Pharmacy Health Information Technology Collaborative

Via Electronic Submission to: http://www.regulations.gov

June 3, 2019

Donald Rucker, MD
National Coordinator
Office of the National Coordinator
for Health Information Technology
330 C Street, SW, Room 7033A
Washington, DC 20201

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

Dear Dr. Rucker:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we appreciate the opportunity to submit comments on the *21st Century Cures Act: Interoperability, Information Blocking, and the Health IT Certification* proposed rule.

Pharmacists provide essential pharmacy and health-related services to patients. Additionally, pharmacists are users of health IT, and in particular, e-prescription and EHR systems. The Collaborative supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicaid and Medicare Services (CMS), in developing the national health information technology (HIT) framework and standards since 2010.

The following are our comments regarding the *21st Century Cures Act: Interoperability, Information Blocking, and the Health IT Certification* proposed rule.

Section IV – Updates to the 2015 Edition Certification Criteria

§170.213 Adoption of the United States Core Data for Interoperability (USCDI)

The Collaborative supports the adoption of USCDI Version 1 (v1) as a standard and believes it will help advance interoperability nationwide, as well revising the 2015 Edition certification criteria to incorporate the USCDI standard in place of the Common Clinical Data Set (CCDS). These are particularly important for transitions of care.

Updated Versions of Vocabulary Standard Code Sets

The Collaborative supports including the newest versions of the minimum standards code sets included in the CCDS into the USCDI v1 to ensure interoperability alignment, particularly those vocabulary standard code sets pertaining to the 2015 Edition criteria for transmission to immunization registries, transmission to public health agencies – syndromic surveillance, and family health history.

Medication Data Request for Comment

The Collaborative suggests keeping the USCDI v1 Medication data class and its two elements, Medications and Medication Allergies, at this stage rather than changing to a new data class entitled, Substance Reactions, with two elements, Substance and Reactions. Medication allergy has a specific meaning and the type of reaction experienced could be life threatening. A medication allergy is not the same as drug (medication) intolerance. It appears this potential change treats medication allergy and medication intolerance equally. The differences between these two need to be taken into account and considered before deciding on an alterative therapy. Pharmacy systems currently document medication allergies and need to adopt appropriate codes and descriptions. More information regarding ONC's thoughts for changing this class would be helpful before suggesting alternatives. Additional time is also needed to determine the potential impact of this possible change on existing pharmacy systems before adopting such a change. The Collaborative recommends tabling this for further discussion.

§170.205(a) Patient Summary Record

The Collaborative supports adopting HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1 C-CDA Companion Guide to support the best practice implementation of USCDI v1 data classes. For pharmacy, the Collaborative supports the use of the Pharmacist Care Plan[1] using HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R1, which incorporates USCDI v1 and FHIR Release 4 for interoperable exchange of medication-related clinical data captured by pharmacists.

[1] https://www.ecareplaninitiative.com/

The CDA and FHIR Pharmacist Care Plan Implementation Guides project is now being balloted by HL7. "The goal of the project is develop an electronic care plan with enhanced medication management content based on the templates in HL7 Implementation Guide for C-CDA Release 2.1: Consolidated Notes and FHIR profiles based on US Core specifications."[2] The Pharmacist Care Plan is key to the incorporation of medication-related goals and outcomes into a patient's care profile and planning. It will serve as a "standardized, interoperable document for exchange of consensus-driven prioritized medication-related activities, plans and goals for an individual needing care."[3]

§170.205(b) Electronic Prescribing

The Collaborative supports updating the electronic prescribing (eRx) SCRIPT standard in 45 CFR 170.205(b) to NCPDP SCRIPT 2017071 to become the eventual baseline for certification, as well for the query of the Prescription Drug Monitoring Program.

§170.205(b)(11) Electronic Prescribing

The Collaborative appreciates and thanks ONC for moving electronic prescribing forward by incorporating more functions critical to pharmacists that not only ensure interoperability alignment but further improve the electronic exchange of information between pharmacists and prescribers in an interoperable two-way process (bidirectional communication/exchange). As technology advances, the need for bidirectional exchange of prescription information increases and is of critical importance to pharmacists to move away from the use of faxes and telephone calls. For the long-term and post-acute care settings, a three-way process is needed to include pharmacy, prescriber and facility/home care systems. The Collaborative also works in consultation with long-term and post acute-care (LTPAC) organizations regarding HIT issues.

§170.315(d)(12) Encrypt Authentication Credentials

The Collaborative supports the proposal that health IT developers must assess their modules' capabilities and attest that either 1) the module encrypts stored credentials in accordance with standards adopted in §170.210(a)(2) or 2) the module does not store authentication credentials.

§170.315(d)(13) Multifactor Authentication

The Collaborative supports the proposal that health IT developers must assess their modules' capabilities and attest that either 1) the module supports authentication through multiple elements the identity of the user with industry recognized standards, or 2) the module does not support authentication through multiple elements the identity of the user with industry recognized standards.

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[2] http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1232

[3] Ibid.

§170.315(b)(12) Data Segmentation for Privacy – Send

The Collaborative supports the proposal to allow a user to create a summary record formatted in accordance with the standard adopted in §170.205(a)(4) and (a)(4)(i), et al, and subject to restrictions on re-disclosure according to the standard adopted in §170.205(o)(1).

§170.315(b)(13) Data Segmentation for Privacy – Receive

The Collaborative supports the proposal to allow a user to receive a summary record formatted in accordance with the standard adopted in §170.205(a)(4) and (a)(4)(i), et al, and subject to restrictions on re-disclosure according to the standard adopted in §170.205(o)(1) and preserve privacy markings to ensure fidelity to the tagging based on consent.

Request for Information on Health IT and Opioid Use Disorder Prevention and Treatment

The Collaborative supports the 2015 Edition certification criteria currently available to assist in the prevention of opioid use disorder, as well as USCDI standards. The certification criteria would support coordination in the detection of opioid misuse, abuse, and diversion, particularly those criterion specific to transitions of care, clinical information reconciliation and incorporation, electronic prescribing, patient health information capture, and social determinants of health.

Prescription Drug Monitoring Programs (PDMPs) could also be an integral component for OUD prevention and treatment. The Collaborative believes ONC has a critical role in helping to resolve the insufficient interoperability issue that exists among current state PDMPs. Primary among the issues creating challenges and barriers to interoperability within the 49-state PDMPs (Missouri does not have a state PDMP) are: no single integrated access to data among states exists; no real-time interoperable data among states; no real-time response for validating accurate data; and different standard sets being used. For PDMPs to become fully interoperable and integrated with current electronic exchanges of health information, these barriers and challenges need to be solved. One possible approach that has been discussed in TEFCA is to move in the direction of integrating access to data by establishing a single “on ramp” to the states’ PDMPs. Although a single on ramp may not necessarily resolve all issues, and it would require buy-in from all states, it would be a first step and one that ONC could help to bring to fruition. ONC could also be instrumental in establishing an industry task force to explore other possible solutions.

The Collaborative supports using the NCPDP SCRIPT Standard, Implementation Guide Versions 10.6, 2017071 and 2013101 and HL7 FHIR Implementation Guide, US Meds STU2 for e-prescribing and requesting a patient’s medication history from a state PDMP, as well as NCPDP Standards-based Facilitator(s) Model for PDMP, all of which will

help to close some interoperability, workflow, and real-time reporting gaps associated with PDMPs.

Section VII – Conditions and Maintenance of Certification

Trusted Exchange Framework and the Common Agreement (TEFCA) – Request for Information

The Collaborative believes health IT developers should be required to participate in TEFCA, once the framework is fully defined and formalized, as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or actions that would inhibit the exchange, access, or use of electronic health information.

Section VIII – Information Blocking

In general, the Collaborative supports the approach ONC is taking to prevent information blocking, particularly with regard to the usability, interoperability, and security of health IT; the business practices of health IT developers related to exchanging electronic health information; and the manner in which users of health IT use such technology. Since pharmacists are not recognized as providers in the Social Security Act, pharmacists need to be named in information blocking regulations to assure pharmacists are not excluded from bidirectional electronic exchange of clinical data.

§170.103 Information Blocking

The Collaborative supports the meaning of information blocking as outlined by ONC to cover practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

§170.102 Definitions

The Collaborative supports the various definitions as presented.

Request for Comment Regarding the Definition of Health Care Provider

The Collaborative believes adopting the definition of health care provider as defined in the Public Health Service Act §3000(3) of 42 U.S.C. 300jj(3) would not achieve ONC's goal to cover all individuals and entities covered by HIPAA. The Public Health Service Act (PHSA) definition lists a limited number of specific health care providers and entities that must comply with PHSA, whereas, the HIPAA definition is broader. Although a pharmacy and a pharmacist are listed as a health care provider, our concern with the PHSA definition, if used by ONC, is

that it could be interpreted as pertaining to just those listed as health care providers. The reason for potential misinterpretation is that the PHSA definition uses the word "includes," which may be misunderstood as meaning the listing of health care providers is exhaustive (the PHSA listing is actually an example of those covered). Experience shows that many misread "includes" to mean that a rule doesn't apply if they're not on the list (courts have been known to accept arguments that the implication of the word "includes" isn't enough). If ONC prefers to use the PHSA definition, then the phrase, "includes, but is not limited to," should be used to satisfy compliance and legal concerns.

Request for Comment Regarding Practices That May Implicate the Information Blocking Provision

An area that appears not to be addressed is a health information exchange that may limit access by a health care provider, who is required to use the HIE, to full patient information if the HIE views the health care provider as not a primary care provider. Pharmacists are health care providers, though in some instances, they are not fully viewed as health care providers by an HIE and may have restricted access to needed patient health care information.

Additionally, as a pharmacist and pharmacy are health care providers under the PHSA definition that ONC proposes to adopt, if a hospital or physician system requests a medication list from a pharmacist, will the pharmacist or pharmacy be penalized if the medication list is not provided in an interoperable way? This could occur if the system is not fully interoperable. In this scenario, who is penalized: the pharmacist, pharmacy, or pharmacy system vendor?

The Collaborative also strongly encourages and recommends that ONC examine the potential impact of the net neutrality repeal on information blocking, if it has not already begun to explore this area. The ending of net neutrality could go well beyond the average Internet user's day-to-day experience. It is our concern that repealing net neutrality may have a major and substantial negative impact on the health care arena, health IT that is reliant on the Internet, and the sharing of health care data via the Internet. Health care programs and providers could find their abilities to provide and share health care data with others slowed if they are not in a position to pay for prioritized access (e.g., fast lanes). ISPs could become information blockers, as they would be controlling the flow of information and data, which would impede achieving the interoperability goals ONC established for the use of health IT nationwide.

Section VII.B.4 Application Programming Interfaces

§170.404 Application Programming Interfaces (Conditions and Maintenance of Certification)

The Collaborative supports adopting HL7's FHIR DSTU2 as a baseline standard conformance requirement. In reviewing the four options ONC presents that could be pursued

for a final rule, it appears there is a fifth option that may provide an optimal approach for health IT developers to demonstrate compliance with §170.315(g)(10). That option would be to adopt FHIR Release 2 (proposed in regulation text) as the baseline reference, while allowing health IT developers who are ready to move to either FHIR Release 3 or the recently published FHIR Release 2. Essentially, ONC would adopt use of all three FHIR releases. This approach would allow more flexibility for advancing FHIR-based interoperability.

VIII.D Proposed Exceptions to the Information Blocking Provisions

§170.201- 203 Exceptions: Preventing Harm, Promoting the Privacy of Electronic Health Information, and Promoting the Security of Electronic Health Information

The Collaborative supports the conditions to qualify for these exceptions.

§170.204 Exception: Recovering Costs Reasonably Incurred

Although the Collaborative supports the conditions to qualify for this exception, we ask that ONC further define "reasonable" or provide additional guidance, as this term may be interpreted differently, depending on the size and maturity of the entity. It's also not clear if health care providers would be able to recover costs associated with compliance to the new rule. We ask ONC for further clarification. See also previous comments regarding the repeal of net neutrality and possible fees that may charged by ISPs for fast lanes and whether such fees charged by ISPs could be recovered, especially by health care providers, without triggering the information blocking provisions.

§170.205 Exception: Responding to Requests that are Infeasible

The Collaborative supports the conditions to qualify for this exception.

§170.206 Exception: Licensing of Interoperability Elements on Reasonable and Non-Discriminatory Terms

The Collaborative supports the conditions to qualify for this exception.

Request for Information on a Potential Additional Information Blocking Exception for Complying with the Common Agreement for Trusted Exchange

As noted previously, the Collaborative believes health IT developers should be required to participate in TEFCA, once the framework is fully defined and formalized, as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or actions that would inhibit the exchange, access, or use of electronic health information. Before commenting on whether ONC should propose a narrow exception to the information blocking provision in a further rulemaking, we would need to know what ONC has in mind for a specific narrow exception.

Section IX – Registries Request for Information: Health IT Solutions Aiding in Bidirectional Exchange with Registries

The Collaborative supports the use of FHIR Release 4 for improving data quality and to access specific or comparative information from various sources, as well as the proposal to prevent health IT developers from preventing registry integration.

Section X – Patient Matching Request for Information: Opportunities to Improve Patient Matching

The Collaborative supports ONC in its efforts to identify patient matching options. We encourage ONC to look at NCPDP's Universal Patient Identifier (UPI), which was developed in partnership with Experian Health, as a solution to match and manage patient identities.[4]

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and nine associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-center care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists' needs. For additional information, visit www.pharmacyhit.org.

[4] https://ncpdp.org/Products/NCPDP-Universal-Patient-Identifier

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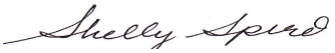
On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *21st Century Cures Act: Interoperability, Information Blocking, and the Health IT Certification* proposed rule.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



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