Pharmacy Health Information Technology Collaborative

<u>**Via Electronic Submission to: https://www.regulations.gov**</u>

October 17, 2018

Office of Security and Strategic Information (OSSI)
Office of the National Coordinator
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: RFI Regarding the 21st Century Cures Act Electronic Health Record Reporting Program

Dear Sir or Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments for the *Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program.*

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC), developing the national health information technology (HIT) framework since 2010.

Pharmacists provide patient-centered care and services, maintain various secure patient care records, and as part of the integrated health care team, they are directly involved with other health care providers and patients in various practice settings. Pharmacists are users of health IT, electronic health records (EHR), and are especially supportive of interoperability standards incorporating HL7, SNOMED CT, LOINC, RxNorm, and NCPDP SCRIPT, and NCPDP Real Time Formulary and Benefits (currently under development). The Collaborative supports use of these particular standards which are important to pharmacists for allergy reactions, immunization (historical and administered), immunization registry reporting, medications, medication allergies, patient problems, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing (including new versions).

The following are our comments regarding questions posed in the RFI.

Section III: Cross-Cutting Topics

Existing Data Sources

What data reported to State agencies (e.g., Medicaid EHR Incentive Program data), if available nationally, would be useful for the EHR Reporting program?

Response: The Pharmacy HIT Collaborative believes data tracking of notifiable diseases and chronic conditions reported to and by Public Health agencies would be useful, especially those pertaining to opioid use (e.g., Prescription Drug Monitoring Programs).

User-Reported Criteria

How can data be collected without creating or increasing burden on providers?

Response: The Collaborative believes using structured architecture, standardizing formats, and implementing interoperability between various EHR systems in the health care community would make collecting and exchanging data smoother. Interoperability within the current health IT framework is still lacking.

What recommendations do stakeholders have to improve the timelines of the data so there are not significant lags between its collection and publication?

Response: The Collaborative suggests that data be published in real time after it is collected. To accomplish this, though, may require a paradigm shift to move away from lag time.

For what settings (e.g., hospitals, primary care physicians, or specialties) would comparable information on certified health IT be most helpful?

Response: The Collaborative believes comparable information on certified health IT would be most helpful for all pharmacy practice settings.   Although pharmacists are not eligible providers under the EHR Incentive and MIPS programs, as noted earlier, they are users of health IT and an integral part of health care teams.

How could HHS encourage clinicians, patients, and other users to share their experiences with certified health IT?

Response: The Collaborative believes that HHS could establish and promote an online forum in which to submit experiences, as well as provide education and outreach about using certified health IT resources to clinicians, patients, and other users (including pharmacists).

Health IT Developer-Reported Criteria

Would a common set of criteria reported on by all developers of certified health IT, or a mixed approach blending common and optional sets of criteria, be more effective as we implement the EHR Reporting Program?

Response: The Collaborative believes a mixed approach could be more beneficial in helping decision makers acquiring certified health IT to compare products needed for their end users. A mixed approach would address areas that may not be fully reflected in a common set of criteria.

Section IV: Categories for EHR Reporting Program

What categories of reporting criteria are end users most interested in (e.g., security, usability and user-centered design, interoperability, conformance to certification testing)? Please list by priority.

Response:
1) Security
2) Conformance to certification testing
3) Interoperability
4) Bidirectional communication
5) Usability and user-centered design
6) Use of standardized and nationally recognized terminology

Security

What reporting criteria could provide information on meaningful differences between products in the ease and effectiveness that they enable end users to meet their security and privacy needs?

Response: The Collaborative believes more complete and detailed disclosures from health IT developers about their certified health IT products would be beneficial for end users, especially complete information regarding identity verification, proofing and authentication. Such information could close some gaps in existing comparison tools.

Describe other useful security and privacy features or functionalities that a certified health IT product may offer beyond those required by HIPAA and the ONC Health IT Certification Program.

Response: Because of the increased sophistication that cyber attackers employ, the Collaborative believes better approaches to user identity verification and authentication would be especially useful, particularly for those using patient portals. Traditional

approaches to authentication are no longer adequate;[1] better approaches are needed. Protecting patient information is paramount. Cybercrime, which is a fast-growing challenge, needs to be kept at the forefront of discussions on certified health IT. Some of the largest cyber attacks and data breaches have been in the health care industry.[2]

The Collaborative recommends establishing more sophisticated, common identity proofing practices and requiring multi-factor authentication for all patient and provider access to any trusted exchange framework and health IT systems, particularly with regard to the various means of accessing health IT systems and electronic health information. Access to health IT systems via mobile phones, email, online services, and other electronic avenues is becoming more commonplace.

Interoperability

What other domains of interoperability (beyond those already identified and referenced above) would be useful for comparative purposes?

Response: The Collaborative recommends looking at cross-domain interoperability, that is, the ability of systems and organizations to interact and exchange information among different areas (i.e., emergency preparedness and those responding to emergencies and disasters). This is an area that is not included in discussions of health IT interoperability. Cross-domain could be of importance to health care providers, particularly pharmacies and hospitals, with regard to disaster planning.

Of the data sources described in this RFI, which data sources would be useful for measuring the interoperability of certified health IT products? Comment on whether state Medicaid agencies would be able to share detailed-level for the purpose of developing more detailed level, such as by health IT product.

Response: Although state Medicaid agencies could be a useful data source, barriers restricting data sharing by Medicaid agencies would need to be addressed. A possibility to overcome one barrier would be for ONC to develop a data sharing agreement with state Medicaid agencies. This could be similar to the model sharing agreement[3] developed by HCFA, HRSA, and the CDC to facilitate collaborations for data sharing between state Medicaid agencies and these federal health agencies. Other state laws pertaining to privacy would also need to be examined.

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[1] "Patient Portal Identity Proofing and Authentication," Guidance from the HIMSS Identity Management Task Force. https://www.himss.org/sites/himssorg/files/Patient_Portal_Identity_Proofing_and_Authentication_Final.pdf (accessed October 5, 2018).

[2] https://www.hipaajournal.com/largest-healthcare-data-breaches-2017/ (accessed October 5, 2018).

[3] https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD102298.pdf (accessed October 5, 2018).
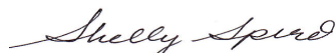
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 The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and ten 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.

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 On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program.*

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

Respectfully submitted,

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