

January 26, 2015

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

The Honorable Diana DeGette
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette:

On behalf of the undersigned organizations, we applaud the members of the Energy and Commerce Committee for their 21st Century Cures Initiative, aimed at accelerating the discovery, development and delivery of promising new treatments to patients. We strongly agree that new technology and data sources, such as physician-led clinical data registries, hold great potential to improve patient care. We strongly encourage the Energy and Commerce Committee, through the 21st Century Cures Initiative, to address interoperability as a means to advancing the work and potential of clinical data registries.

Clinical data registries that are EHR-based are dependent upon the interoperability of health IT. When interoperability is achieved, EHR-based registries are capable of integrating health information from a variety of data sources to be used by providers, researchers and other stakeholders to improve the efficiency and quality of care provided by clinicians, and to improve outcomes for patients. In order to effectively measure quality and performance, registries need access to data collected by electronic health records (EHRs). However, physicians often have difficulty in getting data out of their EHRs to participate in registries. Interoperability with registries is generally a low priority of EHR systems, and it often takes several months for EHRs to respond to their customer requests. While physicians and registries can make suggestions to EHR vendors to improve registries' access to data for use in registries, they may not be adopted unless required by the Office of the National Coordinator (ONC). In some cases, EHR vendors charge physicians significant "add on" fees to access their own patient data. Such charges and delays are preventing physicians from using valuable data to improve care for patients and to decrease health costs.

As a first step, certified EHRs should be able to provide interoperability to external clinical data registries and clinical platforms as part of their core functions. Therefore, we recommend that the Committee mandate that ONC require EHRs certified for Meaningful Use to be capable of integrating with clinical data registries for quality improvement purposes. This should not be an added cost but integral to the system core. Under this new requirement, it would be important that the security of

patient data be maintained. Additionally, physicians should have the rights to data on their practice and performance.

If registries are successful in integrating with an EHR, additional challenges stem from the wide variation across EHR systems in how data is collected, which data fields are built in, and what data fields are named. This variation creates complications when the registry seeks to aggregate and compare data across many different EHR systems. Further, data exchange standards required by Meaningful Use for certified EHR technology are not always sufficient to meet the needs of clinical data registries. The current meaningful use standard for the electronic transfer of patient health information is the Consolidated-Clinical Data Architecture (C-CDA). This standard defines how critical data elements should be structured and encoded to support interoperability and information exchange. The C-CDA provides basic information for transfer of care, but does not provide detailed specialty-specific data needed for national specialty registries.

We recommend that the Committee mandate the ONC to facilitate the sharing of data elements defined by medical specialties to help inform EHRs as to what data elements to collect. Allowing the clinicians to define these standards will result in a common library for all registries, EHRs, and primary data sources to use and make readily available. These would serve as a set of structured data elements based on the clinical evidence, incorporated into clinical guidelines and specified for integration into the EHRs for quality measurement, clinical decision support and post market surveillance. National specialties would do the work of determining what data elements and analyses are most relevant to quality improvement and patient care within a particular specialty. This would better assure that critical data elements are included in different EHR systems for users, and enhance aggregation of data across EHRs. Further, certified EHR vendors should participate in public efforts to define common data standards, such as those efforts underway by the Health Services Platform Consortium and the AMA's Physician Consortium for Performance Improvement National Quality Registry Network (PCPI / NQRN).

Addressing interoperability challenges faced by clinical data registries will result in better care and outcomes for patients through improved provider performance, faster development and implementation of meaningful quality measures, more efficient clinical trials, comparative effectiveness research and the development and adoption of best practices, and improved FDA post-market surveillance and Medicare coverage decisions. Without ONC facilitated EHR interoperability and uniform data fields, EHRs will fail to provide their original intended benefit of improving care for patients at the local, state, and national level. We encourage the Committee to consider these recommendations as you move forward with the 21st Century Cures Initiative, and we would welcome the opportunity to work with you on these issues.

Sincerely,

American Academy of Dermatology Association
American Academy of Ophthalmology
American Academy of Neurology
American Association of Neurological Surgeons

American College of Cardiology
American College of Emergency Physicians
American College of Rheumatology
American College of Surgeons
American Joint Replacement Registry
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society for Radiation Oncology
American Urological Association
National Association of Spine Specialists