October 30, 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 2016 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 supports interoperability among stakeholders and looks forward to continuing to work with ONC on achieving this critical healthcare objective.

Thank you for your consideration of our input.

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@ncpdp.org

Sincerely,

Lee Ann C. Stember
President
National Council for Prescription Drug Programs
lstember@ncpdp.org

cc: NCPDP Board of Trustees
### Tables:

#### Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

**I-A: Allergies**

<table>
<thead>
<tr>
<th>Interoperability Need</th>
<th>Representing patient allergic reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Standard/Implementation Specification</td>
</tr>
<tr>
<td>Standard</td>
<td>SNOMED-CT</td>
</tr>
</tbody>
</table>

**Limitations, Dependencies, and Preconditions for Consideration:**
- Feedback requested

**Applicable Security Patterns for Consideration:**
- NCPDP comment: NCPDP recommends SNOMED-CT should only be used to note the existence of a reaction and its severity. Allergens should be conveyed elsewhere using other code sets.

<table>
<thead>
<tr>
<th>Interoperability Need</th>
<th>Representing patient allergens: medications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Standard/Implementation Specification</td>
</tr>
<tr>
<td>Standard</td>
<td>RxNorm</td>
</tr>
</tbody>
</table>

**Limitations, Dependencies, and Preconditions for Consideration:**
- When a medication allergy necessitates capture by medication class, NDF-RT is best available (as recommended by the HIT Standards Committee)
- Feedback requested

**Applicable Security Patterns for Consideration:**
- NCPDP comment: RxNorm codes are not always available for all medications. The NDF-RT code set is not referenced in either the MU3 or CEHRT final rules.
### Interoperability Need: Representing patient allergens: environmental substances

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard/Implementation Specification</th>
<th>Standards Process Maturity</th>
<th>Implementation Maturity</th>
<th>Adoption Level</th>
<th>Regulated</th>
<th>Cost</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>SNOMED-CT</td>
<td>Final</td>
<td>Unknown</td>
<td>Unknown</td>
<td>No</td>
<td>Free</td>
<td>N/A</td>
</tr>
</tbody>
</table>

#### Limitations, Dependencies, and Preconditions for Consideration:

- Feedback requested

#### Applicable Security Patterns for Consideration:

- Feedback requested

**NCPDP Comment:** NCPDP is concerned that multiple entities, such as USP and CDC, are currently addressing the issue and codification of food substance allergens and that alignment is needed before a standard is named and national adoption begins.

### Interoperability Need: Representing patient medications

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<tr>
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<th>Cost</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>RxNorm</td>
<td>Final</td>
<td>Productation</td>
<td>Yes</td>
<td>Fr ee</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

#### Limitations, Dependencies, and Preconditions for Consideration:

- Feedback requested

**NCPDP Comment:** RxNorm does not cover all medications, including compounded products and over-the-counter and herbals.
I-R: Unique Device Identification

Interoperability Need: Representing unique implantable device identifiers

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard/Implementation Specification</th>
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<th>Implementation Maturity</th>
<th>Adoption Level</th>
<th>Regulated</th>
<th>Cost</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3</td>
<td>Final</td>
<td>Production</td>
<td>● ● ● ● ●</td>
<td>Yes</td>
<td>Free</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Limitations, Dependencies, and Preconditions for Consideration:

- Any HL7 2.x version messaging standard associated with ADT is acceptable.
- A variety of transport protocols are available for use for ADT delivery. Trading partners will need to determine which transport tools best meet their interoperability needs.

Applicable Security Patterns for Consideration:

- Feedback requested

NCPDP Comments: NCPDP has concerns with the use of the Unique Device Identifier (UDI) in the pharmacy industry. The major concern is with the discontinued use of legacy NDC/NHRIC for devices and the mandated use of the UDI. These identifiers are used in billing and the UDI is not a named HIPAA code set. There are ongoing discussions between stakeholders and the FDA on how items sold at retail are to be billed.

Section II: Best Available Content/Structure Standards and Implementation Specifications

II-A: Admission, Discharge, and Transfer

Interoperability Need: Sending a notification of a patient’s admission, discharge and/or transfer status

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<th>Regulated</th>
<th>Cost</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>HL7 2.x ADT message</td>
<td>Final</td>
<td>Production</td>
<td>● ● ● ● ●</td>
<td>No</td>
<td>Free</td>
<td>No</td>
</tr>
</tbody>
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Limitations, Dependencies, and Preconditions for Consideration:

- Any HL7 2.x version messaging standard associated with ADT is acceptable.
- A variety of transport protocols are available for use for ADT delivery. Trading partners will need to determine which transport tools best meet their interoperability needs.

Applicable Security Patterns for Consideration:

- Feedback requested

NCPDP comments: For communications between long term and post-acute care facilities, the NCPDP Census message is also being used to report admissions, discharges and transfers to the servicing pharmacy.
II-D: Drug Formulary & Benefits

**Interoperability Need:** The ability for pharmacy benefit payers to communicate formulary and benefit information to prescribers systems

<table>
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<th>Implementation Maturity</th>
<th>Adoption Level</th>
<th>Regulated</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>NCPDP Formulary and Benefits v3.0</td>
<td>Final</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Limitations, Dependencies, and Preconditions for Consideration:**

- The HIT Standards Committee noted that the NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging alternative.

**Applicable Security Patterns for Consideration:**

- Feedback requested

**NCPDP Comment:** The NCPDP Formulary and Benefit Standard was removed from the certification rule.

II-E: Electronic Prescribing

**NCPDP Comment:** While NCPDP SCRIPT Standard v10.6 is the current mandated version, the version of SCRIPT mandated for use must stay in sync with the versions named under MMA.