

December 16, 2019

The Honorable Diana DeGette  
Committee on Energy and Commerce  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Fred Upton  
Committee on Energy and Commerce  
2183 Rayburn House Office Building  
Washington, DC 20515

Re: Request for Information on 21<sup>st</sup> Century Cures 2.0

Dear Representatives DeGette and Upton:

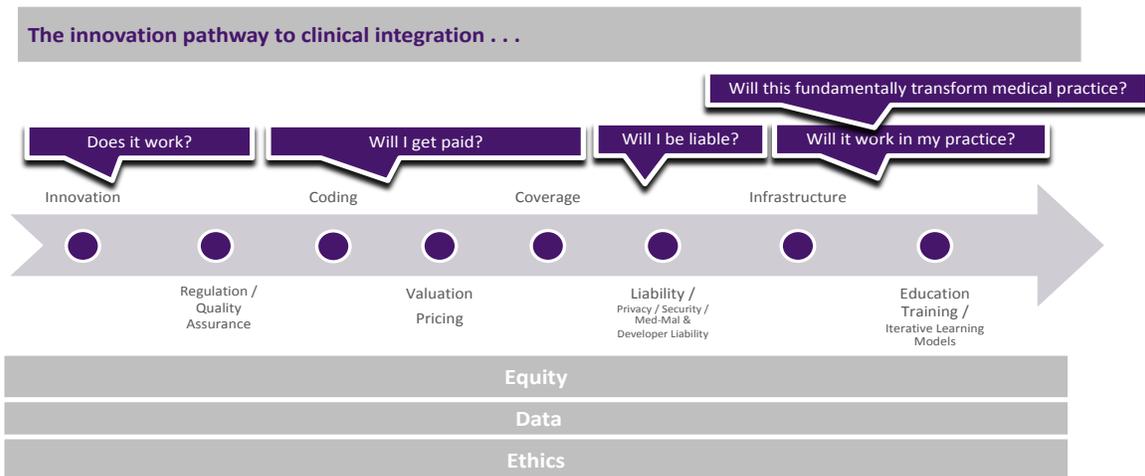
On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments and recommendations in response to the Request for Information (RFI) to support 21<sup>st</sup> Century Cures 2.0. The AMA is strongly committed to advancing the adoption of innovations in digital health (including telehealth, other digital health modalities, augmented intelligence (AI), and associated algorithmically enabled diagnostic and therapeutic services) into clinical practice. The AMA summarizes below the key congressional actions that would address significant barriers to adoption of digital health tools into clinical practice. We strongly urge Congress to move forward to pass legislation, including the Creating Opportunities Now for Necessary and Effective Care Technologies for Health Act (CONNECT for Health) of 2019, that would ensure that statutory and infrastructure impediments do not further delay adoption of digital modalities with demonstrated value and that are foundational to the modernization of health care delivery.

In addition, the AMA has dedicated substantial resources with demonstrable success to increase coverage and clinical adoption of digital health modalities through existing processes. These AMA-wide efforts involve multiple initiatives and extensive external engagement with industry, academia, medical centers, organized medicine, and broad stakeholder coalitions to work collectively to identify and remove barriers to digital health tools and increase coverage and payment across all payers, including Medicare and other federal health programs. Based on the telehealth experience, we would caution that creating new pathways to payment for innovative digital platforms and services, rather than treating digital medicine as medicine, could be counterproductive in the long term and could hinder rather than help speed physician and patient access to these new services and products.

### **Innovation Pathway**

The AMA has identified the overarching categories of issues that must be addressed along the pathway of innovation to clinical integration including research, regulation, payment, liability, infrastructure, and professional development/deployment conditions. The AMA commissioned a study of physicians in 2016 that found that physicians generally view digital modalities for the delivery of health care services favorably, but before adoption the following key questions must be addressed including: (1) will it work; (2) will I be liable; (3) will it work in my practice with my electronic health record (EHR); and (4) will I be reimbursed? These questions are similar to those that consumers are likely to want to know for consumer directed products, including does it work, what are my risks of use, does it fit into my everyday

life, and what will it cost? We have recently reprised the study in 2019 with similar findings and additional considerations that will be incorporated into the AMA's strategy to ensure adoption and meaningful scale. We are able to brief you on these findings.



The AMA's House of Delegates (HOD) has also adopted policy for AI systems in health care, including addressing specific issues related to equity (and bias) and data (including evidence). Additional policy development is underway and we anticipate that the AMA's HOD will be considering additional AI policy in 2020 and beyond. In 2018 and 2019, three seminal reports were adopted by the HOD that included [foundational considerations](#), [regulation and coverage](#), and [professional development and education](#).

Based on the foregoing, the following outlines the parameters for considering the range of policy actions needed by Congress, federal agencies, and health care stakeholders interested in accelerating adoption of 21<sup>st</sup> Century Cures *at scale*.

### **Congressional Action**

In order to advance 21<sup>st</sup> Century health care, the AMA strongly urges Congress to pursue the following legislation and policies in the areas of regulation, payment, and infrastructure:

#### *Regulation and Oversight of Digital Health Modalities*

Clinical integration and widespread adoption of digital health modalities is contingent on oversight that ensures the safety, effectiveness, and equity of software so that physicians and patients are able to trust software functioning as a medical device (SaMD) as well as other algorithmically enabled services that are not subject to FDA regulation. This would be aided with the inclusion of physicians in the established process used by the Food and Drug Administration (FDA) to discuss with industry (manufacturers and developers) and patients the agreement that accompanies the Medical Device User Fee Amendments (MDUFA) to the FDA Reauthorization Act starting in September 2022 (MDUFA V). Because the current statute does not include physicians as a stakeholder, physician organizations were not included in the last

round of discussions until well after the material terms and major policy discussions had already been negotiated at the FDA. Reportedly, the FDA and industry have already initiated discussions for MDUFA V. Unlike other user fee agreements for brand drugs, generics, and biologicals which contained only user fee negotiated fees and review times, the [MDUFA IV agreement](#) contained numerous and substantively important policy provisions. The rapidly expanding role of digital medicine modalities across physician practice types and specialties has elevated the importance of regular and equal engagement with the physician community. This not only benefits the FDA and the physician community, but ultimately innovators as this will increase the trust in the oversight regime and ensure increased adoption when new oversight models and approaches to assessing safety, efficacy, and equity are implemented.

The AMA also wants to ensure that any changes to section 3060(a) of the 21<sup>st</sup> Century Cures Act, titled “Clarifying Medical Software Regulation,” include the input and participation of the physician community. In particular, we would be concerned that any “technical” clarification would further reduce oversight of software used for clinical decision support. Instead of reducing the scope of the FDA’s authority in this area, new approaches to oversight that ensure rigor and trust are more appropriate as adoption will be slowed if physicians and patients are not able to differentiate between software that has been subject to a meaningful and reliable validation process and software that has not (and, which may as a result produce widespread unintended adverse consequences). For example, an algorithm that is not considered SaMD, but is used as clinical decision support and a population health tool developed by Optum and deployed widely by various health systems, discriminated against African American patients resulting in reduced clinical services, even though the African American patients had more severe or complex medical conditions than white patients who received such services. The flawed design, development, methods, and conditions of deployment were only uncovered by [researchers](#) after patients had been impacted. The State of New York’s Financial Services and Health departments opened inquiries. In response, Optum publicly stated that the flawed algorithm is “just one of many data elements intended to be used to select patients for clinical engagement programs, including most importantly, the physician’s expertise and knowledge of his or her patient’s individual needs.” Optum’s response evinces the intention of shifting liability and responsibility from developers, who are better positioned to know and mitigate the risks, to physicians who reasonably relied on the validity of the algorithm and are not likely to be in a position to know or be able to mitigate the risks. Additional consideration is needed concerning the appropriate oversight of algorithms that directly impact patient care but, are not FDA regulated products.

#### *Coverage and Payment*

The AMA strongly urges swift passage of the CONNECT for Health Act as the most important digital health priority before Congress. The removal of these artificial barriers is long overdue so that the Medicare program, beneficiaries, and providers are able to take full advantage of innovative telehealth services. While other federal health programs, state Medicaid programs, and private health plans have allowed adoption of telehealth, the current Medicare restrictions have impeded the uptake of this now well-established service delivery method. As reported by CMS, only 0.25 percent of CMS beneficiaries used telehealth in 2016. Increased access to telehealth is urgently required to help meet the health needs of the swiftly changing demographics of our senior population. Telehealth is also critical for providers to achieve the goals of Medicare payment and delivery reform efforts to improve outcomes and reduce costs. Additionally, passing the CONNECT for Health Act would have the added benefit of supporting adoption and integration of other digital modalities because comprehensive virtual services often depend on the

ability of patients to communicate at key times with their physicians via two-way audio, visual real time telehealth communications.

In addition, the CONNECT for Health Act would codify important clarifications of Stark and Anti-Kickback laws, established prior to the digital revolution, by specifying that appropriate and reasonable provision of technologies to enable virtual services to Medicare beneficiaries is permitted where it is not offered as part of any advertisement or solicitation.

The medical profession has been embracing advances in digital health services that help them diagnose and treat their patients earlier and in less costly care settings, improve workflow, and help patients improve compliance and adherence with their care plans. The CONNECT for Health Act's expansion of telehealth coverage in the Medicare program would spur increased investment and innovation in delivery redesign to benefit all patients

The AMA also recommends that Congress consider waiving Medicare co-pay requirements on de minimis amounts where the costs of recovery exceed the value of the co-pay. This has been a major barrier to providing digital health services to patients.

#### *Infrastructure and Interoperability*

The Cures Act included several important changes to the development, certification, and use of health information technology (health IT). The AMA appreciates the focus on physician burden reduction and attention to information blocking and emphasis on patient data access. While the Department of Health and Human Services (HHS) is currently engaged in rulemaking to implement the health IT provisions in Cures, the AMA believes there are areas in Cures that would benefit from additional clarity. HHS' proposed regulation includes policies that are not in line with the goals of Cures. Several stakeholders, including [large health care provider groups](#), have identified areas for improvement. The following recommendations will help refine and strengthen the original provisions in Cures and meet the Cures 2.0 directive to promote digital health technologies for patients, families, and caregivers.

#### Opportunities to Improve Cures 1.0

- **Adjust definitions of terms:** Congress should clarify its definition of “actor,” “use,” “electronic health information,” and “health information network” to ensure regulations are appropriately scoped.
- **Stagger health IT development and implementation timelines:** Congress should direct HHS to ensure there is appropriate time for vendors to develop, test, and certify new health IT and for physicians to purchase, implement, train on and use updated EHR features (i.e., provide one timeline for development and a subsequent timeline for clinician adoption).
- **Revisit information blocking:** HHS' proposed information blocking regulations are complex, confusing, and unworkable for physicians to implement. Congress should direct HHS to use discretion in its initial enforcement of the data blocking provisions, prioritizing education and corrective action plans over penalties.
- **Expand HITAC representation to include small physician practices:** The Health Information Technology Advisory Committee (HITAC) provides important direction and insight on HHS' health

IT policy efforts. However, the committee does not represent the experiences and needs of resource-limited medical practices. Congress should require that HITAC membership includes representation from practicing physicians, including both small and rural clinics.

- **Protect and promote privacy and security:** Improving data access and exchange must include strengthening privacy and security precautions. HHS' implementation of Cures undervalues patient privacy. While Congress works on national privacy legislation, near term protections must be included in HHS' health IT regulations. Congress should direct HHS to implement a privacy attestation framework, incentivize adoption of segmentation standards/technology, and strengthen policies around vetting consumer-facing applications.

Physicians have endured the unfortunate byproduct of federal policy dictating certified EHR use and development for nearly a decade. While the EHR reporting program's name has changed several times (i.e., *Meaningful Use* to *Advancing Care Information* to *Promoting Interoperability*), the program remains fundamentally flawed, linking "success" to measuring keyboard clicks and tracking physicians in a certified EHR. Certified EHRs are therefore "one size fits all" and specifically built for federal reporting purposes. Documentation "noise" is added to office notes simply to justify federal measures and requirements. This noise hides important clinical facts from patients, detracts from care coordination, and increases physician cognitive burden, burnout and a loss of productivity. Furthermore, innovative tools that are not certified by the Office of the National Coordinator for Health IT but nonetheless help physicians improve patient care are not eligible for inclusion in CMS' evaluations of how physicians use technology. Accordingly, the AMA has identified solutions for Congress to address the legacy EHR issues burdening physicians.

#### Federal Rules Around Use of Health IT

- **Allow providers to use non-certified health IT:** HHS continues to tie all its reporting programs (e.g., Quality Payment Program) to the use of certified EHRs. This linkage negatively impacts EHR usability, patient safety, and interoperability. Congress should remove the certified EHR limitations in the HITECH Act and direct HHS to solicit feedback from stakeholders that identifies additional types of non-certified health IT to count toward federal reporting programs. Doing so will promote adoption of emerging technology that makes sense for a physician's specialty and patient population in addition to the certified EHR technology that over 85 percent of practices have already adopted.
- **Direct HHS to accept physician attestations:** HHS' EHR reporting program still counts the number of clicks physicians take to document a patient's visit. This drives EHR design by forcing developers to continue to focus on the same functionalities already in use and capturing information in a way that can be measured by clicks rather than by what is intuitive and logical for the doctor's workflow, contributing to physician burden and burnout. Originally designed to capture "meaningful use" of certified EHR, prescriptive measurement-based reporting is antiquated. Congress should explicitly direct HHS to accept a physician's "yes" attestation as successfully meeting any and all EHR reporting requirements. This complies with MACRA's requirement that EHR reporting credit be granted based on subsection (o)(2) of HITECH to be considered a meaningful user, while also utilizing the Secretary's discretion allowed under HITECH's subsection (o)(2)(C)(i)(I) to allow a professional to satisfy demonstration of meaningful use through attestation. This will also create new opportunities for EHR design and development.

### **Federal Agencies, AMA, and Stakeholder Efforts to Increase Integration and Scale**

Developing new payment pathways and benefit categories is a topic of understandable focus and intense interest among all innovators and stakeholders interested in driving adoption of digitally enabled modalities. The AMA does not recommend creating new Medicare coverage and payment processes; they can slow rather than speed up coverage and payment as seen with the 1834(m) provisions that initially represented an expansion of Medicare coverage of new technologies but over time became a coverage barrier. Instead, the AMA has had success deploying a comprehensive strategy working with industry, academia, medical centers, organized medicine, and broad stakeholder coalition to address the sometimes complex interplay between coding, valuation, and coverage guided by expert opinion, literature, and health care system data to improve coverage and payment of digital medicine. To support these efforts, in January 2017, the AMA established the Digital Medicine Payment Advisory Group (DMPAG), comprised primarily of nationally recognized digital health physician experts and other practitioners at leading health systems around the country, subject matter expert physicians in coding and valuation, as well as industry experts with knowledge of expected technology advancements. The AMA also staffed the DMPAG with cross-enterprise internal staff experts to provide support along a broad continuum of activities such as environmental surveys and research, coding, valuation, state and federal laws and regulations, and advocacy.

The results have been significant. Beginning January 1, 2019, the Medicare program dramatically expanded coverage of a range of digitally enabled services including, but not limited to, remote physiologic monitoring, internet professional consultations, e-visits, and expanded coverage of certain telehealth services without geographic restrictions and in some cases originating site waivers as well. The latter required congressional action, but several of the digital health modalities (that are not considered telehealth and not subject to the geographic and originating restrictions) were initiated through DMPAG proposals that were navigated through the existing coding, valuation, and coverage processes by advisors, alliances, associations, and coalitions that the AMA coordinated with and engaged. In addition, the DMPAG considered proposals for the creation of new codes and ultimately supported an application to the CPT® Editorial Panel (CPT) to create a code that describes autonomous AI enabled services used to detect more than a minimal amount of diabetic retinopathy. In 2019, the CPT Editorial Panel approved the code and the Centers for Medicare & Medicaid Services will determine whether and how to cover and value the service. (The first FDA *de novo* authorized autonomous AI system, IDx-DR, would be able to use this code to bill.)

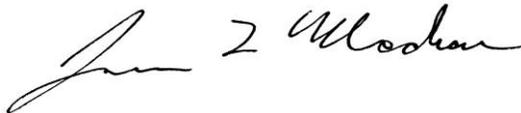
The DMPAG has established two additional workgroups to address key areas where experts are developing proposals to further aid the adoption and scaling of digital health modalities. Standard terminology—consistently defining digital health terms—has become important to ensure that state and federal regulators as well as national federal health programs and commercial payers are using consistent terms to describe the same digital modality of services. Providers and physician practices cannot scale if they do not understand what services are covered and under what conditions because the terms for the service varies between regulators and payers. The workgroup started earlier this summer and a proposal will be stress tested early next year among key stakeholders who will provide additional recommendations for standardization. In addition, a second workgroup is addressing related and, in some aspects, overlapping issues concerning algorithmically enabled diagnostics and digital therapeutic services. This workgroup began meeting in the late fall of 2019 and is expected to have proposals ready for stakeholder feedback in early 2020. Additional experts in design, development, validation, and

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deployment of health care AI-enabled systems and platforms were recruited to participate in this workgroup. The AMA is happy to provide a fuller briefing on the work of the DMPAG and the workgroups.

The AMA appreciates the opportunity to comment.

Sincerely,

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

James L. Madara, MD