Consolidated Health Informatics

Standards Adoption Recommendation

Medications
Subdomain: Structured Product Label

Index

1. **Part I – Sub-team & Domain Scope Identification** – basic information defining the team and the scope of its investigation.
2. **Part II – Standards Adoption Recommendation** – team-based advice on standard(s) to adopt.
3. **Part III – Adoption & Deployment Information** – supporting information gathered to assist with deployment of the standard (may be partial).

Summary

Domain: Medications

Sub-Domain: Structured Product Labeling Sections

Standards Adoption Recommendation:
Logical Observation Identifier Names and Codes (LOINC®)

SCOPE
The major purpose of the SPL specification is to facilitate the submission, review, storage, dissemination, and access to product labeling information. It is intended to:

- Provide labeling information electronically, in a human readable text format that can be exchanged across systems without additional transformation steps.
- Improve dissemination of product labeling critical to improving risk management of regulated products.
- Use standards to improve integration of clinical data.
- Enhance patient safety by enhancing integration of labeling information with other technical and clinical applications.

RECOMMENDATION
LOINC® Clinical SPL section terminology upon gaining approval status by HL7® for the SPL specification and upon incorporation of the terminology into LOINC®

OWNERSHIP
LOINC® owns the standard. LOINC® is managed and documentation controlled by the Regenstrief Institute.

APPROVALS AND ACCREDITATIONS
Balloted and approved thru HL7®

ACQUISITION AND COST
The full LOINC® database and RELMA -- a program for searching and viewing the LOINC® database and mapping local files to LOINC® is available at no cost.

REVISION HISTORY

DATE	VERSION	COMMENT
2/17/2004	Public Document	Final Recommendation
2/24/2006	1.1	Outdated references deleted

Part I – Team & Domain Scope Identification

Target Vocabulary Domain

Common name used to describe the clinical/medical domain or messaging standard requirement that has been examined.

Terminology for Structured Product Labeling Sections

Describe the specific purpose/primary use of this standard in the federal health care sector (100 words or less)

Background on the Terminology for Structured Product Labeling Specification
Product "labeling" includes information for the safe and effective use of the product. For prescription drug products, this is the information contained in the package insert or prescribing information, includes all written, printed, or graphic matter accompanying a drug product [1] described in 21CFR 201.57.

The Structured Product Labeling (SPL) terminology is based on the HL7® Clinical Document Architecture (CDA), the V3 Reference Information Model and uses HL7® Version 3 Data Types, to specify the structure and semantics of labeling for the purpose of exchange. The specification is extensible so future versions could accommodate labeling for many products (e.g., blood, vaccine, veterinary drug, food, dietary supplements, and device labeling). The SPL specification models labeling sections and the terminology is maintained within LOINC® (Clinical).

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For more information the SPL specification is attached to this document.

Terminology for Labeling Sections
The terminology for product labeling sections referenced in the SPL is maintained within LOINC® Clinical and section terms are listed in the table below. LOINC® consists of

[1] Terms defined in the glossary (see 4. Glossary) are cited in double quotes on first mention within this document. Acronyms are not quoted but are expanded in the glossary.

universal names and codes for identifying individual laboratory and clinical results for the purposes of exchange of information. The full LOINC® database and RELMA -- a program for searching and viewing the LOINC® database and mapping local files to LOINC® are available at no cost.

Sub-domains *Identify/dissect the domain into sub-domains, if any. For each, indicate if standards recommendations are or are not included in the scope of this recommendation.*

Table 1. LOINC® Labeling Sections Terminology Referred to in the SPL

Domain/Sub-domain	In-Scope (Y/N)
Boxed warning	Y
Indications and usage	Y
Dosage and administration	Y
How supplied	Y
Contraindications	Y
Warnings	Y
General precautions	Y
Drug interactions	Y
Drug/laboratory test interactions	Y
Laboratory tests	Y
Information for patients	Y
Teratogenic effects	Y
Nonteratogenic effects	Y
Labor and delivery	Y
Nursing mothers	Y
Pediatric use	Y
Geriatric use	Y
Carcinogenesis, mutagenesis, impairment of fertility	Y
Adverse reactions	Y
Controlled Substance	Y
Abuse	Y
Dependence	Y
Overdosage	Y
Description	Y
Clinical pharmacology	Y
Animal pharmacology/toxicology	Y
Clinical studies	Y
References	Y

Information Exchange Requirements (IERs) *Using the table at appendix A, list the IERs involved when using this vocabulary/specification.*

List of IERs involved when using this specification:
Customer Risk Factors
Body of Health Services Knowledge

Case Management Information
Cost Accounting Information
Population Risk Reduction Plan
Improvement Strategy
Resource Availability
Clinical Guidelines

Team Members *Team members' names and agency names with phone numbers.*

Name	Agency/Department
Steve Brown (Team Lead)	**VA**
David Hardy	DOD
Bill Hess	FDA/CDER
Katherine Hollinger	FDA/OC/OWH
Randy Levin	FDA/CDER
Dan Budnitz	CDC
Bill Trick	CDC
Carlene McIntyre	HIS
Stuart Nelson	NIH/NLM
Nancy Orvis	DOD

Work Period *Dates work began/ended.*

Start	End
2/12/2003	4/30/03

Part II – Standards Adoption Recommendation

Recommendation Identify the solution recommended.

Adoption of the LOINC® Clinical SPL section terminology upon gaining approval status by HL7® for the SPL specification and upon incorporation of the terminology into LOINC® (***Update April 04: ballot approved***).

Ownership Structure Describe who "owns" the standard, how it is managed and controlled.

LOINC® owns the standard. LOINC® is managed and documentation controlled by the Regenstrief Institute.

Summary Basis for Recommendation *Summarize the team's basis for making the recommendation (300 words or less).*

Drug Labeling and SPL Background

Drug labeling summarizes the essential scientific information needed for the safe and effective use of drugs and is controlled by the FDA, the regulatory body responsible for assuring the accuracy of labeling. Labeling content is based in regulation[2] and for drug labeling includes the approved indications, effects, dosages, routes, methods, and frequency and duration of administration, relevant warnings, hazards, contraindications, side effects, and precautions and other information. In addition to providing comprehensive prescribing information, labeling must be current and updated whenever new information becomes available. As a result of the evidence-based approach and rigorous review, product labeling provides the most comprehensive, robust and well-maintained single source of clinical information on the safe and effective use of a drug product.

Aware of limitations in the current presentation of this information, FDA has worked with Health Level Seven® to propose a standard specification for the exchange of labeling based upon regulations[3] describing the content of labeling. The specification itself describes section headers and limited descriptive product information.

This specification shares many (but not all) of the goals of the CDA, which are:

1. Facilitate submission, updating, storage, and dissemination of product labeling.
2. Maximize timeliness of product labeling updates.
3. Give priority to delivery of patient care.
4. Allow cost effective implementation across as wide a spectrum of systems as possible.
5. Support exchange of human-readable documents between users, including those with different levels of technical sophistication.
6. Promote longevity of all information encoded according to this architecture.
7. Enable a wide range of post-exchange processing applications.
8. Be compatible with a wide range of document creation applications.
9. Promote exchange that is independent of the underlying transfer or storage mechanism.
10. Prepare the design reasonably quickly.
11. Enable policy-makers to control their own information requirements without extension to this specification.

Terminology Recommendation

The terminology will be added to the LOINC® Clinical and be maintained and controlled under the Regenstrief Institute's procedures. LOINC® terminology is maintained with a formal 6-part name, a unique name for tests identifying code with check digit, synonyms, and other useful information.

The terminology represents section headers for drug information and is referred to in document specifications under development within Health Level 7®. This terminology will provide the basis for development of interoperable drug information.

[2] 21CFR201.56 & 201.57
[3] 21CFR201.56 & .57

Conditional Recommendation If this is a conditional recommendation, describe conditions upon which the recommendation is predicated.

Conditional recommendation: Upon achieving approval status within HL7 and incorporation of the terminology within LOINC® (June, 2003). ***(Update April 04: Conditions removed, available from LOINC)***

Approvals & Accreditations

Indicate the status of various accreditations and approvals:

Approvals & Accreditations	Yes/Approved	Applied	Not Approved

Options Considered *Inventory solution options considered and summarize the basis for not recommending the alternative(s). SNOMED® must be specifically discussed.*

Solution options: No other vocabulary/terminology for drug prescribing information exists containing the content of this specification and the exchange capabilities. Therefore no other standard specification was considered. The terminology may be utilized in part or in its entirety, offering flexibility to users.
Terminology options: The recommended terminology has been derived from regulation. Section headings for drug labeling will be incorporated into LOINC®. SNOMED® does not address the terminology needs for drug product labeling section headers or product descriptors.

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today? All pharmaceutical companies must conform with regulatory requirements addressing prescribing information in a consistent format using the appropriate sections. These sections are in the SPL and are incorporatedinto LOINC®. *What number of or percentage of relevant vendors have adopted the standard?* NA *What number or percentage of healthcare institutions have adopted the standard?* Unknown. *What number or percentage of federal agencies have adopted the standard?*

LOINC® Clinical is not an adopted standard

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Is the standard used in other countries?

Yes.

Are there other relevant indicators of market acceptance?

LOINC® has been endorsed by the American Clinical Laboratory Association and the College of American Pathologists. It has been adopted as an alternate test reporting code by large commercial laboratories including Quest, LabCorp, Mayo Medical Laboratories, and MDS Labs; large HMOs including Kaiser Permanente and Aetna; governmental organizations including the CDC, DOD, VA, and NLM; and has also been adopted by Germany, Switzerland and two Canadian provinces. Current draft proposals for HIPAA electronic claim attachment standards are based on LOINC® codes. LOINC® has also been supported in part by funding from NLM, HCFA, DOD, AHCPR (now AHRQ), and the John A. Hartford Foundation. (NLM N01-LM-9-3517).

Part III – Adoption & Deployment Information

Provide all information gathered in the course of making the recommendation that may assist with adoption of the standard in the federal health care sector. This information will support the work of an implementation team.

Existing Need & Use Environment

Measure the need for this standard and the extent of existing exchange among federal users. Provide information regarding federal departments and agencies use or non-use of this health information in paper or electronic form, summarize their primary reason for using the information, and indicate if they exchange the information internally or externally with other federal or non-federal entities.

Column A: Agency or Department Identity (name)
Column B: Use data in this domain today? (Y or N)
Column C: Is use of data a core mission requirement? (Y or N)
Column D: Exchange with others in federal sector now? (Y or N)
Column E: Currently exchange paper or electronic (P, E, B (both), N/Ap)
Column F: Name of paper/electronic vocabulary, if any (name)
Column G: Basis/purposes for data use (research, patient care, benefits)

Department/Agency	B	C	D	E	F	G
Department of Veterans Affairs						
Department of Defense						
HHS Office of the Secretary						
Administration for Children and Families (ACF)						
Administration on Aging (AOA)						
Agency for Healthcare Research and Quality (AHRQ)						
Agency for Toxic Substances and Disease Registry (ATSDR)						
Centers for Disease Control and Prevention (CDC)						
Centers for Medicare and Medicaid						

Services (CMS)						
Food and Drug Administration (FDA)	Y	Y	Y	B	None	Regulatory, patient care, patient safety, risk management
Health Resources and Services Administration (HRSA)						
Indian Health Service (IHS)						
National Institutes of Health (NIH)						
Substance Abuse and Mental Health Services Administration (SAMHSA)						
Social Security Administration						
Department of Agriculture						
State Department						
US Agency for International Development						
Justice Department						
Treasury Department						
Department of Education						
General Services Administration						
Environmental Protection Agency						
Department of Housing & Urban Development						
Department of Transportation						
Homeland Security						

Number of Terms

Quantify the number of vocabulary terms, range of terms or other order of magnitude. See table below for more information.

How often are terms updated?
Regulatory domains: Updates occur when changes occur in regulations or guidance.
Terminology domains: Terminology updates occur according to the specified schedule for LOINC®.

Range of Coverage

Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)
The drug labeling section terminology is in the process of being incorporated into LOINC®. The specification referring to the terminology is under development and it is anticipated that it will be finalized within the next year. All portions and components of the specification will be complete and can be implemented upon approval by HL7®.

Acquisition: *How are the data sets/codes acquired and use licensed?*
LOINC® terminologies and code sets are non-proprietary.

Cost
What is the direct cost to obtain permission to use the data sets/codes? (licensure, acquisition, other external data sets required, training and education, updates and maintenance, etc.)

No cost associated with the use of data sets/codes.
Cost associated with training, education, updates and maintenance of expertise of personnel is highly dependent upon a variety of factors and an accurate assessment is beyond the realm of this assessment.

Systems Requirements
Is the standard associated with or limited to a specific hardware or software technology or other protocol?

No. The terminology is an interoperability standard based upon LOINC® codes and attributes.

Guidance: *What public domain and implementation and user guides, implementation tools or other assistance is available and are they approved by the SDO?*

User guides are available from the Regenstrief Institute for terminology.

Is a conformance standard specified? Are conformance tools available?
None specified.

Maintenance:
How do you coordinate inclusion and maintenance with the standards developer/owners?
Contact the HL7® RCRIM Technical Committee or LOINC® with inclusions and other

items.

What is the process for adding new capabilities or fixes?
Working with HL7® RCRIM Technical Committee or LOINC® to modify the terminology.

What is the average time between versions?
The terminology is likely to be stable and require few revisions/updates.

What methods or tools are used to expedite the standards development cycle?
None.

How are local extensions, beyond the scope of the standard, supported if at all?
There is development of synonymy within LOINC® where it is applicable.

Customization: *Describe known implementations that have been achieved without user customization, if any.*
Not yet been implemented.

If user customization is needed or desirable, how is this achieved? (e.g, optional fields, interface engines, etc.)
NA

Mapping Requirements

Describe the extent to which user agencies will likely need to perform mapping from internal codes to this standard.

Prior electronic drug labeling section terminology standards have not been available. For the most part there will be no need for mapping between this specification and other standards. For specific components of this specification, where other code sets have been used in place of those specified here there will be a need for mapping.

Identify the tools available to user agencies to automate or otherwise simplify mapping from existing codes to this standard.

UMLS®

Compatibility

Identify the extent of off-the-shelf conformity with other standards and requirements:

Conformity with other Standards	Yes (100%)	No (0%)	Yes with exception

Implementation Timeframe

Estimate the number of months required to deploy this standard; identify unique considerations that will impact deployment schedules.

The deployment time for the terminology standard is approximately 6 months. The actual availability of drug information using this format is likely to take longer and will be based upon acceptance by the regulated industry and the development of regulations requiring the submission of drug product information in this format.

If some data sets/code sets are under development, what are the projected dates of completion/deployment?

The data sets and code sets are currently deployable.

Gaps

Identify the gaps in data, vocabulary or interoperability.
Specification gaps:

- The specification must clear HL7® balloting. This is anticipated to take 12 months or less. ***(Update April 04: Ballot passed)***

Vocabulary gaps:

- Terminology is in the process of being incorporated into LOINC® Clinical.

Obstacles

What obstacles, if any, have slowed penetration of this standard? (technical, financial, and/or cultural)

Considerations for development of regulatory requirements, acceptance of these requirements and implementation by industry and financial considerations for the development of sufficient infrastructure within the regulatory agency to archive process and disseminate drug labeling.