AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Committee on Energy & Commerce
U.S. House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette:

The American Medical Association (AMA) strongly supports the overarching goals of the 21st Century Cures initiative—accelerating the discovery, development, and delivery of new cures—and appreciates the opportunity to provide feedback on the various white papers, committee hearings, and roundtable discussions. There are five specific areas that directly impact physicians' ability to deliver high quality, rapidly advancing health care to patients: 1) electronic medical records and 21st Century technology; 2) telemedicine; 3) personalized medicine and laboratory developed tests; 4) antibiotic development; and 5) protecting patient data. Each of these areas is highlighted below.

Electronic Medical Records and 21st Century Technology

The AMA shares the Committee's view that electronic health records (EHRs) and other health information technology (health IT) have the potential to modernize research, improve data-sharing, and advance medicine. Yet, as physicians are working to achieve these goals, overly prescriptive and rigid government regulation has created barriers and obstacles that are hampering innovation in this space.

Physicians are prolific users of technology and are often among the first to adopt innovations. In fact, a recent survey on mobile technology trends conducted by athenahealth and Epocrates has coined physicians as "digital omnivores." Seventy-two percent of clinicians say they expect to be using tablets, cell phones, and computers in their workflow by 2015.

The Health Information Technology for Economic and Clinical Health (HITECH) Act established incentives to defray the cost of purchasing EHRs, one of the largest barriers to adoption. The incentives have been successful in spurring rapid uptake of these systems. Health IT systems that can exchange information with one another are essential tools to help physicians improve quality and lower costs, and for accelerating the discovery, development, and delivery of new medical treatments.

However, increasingly restrictive and burdensome Meaningful Use (MU) regulations are limiting the ability of physicians and EHR vendors to achieve the goals of the MU program. The reality is that the systems certified by the Office of the National Coordinator for Health Information Technology (ONC) and required for use under the current MU program are often clunky, poor performing, and largely not

interoperable. Furthermore, the Centers for Medicare & Medicaid Services' (CMS) requirements that physicians must meet to obtain incentives and avoid financial penalties are unnecessarily complex. Physicians are frustrated that they are required to use EHRs that have been certified by the federal government but often cannot meet their workflow needs. They are being forced to make financial investments well beyond the amounts available under HITECH in order to meet MU requirements, rather than meeting the needs of their patients and their practice. In fact, a growing number of physicians are discarding their existing systems and are being forced to purchase different ones. In the meantime, the certified systems remain largely incapable of data exchange, a principal goal of HITECH and the very thing needed to advance medicine. These challenges are leading to productivity losses and less time with patients. An article published in the *American Journal of Emergency Medicine* found that "the time spent on documentation to be 30 percent to 40 percent of a workday, with electronic charting taking 30 percent longer than paper charts." At the same time, the vendor marketplace has been challenged to address these issues due to time and resource limitations as they focus instead on designing EHRs to meet overly prescriptive regulatory requirements that fail to address user needs and produce more innovative products.

Improve Interoperability and Usability of EHRs by Streamlining Meaningful Use Regulations

The AMA urges the Committee to consider more effective approaches to the MU program and regulation of health IT:

1. **Remove the existing MU program's "all or nothing" approach by adopting a 50 percent threshold for incurring a penalty and a 75 percent threshold for earning an incentive.** The most immediate action Congress can take to improve interoperability and usability of EHRs is to address the rigidity of the 100 percent pass/fail rate for the MU program. Under the current program, physicians must meet 100 percent of MU requirements all the time to earn an incentive and avoid a penalty. The AMA believes that Congress should move away from this pass/fail approach and instead deem physicians successful Meaningful Users if they meet at least 50 percent of the program's MU requirements to avoid a penalty, and 75 percent to earn an incentive. The AMA has repeatedly advocated that the CMS) and the Office of the National Coordinator for Health Information Technology (ONC) move away from a pass-fail approach. Yet, so far, CMS and ONC have not provided this needed relief and continue to push the program towards future stages. We are concerned that this lack of change will lead physicians and other providers to drop out of the MU program and become discouraged from using EHRs and other technology. More flexibility in the MU program would allow vendors to better tailor tools for physicians and other providers instead of focusing on meeting rigid government requirements that fail to incorporate user needs.

   Eliminate two of the MU measures that are hardest to meet. The Transfers of Care and the View, Download, and Transmit MU measures depend on factors outside of the physician's control, requiring technology or patients to perform tasks. Due to these challenges, providers who are successfully meeting all the other program measures are still facing penalties and can do little to prevent these losses. These measures should be removed from the MU program.

2. **Align various Medicare quality reporting programs.** MU has a quality reporting program within it. Better alignment of the separate Physician Quality Reporting System (PQRS) program and MU quality reporting requirements is needed. Physicians who meet MU quality requirements should be deemed as meeting PQRS. This will ensure that physicians are still actively using EHR technology without requiring them to report on quality measures twice.

3. **Expand current hardship exemptions.** This will provide more ways for certain categories of physicians who face specific obstacles to meet the MU program (i.e., physicians close to retirement where this practice investment does not make sense) can avoid penalties.

4. **Improve interoperability.** Until systems are interoperable, the value of health IT cannot be realized and will hamper innovation. For example, a lack of provider directories that allow physicians and patients to determine where to send information and absence of a single national approach for matching patients to their records are critical pieces to interoperability.

5. **Streamline EHR certification.** Move existing certification criteria away from testing prescriptive measures and concentrate on interoperability, quality measure reporting, and privacy/ security, which will result in more usable systems.

6. **Shorten the 2015 reporting period to 90 days.** Keeping physicians and other health care providers on track with MU requires a shorter reporting period. Vendors still are rolling out Version 2014 and the systems will not be ready in time for a full-year reporting period.

Telemedicine

Telemedicine is a rapidly emerging platform that will push the health care delivery system into the 21st Century. Telemedicine-related technologies will: 1) ameliorate provider shortages; 2) increase access to medical care while improving affordability for geographically remote and underserved populations; and 3) reduce health care cost over time. The AMA is committed to advancing the use of telemedicine while ensuring that these technologies are implemented in a manner that protects patient safety and promotes improved patient outcomes. The diversity of these technologies, clinical practice settings, and medical specialties, along with the rapid rate of innovation, are factors that should be carefully weighed by policy makers.

Alleviate Barriers Through Payment Policy Changes

The AMA urges the Committee to reimburse for more telemedicine services and to promote telemedicine that supports care delivery that is patient-centered, promotes care coordination, and facilitates team-based communication.

1. The AMA supports provisions included in H.R. 4015/S. 2000, the "SGR Repeal and Medicare Provider Payment Modernization Act of 2014," that would allow telehealth services not currently covered under Medicare to be covered services for alternative payment models (APM) and qualifying APM participants, including Pioneer Accountable Care Organizations, to promote care coordination.

2. The AMA supports expanding access to telemedicine services under the Medicare program by removing current law geographic requirements under section 1834(m) of the Social Security Act.

3. The AMA supports mandating coverage allowing dual eligible beneficiaries to receive telemedicine coverage to the extent their Medicaid-only counterparts do.

The AMA supports additional Medicare pilot programs to enable coverage of telemedicine services, including, but not limited to, store-and-forward telemedicine. Because the coverage of and payment for

telemedicine services are related to the evidence in support of telemedicine, the AMA encourages additional research to develop a stronger evidence base for telemedicine. The AMA meets with national medical specialty societies on a regular basis to accelerate efforts to expand the evidence base—this will lead to clinical practice guidelines as well as information that insurers need when making coverage determinations. Additionally, our policy supports the development of pilot programs and demonstration projects to test how telemedicine can be integrated into new payment and delivery models.

State-based Licensure

The AMA strongly supports state-based licensure because it protects the interest of patients and the ability of states to enforce state medical practice laws. State-based licensure provides a method to hold out-of-state providers accountable for the medical services they provide. The AMA is supportive of the work done by the Federation of State Medical Boards (FSMB) to provide an expedited and streamlined licensure process for physicians seeking licenses in multiple states and is committed to assisting the modernization of current state licensure processes. The AMA opposes federal legislation that would preempt or waive licensure and medical practice laws for telemedicine encounters and strongly affirms that physicians must be licensed in the state where the patient receives services.

Personalized Medicine and Oversight of Laboratory Developed Test (LDTs)

Personalized medicine is already having a significant impact on patient testing and treatment, and is a central theme of the 21st Century Cures initiative. As the AMA highlighted in its September 8, 2014, written testimony, LDTs are a critical aspect of the practice of medicine, drive innovation, provide a critical safety-net to combat infectious disease outbreaks and bio-threats, and often constitute the only test option for patients with rare diseases. The AMA believes that the Food and Drug Administration (FDA) framework for the regulation of LDTs, released in July, is counter to the overarching goals of the Cures initiative—accelerating the discovery, development, and delivery of new cures—and urges the Committee to carefully review and consider the impact of this highly disruptive policy change.

FDA Regulation of LDTs Will Harm Patient Access to Diagnoses and Cures

The AMA has significant concerns with the FDA framework for the regulation of LDTs and strongly believes that this new regulatory authority would prevent physicians' ability to provide appropriate and clinically necessary medical care, limit access and delay development of life-saving diagnostic tests for patients, and slow innovation and integration of personalized medicine into modern medical practice.

Duplicative Regulations

As the Cures initiative seeks to reduce regulatory burdens to streamline innovation and new cures, the AMA urges the Committee to consider the significant burden that duplicative regulations will have on the future of personalized medicine.

Legal Authority of the FDA

The AMA questions the FDA's legal authority to regulate LDTs, which are not medical devices as defined by the Food Drug and Cosmetic Act (FDCA), but rather are medical procedures performed by laboratories and are essential services in the practice of medicine. If the FDA proceeds with the current draft proposal, the AMA strongly urges the agency to issue the new requirement through public notice

and comment, and to complete an economic impact analysis outlining the anticipated impact of new regulatory burdens on stakeholders. The AMA believes that the FDA requirements listed for LDTs will represent a major regulatory and cost burden on physicians and laboratories.

Antibiotic Development

The AMA recognizes that antibiotic resistance is of global concern and that there is a critical need to devote resources to new antibacterial medications, a Cures initiative focus. To ensure development of new antibiotic treatments, **the AMA supports H.R. 3742, the "Antibiotic Development to Advance Patient Treatment Act of 2013" (ADAPT), and urges the Committee to include this legislative proposal in the final Cures initiative.** A limited population antibacterial drug (LPAD) mechanism to provide a predictable and feasible approval pathway for pharmaceutical companies, H.R. 3742 would authorize the FDA to evaluate a medication's safety and efficacy in substantially smaller, accelerated clinical trials than currently required. Upon approval, the treatment would be narrowly indicated for use in a small, specific population of patients for whom the benefits of the drug have been shown to outweigh the risks. Additionally, the AMA applauds the H.R. 3742 provision that explicitly provides that the LPAD pathway amendments do not restrict the practice of medicine nor seek to restrain physician clinical decision-making.

Protecting Patient Data

Protecting patient privacy is paramount to physicians. However, as physicians move into an increasingly digitalized environment, more education and training is needed to ensure that the technologies they are using adequately protect patient information and that it remains secure. Physicians generally are not information technologists, and the encryption standards and processes that are necessary to meet Health Insurance Portability and Accountability Act (HIPAA) security requirements and to avoid data breaches are very complex. As evidenced by recent data breaches at large companies and within health care, identifying weaknesses in a practice's security and taking steps to mitigate them are extraordinarily difficult, and physicians need adequate support. Additionally, HIPAA requirements are also complicated and confusing for app developers and other technology companies, and clear guidance is needed to help them navigate these mandates and remove barriers that prevent them from entering the health care marketplace. Otherwise, innovations and new technologies that can advance patient care will be limited.

The AMA appreciates the opportunity to provide comments on the 21st Century Cures initiative and looks forward to working with you and the Committee to ensure policies support and promote physicians' ability to practice medicine in the innovative health care environment of the 21st Century through new technologies and cures.

Sincerely,

James L. Madara, MD