialties – anesthesiology, neurological surgery, orthopedic surgery, physical medicine and rehabilitation – along with board certified physicians who have completed an American Board of Medical Specialties subspecialty board in pain medicine or an Accreditation Council for Graduate Medical Education-accredited pain fellowship to provide pain management services in such settings.[18] This restriction on the scope of physician practice appears to implicate a different range of physicians than the supervision requirement.[19]

H.B. 1896 should be evaluated in the context of existing Tennessee health care clinic regulations and, in particular, existing provisions in the Tennessee Code for adopting pain management clinic regulations. Independent of H.B. 1896, earlier this year Tennessee enacted

legislation that specifically provides for the regulation of pain management clinics.[20] The framework for such regulations appears to be broad. Recently enacted Public Chapter 340 defines pain management clinics directly, requires their certification, and provides for their regulation by the Commissioner of Health, in consultation with the boards of medicine, osteopathic examination, and nursing, as well as the committee on physician assistants.[21] Implementing regulations are expected to address, among other things, clinic operation, personnel and training requirements, standards to ensure quality of patient care, health and safety requirements, reporting requirements, and procedures for inspections and complaint investigations.[22] The statute defines pain management clinics as privately-owned facilities in which specific therapeutic substances of legislative concern are administered;[23] certain large, licensed health care facilities will be exempt from pain clinic regulations.[24]

III. Evaluation of Likely Costs and Benefits of H.B. 1896

We recognize that certain professional licensure requirements or facilities restrictions are necessary to protect patients.[25] Based on the available evidence, however, it is not clear that the restrictions imposed by H.B. 1896 are needed. We are unaware of evidence that the licensed physicians and APNs subject to new limits under the Bill – acting within their respective scopes of practice – increase the risk of harm to patients. Nor have we seen evidence of systematic failures in current supervision and collaboration arrangements between physicians and APNs. For that reason, coupled with concerns about the Bill's competitive impact, we urge careful scrutiny of the basis for H.B. 1896.

Assuming that patient safety does not require these additional restrictions, and given that recent Tennessee legislation already provides for the regulation and certification of pain clinics, the competitive and social costs of H.B. 1896 are unlikely to be offset by countervailing consumer benefits. Rather, rigid statutory limits on the established scope of practice of certain licensed health care professionals may create access problems for some Tennessee health care consumers, by impeding price and non-price competition between providers of pain management services.

a. The Reach of H.B. 1896

H.B. 1896 sweeps broadly: outside Chapter 11-licensed facilities, it would restrict the practice of all "invasive procedures involving any portion of the spine, spinal cord, sympathetic nerves or block of major peripheral nerves."[26] In all pertinent facilities, the Bill would prohibit CRNAs and other APNs from administering any such treatments – independent of their established or prior scope of practice, training, or experience with such treatments – without a physician's direct on-site supervision.[27] The Bill further restricts the physicians who are able to supervise – or directly provide – such treatments in non-Chapter 11 facilities, independent of any prior established supervision or collaboration arrangements, and independent of prior practice experience.[28]

These restrictions appear to apply to many and varied health care settings outside the ambit of Chapter 11. Many large and mid-sized health care facilities are licensed under

Chapter 11– most hospitals, nursing homes, residential hospice facilities, and ambulatory surgical treatment centers, included.[29] But Chapter 11's general requirements are subject to certain exceptions, both express (e.g., federal health care facilities[30]) and implied (e.g., various small physician and nursing practices that are not addressed or defined under the Chapter). As a result, the Bill imposes strict statutory restrictions on health care facilities that are likely to have very different staffing and physical resources.[31]

Smaller physician and nursing practices may be especially limited by H.B. 1896, which would deepen the Bill's impact in rural areas. For example, CRNA practices disproportionately serve rural patients.[32] The Tennessee Association of Nurse Anesthetists has testified that CRNAs are the only licensed providers of anesthesia services in 39 Tennessee counties.[33] Other testimony suggests that, under the Bill's restrictions, some existing pain clinics in Tennessee could not continue to operate as presently staffed.[34] New limits on the physician practice of pain medicine, and physician supervision of APNs, could further exacerbate access problems in rural areas, where physicians already may be in short supply.[35]

Based on these concerns, FTC staff urge the legislature to seek an analysis of the Bill's likely impact on Tennessee patients. Identifying the number, variety, and distribution of clinics subject to the Bill's restrictions – and the number of patients treated there – are important first steps in understanding the Bill's potential costs, as well as its potential benefits.

b. Pending Pain Clinic Regulations May Provide an Alternative Approach to Address Demonstrated Patient Risks or Harms, If Any

As noted above, the Tennessee legislature recently provided for the adoption of pain management clinic regulations under Title 63 of the Tennessee Code.[36] While it is impossible to assess the benefits and costs of these yet-to-be-implemented clinic regulations, they seem to provide an alternative means of addressing any patient protection needs in the area of pain management.

Such a limited regulatory approach may offer advantages over the rigid statutory limits contemplated in H.B. 1896. Rules promulgated by the Tennessee Commissioner of Health, in consultation with the relevant professional boards, will likely be more closely tailored to whatever consumer risks or harms might be demonstrated. Moreover, such rules may prove more flexible than the categorical statutory limits proposed in H.B. 1896, especially as the scientific understanding of chronic pain and pain therapy progresses. Regulatory flexibility will be valuable in dealing with newly understood risks, new therapies, advances in professional knowledge and training, and new models of delivering health care.

Furthermore, as a substantive matter, it is unclear whether additional scope of practice restrictions or supervision requirements will be needed. It is, of course, a state's prerogative to define scope of practice limits for pain management practitioners – be they physicians, CRNAs, or other APNs. FTC staff does, however, urge legislators to consider whether there is an evidentiary basis for additional restrictions on physician or nursing practice, or for the Bill's distinction between physicians permitted to provide pain management services and physicians permitted to supervise the provision of such services. As noted above, the Bill itself appears to

recognize that such professionals currently deliver pain management safely in many clinical settings: H.B. 1896 places no new restrictions on CRNAs, APNs, and MDs who provide such services in Chapter 11 licensed facilities (including most hospitals, nursing homes, renal dialysis facilities, hospice facilities, and ambulatory surgical treatment centers).[37] Available empirical research, which examines the provision of diverse anesthesia and pain management services in some of these settings, suggests that CRNAs operating within the scope of their licensure provide anesthesia and pain management services safely.[38] The evidence also suggests that CRNA safety does not depend on physician supervision requirements.[39]

If, upon further study and experience, the legislature or the Tennessee Commissioner of Health determines that there are demonstrated consumer protection needs for the regulation of physician and APN practice outside Chapter 11 facilities, the legislature should consider whether those needs could be met via the pain clinic regulations. By statute, all privately-owned facilities in which pain commonly is treated with specific therapeutic substances of legislative concern[40] will be subject to new regulations regarding, e.g., clinic operation, personnel and training; standards to ensure quality of patient care; and health and safety requirements.[41] If the regulations turn out not to be comprehensive enough,[42] the legislature may considering amending the statutory authority for pain clinic regulations to address additional patient harms or risks, if they are demonstrated.

c. The Bill's Approach Is Likely to Cause Competitive Concerns, Which May Not be Outweighed by Any Benefits

By imposing new limits on the provision of pain management services, H.B. 1896 may exacerbate health care access problems – especially among some of Tennessee's most vulnerable citizens, including elderly and underserved rural populations. As noted above, CRNA practices disproportionately serve rural patients.[43] Many providers may find it difficult to meet the Bill's supervision requirements, especially in rural counties that presently lack any practicing anesthesiologists and have a short supply of other medical specialists.[44]

H.B. 1896 also may reduce competition on price, convenience, and quality among remaining providers. By limiting the number of APNs and CRNAs who can provide pain management services, the Bill will likely reduce the competitive pressures – and constraints – on those practitioners and facilities that are still able to offer pain treatment. By limiting both the types of physicians who can supervise CRNAs and other APNs and the types of physicians who can provide pain management services directly, the Bill is likely to reduce price and non-price competition further. Higher out-of-pocket prices may force difficult choices on some Tennessee health care consumers who need relief from chronic pain. More generally, higher prices, more limited hours, and reduced distribution of services throughout the state can all tend to reduce access to pain treatment. As an article in *Health Affairs* noted, "when costs are high, people who cannot afford something find substitutes or do without."[45] Finally, the Bill 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.[46]

Conclusion

If evidence reveals that particular interventional pain treatment services require specialized training and experience that CRNAs, APNs, and many physicians do not possess, then the legislature should consider whether Tennessee's established regulatory authority can address those limitations and, if not, how to tailor additional restrictions to address those particular services. Similarly, if evidence reveals that particular clinic settings are associated with distinct patient risks or harms, the legislature should consider whether existing regulatory authority can address those risks or harms without undue cost to Tennessee health care consumers. We urge the House study committee to delve into the safety issues, if any, to ensure that statutory limits on physicians, APNs, and CRNAs are no stricter than patient protection requires. Absent evidence of specific safety issues, however, staff recommend that the Bill be rejected, because it is likely to raise costs and limit access to health care.

We appreciate your consideration of these issues.

Respectfully submitted,

Susan S. DeSanti, Director
Office of Policy Planning

Joseph Farrell,
Director
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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. Gary Odom, Tennessee House of Representatives to Susan S. DeSanti, Director, FTC Office of Policy Planning (Apr. 4, 2011).

[3] H.B. 1896 § 1. Chapter 11 generally requires licensing for any "hospital, recuperation center, nursing home, home for the aged, residential HIV supportive living facility, assisted-care living facilities, home care organization, residential hospice, birthing center, prescribed child care center, renal dialysis clinic, outpatient diagnostic center, ambulatory surgical treatment center, or adult care homes," although it does not apply to any health care facilities operated by the federal government, such as hospitals and clinics operated by the Veterans Health Administration or various small physician and nursing practices. TENN. CODE ANN. § 68-11-204 (2011) (regulation of health and related facilities). Separately, H.B. 1896 imposes similar supervision requirements on physician assistants (PAs) outside certain facilities. *Id.* at § 3. Because PAs commonly practice under physician supervision, the extent to which the proposed requirement would further restrict PA practice is unclear.

[4] For example, H.B. 1896 places no new restrictions on CRNAs, APNs, and MDs working in most hospitals, nursing homes, and ambulatory surgical treatment centers. These types of facilities are licensed under Title 68, Chapter 11, of the Tennessee Code. As described below, most of the restrictions proposed in H.B. 1896 would only apply in facilities not licensed under Chapter 11.

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

[6] *Id.* at 4.

[7] Recently enacted legislation provides for the regulation of pain management clinics, in particular. Tennessee Public Chapter No. 340 (revised Jun. 16, 2011, amending Title 63 of the Tennessee Code to establish the regulation of pain management clinics), *available at* http://state.tn.us/sos/acts/107/pub/pc0340.pdf.

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

[9] 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.")

[10] *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.

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

[12] 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, *supra* note 11.

[13] *See, e.g.,* Letter from FTC Staff to Hon. Timothy Burns, *supra* note 12; Letter from FTC Staff to Massachusetts Dep't of Health (September 27, 2007) (regarding proposed limited service clinic 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 our submission of staff letters, the Louisiana legislature rejected the proposed restrictions on competition, and Massachusetts followed FTC Staff recommendations in adopting its final LSC regulations.

[14] *See* 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. 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.

[15] The Bill defines such procedures broadly, including all "invasive procedures involving any portion of the spine, spinal cord, sympathetic nerves or block of major peripheral nerves," outside Chapter 11-licensed facilities.

H.B. 1896 § 4 (amending TENN. CODE ANN. § 63-7-126); *see also id.* at §§ 1, 4 (applying APN supervision requirements to same range of treatments and applying physician assistant supervision requirements to same range of treatments).

[16] H.B. 1896 § 1. Chapter 11 generally requires licensing for any "hospital, recuperation center, nursing home, home for the aged, residential HIV supportive living facility, assisted-care living facilities, home care organization, residential hospice, birthing center, prescribed child care center, renal dialysis clinic, outpatient diagnostic center, ambulatory surgical treatment center, or adult care homes," although it does not apply to any health care facilities operated by the federal government, such as hospitals and clinics operated by the Veterans Health Administration. TENN. CODE ANN. § 68-11-204 (2011) (regulation of health and related facilities). Separately, H.B. 1896 imposes similar supervision requirements on physician assistants (PAs) outside certain facilities. *Id.* at § 3. Because PAs commonly practice under physician supervision, the extent to which the proposed requirement would further restrict PA practice is unclear.

[17] *Id.*

[18] H.B. 1896 § 4 (adding new TENN. CODE ANN. § 63-6-241). *See supra* note 15, and accompanying text (definition of interventional pain management under H.B. 1896).

[19] For example, the supervision requirements also stipulate that the supervising physician be one "who is actively practicing spinal injections and has current privileges to do so at a facility licensed pursuant to title 68, chapter 11." H.B. 1896 § 1. That appears to imply that appropriately trained specialists who do not routinely practice spinal injections in Chapter 11-licensed facilities, but may do so elsewhere, cannot supervise pain management in non-Chapter 11 facilities. It also appears to imply that many physicians permitted to administer pain management treatments in Chapter 11 facilities cannot supervise such treatments in other clinic settings.

[20] *See supra* note 7.

[21] *See id.* at § 1.

[22] *Id.*

[23] *Id.* (TENN. CODE ANN. § 63-1-301(5), focusing on clinics regularly treating patients with "opioids, benzodiazepine, barbiturates, or carisoprodol, but not including suboxone.")

[24] *Id.* (TENN. CODE ANN. § 63-1-302, excepting limited Chapter 11 facilities in particular, including hospitals, hospice facilities, and nursing homes, and expressly exempting federal health care facilities, as well as medical, dental, and nursing schools). On its face, Section 63's list of exempt facilities is substantially narrower than the full list of facilities subject to licensing under Chapter 11.

[25] In competition terms, licensure requirements or scope of practice restrictions, for example, 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.govibe/consumerbehavior/docs/reports/CoxFoster90.pdf.

[26] H.B. 1896 at § 1.

[27] *Id.*

[28] *Id.* at §§ 1 and 4.

[29] *See supra* note 16, and accompanying text.

[30] TENN. CODE ANN. § 68-11-204(b) (2011) (exempting "any health care facility or local health department operated by the federal government" from Chapter 11 licensing requirements). Chapter 11 also provides that "[s]tate or local government home care organizations may be excluded by the board." *Id.* at 68-11-204(a)(2).

[31] In addition, FTC staff question whether the legislature intends to impose heightened restrictions on some of the facilities that seem to be covered by H.B. 1896. For example, because the Bill concerns facilities that are *not*

licensed under Chapter 11, and because federal health care facilities are exempted from Chapter 11's licensing requirements, it appears that the Bill applies to, among others, all facilities operated by the federal Department of Veterans Affairs. A list of facilities operated by the Veterans Health Administration in Tennessee is available at http://www2.va.gov/directory/guide/state.asp?STATE=TN&dnum=ALL. Hence, the Bill appears to impose special limits on the physicians who practice at VA facilities, but not at Tennessee-licensed hospitals and clinics; and it appears to impose special limits on CRNAs and APNs who practice at VA hospitals and clinics as well. The rationale for such restrictions is unclear. By way of contrast, hospitals and clinics "maintained or operated by the federal government" are exempt from pain clinic regulations to be adopted under recently enacted provisions of Title 63.

[32] *See, e.g.,* Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians,* 29 HEALTH AFFAIRS 1469, 141469 (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).

[33] Pamela Turner, CRNA, Ph.D., Testimony Before the Tennessee S. Comm. on SB 1935 (Apr. 27, 2011). Some pain management services may be provided by physicians in those counties although there is a corresponding shortage of specialist physicians in rural counties and, as noted, and absence of anesthesiologists generally (and, hence, of anesthesiologists with subspecialty training in pain management).

[34] *See* Hillary Hatcher, Testimony Before the Tennessee S. Comm. on SB 1935 (Apr. 27, 2011).

[35] *See, e.g.*, IOM REPORT, *supra* note 5, at 107-109, 112 (regarding physician shortages in rural and other underserved areas).

[36] *See supra* note 7, 20 - 24, and accompanying text.

[37] These are types of facilities licensed under Title 68, Chapter 11, of the Tennessee Code and, as described below, most of the restrictions proposed in H.B. 1896 would only apply in facilities that are not licensed under Chapter 11. For a complete list of facilities licensed under Title 68, Chapter 11, see *supra* note 16. "Most" hospitals, assisted-care living facilities, etc., rather than all because, as noted, federal facilities such as VA Medical Centers are not licensed under Chapter 11.

[38] Regarding hospital-based provision of anesthesia services generally, see, e.g., Department of Health and Human Services (HHS), Health Care Financing Administration (HCF A), Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 CFR Parts 416, 482, and 485, Final Rule, 66 Fed. Reg. 4674, 4674-6 (Jan. 18,2001) (reviewing literature on safety and observing that anesthesia services are safe, with "extremely low" mortality rates and no evidence of safety deficits in CRNA practice); Dulisse & Cromwell, *supra* note 32, at 1474 (observing declining mortality and adverse outcomes with increased CRNA services); Michael Pine, et al., *Surgical Mortality and Type of Anesthesia Provider,* 71 AANA Journal 109, 111 (2003) (observing low mortality rates and no significant differences in risk-adjusted mortality rates by type of anesthesia provider or type of anesthesia practice); *cf.* 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.") The published evidence addresses a broad range of anesthesia services, and the legislative record for H.B. 1896 does not reference any countervailing evidence on CRNA safety for interventional pain management services. 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 32, at 1276 (comorbidities and other difficulties in attributing adverse events to anesthesia); *cf* Smith et al., 93 BRIT. J. ANAESTHESIA at 541 (studies too dissimilar to admit formal meta-analysis). Still, published data generally indicate that CRNAs provide anesthesia and pain management services safely 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.

[39] For example, 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." Department of Health and Human Services, Health Care Financing Administration, Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 CFR Parts 416, 482, and 485, Final Rule, 66 Fed. Reg. 4674, 46746 (Jan. 18,2001). As part of that determination – about both physicians and CRNAs – HHS found "no reason to require a Federal rule . . . mandating that physicians supervise the practice of [state-licensed CRNAs]." *Id.* at 4674. More recently, a study of Medicare data from 1999-2005 found that the "data do not support the hypothesis that patients are exposed to increased surgical risk if nurse anesthetists work without physician supervision." Dulisse & Cromwell, *supra* note 32, at 1474 (analyzing 481,440 hospitalizations over the seven-year period). As above, staff recognizes the potential difficulty of generalizing across classes of patients and practice settings. At the same time, this data is national in scope and comprises a large number of diverse anesthesia procedures performed in different regulatory settings. In the absence of more particular and countervailing evidence, it appears generally suggestive of CRNA safety independent of supervision requirements.

[40] *Id.* (TENN. CODE ANN. § 63-1-301(5), focusing on clinics regularly treating patients with "opioids, benzodiazepine, barbiturates, or carisoprodol, but not including suboxone.")

[41] *Id.*

[42] FTC staff recognizes that some small clinics and some forms of treatment may fall outside the scope of Title 63 pain clinic regulations. The legislature, however, does not appear to have identified these or any other residual areas of patient protection concern.

[43] *See supra* notes 32 - 34 and accompanying text.

[44] *Id.*

[45] 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.

[46] Glance, *supra* note 38, 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.")