

July 6, 2018

Eric D. Hargan
Deputy Secretary
U.S. Department of Health and Human Services
Immediate Office of the Deputy Secretary
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Health Care Sector

Dear Deputy Secretary Hargan:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the U.S. Department of Health and Human Services' (HHS) Immediate Office of the Deputy Secretary in response to the Request for Information (RFI) Regarding Health care Sector Innovation and Investment Workgroup.

The AMA appreciates HHS' interest in spurring investment, increasing competition, and accelerating innovation in the health care sector. While we recognize this RFI is not limited to innovation around technology, we view this as an opportunity to provide to HHS our experience and lessons learned in that space. **The overarching theme is a strong need to ensure that physicians are directly engaged in digital health innovation.** Physicians want a voice in developing, selecting, and implementing health care technology.¹ We generally agree with HHS that there is a need to increase engagement and dialogue between HHS and those focused on innovating and investing in the health care industry. However, engagement alone is not enough. **HHS should also strive to provide a clear outline of what constitutes success and ensure a common understanding among stakeholders.**

The Physician's Perspective

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.

¹ AMA, *Digital Health Study, Physicians' motivations and requirements for adopting digital clinical tools*, (September 2016), Available at <https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/washington/ama-digital-health-report923.pdf>, Accessed June 2018.

In 2016, the AMA conducted a study to investigate physician motivations, current usage, and expectations for integrating digital health tools into their practices.² The survey of 1,300 physicians covered a broad range of digital modalities to deliver clinical care, including telehealth, mobile health, wearable, remote monitoring, mobile applications (apps), and others. Survey findings showed there is enthusiasm among physicians for digital health, with broad-based optimism common among physicians of all age groups, practice settings, and tenures. Additionally, physicians overwhelmingly (85 percent) see potential for digital health to favorably impact patient care, and are also optimistic that digital health has the potential for improving practice efficiencies, patient safety, and diagnostic ability, while reducing physician burnout.

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.³ 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.⁴ 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 HHS better visualize the digital health landscape, the physician’s perspective is critical in completing the picture. We encourage HHS to draw from its experience with incentivizing electronic health record (EHR) adoption and use. Many of the issues with EHRs today derive from a lack of physician input and the misplaced emphasis of regulatory compliance rather than end-user need. **HHS should engage physicians when fostering new, practical, and innovative approaches in digital health to tackle the complicated challenges facing the health care industry.**

Experience in Digital Health Innovation

Our digital health study also showed that physicians want to be consulted, have a role in the decision making process, and feel confident that they will be paid for clinical services rendered using digital health tools. From our research, we gleaned four key questions physicians have about digital health.

- “*Does it work?*” Physicians want to ensure that the digital tools have clinical validation and are interested in working with innovators early on in the design, development, and validation stages.
- “*Will I receive payment?*” Physicians need assurances that digital health solutions provide value, are cost-effective, and there is a path to payment for delivering services using new digital modalities.
- “*Will I be liable?*” Physicians need to have clarity with regard to their potential liability and risk before adopting new technology.
- “*Will it work in my practice?*” Physicians require new innovations that integrate into and improve the daily operations of their practices.

² Id.

³ AMA Policy D-480.972, Guidelines for Mobile Medical Applications and Devices, Year last modified: 2016.

⁴ AMA Policy 1.2.11, Ethically Sound Innovation in Medical Practice, Year last modified: 2017.

The AMA is dedicated to shaping a future where digital health tools are evidence-based, validated, interoperable, and actionable. The AMA has established a number of projects to help address these questions. Our experiences can help to inform HHS' innovation efforts. Major takeaways, ideas, and lessons learned from three AMA-led digital health initiatives are explored in greater detail below. We also believe that HHS can play an important role in addressing these questions. **As such, we recommend HHS' workgroup be provided with ample scope and resources to support digital health development, integration, and use in the physician's practice.** Clinicians and physician organizations waste time and resources on the adoption of solutions that are not sustainable, not scalable, or do not provide positive return on investment. This contributes to fatigue, increased health care costs, and reduced motivation to engage in future implementations of promising solutions.

Physician Innovation Network

The Physician Innovation Network (PIN) is an online community where physicians can find and connect with companies and entrepreneurs who are seeking physician input in the development of health care technology products and services.⁵ Through PIN, the AMA is bringing together the health care innovation and digital health ecosystem. We are connecting physicians and health tech companies to integrate the physician voice into tech products and solutions in the market. Through virtual panel discussions and resources, PIN is providing opportunities for education, exposure to leaders across the industry, and sharing best practices and success stories in health care innovation. PIN enlists experience from external collaborators including startup companies, accelerators and incubators, investors, and physician organizations. Major takeaways from PIN include:

- Physicians want a voice in developing, selecting, and implementing health care technology—over 2400 physicians are active on PIN;
- Digital health companies are looking for physician input into their products and solutions—over 450 companies with approximately 120 opportunities available to physicians at any point in time; and
- The most engaging virtual panel discussions include a variety of stakeholders from across the digital health landscape—panel discussions with app developers, health system leadership, health IT vendors, funders, and entrepreneurs have topped 25,000 views.

Digital Health Physician Adoption Summit

The AMA is working to address physicians' adoption of digital health applications from concept to clinical integration to improve care delivery for patients. Toward this effort, the AMA convened the Digital Health Physician Adoption Summit earlier this year, bringing together 20 leading innovators, researchers, physicians, and decision makers from across the digital health ecosystem.⁶ The participants engaged in dialogue about how best to support physician adoption of safe and effective digital health innovations that will advance the quadruple aim: better health outcomes, improved patient experience, improved clinician experience, and lower cost of care.

⁵ AMA Physician Innovation Network, Available at <https://innovationmatch.ama-assn.org/>, Accessed June 2018

⁶ *Health Care Industry Requires A Roadmap To Accelerate The Impact Of Digital Health Innovations*, Health Affairs Blog, June 8, 2018.DOI: 10.1377/hblog20180606.523635

At the summit, participants shared best practices, lessons learned, perceived gaps in knowledge, and opportunities to improve adoption of digital health innovations. Participants also shared their perspectives on the role that the AMA, the Summit participants, and other key stakeholders might play in bringing the ideas to fruition. The final portion of the Summit was spent identifying opportunities upon which the AMA, the Summit participants, and the broader industry should take action. A large number of ideas were generated across teams, with a shorter list prioritized for voting by the full group. The ideas with the highest number of votes include:

- Digital Health Implementation Playbook—a tool to help physicians and practices implement and scale digital health innovations in clinical practice;
- Digital Health Solution Marketplace—a platform where physicians and practices go to review and select digital health innovations that are safe and effective for implementation;
- End User Feedback Collaborative—a convening of providers, patients, and other users of digital health tools to design, build, and provide feedback on solutions, ensuring all voices are heard;
- Payer Summit on Digital Health—an event that focuses on the role of payers to accelerate coverage, payment, and adoption of digital health innovations; and
- Physician Phenotype Model for Adoption—development and application of a physician phenotyping study to understand what motivates different demographic and behavioral segments of physicians to adopt new solutions.

Digital Medicine Payment Advisory Group

The Digital Medicine Payment Advisory Group (DMPAG) is a collaborative initiative—that has been convened by the AMA since 2017—that engages a diverse cross-section of nationally recognized experts in digital medicine and payment who meet monthly to address barriers to digital medicine adoption by offering actionable recommendations and solutions. The stakeholders were brought together to advance digital medicine adoption as it presents an opportunity to improve access and to offer cost-effective medical care to a large swath of patients with diverse needs. Increasing coverage of digital health modalities has required a concerted effort by knowledgeable professionals as well as input, such as pertinent use cases and clinical data that demonstrate the efficiencies and clinical benefits of digital medicine. The goals of the DMPAG include the following:

- Create and disseminate data supporting the use of digital medicine technologies and services in clinical practice.
- Review existing code sets (with an emphasis on Current Procedural Terminology and other code sets) and determine the level to which they appropriately capture in current digital medicine services and technologies.
- Assess and provide clinical guidance on factors that impact the fair and accurate valuation for services delivered via digital medicine.
- Provide education and clinical expertise to decision makers to ensure widespread coverage of digital medicine (e.g., telemedicine and remote patient monitoring), including greater transparency of services covered by payers and advocacy for enforcement of parity coverage laws.
- Review program integrity issues including, but not limited to, appropriate code use, and other perceived risks unique to digital medicine. Develop guidance and clarity on issues to diverse stakeholder groups.

Since the experts were convened, the DMPAG has supported and informed the development of new codes to facilitate capture of services and technical components of remote patient management and monitoring services, for example. The DMPAG has also collected and analyzed clinical literature and supervised in-depth use cases to evaluate clinical integration of digital methods into practice including remote patient monitoring, telehealth, and e-consults that have been submitted to the Centers for Medicare & Medicaid Services and Congress to expand coverage. The DMPAG continues its efforts to expand the evidence-base and engage with innovators to ensure that the DMPAG is aware of emerging digitally enabled interventions. The DMPAG has also provided public updates to innovators to ensure the latter are aware and proficient in the factors to consider in developing a pathway to payment that supports clinical integration and viability.

Response to HHS Questions

HHS is seeking comment on how to structure the workgroup in order to best support communication and understanding between parties that will spur investment in the health care industry, increase competition, improve innovation, and allow capital investment in the health care sector to have a more significant impact on the health and wellbeing of Americans. HHS also seeks comment more broadly on opportunities for increased engagement and dialogue between HHS and those focused on innovating and investing in the health care industry. The AMA submits the following responses based on AMA research, efforts to establish physician innovator communities, and ongoing collaborations with health systems, incubators, accelerators, and other stakeholders and their associations.

Question #1: Workgroup Area of Focus

The AMA recommends HHS encourage outside parties to provide information about how they are affected by HHS programs or regulatory requirements. As previously mentioned, it is our experience that excessive regulation, or regulation that is too prescriptive, contributes to myriad negative consequences. As such, HHS must contemplate downstream policy implications as a core function of its effort. **HHS should also establish a coordinating effort to facilitate cross-department collaboration.** For instance, the Office of Civil Rights, the Office of Inspector General, the Office of the National Coordinator for Health Information Technology, and the Food and Drug Administration have differing perspectives on and authority over health information security.⁷ Absent alignment across the federal government on these issues, health IT developers, health systems, and physicians will increasingly encounter conflicting guidance, which stymies innovation and adoption.

Question #2: Workgroup Structure and Participation

The AMA recommends that, in addition to those already named in the proposal, physicians, other care team members, health system leadership, and patients should be invited to participate. Including the “end user” voice in digital health innovation is necessary to support uptake and adoption. **We also recommend that HHS consider methods to broaden access and availability to information about the inner workings of the Department.** It is important that nontraditional health care innovators and investors have a clear understanding of agency interactions, policy mechanics, regulatory processes,

⁷ Letter from the Hon. Greg Walden, Hon. Frank Pallone Jr., H. Comm. on Energy and Commerce, Hon. Patty Murray S. Hon. Lamar Alexander, S. Comm. on Health, Education, Labor, and Pensions to The Hon. Alex Azar Sec’y US Dep’t of Health and Human Services, (June 5, 2018), Available at <https://energycommerce.house.gov/wp-content/uploads/2018/06/20180605HHS.pdf>, Accessed June 2018.

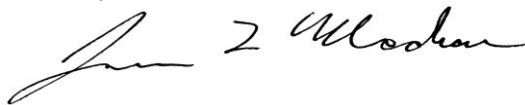
and the culture at HHS. **As previously stated, to ensure this private-public partnership achieves the desired outcomes, HHS should establish metrics and goals to help measure and identify success.** We believe this is an important component in establishing the cadence of stakeholder engagement and will help identify gaps or areas where HHS may need further input.

Question #3: Additional Opportunities for Engagement

The AMA is aware that HHS has been holding “roadshows” geared towards “demystifying” HHS. Events have been held in Boston, Massachusetts (Pulse@MassChallenge) and Chicago, Illinois (MATTER). **We have heard these events have been well received by attendees, and encourage HHS to continue their efforts to engage with individuals and organizations across the nation.** Particularly, we understand that attendees would like more opportunities to interact with agency speakers, with increased time for dialogue. The AMA has held a number of our own town halls and focus groups, and finds significant value in hearing from front-line physicians and clinicians. Additionally, the AMA is a founding member of Xcertia, a non-profit focused on the development of mobile health (mhealth) guidelines for safe, effective use of mhealth apps. There are currently more than twenty-five leading organizations participating, as well as a recent partnership with the Consumer Technology Association. Initial content has been completed covering four areas: operability, security, privacy, and clinical evidence/content. Workgroups have since been assembled to focus on these topics and planning is underway for related validation studies. **Given that representatives from both the Office of the National Coordinator for Health Information Technology, and the Food and Drug Administration are ex officio members of Xcertia, we recommend that HHS leverage Xcertia’s efforts and expertise.** We look forward to assisting HHS in their efforts to engage physicians going forward, and offer our assistance in public-private dialogue to increase innovation in the health care sector.

We greatly appreciate this opportunity to share the views and experiences of the AMA regarding HHS’ request for information. If you have any questions, please contact Matt Reid, Senior Health IT Consultant, Federal Affairs, at 202-789-7419.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and a stylized "M".

James L. Madara, MD