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September 23, 2011

Steven Posnack
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building
200 Independence Ave., SW.
Suite 729D
Washington, DC 20201

RE: 45 CFR Part 170 RIN 0991-AB78 Advance Notice of Proposed Rulemaking: Metadata Standards to Support Nationwide Electronic Health Information Exchange

Dear Mr Posnack:

Overview of the Pharmacy e-Health Information Technology Collaborative and Comments in Response to Metadata Standards to Support Nationwide Electronic Health Information Exchange

   On behalf of the membership of the Pharmacy e-Health Information Technology Collaborative (Collaborative), we are pleased to submit general comments regarding the need to include pharmacists in metadata standards in response to the advance notice of proposed rulemaking (ANPRM), *Metadata Standards to Support Nationwide Electronic Health Information Exchange* (45 CFR Part 170) by the Office of the National Coordinator for Health Information Technology (ONC). The Collaborative provides general comments in response to this notice and also supports the technical comments submitted by the National Council for Prescription Drug Programs (NCPDP).

   Formed in the fall of 2010, the Collaborative's focus is to assure the meaningful use (MU) of standardized electronic health records (EHRs) that supports safe, efficient, and effective medication use, continuity of care, and provides access to the patient-care services provided by pharmacists with other members of the interdisciplinary patient-care team. The Collaborative's goal is to assure that the pharmacist's role of providing patient-care services is integrated into the National HIT interoperable framework. The group is pursuing EHR standards that effectively support the delivery, documentation of, and billing for pharmacist-provided patient care services across all care settings and in MU of EHRs.

Pharmacy e-Health Information Technology Collaborative
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The Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's Associate Members represent e-prescribing networks, a standards development organization, and a transaction processing network. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes three associate members from other pharmacy related organizations. For additional information, visit www.pharmacyhit.org.

Members of the Collaborative were involved in working with a joint Health Level Seven (HL7) and NCPDP working group in the development of the Pharmacist/Pharmacy Provider EHR (PP-EHR), an HL7 functional profile. The Collaborative continues to work with national EHR certification organizations and pharmacy system vendors to assure that the PP-EHR functionality is adopted with the development of certification criteria to meet the MU of EHR concepts related to pharmacy services.

The Collaborative supports pharmacists as meaningful users of EHRs to help collect data and provide clinical services and impact measured outcomes in health care. In relationship to the ANPRM, a standardized PP-EHR will use a set of medication related standards for metadata that would be wrapped around or attached to a summary care record when patients seek to download their health information from the PP-EHR patient portal or transmit it directly to their individual personal health record (PHR). The patient will be able to identify and secure data elements and the source of the clinical data will adhere to privacy and security standards.

The ANPRM requests information regarding standards that ONC should incorporate into a proposed rule for metadata standards in the exchange of information for Stage 2 MU. As a general comment in response to the ANPRM, the Collaborative supports bidirectional communication in information exchanges to pharmacists through EHRs. This will ensure a complete interdisciplinary team approach to medication related care. Communication must include metadata standards that incorporate pharmacists, including functions to exchange medication therapy management (MTM) information and other functions that allow exchange of patient care service information. This is currently possible because the PP-EHR uses HL7 clinical document architecture Release 2 (CDA) and an NCPDP standard already exists for the exchange of this information through the CDA. The Collaborative recommends that the proposed rule includes the NCPDP "Specialized Standard" to exchange medication related information among care providers, payers and patients in all practice settings using health information exchanges (HIE) or eprescribing networks. The Specialized Standard allows for the continuity of care document (CCD) or continuity of care record (CCR) functions using CDA to be exchanged in the following circumstances:

- MTM where an entity may request a service to be preformed and provide clinical documentation or when documenting a service and
- Query functions where an entity exchanges allergies, conditions, medical histories and clinical information.

The Collaborative supports the use of exchanges of information using standard transactions from standards development organizations using CDA, including but not limited to NCPDP and

HL7, when summary information is exchanged. As stated above, the Collaborative supports the technical comments submitted by NCPDP in response to specific questions posed in the ANPRM, but provides answers to specific questions as noted below.

Question 10: With respect to the privacy category and content metadata related to "data type," the HIT Standards Committee recommended the use of LOINC codes to provide additional granularity. Would another code or value set be more appropriate? If so, why?

> The Collaborative agrees with the use of LOINC codes but also supports the adoption of Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED-CT) for the purpose of indexing, storing, retrieving, and aggregating clinical data across patient care settings. To ensure that medication information is transmitted in a standard manner, the Collaborative supports the adoption of RxNORM and Structured and Codified Sig (a codified standard way to electronically document the directions for medication use).

The Collaborative also supports the HIT Standards Committee recommendations presented in Questions 11 and 12.

The Collaborative also encourages ONC to ensure that medication related metadata standards used in the summary care standards allow pharmacists to provide patients with information through a PP-EHR. With the appropriate privacy and security standards in place, pharmacists must be able to access metadata transmitted by other health care providers to perform patient care services. Incorporation of these standards from the very beginning of the process is important because as ONC notes in the summary to the ANPRM, the capabilities in this initial process may be applied to other transfers of summary care records, such as discharge summaries during transitions of care.

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On behalf of the Pharmacy e-HIT Collaborative, thank you again for the opportunity to comment on the ANPRM and the work of ONC to establish the nationwide HIT infrastructure. As the process moves forward, the Collaborative urges you to consider the important role pharmacists play in achieving the clinical and functional objectives to meet meaningful use that results in improvement in patient care and outcomes. For more information, please contact Shelly Spiro, Director, Pharmacy e-HIT Collaborative at shelly@pharmacyhit.org.

Respectfully submitted,
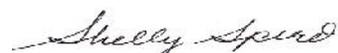
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