March 26, 2012

The Honorable Paul Hornback  
Senator, Commonwealth of Kentucky State Senate  
State Capitol Annex  
Frankfort, Kentucky 40601

Dear Senator Hornback:

The staffs of the Federal Trade Commission’s Office of Policy Planning, Bureau of Competition, and Bureau of Economics appreciate the opportunity to respond to your invitation for comments on Kentucky Senate Bill 187 (“the Bill” or “SB187”). The Bill would remove the requirement that Advanced Practice Registered Nurses (“APRNs”) have a signed collaboration agreement with a physician in order to prescribe nonscheduled medications. The Institute of Medicine (IOM) has identified a key role for advanced practice nurses in improving the delivery of health care. 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 advanced practice nurses play a key role in improving access to health care and “[r]estrictions on scope of practice. . . have undermined [nurses’] ability to provide and improve both general and advanced care.”

You have advised that the currently required collaborative prescribing agreement provides no physician supervision and can be costly to APRNs. As a result, the requirement is likely to limit the availability of APRN care. Kentucky currently suffers from shortages of primary care providers, and these shortages are expected to worsen as more Kentuckians gain health insurance and seek access to primary health care services. By eliminating this requirement, the Bill may improve access and consumer choice for primary care services, especially for rural and other underserved populations, and may also encourage beneficial price competition that can help contain health care costs.

Given the potential benefits of eliminating unwarranted impediments to APRN practice, we recommend that the Kentucky legislature seek to ensure that statutory limits
on APRNs are no stricter than patient protection requires. FTC staff are not experts in
patient care or safety, and we do not offer advice on such matters. But we encourage the
legislature to carefully consider available safety evidence. Absent a finding there are
countervailing safety concerns regarding APRN prescribing practices for nonscheduled
substances, SB187 appears to be a procompetitive improvement in the law that would
benefit Kentucky health care consumers.  

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.  
Competition is at the core of America's economy, and vigorous competition among
sellers in an open marketplace gives consumers the benefits of lower prices, higher
quality products and services, more choices, and greater innovation. Because of the
importance of health care competition to the economy and consumer welfare,
anticompetitive conduct in health care markets has long been a key target of FTC law
enforcement, research, and advocacy. Recently, FTC staff have analyzed the likely
competitive effects of proposed APRN regulations in other states.

II. BACKGROUND: APRN PRACTICE IN KENTUCKY AND SB187

APRNs are licensed by the Kentucky Board of Nursing and subject to the Board’s
regulations. Kentucky law defines advanced practice registered nursing as:

the performance of additional acts by registered nurses who have gained
added knowledge and skills through an approved organized postbasic
program of study and clinical experience; who are certified by the
American Nurses' Association or other nationally established
organizations or agencies recognized by the board to certify registered
nurses for advanced practice registered nursing as a certified nurse
practitioner, certified nurse anesthetist, certified nurse midwife, or clinical
nurse specialist; and who certified in at least one (1) population focus. The
additional acts shall, subject to approval of the board, include but not be
limited to prescribing treatment, drugs, devices, and ordering diagnostic
tests.

APRNs have had prescriptive authority for nonscheduled drugs since 1996,
subject to the requirement that they have a signed collaboration agreement with a
Kentucky physician. APRNs have had prescriptive authority for scheduled drugs (i.e.,
controlled substances) since 2006, again subject to having a collaboration agreement. According to the Kentucky Board of Nursing, for more than fifteen years APRNs have
developed an excellent record of safely and appropriately prescribing medications to
Kentucky health care consumers.
Under current law, however, some APRNs reportedly have had difficulty finding physicians willing to enter into a collaboration agreement. Moreover, although collaborative agreements in theory could encompass varying arrangements, you have advised that the currently required collaborative prescribing agreement “requires a one-time only signature by the physician, but no supervision, patient contact, chart review or co-signature of the prescription” and that those APRNs who do find willing physicians often must pay a physician to enter into the agreement, even if no supervision is involved.

SB187 would remove the requirement that APRNs have a collaborative agreement with a physician in order to prescribe nonscheduled drugs. The Bill also would mandate that APRNs who prescribe scheduled drugs pursuant to collaborative agreements with physicians participate in the Kentucky All Schedule Prescriptions Electronic Reporting (KASPER) program.

III. LIKELY COMPETITIVE BENEFITS OF SB187

FTC staff recognize that certain professional licensure requirements are necessary to protect patients. Consistent with patient safety, however, we urge legislators to also consider the potential benefits of competition, including improved access to care, lower costs, and increased options that passage of SB187 would likely create.

a. SB187 Would Likely Improve Access to Primary Care Services

By 2020 the United States will face an estimated shortage of 91,000 physicians, with a projected dearth of approximately 45,000 primary care physicians and 46,000 specialists. While these shortages will exacerbate health care access problems for many American consumers, the impact of reduced access is likely to be most acute among Medicaid beneficiaries, due not only to geographic misalignment between low-income communities and physician practice locations, but also to low physician participation in state Medicaid programs. Given that APRNs play a key role in filling the gap between demand and supply for health care services, any unnecessary restrictions on APRNs are likely to exacerbate access problems and thereby harm patients.

Eighty-four of 120 Kentucky counties contain federally-designated Health Professional Shortage Areas ("HPSAs"). Federal health care reform will greatly expand the number of people with insurance in Kentucky, likely increasing the demand for primary care services and potentially exacerbating the imbalance between demand for and supply of primary care physicians. An estimated 261,000 Kentuckians who are now uninsured will gain coverage via Medicaid, and an additional 221,000 Kentucky families will receive tax credits to help pay for insurance. Optimizing use of APRNs can mitigate the consequences of current and future shortages of primary care physicians.

The relatively poor health status of many Kentuckians is another factor complicating the access picture. For several diseases that respond well to primary care,
Kentuckians’ health status is worse than the U.S. average, due to lack of health insurance, high poverty rates, and provider shortages, among other factors.  

APRNs are seen by many as crucial to addressing access problems, especially in rural or underserved areas of Kentucky. As a general matter, APRNs make up a greater share of the primary care workforce in less densely populated, less urban, and lower income areas, as well as in HPSAs. APRNs are more likely than primary care physicians to practice in underserved areas and to care for large numbers of minority patients, Medicaid beneficiaries, and uninsured patients. In Kentucky there are currently 4,427 licensed APRNs, and they practice in most of the state’s designated HPSAs. It is also important to note that 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 for primary care physicians. Some reports suggest more APRNs practice in states that allow independent practice. Thus, if Kentucky eliminates the requirement for a collaborative agreement for prescriptive authority, the number of APRNs practicing in Kentucky may increase.

In sum, unnecessary restrictions on APRNs could result in decreased access to health care services, with potentially harmful consequences for Kentucky patients.

b. SB187 Would Likely Lower Costs and Increase Consumer Options

SB187 is likely to reduce the cost of basic health care services and increase consumer options. APRN care is generally less expensive to patients and payers and is often provided in a variety of health care delivery settings, so the bill could spur innovation in health care delivery and widen the range of choices available to consumers. For example, APRNs have played an important role in the expansion of limited service clinics (“LSCs”) in many states. LSCs typically are staffed by APRNs and offer consumers a convenient way to obtain basic medical care at competitive prices. APRN-staffed clinics generally offer weekend and evening hours, which provide greater flexibility for patients, and may provide competitive incentives for other types of clinics to offer extended hours as well. SB187, by eliminating restrictions on APRNs’ ability to prescribe medications, may increase both the number and types of LSCs available to Kentucky consumers.

Furthermore, if SB187 were enacted, APRNs’ costs of doing business likely would decrease, which could affect the prices APRNs charge for their services and thereby reduce costs for consumers as well. You have advised that some APRNs “are finding it difficult to identify a physician who is willing to enter into a collaborative prescribing agreement” and that APRNs find it difficult to develop a sustainable business because collaborating physicians can revoke collaborative agreements at any time for any reason, which would compromise APRNs’ ability to properly treat their patients. Anecdotal evidence suggests some APRNs pay as much as $3,000 to $4,000 per month to collaborating physicians.
c. Legislative Consideration of Health and Safety Issues

The IOM, based on an extensive review of the studies and literature on the safety of APRNs as primary care providers, has recommended that nurses be permitted by state licensing laws to practice to the full extent of their training.\textsuperscript{37} The IOM noted sixteen states and the District of Columbia allow APRNs to practice and prescribe independently, and there were no differences in safety and quality between states with restrictive scope of practice laws and regulations, and those that allow APRNs to practice independently, including prescribing medications without an agreement with a physician.\textsuperscript{38}

The current Kentucky law, in effect since 1996, requires a signed collaboration agreement for APRNs to prescribe nonscheduled prescription drugs. It is our understanding that neither the law, nor general practice in Kentucky, involves collaboration agreements that require chart review, onsite presence by a physician, or any other form of physician supervision or monitoring.\textsuperscript{39} According to the Kentucky Board of Nursing, for the more than fifteen years APRNs have had prescriptive authority, not a single APRN in Kentucky has ever been reported to the Board of Nursing for poor or inappropriate prescribing of nonscheduled drugs.\textsuperscript{40}

IV. CONCLUSION

SB187 would remove the requirement that APRNs who prescribe nonscheduled medications have a collaborative agreement with physicians. Removing this requirement has the potential to benefit consumers by expanding choices for patients, containing costs, and improving access. Accordingly, we encourage legislators to consider whether the requirement is necessary to assure patient safety in light of the prescribing experience of Kentucky APRNs for over fifteen years, as well as the findings of the Institute of Medicine. Maintaining an unnecessary and burdensome requirement is likely to deprive consumers of the benefits that increased competition can provide. Therefore, the Kentucky legislature should carefully review the safety record of APRNs in Kentucky. Absent countervailing safety concerns regarding APRN prescribing practices for nonscheduled substances, SB187 appears to be a procompetitive improvement in the law that would benefit Kentucky health care consumers.
Respectfully submitted,

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Richard A. Feinstein, Director
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1 This staff letter expresses the views of the Federal Trade Commission’s Office of Policy Planning, Bureau of Competition, and Bureau of Economics. 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 staff to submit these comments.

2 Letter from the Hon. Paul Hornback, Commonwealth of Kentucky State Senate, to Susan DeSanti, Director, Office of Policy Planning, Federal Trade Commission (Jan. 18, 2012) [hereinafter Letter from Sen. Hornback]. (The letter requested comments on BR966, which was later introduced to the Kentucky Senate as SB187.) Nonscheduled drugs include antibiotics, diabetes medications, and blood pressure medications. Scheduled drugs include controlled substances, such as sedatives and narcotic pain medication. See also SB187, available at http://www.lrc.ky.gov/record/12RS/SB187.htm.


4 Id. at 4. See also id. at 85-161, 98-99 (discussing nursing scope-of-practice issues and quality of care, including numerous quality of care studies); About the Institute of Medicine, available at http://www.iom.edu/About-IOM.aspx.


6 See KENTUCKY INSTITUTE OF MEDICINE, TASK FORCE REPORT: COMPREHENSIVE STATEWIDE PHYSICIAN WORKFORCE STUDY 6 (“For decades Kentucky has suffered a chronic shortage of physicians, particularly in rural portions of the State”); id. at 7, 10-12, 27 (Table 6), and 36 (Table 7); discussion infra at Section III.a. (discussing physician shortages and access issues in Kentucky); Kentucky Voices for Health, Issue Brief, The New Health Reform Law: What It Means for Kentuckians (July 2010), available at http://www.lrc.ky.gov/record/12RS/SB187.htm.
Although not the subject of your request, we note the March 1, 2012 introduction of SB190, which would impose even greater restrictions on APRNs than currently exist. For the reasons expressed in this letter, FTC staff urge the Kentucky legislature to carefully examine whether the additional restrictions in SB190 are necessary for patient safety. In particular, we recommend that you investigate whether there is any evidence that current APRN practice is harmful to patients. If such evidence exists, we encourage you to consider whether SB190 is tailored to address those potential health and safety concerns.


KY. REV. STAT. ANN. § 314.011 (8) (Definitions). See also 201 KY. ADMIN. REGS. 20:056 (Nursing Board regulations regarding advanced practice registered nurse licensure, program requirements, recognition of a national certifying organization).

See KY. REV. STAT. ANN. § 314.042; Sharon Eli Mercer & Charlotte Beason, APRNs Are Safe Prescribers, 30 Kentucky Board of Nursing Connections Newsletter 24 (Winter 2011), available at http://kbn ky.gov/NR/rdonlyres/1830AD86-E324-499F-B3A5-EE0DDAED8308/275309/Win11 1732.pdf [hereinafter “KBN, APRNs Are Safe Prescribers”] (Charlotte Beason, one of the co-authors, is the Executive Director of the Kentucky Board of Nursing).

Id. Not all states distinguish between scheduled and nonscheduled drugs when specifying APRNs’ prescriptive authority. FTC staff have not taken a position on such a distinction. This staff comment only relates to restrictions on APRNs’ ability to prescribe nonscheduled drugs because SB187 would only eliminate the collaborative agreement requirement with respect to nonscheduled drugs.
17 KBN, APRNs Are Safe Prescribers, supra note 15. See also discussion infra at Section III.c.

18 See Kentucky Board of Medical Licensure Opinion Regarding the Standards of Acceptable and Prevailing Medical Practice for Physicians Involved in Collaborative Agreements with ARNP’s [sic], available at http://www.kbml.ky.gov/NR/rdonlyres/195123EC-A98A-42E0-8C3A-C6251936913A/0/arnp.pdf (noting “[t]he scope of the prescriptive authority and the terms of the collaborative agreement define the roles of the physician and nurse practitioner and establish the frequency and levels of professional judgment that must be exercised by each party”).

19 See Letter from Sen. Hornback. This description appears to be consistent with our understanding, based in part upon the applicable governing laws and regulations, as well as the form agreements on the website of the Kentucky Coalition of Nurse Practitioners and Nurse Midwives. See, e.g., “Collaborative Agreement for Prescriptive Authority for Non-Scheduled Drugs (CAPA-NS),” available at http://www.kcnpnm.org/?page=data_info.

20 See Letter from Sen. Hornback; SB187. Our comments do not address the proposed requirement that APRNs participate in KASPER, except to note that it seems sensible to impose the same electronic monitoring system reporting requirements on all prescribers of controlled substances.


22 See Kaiser Commission, Improving Access, supra note 21, at 1; Leighton Ku et al., The States’ Next Challenge – Securing Primary Care for Expanded Medicaid Populations, 364 N. ENGL. J. MED. 493, 494 (2011) (noting Kentucky is one of eight states facing the greatest challenge to meet the need for primary care by an expanded Medicaid population).


25 CASEY ET AL., UNIVERSITY OF KENTUCKY, CENTER FOR RURAL HEALTH, RURAL KENTUCKY’S PHYSICIAN SHORTAGE 5 (Sept. 2005):

One of the most troubling consequences of rural Kentucky’s long-standing problem with attracting and retaining health care professionals has been limited access to care, most notably preventative measures, which in turn has contributed to an unhealthy population. Residents of rural Kentucky suffer from unusually high rates of diseases that would be most responsive to consistent primary care, including heart disease, hypertension, asthma, diabetes and cancer.

26 Kaiser Commission, Improving Access, supra note 21, at 3.


28 See Kaiser Commission, Improving Access, supra note 21, at 3; AAMC, Physician Shortages, supra note 21.

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

30 See Joanne M. Pohl et al., Unleashing Nurse Practitioners’ Potential to Deliver Primary Care and Lead Teams, 29 HEALTH AFFAIRS 900, 901 (2010), available at http://content.healthaffairs.org/content/29/5/900.full.pdf+html (noting APRNs and physicians assistants are underutilized “despite being qualified to provide primary care at a lower cost than other providers”).


Evidence indicates that the quality of care provided by APRNs in retail clinics is “similar to that provided in physician offices and urgent care centers and slightly superior to that of emergency departments.” Ateev Mehrotra et al., Comparing Costs and Quality of Care at Retail Clinics with that of Other Medical Settings for 3 Common Illnesses, 151 ANNALS INTERNAL MED. 321, 326 (2009) (analyzing 14 quality metrics for commonly treated ailments, including ear, strep, and urinary tract infections, and finding “[f]or most measures, quality scores of retail clinics were equal to or higher than those of other care settings”).

33 Cf. Rena Rudavsky, Craig Evan Pollack, & Ateev Mehrotra, The Geographic Distribution, Ownership, Prices, and Scope of Practice at Retail Clinics, 151 ANNALS INTERNAL MED. 315, 317 (2009) (“In a random sample of 98 [limited service] clinics, all had weekday and weekend hours and 95 (97%) had evening hours (after 6 p.m.) on weekdays.”).
See, e.g., TEXAS BUDGET BOARD STAFF REPORT, supra note 29, at 300 (noting restrictions on APRNs’ scope of practice may limit both the number and types of LSCs available to Texas consumers); MARY TAKACH & KATHY WITGERT, NATIONAL ACADEMY FOR STATE HEALTH POLICY, ANALYSIS OF STATE REGULATIONS AND POLICIES GOVERNING THE OPERATION AND LICENSURE OF RETAIL CLINICS 6 (Feb. 2009) (noting “the most powerful state regulatory tools affecting [retail clinics’] operations are the scope of practice regulations that govern nurse practitioners and other non-physician medical personnel”).

Letter from Sen. Hornback (there have “been a few instances where a physician has withdrawn his signature on the CAPA, leaving the Nurse Practitioner unable to continue with the practice until another physician has been found to sign the CAPA”).

See Letter from Sen. Hornback (noting in “some cases, the physicians are charging a considerable amount of money monthly or annually to sign a CAPA [the collaborative prescribing agreement], although they essentially perform no services for the fee”); FTC staff discussions with representatives of organizations that represent APRNs, including APRNs in Kentucky. In addition, apparently some APRNs pay physicians based on a percentage of their monthly revenue, which can be as high as 10 percent.

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

Id. at 98-99 (noting “[n]o studies suggest that care is better in states that have more restrictive scope-of-practice regulations for APRNs than in those that do not”). See also Julie A. Fairman et al., Perspective: Broadening the Scope of Nursing Practice, 364 N. ENGL. J. MED. 193, 194 (2011) (stating “[t]here are no data to suggest that nurse practitioners in states that impose greater restrictions on their practice provide safer and better care than those in less restrictive states or that the role of the physician has changed or deteriorated”).

See KY. REV. STAT. ANN. § 314.042; 201 KY. ADMIN. REGS. 20:057 (Kentucky Board of Nursing Regulations on the scope and standards of practice of advanced practice registered nurses); “Collaborative Agreement for Prescriptive Authority for Non-Scheduled Drugs (CAPA-NS),” available at http://www.kcnpm.org/?page=data_info; Letter from Sen. Hornback.

KBN, APRNs Are Safe Prescribers, supra note 15 (also noting the “KBN rigorously monitors the prescribing practices of advanced practice registered nurses . . . [which] has included an audit of the annually mandated APRN pharmacology education of five continuing education units per year”).