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

Office of Policy Planning
Bureau of Economics
Bureau of Competition

March 22, 2011

Hon. Daphne Campbell
Florida House of Representatives
1401 The Capitol
402 South Monroe Street
Tallahassee, FL 32399

Dear Representative Campbell:

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 Florida House Bill 4103 ("H.B. 4103" or "the Bill") and the regulation of Advanced Registered Nurse Practitioners ("ARNPs").[2] H.B. 4103 would remove some of the constraints on physician-ARNP supervision arrangements that the Florida legislature adopted in 2006.[3] Your letter expresses concern that the 2006 changes have reduced health care choices and access for Florida consumers, without providing countervailing consumer protection benefits. You have asked FTC staff to analyze the "likely competitive impact" of H.B. 4103, which seeks to replace some of the current constraints on ARNPs' scope of practice with the less-restrictive supervision requirements that existed in Florida before the 2006 legislation took effect.

Based on current evidence, H.B. 4103 appears to represent a procompetitive improvement in the law, one that is likely to benefit Florida health care consumers. As Florida's Department of Health notes in its own analysis of H.B. 4103, reducing current supervision requirements "would allow more access to healthcare."[4] We therefore urge the legislature to consider carefully the impact of the 2006 requirements and to avoid maintaining provisions that would limit ARNP provision of health care services more strictly than patient protection

[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. Daphne Campbell, Florida House of Representatives, to Susan DeSanti, Director, Federal Trade Commission Office of Policy Planning (Feb. 3, 2001).

[3] *Id.* (regarding changes to Fla. Stat. §§ 458.348 and 459.025, which provide for supervision by medical doctors and doctors of osteopathy, respectively).

[4] Florida Dep't Health, Bill Analysis, Economic Statement and Fiscal Note, H.B. 4103, at 4 (Feb. 24, 2011).

requires. For analogous reasons, we urge the legislature to avoid maintaining undue limits on PA provision of health care services.[5]

Unnecessary restrictions on the ability of physicians to supervise ARNPs – or physician assistants ("PAs") – are likely to reduce the availability, and raise the prices, of the health care services that ARNPs and PAs are able to offer Florida health care consumers. In particular, the current restrictions may impose undue burdens on underserved populations, including rural or inner-city patients or the elderly.[6] Restrictions on the scope of practice of ARNPs, PAs, or other health care professionals may be justified if they address demonstrable patient harms and are crafted to provide consumer benefits that offset their costs. The legislative history of the 2006 law suggests, however, that ARNPs and PAs generally had been providing safe care under the supervision standards in effect prior to the 2006 law's enactment.[7] Moreover, the legislative history does not appear to include evidence of particular patient harms that the 2006 legislation was meant to cure. Absent evidence that the heightened restrictions were, and still are, necessary to protect the public, it appears that H.B. 4103 would benefit Florida consumers by facilitating the provision of lower cost and more accessible health care services.

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 focus of FTC law enforcement,[10] research,[11] and advocacy.[12]

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[5] The staff have focused on ARNP issues, as per your request. At the same time, the staff note that analogous issues are presented by restrictions on PA provision of health care services and that excessive supervision requirements for PAs raise similar competitive concerns.

[6] *See, e.g.*, Florida House of Representatives Staff Analysis, Bill # HB 699 CS Health Care (Mar. 8, 2006).

[7] *Id.*

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

[9] *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.").

[10] *See generally,* FEDERAL TRADE COMMISSION (FTC), FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Sept. 2010), *available at* http://www.ftc.gov/bc/110120hcupdate.pdf; FTC, Competition in the Health Care Marketplace, *available at* http://www ftc.gov/bc/healthcare/antitrust/index.htm.

[11] *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.

[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/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

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.[13] In particular, staff have examined apparently excessive restrictions on the scope of practice of ARNPs.[14] A recent report by the Institute of Medicine (IOM) on the Future of Nursing recognizes the importance of this competition perspective and, in particular, the Commission's expertise and experience in addressing undue and anticompetitive restrictions on the scope of nursing practice.[15]

I. Background

A. ARNPs

ARNPs are licensed under Florida's Nurse Practice Act.[16] Under the Nurse Practice Act, ARNPs must meet the general requirements of professional nursing and also complete additional education, such as post-baccalaureate training of one or more years, "[g]raduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills," or training and certification by an appropriate specialty board, such as that for registered nurse anesthetists or nurse midwives.[17] Nationally, "[m]ore than a

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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.

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

[14] *See, e.g.*, Letter from FTC Staff to Kentucky Cabinet for Health and Family Services (Jan. 28, 2010) (regarding restrictions on the scope of practice for nurse practitioners, and others, that would have applied in limited service clinics but not in other limited care settings, such as urgent care centers), *available at* http://www ftc.gov/os/2010/02/100202kycomment.pdf; FTC Staff Comment Before the Alabama State Board of Medical Examiners Concerning the Proposed Regulation of Interventional Pain Management Services (Nov. 3, 2010) (regarding restrictions on the scope of practice of certified registered nurse anesthetists, a specialized sub-category of ARNPs), *available at* http://www.ftc.gov/os/2010/11/101109alabamabrdme.pdf.

[15] INSTITUTE OF MEDICINE, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 5, 10, 105 (2011) [hereinafter IOM REPORT].

[16] FLA. STAT. § 464.001 *et seq.* (2011) (Nurse Practice Act); FLA. STAT. § 464.012 (2011) (certification of advanced registered nurse practitioners); *see also* FLA. ADMIN. CODE ANN. 64B9-4.002, F.A.C. (administrative policies pertaining to certification of advanced registered nurse practitioners).

[17] Fla. Stat. § 464.012(1)(a)-(c) (2011).

quarter of a million nurses are APRNs . . . who hold master's or doctoral degrees and pass national certification exams."[18]

The legislative history of the 2006 ARNP supervision law notes some of the important roles played by "physician extenders," such as ARNPs, in Florida: ARNPs are more likely than alternative providers to serve rural or inner-city areas; ARNPs are more likely to be available outside traditional office hours; and ARNPs play increasingly important roles in caring for senior citizens, due in part "to a severe and growing shortage of geriatricians in the United States."[19]

B. H.B. 4103

H.B. 4103 would remove certain supervision requirements that were adopted in 2006, while retaining the general supervision requirements that predate the 2006 revisions to Florida law.[20] In particular, H.B. 4103 would eliminate restrictions on how physicians may supervise ARNPs. The Bill would rescind the requirements that (a) a primary care physician may not supervise more than four offices besides his or her primary practice location, (b) a specialist physician – except one who provides dermatologic or skin care services – may not supervise more than two offices besides his or her primary practice location, and (c) a physician providing dermatologic or skin care services may not supervise more than one office besides his or her primary practice location.[21] The Bill also would remove certain reporting and notice requirements imposed in 2006.[22]

Standards for ARNP practice protocols still would be established by a joint committee of the Board of Nursing, the Board of Medicine, and the State Surgeon General.[23]

II. Likely Effects on Florida Health Care Consumers

The supervision requirements enacted in 2006 imposed administrative costs and other restrictions on physicians supervising ARNPs. H.B. 4103 is likely to reduce the costs of basic

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[18] IOM REPORT, *supra* note 15, at 23. Although certification exams are administered nationally, and licensure requirements in other states generally are coincident with Florida's, requirements are determined on a state-by-state level. Staff note that, in various states, certified advanced practice nurses may be referred to as "ARNPs," "APRNs," "nurse practitioners," etc. For an overview of ARNP requirements generally, see *id.* at 26, table 1 (types of ARNP practice) and 38-45.

[19] Florida House of Representatives Staff Analysis, Bill # HB 699, *supra* note 6.

[20] *Id.* at §§ 458.348(1)-3) and 459.025 (notice requirements for supervisory relationships, standing orders, and established protocols and establishment of standards by joint committee).

[21] *See* H.B. 4103 (regarding amendments to Fla. Stat. §§ 458.348 and 459.025). H.B. 4103 would also strike requirements that only board-certified dermatologists supervise ARNPs providing dermatologic or skin care services and that supervising practices have a certain geographic proximity to supervised practices. *Id.*

[22] For example, H.B. 4103 would remove the requirement that a supervising physician post in all offices both a current schedule of the physician's own presence in the office and the hours when the office is open while the physician is not present. Fla. Stat. § 458.348(4)(d). The Bill also would strike the separate requirement that supervising dermatologists submit to the board addresses of the offices which the physician supervises. Id. at

[23] *See id.* Notice requirements for supervisory relationships also would continue. *Id.* § 458.348(4)(c)(1).

health care services provided by ARNPs, and some of these cost savings may be passed on to Florida health care consumers, and public and private third-party payers, in the form of lower prices.

FTC staff concur with Florida's Department of Health's assessment that H.B. 4103 "would allow more access to healthcare."[24] By reducing barriers to innovation in health care delivery, the Bill will permit health care providers greater flexibility to offer basic health care through ARNP-staffed clinics. The IOM recently recognized the important role that ARNPs can play in improving access to health care.[25] The IOM also noted, among other things, that "[r]estrictions on scope of practice . . . have undermined the nursing profession's ability to provide and improve both general and advanced care."[26]

Increasing the number of ARNP-staffed clinics may also increase competition to provide basic health-care services. For example, ARNP-staffed clinics generally offer weekend and evening hours, providing flexibility for patients. Further, the existence of such clinics may incent other types of clinics to offer extended hours as well.[27] To the extent that H.B. 4103 increases the deployment of ARNPs in a variety of health care delivery settings, and thereby increases the range of choices available to consumers, the proposed legislation is likely to benefit Florida health care consumers.

ARNPs have, for example, played an important role in the recent proliferation of limited service clinics ("LSCs") in many states. LSCs typically are staffed by ARNPs[28] – with consultation and supervision commonly provided at a distance, via telemedicine[29] – and offer

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[24] Florida Dep't Health, Bill Analysis, Economic Statement and Fiscal Note, H.B. 4103, *supra* note 4, at 4.

[25] *See generally,* IOM REPORT, *supra* note 15 (especially Summary, 1-15).

[26] *Id*. at 4.

[27] *Cf.* Rena Rudavsky, Craig Evan Pollack, & Ateev Mehrotra, *The Geographic Distribution, Ownership, Prices, and Scope of Practice at Retail Clinics*, 151 ANNALS INTERNAL MED. 315, 317 (2009) ("In a random sample of 98 [limited service] clinics, all had weekday and weekend hours and 95 (97%) had evening hours (after 6 p.m.) on weekdays.")).

[28] *See generally* William M. Sage, *Might the Fact that 90% of Americans Live Within 15 Miles of a Wal-Mart Help Achieve Universal Health Care?,* 55 U. KAN. L. REV. 1233, 1238 (2007) (describing the size and scope of limited service clinics); Mary Kay Scott, Scott & Company, *Health Care in the Express Lane: Retail Clinics Go Mainstream*, Sept. 2007, at 22 (report prepared for the California HealthCare Foundation), *available at* http://www.chcf.org/publications.

[29] *See, e.g.*, Sage, *supra* note 28, at 1240, 1245 (improvements in electronic *Within 15 Miles of a Wal-Mart Help* information and decision support); Testimony of Mary Kate Scott, Fed. Trade Comm'n Workshop, Innovations in Health Care Delivery, 25 (Apr. 24, 2008). A complete transcript of the Workshop is *available at* http://www ftc.gov/bc/healthcare/hcd/docs/hcdwksptranscript.pdf (bringing physician into clinic via telemedicine). Evidence shows that the quality of care provided by ARNPs in these clinics is "similar to that provided in physician offices and urgent care centers and slightly superior to that of emergency departments." Ateev Mehrotra et al., *Comparing Costs and Quality of Care at Retail Clinics with that of Other Medical Settings for 3 Common Illnesses*, 151 ANNALS INTERNAL MED. 321, 326 (2009) (analysis of 14 quality metrics for commonly treated ailments otitis media [ear infection], streptococcal pharyngitis [strep], and urinary tract infections). Indeed, "[f]or most measures, quality scores of retail clinics were equal to or higher than those of other care settings." *Id.*

consumers a convenient way to obtain basic medical care at competitive prices.[30] Restrictions on oversight and supervision of ARNPs may limit both the number and types of LSCs available to Florida consumers.

III. Consumer Protection Concerns and Scope of Practice and Supervision

Patient safety or consumer protection concerns can justify licensure requirements and scope of practice restrictions.[31] FTC staff recognize that particular health care procedures may require specialized training or heightened supervision if they are to be safely administered. The staff note, however, that the legislative history of the 2006 law does not appear to include any demonstrated patient harms associated with the supervision requirements that had been in force before its enactment or any evidence that the safety of care provided by ARNPs varies according to such requirements.[32] Moreover, the record does not appear to contain evidence supporting uniquely heightened supervision requirements in the general areas of dermatologic and skin care. In addition, there does not appear to be a safety rationale distinguishing the exemption of various practices from the special supervision requirements imposed under the 2006 law.[33]

The legislative history suggests, rather, that ARNPs in general are safe providers of health care services within their scope of practice.[34] More broadly, the available empirical

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[30] *See* Massachusetts Dept. Pub. Health, Commonwealth to Propose Regulations for Limited Service Clinics: Rules May Promote Convenience, Greater Access to Care (Jul. 17, 2007), *available at* http://www.mass.gov/?pageID=pressreleases&agId=Eeohhs2&prModName=dphpressrelease&prFile=070717_clinics.xml. The types of care offered at LSCs are similar to those offered in urgent care centers and other limited care, outpatient settings. *See, e.g.*, Ateev Mehrotra et al., et al., *Retail Clinics, Primary Care Physicians, and Emergency Departments: A Comparison of Patients Visits*, 27 HEALTH AFFAIRS 1272, 1279 (September/October, 2008).

[31] 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.

[32] That is, the legislative history of the 2006 legislation does not appear to indicate that additional supervision of ARNPs will improve safety of care. The Florida House Report merely notes the concerns of some observers that "nonphysicians remain carefully supervised and trained in their scope of practice." Florida House of Representatives Staff Analysis, *supra* note 6, at n.6. FTC staff have not found empirical studies indicating a relationship between additional ARNP supervision and greater safety. With regard to particular ARNP subspecialties, there is some evidence that supervision requirements do not affect patient safety. *See* Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians*, 29 HEALTH AFFAIRS 1469, 1474 (2010) (reviewing Medicare data for more than 480,000 patients and finding "data do not support the hypothesis that patients are exposed to increased surgical risk if nurse anesthetists work without physician supervision.").

[33] Diverse providers are exempted from the particular supervision requirements imposed under the 2006 law, including, among others, hospitals and other facilities licensed under Chapter 395 of Florida's Public Health law, "or in conjunction with a college of medicine, a college of nursing, an accredited graduate medical program, or a nursing education program; not-for-profit, family-planning clinics . . . rural and federally qualified health centers," health care services provided in certain nursing homes, assisted living facilities, and retirement communities. Fla. Stat. §§ 458.348(e) and § 459.025(e).

[34] Florida House of Representatives Staff Analysis, *supra* note 7, at note 5 and accompanying text (citing Linda Aiken, director of the University of Pennsylvania's Center for Health Outcomes and Policy Research, for the

evidence indicates that APRN-delivered care "across settings, is at least equivalent to that of physician-delivered care as regards safety and quality."[35] Studies also indicate that increased ARNP care may be associated with improved outcomes for particular disease indications or patient populations.[36] Studies of limited service clinics – which offer certain basic primary care services and tend to be staffed by ARNPs without direct, on-site physician supervision – indicate that the clinics provide high quality health care.[37] In addition, studies of ARNP subspecialties, such as certified registered nurse anesthetists, suggest safe delivery of care.[38]

Conclusion

Restrictions on the supervisory relationships between physicians and ARNPs impose costs on Florida health care consumers. H.B. 4103 would reduce those costs. Absent evidence that the special restrictions imposed in 2006 are required to address demonstrable patient harms, FTC staff urge that H.B. 4103 be enacted to remove those restrictions. If particular medical procedures demonstrably require heightened supervision requirements, then staff recommends that the legislature tailor supervision requirements to address those particular services.

We appreciate your consideration of these issues.

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proposition that "over 100 studies have examined the care delivered by nurse practitioners and none demonstrated a negative impact of their care on health.").

[35] Eileen T. O'Grady, *Advanced Practice Registered Nurses: The Impact on Patient Safety and Quality*, in AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, PATIENT SAFETY AND QUALITY: AN EVIDENCE-BASED HANDBOOK FOR NURSES (ed. Ronda G. Hughes) 2-606 (2008). The study surveys empirical research on ARNP quality and safety generally, *id.* at 2-605 – 2-607, as well as research regarding safety and quality of care for ARNP subspecialties. *Id.* at 2-602 – 2-604 (regarding nurse midwives, nurse anesthetists, and clinical nurse specialists); *see also* Sue Horrocks et al., *Systematic Review of Whether Nurse Practitioners Working in Primary Care Can Provide Equivalent Care to Doctors*, 324 BMJ 819 (2002) (British review of 11 trials and 23 observational studies finding increased satisfaction and no health disparities for patients treated by nurse practitioners vs. physicians).

[36] *See, e.g.* Mary D. Naylor, et al., *Transitional Care of Older Adults Hospitalized with Heart Failure: A Randomized, Controlled Trial*, 52 J. AM. GERIATRIC SOC'Y 675, 682-684 (AP[R]N-directed intervention associated with increased time to first readmission or death and reduced total number of rehospitalizations in care of older adults and management of heart failure); *cf.* Jack Needelman et al., *Nurse-Staffing Levels and the Quality of Care in Hospitals*, 346 N. ENGL. J. MED. 1715, 1719-20 (2002) (increased care by registered nurses – which include ARNPs as subset – associated with improved outcomes/reduced adverse events for medical and surgical patients).

[37] Ateev Mehrotra et al., *Comparing Costs and Quality of Care at Retail Clinics with that of Other Medical Settings for 3 Common Illnesses*, 151 ANNALS INTERNAL MED. 321, 326 (2009) (analysis of 14 quality metrics for commonly treated ailments finding quality comparable to physician offices and slightly better than emergency rooms).

[38] *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."); Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians*, 29 HEALTH AFFAIRS 1469, 1469 (2010); Michael Pine et al., *Surgical Mortality and Type of Anesthesia Provider*, 71 AM. ASS'N NURSE ANESTHETISTS J. 109, 116 (2003) ("After adjustment for differences in case mix, clinical risk factors, hospital characteristics, and geographic location, the current study found similar risk-adjusted mortality rates whether anesthesiologists or CRNAs worked alone.").

Respectfully submitted,

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