



April 27, 2015

Karen B. DeSalvo, MD, MPH, MSc  
Office of the National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
200 Independence Avenue S.W., Suite 729-D  
Washington, D.C. 20201

RE: ONC Interoperability Standards Advisory

Dear Dr. DeSalvo:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

NCPDP believes the industry needs to begin to consider standards, transactions, implementation specifications, etc. in a broad view, to ensure they support the needed function without constraints regarding “administrative” or “clinical” or based on provider type or care setting. It is necessary to move beyond artificial distinctions that do not benefit the patient or enhance interoperability. All identified best available standards should include information as to their regulatory status, ballot status and development and/or pilot status. The maturity and level of industry use of a standard needs to be considered in regards to the amount of substantive changes or modifications a standard may be undergoing before it is recommended for widespread use.

Thank you for your consideration of our input. NCPDP welcomes the opportunity to work with ONC representatives to identify, assess, and determine the best available interoperability standards and implementation specifications for industry use toward specific health care purposes.

For direct inquiries or questions related to this letter, please contact

Teresa Strickland

Technical Advisor, Standards Development

National Council for Prescription Drug Programs

E: [tstrickland@ncdpd.org](mailto:tstrickland@ncdpd.org)

Sincerely,

A handwritten signature in black ink, appearing to read "Lee Ann C. Stember".

Lee Ann C. Stember

President

National Council for Prescription Drug Programs

[lstember@ncdpd.org](mailto:lstember@ncdpd.org)

cc: NCPDP Board of Trustees

Questions Regarding the Interoperability Standards Advisory:

- 5-1. **[General]** What other characteristics should be considered for including best available standards and implementation specifications in this list?

**NCPDP Comment:** In addition to the reasoning outlined, standards, transactions, implementation specifications, etc. need to be considered in a broad view, to ensure they support the needed function without constraints regarding “administrative” or “clinical” or based on provider type or care setting.

NCPDP agrees with the statements regarding stability and adoptability; however maturity needs to be considered in regards to the amount of substantive changes or modifications a standard may be undergoing before it is recommended for widespread use.

- 5-3. **[General]** For sections I through IV, what “purposes” are missing? Please identify the standards or implementations specifications you believe should be identified as the best available for each additional purpose(s) suggested and why.

**NCPDP Comment:** Authorization appears to be missing. This can be viewed as authorization for treatment and/or authorization for payment. As stated above, it is necessary to move beyond artificial distinctions that do not benefit the patient or enhance interoperability. NCPDP has previously recommended to NCVHS the electronic prior authorization (ePA) transactions in the NCPDP SCRIPT Standard v2013101 be used and adopted for authorization for pharmacy benefits. More information on ePA transactions for pharmacy may be found on the [NCPDP Website](#) by expanding the NCPDP Resource banner.

Medication History appears to be missing also. Medication History allows for pharmacies, payers and prescribers to exchange a list of medications that have been dispensed or administered to a specific patient for a date range. It can include all medications dispensed/administered or a current medication list. The medication history transactions are found in the NCPDP SCRIPT Standard v10.6.

The NCPDP Specialized Standard v2014101 contains additional transactions that support the pharmacist and pharmacy role in health care and care coordination. Medication Therapy Management (MTM) transactions may be used as the transport for *HL7 Implementation Guide for CDA Release 1 MEDICATION THERAPY MANAGEMENT PROGRAM MEDICARE PART D* and *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes*. In addition, The ClinicalInfoRequest/Response transactions allow the exchange of allergies, conditions, medical histories and all clinical information available to be shared between entities. The information is exchanged using industry standards currently in use within the medical community.

Also, there are no standards listed for RESTful services for unsolicited push of health information. RESTful is currently in use throughout the healthcare industry.

- 5-4. **[General]** For sections I through IV, is a standard or implementation specification missing that should either be included alongside another standard or implementation specification already associated with a purpose?

**NCPDP Comment:** In the long term and post-acute care (LTPAC) setting, the NCPDP SCRIPT Standard v10.6 Census message is also used in addition to the HL7 ADT message to notify a pharmacy of a resident’s admission, discharge or transfer.

NCPDP requests electronic prescribing in Section II be modified to include all messaging available in the NCPDP SCRIPT Standard v10.6 which includes the following:

- New Rx
- Refill Request
- Cancel
- RxFill Notification

Given the regulatory constraints associated with many of the standards/implementation specifications named, many SDOs have created supplemental guidance documents, such as the *SCRIPT Implementation Recommendations* and the *Formulary and Benefit Implementation Recommendations* documents to assist implementers. We recommend these documents also be included.

- 5-5. **[General]** For sections I through IV, should any of the standards or implementation specifications listed thus far be removed from this list as the best available? If so, why?

**NCPDP Comment:** Unstable items still in active development should be included in the list but should have some type of indication that it is still in active development, for example FHIR. By listing all of the items in the same category and without an applicable note, it implies it is stable.

- 5-6. **[Section I]** Should more detailed value sets for race and ethnicity be identified as a standard or implementation specification?

**NCPDP Comment:** NCPDP recommends a more specific code set be used. NCPDP currently uses the CDC code set for coding race and ethnicity data which may be found at <http://phinvals.cdc.gov/vads/ViewValueSet.action?id=66D34BBC-617F-DD11-B38D-00188B398520#>

- 5-7. **[Section I]** Should more traditionally considered “administrative” standards (e.g., ICD-10) be removed from this list because of its focus on clinical health information interoperability purposes?

**NCPDP Comment:** The historical distinction between clinical and administrative now seems to be arbitrary and counter to driving interoperability. As an example, ICD and SNOMED may both be used to support encounter diagnosis as well as pharmacy billing diagnosis associated with the medication being dispensed. NCPDP does not agree with removing ICD as it can provide important clinical information.

- 5-8. **[Section I]** Should “Food allergies” be included as a purpose in this document or is there another approach for allergies that should be represented instead? Are there standards that can be called “best available” for this purpose?

**NCPDP Comment:** All allergies should be encompassed in one category that references multiple standards to express the source of the allergen. For example, medication would use RxNorm, food and environment would use UNII, SNOMED or LOINC.

- 5-11. **[Section I]** Public health stakeholders have noted the utility of NDC codes for inventory management as well as public health reporting when such information is known/recorded during the administration of a vaccine. Should vaccines administered be listed as a separate purpose with NDC as the code set?

**NCPDP Comment:** Yes, NCPDP recommends the use of the NDC codes for inventory management and public health reporting of the administration of vaccines.

- 5-13. **[Section I]** If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, should it be listed in the “implementation specification” column or should a new column be added for value sets?

**NCPDP Comment:** NCPDP recommends a new column be added.

- 5-14. **[Section II]** Several laboratory related standards for results, ordering, and electronic directory of services (eDOS) are presently being updated within HL7 processes. Should they be considered the best available for next year’s 2016 Advisory once finalized?

**NCPDP Comment:** NCPDP cannot recommend inclusion into the 2016 advisory until the standards are finalized and available for review.

- 5-15. **[Section II]** Are there best available standards for the purpose of “Patient preference/consent?” Should the NHIN Access Consent Specification v1.0 and/or IHE BPPC be considered?

**NCPDP Comment:** Whatever standard is used must work for all segments of the industry including pharmacy, and must support a variety of scenarios and state-specific requirements. NCPDP is willing to participate in these discussions.

NCPDP recommends defining the terms preference and consent before a standard is selected.