Consolidated Health Care Informatics

Standards Adoption Recommendation

Medications
Subdomain: Package

Index

Summary

Domain: Medications

Sub-Domain: Package

Standards Adoption Recommendation:
FDA/CDER Data Standards Manual

SCOPE
The purpose of this standard is to enable the federal health care sector to share information regarding drug packages.

RECOMMENDATION
Package name/code as defined in the FDA/CDER Data Standards Manual

OWNERSHIP
The recommended standards are in the public domain, and are administered by the FDA.

APPROVALS AND ACCREDITATIONS
The FDA has regulatory authority over drug package data. The FDA owns the standard, and manages it through two FDA peer-review committees (composed largely of pharmacists and chemists) who consult with both FDA medical officers and with the USP Expert Committees about matters that pertain to drug packaging. It is in widespread use by the Food and Drug Administration (FDA) and is distributed with the National Drug Code.

ACQUISITION AND COST
All package terms are readily available through the FDA's website, and are in the public domain---available at http://www.fda.gov/cder/dsm/drg/Drg00907.htm

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.

Package, a subdomain of Medications

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

A drug package is, generally, any container or wrapping in which any drug is enclosed for use in the delivery or display of such commodities to retail purchasers. If no package is used, the container shall be deemed to be the package. It does not include: (a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors; (b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or (c) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251-256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257-257i). (d) Containers used for tray pack displays in retail establishments. (e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part."

The purpose of this standard is to enable the federal health care sector to share information regarding drug packages.

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.*

Package is itself a sub-domain of the Medications Domain. Please see the overarching domain analysis for more information.

Domain/Sub-domain	In-Scope (Y/N)
This template is included as part of the medications domain	

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

Customer Health Care Information
Care Management Information
Customer Risk Factors
Referral Information
Body of Health Services Knowledge
Tailored Education Materials
Beneficiary Tracking Information
Patient Satisfaction Information
Case Management Information
Cost Accounting Information
Population Member Health Data
Population Risk Reduction Plan
Provider Metrics
Improvement Strategy
Resource Availability
Beneficiary Inquiry Information
Clinical Guidelines
Customer Approved Care Plan

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

Name	Agency/Department
Steven Brown (Team Lead)	**VA**
Randy Levin	FDA
Kathy Hollinger	FDA
Bill Hess	FDA
Stuart Nelson	NLM
Nancy Orvis	DoD
William Trick	CDC
Dan Budnitz	CDC
Carlene McIntyre	InHs

Work Period *Dates work began/ended.*

Start	End
Feburary 2003	May 2003

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

The CHI Medications subgroup recommends the following standards for package: Package name/code as defined in the FDA/CDER Data Standards Manual

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

FDA owns the standard, and manages it through two FDA peer-review committees (composed largely of pharmacists and chemists) who consult with both FDA medical officers and with the USP Expert Committees about matters that pertain to drug packaging. Final publication is coordinated through an FDA Lexicographer, who posts the standard on CDER's website (see http://www.fda.gov/cder/dsm/drg/Drg00907.htm).

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

This dataset was chosen because of its timely peer-reviewed process, its granularity, its inclusion of definitions, and its widespread use by the Food and Drug Administration (FDA) and its subsequent inclusion in data that supports, and is distributed with, the National Drug Code. It was also chosen because of regulatory constraints.

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

This is not a conditional recommendation.

Approvals & Accrediations

Indicate the status of various accreditations and approvals:

Approvals & Accreditations	Yes/Approved	Applied	Not Approved
Full SDO Ballot			
ANSI			

Options Considered *Inventory solution options considered and summarize the basis for not recommending the alternative(s).*

Options

Only one option was found, and that is the package name/code developed and used by FDA in its CDER Data Standards Manual.

Option Analysis

The FDA regulates numerous drug products, and stores detailed information about them in its relational databases. A drug's package is a part of that information. FDA's Center for Drug Evaluation and Research has two peer-review committees (composed largely of pharmacists and chemists) who consult with industry experts about matters that pertain to packaging. That consultation, along with the revision process, is very timely because package terms need to be in FDA relational databases and in a drug's labeling prior to a drug's approval for marketing. A drug's package not only encompasses terms that apply to the conventional drugs that a physician may order, but also encompasses terms that apply to unconventional drugs, such as bulk shipments. For example, cylinders of medical gases are shipped to hospitals, and large jars of drug substance are shipped to pharmacies for compounding purposes. It is essential for regulatory, reimbursement and safety reasons that the FDA's comprehensive list of drug package terms/codes is included in any dataset. It is freely available on the FDA website at http://www.fda.gov/cder/dsm/drg/Drg00907.htm.

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today?

The FDA/CDER Data Standards Manual is used as a basis for FDA's NDC Directory, which is used internationally. The FDA/CDER Data Standards Manual is routinely referenced in regulatory litigation.

What number of or percentage of relevant vendors have adopted the standard?
Unknown

What number or percentage of healthcare institutions have adopted the standard?
Unknown

What number or percentage of federal agencies have adopted the standard?
Unknown

Is the standard used in other countries?
Yes

Are there other relevant indicators of market acceptance?
No

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)						
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.
There are 57 package names/codes in the FDA/CDER Data Standards Manual.

How often are terms updated?
As needed.

Range of Coverage

Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)

All package terms are complete and can be immediately implemented.

Acquisition: *How are the data sets/codes acquired and use licensed?*

All package terms are readily available through the FDA's website, and are in the public domain.

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.)

There is no direct cost to obtain permission to use the data sets/codes.

Systems Requirements

Is the standard associated with or limited to a specific hardware or software technology or other protocol?
No.

Guidance:
See FDA/CDER Data Standards Manual website.

Maintenance:
A detailed description of the FDA process can be found at:
http://www.fda.gov/cder/mapp/7600-4.pdf

What is the average time between versions?
Versions are published as needed.

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?

Local extensions are not supported.

Customization: *Describe known implementations that have been achieved without user customization, if any.*

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

Mapping Requirements

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

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

Unknown.

Compatibility

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

Conformity with other Standards	Yes (100%)	No (0%)	Yes with exception
NEDSS requirements			
HIPAA standards			
HL7 2.x			

Implementation Timeframe

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

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

Not applicable.

Gaps

Identify the gaps in data, vocabulary or interoperability.
None have been identified in over 4 years since the original standard was implemented by FDA .

Obstacles

What obstacles, if any, have slowed penetration of this standard? (technical, financial, and/or cultural)
None.