AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Mike Kelly
U.S. House of Representatives
1707 Longworth House Office Building
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The Honorable Markwayne Mullin
U.S. House of Representatives
1113 Longworth House Office Building
Washington, DC 20515

The Honorable Ron Kind
U.S. House of Representatives
1502 Longworth House Office Building
Washington, DC 20515

The Honorable Ami Bera, MD
U.S. House of Representatives
1431 Longworth House Office Building
Washington, DC 20515

Dear Representatives Kelly, Kind, Mullin and Bera:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to provide our views on innovative policy ideas that improve the quality of care and lower costs for patients. We commend the Health Care Innovation Caucus in its efforts to explore and advance successful, innovative payment models as well as the technologies needed to support the models.

As emphasized in the AMA's recent advocacy efforts and letters to the Administration, we believe in order for physicians to successfully move to a value-driven system, Congress and the U.S. Department of Health and Human Services (HHS) must work together to ensure there are sufficient alternative payment models (APMs) available. Today, most physicians still do not have the option of participating in APMs. We look forward to having the Center for Medicare & Medicaid Innovation (CMMI) continues to analyze and ultimately put in place the innovative models designed by physicians and recommended to the HHS Secretary by the Physician-Focused Payment Model Technical Advisory Committee (PTAC).

The AMA would be happy to provide further detail on any of our responses below, and we look forward to working with the Health Care Innovation Caucus to ensure there are innovative APMs available for physicians in all specialties and practice sizes.

Value-Based Provider Payment Reform

What barriers in each of the following areas limit the full potential of innovation in Medicare and Medicaid?

Fraud and Abuse Laws

The AMA believes that the Anti-Kickback Statute, the Physician Self-Referral Law (also known as the Stark Law), and the Civil Monetary Penalties Law (hereinafter "fraud and abuse laws") severely limit the full potential of innovation in Medicare and Medicaid. Modernizing these laws would help promote choice, competition, and innovative arrangements that pose little risk of fraud and abuse. We urge

Congress and the Administration to examine ways to modernize existing laws and requirements to reflect a more coordinated approach to delivering care while not limiting choice and competition.

Significant changes in health care payment and delivery have occurred since the enactment of Stark. Numerous initiatives are attempting to align payment and coordinate care to improve the quality and value of care delivered. Delivery of care is going through a digital transformation. However, the fraud and abuse laws—in their 30 to 40 years of existence—have not commensurably changed.

These laws were enacted in a fee-for-service world that provided compensation on a piecemeal basis for each face-to-face service that patients receive. The fraud and abuse laws act as a deterrent against overutilization, inappropriate patient steering, and compromised medical judgment with heavy civil and criminal penalties such as treble damages, exclusion from participation in federal health care programs, and potential jail time. The health care system is moving to a world that rewards the delivery of medical care to patients in a more holistic way and considers the outcome of the care provided. An important focus of payment reform is changing payment models to emphasize the value or quality of care provided. However, this emphasis can run afoul of the fraud and abuse laws. For example, even if the primary purpose of an arrangement is to improve patients' health outcomes, as long as one purpose of the arrangement's payments is to induce future referrals, the fraud and abuse laws are implicated (e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient's care between a hospital, physician specialists, and a primary care physician may induce future referrals to the primary care physician to avoid an unnecessary readmission to the hospital).

Fostering the shift to APMs has necessitated reviewing and, in some situations, updating fraud and abuse laws to ensure that they do not unduly impede the development of value-based payment. Through specific statutory authority, both the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General have deemed it necessary to waive the requirements of certain fraud and abuse laws to test the viability of innovative models that reward value and outcomes.

Outside of those models, however, the fraud and abuse laws may still pose barriers to initiatives that align payment with quality and improve care coordination. Tying compensation to the value of care provided, equipping providers with tools to improve care, and investing in tools to clinically and financially integrate all of these may run afoul of these laws. For example, it remains unclear how CMS will view measures that promote value given its long-standing belief that rewarding physicians for meeting utilization targets or for reducing or limiting services generally violates Stark.[1]

Accordingly, the AMA has urged Congress and the Administration to create an anti-kickback safe harbor and a Stark exception to facilitate coordinated care and promote well-designed APMs. This exception should be broad, cover both the development and operation of a model to allow physicians to transition to an APM model, and provide adequate protection for the entire care delivery process to include downstream care partners, entities, and manufacturers who are linking outcomes and value to the services or products provided.

[1] 69 Fed. Reg. 16054, 16088 (Mar. 24. 2004); 72 Fed. Reg. 51052; 51046 (Sept. 5, 2007).

Physician leadership in these new efforts is instrumental to optimizing care, improving population health, and reducing costs. Physicians provide the care, take care of the patients, and see the cost inefficiencies and overutilization. Physicians should not have to be employed by a hospital or sell their practice to a hospital in order to participate in innovative delivery models. Ultimately, physicians should be able to maintain their independent practice while at the same time have access to the infrastructure and resources necessary to participate in APMs.

Certificate of Need

State certificate of need (CON) laws limit the full potential of innovation. By restricting the entry of competitors, especially physician-owned facilities, CON laws have weakened the markets' ability to contain health care costs, undercut consumer choice, and stifled innovation. Numerous studies have shown that CON laws have failed to achieve their intended goal of containing costs. Instead, CON has taken on particular importance as a way for community hospitals to claim territory and to restrict the entry of new competitors.[2] Consequently, CON laws lead to higher health care costs without improving health care quality.[3]

Community hospitals use CON to block the entry of freestanding, physician-owned facilities such as Ambulatory Surgical Centers (ASCs), which are a competitive threat. This is unfortunate because ASCs, as a class of providers, have been found in numerous studies of quality to have complication rates that are low and patient satisfaction that is high.[4] Also, another study published in *Health Affairs* concluded that ASCs "provide a lower-cost alternative to hospitals as venues for outpatient surgeries."[5] Physicians participating in Accountable Care Organizations and/or other value-based reimbursement programs could lower their costs, improve their quality, and become more competitive in the marketplace if they did not have to turn to their community hospital competitors for facility services. Physicians should have the ability to better control facility costs and supervise the overall health care product sold.

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[2] *Id.;* Gaynor, Mostashari and Ginsberg, *Making Health Care Markets Work: Competition Policy for Health Care*, Carnegie Mellon University/Center for Health Policy, Brookings/USC Schaeffer Center for Health Policy and Economics (April, 2017) at 23 available at https://www.brookings.edu/research/making-health-care-markets-work-competition-policy-for healthcare/?utm_ campaign_=Economic%20Studies&utm_ source=hs_email&utm_ medium=email&utm_content= 50778822 (hereinafter "Brookings Competition Report'); Tracy Yee et al., *Health Care Certificate-of-Need Laws: Policy or Politics,* Research Brief 4, National Institute for Health Care Reform (May 2011).

[3] Mitchell, M. & Koopman, C. (2016), *40 Years of Certificate-of-Need Laws Across America*, Mercatus Center, George Mason University, available at https://www.mercatus.org/publication/40-years-certificate-need-laws-across-america; Stratmann, T., & David Wille, D. (2016), *Certificate-of-Need Laws and Hospital Quality*, Mercatus Center, George Mason University, available at https://www.mercatus.org/publications/certificate-needlaws-and-hospital-quality; Rivers, P. A., Fottler, M.D., & Frimpong, J.A., *The Effects of Certificate-of-Need Regulation on Hospital Costs*. Journal of Health Care Finance 36(4), 1–16 (2010); Ginsburg, P. B., *Wide Variation in Hospital and Physician Payment Rates Evidence of Provider Market Power,* Center for Studying Health System Change. HSC Research Brief No. 16. 94 (2010).

[4] *See* L. Casalino et al, *Focused Factories? Physician-owned Specialty Facilities*, Health Affairs 22(6): 56-67 (2003).

[5] *See* Munnich and Parente, *Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up*, Health Affairs 33(5): 764-769 (2014).

Physician-Owned Hospitals

The ban on physician-owned hospitals[6] is a barrier that limits the full potential of innovation in Medicare and Medicaid. The AMA believes physician-owned hospitals should be allowed to compete equally with other hospitals in the delivery system. Limiting the role of physician-owned hospitals only reduces access to high quality health care for patients. Physician-owned hospitals are a benefit to patients and their communities and represent the type of coordinated care that is needed for the future of health care delivery. Providing patients with more choices for health care services and coverage stimulates innovation and incentivizes improved care, lower costs, and expanded access.

In physician-owned hospitals, physicians—who are fundamentally responsible for the existence of the hospital and the maintenance of its standards—can manage hospital costs through innovation and improved efficiency, which increases value. Physician-owned hospitals already are more likely to have operating rooms that they use more efficiently than traditional hospitals. Physician-owned hospitals are also more engaged in general medical and surgical care than other hospitals. Accordingly, by lifting the ban and allowing physician-owned hospitals to compete with other hospitals, the delivery system benefits by increasing competition and patient choice.

Data

One of the greatest barriers physicians face in designing and implementing new approaches to care delivery and payment is their inability to obtain data on the full range of services their patients are receiving today. Most of the savings from improved care delivery come from lower spending on services such as hospital admissions and post-acute care that are not delivered directly by physicians. Some of the biggest opportunities for improved care coordination come from avoiding duplication and conflicts with services delivered by other providers; the problems occur because physicians do not know what other providers have done, and vice versa. Physicians need access to information about the other services their patients are receiving that would enable them to identify and quantify opportunities for savings or take action to achieve these savings. CMS needs to create more effective and user-friendly mechanisms through which physicians can access and analyze CMS claims data, and CMS needs to provide financial support to physicians to help them gather and analyze relevant clinical data that are not contained within claims data.

In current CMS APMs, the upfront investments needed have been higher than necessary. The upfront investments include the high cost of the technology and services physician practices have had to acquire in order to submit data to CMS and analyze the data they receive from CMS, and the high fees associated vendors charge to install customizations necessary to implement APMs. It would be far less expensive overall if CMS made the investments needed to create more efficient and user-friendly systems for data submission and feedback.

[6] Prior to the enactment of the Affordable Care Act (ACA), physicians enjoyed a "whole hospital exception" from the Physician Self-Referral Law (also known as the Stark law). If physicians had an ownership interest in an entire hospital and were authorized to perform services there, physicians could refer patients to that hospital. However, provisions within the ACA eliminated the Stark exception for physicians who do not have an ownership interest as of December 31, 2010. 42 U.S.C. § 1395nn

Financial Risk

Physicians participating in an APM can appropriately take accountability, including financial risk for aspects of their patients' care that they can control or influence. These include decisions on the appropriateness of tests they order, procedures they perform, medications they administer, and whether patients are discharged to their homes or to expensive facilities. Physicians should not be expected to take risk for prices of drugs or biologics or the severity of their patients' conditions and their functional status. Most Medicare spending does not go to physician services, so increasing physicians' financial risk for Medicare spending on hospitals and drugs will be a major barrier to increasing their participation in APMs.

Administrative Burden

Mounting administrative burdens raise the fixed cost of practice, making it harder for physicians to innovate. The AMA applauds the commitment from Congress and the Administration to transform the health care delivery system by focusing on patient-centered care and working with physicians to improve outcomes. The AMA believes that by reducing physicians' administrative burden, the health care delivery system will improve quality of care, decrease costs, and be more effective, simple, and accessible.

The increasing amount of administrative responsibility forced upon physicians adds unnecessary costs not only to physicians and the health care system but also to patients. Unnecessary administrative tasks undercut the patient-physician relationship. For example, studies have documented lower patient satisfaction when physicians spend more time looking at the computer and performing clerical tasks. Moreover, for every hour of face-to-face time with patients, physicians spend nearly two additional hours on administrative tasks throughout the day. The increase in administrative tasks is unsustainable, diverts time and focus away from patient care, and leads to additional stress and burnout among physicians.

By reducing administrative burden, Congress and the Administration can support the patient-physician relationship and let physicians focus on an individual patient's welfare and, more broadly, on protecting public health. For example, prior authorization and other utilization management programs can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. Additionally, the very manual, time-consuming processes used in these programs burden physicians and other health care providers and divert valuable resources away from direct patient care.

We also have a host of other regulatory relief concerns that would reduce the regulatory burden for physicians, while also simplifying the health care system and ensuring patients receive optimal care.

What are examples of successful cross-sector collaboration that has achieved positive health outcomes, patient personalization, and lower costs?

The below models include examples of APMs that we think either have or could achieve positive health outcomes and lower costs, which could be made available for a variety of physicians across payers:

SonarMD

An Illinois gastroenterologist, Dr. Lawrence Kosinski, developed a specialty medical home model for patients with Crohn's disease and ulcerative colitis with support from Illinois Blue Cross Blue Shield. He called it Sonar because his patients were like underwater submarines, and he needed a way to find out if his patients were having a problem before they surfaced in a hospital. The model grew out of data that the payer provided to him showing that, of the more than 50 percent of Crohn's disease patients hospitalized with complications of their disease, less than one-third had seen any physician within the 30 days preceding their hospital admission. Interviews with the patients revealed that the symptoms of their disease had come to seem normal to them over time, so they had no way of knowing that a change needed to be made in their treatment plan to avoid a developing emergency. Under the Sonar model, participating gastroenterologists receive funding support for proactive outreach to patients by nurse care managers. Each patient receives a "ping" via text message, email or phone each month with a few structured questions. The nurses are able to use the patients' responses to these questions, called Sonar scores, to alert the gastroenterologists if they need to see the patient or adjust their medication regimen. The Sonar model has cut the rate of hospitalizations in half, and was the first APM recommended by the PTAC to the Secretary of HHS. The AMA participated in a meeting with Dr. Kosinski and CMS to discuss how to potentially implement this model for Medicare patients with an array of chronic conditions that would benefit from this type of intensive physician-nurse-patient engagement.

Patient-Centered Opioid Addiction Treatment

As a component of our efforts to help bring an end to the epidemic of opioid overdose deaths, the AMA has been working closely with the American Society of Addiction Medicine to develop a physician-focused APM for managing the treatment of opioid use disorder. As the Health Care Innovation Caucus knows, the opioid epidemic is widespread, growing rapidly, and has overtaken many other leading causes of death. The treatment model for opioid use disorder requires interventions that address its medical, psychological, and social components, including medication-assisted treatment. The model aims to broaden coordinated delivery of the full spectrum of services needed for treatment, improve transitions to outpatient care for patients discharged from more intensive levels of care, and reduce the number of avoidable emergency department visits and hospitalizations. Payments under the model would support an evaluation, diagnosis, treatment planning, and treatment induction phase, followed by a maintenance phase. Patient-centered, comprehensive, and collaborative treatment plans would cover care from induction through stabilization, treatment, and long-term recovery. It would also support more intensive management when warranted by special circumstances such as a relapse, comorbidities, or a patient choosing to discontinue the medication. Payments under the model would be adjusted based on performance on outcome measures.

Other Specialist Models

Under the Medicare physician fee schedule, physicians treating patients with chronic diseases, such as rheumatoid arthritis, asthma, headaches, and diabetes, are paid primarily based on the number of times the patient comes to the physician's office. There is no payment for many high-value services, such as phone calls to respond to patient setbacks or complications and consultation with other physicians to improve diagnosis, treatment planning, and care coordination. Payments are often inadequate to support the

additional time and services needed by patients with difficult-to-diagnose or difficult-to-treat conditions. As a result, patients may be inaccurately diagnosed or inappropriately treated, experience continued symptoms of their disease or side effects of medications that could have been avoided, and be hospitalized or seen in an emergency department for problems that could have been prevented. A number of specialty societies are designing physician-focused APMs to improve diagnosis and management of chronic diseases, including the American Academy of Neurology, American College of Rheumatology, American College of Allergy, Asthma & Immunology, American Association of Clinical Endocrinologists and others. Several of these models include elements in common, such as: a one-time payment to support a comprehensive diagnostic work-up, testing, and development of an initial treatment plan; monthly payments to cover the treatment and care management needed to get the condition under good control; payments to cover ongoing care, either by a primary care physician for patients whose conditions are well-controlled or continued care by a specialty team for patients with more difficult-to-control conditions or complex comorbidities; and support for collaboration between specialists and primary care physicians during diagnosis and treatment planning and when needed due to disease progression or other issues.

How have population health, capitation, and direct provider contracting improved patients' health?

We believe the Direct Provider Contracting model proposed by CMMI is one type of APM model that should be available for physicians. Specifically, we have recommended that CMMI develop a family of Direct Provider Contracting models for physicians to pilot. This family of models should allow a broad array of physicians to participate in innovative payment models, including both primary care and specialty physicians. Many specialty societies and practices have already been working to develop APMs that could be implemented using Direct Provider Contracting, and the PTAC has recommended 10 models that are all amenable to being tested using a Direct Provider Contracting model.

In addition, we propose that CMMI structure Direct Provider Contracting models similarly to the approach it is using in the Comprehensive Primary Care Plus (CPC+) initiative, by providing risk-stratified monthly payments to practices based on the type of patients a practice sees. We urge CMMI to only hold physician practices responsible for costs that they can reasonably influence. The AMA does not believe that any physician practice should be held accountable for the total cost of care of a patient population. The CMMI should prioritize models that allow small, independent practices to participate without the need to join or contract with a larger organization, such as models that do not require substantial financial risk or major new capital investments to succeed.

Direct Provider Contracting models should remove barriers in the current payment systems. These barriers can include lack of payment or inadequate payment for high-value services or financial losses for improving health and eliminating unnecessary services. There are also administrative barriers faced by physicians such as prior authorization or lack of access to necessary data.

We recommend that CMMI work collaboratively with the specialty societies and practices that have already put significant work into designing APMs as it further develops its plans for a Direct Provider Contracting model.

How can Congress help the Center for Medicare and Medicaid Innovation achieve its purpose of developing and testing innovative payment and delivery models?

Congress should work with the Administration to ensure that there are a wide variety of APMs, and that APMs are a voluntary option for all physicians. There should be enough value-based care models available to allow for competition and innovation among physician practices. Congress and HHS should also work to ensure physicians in small practices have alternative payment options available that are not cost prohibitive for solo practitioners or small group practices. We urge Congress to encourage HHS and CMMI to test and develop the physician-focused payment models that have been presented to PTAC and that PTAC has approved.

In addition, many of the concerns we hear from physicians about the current payment system have more to do with administrative and regulatory burden than with payment rates. Prior authorization, certification, documentation and reporting requirements, and electronic health record (EHR) systems that do more to hinder than support patient care are enormously burdensome. Congress should take advantage of opportunities to lessen these burdens by waiving Medicare and other payer requirements for all innovative payment models. This could allow for new pilot programs using telehealth for example.

Value-Based Arrangements

What role should Medicare play in creating value-based arrangements and encouraging manufacturers, payers and providers to take on risk?

Medicare must provide adequate payments to support high-quality care and limit physicians' accountability to aspects of quality and cost that physicians can control. Too many of the APMs developed by CMMI have failed to provide the resources physicians need to deliver new types of services, and they inappropriately transfer insurance risk to physicians. Physicians tell us that they are willing to take accountability for the aspects of spending and quality they can control or influence if they have adequate resources and flexibility to deliver high quality care in the most appropriate settings. Physicians are willing to participate in APMs that hold them accountable for decisions over which they have control. Most Medicare spending does not go to physician services, so CMMI should not include Medicare spending on hospitals and drugs toward physicians' financial risk.

Technology and Health Information Technology (IT)

What impact does health IT and data interoperability have on successfully running value-based payment models and contracting? What are some ways to improve interoperability and the sharing of data?

Data interoperability is critical in health care. Whether it is in value-based payment models or traditional fee-for-service, obtaining access to information at the right time and place is essential. Health IT and data interoperability have a significant impact on whether a model is successful. Underlying technologies that connect health IT need to be simplified to improve data integration and exchange to give a consistent view of patient information.

We appreciate CMS' recent proposal to focus the promoting interoperability (PI) program (formally the meaningful use program) on interoperability and improved patient access. To improve interoperability and the sharing of data, the AMA asks that Congress and the Administration promote the simplification of the promoting interoperability program by reducing physician burden through attestation, score physicians at an objective level, and consider new PI measures that can bridge the gaps across the currently siloed components of the Quality Payment Program.

Attestation

The AMA urges that CMS only require physicians to attest to meeting the program's measures—essentially reporting a "yes" or "no" on whether they had at least one patient counted for each measure. By attesting "yes" physicians should receive full credit in each measure, and therefore, credit in the corresponding PI objective. Beyond that, the physician can focus on delivering patient care and not worry about how often a particular function is used or action performed. EHR function use is already captured by the EHR and should be reported to CMS by the health IT vendor. This approach provides physicians with more opportunities to succeed, reduces administrative burden, and places patient care over paperwork, while simultaneously identifying for CMS and the Office of the National Coordinator for Health Information Technology (ONC) which types of measures are truly useful to the physician and patient.

An attestation-based approach also frees health IT vendors to innovate and respond to real-world patient and physician needs, rather than creating a tool to measure, track, and report. CMS' measure requirements significantly impact EHR design and physician reporting requirements artificially drive EHR use. Instead of developing EHRs to meet baseline federal requirements, health IT vendors need more insight into what is actually useful to physicians in real-world practice settings. An attestation-based approach provides vendors with the opportunity to gather and focus on these data to inform future development decisions.

The PI program must pivot away from linking a physician's successful participation to the prescribed use of an EHR. Instead, by having an attestation-based approach, physicians should have more freedom to choose the technology they want to use, and how they want to use it, as long as it helps them support patient care and long-term wellness. CMS and ONC would benefit from receiving more information on the real-world use of technology. Fortunately, health IT vendors can and should provide that data.

Objective Level

The PI program can be improved by scoring it at the objective level—that is, scoring physicians based on reporting a yes/no attestation for one measure from each objective and receiving bonus points for any additional reported measures. Participants should be able to select among the measures within an objective on which they wish to report. While we have heard concerns that allowing physicians flexibility to select the measures they report under each objective could lead to cherry picking, instead, this flexibility would allow physicians to choose measures that are most relevant to their patient population.

Health Information Exchange

To further promote interoperability, the Administration should support additional attestation-based measures to meet the health information exchange (HIE) objective in the PI program. (1) Participate in an HIE and (2) Search for or Directly Request Patient information from an HIE.

Each of these measures would contribute significantly to the PI program's goal of interoperability and greater health information exchange. By its very nature, participation in an HIE advances CMS' goal of decreasing information blocking and also helps to improve patient safety and outcomes by offering clinicians a more complete picture of the patient's health.

What technology is needed to integrate physician networks to be able to effectively manage a population's health?

In general, flexibility is needed in the technology required for APMs. Too many physicians have found that instead of helping them to deliver higher-quality, more coordinated care, certified electronic health record technology (CEHRT) is reducing the time they can spend with patients and increasing their administrative costs. CMS should only require physicians and other providers to use CEHRT as part of APMs if CMS has verified that CEHRT can, in fact, deliver the information needed by participants in the APM efficiently, effectively, and at an affordable cost. APMs should be encouraged to leverage technology to support the goals of the APM and help participants improve communication, patient engagement, collaboration, diagnosis, treatment planning, and quality.

While CEHRT supports some basic, fundamental functionality to help APMs achieve their goals, it is our experience that CEHRT often needs to be enhanced or supplemented before true usefulness is fully realized. Any CEHRT requirement must also provide sufficient flexibility to recognize custom functionality that "builds on" CEHRT—a concept taken directly from one of CMS' priorities for new PI measures in the Quality Payment Program. Often, these additional enhancements are layered on top of CEHRT—creating a new and improved experience for patients and their care team—and is a greater return on investment than the original purchase of the EHR. The effort and value of refining the EHR experience based on patient and physician need should be rewarded by CMS. Going forward, CMS and ONC should take greater responsibility to encourage the development of CEHRT that seamlessly captures, retrieves, shares, and analyzes clinical data to support APMs.

What new technology exists to lower costs, improve efficiency, or improve the quality of care that isn't already widely-deployed?

With technology and innovation, the AMA believes that physicians should be directly engaged in digital health innovation and positively incentivized to adopt innovative technology. Physicians want a voice in developing, selecting, and implementing health care technology.

Digital health encompasses a broad scope of tools that engage patients for clinical purposes; collect, organize, interpret, and use clinical data; and manage outcomes and other measures of care quality. Digital health technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life threatening diseases, and

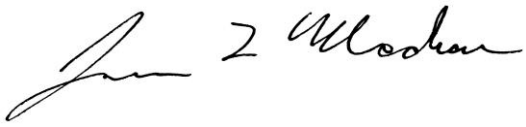
management of chronic conditions outside of traditional care settings. Furthermore, digital health technology has brought new market participants into the health care space—and those participants have brought new innovations.

However, digital health technologies built without physician input risk introducing design flaws and other issues that make the technologies less valuable to patients and their physicians. Physicians want to play a greater role in leading digital health innovations that expand the bounds of science, enhance patient care, shape a better health care system, and improve the health of the nation.[7] Furthermore, physicians desire to participate in development and dissemination of innovation in order to advance medical knowledge, improve the quality of care, and promote the well-being of individual patients and the larger community.[8] Involving physicians throughout the innovation process—including early on—increases the likelihood that those innovations will be feasible once they are on the market.

While involving innovators and investors may help stakeholders better visualize the digital health landscape, the physician's perspective is critical in completing the picture. We encourage Congress and HHS to draw from the experience of incentivizing EHR adoption and use. Many of the issues with EHRs today derive from a lack of physician input and the misplaced emphasis on regulatory compliance rather than end-user need. Congress and HHS should engage physicians when fostering new, practical, and innovative approaches in digital health to tackle the complicated challenges facing the health care industry.

The AMA appreciates the opportunity to provide comments to the Health Care Innovation Caucus and would be happy to provide further detail on any of our above responses. We look forward to working with the Caucus to ensure there are innovative APMs available for physicians in all specialties and practice sizes.

Sincerely,



James L. Madara, MD

[7] AMA Policy D-480.972, Guidelines for Mobile Medical Applications and Deices, Year last modified: 2016.
[8] AMA Policy 1.2.11, Ethically Sound Innovation in Medical Practice, Year last modified: 2017.