

Policy Perspectives

Competition and the Regulation of Advanced Practice Nurses

FEDERAL TRADE COMMISSION

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Policy Perspectives

Competition and the Regulation of Advanced Practice Nurses

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EXECUTIVE SUMMARY

The Federal Trade Commission (FTC or Commission) vigorously promotes competition in the health care industry through enforcement, study, and advocacy. Competition in health care markets benefits consumers by helping to control costs and prices, improve quality of care, promote innovative products, services, and service delivery models, and expand access to health care services and goods. While state legislators and policymakers addressing health care issues are rightly concerned with patient health and safety, an important goal of competition law and policy is to foster quality competition, which also furthers health and safety objectives. Likewise, to ignore competitive concerns in health policy can impede quality competition, raise prices, or diminish access to health care – all of which carry their own health and safety risks.

We are not suggesting that unfettered competition in health care services always leads to the best outcome for consumers. Actual or likely market failure, among other factors, may justify health and safety regulations. However, even well intentioned laws and regulations may impose unnecessary, unintended, or overbroad restrictions on competition, thereby depriving health care consumers of the benefits of vigorous competition. We thus urge policymakers to view competition and consumer safety as complementary objectives, and to integrate consideration of competition into their deliberations.¹

This policy paper builds on FTC staff competition advocacy comments that focus on proposed state-level changes to statutes and rules governing the “scope of practice” of Advanced Practice Registered Nurses (APRNs). Scope of practice rules determine the range of health care procedures and services that various health care professionals are licensed to provide under state law. In the case of APRNs, these rules establish both the range of services APRNs may deliver and the extent to which they are permitted to practice independently, or without direct physician supervision.² Because APRNs and other practitioners, including physicians, may be trained and licensed to provide many of the same health care services, scope of practice restrictions can limit the supply of those primary health care services, as well as competition between different types of practitioners.

FTC staff competition advocacy comments have addressed various physician supervision requirements imposed on APRNs. Physician supervision requirements may raise competition

1. See Section II.B., *infra*.

2. For a general review of APRN scope of practice restrictions, and their variation across the states, *see, e.g.*, INST. OF MED., NAT’L ACAD. OF SCIENCES, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 98-103, 157-61 annex 3-1 (2011) [hereinafter IOM FUTURE OF NURSING REPORT].

concerns because they effectively give one group of health care professionals the ability to restrict access to the market by another, competing group of health care professionals, thereby denying health care consumers the benefits of greater competition.³ In addition, APRNs play a critical role in alleviating provider shortages and expanding access to health care services for medically underserved populations.⁴ For these reasons, the FTC staff has consistently urged state legislators to avoid imposing restrictions on APRN scope of practice unless those restrictions are necessary to address well-founded patient safety concerns.⁵ Based on substantial evidence and experience, expert bodies have concluded that APRNs are safe and effective as independent providers of many health care services within the scope of their training, licensure, certification, and current practice.⁶ Therefore, new or extended layers of mandatory physician supervision may not be justified.

Moreover, additional supervision requirements may not be tailored to accommodate the myriad relationships – collaborative, consulting, or referral-based – among APRNs, primary care doctors, specialty physicians, and other health care professionals, and may impair the abilities of health care professionals and provider institutions to develop new models of health care delivery in response to consumer preferences, health care needs, and new technologies. Under traditional as well as emerging models, all of these providers can contribute to safe, efficient, and coordinated patient care, consistent with each professional’s education, licensure, and

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3. Particular types of physician supervision or “collaborative practice” requirements, and the ways they can empower physicians to impede APRN entry into health services markets, are discussed *infra*, text accompanying notes 37-47.
 4. APRNs already provide a disproportionately high share of primary care services in medically underserved areas and for medically underserved populations, and they may be better able to meet increasing demand in such contexts when they can work independent of undue supervision requirements. *See generally* NAT’L GOVERNORS ASS’N, NGA PAPER: THE ROLE OF NURSE PRACTITIONERS IN MEETING INCREASING DEMAND FOR PRIMARY CARE (2012), <http://www.nga.org/files/live/sites/NGA/files/pdf/1212NursePractitionersPaper.pdf> [hereinafter NGA PRIMARY CARE PAPER].
 5. FTC and staff advocacy comments, testimony, and letters are detailed in Section III of this paper, below, and these and related comments are listed in Appendix 1 of this policy paper, and available on the FTC policy web page at <http://www.ftc.gov/policy/advocacy/advocacy-filings>.
 6. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98-99; NGA PRIMARY CARE PAPER, *supra* note 4, at 7-8 (study funded by U.S. Dep’t Health & Human Servs., reviewing literature pertinent to NP safety and concluding “None of the studies in the NGA’s literature review raise concerns about the quality of care offered by NPs. Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures.”); CHRISTINE E. EIBNER ET AL., RAND HEALTH REPORT SUBMITTED TO THE COMMONWEALTH OF MASSACHUSETTS, CONTROLLING HEALTH CARE SPENDING IN MASSACHUSETTS: AN ANALYSIS OF OPTIONS 99 (2009), http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR733.pdf [hereinafter “EIBNER ET AL., MASSACHUSETTS REPORT”] (“studies have shown that they provide care similar to that provided by physicians.”) Some of the primary research underlying these assessments is cited *infra* note 137.

capabilities. Effective collaboration between APRNs and physicians does not necessarily require any physician supervision, much less any particular model of physician supervision.

The competition concerns voiced in FTC staff’s scope of practice advocacy comments are consistent with the policy analysis of a 2011 Institute of Medicine (IOM) report, *The Future of Nursing: Leading Change, Advancing Health*.⁷ The *Future of Nursing* report provides expert advice based on “[e]vidence suggest[ing] that access to quality care can be greatly expanded by increasing the use of . . . APRNs in primary, chronic, and transitional care,”⁸ and expresses concern that scope of practice restrictions “have undermined the nursing profession’s ability to provide and improve both general and advanced care.”⁹ The report found that APRNs’ scope of practice varies widely “for reasons that are related not to their ability, education or training, or safety concerns, but to the political decisions of the state in which they work.”¹⁰ The report recognizes FTC competition advocacy in this area and specifically exhorts the FTC and the Antitrust Division of the U.S. Department of Justice to pay continued attention to the competition issues raised by scope of practice regulations.

The FTC has looked to the findings of the IOM and other expert bodies – analyses based on decades of research and experience – on issues of APRN safety, effectiveness, and efficiency.¹¹ Based on those expert analyses and findings, as well as our own reviews of pertinent literature and stakeholder views, the FTC staff has urged state legislators and policymakers to consider the following principles when evaluating proposed changes to APRN scope of practice.

- Consumer access to safe and effective health care is of critical importance.
- Licensure and scope of practice regulations can help to ensure that health care consumers (patients) receive treatment from properly trained professionals. APRN certification and

7. IOM FUTURE OF NURSING REPORT, *supra* note 2. The IOM was established in 1970 as the health arm of the National Academy of Sciences. *Id.* at iv. The IOM web page, with links to general descriptions of the IOM, IOM reports, and other IOM activities, is at <http://www.iom.edu/>.

8. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27; *see also id.* at 88 (“Given current concerns about a shortage of primary care health professionals, the committee paid particular attention to the role of nurses, especially APRNs, in this area.”). The extent to which APRNs and other professionals might augment the primary care workforce has been of policy interest for some time. *See, e.g.*, 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) [hereinafter OTA HEALTH TECH. CASE STUDY] (“Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].”).

9. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 4.

10. *Id.* at 5.

11. *See supra* note 6.

state licensure requirements should reflect the types of services that APRNs can safely and effectively provide, based on their education, training, and experience.

- Health care quality itself can be a locus of competition, and a lack of competition – not just regulatory failures – can have serious health and safety consequences. More generally, competition among health care providers yields important consumer benefits, as it tends to reduce costs, improve quality, and promote innovation and access to care.
- Potential competitive effects can be especially striking where there are primary care shortages, as in medically underserved areas or with medically underserved populations. When APRNs are free from undue supervision requirements and other undue practice restrictions, they can more efficiently fulfill unmet health care needs.
- APRNs typically collaborate with other health care practitioners. Effective collaboration between APRNs and physicians can come in many forms. It does not always require direct physician supervision of APRNs or some particular, fixed model of team-based care.
- APRN scope of practice limitations should be narrowly tailored to address well-founded health and safety concerns, and should not be more restrictive than patient protection requires. Otherwise, such limits can deny health care consumers the benefits of competition, without providing significant countervailing benefits.
- To promote competition in health care markets, it may be important to scrutinize relevant safety and quality evidence to determine whether or where legitimate safety concerns exist and, if so, whether physician supervision requirements or other regulatory interventions are likely to address them. That type of scrutiny can be applied not just to the general question whether the State requires physician supervision or collaborative practice agreements, but to the particular terms of those requirements as they are sometimes applied to, for example, APRN diagnosis of patient illnesses or other health conditions, APRN ordering of diagnostic tests or procedures, and APRN prescribing of medicines.

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.¹² Competition is at the core of America's economy,¹³ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, and greater innovation. Innovation may include new and varied service delivery models that respond to the changing needs of the marketplace.

Health care is a major U.S. industry, and health care competition is crucial to the economy and consumer welfare. For these reasons, anticompetitive conduct in health care markets has long been a key focus of FTC law enforcement,¹⁴ research,¹⁵ and advocacy.¹⁶ As a result, the FTC has developed significant expertise regarding competition issues affecting the health care industry.

12. Federal Trade Commission Act, 15 U.S.C. § 45.

13. *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951) (“The heart of our national economic policy long has been faith in the value of competition.”).

14. *See, e.g.*, HEALTH CARE DIV., FED. TRADE COMM’N, AN OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2013), available at <http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf> (covering all actions through March 2013). For information regarding all FTC health care matters, see <http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>.

15. For example, in 2003, the FTC and the DOJ Antitrust Division held 27 days of hearings on health care and competition law and policy. *Competition in the Health Care Marketplace*, FED. TRADE COMM’N, <http://www.ftc.gov/news-events/events-calendar/2003/02/health-care-competition-law-policy-hearings> (last updated Apr. 10, 2013) (links to transcripts and other hearing materials); *see also Innovations in Health Care Delivery*, FED. TRADE COMM’N, <http://www.ftc.gov/news-events/events-calendar/2008/04/innovations-health-care-delivery> (last visited Feb. 28, 2014); *Emerging Health Care Competition and Consumer Issues*, FED. TRADE COMM’N, <http://www.ftc.gov/news-events/events-calendar/2008/11/emerging-health-care-competition-and-consumer-issues> (last visited Feb. 28, 2014); FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005), <http://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report>. A more comprehensive listing of FTC conferences and workshops is available at <http://www.ftc.gov/news-events/events-calendar/all>. Links to more FTC reports are available at <http://www.ftc.gov/policy/reports>.

16. FTC advocacy takes many forms, including letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, and amicus briefs. *See, e.g.*, Letter from FTC Staff to the Hon. Timothy Burns, La. House of Representatives (May 1, 2009), <http://www.ftc.gov/os/2009/05/V090009louisianadentistry.pdf> (regarding proposed restrictions on mobile dentistry); Written Testimony from the Fed. Trade Comm’n and U.S. Dep’t of Justice to the Ill. Task Force on Health Planning Reform (Sept. 15, 2008), <http://www.ftc.gov/os/2008/09/V080018illconlaws.pdf>; Brief of the Fed. Trade Comm’n as Amicus Curiae in *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, No. 1:12-cv-05743 (D.N.J. Mar. 11, 2013), available at <http://www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf>.

Competition research and advocacy are an important part of the FTC's statutory mission.¹⁷ While Section 6 of the FTC Act¹⁸ gives the Commission the authority to conduct investigations that might lead to enforcement actions, it also grants more general authority to investigate and report on market developments in the public interest, including authority to make legislative recommendations based on those investigations.¹⁹

The FTC has frequently utilized this unique authority to explore competition dynamics in the health care industry. For example, in 2003 the Commission and the Antitrust Division of the U.S. Department of Justice jointly conducted extensive hearings on health care competition issues.²⁰ Based on those hearings, along with an FTC-sponsored workshop and independent staff research, the two agencies in 2004 jointly released a comprehensive report on health care competition.²¹ Among other topics, the hearings and report addressed potential competition concerns associated with professional regulations in the health care sector, including licensure and scope of practice

17. For a general discussion of the FTC's "policy research and development" mission and the role of the advocacy program, see, e.g., WILLIAM E. KOVACIC, *THE FEDERAL TRADE COMMISSION AT 100: INTO OUR 2ND CENTURY* (2009), <http://www.ftc.gov/ftc/workshops/ftc100/docs/ftc100rpt.pdf> (regarding "policy R&D" see pp. 92-109; regarding advocacy see pp. 121-24); see also James C. Cooper, Paul A. Pautler, & Todd J. Zywicki, *Theory and Practice of Competition Advocacy at the FTC*, 72 ANTITRUST L.J. 1091 (2005); Maureen K. Ohlhausen, *Identifying Challenging, and Assigning Political Responsibility for State Regulation Restricting Competition*, 2 COMPETITION POL'Y INT'L 151, 156-7 (2006) (competition advocacy "beyond enforcement" of the antitrust laws); William E. Kovacic, *Measuring What Matters: The Federal Trade Commission and Investments in Competition Policy Research and Development*, 72 ANTITRUST L.J. 861 (2005); Timothy J. Muris, Chairman, Fed. Trade Comm'n, Remarks at the International Competition Network Panel on Competition Advocacy and Antitrust Authorities, Creating a Culture of Competition: The Essential Role of Competition Advocacy (Sept. 28, 2002), <http://www.ftc.gov/public-statements/2002/09/creating-culture-competition-essential-role-competition-advocacy>; Arnold C. Celnicker, *The Federal Trade Commission's Competition and Consumer Advocacy Program*, 33 ST. LOUIS U. L.J. 379 (1989); Maurice E. Stucke, *Better Competition Advocacy*, 82 ST. JOHN'S L. REV. 951 (2008). For a recent overview, see Tara Isa Koslov, *Competition Advocacy at the Federal Trade Commission: Recent Developments Build on Past Success*, 8 CPI ANTITRUST CHRON. 1 (2012).

18. 15 U.S.C. § 46.

19. *Id.* at § 46(a), (b), (f).

20. See *Competition in the Health Care Marketplace*, *supra* note 15.

21. FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION* (2004), <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> [hereinafter FTC & DOJ, *A DOSE OF COMPETITION*].

regulations.²² Related professional regulation issues also were the subject of prior FTC research²³ and competition advocacy.²⁴

II. BACKGROUND ON APRNS AND SCOPE OF PRACTICE ISSUES

II.A. Advanced Practice Registered Nurses

Most state practice laws recognize APRNs as a distinct category of nursing professional.²⁵

An APRN is a nurse practitioner with a graduate nursing degree, in addition to undergraduate nursing education and practice experience, who has been trained to provide a broad range of services, including the diagnosis and treatment of acute and chronic illnesses.²⁶ Nationally, “[m]ore than a quarter of a million nurses are APRNs . . . who hold master’s or doctoral degrees and pass national certification exams.”²⁷ In addition, APRNs generally attend nationally accredited education and training programs, and receive certification from nationally accredited certifying

22. *See, e.g., id.* at ch. 2, pp. 25-28, 30-33 (“Through licensure requirements, states may restrict market entry by physicians and allied health professionals . . . and further limit the scope of authorized practice.” *Id.* at 25.).

23. *See, e.g.,* CAROLYN COX & SUSAN FOSTER, BUREAU OF ECON., FED. TRADE COMM’N, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION (1990), http://www.ramblemuse.com/articles/cox_foster.pdf.

24. Comments of the Bureaus of Competition, Consumer Protection, and Economics of the Fed. Trade Comm’n to the Council of D.C. on Proposed Bill 6-317 to Create Specific Licensing Requirements for Expanded Role Nurses (Nov. 22, 1985); Brief of the Fed. Trade Comm’n as Amicus Curiae on Appeal from United States District Court, *Nurse Midwifery Associates v. Hibbett*, 918 F.2d 605 (6th Cir. 1990), *appealing* 689 F. Supp. 799 (M.D. Tenn. 1988). Based on analogous issues, the Commission also has enforced the antitrust laws in credentialing matters. *See In the Matter of Med. Staff of Mem. Med. Ctr.*, 110 F.T.C. 541 (1988) (Complaint) (alleging anticompetitive combination or conspiracy to deny credentials to nurse midwife). For a general discussion of these advocacies and underlying competition issues, see Daniel J. Gilman & Julie Fairman, *Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice*, 24 HEALTH MATRIX (forthcoming 2014).

25. Professional titles and nomenclature (e.g., “APRN,” “ARNP,” “nurse practitioner,” etc.), as well as APRN licensure criteria and scope of practice rules, have been converging nationally, although they still vary across the states. IOM FUTURE OF NURSING REPORT, *supra* note 2, app. D (regarding APRN Consensus Model and Final Report of the APRN Consensus Work Group and the National Council of State Boards of Nursing APRN Advisory Committee). The National Council of State Boards of Nursing posts updated maps of, e.g., states that recognize “APRN” as a professional title, states that permit independent APRN practice, and states that permit independent APRN prescribing. *APRN Maps*, NAT’L COUNCIL OF STATE BDS. OF NURSING, <https://www.ncsbn.org/2567.htm> (last updated Feb. 2014). As implemented in one state’s statutes and regulations, see, e.g., La. Rev. Stat. Ann. § 37:913(3)(a)(b) (2012); *see also* La. Admin. Code tit. 46, pt. XLVII, § 4505 (2012) (Louisiana State Board of Nursing regulations regarding APRNs).

26. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 23, 26.

27. *Id.* at 23. For an overview of APRN requirements generally, see *id.* at 26, table 1-1 (types of APRN practice) and 38-45.

boards.²⁸ There are four types of APRNs: nurse practitioners (NPs); nurse midwives (NMWs); certified registered nurse anesthetists (CRNAs); and clinical nurse specialists (CNSs).²⁹ Despite this range of available specialties, most APRNs are engaged in primary care,³⁰ and most APRNs are trained and licensed to provide a broad range of primary care services.³¹ This policy paper synthesizes FTC staff advocacy comments regarding regulations applicable to APRNs and NPs generally, rather than regulations focused on specialized APRNs such as CRNAs or NMWs.³²

APRNs, like other health care professionals, are subject to various categories of state regulation. In all states and the District of Columbia, APRNs face licensure requirements that determine who may enter the profession.³³ Related scope of practice rules further define the types of services APRNs are authorized to provide and the extent to which they are permitted to practice

28. *See id.* at 23, 41-42.

29. *See id.*

30. *See, e.g.,* CATHERINE DOWER & EDWARD O'NEIL, ROBERT WOOD JOHNSON FOUND., RESEARCH SYNTHESIS REPORT NO. 22: PRIMARY CARE HEALTH WORKFORCE IN THE UNITED STATES, 6 (2011), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2011/rwjf402104/subassets/rwjf402104_1 (“Primary care NPs make up the majority of the profession, with over 60 percent reporting their main clinical specialty to be family care.”).

31. *See, e.g.,* EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 99 (describing range of services); NGA PRIMARY CARE PAPER, *supra* note 4, at 3-4.

32. While this policy paper does not specifically discuss them, other FTC staff advocacy comments have addressed issues pertaining to specialized APRNs, as well as specific business models within which APRNs may practice (such as limited service clinics). *See, e.g.,* Comment from FTC Staff to the Ky. Cabinet for Health and Family Servs. (Jan. 2010), <http://www.ftc.gov/os/2010/02/100202kycomment.pdf> (regarding proposed restrictions on limited service clinics staffed chiefly by APRNs); Comment from FTC Staff to the Hon. Jeanne Kirkton, Mo. House of Representatives (Mar. 2012), <http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf> (regarding restrictions on one category of specialized APRNs). In addition, this policy paper does not discuss Physician Assistant (PA) scope of practice issues, although PAs and APRNs typically are subject to similar types of rules. For a general discussion, see, e.g., Edward S. Sekscenski et al., *State Practice Environments and the Supply of Physician Assistants, Nurse Practitioners, and Certified Nurse-Midwives*, 331 N. ENGL. J. MED. 1266 (1994). Proposals to increase access to primary care often consider expanding the role of both APRNs and PAs. *Id.*; see also IOM FUTURE OF NURSING REPORT, *supra* note 2, at 88, 97-98.

33. For a general discussion of these and other types of professional regulations, see, e.g., COX & FOSTER, *supra* note 23.

independently.³⁴ While entry qualifications for APRNs are increasingly similar from state to state, the regulations that define APRN scope of practice continue to vary widely.³⁵ Some scope of practice restrictions are procedure-oriented, limiting APRNs' ability to prescribe medicines, refer for, order, or perform certain tests or procedures, or treat certain indications.³⁶ Other restrictions focus on the types of patients APRNs may see. For example, APRNs may not be allowed to “examine a new patient, or a current patient with a major change in diagnosis or treatment plan,

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34. TRACY YEE ET AL., NAT'L INST. FOR HEALTH CARE REFORM, RESEARCH BRIEF NO. 13, PRIMARY CARE WORKFORCE SHORTAGES: NURSE PRACTITIONER SCOPE-OF-PRACTICE LAWS AND PAYMENT POLICIES 2 (Feb. 2013), <http://www.nihcr.org/PCP-Workforce-NPs>.

As with other health care professionals, the states may define professional prerogatives and limits broadly or narrowly, through statutory law, administrative rules and decisions, and judicial decisions. *Compare, e.g.*, ALA. CODE §§ 34-21-81(4) (2012), which defines “Advanced Practice Nursing” as “[t]he delivery of health care services by registered nurses who have gained additional knowledge and skills through successful completion of an organized program of nursing education that prepares nurses for advanced practice roles as certified registered nurse practitioners, certified nurse midwives, certified nurse anesthetists, and clinical nurse specialists;” with LA. REV. STAT. ANN. § 37:913(3)(a)-(b) (2012), which describes APRN scope of practice as including:

- (i) Assessing patients, analyzing and synthesizing data, and knowledge of and applying nursing principles at an advanced level.
- (ii) Providing guidance and teaching.
- (iii) Working with patients and families in meeting health care needs.
- (iv) Collaborating with other health care providers.
- (v) Managing patients' physical and psychosocial health-illness status with regard to nursing care.
- (vi) Utilizing research skills.
- (vii) Analyzing multiple sources of data and identifying and performing certain acts of medical diagnosis in accordance with the collaborative practice agreement.
- (viii) Making decisions in solving patient care problems and selecting treatment regimens in collaboration with a licensed physician, dentist, or other health care provider as indicated.
- (ix) Consulting with or referring patients to licensed physicians, dentists, and other health care providers in accordance with a collaborative practice agreement.

See also LA. ADMIN. CODE TIT. 46, PT. XLVII, § 4505 (2012) (Louisiana State Board of Nursing regulations regarding APRNs).

35. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98.; *see also* NGA PRIMARY CARE PAPER, *supra* note 4, at 2.
36. For example, under Florida law, an APRN may “[m]onitor and alter drug therapies,” FLA. STAT. § 464.012(3) (a), but may not prescribe controlled substances, FLA. STAT. § 83902(2) and 8390.5(1) (restricting controlled substance prescription to certain “practitioners” and defining practitioners to include physicians, but not APRNs).

unless the patient is seen and examined by a supervising physician within a specified period of time.”³⁷

In addition, somewhat more than half of U.S. states maintain physician supervision requirements for APRNs.³⁸ In other words, besides limits on the types of patients APRNs may see or the types of procedures APRNs may perform, these states’ scope of practice rules restrict the degree to which APRNs may practice independently. Physician supervision may be required for all APRN practice,³⁹ or for particular practice activities such as prescribing medications.⁴⁰ Supervision rules sometimes define the parameters of supervision more specifically. Some require that APRN patient charts be reviewed at some particular frequency,⁴¹ some limit the number of independent APRNs one physician may supervise,⁴² or restrict the physical distance permitted between a supervising physician and a supervised APRN. Florida law, for example, imposes broad supervision requirements on APRN practice, while also specifying that an APRN cannot

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37. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 101. The report catalogues various regulatory restrictions on nursing practice. *Id.* at 100-02 box 3-1, 157-61 annex 3-1 (regarding state scope of practice restrictions for nurse practitioners).
 38. *See id.*, especially 157-61 annex 3-1 (specifying state-by-state requirements for supervision or mandatory “collaborative practice” for, e.g., APRN treatment, diagnosis, or prescribing). According to the National Council of State Boards of Nursing, 27 states require supervision or a collaborative practice agreement for APRN practice. *See APRN Maps*, *supra* note 25 (follow “CNM” hyperlink under “Independent Practice” heading) (22 states plus District of Columbia permit independent practice).
 39. *See, e.g.*, FLA. STAT. § 464.012(3) (2012) (APRN can perform functions within S.O.P. only after “entering into a supervisory relationship with a physician” and subsequently filing established practice protocol with regulator). LA. REV. STAT. ANN. § 37:913(8) (2012) (formal written collaborative practice agreement required for both “acts of medical diagnosis and prescription”).
 40. Regarding more general and particular statutory definitions, see *supra* note 34 (comparing general Alabama definition with more specific enumeration of APRN practice under Louisiana law). Regarding prescribing, see *APRN Maps*, *supra* note 25 (follow “CNM” hyperlink under “Independent Prescribing” heading) (22 states plus District of Columbia permit independent practice); see also, e.g., LA. REV. STAT. ANN. § 37:913(8) (2012) (formal collaborative practice agreement required for prescribing); W.VA. CODE §§ 30-7-15(a)-(b) (signed collaborative practice agreement with physician required for APRN prescribing).
 41. *See, e.g.*, MISS. CODE ANN. § 73-15-20(3) (2012) (requiring establishment of a “collaborative/consultative relationship”); *Id.* § 73-15-20(C)(3) (each “collaborative/consultative relationship” must include “formal quality assurance/quality improvement program,” including at review of at least the lesser of 20 or 10% of APRN’s charts each month.)
 42. *See, e.g.*, FLA. STAT. § 458.348(4)(a)-(b), (c) (2012) (subsections a-b restrict number of offices physician may supervise).

practice more than a certain distance from the primary place of practice of his or her supervising physician.⁴³

Some supervision rules use different terminology to the same or similar effect. A state may require physician “delegation” of responsibilities to an APRN; Texas law, for example, imposes various supervision and delegation restrictions on APRN prescribing and diagnosis.⁴⁴ Alternatively, a state may impose certain “collaborative practice” requirements on APRNs, requiring that an APRN enter into a written agreement with a physician to define the parameters of the APRN’s permitted practice.⁴⁵ This can be viewed as a *de facto* supervision requirement, to the extent that the APRN cannot practice without securing the approval of an individual physician, whereas the terms of physician practice are in no way dependent on APRN input. In Louisiana, for example, an APRN must practice under a formal written collaborative practice agreement if he or she is to work to the full extent of APRN scope of practice, including “acts of medical diagnosis and prescription,” as otherwise permitted under Louisiana law.⁴⁶ West Virginia and Kentucky law require written collaborative practice agreements for APRN prescribing.⁴⁷

II.B. Competition Perspectives on Professional Regulations that Restrict APRN Scope of Practice

Together, licensure and scope of practice regulations for APRNs and other health care professionals serve important consumer protection objectives, including safety and quality. To meet fully the interests of health care consumers, however, requires weighing competition considerations when evaluating the potential costs and benefits of particular scope of practice

43. *Id.*, § 458.348(4) (c) (requires either on-site supervision or, “[a]ll such offices that are not the physician’s primary place of practice must be within 25 miles of the physician’s primary place of practice or in a county that is contiguous to the county of the physician’s primary place of practice. . . .”); *see also* MO. CODE REGS. ANN. tit. 20 § 2150-5.100 (2) (A)-(B) (2012) (“an APRN who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons” may not be more than 50 miles by road in federally-designated health professional shortage areas and not more than 30 miles by road otherwise).

44. TEX. OCC. CODE ANN. § 157.051 (2012).

45. FTC staff are not aware of any state that imposes comparable requirements of collaborative practice on physician scope of practice, although some states impose various requirements on physicians who elect to enter into collaborative practice agreements with APRNs or others. Whether a state explicitly requires a physician to supervise a collaborating APRN or not, asymmetrical collaboration requirements imposed on APRNs effectively create *de facto* supervision requirements where an APRN can only practice under terms agreeable to a licensed physician. For a general discussion of the relationship between supervision and collaboration requirements, *see* Lauren E. Battaglia, *Supervision and Collaboration Requirements: the Vulnerability of Nurse Practitioners and Its Implications for Retail Health*, 87 WASH. U. L. REV. 1127, 1137-38 (2010).

46. LA. REV. STAT. ANN. § 37:913(8)-(9) (2012) (requiring collaborative practice and a collaborative practice agreement).

47. KY. REV. STAT. § 314.042 (2013); W. VA. CODE § 30-7-15A (2012).

rules. The goal should be to avoid imposing restraints that may tend to impair competition in a way that is greater than necessary to address legitimate health and safety concerns.

II.B.1. Framework for Evaluating Licensure and Scope of Practice Regulations

Licensure is, by its nature, a process that establishes the conditions for entry into an occupation. As a threshold matter, any regulation or law that establishes entry conditions for an occupation tends to reduce the supply of individuals otherwise willing to provide the services associated with that occupation.⁴⁸ Licensure is commonly required for many occupations, however, and can be justified on a number of grounds. Generally, an applicant for licensure must demonstrate a minimum degree of competence, based on education and training, to obtain the government's permission to provide professional services in a given jurisdiction.⁴⁹ Scope of practice rules further define the professional services a licensed health care practitioner is authorized to provide, and may prohibit a health care practitioner from offering certain services without first obtaining a specific license or certification, obtaining and documenting a specific form of supervision, or meeting other regulatory requirements. Unlicensed practice, or the provision of services outside one's scope of practice, generally is prohibited by statute and may be subject to civil or criminal penalties.⁵⁰

Licensure and scope of practice regulations can serve an especially important function in health care. Consumers face serious risks if they are treated by unqualified individuals, and laypersons may find it difficult (if not impossible) to adequately assess quality of care at the

48. George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 13 (1971) ("The licensing of occupations is a possible use of the political process to improve the economic circumstances of a group. The license is an effective barrier to entry because occupational practice without the license is a criminal offense.").

49. See *Competition in the Health Care Marketplace*, *supra* note 15, hyperlink to Jun. 10, 2003 transcript, at 33-34 (statement of Dr. Morris Kleiner, providing context regarding the effects of occupational licensing); see also FTC & DOJ, A DOSE OF COMPETITION, *supra* note 21, ch. 2, at 25 ("Through licensure requirements, states may restrict market entry by physicians and allied health professionals")

50. See, e.g., LA. REV. STAT. ANN. § 37:925 (violations, penalty). Regarding licensure more generally, see, e.g., Morris M. Kleiner, *Occupational Licensing*, 14 J. ECON. PERSP. 189, 191 (2000) ("Occupational licensing is defined as a process where entry into an occupation requires the permission of the government, and the state requires some demonstration of a minimum degree of competency.").

time of delivery.⁵¹ Without entry standards for medicine or nursing, consumers might have difficulty sorting capable practitioners from charlatans and quacks.⁵² For similar reasons, consumers might have difficulty distinguishing between professionals who possess certain basic or general competencies and those with more specialized training and experience, as may be appropriate for particular health needs.⁵³ In addition, the oversight required for ongoing licensure can help identify seriously impaired or malfeasant practitioners (for example, those who have been sanctioned for repeated malpractice or substance abuse). For these reasons, some types of licensure and scope of practice regulations for health care professionals are in the public

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51. See, e.g., Cox & Foster, *supra* note 23, at 5-6, 9-10. In economic terms, licensure-related regulations can be an efficient response to several potential types of market failure, including: information asymmetries between professionals and consumers (as when providers know much more than consumers about both the quality of services at the point of consumption and the potential benefits and risks facing the consumer); costly quality information (as when health care consumers find it difficult to obtain reliable and pertinent quality information about various alternative providers); striking externalities (as when, e.g., there are public health implications of private health care consumption); or professionals serving as both diagnosticians and treatment providers. *Id.*; cf. James C. Cooper, *Public Versus Private Restraints on the Online Distribution of Contact Lenses: A Distinction with a Difference*, 3 J.L. ECON. & POL'Y 331, 343-44 (2007) (with respect to eye care and optical goods, describing consumer reliance on prescribing by eye doctors as due not just to the legal requirement of a prescription but also to consumers' general technical inability to know which contact lenses are most appropriate for their conditions). In his seminal scholarship regarding medical care markets, Arrow considered high information costs and the problem of information asymmetries between buyers and sellers of medical care to be central problems. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 951-52 (1963) ("Uncertainty as to the quality of the product is perhaps more intense here than in any other important commodity.").
52. While licensure and scope of practice regulations may not wholly eliminate quackery and bogus health treatments, the twin histories of medical school and medical licensing requirements help to illuminate why minimum standards are desirable. Certification of medical schools and the development of state licensure acts in the late 19th and early 20th centuries proceeded from serious professional concerns about inadequate institutions and untrained practitioners. For a general account, see W.F. Bynum, *The Rise of Science in Medicine, 1850-1913*, in *THE WESTERN MEDICAL TRADITION 1800-2000*, at 111, 132-35, 165-75 (Bynum et al. eds., 2006).
53. This may be a general concern with the health care professions, distinguishing not just APRNs from physicians but among classes of nurses or doctors. For example, regulations may distinguish licensed practical nurses from registered nurses, registered nurses from APRNs, etc. Analogously, a patient may be well-served by specialty or sub-specialty licensure or certification within medicine if, say she is poorly placed to evaluate a particular doctor's training and experience in cardiac care, but can refer to board certification in cardiology or, jointly, in cardiology and cardiothoracic surgery.

interest.⁵⁴ More generally, proponents of licensure also claim that quality of services may be higher in licensed professions.⁵⁵

At the same time, APRN licensure and scope of practice regulations may sometimes restrict competition unnecessarily, which can be detrimental to health care consumers and have broader public health consequences. APRNs are trained, and in most states licensed, to provide a broad range of primary care services that are also provided by primary care physicians; indeed, there is increasing agreement among health authorities that APRNs could safely provide an even broader range of primary care services, if regulatory and reimbursement policies would permit them to do so.⁵⁶ Additional scope of practice restrictions, such as physician supervision requirements, may hamper APRNs' ability to provide primary care services that are well within the scope of their education and training. When APRN access to the primary care market is restricted, health care consumers – patients – and other payors are denied some of the competitive benefits that APRNs, as additional primary care service providers, can offer. In addition, to a certain extent, some

54. The suggestion of a net social loss is not often made with regard to physician or nursing licensure in particular, and we do not make it here. *But see generally* Daniel B. Hogan, *The Effectiveness of Licensing: History, Evidence, and Recommendations*, 7 LAW AND HUM. BEHAV. 117 (1983) (arguing that licensure has not effectively accomplished its purpose and that there may be more efficient means to provide for minimum standards and curtail quackery).

55. The consistency or magnitude of this effect has not been generally established. Still, while FTC advocacy comments regarding APRNs raise questions about particular scope of practice limits that may be imposed upon APRNs, they do not question the general utility of scope of practice rules or other types of licensure-related requirements for APRNs or other health care professionals. Arrow, in 1963, suggested both the importance of rigid entry barriers via licensure (at least for medicine), Arrow, *supra* note 51, at 966, and also the notion that “the present all-or-none approach could be criticized as being insufficient with regard to complicated specialist treatment, as well as excessive with regard to minor medical skills.” *Id.* at 966-67.

56. 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 2, at 4, 8 (“key message” and policy recommendation regarding scope of practice); OTA HEALTH TECH. CASE STUDY, *supra* note 8, at 39-40 (“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 4, at 7-8 (concluding “Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures. Moreover, the studies suggest that NPs may provide improved access to care.”); 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>.

incumbent physicians may be insulated against the degree of competition APRNs can offer.⁵⁷ It may be in the economic self-interest of those physicians to propose and advocate the adoption of restrictions on APRN licensure and scope of practice; and such physicians might be biased towards doing so.⁵⁸ Other factors, such as historically entrenched forms of training and care delivery, dated or erroneous beliefs about the training or performance of unfamiliar professions, or even professional bias, may contribute to advocacy on behalf of excessive APRN regulation.⁵⁹

As discussed in greater detail below,⁶⁰ a growing body of evidence suggests that APRNs can, based on their education and training, safely perform many of the same procedures and services provided by physicians. Thus, scope of practice restrictions may eliminate APRNs as an important source of safe, lower-cost competition. Such a reduction of competition may lead to a number of anticompetitive effects.⁶¹

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57. This is true even though APRNs and physicians are not perfect substitutes, and even though many of the services provided by APRNs and physicians are complementary rather than competitive. FTC staff do not suggest that APRN and physician scope of practice should be the same, but that both APRNs and physicians are able to provide an overlapping set of services. “Most observers conclude that most primary care traditionally provided by physicians can be delivered by NPs and PAs.” OTA HEALTH TECH. CASE STUDY, *supra* note 8, at 39. *See also* ASS’N OF AMER. MED. COLLS., PHYSICIAN SHORTAGES TO WORSEN WITHOUT INCREASES IN RESIDENCY TRAINING (n.d.), https://www.aamc.org/download/150584/data/physician_shortages_factsheet.pdf [hereinafter AAMC, PHYSICIAN SHORTAGES]. In its projections of physician supply and demand, the AAMC assumes that each additional two NPs (APRNs or physician assistants) reduce physician demand by one, which suggests that APRNs and primary care doctors are actual or potential competitors for at least some set of services.
58. For a general account of the “capture theory” of regulation applied to professionals’ interest in limiting entry via licensure, see, e.g., Stigler, *supra* note 48, at 13-14 (“A central thesis of this paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit” *Id.* at 3). *See also* COX & FOSTER, *supra* note 23, at 18-20 (arguing that income is a significant factor in professionals’ desire for regulation via licensing); Kleiner, *supra* note 50, at 192 (“The most generally held view on the economics of occupational licensing is that it restricts the supply of labor to the occupation and thereby drives up the price of labor as well as of services rendered.”). Recent research regarding other state-licensed professions is “consistent with the hypothesized role by members of an occupation to raise wages by using the powers of government to drive up requirements and capture work for the regulated workers for larger geographic areas.” Morris M. Kleiner & Alan B. Kreuger, *Analyzing the Extent and Influence of Occupational Licensing on the Labor Market*, 31 J. LAB. ECON. S173, S198-99 (2013), available at <http://www.hhh.umn.edu/people/mkleiner/pdf/Final.occ.licensing.JOLE.pdf> (finding substantially higher wages associated with licensure of a profession at the state or federal, instead of local, level, adjusting for educational attainment, age, experience, and other variables, consistent with a monopoly theory of licensure).
59. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27, 107-14; Barbara J. Safriet, *Federal Options for Maximizing the Value of Advanced Practice Nurses in Providing Quality, Cost-Effective Health Care*, in IOM FUTURE OF NURSING REPORT, *supra* note 2, at 451-57.
60. *See* Section III.B., *infra*.
61. In addition to potential competition concerns when one group of competitors seeks to exclude other competitors via regulation, the question whether or to what extent one professional board may regulate the conduct of another profession sometimes raises other complex legal questions as well. *See, e.g.*, Missouri Ass’n of Nurse Anesthetists v. State Bd. of Registration for the Healing Arts, 343 S.W.3d 348, 358 (Mo. 2011) (Missouri board “without authority to make policies, interpretations or determinations that define the scope of practice for APNs” under Missouri law).

Licensure and scope of practice regulations thus have potential positive and negative consequences for health care consumers. Consumers are protected by assurances that their health care providers meet minimum criteria for education, training, knowledge and skills, which supports critical safety and quality objectives. At the same time, however, when licensure and scope of practice restrictions are broader than necessary to protect patient health and safety, they may increase the cost of APRN-delivered services and impede APRNs' ability to enter the market or expand the range of services they offer. These effects, in turn, may diminish competitive pressures that would otherwise apply to price and quality of some physician-delivered services.

II.B.2. Analysis of Scope of Practice Limitations Should Account for the Value of Competition

Policy changes should be based on the best information available, and decisionmakers should strive to identify and evaluate the potential benefits of laws and regulations as well as their potential costs. We urge that the regulatory review process consider the benefits of competition and the potential adverse competitive impact of regulations, along with other legitimate policy goals.⁶²

The approach proposed by FTC staff takes into account the potential competitive impact of professional regulations, as well as any potential countervailing health and safety benefits, the likelihood that the regulations will redress those concerns, and the availability of any less restrictive means of achieving the same legitimate results. This approach also recognizes that competition can work to favor, rather than undermine, health care quality, which means that policymakers do not necessarily have to choose between protecting consumers and promoting competition: increased consumer protection and increased competition can occur at the same time. We urge legislators and policymakers to apply the following analytical framework to evaluate the reasonably available evidence:

- Will the regulation significantly impede competition by, for example, making it more costly or difficult for the regulated group of professionals to enter into competition, or expand their practices, or by otherwise increasing the cost of health care services or reducing their availability?

62. We do not mean to suggest that physician or nursing licensure generally leads to net social loss. Specifically, for purposes of this policy paper, we assume that both a baseline APRN licensing regime and some regulatory limits on APRN scope of practice are necessary and desirable, even where additional scope of practice restrictions may be overly burdensome. *See supra* notes 51-55 and accompanying text. A detailed discussion of the potential competitive harms done by particular undue regulatory restrictions on APRN practice is the subject of Section III.A of this policy paper, *infra*.

- Are there any significant and non-speculative consumer health and safety needs that particular regulatory restrictions, extant or proposed, are supposed to meet?
- Do those particular regulations actually provide the intended benefits – such as improvements in health care outcomes or a reduced risk of harm from poor-quality services – or are there good grounds to think they are likely to provide those benefits?
- Are there other demonstrated or reasonably likely consumer benefits associated with the proposed regulation (e.g., reduced information or transaction costs for consumers who are choosing among providers, reduced consumer confusion in distinguishing among different types of providers, etc.)?
- When consumer benefits are slight, insubstantial, or highly speculative, a regulation that imposes non-trivial impediments to competition is not justified.⁶³
- If pertinent consumer harms have occurred, or risks are found to be substantial, is the proposed regulation likely to redress those harms or risks?
- Are the regulations narrowly tailored to serve the state’s policy priorities? When particular regulatory restrictions address well-founded consumer protection concerns but – at the same time – appear likely to harm competition, consider whether the regulations are narrowly tailored to address those concerns without undue harm to competition, or whether less restrictive alternatives are available.

The next section of this policy paper explains how FTC staff recommend applying this basic framework to proposed APRN scope of practice regulations. In each of the APRN advocacy comments, FTC staff have identified pertinent market information and suggested how it might fit into a more comprehensive policy analysis. None of these advocacies, however, has attempted to provide a comprehensive cost-benefit analysis of existing or proposed APRN scope of practice rules. State legislators and policymakers – who are most familiar with local markets and consumer needs – are urged to consider which specific pieces of information are relevant to assessing the costs and benefits associated with a policy proposal, as well as the relative weight and importance of various policy priorities of interest to consumers in their jurisdictions.

63. *Cf.* *FTC v. Ind. Fed. of Dentists*, 476 U.S. 447, 459 (“Absent some countervailing procompetitive virtue . . . such an agreement limiting consumer choice by impeding the ‘ordinary give and take of the marketplace’ . . . cannot be sustained . . .” (internal citations omitted)).

III. APRN SCOPE OF PRACTICE COMPETITION ADVOCACY COMMENTS AND ADDITIONAL ANALYSIS BY FTC STAFF

In the last three years, FTC staff have issued competition advocacy comments analyzing the likely competitive effects of proposed changes to APRN regulations in Massachusetts,⁶⁴ Connecticut,⁶⁵ West Virginia,⁶⁶ Louisiana,⁶⁷ Kentucky,⁶⁸ Texas,⁶⁹ and Florida.⁷⁰ All of these comments were requested by state legislators. While each comment considered somewhat different statutory and regulatory restrictions, all of the comments addressed policy proposals regarding mandatory physician supervision of APRN practice or “collaborative practice” requirements that could operate as *de facto* supervision requirements. Some of the proposals would have required additional or heightened supervision of APRNs. Other proposals would have removed or lessened pre-existing requirements that APRNs operate under some specified form of physician supervision to provide some or all of the health care services otherwise within the APRNs’ scope of practice, as defined under other state laws and regulations.

Some physician groups have suggested that supervision requirements are justified by the advantages of a team-based approach to health care, and that primary care physicians are best positioned to lead health care teams because they have completed substantially longer programs of education and training than APRNs. For example, a recent report by the American Academy of Family Physicians recommends a “medical home” model of care with a primary care physician

64. FTC Staff Comment Before the Mass. House of Representatives Regarding House Bill 2009 Concerning Supervisory Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 2014), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettsnursesletter.pdf [hereinafter FTC Staff Massachusetts Comment].
65. Comment from FTC Staff to the Hon. Theresa W. Conroy, Conn. House of Representatives (Mar. 19, 2013), <http://www.ftc.gov/os/2013/03/130319aprnconroy.pdf> [hereinafter FTC Staff Connecticut Letter].
66. Written Testimony from FTC Staff to Subcomm. A of the Joint Comm. on Health of the State of W. Va. Legislature (Sept. 10-12, 2012), <http://www.ftc.gov/os/2012/09/120907wvatestimony.pdf> [hereinafter FTC Staff West Virginia Testimony].
67. Comment from FTC Staff to the Hon. Thomas P. Willmott & Hon. Patrick C. Williams, La. House of Representatives (Apr. 20, 2012), <http://www.ftc.gov/os/2012/04/120425louisianastaffcomment.pdf> [hereinafter FTC Staff Louisiana APRN Comment].
68. Comment from FTC Staff to the Hon. Paul Hornback, Commonwealth of Ky. State Senate (Mar. 26, 2012), http://www.ftc.gov/os/2012/03/120326ky_staffletter.pdf [hereinafter FTC Staff Kentucky Letter].
69. Comment from FTC Staff to the Hon. Rodney Ellis & Hon. Royce West, Senate of the State of Tex. (May 11, 2011), <http://www.ftc.gov/os/2011/05/V110007texasaprn.pdf> [hereinafter FTC Staff Texas Letter].
70. Comment from FTC Staff to the Hon. Daphne Campbell, Fla. House of Representatives (Mar. 22, 2011), <http://www.ftc.gov/os/2011/03/V110004campbell-florida.pdf> [hereinafter FTC Staff Florida Letter].

leading each “patient-centered” team.⁷¹ As noted above, the FTC staff has not questioned the utility of team-based care or the notion that some types of care may require extensive medical training. At the same time, particular supervision requirements can burden, rather than facilitate, team-based care. The FTC staff questions, therefore, whether evidence supports a statutory mandate for some particular model of team-based care that is always led by a primary care physician. The FTC staff also asks whether evidence supports the contention that patients receive substandard care, or are harmed, when the law does not impose specific supervision requirements on APRNs and their patients.

This section of the paper synthesizes the points raised in the seven prior advocacy comments, supplemented by additional FTC research and learning. It sets forth the analytical approach recommended by FTC staff to legislators who are weighing the costs and benefits of these types of physician supervision requirements.

The FTC does not purport to advocate a simple or uniform model for how best to coordinate health care, define the scope of APRN practice, or specify the appropriate role for physician supervision. Ultimately, those decisions must be made by state legislators and regulators, and by health care providers themselves, based on their expertise and the best available evidence. The FTC’s role, based on its institutional mission and expertise, is to highlight why, as part of their regulatory review process, policymakers should consider the impact of regulations on competition and consumer protection. Regulatory choices that affect APRN scope of practice may have a direct impact on health care prices, quality, and innovation, often without countervailing benefits.

The discussion below evaluates in greater detail the potential competitive harms that may flow from these types of APRN scope of practice restrictions, as well as the justifications often proffered by their proponents.

71. AMER. ACAD. OF FAMILY PHYSICIANS, PRIMARY CARE FOR THE 21ST CENTURY *i-ii* (2012), http://www.aafp.org/dam/AAFP/documents/about_us/initiatives/AAFP-PCMHWhitePaper.pdf; *cf.* Letter from James L. Madara, Amer. Med. Ass’n, to the Hon. David G. Perry & the Hon. Dan Foster, W. Va. Legislature 2 (Sept. 10, 2012), <http://www.ama-assn.org/resources/doc/arc/ama-letter-ftc-wv.pdf> (“health care delivery is evolving to a physician-led team approach to ensure better care coordination and outcomes for patients.”).

III.A. Potential Competitive Harms from APRN Physician Supervision Requirements

APRN physician supervision requirements raise several related competitive concerns. By restricting APRNs' access to the marketplace, supervision requirements may deprive health care consumers of the many benefits of competition among different types of health care providers. This reduction in competition may exacerbate provider shortages and thereby contribute to access problems, particularly for underserved populations that already lack adequate and cost-effective primary care services. Supervision requirements also can impact the cost and quality of health care services. Finally, rigid "collaborative practice agreement" requirements may be inconsistent with a truly collaborative and team-based approach to health care. Such requirements can impede collaborative care rather than foster it, because they limit what health care professionals and providers can do to adapt to varied health care demands and constrain provider innovation in team-based care.

III.A.1. Restrictive Physician Supervision Requirements Exacerbate Well-Documented Provider Shortages that Could Be Mitigated via Expanded APRN Practice

Expanded APRN practice is widely regarded as a key strategy to alleviate provider shortages, especially in primary care, in medically underserved areas, and for medically underserved populations.⁷² Imposing greater restrictions on APRNs will only exacerbate existing and projected health care workforce shortages by limiting the ability of APRNs to fill gaps in patients' access to primary care services.

The United States faces a substantial and growing shortage of physicians, especially primary care physicians, which has significant consequences for basic health care access for many American

72. See, e.g., IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27-28; see also EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 100 ("Given widespread agreement that there is a critical shortage of primary care physicians in the Commonwealth, expanding scope-of-practice laws could be a viable mechanism for increasing primary care capacity and reducing health care costs." *Id.*); MINN. HEALTH CARE REFORM TASK FORCE, *supra* note 56, at 25-26 (remove regulatory barriers to APRN practice and expand supply of primary care practitioners, including APRNs); NGA PRIMARY CARE PAPER, *supra* note 4, at 11 ("Expanded utilization of NPs has the potential to increase access to health care, particularly in historically underserved areas.") 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).

consumers.⁷³ Beyond aggregate or average projected shortages, the United States suffers from widespread distributional problems in the supply of health care professionals.⁷⁴ Reduced access has the greatest impact on America's poorest citizens, including Medicaid beneficiaries. Physicians are less likely to practice in low-income areas or to participate in state Medicaid programs.⁷⁵ Rural communities, too, are particularly vulnerable to provider shortages and access problems.⁷⁶ According to the U.S. Department of Health and Human Services, by late 2013 there were approximately 5,800 primary care Health Professional Shortage Areas (HPSAs) in

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73. See BUREAU OF HEALTH PROFESSIONS, HEALTH RESOURCES & SERVS. ADMIN., THE PHYSICIAN WORKFORCE: PROJECTIONS AND RESEARCH INTO CURRENT ISSUES AFFECTING SUPPLY AND DEMAND 70-72, ex. 51-52 (2008), <http://bhpr.hrsa.gov/healthworkforce/reports/physwfindings.pdf> [hereinafter HRSA PHYSICIAN WORKFORCE REPORT] (projecting increased shortages of both primary care physicians and specialists); KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1 (by 2020 “the U.S. States will face an estimated shortage of 91,000 physicians, split about evenly between primary care physicians and specialists”); AAMC, PHYSICIAN SHORTAGES, *supra* note 57, at 1 (projected shortfall of approximately 45,000 primary care physicians and 46,000 specialists in the next decade). For a searchable database of HRSA Medically Underserved Areas and Populations (“MUA/P”), see *Find Shortage Areas: MUA/P by State and County*, HEALTH RESOURCES & SERVS. ADMIN., <http://muafind.hrsa.gov/index.aspx> (last visited Nov. 7, 2013) [hereinafter HRSA MUA/P Database]. These projected shortages are important for present concerns and others. We note, however, that such projections of health care needs are, however pertinent, not quite the same as projections of aggregate demand.
74. See generally *Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations*, HEALTH RESOURCES & SERVS. ADMIN., <http://www.hrsa.gov/shortage/> (last visited Nov. 19, 2013) (“As of November 14, 2013: There are currently approximately 5,800 designated Primary Care HPSAs [health professional shortage areas].”); *Primary Care Workforce Facts and Stats*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <http://www.ahrq.gov/research/findings/factsheets/primary/pwork3/index.html> (last visited Nov. 21, 2013) (“Uneven geographic distribution of the health care workforce creates problems with access to primary care.”); cf. Scott A. Shipman et al., *Geographic Maldistribution of Primary Care for Children*, 127 PEDIATRICS 19, 19 (2011) (“Undirected growth of the aggregate child physician workforce has resulted in profound maldistribution of physician resources.”).
75. See KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1; DOWER & O’NEIL, *supra* note 30, at 7 (“Physician supply is lower in communities with high proportions of minority and low-income residents with greater health needs, known as the “inverse care law.”)
76. See generally CTR. WORKFORCE STUDIES, AMER. ASS’N MED. COLLS., RECENT STUDIES AND REPORTS ON PHYSICIAN SHORTAGES IN THE US (Oct. 2012), <https://www.aamc.org/download/100598/data/> (reviewing 33 state reports on physician shortages, 16 national reports on physician shortages, and 22 specialty shortage reports).

the United States.⁷⁷ It has been estimated that approximately sixty-five million Americans live in such officially designated shortage areas.⁷⁸

In many areas, those shortages are expected to persist or worsen, especially in light of health care reform efforts that will enable many more Americans to obtain health care insurance.⁷⁹ As a result, millions of Americans soon will have a greater ability to pay for health care – especially routine primary care and preventive services they currently do without⁸⁰ – but it is unclear how the existing population of practitioners can meet this increasing demand.⁸¹

Each of the seven FTC staff advocacy comments cites state-specific data to underscore national concerns about access to care. In Louisiana, for example, FTC staff noted that

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77. *Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations*, HEALTH RESOURCES & SERVS. ADMIN., <http://www.hrsa.gov/shortage/> (last visited Feb. 3, 2014) (estimating that approximately 7,500 additional primary care physicians would be required to change these HPSA designations, based on a population to practitioner ratio of 3,500:1. HRSA had previously estimated shortages of about 16,000 primary care physicians based on a different model, and continues to recognize that other sources and models suggest higher shortage numbers); *see also* HRSA PHYSICIAN WORKFORCE REPORT, *supra* note 73, at 70-72; KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1 (inadequate supply of primary care providers is one of the “major health care challenges facing the U.S. today”; and it is estimated that “U.S. will face an estimated shortage of 91,000 physicians, split about evenly between primary care physicians and specialists,” by 2020.).
78. Thomas Bodenheimer & Hoangmai H. Pham, *Primary Care: Current Problems and Proposed Solutions*, 29 HEALTH AFFAIRS 799 (2010) (“Sixty-five million Americans live in what are officially deemed primary care shortage areas, and adults throughout the United States face difficulty obtaining prompt access to primary care.”)
79. That is, broader coverage will increase the demand for health care services, independent of its other effects. *See, e.g.*, KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1 (“Under health reform, the pressures on access are certain to grow as millions of newly insured people enter the health care system.”).
80. *See* HRSA PHYSICIAN WORKFORCE REPORT, *supra* note 73, at 70-74 (projected physician shortages will be even worse if ability to pay for care and public expectations of care increase). A number of studies have sought to estimate the extent to which health care reform – including the Patient Protection and Affordable Care Act (ACA) – is likely to exacerbate primary care provider shortages. All of these studies project substantial shortages, but their estimates differ. *See, e.g.*, Adam N. Hofer et al., *Expansion of Coverage under the Patient Protection and Affordable Care Act and Primary Care Utilization*, 89 MILBANK Q. 69, 84 (2011) (estimating predicted demand for primary care utilization stimulated by ACA and predicting 2019 shortfall of 4,307-6,940 primary care physicians, subject to “considerable” geographic variation); Elbert S. Huang & Kenneth Finegold, *Seven Million Americans Live in Areas Where Demand for Primary Care May Exceed Supply by More Than 10 Percent*, 32 HEALTH AFFAIRS 1 (2013); Stephen M. Petterson et al., *Projecting US Primary Care Physician Workforce Needs: 2010-2025*, 10 ANNALS FAMILY MED. 503, 506-07 (2012) (projecting 2025 shortfall of 52,000 primary care physicians, based on increased coverage and, to greater extent, population growth and aging of population). Ku et al. estimate state-by-state primary care needs based on projections for expanded Medicaid populations. Leighton Ku et al., *The States’ Next Challenge – Securing Primary Care for Expanded Medicaid Populations*, 364 NEW ENG. J. MED. 493 (2011).
81. Auerbach et al., *supra* note 72, at 1937-40 (projecting continued shortages of primary care practitioners, despite upswing in primary care medical residencies, if delivery models and scope of practice remain constant).

more than half of Louisiana’s population lives in a federally-designated [HPSA]. All 64 Louisiana Parishes contain HPSAs, and 53 entire Parishes comprise primary care shortage areas. An estimated 765,000 Louisianans – more than 17 percent of the State’s population – lack health insurance.⁸²

FTC staff cited a Louisiana Department of Health and Hospitals report indicating that “[s]hortages affecting the accessibility and availability of primary-care physicians . . . pose a significant problem in the delivery of healthcare in Louisiana.”⁸³ Staff also cited state-specific sources projecting that health care reform would exacerbate shortages as more Louisiana consumers gain health insurance and seek access to primary health care services.⁸⁴ FTC staff have raised analogous concerns about existing professional shortages and access to basic health care services in other APRN advocacy materials.⁸⁵

Health policy experts have long considered the role APRNs might play in alleviating provider shortages, particularly if APRNs are subject to fewer and less costly restrictions. For example, in 1986, what was then the U.S. Congress Office of Technology Assessment observed,

The use of nurse practitioners (NPs) and physician assistants (PAs) to provide primary health care traditionally provided only by physicians developed during the 1960s in response to a perceived shortage and maldistribution of physicians. Societal support for this innovation in the delivery of health-care was based on the

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82. FTC Staff Louisiana APRN Comment, *supra* note 67, at n.25-28 and accompanying text (internal citations omitted). *See also Primary Care: State Profiles*, NAT’L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/issues-research/health/primary-care-state-profiles.aspx> (last updated Nov. 2011) (map indicating Louisiana as one of three states with 49-62% of population in HPSA); *Find Shortage Areas: HPSA by State and County*, HEALTH RESOURCES & SERVS. ADMIN., <http://hpsafind.hrsa.gov/HPSASearch.aspx> (last visited Nov. 7, 2013).
83. OFFICE OF PUB. HEALTH, LA. DEP’T OF HEALTH AND HOSPITALS, 2009 LOUISIANA HEALTH REPORT CARD 203 (2010), http://new.dhh.louisiana.gov/assets/oph/Center-RS/healthstats/DHHHlthCreRprtCrd_2009.pdf; *id.* at 224-26 (describing large majority of state as “health professional shortage area” under LA criteria as well as federal MUA/P criteria); Bureau of Primary Care & Rural Health, *Primary Care HPSA Map of Louisiana*, LA. DEP’T OF HEALTH AND HOSPITALS (Oct. 3, 2012), http://new.dhh.louisiana.gov/assets/oph/pcrh/10-03-2012_PC_MAP.jpg (indicating primary care shortages in most of state); HRSA MUA/P Database, *supra* note 73 (indicating shortage areas throughout Louisiana’s 64 Parishes according to HRSA MUA/P criteria).
84. FTC Staff Louisiana APRN Comment, *supra* note 67, at 2 (citing LA. CTR. FOR NURSING, LA. STATE BD. OF NURSING, NURSING WORKFORCE DEMAND REPORT, 1, 3 (2012)). The FTC staff letter supported a bill that would have reduced supervision requirements for certain APRNs practicing in medically underserved areas or treating underserved populations.
85. *See, e.g.*, FTC Staff Massachusetts Comment, *supra* note 64, at 1-2, 4-5; FTC Staff West Virginia Testimony, *supra* note 66, at notes 23-25 and accompanying text; FTC Staff Kentucky Letter, *supra* note 68, at notes 21-24 and accompanying text; FTC Staff Texas Letter, *supra* note 69, at 4 n.21 and accompanying text; FTC Staff Florida Letter, *supra* note 70, at 2 n.6, 4 n.19, 5 n.24 and accompanying text; FTC Staff Connecticut Letter, *supra* note 65, text accompanying notes 20-30.

potential for NPs and PAs to improve access and to lower costs while maintaining the quality of care.⁸⁶

Moreover, although “[m]ost observers conclude that most primary care traditionally provided by physicians can be delivered by NPs and PAs,”⁸⁷ OTA also observed that APRNs (NPs) faced certain obstacles in meeting emerging demands for their services, such as physician opposition and restrictive state laws and regulations.⁸⁸

For similar reasons, the IOM and other expert bodies continue to recommend that access problems be addressed – at least in part – by increased reliance on APRNs.⁸⁹ APRNs are the fastest-growing segment of the primary care professional workforce in the United States. Between the mid-1990s and the mid-2000s, the number of APRNs per capita grew an average of more than nine percent annually, compared with just one percent per capita growth for primary care physicians.⁹⁰ A recent study suggests that the supply of APRNs should roughly double by 2025.⁹¹

APRNs provide a broad range of primary care services and are responsible for a significant share of primary care in the United States. A 2008 CDC study noted that, by 2006, patients saw an APRN, NMW, or PA at sixteen percent of U.S. primary care visits, with nearly twelve percent of such patient visits attended *solely by an APRN, NMW, or PA*.⁹² Today, APRNs “are

86. OTA HEALTH TECH. CASE STUDY, *supra* note 8, at 3; *see generally id.* at 29-32.

87. *Id.* at 39.

88. *Id.* at 3.

89. *See supra* note 72 and accompanying text.

90. *See* KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 3; *see also* Yong-Fang Kuo et al., *States with the Least Restrictive Regulations Experienced the Largest Increase in Patients Seen by Nurse Practitioners*, 32 HEALTH AFFAIRS 1236, 1236 (2013) (increase in number of practicing NPs and training programs over past two decades); AAMC, PHYSICIAN SHORTAGES, *supra* note 57, at 1 (projecting shortage of approximately 45,000 primary care physicians over next decade, and noting that “the impact will be most severe on vulnerable and underserved populations. These groups include the approximately 20 percent of Americans who live in rural or inner-city locations designated as health professional shortage areas.”).

91. David I. Auerbach, *Will the NP Workforce Grow in the Future*, 50 MED. CARE 606 (2012) (projecting 94% increase in practitioners with APRN or NP training, and 130% increase in those identifying themselves with “NP” title).

92. ESTHER HING ET AL., CDC NATIONAL HEALTH STATISTICS REPORT NO. 4, NATIONAL AMBULATORY MEDICAL CARE SURVEY: 2006 OUTPATIENT DEPARTMENT SUMMARY 6 (2008), <http://www.cdc.gov/nchs/data/nhsr/nhsr004.pdf>.

the most common non-physician health care providers of primary care services,”⁹³ and they provide a large number of primary care services – independently in some states, and subject to collaborative practice agreements or supervision requirements in other states.⁹⁴ APRNs “[t]ake health histories and provide complete physical exams; diagnose and treat acute and chronic illnesses; provide immunizations; prescribe and manage medications and other therapies; order and interpret lab tests and x-rays; provide health teaching and supportive counseling.”⁹⁵

As primary care provider shortages have worsened, APRNs have played an even greater role in alleviating the effects of shortages and mitigating access problems. For example, APRNs make up a greater share of the primary care workforce in less densely populated areas, less urban areas, and lower income areas, as well as in HPSAs.⁹⁶ Relative to primary care physicians, APRNs are more likely to practice in underserved areas and care for large numbers of minority patients, Medicaid beneficiaries, and uninsured patients.⁹⁷ In addition, the shorter and less costly education and training requirements of APRN practice suggest that APRNs may be able to meet

93. NGA PRIMARY CARE PAPER, *supra* note 4, at 4. One recent study, based on Medicare billing data, suggests 9.5% growth in the number of Medicare patients seen by NPs, from 1998 to 2010. Kuo et al., *supra* note 90, at 1238. An April, 2013 Berkeley Forum Report suggests a roughly 10% NP share of primary care visits in the state, with data from other states ranging from 5.1% (New Jersey) to 29.8% (Missouri). BERKELEY FORUM, UNIV. OF CALIFORNIA, BERKELEY, A NEW VISION FOR CALIFORNIA’S HEALTHCARE SYSTEM: INTEGRATED CARE WITH ALIGNED FINANCIAL INCENTIVES app IX, at 7 (2013) (“Nurse Practitioners & Physician Assistants (Initiative Memorandum)”).

94. NGA PRIMARY CARE PAPER, *supra* note 4, at 1 (“Research suggests that NPs can perform many primary care services as well as physicians do.”).

95. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27; *see also* NGA PRIMARY CARE PAPER, *supra* note 4, at 4 (NPs “provide comprehensive services”); EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 99 (enumerating range of NP services).

96. *See, e.g.*, Christine M. Everett et al., *Division of Primary Care Services Between Physicians, Physician Assistants, and Nurse Practitioners for Older Patients with Diabetes*, 70 MEDICAL CARE RES. & REV. 531, 536-37 (2013) (“Panels with PAs/NPs as usual providers appear to have a higher proportion of socially complex patients, when defined according to poverty (Medicaid), disability, and comorbid dementia and depression.”); KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 3; IOM FUTURE OF NURSING REPORT, *supra* note 2, at 107-08; Christine M. Everett et al., *Physician Assistants and Nurse Practitioners as Usual Sources of Primary Care*, 25 J. RURAL HEALTH 407, 408 (2009).

97. *See, e.g.*, Everett et al., *Division of Primary Care Services*, *supra* note 96, at 5 (“participants without insurance or on public insurance other than Medicare had 1.71 times the odds of reporting utilizing at AP/NP”; and observing that women were 1.77 times more likely to recognize a PA/NP as their usual source of care as men); *see also* Michael J. Dill, et al., *Survey Shows Consumers Open to a Greater Role for Physician Assistants and Nurse Practitioners*, 32 HEALTH AFFAIRS 1135, 1137-38 (2013) (women less likely to see APRN than men, and “[w]hites were less likely than other racial or ethnic groups to have reported seeing a physician assistant or nurse practitioner for their most recent medical care, and the most likely to have never seen one.”).

fluctuations in demand more quickly or efficiently than the medical profession, at least for some health care needs.⁹⁸

APRNs in many states already strive to fill the widening gap between demand and supply for health care services. To the extent that legislators and regulators reduce unnecessary limits on APRN scope of practice, populations facing shortages of primary care professionals may see those shortages diminished. Consider the overlapping set of health care services that – independent of regulatory restrictions – could be supplied by both physicians and APRNs. Relaxing the regulatory limits on APRN scope of practice will tend to expand the supply of providers who are willing and able to offer those services at any given price. Either of two sorts of regulatory changes might expand supply. First, to the extent that scope of practice rules are changed to permit APRNs to deliver a given type of service they were trained to provide, but were previously prohibited from providing, the population of providers will increase for that service. Second, when the APRN scope of practice already includes a given service, but the regulatory costs of APRN service provision are lowered (e.g., by removing particular physician supervision requirements), the supply of professionals willing to offer those services at any given price will increase. In underserved areas and for underserved populations, the benefits of expanding supply are clear: consumers will have access to services that were otherwise unavailable. Even in well-served areas, the supply expansion will tend to lower prices for any given level of demand, thus lowering healthcare costs.

The National Governors Association (NGA) recognized the impact of this supply expansion in its paper, “The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care,”⁹⁹ which emphasized APRNs’ critical role in expanding access to care and also echoed many of the other themes in FTC staff’s scope of practice competition advocacy comments. The NGA paper specifically noted that

[t]he demand for primary care services in the United States is expanding as a result of the growth and aging of the U.S. population and the passage of the 2010 [Patient Protection and Affordable Care Act], and this trend is expected to continue over the next several years. NPs may be able to mitigate projected shortages of primary

98. Dill et al., *supra* note 97, at 1135 (2013) (citing shorter training period and greater flexibility to shift specialties as reasons to think APRNs and PAs may be especially suited to filling gaps in access to health care). *But cf.* Auerbach et al., *supra* note 72, at 1938-40 (recognizing some efficiencies in APRN and other nurse training, but nonetheless projecting continued primary care shortages *unless* balance of delivery models change to include greater use of nurse managed care.).

99. NGA PRIMARY CARE PAPER, *supra* note 4.

care services. . . . Expanded utilization of NPs has the potential to increase access to health care, particularly in historically underserved areas.¹⁰⁰

Conversely, when additional and unnecessary restrictions are imposed on APRNs, access problems are more likely to be exacerbated, with patients deprived of basic care. One study suggests that relatively stringent APRN scope of practice rules are associated with fewer per capita practitioners,¹⁰¹ and analogous evidence has been developed regarding restrictions on specialized APRNs¹⁰² and other non-physician health care providers.¹⁰³ A recent study attempts to assess, at least for Medicare patients, the share of primary care treatment undertaken by APRNs or NPs, depending on the state regulatory environment in which they practice.¹⁰⁴ We encourage additional empirical research regarding the effects of alternative scope of practice regulations on access to primary care in underserved areas, and for underserved populations, as well as research regarding the health effects associated with changes in access.

III.A.2. Excessive Supervision Requirements May Increase Health Care Costs and Prices

When particular physician supervision requirements are required for APRN practice, some costs are imposed on both the supervising physician and the supervised APRN. Similarly, when an APRN is required to secure and maintain a collaborative practice agreement with a physician in

100.*Id.* at 11.

101.Sekscenski et al., *supra* note 32.

102.*See id.* (regarding NMWs); Eugene R. Declercq et al., *State Regulation, Payment Policies, and Nurse-Midwife Services*, 17 HEALTH AFFAIRS 190 (1998) (NMW rules “supportive” of practice associated with increased distribution of NMWs and NMW services).

103.For example, some research regarding state dentistry regulations suggests that increasingly stringent licensing requirements may not be associated with better dental health outcomes, but may be associated with fewer dentists per capita. Morris M. Kleiner & Robert T. Kurdle, *Does Regulation Effect Economic Outcomes? The Case of Dentistry*, 43 J. LAW & ECON. 547, 575-76 (2000). *But cf.* Arlene Holen, Pub. Research Inst., Ctr. for Naval Analyses, *The Economics of Dental Licensure* (1978), available at <http://www.cna.org/sites/default/files/research/0203440000.pdf> (finding some positive correlation between stringency of certain dental rules and a proxy for quality of care – lower average malpractice insurance rates – although reaching no conclusions about net benefits).

104.Kuo et al., *supra* note 90, at 1238-40 (study based on 5% sample of Medicare claims data). For various reasons, particular treatments conducted by APRNs may not be accurately reflected in the claims data. *See* David I. Auerbach, *Nurse Practitioner Billing Practices Could Obscure True Numbers*, Reply to Kuo, et al., HEALTH AFFAIRS ONLINE (JULY 2013), <http://content.healthaffairs.org/content/32/7/1236/reply>.

order to practice independently,¹⁰⁵ at least some costs are imposed on both contracting parties.¹⁰⁶ Either sort of cost may harm patients, to the extent that higher costs diminish access to care, and may harm health care consumers, as well as public and private third-party payors to the extent that some increased costs may be passed along as higher prices. These concerns should be considered against the backdrop of the general issue of supply expansion (or contraction), as explained above. Moreover, we note that APRNs tend to be relatively low cost providers, which might enhance savings associated with a supply expansion.¹⁰⁷

Typically, such laws require an APRN to secure an agreement with a particular licensed physician in order to engage in some or all of the APRN's otherwise permitted practice. Those requirements can be akin to physician supervision requirements. Independent of his or her education, training, certification, and experience, an APRN can practice only on terms acceptable to a particular licensed physician. Depending on the particular statutory requirements, those terms might include, for example, the number of times the physician reviews the APRN's charts, the frequency with which, or situations in which, the APRN will consult with the physician, or the physician's approval of the APRN's practice plans or protocols.¹⁰⁸ Each transaction to secure an agreement imposes costs on both the APRN and the physician. Compliance with the contract also can imply costs and benefits for both parties.¹⁰⁹

It is important to remember that collaboration and professional oversight are the norm in states that do not require direct physician supervision or "collaborative practice" agreements. Patterns

105. For purposes of this policy paper, "independent" APRN practice means the APRN is neither employed nor directly supervised by a physician.

106. *See, e.g.*, LA. REV. STAT. ANN. § 37:913(8)-(9) (2012); KY. REV. STAT. § 314.042; W. VA. CODE § 30-7-15a; FTC Staff Connecticut Letter, *supra* note 65, text accompanying notes 32-37. Although costs are imposed on both parties, the immediate impact is asymmetrical: it largely disfavors APRNs. Hence, physicians may tend to be less concerned about these regulatory costs.

107. A study conducted for the Commonwealth of Massachusetts by the RAND Corporation suggests concrete savings that might be associated with expanded APRN (and PA) scope of practice, 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 in the delivery of primary care." EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 103-04 (describing conditions for upper and lower bound estimates and projections). A California report by the Berkeley Forum estimates that expanded use of APRNs and PAs, facilitated by scope of practice and reimbursement reform, should result in a "healthcare expenditure decrease of between \$1.4 billion and \$1.8 billion in current-year dollars from 2013-2022," in that state. BERKELEY FORUM, *supra* note 93, at 2.

108. A summary table of supervisory requirements, state by state, can be found at IOM FUTURE OF NURSING REPORT, *supra* note 2, at 157-61 (annex 3-1, table 3-A1).

109. This cost assumption presumes that the physician is required to provide certain services to the APRN, and invest time in supervising the APRN, as part of the collaborative practice agreement. This may not always be the case, however. *See infra*, text accompanying notes 113-114.

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.¹¹⁰ Health and safety standards may be established by the professions themselves, institutional providers, health and safety regulators, and the courts.¹¹¹ Individual APRNs – even those practicing independently – can and do refer patients to physicians or hospitals. They also may choose to consult or collaborate with physicians where the APRNs (and professional standards) deem it useful or important, and they may develop models of consultation and collaboration that they and collaborating physicians deem useful or important, under terms agreeable to all collaborating parties. None of our questions about the costs (or benefits) of particular legal or regulatory requirements is meant to impugn any privately implemented model of professional collaboration or oversight.

However, to the extent that a “collaboration” agreement covers physician services for which neither party would choose to contract, absent a regulatory requirement, and for which there are no good grounds to suppose that health and safety benefits accrue to patients, those costs are unnecessary. Some of these added costs may be passed on to individual health care consumers, as well as public and private third-party payors.

These types of “collaboration” and supervision requirements establish physicians as gatekeepers who control APRNs’ independent access to the market. Thus positioned, some physicians may simply refuse to enter into such agreements, which could effectively preclude certain APRNs from practicing at all. Other physicians may be willing to form agreements, but may offer prices and other terms that are not competitive; they may be particularly able to do so in markets where potential supervising physicians are in short supply and where APRNs must contract to work at all. Hence, the prices APRNs must pay to obtain collaborative practice agreements may tend to rise, even where the APRNs can find physicians with whom to contract. Consequently, some APRNs who manage to secure mandatory collaboration agreements may pay more for them than

110. 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).

111. Regarding diverse practice settings and APRN collaboration, see IOM FUTURE OF NURSING REPORT, *supra* note 2, at 23, 58-59, 65-67, 72-76; INST. OF MED., NAT’L ACAD. OF SCIENCES, DELIVERING HIGH QUALITY CANCER CARE: CHARTING A NEW COURSE FOR A SYSTEM IN CRISIS, 171-81 (2013) (importance of and different approaches to team-based care in cancer treatment, and roles of APRNs). 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).

they would in independent practice states. Those APRNs are likely to try to pass the increased costs along to their patients or third-party payors, potentially raising the prices of APRN services and further insulating physicians from price competition.¹¹²

Competitive harm is especially likely when state law requires an independently-practicing APRN to secure a physician collaboration agreement, and allows a physician to charge a fee for this agreement, but does not specify any particular services that the physician must provide under the agreement, such as chart review or availability for consultation.¹¹³ In extreme cases, a physician may charge a high fee to enter into an agreement that neither promises nor delivers value in return.¹¹⁴ The APRN may obtain a signature and thereby secure the state's permission to practice, but the APRN receives no other administrative benefits, and the APRN's patients do not receive whatever health or safety benefits might be associated with substantial physician input or oversight. The added costs imposed on the APRN and patients are real, but with no clinical benefits to justify the cost.

FTC staff have seen some evidence that the costs of collaborative practice agreements, including prices paid by APRNs to physicians, may be especially high in markets exhibiting certain characteristics.¹¹⁵ For example, APRNs may find it particularly difficult to form such contracts in rural or other underserved areas where collaborating physicians are in short supply.¹¹⁶ As

112. As discussed above, price competition can be enhanced simply by increasing the supply of health care practitioners who offer a given service or set of services (and in that sense, compete). *See pp. 27-28, supra.* We note, in addition, that APRNs often tend to be lower-cost providers. Of course, for any professional or provider (and throughout health care), the ability to pass increased costs along may be subject to pressures from, and reimbursement choices of, payors. Still, constraints on the provider/practitioner (supply) side limit options on the payor (demand) side.

113. *See, e.g.,* FTC Staff Louisiana APRN Comment, *supra* note 67, at n.18 and accompanying text; FTC Staff West Virginia Testimony, *supra* note 66, at n.20 and accompanying text.

114. *See supra* note 109.

115. For example, the Louisiana comment notes that, according to information submitted by the Louisiana legislators who requested FTC input, "APRNs often must pay ten to forty-five percent of their collected fees to physicians for entering into collaborative practice agreements." FTC Staff Louisiana APRN Comment, *supra* note 67, at 5 (citing letter from Louisiana State Representatives Willmott & Williams); *see also* FTC Staff West Virginia Testimony, *supra* note 66, at n.33 and accompanying text; FTC Staff Kentucky Letter, *supra* note 68; FTC Staff Connecticut Letter, *supra* note 65, at 5. We are not suggesting that any particular fee is appropriate to some particular collaborative agreement. Rather, we are pointing to ad hoc reports of fees that seem high relative to the services actually provided, on top of general competitive concerns about the way such agreements are negotiated.

116. There may be an absolute shortage of practitioners available to supervise APRNs, or a *de facto* shortage may arise when physicians are restricted in the number of APRNs with whom they may collaborate. *See IOM FUTURE OF NURSING REPORT, supra* note 2, at 157-61, Table 3-A1 (state-by-state requirements for physician supervision, collaborative practice, or other physician involvement in APRN practice).

explained above, under these circumstances, the prices physicians charge for collaborative agreements may tend to rise, or the quantity or quality of collaborative input may tend to fall.¹¹⁷

In some cases, the costs imposed on independent APRNs seeking collaborative practice agreements may be prohibitive, destroying the economic viability of an existing APRN practice or deterring entry by others. The viability of an APRN practice also may be compromised by uncertainty or instability in states where APRNs must obtain collaborative agreements in order to practice, but physicians retain the power to terminate agreements at will and without cause, or may simply refuse to renew them.¹¹⁸ In addition, all independent APRNs subject to collaboration agreement requirements face challenges if their collaborating physician moves, retires, or dies and they cannot quickly find a substitute physician willing to sign a collaborative practice agreement.¹¹⁹

III.A.3. Fixed Supervision Requirements May Constrain Innovation in Health Care Delivery Models

As the health care marketplace evolves, new models of provider organization and collaboration typically represent an important form of innovation in health care delivery and quality.¹²⁰

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.¹²¹ In general, laws and regulations should promote rather than limit this kind of innovation. Rigid physician supervision requirements not only inhibit competition by independent APRNs, but also may constrain the ability of physician

117. See *supra* notes 112-14 and accompanying text; see also, e.g., FTC Staff Louisiana APRN Comment, *supra* note 67, at 3, 5. Where potential supervising physicians may be in short supply and high demand, physicians may have little incentive to compete for collaborative practice agreements. That may result not only in higher prices charged to enter into such agreements, but also in less pressure to offer higher quality contract terms (frequency of chart review, availability for consultation, etc.) in agreements into which they do enter.

118. FTC Staff Kentucky Letter, *supra* note 68, at 4; FTC Staff West Virginia Testimony, *supra* note 66, at 5.

119. FTC Staff Louisiana APRN Comment, *supra* note 67, text accompanying note 23 (citing letter from Louisiana Representatives Willmott & Williams); cf. FTC Staff Kentucky Letter, *supra* note 68, at 4 (difficulty contracting and instability when physician can revoke agreement at will); FTC Staff West Virginia Testimony, *supra* note 66, at 5.

120. See IOM FUTURE OF NURSING REPORT, *supra* note 2, at 92-94 (regarding APRN primary care initiatives at the Department of Veterans Affairs, Geisinger Health System, and Kaiser Permanente); IOM, DELIVERING HIGH QUALITY CANCER CARE, *supra* note 111, at 171-81 (importance of team-based approaches generally and models of team-based care employing APRNs at, e.g., the University of Pennsylvania and Memorial-Sloan Kettering Cancer Center); cf. Mitchell et al., *supra* note 111 (IOM-sponsored inquiry into collaborative or team-based care generally).

121. Mitchell et al., *supra* note 111, at 3; *Id.* at 6 (“Each health care team is unique—it has its own purpose, size, setting, set of core members, and methods of communication.”).

practices, hospitals, retail clinics, and other providers to experiment with flexible oversight and collaboration arrangements for employed or otherwise-affiliated APRNs.

Health care providers that employ or contract with APRNs typically develop and implement their own practice protocols and their own team-based collaboration and supervision protocols, to promote improved quality of care, satisfy their business objectives, and comply with applicable regulatory requirements.¹²² They do so independent of the question whether their states impose particular supervision or “collaboration” strictures. Rigid supervision requirements – imposed by statute or regulation – can arbitrarily constrain this type of innovation, as they can impose limits or costs on new and beneficial collaborative arrangements, limit a provider’s ability to accommodate staffing changes across central and satellite facilities or preclude some provider strategies altogether.¹²³ For example, if supervision requires a specific written agreement between an individual APRN and an individual physician,¹²⁴ or restricts the number of APRNs a physician may supervise,¹²⁵ providers may be constrained in their ability to develop and implement more variable or flexible models of team-based care, consultation, and oversight, according to patient needs and institutional needs and resources.¹²⁶ In addition, as addressed in FTC staff’s Florida comments, restrictions on the permissible physical distance between APRNs and supervising

122. *See id.*; Julie Sochalski & Jonathan Weiner, *Health Care System Reform and the Nursing Workforce: Matching Nursing Practice and Skills to Future Needs, Not Past Demands*, in IOM FUTURE OF NURSING REPORT, *supra* note 2, at app. F.

123. *See* Julie Fairman, *Factors Influencing Value – Enhancing Entrepreneurship in Health Care Delivery* (RAND Policy Symposium, Oct. 4, 2011). We recognize that not all such requirements are costly or limiting for all providers and that, there may be practical limits to effective supervision, wherever some form of supervision is desirable.

124. *See, e.g.*, LA. REV. STAT. ANN. § 37:913(3)(a) (2012); *see also* LA. ADMIN. CODE tit. 46, pt. XLVII, § 4505 (2012).

125. *See, e.g.*, MO. CODE REGS. ANN. TIT. 20 § 2150-5.100 (2) (D) (no more than 3 APRNs per collaborating physician); FLA. STAT. § 458.348(4)(a)-(b) (restricting number of offices primary and specialty care physicians may supervise). FTC staff recognize that there may be practical limits to effective supervision of APRNs by physicians (assuming such supervision is sometimes needed), and these kinds of limitations may make sense under particular circumstances. Indeed, some APRNs might welcome them. It might sometimes be important that a physician (or specialist, or sub-specialist) is in the same room, the next room, or at least quickly accessible in the same building. We question, however, whether these kinds of limitations are inherently beneficial in all contexts, such that there is a legitimate basis to impose them arbitrarily across the board, as these regulations do.

126. *Cf.* Christine Everett et al., *Physician Assistants and Nurse Practitioners Perform Effective Roles on Teams Caring for Medicare Patients with Diabetes*, 32 HEALTH AFFAIRS 1942, 1946-47 (2013) (analyzing diabetes quality of care indicators according to profession of caregiver and finding that local factors, including patient characteristics, can influence best team composition, and suggesting that “policies related to system redesign and workforce development should preserve the capacity for flexibility in team implementation and role definition.”).

doctors may restrict providers' ability to develop new models of networked or telemedicine-facilitated collaboration.¹²⁷

APRNs also have played a central role in the development of alternative settings for care delivery, notably retail clinics. Retail clinics – sometimes called “store-based” or “limited service” clinics – typically are located within larger retail stores, such as chain drugstores, and typically are staffed by APRNs. Consumers have found retail clinics to be a convenient, flexible, and cost-effective choice for basic medical care comprising a limited set of primary care services including, for example, treatment for minor infections (sore throats, ear infections, sinus infections, etc.), the provision of immunizations, and routine preventive screening.¹²⁸ Clinics offer accessible locations, expanded hours, and favorable pricing, as well as the ability to fill prescriptions on-site at adjoining pharmacies.¹²⁹ Indeed, there is some evidence that physicians have responded to retail clinic innovation and competition by offering extended hours themselves, in order to meet consumer demand.¹³⁰ To the extent that rigid APRN supervision requirements may inhibit the growth of APRN-staffed retail clinics or prevent alternative settings from operating at all, such restrictions may deny consumers important price and non-price benefits of innovation in health care delivery.

127. FTC Staff Florida Letter, *supra* note 70, at 5 (regarding impact on innovation associated with FLA. STAT. § 458.348(4)(c)); *see also* MO. CODE REGS. ANN. tit. 20 § 2150-5.100 (2) (A)-(B) (requiring that a physician and supervised APRN “shall not be so geographically distanced . . . as to create an impediment to effective collaboration” and, in particular, for “an APRN who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons” that they be not more than 50 miles by road in federally-designated health professional shortage areas and not more than 30 miles by road otherwise).

Providers (either individual or institutional) whose businesses span state lines are doubly restricted. Not only are their permissible collaboration and supervision arrangements limited by the physical distances specified by statute, but providers may not be able to collaborate across state lines unless they hold multiple state licenses. Regarding competition issues raised by physician licensure and telemedicine, *see, e.g.,* Daniel J. Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospect of Practicing Globally While Regulating Locally*, 14 J. HEALTH CARE L. & POL'Y 87 (2011).

128. ROBIN M. WEINICK ET AL., RAND CORP. TECH. REPORT PREPARED FOR THE DEP'T OF HEALTH & HUMAN SERVS., POLICY IMPLICATIONS OF THE USE OF RETAIL CLINICS, 6 (2010); *see also* Ateev Mehrotra & Judith R. Lave, *Visits to Retail Clinics Grew Fourfold from 2007 to 2009, Although Their Share of Overall Outpatient Visits Remains Low*, 31 HEALTH AFFAIRS 1, 5-6 (Web First) (2012).

129. WEINICK ET AL. *supra* note 128, at 6, 9-10.

130. *See, e.g.,* AMER. MED. ASS'N, REPORT 7 OF THE COUNCIL ON MED. SERV. (A-06), STORE-BASED HEALTH CLINICS, 1 (June 2006) (noting that, “[a]s a result of the emergence of store-based health clinics, many physicians have begun to evaluate making changes to their practices in order to become more accessible to patients.”)

III.A.4. Mandated Collaboration Agreements Between APRNs and Physicians Are Not Needed to Achieve the Benefits of Physician-APRN Coordination of Care

Collaboration and coordination among health care providers are very often beneficial.¹³¹

Indeed, improved collaboration and coordination among health care providers are fundamental goals of many current health care quality and cost-containment initiatives. Antitrust law and policy recognize the potential for procompetitive provider collaborations, consistent with such initiatives. But effective collaboration does not require that physicians formally supervise APRNs. On the contrary, as noted in the discussion of innovation, above, rigid supervision requirements may impede, rather than foster, development of effective models of team-based care.¹³²

Collaboration between APRNs and physicians is common in all states, including those that permit APRNs to practice independently.¹³³ Every day, providers routinely communicate with each other, seek each other's opinions, and refer patients to each other.¹³⁴ Physicians consult their colleagues and, where appropriate, refer patients to other health care professionals. For example, a primary care physician often refers patients to specialists who, as a result of their education, training, and experience, are better suited to address particular symptoms or conditions. The majority of APRNs, who work for institutional providers or physician practices, regularly collaborate with physicians and other health care professionals, and even "independently" practicing APRNs typically consult physicians and refer patients as appropriate,

131. For a general discussion of the value of diverse approaches to team based care, *see generally* Mitchell et al., *supra* note 111.

132. *Cf.* IOM, DELIVERING HIGH QUALITY CANCER CARE, *supra* note 111, at 173-74 (IOM Committee "recommends that federal and state legislative and regulatory bodies eliminate ... scope-of-practice barriers to team-based care.")

133. Regarding diverse practice settings and collaboration, *see* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 23, 58-59, 65-67, 72-76; *see generally* Mitchell et al., *supra* note 111.

134. Mitchell et al., *supra* note 111, at 11-12 (questions of team roles and leadership may often be less problematic in the field than when tied to policy debates about, e.g., scope of practice restrictions).

based on the APRN's training, certification, licensure, and experience.¹³⁵ State-level APRN licensure and certification requirements already require safe and responsible practice, including collaboration and referral to meet patients' needs.

Improved collaboration and coordination among *all* health care providers is a fundamental goal of many health care quality and cost-containment initiatives. Team based care, in particular, has been the focus of many private and public innovations in health care delivery.¹³⁶ Effective collaboration does not, however, inherently require that physicians formally supervise APRNs. Unless there are legitimate and substantiated health and safety justifications for mandatory physician supervision of APRNs, state legislators and regulators should carefully consider whether the goals of collaboration and coordination can be achieved via less restrictive alternatives. Under many circumstances, licensed APRNs can safely decide for themselves when their scope of practice requires or encourages collaboration with a physician – just as licensed physicians are trusted to decide when to collaborate with other physicians.

III.B. 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 undercut the valid health and safety concerns that motivate 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.

135. A report by the Robert Wood Johnson Foundation describes several private and public models of innovative ways to use APRNs in team-based care. ROBERT WOOD JOHNSON FOUND., HOW NURSES ARE SOLVING SOME OF PRIMARY CARE'S MOST PRESSING CHALLENGES (2012), <http://www.rwjf.org/content/dam/files/rwjf-web-files/Resources/2/cnf20120810.pdf>. For example, HealthPartners, a large, non-profit provider in Minnesota, has expanded the use of NPs as primary care providers in their "Care Model Process," employing standardized best practices and telemedicine to coordinate care. *Id.* at 3. The report also describes public initiatives in Pennsylvania, *id.* at 4, and Vermont, *id.* at 5. The Department of Veterans Affairs has generally expanded its use of APRNs/NPs in delivering primary care, at least since the mid-90s. In particular, the VA has employed APRNs as "clinical nurse leaders," who coordinate team-based care and provide care directly. *See* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 72, 91-92. The IOM Report also describes innovative use of APRNs in team-based care by Geisinger Health System, *id.* at 92-93, and Kaiser Permanente, *id.* at 93-95. Whereas some of these efforts comprise new or reconfigured roles for APRNs in "medical home" types of approaches, others do not. For example, many retail clinics employ APRNs as primary care practitioners for episodic care, "using written protocols with electronic recordkeeping, decision-support software, and telephonic physician supervision." William M. Sage, *Out of the Box: The Future of Retail Medical Clinics*, 3 HARV. L. & POL'Y REV. ONLINE, 1, 3 (2009).

136. *See id.*; *see generally* Mitchell et al., *supra* note 111; *supra* notes 120-121 and accompanying text.

However, in the course of preparing previous advocacy comments addressing particular supervision requirements, FTC staff have looked to the findings of the IOM and other expert bodies – analyses based on decades of research and experience – on issues of APRN safety, effectiveness, and efficiency.¹³⁷ We have also conducted our own reviews of pertinent literature and considered stakeholder input. Based on our research, the kinds of supervision requirements examined in FTC staff’s APRN advocacies do not appear to be justified by legitimate health and safety concerns. Specifically, our research did not identify significant evidentiary support for either the claim that independent APRN practice gives rise to significant safety concerns, or the claim that mandatory supervision requirements redress such concerns. In Louisiana, for example, there was no record of patient harm associated with expired or defective collaborative practice agreements. Similarly, in Florida, it appeared that statutory restrictions on independent APRN practice were imposed despite, rather than because of, a legislative history suggesting that APRNs had been providing safe care under prior, less restrictive, supervision standards.¹³⁸

FTC staff thus encourage state legislators considering APRN supervision requirements to familiarize themselves with ongoing “natural experiments” in many locations across the United States. As the IOM observed, APRNs have provided diverse primary care services for decades, and in many jurisdictions and care settings they have done so without mandatory physician

137. See, e.g., *supra* notes 6, 8, 86-89 (observations from IOM, the Office of Technology Assessment, and the National Governors’ Association, among others); see also IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98-99 (citing S.A. Brown & D. E. Grimes, *A Meta-analysis of Nurse Practitioners and Nurse Midwives in Primary Care*, 44(6) NURSING RESEARCH 332 (1995); JULIE FAIRMAN, MAKING ROOM IN THE CLINIC: NURSE PRACTITIONERS AND THE EVOLUTION OF MODERN HEALTH CARE (2008); 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); M. Hatem et al., *Midwife-led Versus Other Models of Care for Childbearing Women*, 4 COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD004667 (2008); 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. Munding et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A randomized Trial*, 283 JAMA 59 (2000); OTA HEALTH TECH. CASE STUDY, *supra* note 8; 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 Everett et al., *supra* note 126, at 1942, 1945-46 (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.”).

138. FTC Staff Florida Letter, *supra* note 70, at n. 7 (citing Florida House of Representatives Staff Analysis, Bill # HB 699 CS Health Care (Mar. 8, 2006)).

supervision or collaborative practice requirements. For this reason, the IOM concluded, “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.”¹³⁹ To the contrary, a large body of empirical research strongly suggests that APRNs are safe and effective providers of diverse primary care services.¹⁴⁰ Similarly, we have not seen research suggesting that the safety or quality of primary care services declines when APRN supervision or collaborative practice requirements are lessened or eliminated.

FTC staff recognizes that particular contexts of care – including particular kinds of patients, procedures, or health care settings – might require some form of supervision. We specifically note, however, that independent prescribing authority does not appear to fall within this category. The ability to write prescriptions – at least for non-controlled substances,¹⁴¹ such as prescribing antibiotics to treat strep throat – is one of the defining criteria for independent APRN practice and has been an ongoing source of contention.¹⁴² Studies have examined outcomes associated with APRNs with independent prescribing authority, and the results have suggested comparable outcomes between APRNs and physicians.¹⁴³ FTC staff are not aware of any contrary empirical evidence to support the contention that there are patient harms or risks associated with APRN

139. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98-99.

140. *See supra* note 137. FTC staff had reviewed citations provided in the IOM Report, among others, as part of its literature review.

141. We do not suggest that APRNs cannot safely prescribe controlled substances. Some states permit APRNs to prescribe controlled substances, and we are not aware of any literature indicating that health and problems are associated with this practice. We recognize, simply, that the laws of many states impose special restrictions on the prescribing and distribution of controlled substances, as does federal law, and that special regulatory concerns may be associated with, or justified by, controlled substances, independent of the prescribing professional. *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).

142. *See* FTC Staff Louisiana APRN Comment, *supra* note 67, at 3, 5; FTC Staff West Virginia Testimony, *supra* note 66, at 3-6; *cf.* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 110-11 (regarding opposition by physicians, including the American Medical Association).

143. *See, e.g.* Mundinger et al., *supra* note 137 (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); Elizabeth R. 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 137, at 1048 (no significant difference in patterns of prescribing or health status outcome).

prescribing of non-controlled substances. As the NGA paper concluded, “[m]ost studies showed that [APRN]-provided care is comparable to physician-provided care on several process and outcome measures”¹⁴⁴ and “[e]xisting research suggests that [APRNs] can perform a subset of primary care services as well as or better than physicians.”¹⁴⁵

IV. CONCLUSION

Consumer health and safety are paramount concerns in the regulation of the health professions, and competition is an important mechanism to promote high quality health care. Competition is also a key means of controlling health care costs and allocating health care resources. APRN licensure and scope of practice restrictions, like other professional regulations, may advance important consumer interests. But when these restrictions restrain competition and are not closely tied to legitimate policy goals, they may do more harm than good.

Our nation faces significant challenges in moderating health care spending and in providing adequate access to health care services, especially for our most vulnerable and underserved populations. Numerous expert health policy organizations have concluded that expanded APRN scope of practice should be a key component of our nation’s strategy to deliver effective health care efficiently and, in particular, to fill gaps in primary care access. Based on our extensive knowledge of health care markets, economic principles, and competition theory, we reach the same conclusion: expanded APRN scope of practice is good for competition and American consumers.

As explained herein and in prior FTC staff APRN advocacy comments, mandatory physician supervision and collaborative practice agreement requirements are likely to impede competition among health care providers and restrict APRNs’ ability to practice independently, leading to decreased access to health care services, higher health care costs, reduced quality of care, and less innovation in health care delivery. For these reasons, we suggest that state legislators view APRN supervision requirements carefully. Empirical research and on-the-ground experience demonstrate that APRNs provide safe and effective care within the scope of their training, certification, and licensure. Moreover, effective and beneficial collaboration among health

144. NGA PRIMARY CARE PAPER, *supra* note 4, at 8.

145. *Id.* at 11 (internal citation omitted). Reviews of patient satisfaction with APRN care also are favorable. *See, e.g.*, Mary Naylor and Ellen T. Kurtzman, *The Role of Nurse Practitioners in Reinventing Primary Care*, 29 HEALTH AFFAIRS 893, 894-5 (2010); Dill, *supra* note 97.

care providers can, and typically does, occur even without mandatory physician supervision of APRNs.

When faced with proposals to narrow APRN scope of practice via inflexible physician supervision and collaboration requirements, legislators are encouraged to apply a competition-based analytical framework and carefully scrutinize purported health and safety justifications. In many instances, legislators may well discover that there is little or no substantiation for claims of patient harm. If, however, health and safety risks are credible, regulations should be tailored narrowly, to ensure that any restrictions on independent APRN practice are no greater than patient protection requires.

This policy paper will be available on the FTC website, along with related resources and an up-to-date index of FTC staff comments on APRN issues. The FTC hopes to continue to serve as a resource for state legislators who seek our views on these and other competition policy issues, and we welcome a continued dialogue with all interested stakeholders.

APPENDIX 1

APRN Scope of Practice Advocacies

FTC Staff Comment Before the Massachusetts House of Representatives Regarding House Bill 2009 Concerning Supervisory Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 2014), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusett nursesletter.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 (March 2013), <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 (September 2012), <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) (April 2012), <http://www.ftc.gov/os/2012/04/120425louisianastaffcomment.pdf>.

FTC Staff Letter to the Hon. Paul Hornback, Senator, Commonwealth of Kentucky State Senate Concerning Kentucky Senate Bill 187 and the Regulation of Advanced Practice Registered Nurses (March 2012), http://www.ftc.gov/os/2012/03/120326ky_staffletter.pdf.

FTC Staff Letter to the Hon. Rodney Ellis and the Hon. Royce West, The Senate of the State of Texas, Concerning Texas Senate Bills 1260 and 1339 and the Regulation of Advanced Practice Registered Nurses (May 2011), <http://www.ftc.gov/os/2011/05/V110007texasaprn.pdf>.

FTC Staff Letter to the Hon. Daphne Campbell, Florida House of Representatives, Concerning Florida House Bill 4103 and the Regulation of Advanced Registered Nurse Practitioners (March 2011), <http://www.ftc.gov/os/2011/03/V110004campbell-florida.pdf>.

FTC Staff Comment Before the Council of the District of Columbia Concerning Proposed Bill 6-317 to Create Specific Licensing Requirements for Expanded Role Nurses (Nov. 1985).

Related Advocacies

Retail Clinics / Limited Service Clinics

FTC Staff Comment Before the Kentucky Cabinet for Health and Family Services Concerning Regarding Proposed Rule to Regulate Limited Service Clinics (Jan. 2010), <http://www.ftc.gov/os/2010/02/100202kycomment.pdf>.

FTC Staff Comment to Representative Elaine Nekritz of the Illinois General Assembly Concerning H.B. 5372 to Regulate Retail Health Facilities (Jun. 2008), <http://www.ftc.gov/os/2008/06/V080013letter.pdf>.

FTC Staff Comment Before the Massachusetts Department of Public Health Concerning Proposed Regulation of Limited Service Clinics (Oct. 2007), <http://www.ftc.gov/os/2007/10/v070015massclinic.pdf>.

Certified Registered Nurse Anesthetists

FTC Staff Comment Before the Massachusetts House of Representatives Regarding House Bill 6 (H.2009) Concerning Supervisory Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 2014), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettsnursesletter.pdf.

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) (April 2013), <http://www.ftc.gov/os/2013/04/130424illinois-sb1662.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), <http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf>.

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APPENDIX 2

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