Consolidated Health Informatics

Standards Adoption Recommendation

Medications
Subdomains: Drug Product

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: Drug Product

Standards Adoption Recommendation:
FDA's National Drug Code (NDC)

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

RECOMMENDATION
Food and Drug Administration's (FDA) National Drug Code (NDC) Product Name/Code

OWNERSHIP
FDA owns the standard, it is managed through a two-step process: the FDA first assigns a labeler code to a firm, and then the firm assigns a product code to its drug product.

APPROVALS AND ACCREDITATIONS
All drug products marketed in the United States must comply under regulations managed by FDA.

ACQUISITION AND COST
The NDC list of products and their codes is freely available electronically from the FDA without a licensing agreement at http://www.fda.gov/cder/ndc/index.htm, and has been used domestically and internationally for electronic drug transactions for over 30 years.

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.

Product, 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 product is one or more finished dosage forms, each of which contain one or more ingredients.

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

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.*

Product 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 product:

Food and Drug Administration's (FDA) National Drug Code (NDC) Product Name/Code. We would also like the full Council to encourage the FDA to improve and revise NDC codes and NDC code generation processes in an expeditious fashion to address well-known issues.

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

FDA owns the standard, it is managed through a two-step process: the FDA first assigns a labeler code to a firm, and then the firm assigns a product code to its drug product. The process is required for all drug products marketed in the United States under regulations managed by FDA.

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

FDA's NDC Product Name/Code was chosen for its proven and long-standing use (over three decades) in electronic drug transactions, both domestically and internationally, and its vast scope.

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

1. FDA's NDC Product Name/Code
2. First Data Bank
3. Drug Facts and Comparisons
4. Micromedex/ Physician's Desk Reference

Option Analysis

1. FDA's NDC Product Name/Code. FDA's NDC Directory contains over 146,000 product name and product code data on approved drug products, including prescription, over-the-counter, and bulk drugs. The directory consists of prescription and selected over-the-counter, insulin, domestic, and foreign drug products that are in commercial distribution in the United States. The products have been listed in accordance with the Drug Listing Act and applicable Code of Federal Regulations for submitting drug product information to the FDA. The FDA carefully performs in-depth analyses upon the names of all prescription drug products, and many over-the-counter drug products, before it publishes them to avoid misleading claims in the brand name, and also to avoid look-alike/sound-alike brand names. Product names are then assigned product codes by firm, and FDA is notified of the code at the firm's convenience; because of this potential for lag, it is anticipated that FDA will assume the assignment role. The product code is the second segment of the National Drug Code (NDC), and may be a 3-digit or 4-digit code depending upon the NDC configuration selected by the firm. The product code MUST be used in conjunction with a firm's labeler code (the first segment of the NDC) in order to be meaningful. The NDC list of products and their codes is freely available electronically from the FDA without a licensing agreement at http://www.fda.gov/cder/ndc/index.htm, and has been used domestically and internationally for electronic drug transactions for over 30 years.
2. First DataBank. First DataBank manages the National Drug Data File (NDDF Plus), which combines descriptive and pricing data with a selection of advanced clinical support modules. NDDF Plus delivers information, including product name, on every drug approved by the FDA. First DataBank also offers comprehensive international drug knowledge bases for several countries outside the U.S., including Canada. First DataBank Europe develops drug knowledge base products for the United Kingdom. Each Disease Identifier in their database is linked to various textbook names, as well as preferred professional names and synonyms; layman names and synonyms; and standard abbreviations. This file uses the NDC where applicable, but otherwise has no internationally recognized product identifier. It does not include bulk drug products, and these bulk drug products are necessary for prescription compounding. It is not freely available, and the cost for its use would involve a licensing agreement.
3. Drug Facts and Comparisons. The Drug Facts and Comparisons database is one of the most comprehensive drug database available to healthcare professionals today. It contains product names, along with linkage to new and old National Drug Codes (NDCs) ; Universal Product Codes (UPCs) and Health Related Item (HRI) numbers, Innerpack and Clinic Pack NDCs. This file uses the NDC where applicable, but otherwise has no internationally recognized product identifier. It does not include

bulk drug products, and these bulk drug products are necessary for prescription compounding. It is not freely available, and the cost for its use would involve a licensing agreement.

4. Micromedex/Physician's Desk Reference (PDR). The Physicians' Desk Reference provides current FDA approved data for over 2,800 prescription drugs, along with information on more than 250 drug manufacturers. The PDR contains a subset of all drug products available in the United States. Inclusion in the PDR is based upon whether any particular pharmaceutical firm wishes to pay a fee to advertise their product in the PDR. The FDA did an analysis of the drugs that were included in the PDR, and found that approximately 50% of pharmaceutical firms did not advertise their products in the PDR, and of those that did advertise their products, less than 50% of their products were included. Of particular note, older less profitable drugs were missing, as were many injectables (especially large volume parenterals). This file uses the NDC where applicable, but otherwise has no internationally recognized product identifier. It does not include bulk drug products, and these bulk drug products are necessary for prescription compounding. It is not freely available, and the cost for its use would involve a licensing agreement.

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today?
Vast market penetration both nationally and internationally.

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?
Vendors expressing a significant degree of concern about potential changes to the NDC product code.

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 over a hundred thousand products, both prescription and over-the-counter, each of which has its own product name and product code.

How often are terms updated?
As needed, usually daily. There can be some lag time between assignment by the firm and notification by the firm to the FDA.

Range of Coverage

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

Product names/codes are complete (aside from the lag time between assignment by the firm and notification by the firm to the FDA) and can be immediately implemented.

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

Product names/codes 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 website at http://www.fda.gov/cder/drls/default.htm.

Maintenance:
See FDA/CDER website at http://www.fda.gov/cder/drls/default.htm.

What is the average time between versions?
There is no version. Product terms/codes are electronically available via a web-based search engine in real-time; a downloadable version is also updated quarterly and made available

through the FDA website.

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.)
Users often pad either the labeler code or product code with a leading zero to normalize the number of digits for their computerized systems.

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.
Some drug products are not listed or are incorrectly listed and, therefore, are not included. Regulation changes are being considered to resolve this issue. Need to be cautious so that the vocabulary does not refer to words positioned near the product name which are not a bonafide part of the product's name.

Obstacles

What obstacles, if any, have slowed penetration of this standard? (technical, financial, and/or cultural)
Direct-to-consumer drug advertising where the product name is intentionally misrepresented in order to promote the product's use.