June 3, 2019

Office of the National Coordinator for Health Information Technology (ONC)
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW
Washington, DC 20201.

RE:21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program; RIN 0955–AA01

Dear ONC Staff:

Point-of-Care Partners (POCP) is pleased to provide comments on the subject proposed rule.

POCP is uniquely positioned to comment on this proposed set of requirements. We are a nationally recognized consulting firm in the areas of electronic prescribing (ePrescribing); standards to support payers, prescribers and pharmacies; specialty pharmacy automation; electronic exchange of health and administrative data; interoperability of electronic health records (EHRs); and electronic medication management. POCP also provides related management and strategic consulting services in those areas to a wide range of stakeholders.

Since 2006, POCP has been a leader in the development of standards and transactions being adopted under the Health Insurance Portability and Accountability Act (HIPAA) and Medicare Part D. We have testified frequently before the National Committee on Vital and Health Statistics (NCVHS), as well as provided technical assistance to both CMS and the Office of the National Coordinator for Health Information Technology (ONC). This year, we testified before the United States Senate Special Committee on Aging and the Health Information Technology Advisory Committee (HITECH).

Most recently, POCP has been at the forefront of the development of standards for electronic prior authorization (ePA) and the Real-Time Pharmacy Benefit Check (RTPBC). We currently are helping to lead a multi-stakeholder effort for use of HL7's FHIR (Fast Healthcare Interoperability Resources) standard to facilitate the exchange of clinical and administrative data among payers in support of value-based care. FHIR also shows promise for the development of application programming interfaces (APIs) for patients to access their data and better understand their financial liability for their health care and treatments.

1. Implementation date. The ONC draft rule is closely linked to CMS 9115-P, which was published by the Center for Medicare and Medicaid Services (CMS). They have identical requirements for some things as well as the goal of improving interoperability. Yet they have different compliance dates: 2020 for CMS and varying dates for discrete provisions of ONC's draft regulation. This is confusing to developers, payers and providers—especially in light of the scope of the changes that are proposed (e.g., requiring widespread adoption of FHIR) and the time that stakeholders will need to address them.

Many will believe that CMS' proposed implementation date of 2020 is too aggressive. It will not give enough time for payers, in particular, to adapt to the requirements. Payer systems are designed to bring

data in for the purposes of claims processing. They are not set up to export data. Nor do they depend on use of FHIR. Similarly, developers of electronic health records (EHRs) will need time to build to the requirements; vet, connect with and test various application program interfaces (APIs); and adjust their products' workflows to the incoming payer data. These activities are likely to be time consuming and expensive.

- **Recommendation 1a:** We recommend that the compliance dates for the ONC and CMS draft rules are synced in the corresponding final rules.
- **Recommendation 1b**: We recommend that ONC and CMS work with the industry to adopt the most aggressive schedule feasible for payers and EHRs, no later than January 1, 2022 for both to maintain forward momentum.

2. Focus on standards but not versions. The notice of proposed rulemaking (NPRM) specifies a myriad of required standards. However, it stops short of specifying standards to be used for certain requirements, such as the mandated Export Format. It also does not specify a version of FHIR to be supported by APIs. The proposal is to allow technology suppliers flexibility to evolve versions as the technology advances. We understand the rationale for not mandating a particular version; otherwise, ongoing rules would be needed as versions change. The unintended consequence, however, could be a free-for-all with different vendors supporting different versions. It will be challenging enough for technology suppliers to support the mandated API's and standards. That challenge will be multiplied if multiple versions of standards need to be supported as well.

We believe the required support of all these standards and versions perpetuates the need for clearinghouses and integration vendors. Not everyone will be able to transition to new standards at once due to the breadth of such an undertaking and the large number of distributed systems. There will be a need for translation by clearinghouses and integration vendors for some time into the future.

- **Recommendation 2a: CMS cite the use of specific standards. If not, the final rule should acknowledge the role of--and use of—clearinghouses and integration vendors.**

3. Enforcement. Stakeholders are interested in enforcement, especially since the 21st Century Cures Act allows for civil monetary penalties of up to $1 million per violation. It appears that enforcement will operate on a case-by-case, complaint-driven basis, which starts with a corrective action plan. The Department of Health and Human Services has experience with this approach in enforcing provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

However, the proposed rule lacks specificity concerning penalties. Clarification is needed because not all violations are of sufficient severity to fall into the $1 million range — or will they? At what point will penalties be invoked?

- **Recommendation 3a: ONC should expeditiously develop an enforcement rule that lays out a penalty structure for information blocking violations.**

4. Fees. Many entities are interested in the fees that might be charged by developers. Beginning on page 7487, the proposed rule lays out, in broad-brush categories, which fees are allowed, and which are prohibited. Fees that are not based on objective criteria or considered "reasonable" may be classified as "information blocking," which could invoke penalties. Costs not included as part of ONC's "permitted fees" will be expressly prohibited.

The proposed regulation does not specify what constitutes reasonable and unreasonable fees. Can the categories of permissible fees be updated, as business needs arise in our evolving healthcare system or in response to needs of categories of stakeholders? Can ONC determine a range of reasonable and necessary fees, such as is done under the Medicare fee schedule? Will reasonable and necessary fees be decided on a case-by-case basis? What is the process to determine what are reasonable and necessary fees?

- **Recommendation 4a: At a minimum, ONC should further clarify what constitutes reasonable and unreasonable fees and create a method for amending and updating the kinds of fees that are allowable.**

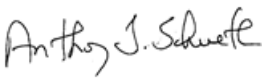
5. Expediting the final rule. The lengthy federal rulemaking process often has had the unintended consequence of impeding progress and stifling innovation. That is because developers, quite naturally, wait until the final rule is published to make business decisions. Most will need to readjust their business decisions to comply. Innovation often slows to a crawl in the interim. This often takes years. In the meantime, many stakeholders are left on hold for planning and revising contracts, which costs time and money. We look forward to the final rule's providing greater clarity on certain aspects of interoperability in an expeditious time frame.

- **Recommendation 5a. ONC should expedite publication of the final rule.**

Conclusion. Point-of-Care Partners is pleased to offer comments on the proposed regulation. Please do not hesitate to ask for clarifications or additional information. You can reach me at tonys@pocp.com.

Thank you for the opportunity to comment on this draft regulation.

Sincerely,



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