National Council for Prescription Drug Programs
NCPDP

Recommendations to NCVHS Regarding the Usability of RxNorm As A Drug Interoperability Vocabulary

February 1-2, 2005

Purpose

The purpose of this document is to:

1. Describe the functional requirements of a drug concept interoperability vocabulary.
2. Detail the steps required for implementation of a drug concept interoperability vocabulary within health information systems.
3. Assess the current acceptability of RxNorm in supporting drug interoperability requirements.
4. Provide recommendations to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security regarding the adoption of RxNorm within applicable messaging standards.

Assumptions

The primary assumption is that existing local and proprietary drug vocabularies will continue to be used within healthcare provider and payer systems. This assumption is based upon the current widespread adoption and implementation of pre-existing medication vocabularies within point-of-care health information system applications.

As drug concepts are exchanged as part of messaging transactions between healthcare providers and/or payers, it is proposed that an RxNorm concept would be included *in addition to* the drug concept code and text description native to the "senders" application. Thus, the primary purpose of the RxNorm concept is to provide the automated translation of drug concepts between health information systems that use disparate drug vocabularies.

Proposed MMA Drug Concept Interoperability Requirements

The ideal drug concept interoperability vocabulary has the following characteristics:

- Drug concepts are assigned permanent identifiers.
- The meaning of a unique drug concept does not change over time.
- Drug concepts are made publicly available on a timely basis (publication should mirror the market release date of related packaged products).
- Editorial policy for the naming of drug ingredients, brand name, dosage form, strength and strength unit of measure is published and is consistently applied.
- Change history is published (e.g., obsolescence, replacement).
- The comprehensiveness of the interoperable vocabulary should cover all medications and medical supplies likely to be prescribed or ordered within the United States market.
- A liaison is provided to the industry to handle editorial policy questions, provide implementation support on a timely basis and participate in related industry workgroups.
- The entity responsible for authoring interoperable vocabulary content provides a responsive customer support service.

- Cross-references between the drug concept interoperability vocabulary and external source contributing vocabularies are maintained and published on a timely basis (used within licensing constraints specified by source vocabularies).
- The meaning of the linked interoperability vocabulary term must be equivalent to the meaning of the external source vocabulary term.
- A governing body is established to approve editorial policy, establish use cases, review content authoring processes and review ongoing quality improvement procedures.
- The governing body deems the interoperable vocabulary as ready for "production" release and use within health information systems.

Messaging Transaction Candidates

The following lists of ambulatory[1] service-based message types are candidates for the inclusion of interoperability drug concepts. Reference is made to the possible terminology type that would be applicable from RxNorm or administrative code sets:

- Prescriber inquiry into Prescription Drug Plan (PDP) formularies to determine prospective patient drug eligibility
    - Should support Brand Name (BN), Ingredient (IN), Semantic Brand Drug (SBD), Semantic Clinical Drug (SCD) or NDC
- Prescriber submission of prospective patient drug to PDP for Prior Authorization approval
    - Should support Brand Name (BN), Ingredient (IN), Semantic Brand Drug (SBD), Semantic Clinical Drug (SCD) or NDC
- PDP system submission of patient drug Prior Authorization approval request outcome to prescriber system
    - Should support Brand Name (BN), Ingredient (IN), Semantic Brand Drug (SBD), Semantic Clinical Drug (SCD) or NDC
- PDP publication of drug formulary benefits
    - Should support Brand Name (BN), Ingredient (IN), Semantic Brand Drug (SBD), Semantic Clinical Drug (SCD) or NDC
- PDP submission of patient drug history to prescriber
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug(SCD) or NDC
- Prescriber patient prescription submission to a specific pharmacy
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug(SCD) or NDC
- Prescriber patient drug history submission to a specific pharmacy
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug(SCD) or NDC
- Prescriber patient drug history submission to another health care provider
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug(SCD) or NDC
- Pharmacy to prescriber dispensing outcome (e.g., prescription filled, prescription picked-up, prescription not picked-up, drug-problem reporting)
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug(SCD) or NDC
- Pharmacy patient drug history submission to another health care provider
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug (SCD) or NDC
- Hospital patient medication history to another health care provider
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug(SCD) or NDC
- Hospitalized patient discharge medications to a specific pharmacy
    - Should support Semantic Brand Drug (SBD), Semantic Clinical Drug(SCD)or NDC

Steps Required for Industry Implementation of RxNorm

The following tasks must be accomplished to support a successful implementation:

- A governing body deems the interoperable vocabulary as ready for "production" release and use within health information systems.

[1] Message types appropriate for hospital-based services (i.e. HL7) has not been evaluated by this group.

- The industry becomes convinced that a demonstrable business need is present for the inclusion of RxNorm within applicable messaging standards. Widespread implementation will be stymied unless vendors and self-programming entities perceive that the integration of the interoperable drug vocabulary will provide value or an adequate return on investment in exchange for the associated development costs.
- RxNorm is published on a regular basis using permanent identifiers. Incremental updates are provided at an interval no greater than weekly. Medications likely to be prescribed must be coded to Semantic Clinical Drug concepts; associated Semantic Brand Drug concepts are required for innovator products.
- RxNorm cross-references to UMLS contributing vocabularies are published on timely basis.
- An RxNorm "liaison" is made available to the industry to assist with implementation activities and to resolve outstanding content issues.
- Messaging standards are updated as needed to accommodate the inclusion of RxNorm concepts. Related messaging standard implementation guides are written and provided to the industry.
- Drug knowledge base vendors and entities using in-house drug vocabularies import RxNorm into database files. As needed, additional cross-reference work occurs to ensure that RxNorm Ingredient, Brand Name, Semantic Clinical Drug and Semantic Brand Drug concepts are linked to analogous concepts. Integrated RxNorm files are then made available customers.
- The industry becomes comfortable with the use of RxNorm cross-reference files and concerns regarding potential liability are eased.
- Prescriber, Pharmacy, Prescription Drug Plan, Long Term Care Systems and other ancillary systems are modified to import RxNorm concepts. Systems are further modified to send and interpret RxNorm values within applicable electronic transactions. Note that typically, a significant time lag between the development of updated health information systems and the subsequent implementation within end-user systems occurs. This time lag can range from months, to years, depending upon the number of production versions supported by vendor or self-programming entities.

Current Barriers to RxNorm Implementation

The following issues are impeding the implementation of RxNorm within health information systems:

- No clear "owner" of RxNorm has stepped forward to clearly enunciate the business requirements intended to be satisfied by RxNorm. Without clear business requirements and a plan for acceptance testing, it is impossible to state with conviction that the design of RxNorm is adequate to meet the interoperability needs of the industry.
- The business need for the *mandatory* inclusion of RxNorm concepts within applicable messaging standards has yet to be established. In the absence of an accepted interoperability vocabulary, National Drug Codes (NDC), Universal Product Codes (UPC) and Health Related Identifiers (HRI) continue to be the drug identifiers used within billing transactions and emerging dispensing history sharing applications with prescribers. Mandating the use of RxNorm as an e-prescribing requirement is premature at the present time, as emerging e-prescribing systems have been successfully implemented without the use of an interoperable drug vocabulary. Once RxNorm has been proven to be fully comprehensive, well tested and deemed reliable, the industry will see that business efficiencies can be gained by inclusion of RxNorm concepts within applicable transactions (e.g., determination of drug formulary coverage, prior authorization requests, e-prescribing). Revision of applicable messaging standards to *optionally* reference RxNorm may gain more industry acceptance, as implementation will naturally occur over the course of time as business partners recognize advantageous returns on investment.
- Permanent identifiers have yet to be assigned to RxNorm concepts. The UMLS 2004 AA, UMLS 2004 AB and the November 2004 cumulative RxNorm data file each have

assigned different code values to the same concept. For example, the Semantic Clinical Drug of "Propranolol 40 MG Oral Tablet" (2004 AB Concept Unique Identifier or "CUI" C0979844) was assigned the code of "RX311914" within the 2004 AA UMLS, "RX401283" within the 2004 AB UMLS and "RX10312686" within the cumulative RxNorm file dated November 17, 2004. Because RxNorm concepts will be published between UMLS quarterly issue dates, we have been informed by the National Library of Medicine (NLM) that CUI values will not be available. Thus, the assumption is that the RxNorm "code" must be used within messaging transactions to identify drug concepts. Although we have been advised recently by NLM personnel that the 2005 AA version of UMLS should now have stable RxNorm codes assigned, we would like to witness the successful publication of RxNorm for a couple of production cycles prior to recommending the construction of required cross-reference files to proprietary drugs.

- Timely publication of RxNorm. NLM has outlined an effective publication process in which RxNorm files will become ultimately available on a weekly basis. The first cumulative file is available now (file dated of November 17, 2004). We understand that incremental weekly updates will be made available in the near future. Thorough testing of the new publication process has not yet occurred.
- Availability of an industry RxNorm "liaison". We are not aware of the funding or approval status of this NLM position or positions.
- Existing drug knowledge base vendors maintain concepts that define medicinal agents at the level of "pharmaceutical equivalence." RxNorm defines medicinal agents at the level of "clinical significance." Because RxNorm normalizes strength information, removes ingredient salts when considered clinically insignificant and represents the "administered" dosage form, vendor drug concepts many times are more specific than the linked RxNorm concept. Thus, one RxNorm concept may have cross-reference linkages to many vendor concepts. In most cases this is clinically irrelevant. However, in certain circumstances, the differences can be significant, and present possible patient safety and health care provider liability concerns to the industry. The potential issue is that translations from a vendor clinical drug to an RxNorm Semantic Clinical Drug may at times be ambiguous or may lose the prescriber's intent. Presented below are examples of differences between RxNorm Semantic Clinical Drug (SCD) concepts and cross-referenced database vendor's generic identifiers:

Normalized RxNorm Strength

RXNCONSO_CODE	Vendor	RXNCONSO_STR	Generic Identifier	Generic Description
RX10239191	FDB	Amoxicillin 50 MG/ML Oral Suspension	8998	AMOXICILLIN TRIHYDRATE 250MG/5ML ORAL SUSPENSION, RECONSTITUTED, ORAL (ML)
RX10239191	FDB	Amoxicillin 50 MG/ML Oral Suspension	8999	AMOXICILLIN TRIHYDRATE 50MG/ML ORAL DROPS, RECONSTITUTED, ORAL
RX10239191	Medi-Span	Amoxicillin 50 MG/ML Oral Suspension	00042	Amoxicillin (Trihydrate) For Susp 250 MG/5ML
RX10239191	Medi-Span	Amoxicillin 50 MG/ML Oral Suspension	00040	Amoxicillin (Trihydrate) For Susp 50 MG/ML
RX10239191	Multum	Amoxicillin 50 MG/ML Oral Suspension	1245	amoxicillin 50 mg/mL oral liquid
RX10239191	Multum	Amoxicillin 50 MG/ML Oral Suspension	1250	amoxicillin 250 mg/5 mL oral liquid
RX10239191	NDF-RT	Amoxicillin 50 MG/ML Oral Suspension	C32258	AMOXICILLIN 250MG/5ML SUSP,ORAL
RX10239191	NDF-RT	Amoxicillin 50 MG/ML Oral Suspension	C32288	AMOXICILLIN TRIHYDRATE 250MG/5ML SUSP
RX10239191	NDF-RT	Amoxicillin 50 MG/ML Oral Suspension	C32312	AMOXICILLIN TRIHYDRATE 50MG/ML DROPS,ORAL

Removal of Ingredient Salt

RXNCONSO_CODE	Vendor	RXNCONSO_STR	Generic Identifier	Generic Description
RX10310165	FDB	Erythromycin 250 MG Oral Tablet	9238	ERYTHROMYCIN ESTOLATE 250MG ORAL TABLET
RX10310165	FDB	Erythromycin 250 MG Oral Tablet	9255	ERYTHROMYCIN STEARATE 250MG ORAL TABLET
RX10310165	FDB	Erythromycin 250 MG Oral Tablet	9260	ERYTHROMYCIN BASE 250MG ORAL TABLET
RX10310165	Medi-Span	Erythromycin 250 MG Oral Tablet	00248	Erythromycin Estolate Tab 250MG
RX10310165	Medi-Span	Erythromycin 250 MG Oral Tablet	00245	Erythromycin Stearate Tab 250MG
RX10310165	Medi-Span	Erythromycin 250 MG Oral Tablet	00235	Erythromycin Tab 250MG
RX10310165	Multum	Erythromycin 250 MG Oral Tablet	1489	erythromycin 250 mg oral tablet
RX10310165	Multum	Erythromycin 250 MG Oral Tablet	1495	erythromycin stearate 250 mg oral tablet
RX10310165	NDF-RT	Erythromycin 250 MG Oral Tablet	C39106	ERYTHROMYCIN 250MG TAB
RX10310165	NDF-RT	Erythromycin 250 MG Oral Tablet	C39146	ERYTHROMYCIN ESTOLATE 250MG TAB
RX10310165	NDF-RT	Erythromycin 250 MG Oral Tablet	C39170	ERYTHROMYCIN STEARATE 250MG TAB

Differentiation of Formulation with "inactive" Ingredient (Diprosone® vs Diprolene®)

RXNCONSO_CODE	Vendor	RXNCONSO_STR	Generic Identifier	Generic Description
RX10197405	FDB	Betamethasone 0.0005 MG/MG Topical Ointment	7569	BETAMETHASONE DIPROPIONATE 0.05% TOPICAL OINTMENT(GM)
RX10197405	FDB	Betamethasone 0.0005 MG/MG Topical Ointment	7562	BETAMETHASONE DIPROPIONATE/PROPYLENE GLYCOL 0.05% TOPICAL OINTMENT(GM)
RX10197405	Medi-Span	Betamethasone 0.0005 MG/MG Topical Ointment	05589	Augmented Betamethasone Dipropionate Oint 0.05%
RX10197405	Medi-Span	Betamethasone 0.0005 MG/MG Topical Ointment	05886	Betamethasone Dipropionate Oint 0.05%
RX10197405	Multum	Betamethasone 0.0005 MG/MG Topical Ointment	732	betamethasone dipropionate, augmented 0.05% topical ointment
RX10197405	Multum	Betamethasone 0.0005 MG/MG Topical Ointment	710	betamethasone dipropionate 0.05% topical ointment
RX10197405	NDF-RT	Betamethasone 0.0005 MG/MG Topical Ointment	C33966	BETAMETHASONE DIPROPIONATE 0.05% AUGMENTED OINT
RX10197405	NDF-RT	Betamethasone 0.0005 MG/MG Topical Ointment	C33972	BETAMETHASONE DIPROPIONATE 0.05% OINT,TOP

Problems with ambiguous cross-references are mitigated when the RxNorm "Semantic Brand Drug" concept is used, as one-to-one cross-reference links to vendor concepts will occur on a more frequent basis.

- Lack of RxNorm Semantic Brand Drug links to NDC. Within UMLS, the Semantic Clinical Drug is linked to NDC values in the attribute file. Semantic Brand Drug concepts are not linked to applicable NDC values. For example, the Semantic Clinical Drug "Fluoxetine 20 MG

Oral Capsule" is linked to all NDCs while the Semantic Brand Drug "Fluoxetine 20 MG Oral Capsule [Prozac]" is not linked to any NDCs. Without Semantic Brand Drug links to NDC, the time and expense required for the drug knowledge base vendors or self programmers to provide RxNorm Semantic Brand Drug links to equivalent proprietary "name based" identifiers will be significant.

Recommendations

NCPDP has the following suggestions and comments:

- A governing body should be established to define RxNorm requirements, certify acceptance testing, production processes and editorial policy.
- Once industry participants have completed the analysis necessary to establish proper usage requirements from the drug databases to the RxNorm concepts for the appropriate use cases, it is expected that a submission for the appropriate RxNorm concepts to be included in the appropriate NCPDP messaging standards will take place.
- We recommend that RxNorm continue to be funded, developed and tested. As RxNorm matures and interoperability business needs become more apparent, we believe that business partners will eventually call for the addition of RxNorm concepts within messaging transactions on a development time-line independent of MMA.

Thank you.