

UNITED STATES OF AMERICA

FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

February 10, 2016

The Hon. Kent Leonhardt Senate of West Virginia State Capitol, Room 200-W Charleston, WV 25305

Dear Senator Leonhardt:

The staffs of the Federal Trade Commission Office of Policy Planning, Bureau of Economics, and Bureau of Competition¹ appreciate the opportunity to respond to your invitation for comments on the likely competitive impact of Senate Bill 516, as amended by the Senate Health Committee during the 2015 session ("S. 516" or "the Bill"). In particular, you asked that we comment on the likely competitive effect of the amendment to the Bill that would place the regulation of certain advanced practice registered nurses ("APRNs") under the authority of the West Virginia Board of Medicine or Board of Osteopathy. For reasons explained below, we urge the West Virginia legislature to avoid restrictions on APRN practice that are not narrowly tailored to address well-founded patient safety concerns.

The competitive implications of various APRN regulations, including mandatory collaborative practice agreements, are analyzed in the attached 2014 FTC staff policy paper, *Policy Perspectives: Competition and the Regulation of Advanced Practice Registered Nurses.* As explained in the policy paper, FTC staff recognize the critical importance of patient health and safety, and we defer to state legislators to determine the best balance of policy priorities and to define the appropriate scope of practice for APRNs and other health care providers. But even well-intentioned laws and regulations may entail unnecessary, unintended, or overbroad restrictions on competition. Undue regulatory restrictions on APRN practice can impose significant costs on health care consumers – patients – as well as both public and private third-party payors. The FTC staff policy paper observes, in particular, that state-mandated "collaborative practice" agreements raise considerable competitive concerns, potentially impeding access to care and frustrating the development of innovative and effective models of team-based health care. We recommend that the West Virginia legislature consider such effects when evaluating the regulatory reforms in S. 516 or similar proposals.

Expert bodies, including the Institute of Medicine ("IOM"), ⁶ have determined 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." We recommend that you examine carefully purported safety justifications for West Virginia's current APRN collaborative

agreement requirements in light of the pertinent evidence, evaluate whether such justifications are well founded, and consider whether less restrictive alternatives would protect patients without imposing undue burdens on competition and on patients' access to basic health care services. Based on this analysis, it may be determined that removing these restrictions on APRN prescribing significantly benefits West Virginia's health care consumers. S. 516 may promote such benefits, at least to the limited extent that it would permit independent APRN prescribing.

In addition, we urge you to scrutinize purported safety justifications for the restrictions on APRN prescribing that the Bill would maintain or introduce – both the proposed conditions for obtaining a prescribing license and the proposed bar to independent prescribing by Certified Nurse Midwives ("CNMs") and Certified Registered Nurse Anesthetists ("CRNAs"), classes of specialist APRNs.

Finally, we urge you to consider whether to allow independent regulatory boards dominated by medical doctors and doctors of osteopathy to regulate APRN prescribing, given the risk of bias due to professional and financial self-interest.

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. ⁸ Competition is at the core of America's economy, ⁹ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, and greater innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key focus of FTC law enforcement, ¹⁰ research, ¹¹ and advocacy. ¹² In addition to the attached policy paper, FTC staff have analyzed the likely competitive effects of proposed APRN regulations in other states, observing that removing excessive supervision requirements can achieve significant consumer benefits. ¹³

II. The 2015 Senate Bill 516, as Amended

- S. 516 proposed various amendments to West Virginia statutory provisions governing advanced practice nursing. Among other things, the Bill would grant the Board of Medicine and the Board of Osteopathy the authority to license certain APRNs to prescribe medicines without the formal, written collaborative agreement now required for APRN prescribing in West Virginia. ¹⁴ Approval of such a prescribing license would require, among other things, that the APRN,
 - 1) [h]as at least five years of clinical prescribing experience in a collaborative arrangement with a physician . . .
 - 2) Is working solely in an area that has been designated . . . as a Health Professional Shortage Area; and

3) Has a recommendation from his or her collaborative physician which recommends that the [APRN] be permitted to prescribe without a collaborative arrangement.¹⁵

The Bill stipulates, however, that two significant categories of APRNs – CNMs and CRNAs – "shall not be permitted to prescribe without a collaborative agreement." Finally, the remainder of West Virginia APRNs who did not (or could not) secure a prescribing license would still require a "standardized written agreement" with a physician to write prescriptions, and the Board of Medicine and the Board of Osteopathy jointly would propose rules governing such agreements. ¹⁷

III. LIKELY COMPETITIVE IMPACT OF S. 516

a. Excessive Restrictions on Advanced Practice Nursing Raise Competition Concerns

FTC staff recognize that certain professional licensure requirements and scope of practice restrictions may be needed to protect patients. ¹⁸ Consistent with patient safety, however, we urge legislators to consider that independent APRN prescribing may facilitate greater competition, which also may benefit health care consumers. If APRNs are better able to practice to the full extent of their education, training, and abilities, and if institutional health care providers are better able to deploy APRNs as needed, West Virginia health care consumers are likely to benefit from improved access to health care, lower costs, and additional innovation.

The ability to write prescriptions is one of the defining criteria for independent APRN practice. ¹⁹ In brief, APRNs cannot practice independently if they cannot write prescriptions independently. Twenty-two states and the District of Columbia now permit independent prescribing by advanced practice nurses. ²⁰ As the IOM observes, studies suggest that APRNs are safe and effective in writing prescriptions, that APRNs and MDs have comparable prescribing patterns, and that patients of APRNs and MDs have comparable outcomes when APRNs can prescribe medicines independent of physician supervision. ²¹

Section III of the FTC staff policy paper discusses in detail the potential competitive harms from overly restrictive APRN supervision requirements, including the types of mandatory practice agreements now required under West Virginia law.²² The policy paper analyzes three basic issues of particular relevance to S. 516.

First, regulatory constraints on APRN practice limit the ability of APRNs to expand access to primary care services and ameliorate both current and projected health care workforce shortages. The United States faces a substantial and growing shortage of physicians, especially in primary care. As a result, many Americans may face limited access to basic health care services, particularly in poor or rural areas. United access to basic health care services, particularly in poor or rural areas. United access to basic health care services, particularly in poor or rural areas. Expanded as primary care health professional shortage areas ("HPSAs"), and parts of all but four of the remaining 30 counties are HPSAs. Expanded APRN practice – including independent prescribing – is widely regarded as a key strategy to alleviate such provider shortages, especially in medically underserved areas and for medically

underserved populations.²⁶ Nationally, APRNs already "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."²⁷

Second, legal or regulatory hurdles to APRN practice may raise the costs of APRN services, thereby reducing supply and further diminishing access to basic primary care. APRNs tend to provide care at lower cost than physicians. Collaborative practice requirements may, however, add additional costs to those services. Both patients and third-party payors are harmed to the extent that higher costs are passed along as higher prices. In contrast, when collaborative practice requirements are reduced, the supply of professionals willing to offer APRN services at any given price is likely to increase. In underserved areas and for underserved populations, the benefits of expanding supply are clear: consumers may gain access to services that otherwise would be unavailable. Even in well-served areas, a supply expansion tends to lower prices and drive down health care costs.

Third, "rigid supervision [and collaborative agreement] requirements may impede, rather than foster, development of effective models of team-based care."³² Health care providers that employ or contract with APRNs typically develop and implement their own practice protocols, hierarchies of supervision, and models of team-based care to promote quality of care, satisfy their business objectives, and comply with regulations. Collaboration between APRNs and physicians is common in all states, including those that permit APRNs to practice independently.³³ Most APRNs work for institutional providers or physician practices with established channels of collaboration and supervision, and even "independently" practicing APRNs typically consult physicians and refer patients as appropriate. ³⁴ Moreover, new models of collaboration are an important area of innovation in health care delivery. Proponents of teambased care have recognized the importance of this innovation, given the myriad approaches to team-based care that may succeed in different practice settings.³⁵ Rigid collaborative practice requirements "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."36 FTC staff have reviewed reports from expert health agencies as well as the published academic literature, but are unaware of evidence that statutory practice agreement requirements are needed to achieve the benefits of team-based health care.

The competitive impact of unnecessary APRN regulations is concerning in light of evidence that independent practice – including independent prescribing – by APRNs might offer substantial benefits to West Virginia health care consumers. As noted above, the competition issues analyzed in the FTC staff policy paper reinforce health policy findings and recommendations of expert bodies such as the IOM. For example, a 2011 IOM report identifies a key role for APRNs in improving health care delivery, while expressing concern about undue restrictions on APRN prescribing and practice. The Based on a rigorous examination of APRN practice issues, the IOM found that "[r]estrictions on scope of practice . . . have undermined [nurses'] ability to provide and improve both general and advanced care. Similarly, in 2012, the National Governors Association ("NGA") reported on APRNs' potential to address increased demand for primary care services, particularly in historically underserved areas.

report noted the high quality of primary care services provided by APRNs, who "may be able to mitigate projected shortages of primary care services." ⁴⁰

Because these restrictions may constrain the supply of health care providers, they may enable physicians to charge higher prices for services that APRNs otherwise might offer. In brief, as the policy paper points out,

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 incumbent physicians may be insulated against the degree of competition APRNs can offer. 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. 42

b. Restrictions Placed on Specialist APRNs, Such as Nurse Midwives and Nurse Anesthetists, May Also Harm Competition

Supervision requirements for specialist APRNs raise competition concerns similar to those raised by the imposition of supervision requirements on primary care APRNs. ⁴³ Restrictions on the scope of practice of specialist APRNs may exacerbate access problems associated with physician shortages, diminish price and quality competition among available health care providers, and frustrate the development of innovative models of health care delivery. Yet the Bill would not permit independent prescribing at all for two of the four major categories of APRNs: CNMs and CRNAs. ⁴⁴ As noted above, 20 states and the District of Columbia permit independent prescribing by CRNAs, ⁴⁵ and 21 states and the District of Columbia permit independent prescribing by CNMs. ⁴⁶ We urge the legislature to consider whether the available empirical evidence or the considerable experience of other states supports maintaining West Virginia's restrictions on CNM and CRNA prescribing. If not, West Virginia health care consumers – particularly those in rural and other underserved areas – might benefit greatly if those restrictions were lifted.

FTC staff recognize that certain licensure requirements and scope of practice restrictions can serve to protect patients; ⁴⁷ this is true for all APRNs and, indeed, for all health care professionals. In particular, special practice requirements or other restrictions may be recommended for indications or treatments associated with heightened consumer risks. ⁴⁸ We note, however, the IOM's concern that excessive scope of practice restrictions may impede access to the specialized care that CNMs and CRNAs have both the training and experience to provide. ⁴⁹ We also note the IOM's observation that "most states continue to restrict the practice of APRNs beyond what is warranted by either their education or their training," which "support broader practice by *all types of APRNs*." ⁵⁰ Because particular regulatory restrictions on CNMs and CRNAs may harm consumers without offering countervailing health and safety benefits, we have recommended that policy makers apply the same basic framework and considerations to all APRN policies, including those regarding specialist APRNs. ⁵¹

Consider, in particular, that physician shortages can compound access problems wherever physician supervision is required for APRN prescribing. As the IOM points out, "[a]ccess to competent care is denied to patients, especially those located in rural, frontier, or other underserved areas, in the absence of a willing and available 'supervising' physician.'"⁵² Yet specialist physicians, including OB/GYNs – and not just primary care doctors – may be in short supply, ⁵³ particularly in rural areas. ⁵⁴ As further noted by the IOM, "while one in five U.S. residents live in rural areas, only one in ten physicians practice in those areas."55 A recent report on rural health policy notes that physician supply generally decreases as areas become more rural, and that this is particularly true for certain types of specialists. ⁵⁶ For example, it has been observed that the supply of obstetricians and gynecologists decreases steadily as practice locales become more rural: 16 OB/GYNs per 100,000 persons were found in central counties of large metro areas but only 3 OB/GYNs per 100,000 persons were found in most rural counties.⁵⁷ With regard to anesthesia care, we note that, according to a 2015 workforce report on the mid-Atlantic region by the American Society of Anesthesiologists, "West Virginia has the lowest ratio of physician anesthesiologists to total surgeons,"58 and the lowest ratio of physician anesthesiologists to nurse anesthetists.⁵

Consider, too, that CRNAs and CNMs may be particularly well positioned to help alleviate the access problems associated with specialist physician shortages. For example, the IOM Report observes that CRNAs administer more than 65% of all anesthetics to U.S. patients, and that, generally, they "[a]dminister anesthesia and provide related care before and after surgical, therapeutic, diagnostic, and obstetrical procedures, as well as pain management." Moreover, reviewing the safety literature, the IOM states that, "evidence shows that CRNAs provide high-quality care . . . [while] there is no evidence of patient harm from their practice." The U.S. Department of Health and Human Services has, on multiple occasions, reviewed the available literature on the quality of anesthesia services in publishing various rules regarding the provision of hospital anesthesia services under the Medicare and Medicaid programs, but has not found that risks warrant further restrictions on CRNA practice. ⁶²

The IOM has also observed that CNMs, working within their scope of practice, provide high-quality care, noting for example, that "[t]wo systematic reviews have found that women given midwifery care are more likely to have shorter labors, spontaneous vaginal births without hospitalization, less perineal trauma, higher breastfeeding rates, and greater satisfaction with their births." In fact, the American Congress of Obstetricians and Gynecologists "supports the full scope of practice for CNMs." Its companion organization, the American College of Obstetricians and Gynecologists recognizes that CNMs are "independent providers," who, like obstetricians and gynecologists, are "experts in their respective fields of practice." Instead of recommending mandatory supervision or formal "collaborative practice" agreements, they suggest that OB/GYNs and CNMs "may collaborate with each other based on the needs of their patients."

c. Excessive Restrictions on Independent Prescribing Licenses Might Undercut the Bill's Potential Benefits

The Bill may offer significant benefits to West Virginia's health care consumers to the extent that it permits independent prescribing and practice by APRNs. Those potential benefits could be denied, however, if the requirements for an independent prescribing license are too

strict. Several provisions of S. 516 are concerning in that regard. First, the Bill would only permit APRNs "working *solely* in an area that has been designated . . . as a Health Professional Shortage Area" to secure a prescribing license. ⁶⁷ Access to basic health care services in HPSAs is important and, as we have discussed, justifies scrutiny of APRN practice restrictions. Yet there is no clear reason why only APRNs working in HPSAs should be eligible for prescribing licenses. Moreover, APRNs – and institutional providers employing APRNs – may be discouraged from securing the required license, and entering underserved areas, if a license does not permit any practice, however limited, outside an HPSA.

Second, the requirement that an APRN have "a recommendation from his or her collaborative physician . . . [to] be permitted to prescribe without a collaborative arrangement," raises concerns about professional and financial conflicts of interest. We understand that this requirement might have been intended as a way to obtain information regarding a particular APRN's prescribing practices. If so, there remains the question about what would be required – and not required – for the APRN to secure the recommendation. More fundamentally, there is a basic concern that conflicting interests could bias such perspectives, delaying or perhaps denying access to a license for reasons having nothing to do with the quality of care an APRN provides. On its face, this provision would require that an APRN who is contracting with a supervising physician – for example, as the physician's employee or as an independent service provider paying a fee or a percentage of billing for a physician's supervision – would need to secure the permission of that particular physician to compete with her. ⁶⁹

Third, because the Bill would assign regulatory authority over APRN prescribing to the Boards of Medicine and Osteopathy, it raises concerns about potential biases and conflicts of interest. The IOM has argued that common restrictions on independent APRN practice and prescribing are not evidence-based, and that historically entrenched forms of training and care delivery, dated or erroneous beliefs about the training or performance of APRNs, and professional bias are factors in physician opposition to regulatory reform. Yet an APRN meeting all the requirements of independent prescribing under S. 516 would need to secure a prescribing license from West Virginia's Board of Medicine or Board of Osteopathy; and the Board issuing that license would then regulate that APRN's ability to practice under that license. A controlling number of the membership of each of these regulatory boards consists of doctors of medicine or doctors of osteopathy, respectively. The security of the prescribing to the prescribent to the prescribing to the prescribing to the prescribing to t

FTC staff recognize West Virginia's prerogatives in designing regulatory oversight for the State's health care professionals; and we defer to the legislature how best to incorporate expert input – including physician input – into its regulatory process. At the same time, we strongly suggest that it may be problematic to have independent regulatory boards dominated by medical doctors and doctors of osteopathy serve as regulators of APRN prescribing. As the Commission has noted in Congressional testimony about occupational regulation more generally,

From a competition standpoint, occupational regulation can be especially worrisome when regulatory authority is delegated to a board composed of members of the occupation it regulates. The risk is that the board will make regulatory decisions that serve the private economic interests of its members and not the policies of the state. These private interests may lead to the adoption

and application of occupational restrictions that discourage new entrants, deter competition among licensees and from providers in related fields, and suppress innovative products or services that could challenge the status quo. ⁷²

In North Carolina State Board of Dental Examiners v. FTC, similar concerns about professional bias and its effects on competition helped explain limits to a state regulatory board's ability to insulate itself against allegations of anticompetitive conduct. There, the dentist-dominated board had sought to exclude non-dentists from providing basic teeth-whitening services using non-prescription materials. In that case, the U.S. Supreme Court observed that, "established ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern. Dual allegiances are not always apparent to an actor . . . ,,74

IV. CONCLUSION

Absent countervailing safety concerns regarding APRN practice, removing extant supervision requirements to permit independent APRN prescribing has the potential to benefit consumers by improving access to care, containing costs, and expanding innovation in health care delivery. S. 516 could benefit patients, as it would permit a route to independent prescribing, at least for some APRNs, at least under certain conditions. The Bill raises significant competitive concerns nonetheless, first because of the many conditions and exclusions it would impose on independent APRN prescribing, and second because of the regulatory conflicts of interest that appear to be inherent in the Bill's requirements of physician permission for and oversight of APRN prescribing. Accordingly, we encourage the legislature to consider whether these requirements are necessary to assure patient safety in light of West Virginia's own regulatory experience, the findings of the IOM and other expert bodies, and the experience of other states. Removing unnecessary and burdensome requirements may benefit West Virginia consumers by increasing competition among health care providers.

Respectfully submitted,

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¹ This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission or of any individual Commissioner. The Commission, however, has voted to authorize us to submit these comments.

² Letter from the Hon. Kent Leonhardt, W.V. Senate, to Marina Lao, Dir., Office of Policy Planning, Fed. Trade Comm'n (Oct. 10, 2015) (on file with Office of Policy Planning). We understand that bills containing many of the same provisions are being introduced for consideration in 2016.

³ *Id*.

⁴ FED. TRADE COMM'N STAFF, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES (2014), https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf [hereinafter FTC STAFF POLICY PERSPECTIVES].

⁵ *Id.* at 37.

⁶ The IOM – established in 1970 as the health arm of the National Academy of Sciences – provides expert advice to policy makers and the public.

⁷ FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 2, n.6 and accompanying text (*citing* INST. OF MED., NAT'L ACAD. OF SCIENCES, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 98-99 (2011) [hereinafter IOM FUTURE OF NURSING REPORT]).

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

⁹ Standard Oil Co. v. Fed. Trade Comm'n, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

 $^{^{10} \}textit{See} \textit{ Fed. Trade Comm'n, Competition in the Health Care Marketplace, } \underline{\textit{https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.}}$

¹¹ See Fed. Trade Comm'n & U.S. Dep't of Justice, Improving Health Care: A Dose of Competition (2004), health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf [hereinafter FTC & DOJ, Improving Health Care].

¹³ See, e.g., Letter from FTC Staff to the Hon. Jenny A. Horne, S.C. House of Representatives, regarding House Bill

nurse anesthetists, and nurse practitioners).

Bill 6-317 to Create Specific Licensing Requirements for Expanded Role Nurses (Nov. 1985) (nurse midwives,

¹² FTC and staff advocacy may consist of letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.*, Letter from FTC Staff to Timothy G. Burns, Representative, La. House of Representatives (May 1, 2009), https://www.ftc.gov/system/files/documents/advocacy_documents/louisiana-house-representatives-concerning-louisiana-house-bill-687-practice/v090009louisianadentistry.pdf (regarding proposed restrictions on mobile dentistry); Joint statement from the FTC and DOJ to the Ill. Task Force on Health Planning Reform (Sept. 15, 2008), <a href="https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-and-department-justice-written-testimony-illinois-task-force-health-planning-reform-concerning/v080018illconlaws.pdf (concerning Illinois certificate of need laws); Brief of Amicus Curiae Federal Trade Commission, In Support of Appellants and Urging Reversal, In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-amicus-curiae-brief-re-ciprofloxacin-hydrochloride-antitrust-litigation-concerning-drug-patent/080129cipro.pdf; FTC & DOJ, IMPROVING HEALTH CARE, <a href="https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-amicus-curiae-brief-re-ciprofloxacin-hydrochloride-antitrust-litigation-concerning-drug-patent/080129cipro.pdf; FTC & DOJ,

³⁵⁰⁸ and 3078 on Advanced Practice Registered Nurse Regulations (Nov. 2, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-south-carolina-representativejenny.horne-regarding-house-bill-3508-3078-advanced-practice-registered-nurse-regulations/151103scaprn.pdf; Letter from FTC Staff to the Hon. Jeanne Kirkton, Mo. House of Representatives (Apr. 21, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-representative-ieanne-kirktonmissouri-house-representatives-regarding-competitive/150422missourihouse.pdf (regarding collaborative practice arrangements between physicians and APRNs); Letter from FTC Staff to the Hon. Kay Khan, Mass. House of Representatives (Jan. 17, 2014), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staffcomment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirementsnurse-practitioners-nurse-anesthetists/140123massachusettnursesletter.pdf (regarding supervisory requirements for nurse practitioners and nurse anesthetists); Letter from FTC Staff to Theresa W. Conroy, Representative, Conn. House of Representatives (Mar. 19, 2013), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-theresa-w.conroyconnecticut-house-representatives-concerning-likely-competitive-impact-connecticut-housebill/130319aprnconrov.pdf (APRNs); Prepared Statement from FTC Staff to Subcommittee A of the Joint Committee on Health of the State of West Virginia Legislature (Sept. 10-12, 2012). https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-testimony-subcommittee-wvlegislature-laws-governing-scope-practice-advanced-practice/120907wyatestimony.pdf (APRNs): Letter from FTC Staff to Thomas P. Willmott & Patrick C. Williams, Representatives, La. House of Representatives (Apr. 20, 2012). https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-louisiana-houserepresentatives-likely-competitive-impact-louisiana-house-bill-951/120425louisianastaffcomment.pdf (APRNs in medically underserved areas); Brief of the Federal Trade Commission 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); FTC Staff Comment Before the Council of the District of Columbia Concerning Proposed

¹⁴ *Compare* proposed § 30-3-7b *with* W. Va. Code § 30-7-15a (2015).

¹⁵ Proposed § 30-7-15d.

¹⁶ *Id.* Most APRNs fall into one of four broad categories: Nurse Practitioner, Clinical Nurse Specialist, Nurse Anesthetist, and Nurse Midwife. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 7, at 41-42.

¹⁷ Id

¹⁸ For example, licensure requirements or scope of practice restrictions may sometimes offer an efficient response to certain types of market failure arising in professional services markets. *See* CAROLYN COX & SUSAN FOSTER, FED. TRADE COMM'N, BUREAU OF ECONOMICS, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION 5-6 (1990), *available at* http://www.ftc.govibe/consumerbehavior/docs/reports/CoxFoster90.pdf.

¹⁹ See, e.g., IOM FUTURE OF NURSING REPORT, supra note 7, at 100, 332; FTC Staff Louisiana APRN Comment, supra note 13, at 3, 5; West Virginia Testimony, supra note 13, at 3-6.

²⁰ According to the National Council of State Boards of Nursing, 22 states and the District of Columbia, permit independent prescribing for certified nurse practitioners, Nat'l Council State Bds. Nursing, CNP Independent Prescribing Map, https://www.ncsbn.org/5408.htm (checked 12/10/15); 20 states and the District of Columbia permit independent prescribing for nurse anesthetists, Nat'l Council State Bds. Nursing, CRNA Independent Prescribing Map, https://www.ncsbn.org/5408.htm (checked 12/10/15); and 21 states and the District of Columbia permit independent prescribing for nurse midwives, Nat'l Council State Bds. Nursing, CNM Independent Prescribing Map, https://www.ncsbn.org/5409.htm (checked 12/10/15). We are aware that prescribing authority remains a source of contention. INST. OF MED., NAT'L ACAD. OF SCIENCES, ASSESSING PROGRESS ON THE INSTITUTE OF MEDICINE REPORT, 2-5 – 2-7 (2015); IOM FUTURE OF NURSING REPORT, *supra* note 7, at 110-11 (regarding opposition by physicians, including the American Medical Association). The policy goal of meeting the needs of patients in medically underserved areas does not fully explain the Bill's requirement that APRNs could only be licensed to prescribe independently if practicing *solely* in a HPSA. For example, an APRN could not contemplate working three days a week at a retail clinic that is not in a HPSA, and two days a week independently at a clinic in a HPSA, and still secure or maintain an independent prescribing license. It is clear that this could impose a cost on APRN entry into underserved areas, but it is unclear how consumers might benefit from the restriction.

²¹ See, e.g., M.O. Mundinger et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A randomized Trial*, 283 JAMA 59 (2000) (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," and finding no significant difference in patients' health status or physiologic test results); Lenz et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: Two-year Follow-up*, 61 MED. CARE RES. REV. 332 (2004) (Two-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); Pamela Venning et al., *Randomised Controlled Trial Comparing Cost Effectiveness of General Practitioners and Nurse Practitioners in Primary Care*, 320 BRIT. MED. J. 1048, 1050 (2000) ("There was no significant difference in patterns of prescribing or health status outcome. . . ."). FTC staff are not aware of any empirical evidence supporting a contrary contention that patient harms or risks are particularly associated with APRN prescribing.

²² FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 18-38. For West Virginia's requirement of a collaborative agreement with a supervising physician, see W. Va. Code § 30-7-15a (2015).

²³ FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 20.

²⁴ *Id.* at 21; IOM FUTURE OF NURSING REPORT, *supra* note 7, at 106-7 ("Expanding the scope of practice for NPs is particularly important for the rural and frontier areas of the country. Twenty-five percent of the U.S. population lives in these areas; however, only 10 percent of physicians practice in these areas (NRHA, 2010). People who live in rural areas are generally poorer and have higher morbidity and mortality rates than their counterparts in suburban and urban settings, and they are in need of a reliable source of primary care providers (NRHA, 2010).

²⁵ HPSA Find, U.S. DEP'T HEALTH & HUMAN SERVS.: HRSA DATA WAREHOUSE, http://datawarehouse.hrsa.gov/tools/analyzers/HpsaFind.aspx (search "West Virginia" "All Counties," "Primary Care," for listing of HPSAs county by county). The "Primary Care HPSA" designation is based on the physician to population ratio. U.S. Dep't Health & Human Servs., HRSA, Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations, http://www.hrsa.gov/shortage/ (last checked 12/11/15).

²⁶ See, e.g., IOM FUTURE OF NURSING REPORT, supra note 7, at 27-28; NAT'L GOVERNORS ASS'N, NGA PAPER: THE ROLE OF NURSE PRACTITIONERS IN MEETING INCREASING DEMAND FOR PRIMARY CARE, 11 (2012), http://www.nga.org/files/live/sites/NGA/files/pdf/1212NursePractitionersPaper.pdf. We do not suggest that reforming APRN scope of practice restrictions is a panacea for primary care access problems. Rather, reducing undue restrictions on APRN scope of practice can be one significant way to help ameliorate existing and projected access problems.

²⁷ FTC STAFF POLICY PERSPECTIVES. *supra* note 4. at 25.

²⁸ *Id.* at 28. For example, 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." Christine E. Eibner et al., RAND Health Report Submitted to the Commonwealth of Massachusetts, Controlling Health Care Spending in Massachusetts: An Analysis of Options, 103-104 (2009), http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR733.pdf (describing conditions for upper and lower bound estimates and projections).

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.

²⁹ FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 27-28.

³⁰ "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." FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 20 (citing, *e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 7, at 98-103, 157-61 annex 3-1 (2011); 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; NAT'L GOVERNORS Ass'n, NGA Paper, *supra* note 26.

³¹ The National Governors Association recognized the impact of this supply expansion in its NGA PRIMARY CARE PAPER, *supra* note 30.

³² FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 34.

³³ Regarding diverse practice settings and collaboration, see IOM FUTURE OF NURSING REPORT, *supra* note 7, at 23, 58-59, 65-67, 72-76; *see generally* Pamela Mitchell et al., *Core Principles & Values of Effective Team-Based Health Care* (Discussion Paper, Institute of Medicine 2012), http://nam.edu/wp-content/uploads/2015/06/VSRT-Team-Based-Care-Principles-Values.pdf (IOM-sponsored inquiry into collaborative or team-based care).

³⁴ 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.

³⁵ *Id.* at 31 (citing Pamela Mitchell et al., *supra* note 33).

³⁶ FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 32.

³⁷ See generally IOM FUTURE OF NURSING REPORT, supra note 7 (especially Summary, 1-15; 99 - 102).

³⁸ *Id*. at 4.

³⁹ National Governors Association, *The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care* (Dec. 20, 2012), http://www.nga.org/cms/home/nga-center-for-best-practices/center-divisions/page-health-division/col2-content/list---health-left/list-health-highlight/content-reference-2@/the-role-of-nurse-practitioners.html [hereinafter NGA, *Role of Nurse Practitioners*].

⁴⁰ *Id.* at 11.

⁴¹ This is true even though many of the services provided by APRNs and physicians are complementary rather than substitutes. 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.).

⁴² FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at 14 -15.

⁴³ As noted above, there are four types of APRNs: nurse practitioners ("NPs"); nurse midwives ("CNMs"); certified registered nurse anesthetists ("CRNAs"); and clinical nurse specialists ("CNSs"). *See supra* note 16. All four types

of APRN consist of nurse practitioners with graduate nursing degrees, in addition to undergraduate nursing education and practice experience. IOM FUTURE OF NURSING REPORT, *supra* note 7, at 23, 26.

⁴⁴ See text accompanying note 16, supra.

⁴⁵ Nat'l Council State Bds. Nursing, CRNA Independent Prescribing Map, https://www.ncsbn.org/5408.htm (checked 12/10/15).

⁴⁶ Nat'l Council State Bds. Nursing, CRNA Independent Prescribing Map, https://www.ncsbn.org/5409.htm (checked 12/10/15).

⁴⁷ FTC STAFF POLICY PERSPECTIVES, *supra* note 4, at text accompanying notes 51-55.

⁴⁸ See, e.g., FTC Staff Comment to the Hon. Heather A. Steans, Illinois State Senate, Concerning Illinois Senate Bill 1662 and the Regulation of Certified Registered Nurse Anesthetists (CRNAs), 2-3 (April 2013), http://www.ftc.gov/os/2013/04/130424illinois-sb1662.pdf.

⁴⁹ IOM FUTURE OF NURSING REPORT, *supra* note 7, at 96.

⁵⁰ *Id.* at 98 (emphasis added).

⁵¹ See, e.g., Letter from FTC Staff to Kay Khan, Representative, Mass. House of Representatives, *supra* note 13 (regarding supervisory requirements for both nurse practitioners and nurse anesthetists); Letter from FTC Staff to Heather A. Steans, Senator, Ill. State Senate (concerning the regulation of CRNAs); Brief of the Federal Trade Commission 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).

⁵² IOM FUTURE OF NURSING REPORT, *supra* note 7, at 450.

⁵³ 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; 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/physwfissues.pdf [hereinafter HRSA PHYSICIAN WORKFORCE REPORT] (HRSA's most recent workforce report on physician supply and demand, projecting increased shortages of both primary care physicians and specialists).

⁵⁴ See Ass'n of Amer. Med. Colls., supra note 53 (noting impact of physician shortfalls to be "most severe" in rural and other underserved areas); see also HRSA Physician Workforce Report, supra note 53, at 8, n. 4 (HRSA's supply model was designed primarily as a national model and thus did not track geographic differences, but HRSA nonetheless noted that "[t]he physician workforce is . . . unevenly distributed throughout the Nation, with pockets of severe shortages (primarily in poor, rural and inner-city areas)."); IOM FUTURE OF NURSING REPORT, supra note 7, at 106-107; MICHAEL MEIT ET AL., RURAL HEALTH REFORM POLICY RESEARCH CENTER, THE 2014 UPDATE OF THE RURAL-URBAN CHARTBOOK, 56 (2014).

⁵⁵ IOM FUTURE OF NURSING REPORT, *supra* note 7, at 257.

⁵⁶ MEIT ET AL., *supra* note 54, at 4. Overall, according to the National Rural Health Association, there are more than three times as many specialists per 100,000 population practicing in urban areas as in rural areas. Nat'l Rural Health Ass'n, What's Different About Rural Health Care, http://www.ruralhealthweb.org/go/left/about-rural-health (last checked Jan. 11, 2016).

⁵⁷ MEIT ET AL., *supra* note 54, at 56.

⁵⁸ Amer. Soc. Anesthesiologists, Health Pol'y Res. Dep't, Anesthesia Workforce Summary: Mid-Atlantic Caucus, 6 (Feb. 2015).

⁵⁹ *Id*. at 11.

⁶⁰ IOM FUTURE OF NURSING REPORT, *supra* note 7, at 26.

⁶¹ *Id.* at 111 ("A study ... found no increase in inpatient mortality or complications in states that opted out of the CMS requirement that an anesthesiologist or surgeon oversee the administration of anesthesia by a CRNA.").

⁶² For example, in 2001, the Centers for Medicaid and Medicare Services concluded that anesthesia services generally were safe and, in particular, that there was "no need for Federal intervention in State professional practice laws governing [CRNA] practice. . . . [and] no reason to require a Federal rule . . . mandating that physicians supervise the practice of [state-licensed CRNAs]." Dep't Health and Human Servs. (HHS), Health Care Financing Administration (HCF A), Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 CFR §§416, 482&485, Final Rule, 66 Fed. Reg. 4674, 4675 (Jan. 18, 2001); *cf*.HHS Health Care Financing Administration (HCF A), Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 CFR §§ 416, 482 & 485, Final Rule, 66 Fed. Reg. 56762, 56762-63 (Nov. 13, 2001) (repeating observations on safety literature, but noting potential utility of independent study of question whether safety or quality effects are associated with state regulations permitting independent CRNA practice).

⁶³ IOM FUTURE OF NURSING REPORT, *supra* note 7, at 57 (citing Marie Hatem *et al.*, *Midwife-led Versus Other Models of Care for Childbearing Women*. COCHRANE DATABASE OF SYSTEMATIC REVIEWS (4):CD004667 (2008); Ellen D. Hodnett *et al.*, *Continuous Support for Women During Childbirth*, COCHRANE DATABASE SYSTEMATIC REVIEWS 7(3) (2007).

⁶⁴ Am. Cong. of Obstetricians and Gynecologists Comments to the Fed. Trade Comm'n, Apr. 30, 2014.

⁶⁵ Am. Coll. Nurse Midwives and Am. Coll. Obstetricians and Gynecologists, Joint Statement of Practice Relations Between Obstetricians-Gynecologists and Nurse Midwives/Certified Midwives, Feb. 2011 (Reaffirmed by ACOG Exec. Bd. July 2014).

⁶⁶ Id.

⁶⁷ See supra note 15 and accompanying text (emphasis added).

⁶⁸ Proposed § 30-7-15d. The Bill is silent on the question how an APRN would secure that recommendation in the event that his or her supervising physician becomes deceased, leaves the state, or otherwise surrenders her license to practice medicine or osteopathy in West Virginia. Presumably, the APRN would be required to secure a new collaboration agreement, practice under it, and then seek a recommendation.

⁶⁹ As with primary care APRNs, specialist APRNs may provide both complementary and substitute services to those provided by specialist physicians. Note that physicians and APRNs compete when they offer a significant number of overlapping, or potentially substitute, services. Hence, *if* they exert or are likely to exert significant competitive pressure on each other, physicians and APRNs may be competitors *even if* they often work in collaboration, even if they do not offer an identical range of services, and even if consumers do not value their services equally. *See* Daniel J. Gilman and Julie Fairman, *Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice* 24 HEALTH MATRIX 143, 155-156 (2014) ("to say such professionals are competitors is to say that their services are potential substitutes, but to say that services are potential substitutes is not to say that they are indistinguishable. We do not suppose that these groups of competitors are perfect substitutes across the full range of services they offer or even for any particular service. We do not suppose that substitution is equally (or even significantly) effective across the whole geographic area in which each competing professional (or firm) does business. And we do not suppose that competitors are professionals (or firms) who do not, or should not, collaborate or offer complementary services.")

⁷⁰ IOM FUTURE OF NURSING REPORT, *supra* note 7, at 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 7, at 451-57 ("I want to be clear that I mean to attribute no malice or ill will to individual actors in the scope-of-practice battles. The problems have become structural and cultural, and we all—physicians included—pay a huge price for the consequences, measured in extra real dollars spent on health care, in lack of access to competent care, and in the constant antagonism among health care professionals who would be better served by working cooperatively to provide optimal care.").

⁷¹ See W. Va. Code §30-3-5 (2015) (Board of Medicine, stipulating that 10 of 15 members of the board be doctors – 8 M.D.s and two doctors of podiatric medicine – and one a physician's assistant); W. Va. Code § 30-14-3 (2015) (Board of Osteopathic Medicine, stipulating that 4 of 7 members be osteopathic physicians and one an osteopathic physician assistant). Although S. 516 would expand each board slightly, and admit one APRN to each board, each board would remain a physician dominated board for voting and other practical purposes.

⁷² Prepared Statement of the Fed. Trade Comm'n on License to Compete: Occupational Licensing and the State Action Doctrine Before the S. Comm. on the Judiciary, 114th Cong. (Feb. 2, 2016); *see also* Prepared Statement of the Fed. Trade Comm'n on Competition and the Potential Costs and Benefits of Professional Licensure Before the H. Comm. on Small Bus., 113th Cong. (2014).

⁷³ N.C. State Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101 (2015). In that case, the Court clarified the conditions under which an independent regulatory board could (or could not) raise a defense to federal antitrust allegations based on the "State Action Doctrine," and did not address the policy merits of North Carolina's statutes governing that regulatory board. However the Court's competition concerns about one group of professionals excluding another based on financial incentives are directly analogous to concerns about empowering physicians to bar or regulate APRN prescribing.

⁷⁴ *Id*. at 1111.