Recommendation
Over the last several months, leadership in the House Energy & Commerce Committee and the Senate Health, Education, Labor, and Pensions (HELP) Committee have passed bi-partisan legislation to advance medical innovation in the United States. AMIA urges Congress to move forward with compromise legislation this year which includes vital funding for efforts such as the Precision Medicine and Cancer Moonshot Initiatives.

House of Representatives
AMIA members enthusiastically supported House passage of H.R. 6 last year, which included dozens of provisions meant to improve the pace of discovery and innovation within our national research enterprise so that cures could be integrated more efficiently into care delivery for all Americans. As the national association for clinicians who leverage data and IT solutions to improve care, as well as the home for clinical researchers who utilize vast amounts of data and information to bring cures from the bench to the bedside, AMIA believes 21st Century Cures contains dozens of import provisions. Below we highlight some of those provisions we believe are foundational to deliver improved care for patients:

- **Section 2 – NIH and Cures Innovation Fund**
  - **Title 1 – Discovery**
    - Subtitle A – National Institutes of Health Funding
    - Subtitle F – Advancement of NIH Research and Data Access
    - Subtitle G – Facilitating Collaborative Research
  - **Title II – Development**
    - Subtitle A – Patient-Focused Drug Development
    - Subtitle C – FDA Advancement of Precision Medicine*
    - Subtitle D – Modern Trial Design and Evidence Development
    - Subtitle N – Sensible Oversight for Technology Which Advances Regulatory Efficiency (aka SOFTWARE Act)*
    - Subtitle O – Streamlining Clinical Trials
  - **Title III – Delivery**
    - Subtitle A – Interoperability*

U.S. Senate
We have also worked closely with the Senate HELP Committee to develop a host of corollary biomedical innovation bills. AMIA’s *EHR 2020 Task Force Report on the Status and Future Direction of EHRs*, served as the framework for five HELP Committee hearings in 2015, which included testimony from AMIA Board Chair, Thomas H. Payne, MD, Medical Director of IT Services with UW Medicine at the University of Washington. The Improving Health Information Technology Act of 2016 (S. 2511) was introduced and reported out of committee earlier this year, and is among those Senate bills AMIA supports. AMIA is especially appreciative of S. 2511 and S. 1101, known as the MEDTECH Act. We believe these efforts build upon and improve related House bills and would make strong additions to compromise legislation.

* = similar provisions passed by Senate HELP Committee as of September 2016
Data Sharing

As health informatics professionals, we believe data sharing is foundational to advance scientific discovery; conduct comparative effectiveness research; prevent medical errors; and promote biomedical research rigor, transparency and reproducibility. For instance, we are particularly supportive of Section 1124 – Accessing, Sharing, and Using Health Data for Research Purposes (H.R. 6), which would facilitate research using EHR data by hospitals and physicians under the HIPAA Privacy Rule. This provision would remove current legal barriers that limit how data generated within routine healthcare settings can be leveraged to discover new cures, deliver better care and act as more effective drivers of improved public health. Notably, there is no general exception for HIPAA covered entities to conduct quality improvement research where the primary purpose is to advance knowledge and to share what is learned through peer-reviewed publication and other means.3

Given the trend of increased digitization of health care through adoption of EHRs and other HIT, and advances in computational speed and complexity, we are entering a period of tremendous potential. Using biomedical informatics tools that include privacy-protections, it is possible to distribute a query for data across multiple sites and return a large, representative set of patient data allowing investigators to identify healthcare delivery “best practices” as well as potential new cures for disorders such as autism, diabetes, depression, and arthritis. It is essential, however, for our privacy laws to evolve in order for these techniques to be used equitably across the nation.

Another important provision in Section 1121 – Clinical Trial Data System would create a shared resource for publicly-funded research and analysis beyond any individual project. Such a system will be vital for efforts like the Cancer Moonshot, or Precision Medicine to be successful.

These are only a few examples within H.R. 6 that would have extraordinarily important implications for patients and for our nation’s capacity to be a leader in biomedical innovation. There are dozens more such provisions, which is why it is vital that Congress pass comprehensive legislation this year.

---

3 At § 45 CFR 164.501 and 164.506