

February 23, 2015

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:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate your leadership and comprehensive approach to identifying legislative proposals that would accelerate the discovery, development, and delivery of new cures. The AMA welcomes the opportunity to comment on this initial draft of the “21st Century Cures Act” (Cures). Physicians, along with patients, are at the forefront of a fundamental transformation in healthcare resulting from the intersection of genetic and genomic breakthroughs, the rapid growth of digital capabilities, and the resultant new tools for patients and physicians. Leveraging these new capabilities will require new pathways for research where patients and physicians have a greater role as part of a learning health care environment, strategic modernization of regulatory oversight, coverage and payment flexibilities, and, critical to all the foregoing, development of a workable, interoperable data sharing infrastructure. In our prior comments to the Committee, the AMA outlined needed reforms in five areas that directly impact physicians’ ability to deliver high quality care to patients in this new environment: 1) electronic health records (EHRs) and 21st Century technology; 2) telemedicine; 3) personalized medicine and laboratory developed testing services and procedures; 4) antibiotic development; and 5) protecting patient data. We appreciate that the Committee included provisions in the draft legislation that address a number of areas we outlined and include comments below on those and other provisions.

As a threshold matter, the AMA appreciates that the Committee continues to deliberate in a number of key areas of significant interest to physicians and their patients. Specifically, there remain placeholders for interoperability, precision medicine, and modernizing regulation of diagnostics. We would welcome the opportunity to meet with the Committee to discuss in greater detail our recommendations in these critical areas.

Section 2181. Interoperability

The AMA looks forward to additional information on Section 2181 concerning interoperability and working toward the goal of an interoperable health information infrastructure. The promise of 21st Century cures is inextricably linked with the ability of physicians and patients to use technologies that support effective communication and that allow them to move information seamlessly through the health care continuum. However, there are substantial barriers to making the foregoing a reality.

It is not possible to divorce the lack of an interoperable health care infrastructure from the prescriptive nature of the Meaningful Use (MU) program. The MU statute requires physicians to use certified EHRs in order to meet MU requirements. While the statute lists a discrete set of MU requirements—one of which is interoperability—the implementation of this program has resulted in a substantial expansion of the program, adding numerous and overly complex measures that have nothing to do with data exchange. Vendors must prioritize their development process to meet this unwieldy set of mandates in order to obtain certification. What this means is certified systems are created with the MU requirements as the first priority while physician client needs (and thus patient needs) are a distant second. The MU requirements are in effect a barrier to interoperability because they are taking away valuable time and resources that could be better spent addressing the key issue of interoperability.

Prior to MU, the early development of EHRs was centered on customer needs and was poised to flourish in a traditional consumer-driven marketplace. Although well intended, the heavy handed approach of the MU program is marked by regulatory overreach which is stifling innovation and is negatively impacting the adoption of new technologies. The program is excessively burdensome to vendors, physicians, and medical staff alike. In particular, the challenges physicians are experiencing with EHRs that cannot interoperate is evidenced by their low participation in the MU program and the high level of dissatisfaction with these products. Many MU requirements are tied to the assumption that EHRs are fully capable of interoperability. This is not the case, and as a result, the majority of physicians may face MU penalties. To date, many have elected to take these financial penalties rather than continue investing in systems that lack interoperability and force them to care for patients in a manner that does not improve quality or drive efficiency.

We strongly urge the Committee to consider that improving interoperability and usability of EHRs is tied to streamlining MU regulations for physicians. Specifically, the AMA urges the Committee to consider more effective approaches to the MU program and regulation of health information technology including:

- Removing the Pass-Fail Approach of the Meaningful Use Program. 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 to earn an incentive and avoid a penalty. In turn, vendors must certify to meet all of the MU requirements. As discussed above, this prioritizes MU measures over interoperability and usability.
- Promote interoperability. The MU incentives were predicated on significant cost savings associated with exchanging information across EHRs. Data exchanged today, however, essentially amounts to multi-page documents that cannot be easily transmitted or incorporated into the patient's chart, reducing the utility of this information. Additionally, physicians are often charged tens of thousands of dollars for costly interfaces and data exchange fees. Importantly, the information stored and exchanged in the EHR is not in a usable format for quality improvement and lacks standardized data elements, data formats, and definitions. This is a cornerstone of interoperability that must be adopted to improve outcomes and eliminate administrative cost to clinicians, hospitals, and others who have to map their data differently every time they send it to an external entity.

- Streamline EHR certification. The Centers for Medicare & Medicaid Services (CMS) MU requirements and the focus of the Office of the National Coordinator for Health Information Technology (ONC) certification process should prioritize interoperability and EHR usability. The current process simply ensures that EHRs meet the MU measures without addressing if information can be exchanged, incorporated, and presented to a physician in a contextual and meaningful manner.
- Align various Medicare quality reporting programs. MU includes a separate quality reporting program. Better alignment of the Physician Quality Reporting System (PQRS) program and MU quality reporting requirements is needed. Physicians who meet the more robust PQRS quality requirements should be deemed as meeting MU. This will ensure that physicians are still reporting on quality measures to improve care and will reduce administrative burden by not having to report on quality measures twice.
- Expand current hardship exemptions. Expansion of hardships will provide more ways for certain categories of physicians who face specific obstacles to meet the MU program (e.g., physicians close to retirement where this practice investment does not make sense) can avoid penalties.

The foregoing are concrete solutions that will increase the capability of physicians and the health care system to adopt technology solutions that are the necessary prerequisite to changes in the current approaches to research, regulation, clinical practice, and insurance coverage. All of the foregoing enterprises require access to reliable, high quality data that is available along the continuum. Creating silos of information will not accelerate cures nor will it create the requisite efficiencies needed to leverage the benefits of next generation technologies.

Section 2161. Modernizing Regulation of Diagnostics

Physicians have been at the forefront of one of the greatest revolutions in medicine—the application of genetic knowledge to clinical practice. Physicians have been and continue to be at the intersection of providing patients’ medical care and advancing clinical knowledge to improve upon the current standard of care. Millions of testing procedures are performed reliably, accurately, and safely every year running the gamut of simple clinical procedures to highly complex—including certain genetic and next generation testing services. It is estimated that approximately 70 percent of clinical decisions are guided in part by clinical testing. As a result, the AMA has serious concerns that the Food and Drug Administration’s (FDA) proposal to regulate laboratory developed testing services and procedures will choke off the primary development pipeline for new diagnostics, deny patients access to treatments and cures, and compromise the nation’s public health capabilities, including diminishing our ability to detect and combat bio-threats and infectious disease outbreaks.

The AMA is not alone in these concerns. During an FDA hosted two-day meeting in January on the Agency’s proposed regulation of laboratory developed testing services, a wide array of stakeholders raised the same or similar concerns—including the association representing public health clinical laboratories and member laboratories. The latter in comments to the FDA’s docket outlined a grim reality that the FDA’s proposal would not only curtail the capacity and needed flexibilities of community laboratories that provide surge capacity during an outbreak, and sentinel network laboratories that provide detection capabilities for the public health laboratories, but every state’s public health laboratory would be hamstrung should the guidance be finalized. Furthermore, the FDA’s proposal will impose another

layer of regulation—beyond the Clinical Laboratory Improvement Amendments (CLIA) and, for many laboratories, third-party accreditors and state regulatory oversight. In addition, the FDA’s proposal involves regulation of the practice of medicine—achieved by treating physician services and procedures as devices, a questionable legal fiction.

The AMA does agree that there is a need to modernize the existing regulatory framework for laboratory developed testing services that are offered by physicians to their patients and provided in laboratories subject to CLIA, as well as the regulations for commercial diagnostics kits mass produced by manufacturers that are currently regulated by the FDA. However, the steps for achieving the foregoing include modernizing CLIA by mandating third-party accreditation of all clinical laboratories and increased transparency of documentation of laboratory clinical and analytical validation. In addition, the AMA urges Congress to confer the FDA with explicit authority to regulate direct-to-consumer tests and testing services where incorrect results could cause harm to patients and the test methodology is not transparent nor well understood (as in the case of tests that use complex and proprietary algorithms to produce results). The AMA also supports streamlining the oversight for manufacturer commercial kits subject to FDA regulation, including greater flexibilities for manufacturers to incorporate modifications.

The push to regulate laboratory developed testing services appears to be related to concerns with highly complex genetic/genomic tests. The AMA agrees that a small subset of complex genetic/genomic tests, e.g., those that use proprietary and non-transparent algorithms that do not lend themselves to review and refinement by laboratory physicians and professionals, should be subject to oversight, potentially by the FDA. The AMA supports an oversight mechanism that would ensure the analytical and clinical validity of such tests. However, the FDA’s proposed framework goes far beyond addressing those “black-box” tests, and instead subjects a massive number of laboratory developed testing services to costly and burdensome requirements that would add little or no value to the testing services but would severely disrupt their availability to patients and treating physicians. It is notable that this massive interruption in clinical practice and commitment of the FDA’s time and resources into the development of a new infrastructure will divert limited time, resources, and effort from developing and implementing a viable and agile framework to address the complex regulatory challenges posed by next generation sequencing—a technology and method that will likely overtake existing methods the Agency is attempting to regulate. This will have implications for President Obama’s Precision Medicine Initiative which will rely upon next generation sequencing along with whole genome sequencing to generate relevant breakthroughs.

Section 2301. Precision Medicine

The AMA is very interested in working with both Congress and the Obama Administration to advance a number of the broad objectives outlined to date concerning President Obama’s Precision Medicine Initiative (Initiative) including the 1 million genome project that would be led by the National Institutes of Health (NIH). The Initiative is not limited to personalized medicine (genetic and genomic testing and related tailored prevention or treatments), but contemplates novel research methods, uses of digital health, and is premised on a level of data interoperability and databases that do not currently exist. The AMA looks forward to specific language related to Section 2301. It is notable that the final Cures legislation could have a significant impact on the feasibility of the Initiative. For instance, lack of interoperability will be a serious barrier to these efforts as already outlined during a two day NIH meeting concerning the million genome project. In addition, FDA regulation of digital health and laboratory developed testing

services will have implications for the million genome project's use of such tools to advance medical knowledge and patient engagement.

Section 4181. Telemedicine

The AMA strongly supports the Committee's efforts to remove restrictions on Medicare coverage of telemedicine services that do not reflect the magnitude of technological changes since the Medicare telehealth statutory provisions were adopted. The AMA urges the Committee to reimburse for more telemedicine services as well as to promote telemedicine that supports care delivery that is patient-centered, promotes care coordination, and facilitates team-based communication. We appreciate that the framework outlined by the Committee as part of Section 4181 attempts to expand coverage, but it may add extra complexity by establishing a second coverage pathway. We urge the Committee to consider a streamlined approach that the AMA supports by including:

- provisions of 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;
- expanded access to telemedicine services under the Medicare program by removing current geographic requirements under section 1834(m) of the Social Security Act; and
- coverage of telemedicine services for dual eligible beneficiaries to the same extent as their Medicaid-only counterparts.

Furthermore, 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 continues to regularly meet with national medical specialty societies to provide support for their efforts to expand the evidence base—this will lead to clinical practice guidelines as well as information that insurers need when making coverage determinations. 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. Therefore, the AMA appreciates the Sense of Congress language included in this section and has suggested relevant modifications to the Committee to reflect the nature and scope of the Federation of State Medical Board's Interstate Compact. **We welcome the opportunity to continue working with the Committee to identify flexibilities to increase telemedicine coverage in the Medicare program.**

Sections 1061-1064. Antibiotic Development

For years, AMA has recognized that antibiotic resistance represents a serious public health threat and strongly supports the inclusion of provisions in the draft legislation that would establish important incentives and pathways to accelerate development of next generation antibiotics. The AMA has publicly supported H.R. 3742, the "Antibiotic Development to Advance Patient Treatment Act of 2013" (ADAPT), and appreciates the inclusion of similar provisions in the draft legislation. While certain

prescribed activities outlined in these provisions may need to account for FDA capacity and resources, overall there is a compelling need for these provisions and **the AMA strongly supports the inclusion of these provisions in the legislation that is ultimately introduced.**

Section 2087. Quality Activities Clarification; and Sections 3001-3002. Clinical Research Modernization Act

The AMA strongly supports efforts to clarify and modernize the quality reporting infrastructure protections and those protections related to research involving human participants. To that end, the AMA strongly supports Sections 3001-3002 that would modernizes the requirements vis-a-vis institutional review board (IRB) processes, particularly for clinical trials conducted at multiple sites. These provisions will reduce regulatory duplication and unnecessary delays that have plagued research that spans multiple sites. This is essential to increase the number of research activities that seek scale—including, for example, the President’s Precision Medicine Initiative Million Genome project. Furthermore, Section 2087 provides much needed clarification that quality improvement activities are not subject to the Common Rule. This has been a source of confusion and a resource drain for national medical specialties that, as part of quality improvement activities, have established clinical data registries and are already complying with the Health Information Portability and Accountability Act (HIPAA) privacy and security requirements. When institutions insist on compliance with the Common Rule requirements when the activities are for quality improvement, it has imposed substantial and costly barriers to these essential activities that improve patient health outcomes. **Therefore, the AMA strongly supports the inclusion of these provisions in the legislation that is ultimately introduced.**

Section 2091. Commission on Data Sharing for Research and Development; and Section 2092. Recommendations for Development of Clinical Data Registries

The AMA applauds the Committee’s efforts to develop an infrastructure that can support the continuum of activities (research, regulatory, quality improvement, clinical decision support, and coverage, for example) that can be facilitated by state-of-the-art clinical data registries. National medical specialty societies have led the way in the establishment of such registries to support quality improvement, development of the evidence base, and other essential activities. However, we do have a few concerns related to sections 2091(b)(2) and 2092, which create new categories of registries/registry requirements that fail to take into account existing and developing quality registries (including Qualified Clinical Data Registries (QCDR)) for quality reporting under PQRS, Medicare value-based modifier, and MU. Specialties are devoting substantial resources to create and maintain registries. Quality registries are also being used for research purposes, post-market surveillance, coverage decisions, and reimbursement, not just for quality improvement. **We would like to work with the Committee and with medical specialties to ensure that the new language is harmonious with existing registry features and requirements.**

Ensuring interoperability is another critical challenge in this space. Taking initial steps to improve the underlying data captured within the EHR and registries is a key component of moving medicine forward, but one that requires a collective effort from the medical community. These definitions should be developed through a consensus process that includes all specialties and practitioners (not just physicians) who understand the clinical context of the data elements based on the patients for whom care is provided. Semantic interoperability, syntactic interoperability, and functional standards are key to establishing the data exchange consistency needed across health information technology. Any future benefits from

alternative payment models and value-based pay are premised on registries, vendors, and payers working with medical associations to establish this level of standardization. For physicians and the research community to fully realize the full potential of data aggregation the following things must occur:

- Interoperability between registries and EHRs. There are specific formats to move data and program language to exchange data. However, not all registries are operating on the same standards. There is a need to encourage registries, such as QCDR to exchange data with EHRs through a uniform standard. CMS requires QCDRs to submit their data in one format and the CMS standards should be a sufficient starting point. It must be recognized that standards evolve over time and may be inappropriate to mandate a specific standard through legislation, especially as technology evolves.
- Clinical Data Definitions. There is a need to define clinical data definitions so any time a data element is captured/exchanged it means the same thing across registries and EHRs. There are some registries, large health systems, and third-party vendors who have begun this work. However, if every society, health system and vendor creates these standards, we still will not have a set of national standards. By requiring EHR vendors, registries and all other electronic data systems for performance measurement/evaluation and clinical decision support to use standard definitions it would facilitate “semantic” interoperability.
- Standard Formats. There is the need for the most common data elements to be standardized in a universal format. For example, date of birth can be entered as 012915 or January 1, 2015, into the EHR and/or registry. This level of variability makes it difficult to query and exchange data across systems. Here “syntactic” interoperability, like semantic interoperability, requires the establishment of standard data formats so that two exchanging systems know how the data should be formatted and incorporated.
- Functional Standards. EHR data is in an unstructured free text format. To enhance quality, a third party and/or an individual needs to scrub and clean this information to make it meaningful. For example, when a patient complains of shortness of breath, this is simply typed into the EHR, but for performance improvement you need to know exactly what the patient means by shortness of breath. Is it shortness of breath because the patient just walked a mile or due to a particular condition? The functional status types of definitions have not been widely defined because it is neither needed nor relevant for payment. To begin this work, stakeholders must start with the most universal data elements and most commonly used standards.

The AMA and national medical specialty societies are ready to assist with this task. We welcome the opportunity to work with the Committee on a grant program at the Department of Health and Human Services to launch and maintain this work within the private sector in the interest of the public good.

Section 4381. Exempting from manufacturer transparency reporting certain transfers used for educational purposes

The AMA has been a staunch advocate of transparency in the interactions between physicians and industry and inclusion of the Physician Payment Sunshine Act in the Affordable Care Act. We believe that inclusion of this provision in the final Cures legislation is needed to remedy onerous and burdensome reporting obligations imposed by CMS that have already chilled the dissemination of medical textbooks,

peer-reviewed medical reprints and journals, and to avert a similar negative impact on access to independent certified and/or accredited continuing medical education (CME). This provision would ensure that efforts to promote transparency do not undermine efforts to provide the most up-to-date peer-reviewed medical knowledge, which through timely dissemination improves the quality of care patients. **The AMA strongly supports this provision.**

Sections 4281. Medicare Part D Lock-In

The AMA has long advocated for public policy solutions that will combat prescription drug diversion, abuse, overdose and death. Supporting physician clinical decision-making at the point of care through modernized, up-to-date patient specific information on dispensed prescription medications has been a major public policy initiative that we continue to support because it is sensible, proven, and it works. The AMA is extremely concerned that a number of legislative proposals would limit clinical decision-making or prevent physicians from providing patients with necessary medical treatment and referral.

There have been a number of proposals for a Medicare lock-in program that would, for example, authorize Part D prescription drug plans (PDPs) to determine that certain patients are misusing controlled substances, and then impose coverage limits so patients could only obtain controlled substance prescriptions from one physician and have them filled at one pharmacy. In response to various iterations of the foregoing proposal, the AMA has noted that PDPs only have information about their subscribers' claims for Medicare-covered drugs; they do not know their health status, treatment plans, or diagnoses. Many problems would result from adoption of the policy. For example, hospitalized patients could be prevented from filling prescriptions provided at discharge because they were not from the designated prescriber. Patients may not be able to easily access a designated pharmacy or prescriber. Moreover, patients may be seeing more than one physician who legitimately prescribes needed controlled substances. The proposal to lock-in certain Medicare beneficiaries is not a proven strategy, could be expanded without adequate justification, is premised on the faulty assumption that insurance company decisions to lock-in patients to certain providers and/or pharmacies could actually be appealed in a timely way, and fails to account for a significant and carefully tailored set of policies that are already working in the Medicare Part D prescription drug program.

The AMA has been actively engaged with CMS, along with other stakeholder organizations representing providers and patients on Medicare Part D issues, and submits comments every year on draft guidance issued for Part D plans. For cost year 2013, CMS authorized Part D plans to implement utilization measures to address outliers in opioid analgesic prescribing/dispensing. The Medicare Part D Overutilization Monitoring System (OMS) was implemented on July 31, 2013, to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of prescribed medications as required by regulation. This represented a second round of guidance issued to plans that began in 2011 for cost year 2012. The AMA provided comments to modify and target utilization review for outliers of opioid analgesics and emphasized the importance of communicating with prescribers where: (1) multiple prescribers were involved and may have been unaware of existing prescriptions issued by others; or (2) prescriber DEA number had been illegally used. Part D plans have been authorized since cost year 2013 to employ utilization review and directed to communicate with prescribers and, if necessary, beneficiaries prior to implementing point-of-sale edits or point of sale denials. While this places the burden on payers—Part D plan—to communicate with prescribers and pharmacies, it is an appropriate alternative to imposing substantial burdens on patients

who may be inappropriately locked-in and their health care providers who have to contend with a broken Part D appeals process that all major stakeholders agree is not functional.

Section 4281, like earlier Part D lock-in proposals, suffers from a number of infirmities that will harm patients and their access to medically necessary medication. First, this provision is overly broad and could eliminate pharmacy choice for a large number of beneficiaries. Unlike other lock-in proposals, Section 4281 would authorize PDPs to initiate lock-in without evidence that a patient is misusing, abusing, or diverting their medication, only that they have obtained coverage for medication that the plan believes has a potential for fraud or abuse. (Section 4281 does not limit PDPs to medications that are demonstrated to be diverted, abused, or misused by the Centers for Medicare & Medicaid Services, for example.) PDPs are not required to first notify prescribing physicians that the appropriateness of the prescription(s) are in question—instead PDPs are authorized to notify beneficiaries even though PDPs do not have access to the patient’s medical record. Second, this provision would permit PDPs to lock the patient into the pharmacy of the PDP’s choice. The foregoing is a glaring and obvious conflict of interest where plans are able to select pharmacies based on cost as opposed to patient accessibility. Furthermore, PDPs are not required to do anything more than what they currently do to monitor use of medications by their beneficiaries. PDPs are not required to provide any assistance to beneficiaries. These provisions are not designed to promote improved patient health outcomes nor to stop misuse, abuse, or diversion of covered Part D medication. In contrast, the OMS program includes an effective mechanism to facilitate communication between all relevant prescriber(s) and the PDP and ensures that clinical considerations are the basis of subsequent prescriptions and necessary therapeutic interventions. **The AMA strongly urges the Committee to remove this provision from the final legislation.**

Sections 2061-2063. Sensible Oversight for Technology which Advances Regulatory Efficiency

The transformation of medicine is already well underway and driven by the rapid uptake and use of digital health products and the software that supports these devices. The AMA supports efforts to increase regulatory flexibilities that are essential for innovation to occur. The AMA has generally welcomed the prodigious efforts of the FDA to update oversight and guidance in the digital health space to better reflect the appropriate balance between risk and benefits as well as the need to adopt a risk-based approach given the finite Agency resources and the looming wave of products and devices under development. We also appreciate that regulatory certainty is essential to ensure that developers understand the rules of the road and are able to forecast and plan an appropriate development pathway. It is for this reason the AMA is interested in sections 2061-2063 which would create a completely new regulatory framework. Directing the FDA to develop new regulations could delay finalization of the oversight structure for at least two to three years, potentially. **In addition, the AMA does have questions related to the risks that physicians would assume under the proposed framework under Sections 2061-2063.** These provisions also raise issues that are directly related to the Precision Medicine Initiative, and we would welcome the opportunity to discuss with the Committee.

Section 2088. Access to CMS Claims Data for Purposes of Fraud Analytics

AMA policy supports fraud prevention that is targeted and conducted by appropriate authorities. This section would allow authorized third parties to have real time access to claims data for fraud prevention. **The AMA would not support this provision since the U.S. Department of Health and Human Services Office of the Inspector General, the CMS contractors, the U.S. Department of Justice, and state Medicaid Fraud Units have access to this information and have appropriate safeguards and**

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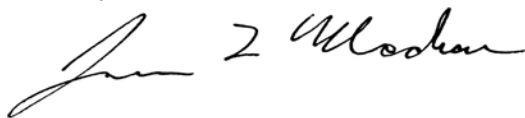
capabilities in place. Expanding access to entities without existing safeguards and less accountability to the public will only result in poorly targeted fraud efforts and other unintended consequences, such as identify theft.

Section 4241. Treatment of Global Surgery Services Rule

In the 2015 Final Medicare Physician Fee Schedule Rule, CMS finalized a policy to transition 10- and 90-day global period codes to 0-day global period codes in 2017, and 2018, respectively. Because the current CMS policy will have a wide-ranging impact on patients, physicians, hospitals, third-party payers, and Medicare, we appreciate that the Committee has included a provision that would prevent implementation of this policy. Global codes include necessary services normally furnished by a surgeon before, during, and after a surgical procedure. Global codes are classified as 0-day (typically endoscopies or some minor procedures), 10-day (typically other minor procedures with a 10-day post-operative period), or 90-day (typically major procedures with a 90-day post-operative period). Approximately 4,200 of the over 9,900 Current Procedural Terminology (CPT) codes are 10- or 90-day global codes. Despite the fact that the policy will affect 10-day global codes in 2017 and 90-day global codes in 2018, CMS has not yet developed a methodology for making this transition. The Agency has stated that it does not know how best to proceed. Nevertheless, CMS must begin to transition all these codes no later than February 2016. Implementation of this policy has consequences related to the objectives of the 21st Century Cures Initiative because, among other problems, it obstructs clinical registry data collection and quality improvement initiatives and will likely negatively impact patient care as it creates disincentives to follow-up care through imposition of additional co-pays. **The AMA strongly supports the inclusion of section 4241 in the bill that will be introduced.**

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 the proposed 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,

A handwritten signature in cursive script, appearing to read "James L. Madara".

James L. Madara, MD