AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

June 17, 2015

The Honorable Fred Upton, Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Ranking
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone,

On behalf of the American Association of Orthopaedic Surgeons (AAOS) and the undersigned orthopaedic specialty societies, we applaud your work on the 21st Century Cures initiative. This forward-looking framework has the potential to accelerate innovation, boost research, streamline drug and device approvals, and enhance interoperability and telemedicine, all of which will improve patient care exponentially. We share the goal of accelerating cures for patients, and the policy and programmatic improvements in this legislation are needed to do so. Sharing of research data and increased coordination, along with provisions for including patient experience into the regulatory decision-making process, are important steps. Further, physicians, through electronic health information exchange, should be able to modernize their practices to support the coordinated care that will improve health and prevent costly complications, and enable their participation in new payment and delivery models. We believe this can also effectively improve quality, safety, and efficiency of health care delivery and provide more opportunities for patients to become more active participants in their own care.

TITLE I

Subtitle A, Section 1002 – NIH Innovation Fund

We support increased funding for National Institutes for Health (NIH) and furthering research, especially on musculoskeletal conditions, which provide a significant return on investment.

Subtitle B – National Institutes of Health Planning and Administration

We support NIH reforms including travel to scientific conferences and meetings important to the mission of NIH.

TITLE II

Subtitles L, M – Medical Devices

Devices are integral to an orthopaedist's practice, whether it's an artificial hip or a pedicle screw. The 21st Century Cures bill makes a number of significant improvements to the device approval process at the Federal Drug Administration (FDA). Many of the measures outlined in the bill support/augment initiatives FDA has already begun exploring. It would require the FDA to establish a priority review program for certain breakthrough medical device technologies for more effective treatment of life-threatening or irreversibly debilitating diseases or conditions (Subtitle L, Section 2201 – Priority Review for Breakthrough Devices). The legislation also allows third party quality system assessment to expedite the review process and facilitate a prompt FDA decision; clarifies that valid scientific evidence may include registry data, studies published in peer-reviewed journals, and data collected in countries other than the US as long as certain criteria are met; allows the FDA to focus its

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430
www.aaos.org/dc

oversight on certain Class I and Class II devices that pose more risks to patients; and improves the medical device classification panel review process at the FDA to ensure adequate expertise and allow for presentation by the device sponsor.

Subtitle M, Section 2227 – Humanitarian Device Exemption Application

We strongly support the change to the Humanitarian Use Device exemption, which gives the FDA the authority to increase the humanitarian device exemption to diseases and conditions that affect up to 8,000 individuals in the US (currently 4,000). This will allow more people to be helped who manifest rare conditions.

Subtitle K, Section 2181 – Enhancing Combination Products Review

We support requiring the FDA to issue a final guidance describing the role of all agency centers when reviewing a combination product. The trend for new orthopaedic products will continue to be combination products. There needs to be greater transparency to the determination of primary mode of action and an honest assessment of how that determination is impacting innovation.

Subtitle N, Section 2243 – Exclusion from Definition of Device

We support this section, which updates the regulatory laws around software and creates clarity for developers and reviewers alike.

Subtitle O – Streamlining Clinical Trials

We support removing the limitation on the use of central institutional review boards (IRBs) in medical device trials. Many devices used to treat special populations are still under investigation (Investigational Device Exemption (IDE), etc.) and use of the device outside of the ongoing study is subject to additional review by FDA and, locally, IRBs. While FDA has a mechanism in place to expedite the review of these requests, many IRBs are not familiar with or equipped to provide a rapid turnaround. Many institutions require IRB review in an effort to ensure patient safety and minimize liability. A centralized IRB, with experience in these kinds of requests and with processes in place to enable quick reviews, will pave the way to expedited access to care for patients with no other diagnostic or treatment alternatives.

TITLE III

Subtitle A, Section 3001 – Ensuring Interoperability of Health Information Technology

We have actively encouraged our memberships to adopt health information technology (HIT) and have provided tools for them to become meaningful users of electronic health records (EHRs). We believe that HIT is a fundamental component to improving our nation's health care system, and more and more orthopaedic surgeons are integrating EHR technology in their practices and meeting meaningful use requirements. However, the electronic exchange of health information is not possible without interoperability.

We applaud the effort in this legislation to work toward the goal of a national interoperable health information infrastructure.

Interoperability is vital to success of EHRs and in enhancing access to quality care. It is what makes an EHR useful. When data-sharing works, it has good results – when doctors use EHRs and share data with other providers, they could, for example, monitor their sickest patients and use that awareness to improve care and cut costs.

However, data blocking impedes innovation and care, while adding barriers to physician compliance with regulatory requirements.

This bill includes for the first time a framework for improving interoperability of qualified electronic health records and health information technology. It describes what the framework would look like, creates a charter organization to work with the health information technology standards and policy committees to give Health & Human Services (HHS) recommendations around interoperability, and allows providers to exchange patients' medical records under Health Insurance Portability and Accountability Act (HIPAA) without patients' express consent. The bill also creates a way for vendors to be decertified in future years if they don't meet certification criteria, including the definition of interoperability.

It is especially important that, rather than leaving providers with software that can't meet federal requirements, providers will be able to request a hardship exemption from the meaningful use program to avoid payment cuts. The government should not financially penalize doctors whose electronic records systems fail to demonstrate the capacity to share data.

Further, we believe one particular opportunity for the exchange of health information across the spectrum of health care providers lies with clinical data registries. Clinical registries can be a powerful tool for scientific discovery, clinical transformation and quality improvement. For these reasons, attention on national clinical registries is increasing among medical specialty societies and policy makers. Congress has recently enacted legislation that incentivizes registry participation by deeming registries as a portal for physicians to participate in the Physician Quality Reporting System (PQRS) and the new Medicare Incentive Payment System (MIPS) program. However, the lack of interoperability between electronic health records and clinical data registries has been a serious impediment to data collection efforts. We support extending the reach of clinical data registries to allow for other providers involved in a patient's care to participate and thus have access to relevant patient information. Orthopaedic registries may be most helpful in the case of identifying medical devices implanted in patients, which is why we have funded development of the American Joint Replacement Registry. While not in the current legislation, we would also like to see an Interdepartmental Clinical Registry Development and Support program. This initiative would link the Agency for Healthcare Research & Quality (AHRQ) Registry of Patient Registries program, the CMS Center for Clinical Standards and Quality and the FDA Medical Device Epidemiology Network Initiative (MDEpiNET) to expand and standardize patient outcomes tracking and reporting.

Subtitle B, Section 3021 – Telehealth Services under the Medicare Program

We support the provisions in the proposal that would help advance opportunities for telemedicine and new technologies to improve the delivery of quality health care services to Medicare beneficiaries.

Subtitle C, Section 3041 – Exempting From Manufacturer Transparency Reporting Certain Transfers Used for Education Purposes

This section would exempt certain transfers of value to physicians from reporting requirements that physicians have indicated hinder them from participation in important continuing medical education activities.

We are supportive of clarifying that those peer-reviewed journals, journal reprints, journal supplements, and medical textbooks are excluded from the reporting requirements under the Sunshine Act.

Subtitle E, Section 3081 – Improvements in the Medicare Local Coverage Determination (LCD) Process

We support adding transparency to the Medicare LCD process.

Much like private insurers, Medicare has local coverage determinations. The LCD tells you what Medicare will cover in its Medicare Administrative Contractor (MAC) jurisdiction. Failure to follow the requirements of an LCD will result in an overpayment, which could be sought after an audit. Physicians are facing improper payment audits in a number of jurisdictions where the MAC has not developed formal coverage guidance on the audited procedure. This means that Medicare can recoup payments from surgeons after surgeries have already been performed due to so-called "documentation errors" based on documentation requirements that were never made known to the surgeons. Adding transparency to the LCD process is a step in the right direction.

Finally, we support the language that would exempt FDA user fees from sequestration. The user fees are critical to ensuring that the FDA is able to fulfill its mission to provide timely access to safe and effective new medicines and devices.

We appreciate your efforts and look forward to working with you to promote an innovative health care environment in the 21st century which will encourage excellence in the quality of care. If you have any questions or would like additional information, please contact Julie Williams at the AAOS Office of Government Relations at jwilliams@aaos.org or 202-546-4430.

Sincerely,

American Association of Orthopaedic Surgeons
Arthroscopy Association of North America
Ruth Jackson Orthopaedic Society
Scoliosis Research Society
American Shoulder and Elbow Surgeons
Pediatric Orthopaedic Society of North America
Cervical Spine Research Society
American Orthopaedic Society for Sports Medicine
Orthopaedic Trauma Association
Knee Society
American Spinal Injury Association
American Orthopaedic Foot and Ankle Society
American Society for Surgery of the Hand
American Association of Hip and Knee Surgeons