December 16, 2019

The Honorable Diana DeGette
Member of Congress
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
Member of Congress
2183 Rayburn House Office Building
Washington, DC 20515

Dear Congresswoman DeGette and Congressman Upton:

On behalf of the over 82,000 members of the American College of Surgeons (ACS), thank you for your leadership and continued interest in the 21st Century Cures Act and for the opportunity to share feedback and goals as part of the Cures 2.0 initiative. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The ACS puts the welfare of our surgical patients above all else, and we support policies and regulations that promote high-quality care, reduce the regulatory burdens placed on physicians, streamline clinical workflows, and empower patients with data.

Background

The 21st Century Cures Act has done a great deal to advance the use of health information technology and reduce administrative burdens, among many other advances in the health care system at large. However, there are facets of the Cures Act that have yet to be finalized or fully implemented as the Centers for Medicaid and Medicare Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) have yet to release final rules to guide standards and implementation, most notably for interoperability.

ACS believes that these components are foundational to furthering health information technology, as interoperability standards will provide the foundation to building a more advanced health IT ecosystem. The current definition of Electronic Health Information (EHI) as defined in the ONC proposed rule, is an onerous and overly expansive definition, as it encompasses an Electronic Health Record’s entire database, including but not limited to clinical, administrative, and claims/billing data. While the ACS’ many concerns over this definition are outlined in our comment letters to ONC and CMS, we believe that this definition should instead be limited to the U.S. Core Data for Interoperability (USCDI) standards.1 Assuming that the foundational interoperability standards are

part of the final rules, ACS outlines the prioritization of steps needed to further advance along the health IT continuum.

As Congress develops Cures 2.0, ACS recommends that the landscape systematically moves beyond a simple, EHR-centric system to a system that a patient could approach and understand. To achieve this, the focus should shift to patient-conditions and away from payment and reimbursement. The system must be grounded in an open-source architecture, using standard knowledge artifacts (discrete data points or clinical information within a workflow), allowing for data to move to various repositories, such as EHRs and registries using national standards. Specifically, ACS recommends:

- Further enhance interoperability through a vendor-agnostic, open-source patient cloud;
- Provide governance to a knowledge repository containing knowledge artifacts (standard workflows and semantic standards);
- Provide guidance to agencies on developing a process for digital services certification, including clinical and technical verification, of new products (including wearables, third-party applications, and Artificial Intelligence/Machine Learning);
- Update privacy regulations to better align with advanced technology;
- Create a Universal Patient Identifier (UPI).

**Digital health with the patient at the center**

*Further enhance interoperability through a vendor-agnostic, open-source patient cloud*

The ACS’ long-term vision of a patient-centric care model supported by team-based care, rooted in a culture of continuous quality improvement, can be achieved through advanced digital technology and a standard data infrastructure. **Federal support of a vendor-agnostic, open-source patient cloud architecture would shift the industry to a patient-centric system that eases the current burdens with interoperability.** The patient cloud aggregates data through a common data model to create a single, unique, and more complete patient medical record, providing physicians with the information they need to deliver the highest quality care while keeping costs low, and gives the patient agency over their own data. Grounded in standards for data exchange from the initial 21st Century Cures Act, a patient cloud could bi-directionally exchange health data through Application Programming Interfaces (APIs) using Fast Healthcare Interoperability Resources (FHIR) between any system, including EHRs, third-party
applications, registries, and wearable devices. Federal support of a patient cloud will further advance interoperability, allow for the use of more advanced technologies, and empower the patient and clinician with more accurate, current, and complete data. It is conceivable that multiple vendors could implement a common architecture and share across platforms. Individual commercial platforms which conform to a standard common data model can also add their own services as an overlay to meet the various needs in their markets. Without this open-source cloud platform and common data model, the industry will remain siloed, limited by costly proprietary solutions to data exchange and aggregation.

*Provide governance to a knowledge repository*

As a step toward achieving data consistency and standardization within the cloud, ACS recommends the creation of a knowledge repository, containing clinical care models and key knowledge artifacts, housed in the National Library of Medicine (NLM), and governed at the Federal level, similar to the National Interoperability Collaborative (NIC) in the United Kingdom\(^2\). These care models and knowledge artifacts housed within the knowledge repository would include standard workflows for clinical conditions, including the discrete data points to document throughout the process. By creating semantic standards for data collection and clinical workflows, structured, discrete data would enable the capture of high-fidelity data across organizations and systems, increasing interoperability and expanding digital health beyond EHR-centric models. **Lawmakers should work with specialty societies and agencies to develop a governance structure for the knowledge repository and to provide oversight to ongoing maintenance and updates to semantic standards and workflows to ensure they remain current with clinical practice guidelines.**

Governing the model could be constructed similarly to the DaVinci project, where specialty societies and physician informaticists inform the standards to be implemented, review the clinical guidelines, and agencies provide oversight to manage long-term maintenance and ensure sustainability.

Given standardized care models and knowledge artifacts, technology solutions could be laid on top of workflows, creating digital representations through computer-readable code, and providing clinicians with access to the most current clinical best practices within their source system(s). A vendor-agnostic data model will encourage innovation, minimize free-text workflows, and avoid proprietary models from

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\(^2\) [https://nic-us.org/](https://nic-us.org/)
developing, as well as create consistency across systems and clinicians that will enhance data reliability and validity. This would allow for living notations of knowledge artifacts, and would move away from an EHR-centric system, to one designed to ensure patients receive high-quality care based in the most current clinical practice, facilitated by advanced technology solutions and an open-source patient cloud.

It is important to realize the ACS construct focuses on *curating surgical healthcare knowledge* using standards and structured data capture in a platform separate and distinct from the EHRs. This way, the knowledge artifacts are available for supporting optimal care by sharing those artifacts back to EHRs, to registries, and to other stakeholders. This represents a change in data flows. These data are captured using structured, standard, aggregated and normalized within a cloud, and then delivered to EHRs, registries and other stakeholders. Without standard knowledge artifacts, workflows and data capture will remain mired in system and vendor specificity, increasing the burden to exchange data, and making benchmarking across cohorts lack rigor and meaningful comparison.

**Advanced digital health technologies: Developing a process for technology certification**

The shift to cloud environments and the use of standard, accessible knowledge artifacts to design shared workflows will better enable an ecosystem that can make the most of advanced technologies, including AI/ML and the Internet of Things (IoT). **Lawmakers should provide guidance to agencies to develop a certification process for advanced technologies, including AI/ML, in order to ensure the safety and efficacy of new solutions.** ACS recommends a certification process for technology and software that falls outside of the FDA’s purview to ensure that the product has used appropriate clinical logic, valid technology and standards, and is meeting privacy requirements. Without a certification process, patients and clinicians will be left on their own to verify if a source or product is trusted, further complicated by information blocking provisions from the ONC’s Cures proposed rule. The current openness of the third-party application market puts patient safety at risk, and will create further administrative burden for clinicians.

Today, the amount of knowledge that a physician needs to provide high-quality, evidence-informed care is too much for any human to process, and the amount of knowledge needed will only continue to grow as research and new discoveries quickly
outpace traditional medical education. Information learned in medical school or during Residency will quickly become old, and technology is needed for physicians to maintain an understanding of the most current clinical practice guidelines and medical research—as well as to amalgamate health data from disparate systems. AI is a technology option that can store, process, and review mass amount of data from multiple sources and guide providers through treatment options based on individualized patient needs and diagnoses. Further, AI as a knowledge management and curation system can allow providers more time to be caregivers. These technologies could be developed and designed using the standard knowledge artifacts designed above.

Existing AI technology in use in healthcare and the associated research focuses on the effective, efficient, and knowledge-curating aspects of AI. This ability to recognize abnormalities, predict comorbidities, and determine risk has increased diagnostic accuracy, expanded access to care, and created a space for expert consultation. While many of these tasks remain possible for physicians to perform with high accuracy, AI software is able to do a higher volume of these tasks in a shorter amount of time, and with a high validity and success rate. Further, if AI is taking on image review and diagnostic assessment, it leaves physicians with more face to face time directly with patients, to design care plans catered to the individual patient. This type of technology could allow physicians to get away from the burden of documentation fueled by payer needs, and to re-design patient care to be driven by the individual patient and their needs.

ACS believes that the move towards a patient cloud, grounded in standards for data exchange, together with semantic interoperability and consistent data models, will create an environment ripe for the use of advanced technology. However, before widespread implementation of AI solutions once the technical infrastructure is in place, the government and industry must remain aware of the potential issues and challenges with AI, including inequities within homogenous data sets used for development and challenges with long-term updates and maintenance to algorithms based on ever-updating clinical practice and changing knowledge artifacts. These


4 Ibid.

challenges, as well as concerns regarding privacy and confidentiality (both from a development and testing perspective, as well as from a data exchange perspective), create the need for a certification process for these technologies that balances the need for safety and yet does not stifle innovation. An example of a possible certification process is detailed below:

1. ONC, in partnership with societies and physician and technical expert panels, create a technology certification process for technologies that fall outside of FDA guidance and ONC CEHRT (similar to the Trusted Exchange Framework and Common Agreement (TEFCA) and the Sequoia project);

2. Specialty societies or physician panels review the products for clinical accuracy and appropriate use of the knowledge artifacts;

3. All products attest to certain minimum privacy and security requirements.

**Patient privacy and confidentiality**

Having patient information available in an open-source cloud architecture for patients and clinicians would take both digital health services to a new level and enhance the quality of care patients receive. As digital health continues to expand, privacy and security standards need to be updated to keep pace with modern technology and the innovative ways in which patients and providers access and interact with health data. **ACS urges Congress to continue working with federal agencies such as the Office of the National Coordinator for HIT (ONC), the Office for Civil Rights (OCR) and the Office of the Inspector General (OIG) to more broadly re-evaluate current enforcement mechanisms.** Current regulations need to be updated to better ensure that data sharing will not occur unless a patient explicitly authorizes it and limit the extent to which third-party/direct-to-consumer applications and other non–HIPAA-covered entities can use and share patient data.

In order for interoperability to advance in a safe, patient-centered way, a universal patient identifier (UPI), is a core element of the ecosystem. Inaccurate patient matching can lead to adverse events, compromised safety and privacy, inappropriate and unnecessary care, unnecessary burden on both patients and physicians to correct misidentification, time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges, increased health care costs, and poor oversight of fraud and abuse. Inaccurate data matching poses a significant risk to patient safety because information may be unavailable when needed or records may be merged incorrectly, leading to inappropriate treatment choices.
Errors in individual data matching will be compounded with the expansion of electronic health information sharing. Further, in the absence of a UPI, algorithms are left to rely on other personal data, including, but not limited to, social security number, birthdate, address, and credit information. **ACS continues to support legislative efforts to allow HHS to explore and adopt a UPI as it would help to ensure that surgeons have a safer, more accurate and consistent way of linking their patients to their health information across the continuum of care.**

**Patient engagement**

In order to fully engage in their care, particularly in this more complex digital landscape, patients need information on treatment options and outcomes that can be assessed, and an opportunity to work with their care team to set goals and share feedback through Patient Reported Outcomes (PROs). Using digital health tools, including certified third-party applications, can be an option through which patients can access health information, communicate with their care team, and comprehend their health and treatment options in easily-understood terms, including videos and step-by-step guides to prepare for procedures. Access to health data through various safe mediums, done so with health literacy in mind, can empower patients to manage and improve their health. **Incorporating PROs into existing reporting programs will shift the system towards value as defined by the patient, rather than by the payer.** This, alongside many of the health IT advances discussed above, will help put the patient at the center of their care, and provide meaningful data to clinicians to reduce administrative burden and improve quality of care.

Thank you again for the opportunity to provide feedback as part of the Cures 2.0 initiative ACS looks forward to working with Congress to expand on the important work of the 21st Century Cures Act. Please contact Hannah Chargin in the ACS Division of Advocacy and Health Policy at hchargin@facs.org if you have any questions or need additional information.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director