30 May 2019

Dr. Donald Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street NW
Washington, DC 20201

Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program - Proposed Rule; 45 CFR Parts 170 and 171; RIN 0955-AA01

Dear Dr. Rucker,

The Physicians' Electronic Health Record Coalition (PEHRC) is comprised of more than 20 medical societies representing more than 600,000 physicians, who share information to support the use of health information technology. PEHRC provides a forum for members to collaborate in their understanding of health information topics. We offer the following comments in response to the Office of the National Coordinator for Health Information Technology's (ONC's) proposed rule to implement certain provisions of the 21st Century Cures Act (the Proposed Rule). We appreciate the opportunity to provide comments on this proposed rule. We do recommend a more gradual phased-in, incremental implementation beyond the 24-month timeline, to ease adoption of new requirements and increase compliance success. We further recommend that the concerns outlined below be addressed prior to implementation.

1. Definition

a. Health Information Networks: We would like a clarification on whether specialty registries will be considered Health Information Networks and therefore be subject to the info blocking provisions;"
b. Developer of Health IT: In addition, we ask for clarification on the definition of a health IT developer. Health IT developer as stated appears to be focused on certified EHR vendor in context of ONC Health IT Certification Program. PEHRC supports defining "health IT developer of certified health IT" as including developers and offerors of certified health IT that continue to store EHI that was previously stored in health IT certified in the Program. This would include non EHR companies that provide ancillary EHR support and HIE vendors. We support continuing the data blocking provisions for as long as a developer continues to hold the EHI.

2. Implementation Timeline: The PEHRC agrees that providers should be able to export EHI in the cases identified in a timely manner, without subsequent developer assistance.

However, we have concerns that the 24-month implementation time frame will be inadequate to complete this change. The timeline for developers may be onerous, particularly for smaller developers with fewer resources. Delays in complying with the 24-month window may strain users in meeting adoption deadlines. We urge ONC to allow a phased in approach to meet requirements to ensure that all affected parties can effectively come into compliance.

3. Application Programming Interfaces (APIs): ONC's proposal includes new API certification criteria; new standards and implementation specifications. ONC proposes that API Technology Suppliers must develop, test, certify and make APIs available to their customers within 24 months of the final rule's effective date. Physicians would also be required to deploy new APIs in their clinics within the same 24-month timeframe. Developer completing and provider deployment should not have the same deadlines. Developing, testing, deploying, and subsequent training and implementing for users cannot be done simultaneously. The PEHRC recommends an additional 12 months for deployment by providers.

4. Burden and Information Overload:
    a. ONC rules are still overly complex for clinicians to understand, and we would encourage modification of the rules to reduce the complexity/burden and to develop a white paper/education material specific to providers to clarify requirements and impact. PERHC would be pleased if asked to participate in development of such material on behalf of our specialty membership. PEHRC is also concerned about the potential cost for providers given the cost for API development and charges from vendors. We are also concerned about the need for a robust data segmentation and consent management capability to manage EHI.
    b. While we agree with the intent to improve interoperability and to ultimately empower patients with their data, however, PEHRC is concerned with the high potential for propagation of useless information and/or information in unusable form especially given the data quality and challenges with semantic interoperability
    c. ONC would adopt two new privacy and security transparency attestation certification criteria, which would identify whether certified health IT supports encrypting authentication credentials and/or multi-factor authentication. PEHRC generally supports this next step of identifying the certification criteria, as long as the authentication does not interfere with clinical care. Physicians who used EHRs and computerized physician order entry are less satisfied with the amount of time spent on clerical tasks and were at higher risk for professional burnout. Requirement in this proposed rule must not contribute to that problem.

5. Privacy and Security: The intent of the Cures Act and this proposed rule are to provide patients with access to their EHI, and the ability to exchange and use it without special

effort. While we recognize that HIPAA does not apply to patients or developers of apps who are authorized by the patients, PEHRC is concerned that patients may not fully understand the implications and data use rights afforded to the developers. We recommend that ONC develop guidelines to educate patients on potential privacy and security risks associated with sharing personal health information through apps even when not covered by HIPAA.

The PEHRC also is concerned about provider protection if they choose to withhold patient information for the purpose of protecting privacy. While we recognize that there is an explicit exception within the information blocking provisions for this purpose, we believe that requirements within information blocking provisions for providers to comply with all data requests by sharing all relevant information may conflict with HIPAA's minimum necessary provision. We ask that ONC issue guidance to clarify how providers can meet requirements of both provisions and adequately protect patient data, without violating compliance requirements.

Conclusion:

The PEHRC supports the goals of improving interoperability and data exchange to provide patients, providers, payers, and researchers the information needed to improve clinical outcomes and control costs.

While not perfect, there have been many initiatives and partnerships to address interoperability (eHealth Exchange, Carequality, Common Well Alliance, etc. To this extent, we would like clarification from ONC on how to leverage efforts to date to achieve shared goals of interoperability.

Lastly, we hope that ONC will implement its final rule in such a way that costs and administrative burdens associated with health care information technology are not increased for providers.

Please contact me at honspak@gmail.com if you have any questions about these comments.

Sincerely,

Hon S. Pak, MD MBA
Chair, PEHRC