June 3, 2019

Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT
        Certification Program proposed rule

Dear Dr. Rucker:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals
are to ensure optimal care under the highest standards of medical practice for patients with kidney disease
and related disorders. RPA acts as the national representative for physicians engaged in the study and
management of patients with kidney disease.

We are writing to offer our comments to ONC regarding the proposed rule on 21st Century Cures Act:
Interoperability, Information Blocking, and the ONC Health IT Certification Program. RPA believes the
use of common data elements and improved accessibility to health information has the potential to
transform care delivery and improve kidney patient outcomes. Additionally, RPA believes that access to
electronic health records (EHRs) should have reduced the friction of collecting, organizing, and sharing of
data. Unfortunately, digital records are only part of the equation. For instance, ONC's previous
certification efforts addressed data structure but lacked focus on implementing technology consistently
across EHRs. Efforts by others to establish governance models for trusted exchange practices lacked
oversight to ensure a uniform understanding of shared medical information. This lack of coordination has
been detrimental to providing optimal patient care across sites of service, including physician practices,
dialysis units, hospitals and skilled nursing facilities. This lack of interoperability is particularly
dangerous to the nation's nearly 750,000 end-stage renal disease (ESRD) patients.

ESRD patients need frequent, ongoing dialysis care. They typically have multiple chronic conditions that
require numerous prescribed medications, treatment plans, and lab tests from multiple sources. Dialysis
providers are challenged by incomplete transfer of pertinent clinical data from patient hospitalizations,
impeding safe care transitions. Among ESRD patients, more than one in three hospital discharges were

followed by a readmission within 30 days (35.4%), compared to 21.6% for patients with chronic kidney disease (CKD) and only 15.3% for older Medicare beneficiaries without a diagnosis of kidney disease (i.e., those greater than 66 years old).[1] The disproportionate readmission rates of ESRD patients' calls into question the communication and care coordination occurring as patients return to outpatient dialysis facilities from acute hospitalization, as well as highlight the need for improved interoperability. The RPA appreciates ONC's efforts in correcting these interoperability problems in the proposal and we have included specific recommendations below.

The ability to access the right medical information at the right time for the right individual are three needs most often cited as the potential of health IT. Achieving this "triple need" requires an orchestration of technical capability (validated through testing), trust between parties (established through transparent practices), and consistency in data structure and meaning (agreed upon common data models). Together, these three pillars support the access, exchange, and use of electronic health information.

- Interoperable technology must "enable the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user." It takes a significant amount of effort (both in time and resources) to use unstructured electronic health information. Structure helps retain information's original meaning. Moreover, structure helps prevent quality degradation of the patient's record.

- The Cures Act states that certified health IT developers are required to successfully test the "real world use of the technology for interoperability."

- A national framework must establish a "common set of rules for trusted exchange." HHS must also "promote patient access to health information in a manner that would ensure that such information is available in a form convenient for the patient, in a reasonable manner, without burdening the health care provider involved."

Congress intentionally promotes a consistent theme of data usability across Title IV of the Cures Act. Forgoing data use for quantity, or sacrificing data value for volume, would miss the clear message in Cures—data needs to be accessible, but also understandable and actionable.

RPA offers the following recommendations on ONC's proposed rule:

- RPA supports ONC's proposal to require all certified health IT systems to comply with the U.S. Core Data for Interoperability version 1 (USCDI v1). RPA urges ONC to prioritize its effort to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion. We also urge ONC to implement technology in regulatory standards only after they have been field-tested.

- RPA supports ONC's proposal for certified health IT developers to adopt and implement new requirements around application programing interface (API) design, function, and use. This will enhance interoperability and reduce implementation complexity and cost. We support requiring

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[1] US Renal Data System: USRDS 2018 Annual Data Report: Atlas of Chronic Kidney Disease & End-Stage Renal Disease in the United States. Bethesda, Md., National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2018.

the adoption of Fast Healthcare Interoperable Resources (FHIR) Release 4 and compliance with HL7 U.S. Core FHIR Implementation Guides.

- RPA appreciates ONC's efforts to address excessive fees charged by EHR vendors to connect their products with other health IT systems, health information exchanges, and third-party applications. However, we believe that ONC should include in the framework a structure which is usable by practicing physicians with clear tiers and easily understood descriptors for each tier.

- RPA believes that patient consent and privacy, data provenance, governance, and state and federal law compliance must be inherent in technology development.

- RPA believes that ONC should align its information blocking requirements with the certified capabilities of health IT vendors—i.e., the USCDI and APIs. Information blocking should be evaluated through the lens of access, use, and exchange of the USCDI.

- RPA supports the use of APIs and consumer-facing applications (apps). However, RPA has strong concerns with apps being provided equal protections and benefits with those of patients. The apps frequently do not provide patients with clear terms of how that data will be used— licensing patients' data for marketing purposes, leasing or lending aggregated personal information to third parties, or outright selling it. These practices jeopardize patient privacy, commoditize an individual's most sensitive information, and threaten patient willingness to utilize technology to manage their health. Patients should be the primary authority in designating rights to access, exchange, and use of their data. ONC should require that all certified APIs include mechanisms to strengthen patients' control over their data.

- RPA recognizes the potential benefits of bulk data access for public and population health and quality improvement. However, we have concerns with the potential pitfalls of entities having unprecedented access to patient information. Important parameters must still be established to maintain patient privacy, data security and usability, and adherence to federal and state law. We urge ONC to take a methodical approach in its promulgation of information blocking and EHI regulation.

- RPA supports maintaining the Health Insurance Portability and Accountability Act's (HIPAA) minimum necessary standard. However, the proposed rule conflates payers' needs with clinicians' needs to access, exchange, or use health information. Physicians must be permitted to retain their professional judgment to protect their patients' rights or privacy, including their designation for what constitutes minimum necessary.

- Recent research has shown that cyberattacks are inevitable and increasing and numerous agencies across the federal government recognize cybersecurity as a patient safety issue. ONC's policy allows a consumer-facing app developer the ability to *read, write,* and *modify* a patient's entire medical record which leaves patient records vulnerable to cyberattacks. ONC should do more to ensure EHR vendors develop and test to industry protective measures, prescribed standards, and security protocols.

- RPA believes ONC's definitions of Health Information Networks (HINs) and other terms are inconsistent. This creates separate interpretations, adds subjectivity, and introduces unnecessary vagueness and inconsistency. We strongly recommend that the definition of HIN be narrowed to include only entities that are an actual network (or formalized component of an actual network) and have an actual operational role and responsibility for the network.

- RPA supports many of the proposals for certified EHR technology (CEHRT). However, ONC's physician adoption timeline is overly ambitious and usurps CMS' authority to determine EHR adoption. To prevent significant confusion for physicians about program requirements, we strongly recommend ONC refrain from adjusting the 2015 Edition Base EHR definition and recommend naming a new Edition. Furthermore, RPA recommends ample time be allowed for adoption.

RPA believes the iterative introduction of information technology in health care has long had the potential to transform health care. However, RPA warns that ONC must be vigilant in identifying unintended consequences of deploying health IT without a well-thought-out plan and priorities. Lacking fundamental elements to facilitate safe, effective, and interoperable EHRs, patients and physicians have been negatively impacted, such as the current issues surrounding the lack of interoperability between physician practices and dialysis units, which limit the transfer of critical patient information. Health IT as it has been implemented to data often burdens physicians rather than providing clinical benefit.

The passage of Cures provides an opportunity to correct the course of health IT. Congress wisely included provisions addressing physician burden, EHR usability and vendor practices, interoperability, information blocking, and patient information empowerment. ONC has taken up this charge and proposed a sweeping set of changes to health IT certification as well as a thorough interpretation of congressional intent. Several of the proposed changes, especially around health IT vendor practices and EHR performance, are welcome and respond to concerns raised by the RPA and clinical community.

RPA believes that ONC's broad interpretation of legislative language, compressed development and adoption timelines, complex regulatory requirements, and emphasis on data quantity will dramatically impact patient privacy and safety, data security, and further exacerbate physician burden and concerns with health IT. Without addressing these issues, the U.S. Department of Health and Human Services (HHS) may fail at meeting the goals set out by Congress in Cures.

RPA appreciates that ONC is promoting greater access to structured data elements, requiring the widespread use of APIs, and limiting excessive fees and contractual limitations that prevent interoperability. RPA welcomes the opportunity to work collaboratively with ONC. Thank you for considering these suggestions and please let us know if you have any questions. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

Jeffrey A. Perlmutter, MD
President