

April 30, 2014

The Honorable Edith Ramirez
Chairwoman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Health Care Workshop, Project No. P13-1207

Dear Chairwoman Ramirez:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to provide our comments on the March 2014 Federal Trade Commission (FTC) *Examining Health Care Competition* workshop. As you know, we worked closely with FTC staff prior to the workshop to provide substantive background and our perspective on the issues covered in the workshop. We were particularly pleased that the FTC extended an invitation to Steven Stack, MD, Immediate Past Chair of the AMA Board of Trustees, to discuss his experience with electronic health records (EHRs) on the health information technology (HIT) panel. Overall, we found the discussions at the workshop to be in-depth and informative, and we look forward to working with the FTC on these important health care issues in the future. We offer below our specific comments on HIT, professional regulation, telemedicine, quality, and price transparency. We also briefly discuss other areas that we believe merit continued FTC attention, including antitrust barriers to physician participation in new delivery and payment models.

Advancements in Health Care Technology

The AMA appreciated the opportunity to participate in the panel on advancements in health care technology, which highlighted competition issues associated with EHRs. Based on the panel discussions and our own member experiences, the AMA has identified three key areas that we believe may pose impediments to physicians' successful use of EHRs and their ability to help improve care quality. **We encourage the FTC to explore these three topics in more detail to better understand the prevalence of these concerns and determine if market competition is being negatively impacted.**

1. Data lock-in

The AMA has found that data lock-in and barriers to transferring data across EHRs represent a critical concern for many physicians. The AMA recently sponsored a RAND study to characterize factors that

influence physician professional satisfaction.¹ Despite having no initial focus on EHRs, one of the key findings of the study was that, while nearly all of the physicians interviewed saw the benefits of moving from paper to electronic records, EHRs decreased professional satisfaction in many ways, including poor usability, time-consuming data entry, and the inability to exchange health information between EHR products and across care settings. The RAND study has a number of insightful vignettes from practicing physicians that we encourage FTC staff to read as we believe they may shed light on physician perspectives regarding EHRs.

While many factors can cause data lock-in, anecdotal evidence from our members and statements from panelists described cost as a key barrier. We know of physicians who incurred significant fees, upwards of thousands of dollars, to transfer data from one EHR product to another. Others stated that they were charged extra fees to set up portals or interfaces to facilitate data migration. Physicians who are seeking to purchase a new EHR and migrate their patient data may face significant expenses. These “switching costs” are in addition to the expenses incurred to purchase, train staff, and implement EHR systems. Altogether, expenses due to data lock-in may restrain competition and restrict physician choice in the EHR marketplace.

In addition to costs, technical barriers can also lead to data lock-in. Both highly customized systems or information that is not coded but stored as free text can prohibit data migration. Data stored within one EHR may not be compatible with another system, and vendors may only permit or be capable of data transfer across their own products. These barriers may compel providers to purchase EHRs from the same vendor to ensure data transfer despite a lack of satisfaction with the product and the opportunity to purchase a superior, more efficient, or less expensive product from another vendor.

Data lock-in is particularly concerning given that many physicians have signaled that they want to switch EHR systems. A survey conducted by Black Book Rankings found that approximately one in six medical practices considered switching their EHR vendor in 2013.² Others have little choice but to change EHRs, as vendors sunset certain products or decide not to seek Stage 2 Meaningful Use (MU) certification. In sum, physicians have compelling reasons to change their EHRs, but their choice may be limited due to data lock-in. The AMA is concerned that these limitations may incentivize providers to remain with their existing vendor or not consider other product choices.

2. Contract transparency

As highlighted by the panelists, another concern potentially hindering EHR market competition is the lack of transparency in EHR contracts. In particular, contract provisions may be unclear or fail to itemize specific expenses. The Office of the National Coordinator of Health Information Technology (ONC) addressed the issue of contract transparency in its 2014 EHR Certification Final Rule that required vendors to outline additional types of expenses, such as “one-time” or “ongoing,” that affect a product’s

¹ The RAND Corporation with Sponsorship by the American Medical Association. Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. October 2013. Available at http://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR439/RAND_RR439.pdf.

² Black Book Rankings. Electronic Health Record Sellers Face Make-or-Break Year of Client Ultimatums and Revolts, Reveals 2013 Black Book Survey. February 2013. Available at <http://www.prweb.com/releases/2013/2/prweb10416655.htm>.

total cost of ownership.³ Yet, the regulation only requires clarity in the types of costs that need to be disclosed, not the actual dollar amounts, leaving broad discretion and uncertainty.

Some vendor contracts also include “gag” clauses that limit physicians’ ability to expose problems with their EHRs, potentially including patient safety issues. We have heard that certain EHR contracts require multi-year terms that limit a provider’s ability to switch products. Furthermore, the EHR software terms and conditions may restrict physicians from using their EHRs for data sharing, such as with health information exchanges or accountable care organizations (ACOs).

The Electronic Health Record Association (EHRA) has sought to mitigate these contract issues through its voluntary Developer Code of Conduct. The Code explicitly states that products should, “enable our customers to exchange clinical information with other parties, including those using other EHR systems, through standards-based technology, to the greatest extent possible” and “work with our customers to facilitate the export of patient data if a customer chooses to move from one EHR to another.”⁴ The AMA supports this effort and encourages other practices that may ensure greater clarity and fairness for physicians.

3. Choice in the EHR market

Some small physician practices have reported that they have little choice when purchasing an EHR. Data from ONC shows that only five vendors are used by an estimated 52 percent of attesting physicians in ambulatory care settings.⁵ For EHRs to fully support patient care, a robust marketplace is needed. Yet, the market appears to be contracting further as the EHR MU program becomes more complex and onerous. As of March 2014, only 81 EHRs were certified for Stage 2, compared to 991 products that were available to physicians in Stage 1 of the program. In addition, the Certification Commission for Healthcare Information Technology (CCHIT), one of the most prominent entities tasked with certifying EHRs, announced in January that it was discontinuing their EHR certification service because so few vendors are seeking certification for Stage 2. As more products drop out of the EHR market, physicians may be compelled to purchase EHRs from the largest vendors, fearing that other companies may not continue their services. This may further limit competition and restrict consumer choice in the EHR market.

The AMA believes that physicians should have the ability to choose among EHRs and health information technology (HIT) products and identify those that work best for their clinical practice and their patients. Without robust choice in the EHR and HIT marketplace, physicians will continue to lack access to products that fit the needs of their patients and practice. We are concerned that certain specialties and sub-specialties are facing barriers to obtaining products that are tailored to their specific patient populations, as most products, following the MU program, are focused primarily on primary care. The AMA is also concerned that as the ONC expands beyond EHR certification to other products, other HIT markets may be similarly constrained if inflexible certification requirements are employed.

³ Office of the National Coordinator for Health Information Technology. Certification and EHR Incentives. Available at <http://www.healthit.gov/policy-researchers-implementers/certification-and-ehr-incentives>.

⁴ Electronic Health Record Association. EHR Developer Code of Conduct. June 11, 2013. Available at <http://www.himsssehra.org/docs/EHR%20Developer%20Code%20of%20Conduct%20Final.pdf>.

⁵ Conn, J. 5 EHR Vendors Lead Pack in Ambulatory-care Niche. Modern Healthcare. September 24, 2013. Available at <http://www.modernhealthcare.com/article/20130924/NEWS/309249937>. Accessed February 24, 2013.

In addition to the three concerns identified, the AMA also encourages the FTC to fully consider the environment and regulatory framework that impacts the EHR market and how vendors must tailor their products. While the MU program has facilitated widespread adoption of EHRs, it has done little to prevent, and may potentially exacerbate, a lack of competition among EHR vendors. The MU program has created an environment that encourages EHR vendors to “teach to the test” to meet strict certification requirements aimed at ensuring that physicians can meet the multitude MU program measures. This certification process, however, fails to focus on efforts to improve interoperability, facilitate patient care, and enhance the efficiency of delivering physician services to patients. In particular, the 2014 ONC certified technology criteria requires a comprehensive software upgrade for physicians from their 2011 version, directing vendor resources away from achieving other EHR improvements. The version 2014 software must support more than 125 MU requirements for physicians, which many vendors report involve a tremendous amount of complexity and time.

With market forces being driven primarily by a government mandate, physicians are worried that “walled gardens” (i.e., business practices that block data exchange) will persist and limit care coordination. For these reasons, the AMA continues to advocate for greater flexibility in the MU program requirements and a substantial overhaul of the certification process to allow for the development of innovative EHRs in a more competitive marketplace. We encourage the FTC to take into consideration the requirements and limitations of the MU program as the agency studies market concerns related to EHRs and HIT.

Professional Regulation of Health Care Providers

The AMA has identified the strategic goal of long-term medical practice sustainability and satisfaction through effective care delivery and payment. As part of the path to achieve this goal, the AMA is developing best practices for care delivery that improve outcomes and health, increase productivity, and save lives and money. Some of this work focuses on ways in which physicians may develop and implement practice tools to ease efficiency and workflow.

As previously mentioned, last year the AMA commissioned RAND Health to study factors affecting physician professional satisfaction and implications for patient care, health systems, and health policy.⁶ RAND interviewed and surveyed physicians, allied health professionals, and other staff in 30 practices across six states, including a variety of practice sizes, specialties, and ownership models.

One of RAND’s findings was that working with adequate numbers of well-trained, trusted, and capable allied health professionals and support staff was a contributor to greater physician professional satisfaction and practice sustainability. The report found that support from such staff enabled physicians to achieve a more desirable mix of work content. In particular, several study participants appreciated having a long-term relationships with allied health professionals and support staff, with some such relationships spanning decades. This work builds on academic literature which has suggested practice innovations that may address barriers to the relationship between physicians and patients, take advantage of the resources of the health care team, and improve care for patients.⁷

⁶ AMA-RAND. Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. October 2013.

⁷ Sinsky CA, Willard-Grace R, Schutzbank AM, et al. In Search of Joy in Practice: A Report of 23 High-Functioning Primary Care Practices. Annals of Family Medicine. May/June 2013.

Inherent in the RAND findings and the practice innovations suggested in the academic literature are the joint concepts of the health care team working together and every member of the team best utilizing his or her training and clinical expertise. **It is through this lens that the FTC's recent panel on occupational regulation and numerous advocacy letters regarding state scope of practice legislation are most troubling. Physicians and allied health professionals must work together as a team to deliver high value, quality, and accessible care to patients. Rather than focus on promoting independent practice, we urge the FTC to do a thorough environmental review of the ubiquity and success of the health care team model across our health care system.**

1. Team-Based care in practice

As the Institute of Medicine report on the Future of Nursing recognizes, such health care leaders as Geisinger Health System, Kaiser Permanente, and Intermountain Healthcare Medical Group are leading the way in aligning the roles of all members of the health care team, including advanced practice registered nurses (APRNs), in order to provide high value while improving quality and access to care. These organizations rely upon physician-led health care teams to ensure that services address patient needs.

On the physician practice level, recent studies have demonstrated that a redesigned, shared-care model of work distribution and responsibility can increase access to care by reducing waste and improving efficiency.⁸ Such literature has recommended the following potential solutions: (1) sharing clinical care among a team, with expanded rooming protocols, standing orders and panel management; (2) sharing clerical tasks with collaborative documentation (scribing), non-physician order entry, and streamlined prescription management; and (3) improving team functions through co-location, team meetings, and work flow mapping.⁹

For instance, many of the clerical duties that physicians have always performed, such as writing a note about each patient visit, take up more of the physician's time since introduction of the electronic health record. Physician practices have found that empowering staff such as medical assistants¹⁰ or scribes¹¹ to help document the office visit can markedly improve physicians' efficiency, increasing the time physicians spend interacting directly with patients and allowing physicians to manage a larger panel of patients.

⁸ Shipman SA, Sinky CA. Expanding Primary Care Capacity by Reducing Waste and Improving the Efficiency of Care. Health Affairs. 2013;32(11):1990-97.

⁹ Id.

¹⁰ Id.

¹¹ Bank AJ, Obetz C, Konrardy A, et al. Impact of Scribes on Patient Interaction, Productivity, and Revenue in a Cardiology clinic: A Prospective Study. ClinicoEconomics and Outcomes Research. 2013;5:399-406. (Finding a 57-59% increase in physician productivity and estimated \$5.4 million in savings from use of scribes in a cardiology clinic.) See also Arya R, Salovich DM, Ohman-Strickland P, et al. Impact of Scribes on Performance Indicators in the Emergency Department. Acad. Emerg. Med. 2010;17(5):490-494. (The use of scribes increased emergency department patients seen per hour by 0.8, and work RVUs generated per hour by 2.4.)

Similarly, research suggests lessening the administrative burdens associated with interacting with payers could reduce the estimated \$23-31 billion spent annually on these matters.¹² Further, relaxing institutional and state policies and rules for prescription renewals to allow for 12- to 15-month prescriptions for chronic conditions could save physicians an average of 30 minutes per day.¹³ These innovative strategies and care models have the added benefit of reducing physician burnout, increasing direct physician-patient interaction time, and improving professional satisfaction of all members of the health care team.¹⁴

These research and case studies indicate that efforts to empower non-physician clinicians within physician-led health care teams, combined with redesigned workflows and optimal use of technology, could yield additional time and resources necessary to offer patients millions of additional visits per year.¹⁵ Institutional, state, and federal policy should be aligned to support these dynamic and innovative models of care.

It is also of note that physician-led models of care have demonstrated significant cost savings. For example, preliminary data released by a physician-led medical home that is partnering with Blue Cross Blue Shield of Michigan showed \$310 million in savings since 2008, including \$155 million saved in 2012 alone.¹⁶ It is also notable that physicians supported 9,968,342 jobs nationally in 2012. Thus, physician-led health care teams present significant opportunities for innovation across the entire health care system.¹⁷

2. Complementary skills

In evaluating the potential benefits of flexible health care team utilization, the FTC should continue to recognize that allied health professionals and physicians have skills, knowledge, and abilities that are more complementary rather than equivalent.¹⁸ Physicians are educated and clinically trained over many

¹² *Id.* *Citing* Casalino LP, Nicholson S, Gans DN, et al. What Does it Cost Physician Practices to Interact with Health Insurance Plans? *Health Affairs*. 2009;28(4):w533-43.

¹³ Sinsky CA, Willard-Grace R, Schutzbank AM, et al. In Search of Joy in Practice: A Report of 23 High-Functioning Primary Care Practices. *Annals of Family Medicine*. 2013;11(3):272-78. *See also* Shipman 2013.

¹⁴ Sinsky 2013. *See also* Shipman 2013.

¹⁵ Shipman 2013.

¹⁶ Paustian ML, Alexander JA, El Reda DK, et al. Partial and Incremental PCMH Practice Transformation: Implications for Quality and Costs. *Health Services Research*. 2013;1-23. *See also* Patel K, Nadel J, West M. Redesigning the Care Team: The Critical Role of Frontline Workers and Models for Success. Engelberg Center for Health Care Reform at Brookings. March 2014. (Demonstrating savings of \$200 per appointment through expanded use of medical assistants, along with demonstrable improvements in hospital readmissions, patient health outcomes, and patient satisfaction.). *See also* Blackmore CC, Edwards JW, Searles C, et al. Nurse Practitioner-Staffed Clinic at Virginia Mason Improves Care and Lowers Costs for Women with Benign Breast Conditions. *Health Affairs*. 2013;32(1):20-26. (Finding “substantial improvements in care timeliness and efficiency” as well as an estimated direct cost savings of 19 percent of following implementation in a physician-led integrated health center, of a breast clinic based on the use of APRNs for the care of women with symptomatic breast complaints.).

¹⁷ IMS Health. National Report: The National Economic Impact of Physicians. March 2014. Available at <https://download.ama-assn.org/resources/doc/arc/x-pub/economic-impact/us-study.pdf>.

¹⁸ Federal Trade Commission. Competition and the Regulation of Advanced Practice Registered Nurses. March 2014.

years to provide the complete array of differential diagnoses, develop a treatment plan that addresses multiple organ systems, and order and interpret tests within the context of a patient's overall health condition. Physicians' exposure to surgical and other invasive procedures also help inform their care for patients with complex medical needs.

In contrast, APRNs, for example, receive education and training which is more focused, either on primary care (usually of particular populations) or specialty areas (such as psychiatric care or cardiology). APRNs in primary care possess a background that is particularly suited to caring for patients who need basic preventative care or treatment of straightforward acute illnesses and previously diagnosed, uncomplicated chronic conditions. While there is little research on the ability of APRNs to independently manage patients with complex and undifferentiated medical problems, their place in the health care team is absolutely essential.¹⁹

In recognition of the success of team-based care, states have recently passed laws which address systemic challenges to access to care and preserve physician leadership of the health care team. For example, in 2012 Virginia redesigned the physician-nurse practitioner relationship to allow for increased APRN prescriptive authority, and more flexible guidelines for team-based care in hospitals and physician practices.²⁰ And in 2013, Texas revamped its state laws governing physician supervision of nurse practitioners (NPs) to allow flexibility in group practices that utilize multiple APRNs, and ease rules governing quality assurance and prescriptive authority.²¹ These state legislative trends support a team-based, physician-led model of care that encourages dynamic, innovative, patient-centered care teams.

3. Licensure

The FTC panel discussed the concept of licensure at some length. As the FTC has recognized, licensure serves an important function in health care, as consumers face serious risks if they are treated by unqualified individuals, and laypersons may find it difficult, if not impossible, to adequately assess quality of care at the time of delivery.²² Both federal and state governments have been entrusted to ensure that individuals providing health care services are academically qualified, have completed the necessary training, and are constantly evaluated for their clinical acumen.

Indeed, every licensed health care profession recognizes the importance of patient safety by actively engaging in ensuring that unlicensed or improperly licensed individuals are not permitted to perform the services and procedures within that profession's scope of practice. In that vein, occupational regulations that require the successful completion of a rigorous academic program, prescribed years of post graduate training, national certification, and continuous certification of both academic and performance competencies are necessary steps to ensure that consumers of health care services have confidence that the licensed health care professional can provide competent, safe care.

¹⁹ However, a recent study suggests that using NPs to care for complex patients may actually drive up the cost of care due to inappropriate referrals to tertiary care settings. Lohr RH, West CP, Beliveau M, et al. Comparison of the Quality of Patient Referrals from Physicians, Physician Assistants, and Nurse Practitioners. Mayo Clinic Proceedings. 2013;88(11):1266-71.

²⁰ Virginia House Bill 346, 2012 Regular Session (2012).

²¹ Texas Senate Bill 406, 83rd Legislature (2013).

²² Federal Trade Commission. Competition and the Regulation of Advanced Practice Registered Nurses. March 2014.

The AMA supports the use of patient-centered, team-based patient care in which physicians and other health professionals work together, sharing decisions and information, for the benefit of the patient. In particular, the AMA believes that physician-led health care teams can achieve the triple aim by optimizing such functions as prevention, population management, care coordination, and the avoidance of unnecessary referrals, procedures, emergency department use and hospitalizations. **We urge the FTC to examine the prevalence and success of health care teams in innovative, integrated health care systems and physician practices alike. The FTC should avoid promoting independent practice or critiquing state-based licensure. We think the better course is to support physician-led, team-based solutions to the nation's growing workforce needs.**

Telemedicine

The interest in telemedicine (also often referred to as “connected health”) among state and federal regulators, lawmakers, physicians, allied health professionals, and telecommunication and technology companies has grown rapidly over a relatively short period of time. Current telecommunication technologies have been touted as: (1) ameliorating provider shortages; (2) increasing access to medical care while improving affordability for geographically remote and underserved populations; and (3) over time reducing health care costs. It is widely expected that the broad-range of new technologies that support or enable medical practice will only continue to grow. There is increasing support among policymakers and early adopter physicians to modify or alter mechanisms that safeguard patient safety in order to permit utilization of technologies used commonly and reliably in other service sectors of the economy. The AMA is in the process of a comprehensive review of the foregoing considerations and the challenges to ensure that such telecommunication technologies are implemented in a manner that protects patient safety and promotes improved patient health outcomes. The diversity of telecommunication technologies, clinical practice settings, and medical specialties, along with the rapid rate of innovation, are factors that should be carefully weighed by policymakers.

In brief, there are broad considerations that the AMA urges policymakers to consider.

1. Patient safety (consumer protection)

The relationship of trust between the patient and physician has long been understood as foundational to ethical practice in medicine. AMA policy stresses that such relationships must be predicated on: open and honest communication between the physician and the patient, including disclosure of all information necessary for the patient to be an informed participant in his or her care; commitment of the physician to be an advocate for the patient and for what is best for the patient, without regard to the physician's personal interests; provision by the physician of that care which is necessary and appropriate for the condition of the patient and neither more nor less; and avoidance of any conflict of interest or inappropriate relationships outside the therapeutic relationship.

The AMA supports state-based medical licensure because it protects the interests of patients and the ability of states to enforce state medical practice laws. Specifically, state licensure is the mechanism by which medical practice laws are enforced, including minor consent laws and reproductive and end of life medical practice laws, for example. Without state licensure a physician could disregard medical practice laws of another state where a patient is located since this state would not be in a position to compel compliance with its medical practice laws. Furthermore, patients and other health care providers from other states who become involved in litigation would have significant burdens resolving conflicts of law

as it would not be clear which applicable state laws of medical practice, standards of care, or medical liability apply.

As an alternative to state-based licensure, national licensure would be costly, complicated, and time-consuming. We need look no further than programs setup on a national scale in the recent past requiring physician and provider enrollment in Medicare. It could be years before such an infrastructure is designed and implemented and likely would be subject to legal challenges. Instead, solutions that focus on modernizing current state licensure processes are strongly supported by the AMA. In fact the Federation of State Medical Boards (FSMB) is already developing a model compact for licensure, which may offer a very important mechanism to facilitate licensure in the context of telemedicine as well as resources to further modernize the licensure application process.

2. Promoting patient centered care and care coordination

The AMA urges policymakers to promote telemedicine that will support care delivery that is patient centered, promotes care coordination, and facilitates team-based communication. Related to the foregoing, we urge policymakers to support telemedicine that promotes interoperability of systems, products, and platforms—or minimally portability of data. Telemedicine should be consistent with and serve as infrastructure for new value-based accountable care delivery models, and without data portability, new telemedicine models—particularly outpatient care—may further fragment care and create additional silos instead of building medical neighborhoods of collaboration. Promoting patient care coordination through medical home and accountable care models will become achievable where data portability and interoperability are promoted in the context of telemedicine. The foregoing is more likely where telemedicine technologies are used to extend the capacity and reach of physicians and health care practices and systems in the community where a patient resides. Alternatively, such care coordination and new delivery models will become more difficult to implement if new telemedicine platforms and options create barriers to engagement with a patient’s treating physicians, medical home team, and neighborhood.

3. Evidence base and clinical standards of care

Policymakers should also increase support for further development of research and evidence regarding the impact telemedicine has on quality and costs. There is a developing body of research on an array of telemedicine technologies and services, but the evidence base in some areas does not exist or is limited. As the technologies proliferate and the medical services that are covered expand, there will be increasing pressure to ensure that there is a clinical evidence base to support new applications, and uses are safe and efficacious. Research has moved from demonstrating the technology works and is functional to evaluating the comparative effectiveness of services offered through telecommunication modalities as compared to in-person services.

Telemedicine is not a separate medical specialty. Standards of care for telemedicine/telehealth services in some areas are well-established, but in many other areas remain a work in progress where a number of pace setting specialties have been very involved in developing relevant clinical practice guidelines. National medical specialty societies continue to develop clinical guidelines or position statements relating to telemedicine and telehealth—these include the American College of Radiology, American Academy of Dermatology, American Psychiatric Association, and Society of American Gastrointestinal and Endoscopic Surgeons, for example. The AMA is engaging both national specialty and state medical

societies concerning practice guidelines as well as policies broadly governing telemedicine and expects more activity in this area.

Measuring and Assessing Quality of Health Care

The AMA is committed to helping physicians provide the highest quality of care to patients. As the nation's health care system continues to evolve, the AMA is dedicated to supporting sustainable physician practices that result in better health outcomes for patients. This work is captured in the AMA's five-year strategic plan, which emphasizes three core areas of focus: improving health outcomes; accelerating change in medical education; and enhancing physician satisfaction and practice sustainability by shaping delivery and payment models.

In recognition of physicians' professional responsibility to provide quality health care, the AMA began developing physician performance measures in 1998, and in 2000 convened the Physician Consortium for Performance Improvement® (PCPI®). The PCPI develops, tests, implements, and disseminates evidence-based measures that reflect the best practices and best interests of medicine. The PCPI also works with outside organizations to advance the science of performance measurement, utilize PCPI measures in public and private reporting programs, and define the appropriate use of data to evaluate and guide improvement in practice. Over the next year, the PCPI will create an outcomes toolkit for PCPI member organizations to support their ability to identify both leading outcomes relevant to their patient population(s) and a pathway to collect outcomes data. The PCPI also plans to promote broad access to outcomes information created by its member organizations.

Measure development and implementation, however, are costly endeavors, and without substantial resources it will be difficult for quality measurement to continue evolving. We offer below some examples of the complexities surrounding quality measurement for the FTC to be thinking about as it reviews potential competition issues in this space.

1. Misaligned federal programs

Medicare currently has three individual quality reporting programs that apply to physicians today: the Physician Quality Reporting System (PQRS); Value-Based Payment Modifier (VBM); and EHR Incentive Program. Each program was created by a separate statute, and has its own unique set of detailed reporting requirements, corresponding incentives and penalties established in law. But there exist untapped opportunities to align the requirements in a manner that ensures greater consistency among the various programs.

For example, the quality reporting measures established under PQRS vary from those that physicians must meet in order to be a "meaningful user" of a certified EHR within the EHR Incentive Program. The result is a reporting burden so substantial that many physicians find it impossible to comply with these requirements, and have elected instead to suffer the consequences, including penalties. The unfortunate result is a rather low level of physician participation in both PQRS and the EHR Incentive Program.

Enhanced program alignment would greatly reduce the administrative burden on physicians and other providers. Many of the PQRS quality measures are not available in the EHR Incentive Program. A physician may receive credit under both PQRS and the EHR Incentive Program's quality reporting requirements by submitting electronically specified MU quality measures through certified EHR

technology. However, the EHR Incentive Program has more restrictive and less flexible reporting requirements, and a more limited number of measures than PQRS. Furthermore, submission through certified EHR technology is not an option for the many physicians whose EHR systems do not meet certification standards.

The burden is even greater for the many specialists who have few quality measures to select from in the EHR Incentive Program. These physicians have no choice but to dually (and separately) report under both programs in order to avoid penalties or receive incentives. In addition, there is less transparency with respect to the inclusion of new quality measures, and less frequent updating of measures, in the EHR Incentive Program. In contrast, PQRS has a clearly spelled out pathway and timeline for including new measures within its program and allows for regular updates of measures and measure specifications. PQRS measures are updated on a yearly basis, unlike those for MU.

Furthermore, the timelines for reporting periods do not align. Currently, PQRS uses a 12-month reporting period. The EHR Incentive Program is 90 days for the first year (Stage 1) and 12 months thereafter. However, regardless of participation, physicians only have to report for 90 days in 2014.

2. Inconsistency among payers

Private insurers currently have physician pay-for-performance (P4P)/quality programs that compete with, and differentiate from, the extensive Medicare quality programs. Each insurer seems to have its own quality measures with different requirements and its own report card. Having to manage multiple programs is extremely costly and resource intensive for a physician practice, and makes it very difficult for a practice to focus on quality improvement. In addition, with varying methodologies for measuring quality, it is possible for a physician to have high quality marks under one plan and poor marks under another. Private insurers should also not be able to use proprietary “black box” measures; often insurers use proprietary measures, making it nearly impossible for a practice to fully analyze the measure specifications or have an understanding for how the insurer is measuring them. If tiered as a poor provider in such an arbitrary system, a physician or practice runs the risk of being kicked out of a network and patients potentially have less access to health care services and higher out of pocket costs. Prior to taking punitive action, an insurer should undertake efforts to assist physicians. P4P or quality programs must also take into consideration various specialties and group practice sizes. Taking a one-size-fits-all approach is an ineffective strategy to improve health care quality and promote innovative and more efficient health care delivery programs.

One of the biggest challenges we are finding is the ability of small practices to have both sufficient resources and patient sample size to implement and manage quality improvement plans within their practice. Many small practices have an insufficient number of patients to support the hiring of specialized staff to address particular patient needs, improve quality of care, and avoid costly services outside the practice. However, multiple small practices can work together to support these specialized resources.

Many small practices also do not have enough patients to justify hiring staff to collect extensive information for quality reporting. They find it particularly difficult to analyze data on their patients from multiple sources (e.g., multiple health plans), in multiple formats, and with differing performance standards unique to each payer. Medicare and other payers can help by minimizing the administrative burden of data collection and reporting requirements by aligning its data reporting systems and quality measures among payers.

Small practices also have difficulty participating in new payment models that are structured in ways that favor large practices. For example, in its shared savings programs, the Centers for Medicare & Medicaid Services (CMS) has established larger minimum savings thresholds for smaller providers than for larger providers, and in its Comprehensive Primary Care Initiative, CMS has made it impossible for an individual practice to obtain shared savings, no matter how well it performs, unless all of the practices participating in the program across the state or region have performed at higher-than-minimum levels. Going forward, it will be critical for payers to allow more flexibility in their reporting requirements and to test delivery and payment innovations that allow small, independent practices to clinically align in ways that protect their autonomy.

3. Care coordination

In an effort to address care coordination loopholes, the AMA-convened PCPI has initiated a performance improvement project to address physician-to-physician referrals in the ambulatory setting by establishing accountability standards and improving information transfer. This project, *Closing the Referral Loop (CRL)*, aims to achieve higher satisfaction and understanding of the referral among patients and physicians. Objectives of the CRL project include:

- Test a model for quality improvement spread that includes “intermediate” organizational support for projects (e.g., state model);
- Build collaborative relationships with organizations that have improvement expertise and infrastructure that complements PCPI’s capability;
- Develop more “closing the referral loop” experts and build a learning community;
- If the pilot project is successful, expand the CRL project with external funding;
- Share learning through PCPI, AMA, and external partners’ communication channels; and
- Assess the PCPI’s role as a stimulator of quality improvement at the national level.

4. Risk adjustment crucial

Quality measures, especially those evaluating outcomes, must incorporate risk adjustment that accounts for socioeconomic status (SES) and other demographic factors. Lack of adjustment can lead to inaccurate and misleading conclusions about quality and performance measurement. This could, in turn, lead to increases in disparities in health care. A simple examination of performance scores without adjustment for patients’ SES and/or socio-demographic situation ignores a number of factors that are known to influence quality and cost of care. For example, SES and cultural status can affect health status, impede ideal communication between the patient and the physician, and hamper the patient’s desire and/or ability to follow a given treatment plan. To ignore these factors could lead to the conclusion that physicians and practices that serve low income patients provide lower quality care than those serving high income patients, when the difference in scores could actually be due to differences in patient mix rather than differences in quality of care provided. To hold physicians accountable if outcomes differ for these patients, without accounting for the factors that contribute to that difference, would unfairly penalize physicians for things outside of their control. Also, if performance measures are not adjusted for demographic factors, physicians may be hesitant to treat low income patients which could result in increased disparities of care. In addition, disadvantaged patients often require more resources for physicians to properly treat since these patients may enter the health system with more unaddressed health problems, are more likely to have multiple chronic conditions, and require additional physician effort both at their initial visits and follow-up care.

Medicare's current VBM methodology, which calculates resource use, patient outcomes, and the "value" of a service to an individual patient, does not accurately reflect patient, provider, and community differences in a meaningful way. This is true at the level of the hospital, region, individual physician practice, and individual patient. For this to occur, additional work is needed to develop a more granular specialty list, refine the specialty mix adjustments, complete a robust Medicare-specific episode grouper, and develop and pilot cost measures appropriate for use at the physician level to replace current measures designed for use at the population or hospital level.

Price Transparency of Health Care Services

The AMA is a strong advocate for transparency and believes that physicians, patients, and their families should have access to information about the price and quality of their care. In support of providing information about health care services, the AMA has recognized and championed many transparency efforts, including promotion of model state legislation to establish health care payment standards, direct advocacy with health plans to improve cost transparency, education for physicians regarding the importance of health care payment data, and promotion of the Qualified Entity (QE) program and clinical data registries that seek to disseminate information on the quality and cost of health care. We believe more can and should be done to share health care data and stand ready to work with policymakers on innovative ways to provide meaningful information to patients and providers.

We also strongly agree with panelists' statements that price transparency without the appropriate context and quality information can be misleading and may have unintended consequences on health care choices and competition. Current data release efforts have provided information in dense, complex formats that fail to recognize data limitations or the potential for misinterpretation. In an effort to clarify and improve transparency efforts, we are outlining a number of the key barriers and potential unintended consequences if price information is not provided in a meaningful manner. **We hope that the FTC and others can use this information to improve future transparency efforts so that more timely, accurate, and useful data are provided to patients, physicians, and other stakeholders.**

1. Barriers to price transparency

One of the barriers to price transparency as highlighted by the panelists is a lack of consensus on what is meant by "price." Unlike other markets, the price of health care services may be interpreted to mean the amount charged, the reimbursement rate, the provider's income, or the beneficiary cost-sharing amount. Without a clear understanding of what kind of price information will be beneficial to inform care choices we expect there to be continued confusion and incorrect conclusions.

A clear example of this problem is the recent release of Medicare physician charge data by CMS. This data included physician charge information that does not represent the final amount of money earned by a physician, does not define reimbursement rates, and has no bearing on the amount charged to a beneficiary. Yet, we have seen this information misused by reporters and other entities to convey information about the price of care. The AMA believes that these charge data are misleading and confusing and will not help guide patient and physician care choices.

Because of the likelihood of misrepresentations, the AMA recommends that the release of price or other physician data should adhere to certain safeguards to help ensure information that is accurate and useful. Key to these safeguards is providing physicians with the opportunity to review and

correct their information so that the data are accurate. Data in any format are typically not perfect, and we believe that incorrect information will simply not improve understanding about health care services.

Similarly, the AMA believes that transparency is twofold—it requires not only access to the data but understanding the scope, context, and limitations of the information. While each data set is likely to be different, the AMA has identified aspects of physician data that if not understood may confuse and lead to inaccuracies or misinterpretations. Specifically, from the recent release of Medicare claims data, the AMA has identified the following data limitations:

- **Quality** – data that lack explicit information on quality of care provided or quality measurement should not be used to evaluate the value of care provided. Such data solely focus on payment and utilization of services without consideration of health outcomes.
- **Attribution** – data organized by National Provider Identifier (NPI) may fail to recognize that residents, physician assistants, nurse practitioners, and others under a physician’s supervision can all file claims under the provider’s NPI. Without modifiers to explain who is actually performing the service, it may appear that a provider is billing more services than possible or the data may attribute services to a provider when they were actually only assisting in a procedure.
- **Charges vs. Payment** – Medicare charge data are not an accurate portrayal of payment. Medicare and other payers pay fixed prices for services based on fee schedules and the amount paid to a physician is generally far less than what was initially charged.
- **Site of service** – data may fail to include facility fees, which are an additional costs for services provided in a hospital or outpatient department and often result in higher Medicare payments when compared to the same service in the physician’s office.
- **Patient population** – data may not be risk adjusted and therefore may fail to explain variances for more severe patients that require more complex treatments.
- **Specialty descriptions** – data may over generalize different specialties and practice types, which could be misleading when trying to make apples-to-apples comparisons between physicians.
- **Missing information** – the data could be an incomplete representation because they do not include data for other payers, including private insurance and Medicaid, that may represent the majority of a provider’s patients.
- **Cost of drugs** – if price data include the costs of drugs they may fail to explain that the total payment is to compensate for the price of the drug itself, many of which are very expensive and are required to treat such serious conditions as cancer and macular degeneration, and are not profits for the physician.
- **Coding and billing changes** – any analysis using the data should take into account changes in Medicare's coding and billing rules that may be different over time and across regions of the country (e.g., local coverage determinations).

The AMA encourages efforts to improve CMS’ current data release to more accurately and effectively provide information to patients and consumers. Data divorced from their context are not transparent and may undermine efforts to understand this information. Rather than focusing on simply providing access, we support more meaningful efforts, such as those being promoted by clinical data registries and QEs, that tie quality information to payment data, providing a more comprehensive and granular picture of health care.

2. Potential unintended market implications of price transparency

Given that the price information may easily be misconstrued or misinterpreted, the AMA is concerned that existing price data may not improve care competition but may have unintended consequences. Rather than driving down costs and improving care quality, the data could create perverse incentives. For example, the recent release of physician Medicare claims data has highlighted certain providers as outliers, suggesting they are not cost-efficient. In fact, this information has been shown to be inaccurate and at times has falsely identified providers that are providing the highest quality of care for patients.

We are also concerned that payers and other entities may use the information to establish narrow provider networks in an effort to control costs. If, however, the data are inaccurate or misinterpreted, those excluded for being “outliers” may actually be providing high quality care that is entirely appropriate and cost-effective for their patient population. Evidence from past experiences in the Medicare Advantage market shows that narrow networks can disrupt long-established patient-physician relationships, interfere with existing physician referral networks, and undermine the adequacy of available subspecialists. Ultimately, tools based on inaccurate data to create tiered or narrow provider networks may ultimately drive costs up and lead to lower quality care.

In addition, the AMA believes that publishing physician charge data may disadvantage their ability to negotiate rates with private payers. With this information, payers can easily dictate contract terms and prices. Physicians are further disadvantaged because the data release are one-sided—it highlights what physicians charge without any detail or transparency on private payer rates. Without this information, physicians’ ability to contract and engage in meaningful negotiations may be eroded.

Finally, the impact price transparency will have on reducing costs is not entirely clear. Panelists highlighted that cost data may lead physicians to review their rates to align with competitors but also cautioned that in some cases there may be an incentive to not lower but raise prices. This is more likely if high rates are also thought to be associated with higher quality, which again underscores the need for price information to be combined with quality data so that a more accurate picture of care is described. We also understand that the data may be used to combat fraud and abuse. The limitations of the data suggest that many of these efforts may incorrectly target physicians, wasting resources instead of saving them. Further, unguarded access to the data may also facilitate fraud, since information on services, charges, and the provider’s NPI could be easily misappropriated by others.

More research is needed to understand what type of pricing information patients, employers, and providers need to improve health care decision-making. In particular, physicians participating in new delivery programs, such as the Medicare Shared Savings Program, are increasingly held accountable for the cost and quality of their care and are seeking data to inform their health care choices. Yet, for these models to be a success, physicians need to be able to look at outcomes, identify shortcomings in practice processes, and see where costs can be better managed in real time. The AMA believes that the release of raw claims data will not provide this much needed information. Even with this data physicians do not have real-time information about their patients, lack data from other payers, and remain unable to determine if they have participated successfully in quality reporting programs until several months after the reporting period has ended. Instead, efforts should focus on providing this key information so that advancements in the delivery of health care services can be achieved. **We suggest the FTC monitor how price data are being used, and by whom, to determine the impact on improving health care quality and encourage more innovative and beneficial transparency efforts.**

Payment and Delivery Reform

In the last panel of the workshop, some panelists offered their thoughts on health care competition issues related to payment and delivery reform. These issues are of particular interest to physicians, many of whom are engaged in practice transformation as new health care payment and delivery models evolve. These transformational efforts often entail physician-driven clinical integration that necessarily requires significant physician investments in time and money for acquiring the necessary infrastructure and for coordinating and integrating other providers throughout the care continuum.

It is through this lens that the AMA views antitrust policy and law; we encourage the FTC to strike the right balance between allowing collaborations and innovations amongst physicians and other care delivery partners, and monitoring market developments that may preclude physician engagement in new models. We were encouraged by the FTC and the Department of Justice's work on Statement of Antitrust Enforcement Policy for ACOs in the Medicare Shared Savings Program.

In regard to the panelists' comments on health care market consolidation, we urge the FTC to examine mergers individually, taking into account the case-specific variables of market power and patient needs as determined, in part, by physician input. It is important that health care markets should be sufficiently competitive to allow physicians to have a choice for admitting patients and to have practice options.

Moreover, physicians should be able to engage in new clinically integrated health care delivery models such as ACOs without the necessity of being acquired or employed by a health care system. Accordingly, we ask that the FTC take a flexible approach in its evaluation of physician-driven collaborations. Finally, because physician driven delivery models are often smaller and more vulnerable to anticompetitive market foreclosures than are hospitals, the competition generated by physician driven clinical integrations may have a special need for antitrust protection.

We are also cognizant that the growth rate and scale of hospital employment of physicians will create new issues for physicians related to patient care, such as oversight of quality and resource utilization. The outcome for patients as consumers may be positive or negative, depending upon how the relationship between hospitals and employed physicians evolves. In any event, we believe that strong physician leadership in these systems is essential to meet cost, quality, and patient experience goals.

We noted that some panelists expressed concern with provider lock-in via EHRs; however, we have not observed this as a key barrier for physicians who seek to move into or out of new delivery models or arrangements. Instead, the interoperability of disparate systems and the ability to exchange data to promote care coordination remain a challenge. Moreover, the availability of alternative practice opportunities and agreements not to compete are higher bars for physician mobility in the marketplace. Upfront costs for physicians to participate and lead ACOs can be prohibitive. Importantly, these costs include the price to purchase and maintain an EHR and other HIT. For that reason, the AMA supports the ability of hospitals and other entities to donate EHRs, and would have serious concerns about any constraints on such donations.

Going forward, we continue to be interested in the question of how current antitrust guidance and enforcement fosters or prohibits physician leadership and participation in new care arrangements. We are cognizant that there is a diverse range of barriers for physicians in this space—including access to infrastructure, appropriate data, etc.—and are taking a holistic view in terms of our advocacy. At the

The Honorable Edith Ramirez

April 30, 2014

Page 17

same time, we want to be sure that we are responsive to obstacles that physicians are facing, and may identify areas in the future through our work with physician practices where additional antitrust guidance is needed.

Conclusion

We appreciate the opportunity to comment on the FTC's *Examining Health Care Competition* workshop. We look forward to continuing our work with the FTC on these important issues. If you have any questions about our comments or work on these issues, please contact Cybil Roehrenbeck, JD, Federal Affairs, at (202) 789-8510 or cybil.roehrenbeck@ama-assn.org.

Sincerely,

James L. Madara