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

Office of Policy Planning
Bureau of Competition
Bureau of Economics

January 17, 2014

The Hon. Kay Khan
Massachusetts House of Representatives
Room 146, State House
Boston, MA 02133-1054

Dear Representative Khan:

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 the likely competitive impact of House Bill 2009 ("H.2009" or "the Bill").[2] The Bill would remove certain supervision requirements now imposed on nurse practitioners ("NPs") and nurse anesthetists ("NAs") under Massachusetts law. In particular, the Bill would permit NPs and NAs to order tests and therapeutics, and issue written prescriptions, without establishing a formal supervisory agreement with a particular Massachusetts physician. It would also permit properly licensed and registered NAs and NPs to administer and dispense certain controlled substances without these types of formal supervisory agreements. Absent good grounds to continue the current supervision requirements, removing them may offer Massachusetts health care consumers and third-party payors significant benefits.

A report by the Institute of Medicine ("IOM") has identified a key role for advanced practice registered nurses ("APRNs"), including NPs and NAs, 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. Based on an intensive examination of APRN practice issues, the IOM found that "[r]estrictions on scope of practice . . . have undermined [nurses'] ability to provide and improve both general and advanced care."[4] Similarly, in 2012, the National Governors Association (NGA) reported on APRNs' potential to address increased demand for primary care services, particularly in historically underserved areas.[5] The report noted the high quality of primary care services provided by APRNs, who "may be able to mitigate projected shortages of primary care services."[6]

Additional research suggests that Massachusetts, specifically, is affected by the national health care delivery problems discussed in the IOM and NGA Reports. While Massachusetts as a whole is rich in medical resources, serious shortages exist in some areas of practice and some geographic areas within the state. For example, a recent report

by the Massachusetts Medical Association observes that primary care doctors are in short supply, describing statewide family medicine shortages as "critical" and internal medicine shortages as "severe."[7] The same report highlights regional physician shortages, especially in Western Massachusetts.[8] Existing supervision requirements in Massachusetts limit the abilities of APRNs to alleviate these shortages.

APRN supervision requirements raise several related competitive concerns. By restricting APRNs' access to the marketplace, supervision requirements may deprive health care consumers of some of the benefits that provider competition can offer. Undue impediments to competition can affect the cost and quality of available health care services and restrict provider innovation in health care delivery. Excessive supervision requirements also can exacerbate provider shortages and access problems, particularly for underserved populations that already lack adequate and cost-effective primary care services.

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 defer to Massachusetts on the ultimate health and safety standards that the Commonwealth may choose to establish. We recommend, however, that the legislature seek to maintain only those NA and NP supervision requirements that advance patient protection. In particular, we urge the legislature to examine carefully any purported safety justifications for the Commonwealth's current NP and NA supervision requirements, evaluate whether these justifications are well-founded, and consider whether less restrictive alternatives would protect patients without unduly burdening competition. To that end, it may be particularly useful to look at APRN practice in states that do not require supervision, and to consider the available evidence regarding patient benefits and harms in those states, including the findings of the IOM, the NGA, and other experts in the field. If there are not good grounds to impose across-the-board supervision restrictions on all services performed by NPs and NAs, removing these restrictions in whole or part may offer significant benefits to Massachusetts health care consumers and payors.

I. INTEREST AND EXPERIENCE OF THE FTC

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, 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,[11] research,[12] and advocacy.[13] Recently, FTC staff have analyzed the likely competitive effects of proposed advanced practice nursing regulations in other states, observing that removing overly burdensome supervision requirements can achieve significant benefits.[14]

II. HOUSE BILL 2009

H.2009 proposes numerous amendments to Massachusetts statutory provisions governing advanced practice nursing. Collectively, these changes would permit what is sometimes termed "independent practice" by NPs and NAs in Massachusetts.[15] For purposes of FTC staff's response to your comment invitation, several provisions stand out as relevant to our competition analysis.

First, amendments to Chapter 112, Section 80B of the General Laws of Massachusetts would include NAs among the named categories of APRNs, or "duly authorized nurses in advanced roles," and would streamline APRN regulation by assigning rule-making authority to the Board of Nursing.[16]

Second, amendments to Chapter 112, Section 80E would remove the general requirement that a NP order tests and therapeutics, or prescribe medications, only under a formal supervisory agreement with a physician.[17] Similarly, amendments to Section 80H would remove the requirement that NAs delivering perioperative care – anesthesia and pain medicine before and after surgery – order tests and therapeutics, or prescribe medications, only under a formal supervisory agreement with physician.[18] Amendments to Section 80H also would lift the requirement that prescriptions written by an NA, otherwise consistent with Massachusetts and federal laws and regulations, include the name of a supervising Massachusetts physician.[19]

Third, amendments to Chapter 112, Section 211 would permit NAs to administer drugs or therapeutic agents via intravenous or extracorporeal circuit, and would permit NAs (as well as physicians) to administer (and order and supervise) anesthetic agents via intravenous or extracorporeal circuit.[20]

Fourth, the Bill would amend Massachusetts controlled substances laws to remove supervision requirements, for certain controlled substances, for NAs and NPs otherwise registered and licensed to dispense, administer, or prescribe controlled substances. Amendments to Chapter 94C, Section 1 would stipulate that NPs and NAs are "practitioners" who are permitted to write medication orders – orders for a drug to be dispensed for immediate administration in a hospital, ambulatory care clinic, or other health care facility – for certain controlled substances.[21] These amendments also would include NPs and NAs among those providers allowed to administer controlled substances, as appropriate, for the alleviation of pain and suffering, as well as treatment or alleviation of disease.[22] Amendments to Chapter 94C, Section 18 would provide that prescriptions for certain controlled substances (Schedules III-VI) could be written by properly authorized and registered NAs and NPs, as clinically appropriate.[23]

III. LIKELY COMPETITIVE BENEFITS OF H.2009

FTC staff recognize that certain professional licensure requirements and scope of practice restrictions can be important to patient welfare.[24] Consistent with patient safety, however, we urge legislators to consider the potential benefits of enhanced competition

that H.2009 may facilitate. If APRNs are better able to practice to the extent of their education, training, and abilities, and if institutional health care providers are better able to deploy APRNs as needed, Massachusetts health care consumers are likely to benefit from lower costs, additional innovation, and improved access to health care.

a. H.2009 WOULD LIKELY IMPROVE ACCESS TO PRIMARY CARE SERVICES, AS IT HELPS EXPAND THE SUPPLY OF SERVICES AND PROVIDERS

The United States faces substantial and growing shortages of physicians.[25] While these shortages will exacerbate health care access problems for many American consumers, the impact of reduced access is likely to be most acute among underserved populations and areas, due not only to geographic misalignment between rural and low-income communities and physician practice locations, but also to low physician participation in state Medicaid programs.[26] Expanding the supply of independent primary care practitioners, and hence available primary care services, is one way to ameliorate such shortages.

The Commonwealth also faces provider shortage issues and resulting access challenges. According to a report by the Massachusetts Department of Public Health, "[i]mplementation of Health Care Reform has identified and potentially exacerbated a clear imbalance of primary care access across the state, with long wait times and closed practices."[27] A 2013 study by the Massachusetts Medical Association identifies persistently high wait times for internal medicine and pediatric visits.[28] The same report, as noted above, observes that family medicine shortages are "critical," and internal medicine shortages "severe," statewide.[29] Regional shortages are observed across practice areas, including primary care, especially for Western Massachusetts.[30] Consistent with those findings, the NGA report points out that there are 75 federally-designated primary care Health Professional Shortage Areas ("HPSAs") in Massachusetts.[31]

Many health care authorities see wider deployment of APRNs as crucial to addressing both extant and projected access problems, including in Massachusetts.[32] APRNs are the fastest-growing segment of the primary care professional workforce in the United States,[33]and they make up a greater share of the primary care workforce in less densely populated, less urban, and lower income areas, as well as in federally-designated HPSAs. Relative to primary care physicians, APRNs are more likely to practice in underserved areas and to care for large numbers of minority patients, Medicaid beneficiaries, and uninsured patients.[34] In addition, some reports suggest that more APRNs practice in states that allow independent practice (i.e., practice without immediate supervision or collaborative agreement requirements).[35] A study of physician supply and demand by the American Association of Medical Colleges recognizes that one way to meet "future demand for physician services is expanding the role of . . . NPs where the physician shortage is expected to be greatest, i.e., in primary care."[36] The AAMC also recognizes that expanding the primary care roles now filled by NPs (and physician assistants) can free up physicians to focus on more complex cases or more severely ill patients.[37] With respect to Massachusetts, specifically, a study conducted for the

Massachusetts Division of Health Care Finance and Policy suggests some of the potential for regulatory reform: "Given widespread agreement that there is a critical shortage of primary care physicians in the Commonwealth, expanding scope-of-practice ... [for APRNs] could be a viable mechanism for increasing primary care capacity and reducing health care costs."[38] Thus, if Massachusetts eliminates APRN supervision requirements, the Commonwealth may benefit from growth, both in the number of APRNs providing primary care services and in the overall availability of primary health care services.[39]

Similar issues face rural hospitals and surgical facilities seeking to provide adequate anesthesia services during surgery and adequate pain treatment before and after surgery. According to one source, more than half of all anesthesiologists practicing in Massachusetts are based in two counties, Suffolk and Middlesex.[40] Indeed, several Massachusetts counties have very few board-certified anesthesiologists, and Nantucket has none.[41] That may reflect a local undersupply of anesthesiologists; and because NAs cannot practice without physician supervision, it may limit both providers' ability to deploy NAs to help meet demand and training opportunities for NAs in underserved areas. It is worth noting that, nationwide, NA practices disproportionately serve rural patients,[42] and NAs are better able to help fill unmet needs when they are able to practice more flexibly in underserved areas. It appears that H.2009's proposed changes to NA supervision requirements alone – with no increase or redistribution of the state's health care workforce, and no further expansion of the scope of NA practice – could have a significant impact on access to NA providers and services. For example, H.2009 would increase the population of independent, licensed anesthesia providers in Hampden County by more than 60 percent.

In sum, the Bill's elimination of APRN supervision requirements may improve access to primary care and other needed services, including surgical and perioperative anesthesia services, especially for rural and other underserved populations.

b. H.2009 COULD HELP TO MODERATE HEALTH CARE COSTS AND PRICES

Mandatory physician supervision requirements can impose unnecessary costs on the supervising physician and the supervised APRN, as well as any institutional health care providers potentially employing them. When this regulatory burden is reduced (e.g., by removing particular physician supervision requirements), the supply of professionals willing to offer those services at any given price increases. Expansion of supply tends to lower prices for everyone, which will be particularly beneficial in underserved areas and for underserved populations. Even in well-served areas, supply expansion will tend to lower prices and reduce health care costs.

Moreover, because APRNs tend to be relatively low cost providers, expanding their ability to provide additional services may lower the average costs of those services, potentially enhancing savings associated with a supply expansion.[43] Although FTC staff have not independently projected any specific potential savings from H.2009, we note that a study conducted for the Commonwealth of Massachusetts by RAND Health does

suggest a particular range of savings that expanded APRN (and physician assistant) scope of practice could achieve, due to the lower costs and prices that tend to be associated with APRN-delivered services: "between 2010 and 2020, Massachusetts could save $4.2 to $8.4 billion through greater reliance on NPs and PAs [physician assistants] in the delivery of primary care."[44] The same report indicates additional potential savings of up to $6 billion, if regulatory and payment reform were to facilitate expanded use of retail clinics.[45] NAs also are relatively low cost providers, and at least one study suggests that independent NA practice is the most cost-effective model for anesthesia care.[46]

c. H.2009 COULD HELP TO FOSTER INNOVATION IN HEALTH CARE DELIVERY

As the health care marketplace evolves, new models of provider organization and collaboration typically represent an important form of innovation in health care delivery.[47] Restrictions on APRNs may limit not only physician-APRN collaborations, but also the ability of health care providers to develop, test, and implement the most efficient teams of primary care and anesthesia professionals.[48] Proponents of team-based care have recognized the importance of innovation in this area, and the diversity of approaches to team-based care that may be successful in different practice settings, or in treating different patient populations.[49] In general, laws and regulations should promote this kind of innovation, not limit it, directly or indirectly. Rigid physician supervision requirements not only restrict competition by independent APRNs, but also may constrain the ability of physician practices, hospitals, clinics, and other providers to experiment with flexible oversight and collaboration arrangements for employed or contractually-affiliated APRNs.

For example, APRNs have played an important role in the expansion of "retail" or "limited service clinics" ("LSCs") in Massachusetts and many other states. LSCs typically are staffed by APRNs[50] and offer consumers an efficient and convenient way to obtain basic medical care at competitive prices.[51] APRN-staffed clinics generally offer weekend and evening hours, which provide greater flexibility for patients, and may provide competitive incentives for other types of clinics to offer extended hours as well.[52] By eliminating restrictions on APRNs' ability to work independently within their full scope of practice, the Bill may increase both the number and types of clinics available to Massachusetts consumers.[53]

Other reports highlight diverse private and public innovations in deploying APRNs in team-based health care.[54] Regulatory flexibility may be key to this type of innovation, to the extent that providers and other health experts have not settled on a single best model of team based care. As one report observes, "[e]ach health care team is unique—it has its own purpose, size, setting, set of core members, and methods of communication."[55]

IV. APRN SUPERVISION REQUIREMENTS SHOULD SERVE WELL-FOUNDED PATIENT PROTECTION CONCERNS

FTC staff fully recognize the critical importance of patient health and safety. None of the forgoing discussion is meant to downplay the valid health and safety concerns reflected in many regulations governing health care professionals. We defer to state legislators to survey the available evidence, determine the optimal balance of policy priorities, and define the appropriate scope of practice for APRNs and other health care providers. As the Massachusetts legislature engages in this exercise, however, we urge it to carefully consider the findings of the IOM and other expert bodies – findings based on decades of research and experience – on issues of APRN safety, effectiveness, and efficiency.[56] The IOM, based on an extensive review of the safety literature, has recommended that nurses be permitted by state licensing laws to practice to the full extent of their training.[57]

The IOM Report notes that 16 states and the District of Columbia allow APRNs to practice and prescribe independently, and that no differences in safety and quality have been associated with state laws that permit APRNs to practice independently.[58] The ability to write prescriptions is one of the defining criteria for independent APRN practice and has been an ongoing source of contention.[59] As the IOM observes, however, studies have examined outcomes associated with APRNs that have independent prescribing authority, and the results have suggested that APRN and physician primary care outcomes are comparable.[60] FTC staff are not aware of any contrary empirical evidence to support the contention that there are patient harms or risks particularly associated with APRN prescribing.

FTC staff also understand that the distribution, prescription, and use of controlled substances may prompt heightened regulatory concern. There have been, for example, ongoing national concerns about diversion and misuse of pain medicines.[61] Our sister agency, the federal Food and Drug Administration, "has become increasingly concerned about the abuse and misuse of opioid products," in particular, and may shortly propose new regulations for hydrocodone combination products.[62] Likewise, we understand that various medical risks may be associated with certain pain management procedures,[63] and we do not attempt to assess those risks for the medical contexts in which they apply.[64]

However, staff recommends that the legislature consider whether APRN administration or prescription of controlled substances raises particular concerns and, if so, whether physician supervision requirements are likely to be successful or cost-effective ways minimize any added risk. It may be relevant to consider, in particular, that H.2009 would not remove state or federal oversight of controlled substance prescribing, distribution, or administration. In addition, the 2012 NGA Report identifies 15 states, plus the District of Columbia, in which APRNs may independently prescribe controlled substances and staff encourages the legislature to look to the experience of those states when weighing any health or safety risk that may be associated with H.2009.[65]

Current Massachusetts supervision requirements appear to impede NAs particularly in their ability to provide anesthesia care and perioperative pain treatment to the extent permitted in other states. The IOM Report observes that NAs administer more than 65% of all anesthetics to U.S. patients, and that, generally, they "[a]dminister anesthesia and provide related care before and after surgical, therapeutic, diagnostic, and obstetrical procedures, as well as pain management."[66] The U.S. Department of Health and Human Services has reviewed several times the available literature on the quality of anesthesia services in publishing rules regarding the provision of hospital anesthesia services, under the Medicare and Medicaid programs, but has not found that risks suggest further restrictions on NA practice. For example, in 2001, the Centers for Medicaid and Medicare Services ("CMS") concluded that anesthesia services generally were safe and, in particular, that there was "no need for Federal intervention in State professional practice laws governing [NA] practice. . . . [and] no reason to require a Federal rule in these conditions of participation mandating that physicians supervise the practice of [state-licensed NAs]."[67] The IOM too, has reviewed the safety literature, suggesting that "evidence shows that [NAs] provide high-quality care . . . [while] there is no evidence of patient harm from their practice.[68]

We encourage Massachusetts legislators to review available empirical literature, as well as evidence from other states with less restrictive NP and NA supervision requirements, particularly when assessing continued reliance on broad statutory supervision requirements.

V. CONCLUSION

H.2009 would streamline APRN regulation and permit APRNs to more fully employ their education and experience in serving Massachusetts health care consumers, with regulatory oversight, but without certain formal physician supervision requirements now imposed under Massachusetts law. Absent countervailing safety concerns regarding APRN practice, removing these supervision requirements has the potential to benefit consumers by improving access to care, containing costs, and expanding innovation in health care delivery. Accordingly, we encourage legislators to consider whether these requirements are necessary to assure patient safety in light of your own regulatory experience, the findings of the IOM and other expert bodies, and the experience of other states. Removing unnecessary and burdensome requirements may benefit Massachusetts consumers by increasing competition among health care providers.

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 the Hon. Kay Kahn, Massachusetts House of Representatives to Andrew I. Gavil, Director, Fed. Trade Comm'n Office of Pol'y Planning, Aug. 20, 2013. FTC staff were asked to comment on companion bills in the Massachusetts legislature, H 2009 and S 1079. For brevity, this comment refers solely to H 2009, although its policy analysis applies equally to parallel provisions in the Senate bill.

[3] *See generally* INST. OF MED., NAT'L ACAD. OF SCIENCES, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH (2011) [hereinafter IOM FUTURE OF NURSING REPORT] (especially Summary, 1-15).

[4] *Id*. at 4.

[5] National Governors Association, *The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care* (Dec. 20, 2012), at: http://www.nga.org/cms/home/nga-center-for-best-practices/center-divisions/page-health-division/col2-content/list---health-left/list-health-highlight/content-reference-2@/the-role-of-nurse-practitioners html [hereinafter NGA, *Role of Nurse Practitioners*].

[6] *Id.* at 11.

[7] MASS. MED. SOC'Y, 2013 MMS PHYSICIAN WORKFORCE STUDY, 12 (Sept. 2013).

[8] *Id.* at 3, 19-20.

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

[10] Standard Oil Co. v. Fed. Tr. Comm'n, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

[11] *See* FTC, An Overview of FTC Antitrust Actions in Health Care Services and Products (Dec. 2011), *available at* http://www ftc.gov/bc/healthcare/antitrust/hcupdate.pdf; FTC, Competition in the Health Care Marketplace: Formal Commission Actions (1996 – 2008), *available at* http://www ftc.gov/bc/healthcare/antitrust/commissionactions.htm.

[12] *See* 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 12.

[14] *See, e.g.*, FTC Staff Comment to the Hon. Heather A. Steans, Illinois State Senate, Concerning Illinois Senate Bill 1662 and the Regulation of Certified Registered Nurse Anesthetists (CRNAs) (Apr. 2013), *available at* http://www.ftc.gov/os/2013/04/130424illinois-sb1662.pdf; FTC Staff Letter to the Hon. Theresa W. Conroy, Connecticut House of Representatives, Concerning the Likely Competitive Impact of Connecticut House Bill 6391 on Advance Practice Registered Nurses (Mar. 2013), *available at* http://ftc.gov/os/2013/03/130319aprnconroy.pdf; FTC Staff Testimony Before Subcommittee A of the Joint Committee on Health of the State of West Virginia Legislature on The Review of West Virginia Laws Governing the Scope of Practice for Advanced Practice Registered Nurses and Consideration of Possible Revisions to Remove Practice Restrictions (Sept. 2012), *available at* http://www.ftc.gov/os/2012/09/120907wvatestimony.pdf; FTC Staff Comment Before the Louisiana House of Representatives on the Likely Competitive Impact of Louisiana House Bill 951 Concerning Advanced Practice Registered Nurses ("APRNs") (Apr. 2012), *available at* http://www.ftc.gov/os/2012/04/120425louisianastaffcomment.pdf; 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.

[15] The phrase "independent practice" here, and commonly, refers to state regulatory schemes that do not require direct supervision of an APRN by a particular physician for an APRN to deliver services otherwise within his or her scope-of-practice. "Independent practice" does not, however, mean isolated or unregulated practice. Collaboration and professional oversight are the norm in states that do not require direct physician supervision. Patterns of collaboration are independently established by institutional providers, from large hospital systems to small physician practices, to individual practitioners, with the particulars varying according to resources and demands at the point of service, and standards of care, as well as other regulations. It has been reported that more than half of all nurse practitioners are employed in private physician practices (27.9%) or hospitals (24.1%), among other institutional provider settings. John K. Iglehart, *Expanding the Role of Advanced Practice Nurse Practitioners – Risks and Rewards*, 368 N. ENGL. J. MED. 1935, 1937 (2013). Regarding diverse practice settings and APRN collaboration, see IOM FUTURE OF NURSING REPORT, *supra* note 3, at 23, 58-59, 65-67, 72-76; regarding the evolution and diversity of team-based care, see generally Pamela Mitchell et al., Nat'l Acad. of Sciences, Inst. of Med. Discussion Paper, *Core Principles & Values of Effective Team-Based Health Care* (2012), http://www.iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Team-Based-Care-Principles-Values.pdf (IOM-sponsored inquiry into collaborative or team-based care).

[16] H 2000, §§ 16-17. Existing law requires that nursing regulations be promulgated by the Board of Nursing "in conjunction with the board of registration in medicine . . . . only after the two boards have met, consulted and concurred on the content of such regulations." MASS. GEN. LAWS ch. 112, § 80B. These amendments further stipulate that the authority to promulgate rules that "govern the provision of advanced practice nursing services and related care, including but not limited to the ordering and interpreting of tests and the ordering of treatment and therapeutics," would rest with the Board of Nursing.

[17] H 2000, § 17. Staff notes that this amendment would leave the requirement in place for psychiatric nurse mental health specialists.

[18] *Id.* at § 18.

[19] *Id.*

[20] *Id.* at§§ 21-22.

[21] *Id.* at § 2.

[22] *Id.* at §§ 21-22.

[23] *Id.* at §§ 13-15.

[24] 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.

[25] *See* Kaiser Commission on Medicaid and the Uninsured, *Improving Access to Adult Primary Care in Medicaid: Exploring the Potential Role of Nurse Practitioners and Physician Assistants*, at 1 (Mar. 2011), *available at* http://www.kff.org/medicaid/upload/8167.pdf [hereinafter "Kaiser Commission, *Improving Access*"]; the Association of American Medical Colleges (AAMC) Physician Shortages Factsheet, *available at* https://www.aamc.org/download/150584/data/physician_shortages_factsheet.pdf (in its projections of physician supply and demand, the AAMC assumes that each additional two NPs (or Physicians Assistants) reduce physician demand by one) [hereinafter "AAMC, *Physician Shortages*"]; 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, 70-72, exhibits 51-52 (2008), *available at* http://bhpr.hrsa.gov/healthworkforce/reports/physwfissues.pdf. [Hereinafter HRSA PHYSICIAN WORKFORCE REPORT].

[26] *See* Kaiser Commission, *Improving Access*, *supra* note 25, at 1.

[27] Mass. Dep't Public Health. Health of Massachusetts, 38 (Apr. 2010).

[28] 2013 MMS PHYSICIAN WORKFORCE STUDY, *supra* note 7, at 6 (recent increases to a 25 day average for new patient pediatric visits and 50 days for internal medicine).

[29] 2013 MMS PHYSICIAN WORKFORCE STUDY, *supra* note 7, at 12.

[30] *Id.* at 3, 19-20.

[31] NGA, *Role of Nurse Practitioners*, *supra* note 5. *See also* Kaiser Family Foundation, statehealthfacts.org, Primary Care Health Professional Shortage Areas (HPSAs), *available at* http://www.statehealthfacts.org/comparemapreport.jsp?rep=112&cat=8&utm_source=shfonl&utm_medium=email&utm_campaign=040512short (indicating 12.2% of Connecticut population living in HPSA) (last checked Mar. 4, 2013). For a general description of HPSAs, see U.S. Dep't Health and Human Servs., HRSA, Guidelines for Primary Medical Care/Dental HPSA Designation, http://bhpr.hrsa.gov/shortage/hpsas/designationcriteria/medicaldentalhpsaguidelines.html (last checked Mar. 4, 2013).

[32] The ability of APRNs to provide safe and effective primary care services is a central observation of the IOM report and many other studies. IOM FUTURE OF NURSING REPORT, *supra* note 3, at 4, 8 ("key message" and policy recommendation regarding scope of practice); OFFICE OF TECH. ASSESSMENT, U.S. CONG., HEALTH TECH. CASE STUDY 37, NURSE PRACTITIONERS, PHYSICIAN ASSISTANTS, AND CERTIFIED NURSE-MIDWIVES: A POLICY ANALYSIS, 39 (1986) ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants]."); *see generally* NGA PRIMARY CARE PAPER, *supra* note 5; KAISER FAMILY FOUND., IMPROVING ACCESS TO ADULT PRIMARY CARE IN MEDICAID: EXPLORING THE POTENTIAL ROLE OF NURSE PRACTITIONERS AND

PHYSICIAN ASSISTANTS (Mar. 2011), http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8167.pdf [hereinafter KAISER FOUND., IMPROVING ACCESS]; MINN. HEALTH CARE REFORM TASK FORCE, ROADMAP TO A HEALTHIER MINNESOTA: RECOMMENDATIONS OF THE MINNESOTA HEALTH CARE REFORM TASK FORCE 25-26 (2012), http://mn.gov/health-reform/images/TaskForce-2012-12-14-Roadmap-Final.pdf.

[33] *See* Kaiser Commission, *Improving Access*, *supra* note 25, at 3; AAMC, *Physician Shortages*, *supra* note 20.

[34] Kaiser Commission, *Improving Access*, *supra* note 25, at 3.

[35] *See, e.g.*, TEXAS LEGISLATIVE BUDGET BOARD STAFF, TEXAS STATE GOVERNMENT EFFECTIVENESS AND EFFICIENCY: SELECTED ISSUES AND RECOMMENDATIONS 297, 300 (Jan. 2011) (submitted to the 82nd Texas Legislature) (indicating that the number of advanced practice nurses is lower in states with restrictive regulatory environments, and these restrictions may "limit the expansion of retail clinics, which generally employ APRNs to provide a limited range [of] primary healthcare") [hereinafter TEXAS BUDGET BOARD STAFF REPORT]; Julie A. Fairman et al., *Perspective: Broadening the Scope of Nursing Practice*, 364 N. ENGL. J. MED. 193, 194 (2011) (noting "nurses tend to move from more restrictive to less restrictive states . . . with a resulting loss of access to care for patients").

[36] MICHAEL J. DILL & EDWARD S. SALSBERG, CTR. FOR WORKFORCE STUDIES, AAMC, THE COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS THROUGH 2025, 66 (Nov. 2008), *available at* https://members.aamc.org/eweb/upload/The%20Complexities%20of%20Physician%20Supply.pdf.

[37] *Id.*

[38] CHRISTINE E. EIBNER ET AL., RAND HEALTH REPORT SUBMITTED TO THE COMMONWEALTH OF MASSACHUSETTS, CONTROLLING HEALTH CARE SPENDING IN MASSACHUSETTS: AN ANALYSIS OF OPTIONS, 100 (2009).

[39] We do not suggest that reforming APRN scope of practice restrictions is a panacea for primary care access problems in the U.S. Rather, reducing undue restrictions on APRN scope of practice can be one significant way to help ameliorate existing and projected access problems. *Cf.* David I. Auerbach et al., *Nurse-Managed Health Centers and Patient-Centered Medical Homes Could Mitigate Expected Primary Care Physician Shortage*, 32 HEALTH AFFAIRS 1933, 1938-40 (2013) (projected shortages very unlikely to be met by increase in number of primary care practitioners under current delivery models, but can be substantially alleviated by increased use of, e.g., nurse managed health centers, which depend on changes in scope of practice restrictions, among other things).

[40] AANA Res. Div., Amer. Ass'n Nurse Anesthetists, Massachusetts Anesthesia Providers (Mar. 2013).

[41] *Id.*

[42] *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).

[43] EIBNER ET AL., *supra* note 38, at 103-4 (describing conditions for upper and lower bound estimates and projections).

[44] *Id.* at 99 ("Visits to NPs and PAs are considerably less expensive than visits to MDs. According to data from the Medical Expenditure Panel Survey (MEPS), the average cost of an NP or PA visit is between 20 and 35 percent lower than the average cost of an office-based visit with a physician.").

[45] *Id.* at 87.

[46] P.F. Hogan et al., *Cost Effectiveness Analysis of Anesthesia Providers*, 28 NURSING ECONOMIC$ 159 (2010).

[47] *See* IOM FUTURE OF NURSING REPORT, *supra* note 3, at 92-94.

[48] Regarding diverse practice settings and APRN collaboration, see IOM FUTURE OF NURSING REPORT, *supra* note 3, at 23, 58-59, 65-67, 72-76; regarding the evolution and diversity of team-based care, see generally Pamela Mitchell et al., Nat'l Acad. of Sciences, Inst. of Med. Discussion Paper, *Core Principles & Values of Effective Team-Based Health Care* (2012), http://www.iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Team-Based-Care-Principles-Values.pdf (IOM-sponsored inquiry into collaborative or team-based care).

[49] Mitchell et al., *supra* note 48, at 3.

[50] *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 LSCs); Mary Kay Scott, Scott & Company, *Health Care in the Express Lane: Retail Clinics Go Mainstream*, at 22 (Sept. 2007) (report prepared for the California HealthCare Foundation), *available at* http://www.chcf.org/publications.

[51] *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., *Retail Clinics, Primary Care Physicians, and Emergency Departments: A Comparison of Patients Visits*, 27 HEALTH AFFAIRS 1272, 1279 (2008).

[52] *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.").

[53] *See, e.g.*, TEXAS BUDGET BOARD STAFF REPORT, *supra* note 35 at 300 (noting restrictions on APRNs' scope of practice may limit both the number and types of LSCs available to Texas consumers); MARY TAKACH & KATHY WITGERT, NATIONAL ACADEMY FOR STATE HEALTH POLICY, ANALYSIS OF STATE REGULATIONS AND POLICIES GOVERNING THE OPERATION AND LICENSURE OF RETAIL CLINICS 6 (Feb. 2009) (noting "the most powerful state regulatory tools affecting [retail clinics'] operations are the scope of practice regulations that govern nurse practitioners and other non-physician medical personnel").

[54] IOM FUTURE OF NURSING REPORT, *supra* note 3, at 92-94 (regarding APRN primary care initiatives at the Department of Veterans Affairs, Geisinger Health System, and Kaiser Permanente); *cf.* Mitchell et al., *supra* note 48 (IOM-sponsored inquiry into collaborative or team-based care generally).

[55] Mitchell et al., *supra* note 48, at 6.

[56] *See* IOM FUTURE OF NURSING REPORT, *supra* note 3, at 98-99 (citing, e.g., S.A. Brown & D. E. Grimes, *A Meta-analysis of Nurse Practitioners and Nurse Midwives in Primary Care*, 44(6) NURSING RESEARCH 332 (1995); S.W. Groth et al., *Long-term Outcomes of Advanced Practice Nursing*, in NURSE PRACTITIONERS: EVOLUTION AND FUTURE OF ADVANCED PRACTICE (5th ed., E. M. Sullivan-Marx et al., eds. 2010); P.F. Hogan et al., *Cost Effectiveness Analysis of Anesthesia Providers*, 28 NURSING ECONOMIC$ 159 (2010); S.E. Horrocks et al., *Systematic Review of Whether Nurse Practitioners Working in Primary Care Can Provide Equivalent Care to Doctors*, 324 BMJ 819 (2002); F. Hughes et al., *Research in Support of Nurse Practitioners*, in NURSE PRACTITIONERS: EVOLUTION AND FUTURE OF ADVANCED PRACTICE (5th ed., E. M. Sullivan-Marx et al., eds. 2010); M. Laurant et al., *Substitution of Doctors by Nurses in Primary Care*, 2 Cochrane Database of Systematic Reviews, CD001271 (2004); M.O. Mundinger et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A randomized Trial*, 283 JAMA 59 (2000); OFFICE OF TECH. ASSESSMENT, U.S. CONG., HEALTH TECH. CASE STUDY 37, NURSE PRACTITIONERS, PHYSICIAN ASSISTANTS, AND CERTIFIED NURSE-MIDWIVES: A POLICY ANALYSIS (1986); *see also* Robin P. Newhouse et al., *Advanced Practice Nurse Outcomes 1990-2008: A Systematic Review*, 29 NURSING ECON. 1, 18 (2011) ("APRNs provide effective and high-quality patient care."); P. Venning et al., *Randomised Controlled Trial Comparing Cost Effectiveness of General Practitioners and Nurse Practitioners in Primary Care*, 320 BMJ 1048 (2000) (no significant difference in patterns of

prescribing or health status outcome); *see also* Christine Everett et al., *Physician Assistants and Nurse Practitioners Perform Effective Roles on Teams Caring for Medicare Patients with Diabetes*, 32 HEALTH AFFAIRS 1942 , 1945-6 (2013) (outcomes generally equivalent for NP, PA, and MD caregivers in 13 comparisons, superior for NP or PA care in 4, and superior for MD care in 3; "PAs and NPs can fill a range of roles on primary care teams, even for older patients with clinically challenging conditions such as diabetes.").

[57] IOM FUTURE OF NURSING REPORT, *supra* note 3, at 85-161; *see especially id.* at 98 (with respect to many primary care services, "the contention that APRNs are less able than physicians to deliver care that is safe, effective, and efficient is not supported by the decades of research that has examined this question") (internal citations omitted).

[58] *Id.* at 98-99 (noting "[n]o studies suggest that care is better in states that have more restrictive scope-of-practice regulations for APRNs than in those that do not"). *See also* Julie A. Fairman et al., *Perspective: Broadening the Scope of Nursing Practice*, 364 N. ENGL. J. MED. 193, 194 (2011) (stating "[t]here are no data to suggest that nurse practitioners in states that impose greater restrictions on their practice provide safer and better care than those in less restrictive states or that the role of the physician has changed or deteriorated"); *Cf.* 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) (for retail clinic settings largely staffed by APRNs, analyzing 14 quality metrics for commonly treated ailments, including ear, strep, and urinary tract infections, and finding "[f]or most measures, quality scores of retail clinics were equal to or higher than those of other care settings")..

[59] *See* FTC Staff Louisiana APRN Comment, *supra* note 14, at 3, 5; West Virginia Testimony, *supra* note 14, at 3-6; *cf.* IOM FUTURE OF NURSING REPORT, *supra* note 3, at 110-11 (regarding opposition by physicians, including the American Medical Association).

[60] *See, e.g.* Mundinger et al., *supra* note 56 (comparing outcomes for 1316 ambulatory care patients randomly assigned to APRN and MD primary care providers, where APRNs had "same authority to prescribe, consult, refer, and admit patients" found no significant difference in patients' health status or physiologic test results); Lenz et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: Two-year Follow-up*, 61 MED. CARE RES. REV. 332 (2004) (2-year follow-up data for Mundinger et al. consistent with preliminary results); Ann B. Hamric et al., *Outcomes Associated with Advanced Nursing Practice Prescriptive Authority*, 10 J. Amer. Acad. Nurse Practitioners 113 (1998) (safety and effectiveness in study of 33 APRNs in 25 primary care sites); Venning et al., *supra* note 56, at 1048 ((no significant difference in patterns of prescribing or health status outcome).

[61] *See, e.g.*, Prescription Drug Diversion: Combating the Scourge: Hearing Before the H. Subcomm. On Commerce, Manufacturing and Trade of the H. Comm. on Energy and Commerce, 112th Cong. (Mar. 1, 2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Admin., U.S. Dep't Justice); Nora D. Volkow et al., *Research Letter: Characteristics of Opioid Prescriptions in 2009*, 305 JAMA 1299, 1300 (2011) (noting increases in opioid prescriptions and associated increases in abuse and overdoses as cause of concern and need for further research). Looking at distinct (or partly distinct) populations, one might be simultaneously concerned about both abuse and under-treatment: "Ironically, while many people with pain have difficulty obtaining opioid medications, nonmedical users appear to obtain them far too easily . . . so much so that the diversion of opioid analgesics has become a national public health problem." IOM FUTURE OF NURSING REPORT, *supra* note 3, at 146.

[62] Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Nov. 24, 2013, *available at* http://www.fda.gov/drugs/drugsafety/ucm372089.htm.

[63] *See, e.g.*, ROBIN HASHIMOTO ET AL., WASHINGTON STATE HEALTH CARE AUTHORITY, HEALTH TECHNOLOGY ASSESSMENT, SPINAL INJECTIONS (Updated Final Evidence Report March 10, 2011), *available at* http://www.hta.hca.wa.gov/documents/updated_final_report_spinal_injections_0310-1.pdf (reviewing evidence of efficacy, safety, and cost-effectiveness for diverse spinal injections); *see also* James P. Rathmell et al., *Injury and Liability Associated with Cervical Procedures for Chronic Pain*, 114 ANESTHESIOLOGY 918 (2011) (based on data from Data from American Society of Anesthesiologists'

closed claims database between 2005 and 2008, injuries related to cervical interventional pain treatment were often severe and related to direct needle trauma to the spinal cord); Dermot R. Fitzgibbon et al., *Chronic Pain Management: American Society of Anesthesiologists Closed Claims Project*, 100 ANESTHESIOLOGY 98 (2004) (frequency and payments of claims associated with chronic pain management by anesthesiologists increased in the 1990s; brain damage and death were associated with epidural steroid injection only when opioids or local anesthetics were included).

[64] *See* ROBIN HASHIMOTO ET AL., SPINAL INJECTIONS. Regarding effectiveness in different clinical contexts, *compare* Stephen Choi & Richard Brull, *Is Ultrasound Guidance Advantageous for Interventional Pain Management? A Review of Acute Pain Outcomes*, 113 ANESTHESIA & ANALGESIA 596 (2011) (review of randomized controlled clinical trials concluding "at present, there is insufficient evidence in the contemporary literature to define the effect of US [ultrasound] guidance on acute pain and related outcomes compared with traditional nerve localization techniques for interventional acute pain management) *with*

[65] NGA, *Role of Nurse Practitioners*, *supra* note 5, at 12-13.

[66] IOM FUTURE OF NURSING REPORT, *supra* note 3, at 26.

[67] Dep't Health and Human Servs. (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, 4675 (Jan. 18, 2001); *cf.*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. 56762, 56762-63 (Nov. 13, 2001) (repeating observations on safety literature, but noting potential utility of independent study of question whether safety or quality effects are associated with state regulations permitting independent CRNA practice).

[68] IOM FUTURE OF NURSING REPORT, *supra* note 3, at 111 ("A study ... found no increase in inpatient mortality or complications in states that opted out of the CMS requirement that an anesthesiologist or surgeon oversee the administration of anesthesia by a CRNA.").