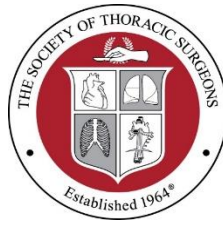


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June 3, 2019

Submitted via regulations.gov

Don Rucker, M.D.

National Coordinator for Health Information Technology (ONC)
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

RE: HHS-ONC-2019-0002; 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker,

On behalf of the members of The Society of Thoracic Surgeons (STS), I am writing to provide comments on the interoperability and information blocking proposed rule, as published in the *Federal Register* on March 4, 2019. We appreciate the opportunity to provide feedback on proposed policies related to electronic health information interoperability and tactics that mitigate information blocking to clinical data registries.

Founded in 1964, STS is a not-for-profit organization representing more than 7,500 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

General Comments

STS has long supported the shift to a value-based health care system. The flow of clinical and claims data is the cornerstone to move from a siloed health system to a value and team-based paradigm. The Society fully supports the intent of the Office of the National Coordinator (ONC) to propose policies that move toward greater patient access to their health data and increased transparency throughout the health care system. At the same time, we remain concerned that both the ONC notice of proposed rulemaking (NPRM) and the Centers for Medicare and Medicaid Services (CMS) NPRM focus on the patient's access to their data and mitigation of information blocking. Neither NPRM discusses the importance of physician access to health data for quality improvement. **We urge ONC and CMS to recognize and encourage Health Information Portability and Accountability Act (HIPAA)-compliant flow of data between physicians to empower team-based, quality care that will yield better outcomes more efficiently.**

The ONC NPRM focuses on providing patients with all of their personal health information (PHI). STS believes that patients must be active participants in their care team, and empowering patients with their PHI would allow them to be better informed during medical decision making. However, we fear that providing all of the PHI without relevant clinical context will overwhelm patients and have negative effects on patient participation in their health care. **We urge ONC to carefully consider methods of providing patients with their health information that include appropriate clinical context (e.g., normal ranges in blood work, baseline evaluations, and current evaluations).**

Information Blocking

The 21st Century Cures Act (Cures Act) prohibits information blocking by health providers, developers of certified health information technology (HIT), health information exchanges (HIE) such as qualified clinical data registries (QCDR), and health information networks (HIN). STS has long advocated for this provision and believes that without the HIPAA-compliant exchange of data, interoperability will never be achieved and the health care system will continue to be compartmentalized to the detriment of patients.

The STS National Database (Database), approved by CMS as a QCDR, was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The Database has four components—Adult Cardiac, General Thoracic, Congenital Heart Surgery, and Intermacs, a registry for patients receiving mechanical circulatory support for advanced heart failure. The fundamental principle underlying the STS National Database initiative has been that surgeon engagement in the process of data collection on every case combined with robust risk adjustment based on pooled national data, and feedback of the risk-adjusted data provided to the individual practice and the institution, provides a powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients. Published studies indicate that the quality of care has improved as a result of research and feedback from the STS National Database. The Database has facilitated advancements in many aspects of health care policy including public reporting of health care quality measures, facilitating medical technology approval and coverage decisions, and even saving money by helping cardiothoracic surgeons choose the most efficient and effective way to treat patients. Following the passage of the Cures Act, which included explicit language prohibiting barriers to exchange of information between EHRs and “clinician-led clinical data registries,” we hoped that the exchange of data between EHRs and the Database would facilitate further quality improvement activities within cardiothoracic surgery. However, due to information tactics of EHR vendors, the possibility of greater data access for quality improvement has not been realized. ONC has acknowledged that EHR vendors are using licensing agreements to control the data flow to applicable third parties, such as clinical data registries. This barrier to information exchange hinders the improvement of our health care system.

While we support ONC efforts to eliminate data blocking between entities, we have several concerns with the NPRM:

Broad Definitions Create Unintended Consequences for QCDRs/Conflict with HIPAA

ONC proposes to define HIE as an individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities for a limited set of purposes. It is our understanding that clinical data registries would fall under this definition of HIE and would be

subject to the requirements concerning data exchange and information blocking enforcement. Clinical data registries such as the Database are not originating sources of data. Instead, the Database serves as a data collection tool at the point of care and is focused on quality improvement. STS maintains business associate agreements with participants contributing data to the Database and the Society is contractually obligated not to share PHI with any outside party unless explicitly authorized by the Database participant. However, under the HIE requirements, registries would be required to provide a patient's EHI to a patient or third-party requestor in a timely manner.

The HIE requirements would conflict with HIPAA's minimum necessary requirement. Under HIPAA, physicians and other covered entities must take steps to limit the use or disclosure of PHI to the minimum necessary to perform the intended purpose. Physicians want to keep their patient's health information secure. The NPRM proposes that all EHI should be disclosed when requested unless an exception applies. The proposed requirement for physicians to disclose all EHI is confusing and puts providers in a tenuous position. While a provider does not want to be accused of violating HIPAA by sharing all EHI, they will also be concerned about being accused of information blocking if they do not provide all health information to the requesting party. The current proposal puts the onus on the physician to determine how to comply with these conflicting paradigms.

Therefore, we strongly urge ONC to consider these conflicting requirements carefully. Specifically, we encourage ONC to work with QCDRs to identify feasible and appropriate provisions for data export in response to EHI requests. In addition, we urge ONC to publish educational tools for physicians on the best approaches to ensuring patient information remains private within an EHR when it is exchanged electronically, and that access is only granted to those who should have access. Any penalties for violations of data-blocking provisions should not be implemented until the agency has clarified the conflicting requirements.

Exceptions to the Prohibition of Information Blocking

To secure a patient's most personal information while promoting information exchange, ONC has proposed a number of exceptions to ensure that PHI is secure in an interoperable HIT ecosystem. STS appreciates these proposals and provides the following comments:

Preventing Harm

STS supports the ONC proposal to provide an exception to information blocking enforcement in circumstances that are reasonable and necessary to prevent harm to the patient or another person. This includes corrupt or inaccurate data recorded or incorporated in the patient's EHR, risk of misidentifying a patient or patient's EHR, a determination that the disclosure of the EHI would likely endanger life or cause physical harm, or belief that withholding the information will reduce the likelihood of harm. STS strongly supports these exceptions to ensure that patients are protected.

Promoting Security of EHI

ONC is proposing an exception to the information blocking provision that would permit actors to engage in practices that are reasonable and necessary to promote the security of a patient's EHI. STS fully supports the intent of this exception. The security of a patient's EHI is of utmost importance within the health IT landscape. Allowing this exception promotes the need for a patient's information to be secure throughout the information exchange infrastructure. We are concerned, however, that EHR developers

will continue to deny access to data based on the false premise that the transfer of data will violate HIPAA and will jeopardize the security of the patient's EHI. **We urge ONC to advise EHR developers and vendors that HIPAA compliance is not a justification for withholding data, particularly to clinical data registries that comply with all HIPAA requirements.**

Recovering Costs Reasonably Incurred

STS appreciates that ONC interprets the definition of information blocking to include fees for access, exchange, or use of EHIs. STS contends that unreasonably high fees charged by EHR vendors are the primary hindrance in the exchange of patients' data between EHRs and registries. EHR vendors charge exorbitant fees that prevent clinical data registries, such as the Database, from accessing valuable data that will allow for health quality analysis and quality improvement. Therefore, we support the ONC proposal to limit an actor's ability to charge fees based on objective and verifiable criteria that are uniformly applied, and that is reasonably related to the actor's cost of providing the type of access.

Additionally, we support the ONC proposal to prohibit actors from charging fees based on whether the requester is a competitor or potential competitor. EHR developers have been working to create their own, inferior registries in competition with the clinician-led clinical data registries that were developed to improve health care quality. The proposed exception will prevent EHR developers from charging high fees to potential competitors, including clinical data registries like the Database. We welcome this provision and urge ONC to require EHR vendors to disclose the methodology behind their fees.

Responding to Requests that are Infeasible

STS appreciates that ONC recognizes that some requests are not feasible. However, we fear that this exception will allow EHR vendors additional justification to deny access to data inappropriately. Therefore, we urge ONC to include provisions within this proposed exception that will require an actor, specifically an EHR vendor, to provide a detailed written explanation of why the request cannot be fulfilled. This will require EHR vendors to justify why they cannot fulfill the request. **We urge ONC to enforce the statutory requirement that, when the request cannot be fulfilled, the actor should work with the requester in a timely manner to provide alternative ways to access, exchange, or use the requested EHI.**

Price Information

In the NPRM, ONC notes that the Department of Health and Human Services (HHS) is considering subsequent rulemaking to expand access to price information for the public. Price transparency has been a priority for both Congress and the Administration to help to address rising health care costs. STS believes ONC and HHS should consider more than just greater access to price information, but to emphasize value transparency. Value, a function of quality over cost, is the next frontier for increased price transparency. By combining Medicare claims data (i.e., the cost component) and the quality data captured in the Database, we could be in a position to provide value transparency, allowing patients to make the most informed decision on their health care and allowing the marketplace to promote value-based care. Rather than simply providing patients with price information, **we strongly urge ONC and the Administration to put more emphasis on the need for value transparency.**

To determine value, STS has advocated that CMS fully implement Section 105(b) of the Medicare Access and CHIP Reauthorization Act (MACRA) to allow us to combine Medicare claims data and

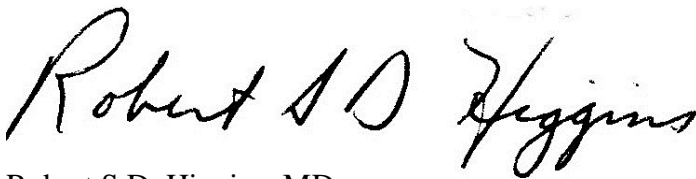
outcomes data from the Database to quantify value. **We urge ONC to work with CMS to implement this statute and work with clinical registries to promote value transparency.** Providing patients with the value proposition of treatment will allow for more informed discussions on the risks and benefits for that patient and will continue to shift the focus to a value-based health care system. By merely providing patients with the ticket price, we fear that this information will overwhelm, discourage, and possibly prevent patients from seeking the appropriate treatment they need. Instead, **we urge ONC and HHS to put more emphasis on value transparency.** This will allow patients to understand their treatment options better and be more informed participants in their care planning.

Registry Request for Information

The Cures Act focuses on interoperability and bidirectional exchange between EHRs and registries, including clinician-led clinical data registries. While STS appreciates the proposals outlined in the NPRM to further advance interoperability and data exchange between various entities within the health care system, we are concerned that ONC has not set forth specific proposals to further improve the data exchange between EHRs and registries. As previously stated, EHRs have created significant barriers to registries' access to data, including imposing unreasonably high fees for data transfer, denying access on the assertion of HIPAA compliance, claims of violation of intellectual property, and lack of common technical profiles and standards across EHR systems. These barriers interfere with and materially discourage access to information, as well as violate the letter and the spirit of the provisions of the Cures Act that prohibit information blocking. EHR vendors may also use information blocking to prevent providers from participating in clinical data registries while the EHR vendor simultaneously develops an application or software to compete with the registry. Unfortunately, the proposals outlined in the NPRM do not explicitly address data exchange policies with clinical registries. STS looks forward to additional proposals focused on the data exchange for clinical registries.

Interoperability will move health care towards a value-based system that emphasizes care coordination while empowering patients to be informed participants in their care. We welcome the opportunity to serve as a resource as ONC finalizes their proposals and provide additional clarification and guidance on data exchange to clinical data registries. Please contact Courtney Yohe Savage, STS Director of Government Relations, at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink that reads "Robert S.D. Higgins". The signature is written in a cursive, flowing style.

Robert S.D. Higgins, MD
President