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

Office of Policy Planning
Bureau of Competition
Bureau of Economics

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To whom it may concern:

The staff of the Federal Trade Commission [Office of Policy Planning, Bureau of Economics, and Bureau of Competition[1]] appreciates the opportunity to respond to your request for comments Proposed Rule § 193.13 (Proposed Rule).[2] The Proposed Rule appears to impose additional supervisory requirements on the administration of anesthesia by a Texas certified registered nurse anesthetist (CRNA), and appears to suggest additional exposure to potential liability for Texas physicians who delegate to a CRNA "the ordering of drugs and devices necessary for the nurse anesthetist to administer an anesthetic or an anesthesia-related service."[3] Although the particular supervisory requirements contemplated by the Proposed Rule are unclear, any such requirements or increased liability may contract the supply, decrease the availability, or increase the cost of anesthesia services in Texas, without offering countervailing benefits to Texas health care consumers or third-party payors. Such risks might be greater in rural and other medically underserved areas of Texas.

Supervision requirements for CRNAs and other advanced practice registered nurses (APRNs) raise several related competitive concerns. By restricting CRNAs' access to the marketplace, supervision requirements may deprive health care consumers

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

[2] Proposed Chapter 193. Standing Delegation Orders, 22 TAC §§193.5, 193.13, 193.17, 193.21, 44 Tex. Reg. 6669 et seq. (Nov. 8, 2019).

[3] *Id.* at 6671 (proposing amendments to 22 TAC § 193.13).

of some of the benefits that provider competition can offer. Undue impediments to competition can affect the cost and quality of available health care services and restrict provider innovation in health care delivery. Excessive supervision requirements also can exacerbate provider shortages and access problems, particularly for underserved populations that already lack adequate and cost-effective health care services.

According to recent data, sixty-four of the eighty-five Critical Access Hospitals[4] in Texas are located in counties where there are no anesthesiologists; and thirty-three of those hospitals are in counties where CRNAs are the only licensed, specialized providers of anesthesia and anesthesia-related services.[5] In light of that and related data, we urge you to consider the supply and availability of specialist provider services across rural Texas, as well as other underserved communities, which may face both provider and facilities shortages. In particular, we urge you to examine carefully any purported safety justifications for heightened supervision requirements, evaluate whether these justifications are well founded, and consider whether less restrictive alternatives would protect patients without unduly burdening competition and consumers. To that end, it may be particularly useful to look at CRNA practice in states that do not require such supervision, and to consider the available evidence regarding patient benefits and harms in those states, including the findings of the Institute of Medicine and other experts in the field.[6]

I. INTEREST AND EXPERIENCE OF THE FTC

The FTC Act charges the FTC with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[7] Competition is at the core of America's economy,[8] and vigorous competition among sellers in an open marketplace

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[4] Critical Access Hospitals (CAHs) are designated as such by both the states in which they are located and the Department of Health and Human Services. They must, among other things, "[b]e designated by the State as a CAH; be located in a rural area or an area that is treated as rural; be located either more than 35-miles from the nearest hospital or CAH or more than 15 miles in areas with mountainous terrain or only secondary roads; . . . . [and] and furnish 24-hour emergency care services 7 days a week." Centers for Medicare & Medicaid Servs., Critical Access Hospitals, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.html.

[5] For locations of CAHs, see Flex Monitoring Team, Univ. Minn., Univ. N.C. at Chapel Hill & Univ. Southern Main, Critical Access Hospitals Locations, https://www.flexmonitoring.org/data/critical-access-hospital-locations/?search_state=TX&filter_search=yes#result-list (noting list current as of Oct. 11, 2019); https://data.hrsa.gov/tools/data-explorer. For a map of Texas anesthesia providers based on the National Provider Identifier Registry, see Texas Ass'n Nurse Anesthetists, County-Level Map, https://www.txana.org/uploads/files/general/County_TX_map_AANA.pdf.

[6] *See, e.g.*, INST. OF MED., NAT'L ACAD. OF SCIENCES, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 108–111 (2011) [hereinafter IOM FUTURE OF NURSING REPORT]) (citing diverse evidence in concluding that CRNAs provide high-quality care, with no evidence of patient harm, with respect to anesthesia and acute services).

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

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

gives consumers the benefits of lower prices, higher quality products and services, and greater innovation. Competition among employers also helps employees secure fair returns for their labor.[9] 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] FTC staff have analyzed the likely competitive effects of proposed advanced practice nursing regulations in other states, observing that removing overly burdensome supervision requirements can achieve significant benefits.[13] FTC staff have submitted analyses regarding CRNA or nurse anesthetist restrictions in particular to both federal and state authorities.[14]

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[9] *See, e.g.*, FED. TRADE COMM'N & U.S. DEPT'T OF JUSTICE, ANTITRUST GUIDANCE FOR HUMAN RESOURCE PROFESSIONALS, 2 (2016), https://www.ftc.gov/system/files/documents/public_statements/992623/ftc-doj_hr_guidance_final_10-20-16.pdf.

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

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

[12] FTC and staff advocacy may comprise letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.*, Joint Statement of the Fed. Trade Comm'n and the Antitrust Div. of the U.S. Dep't Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program (2017), https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-us-department-justice-regarding/v170006_ftc-doj_comment_on_alaska_senate_bill_re_state_con_law.pdf; FTC Staff Comment Before the Dep't of Health & Human Servs. Regarding the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (2019), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-health-human-services-regarding-21st-century-cures-act-interoperability/v190002_hhs_onc_info_blocking_staff_comment_5-30-19.pdf; Brief for the United States and the Fed. Trade Comm'n as *Amici Curiae* Supporting Plaintiffs-Appellees, Teladoc, Inc. v. Texas Medical Board, (5th Cir. Dec. 9, 2016) (Case: 16-50017); Fed. Trade Comm'n, The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study (2005), (https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf).

[13] *See generally* FED. TRADE COMM'N, FTC 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.

[14] *See, e.g.*, FTC Staff Comment to the Senate of West Virginia Concerning the Competitive Impact of WV Senate Bill 516 on the Regulation of Certain Advanced Practice Registered Nurses (2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-senate-west-virginia-concerning-competitive-impact-wv-senate-bill-516-regulation/160212westvirginiacomment.pdf; FTC Staff Comment to the Dep't of Veterans Affairs: Proposed Rule Regarding Advanced Practice Registered Nurses (2016), https://www.ftc.gov/system/files/documents/advocacy_documents/comment-staff-ftc-office-policy-planning-bureau-competition-bureau-economics-department-veterans/v160013_staff_comment_department_of_veterans_affairs.pdf; FTC Staff Comment Before the Massachusetts House of Representatives Regarding House Bill 2009 Concerning Supervisory Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 2014),

II. Additional Background Supports the Competition Perspective

FTC staff policy work is cognizant of, and sometimes carried out in concert with,[15] expert authorities in health and safety matters who may not have an express competition mission. We note, for example, that Reports by the Institute of Medicine (IOM) have identified a key role for advanced practice nurses—including CRNAs—in improving the delivery of health care.[16] The IOM, established in 1970 as the health arm of the National Academy of Sciences, provides expert advice to policy makers and the public and has conducted an intensive examination of issues surrounding advanced nursing practice. Among other things, the IOM found that "[r]estrictions on scope of practice . . . have undermined [nurses'] ability to provide and improve both general and advanced care."[17] In a separate study examining pain as a public health problem, the IOM found that regulatory barriers "limit the availability of pain care and contribute to disparities found among some groups."[18]

Additional research suggests that Texas, specifically, faces the health care delivery problems identified in the IOM reports. Although some Texas cities enjoy substantial specialized medical resources, rural Texas, as well as other underserved communities, face both provider and facilities shortages. For example, a 2017 report by the Texas A&M Rural Health Institute, discussing concerns about access to health care for rural Texans, notes that "[i]n Texas, more than 170 of the 254 counties are rural."[19] That rural population of more than three million Texans tend to be "older, poorer,

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https://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/140123massachusettnursesletter.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.

[15] For example, FTC staff provided informal technical assistance to the Department of Health and Human Services as the Department was implementing certain provisions of the 21st Century Cures Act. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Criteria, 84 Fed. Reg. 7424, 7424 (proposed Mar. 4, 2019) (to be codified at 45 CFR Parts 170 and 171). In addition, at ONC's invitation, the FTC have participated in the Federal Health IT Advisory Council that develops the Federal Health IT Strategic Plan, and in the federal Interagency Information Blocking Working Group; and FTC staff regularly collaborates with ONC staff to identify potential competition issues relating to health IT platforms and standards, as well as on privacy and security issues.

[16] IOM FUTURE OF NURSING REPORT INST. OF MED., *supra* note 6, at 98–99.

[17] *Id.* at 4.

[18] INSTITUTE OF MEDICINE, COMMITTEE ON ADVANCING PAIN RESEARCH, CARE, AND EDUCATION, RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 2, 80, 157 (2011) [hereinafter IOM PAIN REPORT].

[19] TEXAS A&M UNIVERSITY RURAL & COMMUNITY HEALTH INSTITUTE (RCHI), WHAT'S NEXT? PRACTICAL SUGGESTIONS FOR RURAL COMMUNITIES FACING A HOSPITAL CLOSURE (exec. summ. at iv.) (2017). Retrieved from https://www.rchitexas.org/. "Of the 254 counties in Texas, 177 were deemed "rural" by the Texas Department of Agriculture and 172 are deemed "rural" by the Texas Department of State Health Services." *Id.* at 3.

and--according to recent surveys--less healthy than their urban and suburban counterparts."[20] As noted above, sixty-four of the eighty-five Critical Access Hospitals in Texas are located in counties where there are no anesthesiologists; and thirty-three of those hospitals are in counties where CRNAs are the only licensed, specialized providers of anesthesia and anesthesia-related services.[21]

Heightened supervision requirements are likely to exacerbate such provider and facilities shortages and access problems associated with them.

III. PROPOSED 22 TAC § 193.13

The Proposed Rule would stipulate that physicians may delegate the authority to administer anesthesia or anesthesia-related services only to a CRNA "acting under adequate physician supervision."[22] In addition, the Proposed Rule would stipulate that the delegating physician is responsible for, *inter alia*, "determining and insuring that it is reasonable, sound medical judgment to delegate to certified registered nurse anesthetist [and] (2) that the delegated acts can be properly and safely delegated performed in its customary manner."[23] Although the particular requirements of "adequate physician supervision" are not set forth in the Proposed Rule (or, apparently, in Texas statutes), the Proposed Rule would hold that "[t]he delegating physician is ultimately responsible for the certified registered nurse anesthetist performing delegated acts."[24] That is, the Proposed Rule suggests that delegating physicians are subject to regulatory enforcement for failure to adhere to unclear supervisory requirements; it may also suggest exposure to civil liability.

IV. Discussion

A. Texas Law Requires Delegation of Authority to CRNAs, But Not the Direct Supervision of CRNA Practice

The proposed amendments to Section 193.13 are supposed to add "clarifying language and new subsections (d), (e) and (f) relating to the roles and responsibilities of the delegating physician and CRNAs."[25] The Board notes that "[t]his clarifying language is a direct result of a recent Attorney General Opinion directly on point."[26] However,

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[20] *Id.* at iv.

[21] *See supra* note 5.

[22] 44 Tex. Reg. at 6671.

[23] *Id.*

[24] *Id.*

[25] 44 Tex. Reg. at 6669.

[26] *Id.*

some of the proposed regulations appear to be at odds with a recent opinion letter by Texas Attorney General Ken Paxton,[27] as well as prior Attorney General Opinions.[28]

The proposed assignments of responsibility seem to exceed, rather than implement, Texas law. First, as Attorney General Paxton explained, Texas law expressly limits the liability of a delegating physician for the act of delegation and the practice of a CRNA to whom the physician delegates authority. In a 2019 opinion analyzing Texas law on delegation to a CRNA, the Attorney General notes that Texas law expressly "limits a physician's liability 'for an act of [an] . . . advanced practice registered nurse solely because the physician signed a standing medical order [and a] standing delegation order . . . authorizing the . . . advanced practice registered nurse to administer, provide, prescribe, or order a drug or device.'"[29] The Attorney General notes that the limitation on liability does not apply "if 'the physician has reason to believe the . . . advanced practice registered nurse lacked the competency to perform the act.'"[30] That is, the limitation on liability appears to apply only when the delegating physician has actual or constructive knowledge that the APRN--in this case, a CRNA--is not competent to perform the delegated act.

The Attorney General's opinion also cites provisions of the Texas Occupations Code declaring that the pertinent section "shall be liberally construed to permit the full use of safe and effective medication orders to use the skills and services of certified registered nurse anesthetists."[31] In particular, the physician's delegation to a CRNA "is not required to specify a drug, dose, or administration technique," and "the nurse anesthetist may select, obtain, and administer those drugs and apply the medical devices appropriate to accomplish the order and maintain the patient within a sound physiological status."[32] That is, under Texas law, the manner in which delegated anesthesia practice is to be performed may be determined by the CRNA. The Attorney General does not cite, and we are unaware of, any statutory basis for additional expectations of supervision by a delegating physician.

Finally, the Attorney General notes that a prior opinion addressed the question "whether section 157.058 requires a physician to directly supervise a certified registered nurse anesthetist's provision of anesthesia and concluded that a physician is not required to do so."[33]

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[27] Letter from Ken Paxton, Attorney General of Texas, to Sherif Zaafran, M.D., President, Texas Medical Board, Opinion No. KP-0266 (Sept. 5, 2019).

[28] Tex. Att'y Gen. Op. No. JC-0117 (1999).

[29] Letter from Ken Paxton, Attorney General of Texas, *supra* note 27 at 3 (citing Tex. Occ. Code § 157.060).

[30] *Id.*

[31] *Id.* (citing Tex. Occ. Code § 157.058).

[32] *Id.*

[33] *Id.* at 2 (citing Tex. Att'y Gen. Op. No. JC-0117 (1999)).

Although the Board of Medicine may have some regulatory authority over a physician's act of delegation, the Attorney General's reading of the plain language of Texas statutes appears to suggest the following:

- first, the law does not require the direct supervision of CRNAs;
- second, the legal responsibility (or liability) of delegating physicians is expressly limited by Texas law;
- third, particular treatment decisions of CRNAs, acting under delegated authority, are the independent responsibility of those CRNAs; and
- finally, Texas delegation requirements "shall be liberally construed to permit the full use of safe and effective medication orders to use the skills and services of certified registered nurse anesthetists."[34]

Although the Proposed Rule does not stipulate particular supervisory acts physicians must undertake, it does specify a requirement of "adequate supervision" that is not required under Texas law, according to the Attorney General's recent opinion and the plain language of Texas statutes. Moreover, the Proposed Rule would require a degree of oversight regarding particular "delegated acts" and the "manner" in which they are delivered not contemplated under Texas law. Delegating surgeons--who are not specialized in anesthesia or related services--might be uncertain about their exposure to Board discipline and other liability if the Proposed Rule were adopted; and rural hospitals that depend on CRNAs for specialized care might also face additional liability if the Proposed Rule were adopted. Moreover, uncertainty about the precise scope of adequate supervision would itself impose a degree of risk, and hence cost, on delegating physicians and institutional providers employing CRNAs.

B. Unnecessary Supervision Requirements Can Increase the Cost of, and Decrease Access to, Needed Anesthesia-Related Services

FTC staff recognize that certain professional licensure requirements and scope-of-practice restrictions may protect patients.[35] Consistent with patient safety, however, we have urged regulators and legislators to consider the benefits that more competition from independent APRNs--including CRNAs—might provide—especially benefits to patients. 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, health care consumers--patients--are likely to benefit from improved access to health care, lower costs, and additional innovation.

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[34] *Id.* at 3 (quoting TEX. Occ. Code § 157.058

[35] 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), http://www.ftc.govibe/consumerbehavior/docs/reports/CoxFoster90.pdf.

Section III of the FTC staff's 2014 Policy Paper discusses in detail the potential competitive harms from overly restrictive APRN supervision requirements generally.[36] The Policy Paper analyzes these competitive harms as potential consequences of market-wide regulations, and the potential benefits of policy reform as those likely to follow the repeal or retrenchment of such regulatory constraints. Imposing additional constraints can interfere with the ability of Texas hospitals and Texas patients to recognize the benefits that using CRNAs could provide.

The Policy Paper analyzes three basic issues of particular relevance to the Proposed Rule. First, regulatory constraints on APRN practice limit the ability of APRNs to expand access to care and to ameliorate both current and projected health care workforce shortages.[37] 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.[38] Mandatory supervision and "collaborative practice" requirements may, however, increase the cost of those services.[39] In contrast, when these types of supervisory requirements are relaxed, 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 gain access to services that otherwise would be unavailable.[40] Even in well-served areas, expanding the supply of APRN services tends to lower prices and drive down health care costs. Third, rigid supervision requirements may impede, rather than foster, development of effective models of health care delivery—including team-based care.[41]

Supervision requirements for CRNAs raise competition concerns similar to those raised by the imposition of supervision requirements on primary care APRNs or certified nurse practitioners (CNPs).[42] FTC staff recognize that certain licensure requirements and

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[36] *See generally,* FTC STAFF POLICY PAPER, *supra* note 13. According to the National Council of State Boards of Nursing, 22 states and the District of Columbia permit "independent practice" by CRNAs, requiring neither supervision nor delegation. Nat'l Council State Bds. Nursing, CRNA Independent Practice Map, https://www.ncsbn.org/5404.htm.

[37] FTC STAFF POLICY PAPER, *supra* note 13, at 20 (regarding APRNs generally).

[38] *Id.* at 28.

[39] FTC STAFF POLICY PAPER, *supra* note 13, at 27–31.

[40] "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 PAPER, *supra* note 13, at 20 (citing, *e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 6, at 98–103, 157–61, annex 3-1 (2011).

[41] FTC STAFF POLICY PAPER, *supra* note 13, at 34.

[42] As noted above, there are four types of APRNs: nurse practitioners ("CNPs"); nurse midwives ("CNMs"); certified registered nurse anesthetists ("CRNAs"); and clinical nurse specialists ("CNSs"). *Id.* at 33,155, 33,160 (to be codified at § 17.415(a)); *see also* IOM FUTURE OF NURSING REPORT, *supra* note 6, at 23, 26 table 1-1 (types of APRN practice). All four types of APRN consist of nurse practitioners with graduate nursing degrees, in addition to undergraduate nursing education and practice experience. *Id.* at 23, 26.

scope-of-practice restrictions can serve to protect patients.[43] 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 patient risks.[44] We note, however, the IOM's concern that excessive restrictions may impede access to specialized care that CRNAs are qualified to provide, based on their training and experience.[45] 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*."[46] Because particular regulatory restrictions on CRNAs may dampen competition in ways that harm patients, institutional health care providers, and payors—without offering countervailing health and safety benefits—we have recommended that policy makers apply the same competition-oriented framework and considerations to all APRN policies, including those policies affecting specialist APRNs.[47]

Importantly, access problems are not unique to primary care. 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."[48] Yet specialist physicians such as anesthesiologists—and not just primary care doctors—may be in short supply,[49] particularly in rural areas.[50] 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.[51] For

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[43] FTC STAFF POLICY PAPER, *supra* note 13, at text accompanying notes 51–55.

[44] *See, e.g.,* FTC Staff Comment to the Dep't of Veterans Affairs, supra note 14, at 6.

[45] IOM FUTURE OF NURSING REPORT, *supra* note 13, at 96.

[46] *Id.* at 98 (emphasis added).

[47] *See, e.g.*, FTC Staff Comment to the Dep't of Veterans Affairs, supra note 14; FTC Staff to the Hon. Heather A. Steans, *supra* note 14; Letter from FTC Staff to Kay Khan, , *supra* note 14.

[48] IOM FUTURE OF NURSING REPORT, *supra* note 6, at 450.

[49] ASS'N OF AM. 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, exs. 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).

[50] *See* ASS'N OF AM. MED. COLLS., *supra* note 49 (noting impact of physician shortfalls to be "most severe" in rural and other underserved areas); see also HRSA PHYSICIAN WORKFORCE REPORT, *supra note* 49, 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 6, at 106–07; MICHAEL MEIT ET AL., RURAL HEALTH REFORM POLICY RESEARCH CENTER, THE 2014 UPDATE OF THE RURAL–URBAN CHARTBOOK 56 (2014) [hereinafter MEIT ET AL.].

[51] MEIT ET AL., *supra* note 50, at 4. Overall, according to the National Rural Health Association, there are more than three times as many specialists per 100,000 people practicing in urban areas as in rural areas. *What's Different About Rural Health Care*, NAT'L RURAL HEALTH ASS'N, http://www.ruralhealthweb.org/go/left/about-rural-health (last visited Jan. 11, 2016).

example, many CRNAs provide basic anesthesia services in rural counties where there are no anesthesiologists.[52] One hundred sixteen Texas counties lack practicing anesthesiologists;[53] and, as noted above, sixty-four of the eighty-five Critical Access Hospitals[54] in Texas are located in counties where there are no anesthesiologists; and thirty-three of those hospitals are in counties where CRNAs are the only licensed, specialized providers of anesthesia and anesthesia-related services.[55]

FTC staff urge you to consider whether CRNAs can help alleviate the access problems associated with specialist physician shortages, in a manner consistent with patient health and safety. For example, the IOM Future of Nursing Report observes that CRNAs administer more than 65 percent of all anesthetics to U.S. patients and that they "[a]dminister anesthesia and provide related care before and after surgical, therapeutic, diagnostic, and obstetrical procedures, as well as pain management."[56] Based on the safety literature, the IOM states: "evidence shows that CRNAs provide high-quality care . . . [while] there is no evidence of patient harm from their practice."[57] Similarly, the U.S.

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[52] *See, e.g.*, 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, at 3 (March 2012), http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf ("Staff notes that CRNA practices disproportionately serve rural patients, and the Missouri Association of Nurse Anesthetists has testified that CRNAs are the only licensed providers of anesthesia services in 31 Missouri counties."); FTC Staff Letter to the Hon. Gary Odom, Representative, Tennessee House of Representatives, Concerning Tennessee House Bill 1896 and the Regulation of Providers of Interventional Pain Management Services, at 4 (Sept. 2011), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-gary-odom-tennessee-house-representatives-concerning-tennessee-house-bill.b.1896-and-regulation-providers-interventional-pain-management-services/v11001tennesseebill.pdf (CRNAs only licensed providers of anesthesia services in 39 Tennessee counties); *cf.* Letter from FTC Staff to the Hon. Kay Khan, Representative, Mass. House of Representatives, *supra* note 13, at 5 (geographic shortages of anesthesiologists in rural Massachusetts counties).

[53] Texas Ass'n Nurse Anesthetists, County-Level Map, https://www.txana.org/uploads/files/general/County_TX_map_AANA.pdf.

[54] Critical Access Hospitals (CAHs) are designated as such by both the states in which they are located and the Department of Health and Human Services. They must, among other things, "[b]e designated by the State as a CAH; be located in a rural area or an area that is treated as rural; be located either more than 35-miles from the nearest hospital or CAH or more than 15 miles in areas with mountainous terrain or only secondary roads; . . . . [and] and furnish 24-hour emergency care services 7 days a week." Centers for Medicare & Medicaid Servs., Critical Access Hospitals, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.html.

[55] For locations of CAHs, see Flex Monitoring Team, Univ. Minn., Univ. N.C. at Chapel Hill & Univ. Southern Main, Critical Access Hospitals Locations, https://www.flexmonitoring.org/data/critical-access-hospital-locations/?search_state=TX&filter_search=yes#result-list (noting list current as of Oct. 11, 2019);

. For a map of Texas anesthesia providers based on the National Provider Identifier Registry, see Texas Ass'n Nurse Anesthetists, County-Level Map, https://www.txana.org/uploads/files/general/County_TX_map_AANA.pdf.

[56] IOM FUTURE OF NURSING REPORT, *supra* note 6, at 26.

[57] *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.").

Department of Health and Human Services has, on multiple occasions relating to Medicare and Medicaid rules for the provision of hospital anesthesia services, reviewed the available literature on the quality of anesthesia services, and has not found risks that would warrant further restrictions on CRNA practice.[58]

V. Conclusion

Although the particular supervisory requirements contemplated by the Proposed Rule are unclear, any such requirements or increased liability may contract the supply, decrease the availability, or increase the cost of anesthesia services in Texas, without providing offsetting benefits to Texas health care consumers or third-party payors. The risk of competitive harm applies statewide, but it is likely to be greater in rural and other medically underserved areas of Texas.

We recognize that patient health and safety concerns are critically important when states regulate the scope of practice of health care professionals, and FTC staff defer to the Texas legislature on the ultimate health and safety standards that the state may choose to establish. We recommend, however, that Texas maintain only those CRNA supervision requirements that advance patient protection, and that the Texas Medical Board avoid adopting regulations that impede CRNA practice in ways that have not been contemplated by the legislature, and that do not demonstrably advance consumer welfare. Correspondingly, we recommend that the Board not impede physician delegation of anesthesia or anesthesia-related services to CRNAs in ways that the legislature did not contemplate and that do not demonstrably advance patient welfare. In particular, we urge you to examine carefully any purported safety justifications for heightened supervision requirements, evaluate whether these justifications are well founded, and consider whether less restrictive alternatives would protect patients without unduly burdening competition. In brief, pending further demonstration of the need for the Proposed Rule, we recommend that you do not adopt it.

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[58] 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 & Human Servs. (HHS), Health Care Financing Administration (HCFA), Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 C.F.R. §§ 416, 482 & 485, Final Rule, 66 Fed. Reg. 4674, 4675 (Jan. 18, 2001); *cf.* HHS Health Care Financing Administration (HCFA), Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 C.F.R. §§ 416, 482 & 485, Final Rule, 66 Fed. Reg. 56,762, 56,762–63 (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).

Respectfully submitted,

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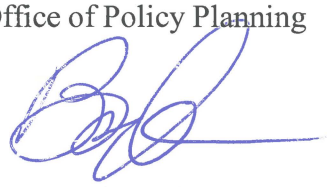

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