April 29, 2014

Federal Trade Commission (FTC)
Office of the Secretary
600 Pennsylvania Ave., NW, Room H-133 (Annex X)
Washington, DC 20580

Filed online at https://ftcpublic.commentworks.com/ftc/healthcareworkshop

Re: Health Care Workshop, Project No. 131207

Dear Sir/Madam:

On behalf of the members of the American Podiatric Medical Association, Inc. (APMA), the national organization representing the vast majority of America’s foot and ankle physicians and surgeons, I welcome the opportunity to submit comments on professional regulations; innovations in health care delivery; advancements in health care technology; measuring and assessing health care quality; and price transparency for health care services.

APMA defines podiatric medicine as the profession of health sciences concerned with diagnosing and treating conditions affecting the human foot, ankle, and their governing and related structures, including the local manifestations of systemic conditions, by all appropriate systems and means. Podiatrists are specialists who are educated and trained to address conditions affecting the lower extremity and are recognized as physicians in the majority of states and by the federal government. Given its specialization, podiatric medicine is to the foot and ankle what ophthalmology is to the eye or cardiology is to the heart.

**Professional Regulation of Health Care Providers**

APMA appreciates that the FTC is seeking information on how professional regulations governing the scope of practice for health care providers may affect competition.

**Education and Training for Doctors of Podiatric Medicine**

Similar to allopathic medical training, the education, training, and experience of doctors of podiatric medicine (DPMs) include four years of undergraduate work, followed by four years in an accredited podiatric medical school. Following graduation, DPMs complete a three-year residency in an approved hospital-based program. Additionally, like our MD colleagues, some podiatrists complete fellowships for additional training in a specialty area. The significant
difference between education training models of allopathic doctors and podiatric medical doctors is that podiatric medical education begins to focus on the specialty area earlier on in the educational process.

According to the *American Medical Association’s Health Care Careers Directory*, “Colleges of podiatric medicine offer a core curriculum similar to that in other schools of medicine.” Podiatric medical college is a four-year program with the first two years focused on the basic medical sciences and the second two years focused on clinical medical education. The first two years of education at podiatric medical colleges are devoted to medical sciences including, but not limited to, gross and microscopic anatomy, biochemistry, pathology, microbiology, physiology, and pharmacology. During the third and fourth years, students engage in clinical education based in accredited hospitals, clinics, and private practice settings. During these third-and fourth-year rotations, students are afforded intense medical and surgical training related to the human body with emphasis on the lower extremity.

With earlier exposure to the specialty occurring in the colleges of podiatric medicine, graduates are well prepared for the more intensely focused clinical training provided in their subsequent podiatric residency program. Following graduation from podiatric medical college, doctors of podiatric medicine participate in a hospital-based three-year comprehensive podiatric medicine and surgery residency program. During residency, podiatrists receive advanced training in general medicine and surgery and participate in clinical rotations in anesthesiology, internal medicine, pathology, radiology, emergency medicine, and orthopedic and general surgery as well as elective rotations. Throughout residency training, emphasis is placed on diagnosing and managing patients with lower extremity pathology.

**Scope of Practice Issues**

Podiatrists are recognized by all 50 states, the federal government, and national accrediting agencies as independent health-care practitioners who are permitted to provide medical and surgical care within their scope of practice. Every state has a podiatric scope of practice statute and regulatory entity that oversees the practice of podiatric medicine. Forty-five states and the District of Columbia authorize surgical treatment at or above the ankle in the scope of practice for podiatrists. The five states that do not authorize podiatrists to treat the ankle are Alabama, Kansas, Massachusetts, Mississippi, and South Carolina. Also, additional states have removed procedures such as ankle fractures or amputations from the podiatric scope of practice or additional qualifications may be required before podiatrists can perform certain specific surgeries. These podiatric scope of practice laws that are unnecessarily restrictive given podiatrists’ education, training and experience. These restrictive laws are not supported by evidence showing improved quality of care and patient safety, and serve as a deterrent for both new and experienced podiatric physicians to practice in these states and force them to treat patients in bordering states.
Several state podiatric medical societies continue to advocate for a legislative update of their antiquated state podiatric scope of practice laws to reflect podiatrists’ education, training, and experience. On April 14, 2014, the Governor of Maryland approved Senate Bill 162, which amended the podiatric scope of practice to include the surgical treatment of acute ankle fractures. The Kansas Senate has passed Senate Bill 316, which would allow podiatrists to perform surgery on the ankle and tendons as well as amputate part of the foot (as may be necessary to the proper practice of podiatry) with specified qualifications. This legislation was introduced to the Kansas House of Representatives on March 14, 2014. The Hawaii House of Representatives passed House Bill 1880, which would permit podiatrists to perform ankle surgery with qualifications. The legislation was introduced to the Hawaii Senate and has passed second reading.

In recent years, state scope of practice laws have become more varied, overly descriptive, and include qualifications such as residency and board certification requirements that are more appropriate for hospital privileging forms than scope of practice statutes. The trend in podiatric scope of practice laws in recent years is to create tiered scope of practice standards. For example, Colorado, the law was changed in 2010 to permit treatment of ankle below the level of the dermis but with qualifications. See Colo. Rev. State §12-32-101.5.

It is likely that the podiatric medical profession will see more of these types of scope of practice tiered statutes become implemented, as at least one state is moving in this direction. Certainly, these developments advance the practice of podiatric medicine and benefit patients as they create needed access to expert foot and ankle care provided by podiatrists. While they are not the ideal law, they are the most politically realistic laws that were able to be passed by the respective legislatures and are accomplishments. As has been communicated to APMA by different state societies, legislators favor these tiered laws because they are a means to a compromise between the orthopedic and podiatric professions. There are many contributing factors that have caused tiered scope of practice statutes to be the preferred podiatric scope of practice statues of state legislators.

Restrictive scope of practice statutes can adversely affect podiatrists’ ability to provide timely care to their patients. For example, when an individual has diabetic neuropathy, the ankle joint may break down and become deformed. This deformity, if severe enough and if left untreated, can eventually lead to a lower-leg amputation. Restrictions are not in place because not because podiatrists lack the medical expertise or judgment, but because the condition has crossed the anatomical border.

APMA believes that scope of practice should operate as a ceiling, not a floor. The scope of practice should never be the lowest common denominator for a medical profession or specialty; rather, it should represent the maximum level to which a medical professional can provide patient care. The degree to which podiatrists practice their specialty must be demonstrated by the individual’s requisite education, training, and experience. The credentialing and privileging of Doctors of Podiatric Medicine should be the same as MDs and DOs, i.e., via proper
documentation of education, training, and experience. Just as allopathic and osteopathic doctors exercise medical and ethical judgment about their practices, doctors of podiatric medicine are required to do the same.

Allowing podiatrists to practice to the full extent of their education, training, and experience will result in increased competition and improved access to health care. Consumers have more health care provider options, which will likely result in greater competition. An example of improved access through increased health care provider options is the inclusion of podiatrists in state Medicaid programs. Currently, DPMs included under the Medicaid definition of physician, meaning state legislators have the option to and have cut care provided by podiatrists out of state budgets to the detriment of vulnerable and underserved populations. In addition to the disruption of existing physician-patient relationships, not including podiatrists in a state Medicaid program will increase the cost of care for this population. In Foot in Wallet Disease: Tripped up by "Cost Saving" Reductions, researchers Grant H. Skrepnek, PhD, RPh, Joseph L. Mills, MD, and David G. Armstrong, DPM, MD, PhD, analyzed data for all Medicaid diabetic foot infection hospital admissions across the state over five years (2006—2010), a time period before and after the state’s decision in 2009 to exclude DPMs from its Medicaid program. The study concludes that each $1 of Medicaid program “savings” the state anticipated from the elimination of podiatric medical and surgical services actually increased costs of care by $44.

Value of Care by Podiatrists

Our health-care system increasingly requires the skills of podiatrists because we play a critical role in treating lower extremity complications related to diabetes, obesity and other chronic conditions. Take diabetes as an example: The early-warning signs of diabetes are often found in manifestation of complications in the lower extremity. As such, podiatrists are frequently the first health-care provider to detect, treat, and therefore significantly prevent or reduce complications, such as lower limb amputations. If federal and state legislative and regulatory barriers prevent podiatrists from practicing to the full extent of their education, training, and experience, not only will competition be limited, patients will have limited access to health care and costs to the health care delivery system will increase.

According to the CDC, nearly 26 million Americans live with diabetes. Diabetes is the leading cause of non-traumatic lower-limb amputation; however, amputations can be prevented. Two peer-reviewed published studies evaluated care by podiatrists for patients with diabetes and demonstrated that compared to other health-care professionals, podiatrists are best equipped to treat lower extremity complications from diabetes, prevent amputations, reduce hospitalizations and provide savings to our health-care delivery systems.

A study conducted by Thomson Reuters Healthcare and published in the Journal of the American Podiatric Medical Association compared outcomes of care for patients with diabetes treated by podiatrists versus outcomes of care provided by other physicians. The study estimated that $10.5
billion in savings over three years can be realized if every at-risk patient with diabetes sees a podiatrist at least one time in a year preceding the onset of an ulceration. The value of podiatrists in treating and preventing complications from diabetes was supported by an independent study conducted by Duke University and published in Health Services Research, which found that Medicare-eligible patients with diabetes were less likely to experience a lower extremity amputation if a podiatrist was a member of the patient care team, and patients with severe lower extremity complications who only saw a podiatrist experienced a lower risk of amputation compared with patients who did not see a podiatrist.

Unlike federal law that may refer to the Medicare definition of physician when defining physician in health care statutes, states generally do not have one single definition of physician. One state statute may define physicians as MD/DO and DPM while another state statute may limit the definition of physician to MD/DO. Generally, non-governmental entities, like hospitals and private insurance companies are not bound by one single definition of physician. However, by defining doctors of podiatric medicine as physicians in the practice acts creates a strong persuasive argument that podiatrists should have parity with their MD/DO colleagues by payers, hospitals, other health systems, and governmental agencies. For example, Oregon House Bill 2622 amended the Oregon Medical Practice Act to include podiatrists in the definition of “physician.” Though this legislation did not have a fee parity component, the Oregon Podiatric Medical Association successfully advocated for Lifewise, a large private payer in Oregon, to reimburse DPMs under the physician fee schedule. This example illustrates how physician definition legislation can result in proper reimbursement for services rendered.

**Innovations in Health Care Delivery**

APMA values that the FTC is seeking a better understanding of the potential benefits of new models in health care delivery. APMA and its podiatrist members generally support innovations in health care delivery, provided that key members of the health care team, such as podiatrists, are not excluded from participation. Also, new models in health care delivery should include fair and accurate valuations of services rendered by health care providers.

By way of example, podiatrists were not included in the statutory definition of “ACO professional” (which was restricted to doctors of medicine and osteopathy, nurse practitioners, physician assistants and clinical nurse specialists). But through the notice-and-comment rulemaking process, CMS included podiatrists in the definitions of “ACO participant” and “ACO provider/supplier.” These definitions are as follows:

- ACO participant: a Medicare-enrolled provider of services and/or a supplier (as identified by a tax identification number or TIN); and
- ACO provider/supplier: a provider of services and/or a supplier that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number
assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.

Under these definitions, podiatrists are clearly able to participate in ACOs and share in any savings that such ACOs are able to produce. APMA applauds CMS for defining the new terms “ACO participant” and “ACO provider/supplier” in a way that would permit broad participation in ACOs and the MSSP. We remain disappointed and somewhat puzzled regarding the narrow statutory definition of the term “ACO professional,” and cannot understand why one category of physician (e.g., a doctor of medicine specializing in orthopedics) should have greater standing in forming an ACO than another category of physician, specifically a podiatrist who specializes in the care of foot and ankle conditions.

While these models are still relatively new, it appears that podiatric physicians are being recognized for the role they play in the health-care continuum, providing medically necessary and appropriate quality care and reducing the cost of care. APMA strongly encourages Congress, policymakers, health systems and payers to include podiatrists in alternative payment and delivery models. The health-care delivery system must utilize all licensed health care providers to the full extent of their license. There should be no impediments which would limit the full access to all types of health care professionals and prevent these health care professionals from providing the care they are trained to provide.

**Advancements in Health Care Technology**

APMA understands that recent advancements in health care technology have competitive effects and appreciates that the FTC invites public comment on the effect on physicians and patients. Health care technology advancements may be well-intentioned but can have adverse effects on the practice of medicine. Many legislative and regulatory requirements adopted and implemented as a result of these advancements are costly and time-consuming for health care providers though podiatrists have been frontrunners in transitioning to the use of EHRs. Importantly, these burdensome requirements decrease the amount of patients that health care providers can see and the amount of time spent with patients.

While intense competition exists between innovators and vendors, the federal government should focus more on facilitating the appropriate exchange of clinical information between health care providers for the benefit of patient care. Relatedly, facilitating exchange of clinical information include allowing patients to access their protected health information using a single portal.

We would also recommend that special consideration should be given to solo and small group practitioners as well as health-care professionals in rural areas and health professional shortage areas (HPSAs). APMA has worked closely with U.S. Rep. Renee Ellmers (R-NC), who had submitted comments to CMS, which included her concerns on Meaningful Use Stage 2 goals and the effect on solo and small practitioners. We agreed with Rep. Ellmers that “the Stage 2 goals
may be too ambitious for some small or solo practice physicians to meet. APMA continues to be concerned about physicians in solo or small practices who do not have, and who simply cannot afford, health IT.” In 2011, APMA member Denise Lea Elliott, DPM, testified on this issue before the House Committee on Small Business’ Subcommittee on Health Care and Technology and shared her personal experience and concerns moving toward Stage 2. Thus, we recommend that the FTC take in consideration that many physicians today are in small or solo practices and the additional hardships and cost these physicians must encounter when transitioning to using new health technology.

Measuring and Assessing Quality of Health Care

Given APMA’s role in developing and promoting quality measures for physicians, including podiatrists for programs such as meaningful use and the Physician Quality Reporting System (PQRS), we value the FTC’s efforts to examine recent developments in the measurement and assessment of health care quality.

The SGR Repeal and Medicare Provider Payment Modernization Act of 2014 (H.R. 4015/S. 2000) legislation would have given physician specialty societies enhanced opportunities to recommend quality measures for use under the Merit-Based Incentive Payment System (MIPS) that are most relevant to their specialties. APMA appreciated the bill’s emphasis on evidence-based measurement rather than National Quality Forum (NQF) endorsement and the funding of specialty society measure development. We also appreciated that existing measures and measures from Qualified Clinical Data Registries would not have been subject to additional and burdensome measure requirements and that these measures will be automatically included in the first program year’s final list of quality measures.

APMA recognizes the difficulty in transitioning from process measures to outcome measures. For example, in many instances, patients have multiple chronic conditions (e.g., diabetes, heart disease, kidney disease), which results in difficulties in attributing the outcome to a single intervention or measure. Also, quality measures are patient dependent, meaning that patients must be compliant with their prescriptions and recommend programs; otherwise the intended outcome will be less likely to occur though appropriate protocols were followed. Also, consideration should be given to the notion that using quality measurement as a provider-selection tool for patients may result in patients selecting providers whose patients have good outcomes, making them appear to be high-performing providers.

Adequate risk adjustment is necessary to ensure more accurate performance data and more fair comparisons. APMA appreciated that the under the previously referenced legislation, resource use measurement would incorporate additional research and recommendations on how to improve risk adjustment methodologies to ensure that professionals are not penalized for serving sicker or more costly patients.
Price Transparency of Health Care Services

APMA values the FTC’s efforts to better understand the competitive implications of price transparency for health care services.

The benefit designs that utilize price transparency to control costs are those designs under which a consumer’s cost sharing responsibility is based on either billed charges, a fee schedule, or negotiated price (i.e., those without fixed dollar amount cost sharing). They include benefit designs that involve high deductibles, coinsurance, reference pricing, or otherwise allow for balance billing. However, price transparency allows consumers to take into consideration only cost unless additional information is added to address quality.

In providing price information to consumers, focus should be placed on the services for which consumers are most likely to do price shopping and those for which price may affect their decisions. For example, consumers are unlikely to price shop for emergency services or other services for which they cannot predict a need. Therefore, focus should be placed on commonly used services, such as routine outpatient care for chronic conditions. Focus should also be placed on services for which a consumer’s cost sharing responsibility could greatly vary – those subject to coinsurance or deductibles, rather than those that would exceed most deductibles and be covered in full.

In providing information to physicians and other providers to assist them in making referral and treatment information, a significantly broader range of information would be needed.

To provide consumers with meaningful information to make health care choices, there are two potential sources of information: If the consumer’s cost sharing obligations are based on billed charges, consumers will need that information from the relevant provider. However, if the prices are based on the provider’s contract with the health plan, consumers will need the relevant information from the health plan. Most providers have difficulty receiving from health plans information on what they will be paid on a service-by-service basis. Physicians will also need access to both providers’ charges and to the amounts health plans pay the providers.

With the increasing use of payment mechanisms and participation criteria that hold physicians and other health care providers responsible for the cost of care, physicians are a key audience for price information. Pricing information can assist physicians in making decisions about referrals and treatment modalities. Price-based competition for such referrals has the potential to bring down costs in for the highest cost providers.

Access to competitive information may result in increased prices for the lowest cost providers. However, priced-based competition is likely to lower prices of the highest cost providers.
Without adding information about quality to pricing data, consumers and others using the data cannot assess value. Thus, it is extremely important to include quality data along with pricing data. Obviously there is no consensus regarding the best quality measurement tools and there is rarely uniform adoption of quality measurement tools. Therefore, all quality data derived from tools that give the provider an opportunity to review the underlying data and appeal any findings that the provider believes are incorrect should be furnished.

Thank you for the opportunity to provide information on the competitive dynamics of health care, and we hope the above comments are helpful. If you have any questions regarding our comments or need more information, please contact Scott Haag, JD, MSPH, Director of APMA’s Center for Professional Advocacy and Health Policy & Practice department, at 301-581-9233 or via e-mail at slhaag@apma.org.

Sincerely,

Frank A. Spinosa, DPM
President, APMA