ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

March 26, 2019

The Honorable Lamar Alexander
Chairman
Health, Education, Labor & Pensions
Washington, DC 20515

The Honorable Patty Murray
Ranking Member
Health, Education, Labor & Pensions
Washington, DC 20515

Chairman Alexander and Ranking Member Murray,

On behalf of the American Society of Clinical Oncology (ASCO), thank you for your work on 21st Century Cures, a landmark piece of legislation which will help accelerate the discovery, development, and delivery of promising treatments to cancer patients across the country. ASCO applauds the HELP Committee for examining the implementation of provisions of this important healthcare law in its hearing entitled "Implementing the 21st Century Cures Act: Making Electronic Health Information Available to Patients and Providers."

ASCO, on behalf of our members and along with other stakeholders in organized medicine, has been monitoring the implementation of legislation stemming from the 21st Century Cures Act and providing input and comments as rules are implemented. As this legislation was being drafted, we submitted statements to the Committees of jurisdiction, and we continue to provide feedback to the relevant agencies as they implement the rules governing HIT use and development.

Despite our many steps forward in this area, our members are still plagued by a lack of interoperability between different types of electronic medical records (EMRs) in addition to a lack of interoperability between EMRs and other forms of health information technology including electronic systems such as registries, genomic testing laboratories, and hospital laboratory information systems. These types of technology hold great promise for improving and enhancing patient care, especially in the realm of care coordination and quality improvement. To further enhance healthcare quality, we should move with urgency towards realizing the vision of seamlessly integrated health information, easily and securely accessible to all patients. The CURES Act is instrumental in these efforts, as it addresses some of the technical limitations and business practices that may contribute to the current limitations of true interoperability.

As part of the implementation of CURES, on March 4, 2019, the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC),

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released its proposed rule, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program." At the same time, the Centers for Medicare & Medicaid Services released a companion proposed rule addressing interoperability and patient access to electronic health information in programs under their authority. Together, these two proposed rules place strong emphasis on the availability and widespread use of application programming interfaces (APIs) for exchange of and access to electronic health information; place special focus on patients' access to their electronic health information; and when finalized will impact all stakeholders in the healthcare system.

The ONC rule describes proposed standards for interoperability, provides for updates to the ONC Health IT certification programs, and sets out long-anticipated proposals on information blocking. For the latter, ONC proposes seven exceptions to the information blocking provision in the rule: 1. Preventing Harm; 2. Promoting the Privacy of EHI; 3. Promoting the Security of EHI; 4. Recovering Costs Reasonably Incurred; 5. Responding to Requests that are Infeasible; 6. Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms; and 7. Maintaining and Improving Health IT Performance. ASCO will be providing detailed comments in response to the agency's proposals, but we would like to note broadly here that ASCO strongly supports the promotion of privacy and security of EHI. We further note this is an area that requires careful monitoring to ensure that these exceptions to information blocking do not become "loopholes" allowing actors to claim them as reasons for blocking interoperability and the free flow of data.

Cures also focuses on interoperability and bidirectional exchange between EHRs and registries, including clinician-led clinical data registries. Section 4005(a) of the Cures Act requires that electronic health records (EHRs) be capable of transmitting data to and, where applicable, receiving and accepting data from clinician-led clinical data registries, in accordance with standards recognized by ONC. In its proposed rule, rather than laying out concrete proposals in this area, ONC seeks information on how health IT solutions and ONC's proposals can aid bidirectional exchange with registries for a wide range public health, quality reporting, and clinical quality improvement initiatives. We hope that ONC will work closely with established and emerging qualified clinical data registries (QCDRs) in these efforts, as organizations maintaining these registries are well positioned to assist in answering some of these questions and demonstrate the real-world problems involved in attempting to achieve bidirectional flow of data for quality improvement purposes.

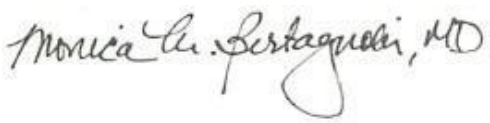
Prior to the publication of the two proposed rules discussed above, in January 2018 ONC released its "US Core Data for Interoperability" (USCDI), which specifies a common set of health care record data classes required for health data interoperable exchange. We support ONC's work in this area, and note that by necessity, these data classes initially tend to be broad and encompassing of primary care; this leaves open an opportunity for specialty societies and other interested stakeholders to engage in the development of data classes, elements, and terminology needed by smaller groups of specialty physicians. Additionally, in its *Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and* EHRs—also required by Cures--ONC specifically identifies that clinical specialty societies could continue to provide input to define proper clinical standards for documentation and establish what is required for high quality patient care.

Under our CancerLinQ (CLQ®) subsidiary, ASCO is currently developing a set of "Minimal Common Oncology Data Elements" (mCODE™), an effort designed to result in a parsimonious set of consensus-developed oncology data elements necessary for critical information exchange between EHRs, for clinical care, quality reporting, and other use cases. This set of oncology data elements is envisioned by ASCO to form the basis of an initial parsimonious set of necessary data that should populate all electronic health records (EHRs) serving patients with cancer. Adoption of these data elements, which are being developed by experts in the fields of oncology and informatics, would greatly streamline the exchange of basic needed data necessary for oncologists. The National Cancer Institute (NCI) is engaged with this project, and we look forward to collaborating with ONC wherever possible to encourage consideration and adoption of these elements when they are finalized. We have previously provided ONC with our description of this work and will continue to keep the agency abreast of our efforts; we are currently engaged in a pilot project with a large healthcare system as proof of concept in anticipation of wider adoption of these oncology data elements, which we believe would streamline communication between care providers and positively impact patient care.

Finally, we would like to highlight for the Committee that we appreciate ONC's efforts to support enhancements to prescription drug monitoring program (PDMP) integration as a priority use case for standards-based health IT solutions. ONC believes that these efforts can help to address the near term need to support high priority use cases for bidirectional exchange between health care providers and registries, and ASCO would agree especially in this case that PDMP integration is of great interest to our members, especially in light of widespread use of these systems that often overlay additional unnecessary administrative burden onto a necessary patient care function.

We commend the Committee for its leadership and bipartisan work on this issue. We look forward to working with the Committee as implementation of 21st Century Cures continues. If you have any questions or would like more information, please contact Amanda Schwartz at Amanda.Schwartz@asco.org.

Sincerely,



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