

**Consolidated Health Informatics**  
**Standards Adoption Recommendation**  
**Medications**  
**Subdomain: Manufactured Dosage Form**

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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: Manufactured Dosage Form**

### **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 dosage forms. A manufactured dosage form is the way of identifying the drug in its physical form. A 1999 Food and Drug Administration (FDA) Draft Guidance for Industry states, "A dosage form is the way of identifying the drug in its physical form". In determining dosage form, FDA examines such factors as (1) physical appearance of the drug product, (2) physical form of the drug product prior to dispensing to the patient, (3) the way the product is administered, (4) frequency of dosing, and (5) how pharmacists and other health professionals might recognize and handle the product.

#### **RECOMMENDATION**

FDA/CDER Data Standards Manual

#### **OWNERSHIP**

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 Committee on Nomenclature and Labeling about matters that pertain to dosage form.

#### **APPROVALS AND ACCREDITATIONS**

Section 502(e)(3) of the Food Drug and Cosmetic Act, requires the FDA to regulate the drug dosage form.

#### **ACQUISITION AND COST**

All dosage form terms are readily available through the FDA's website, and are in the public domain via the FDA's CDER's website at:

<http://www.fda.gov/cder/dsm/DRG/drg00201.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.*

Manufactured Dosage Form, a subdomain of Medications

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

A manufactured dosage form is the way of identifying the drug in its physical form. A 1999 Food and Drug Administration (FDA) Draft Guidance for Industry states, "A dosage form is the way of identifying the drug in its physical form. In determining dosage form, FDA examines such factors as (1) physical appearance of the drug product, (2) physical form of the drug product prior to dispensing to the patient, (3) the way the product is administered, (4) frequency of dosing, and (5) how pharmacists and other health professionals might recognize and handle the product.

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

**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.*

**Dosage form 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)
<b><u>This template is included as part of the medications domain</u></b>	

**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
<b>Steven Brown (Team Lead)</b>	<b>VA</b>
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
February 2003	May 2003

## Part II – Standards Adoption Recommendation

**Recommendation** *Identify the solution recommended.*

The CHI Medications subgroup recommends the following standards for manufactured dosage form:

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 Committee on Nomenclature and Labeling about matters that pertain to dosage form. Final publication is coordinated through an FDA Lexicographer, who posts the standard on CDER's website (see <http://www.fda.gov/cder/dsm/DRG/drg00201.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), the United States Pharmacopeia (USP), and the end-users who purchase their products. 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 & Accreditations**

*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).*

Approved Drug Products with Therapeutic Equivalence Evaluations (Appendix C of FDA's "Orange Book")
FDA/CDER Data Standards Manual
Health Level Seven <sup>®</sup> , Inc.

## Option Analysis

1. Approved Drug Products with Therapeutic Equivalence Evaluations (Appendix C of FDA's "Orange Book"). This list contains a list of drug dosage forms, some of which are relatively non-granular because they are used to represent FDA's "therapeutic equivalence" evaluations. For example, the Orange Book does not have a dosage form term for "powder for injectable solution" because the FDA assumes that injectable dosage forms are instantly bioavailable. If the Orange Book were to create more granular injectable dosage form terms, then federal regulation would not permit claims of "sameness" for some approved injectable drug products. It is freely available electronically from the FDA.
2. FDA/CDER Data Standards Manual. The FDA regulates numerous drug products, and stores detailed information about them in its relational databases. Dosage form 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 both FDA medical officers and with the USP Expert Committee on Nomenclature and Labeling about matters that pertain to dosage form. That consultation, along with the revision process, is very timely because dosage form terms need to be in FDA relational databases and in a drug's labeling prior to a drug's approval for marketing. In addition, there are regulatory constraints, such as Sec 502(e)(3) of the Food Drug and Cosmetic Act, that requires the FDA to use the official name of the drug, which is often the USP name; the USP name of a drug includes the drug dosage form. The FDA peer-review committees also develop acceptable regulatory definitions for each of the dosage forms that are in harmony with USP definitions, and with regulatory and court-determined definitions of particular dosage forms. It is freely available on the FDA website at <http://www.fda.gov/cder/dsm/DRG/drg00201.htm>.
3. Health Level Seven<sup>®</sup>, Inc. The current HL7<sup>®</sup> dosage form list contains a small subset of that which is in the CDER Data Standards Manual. The HL7<sup>®</sup> dosage form list has a particular use case, which is primarily for representing how a dosage form is prescribed (or "ordered") by a physician. For example, when a physician writes a prescription, he/she usually does not care whether an injectable drug product comes as a lyophilized powder or a premixed solution, but rather just that it is an injection. In addition to the physician use case, other use cases, such as regulatory, pharmacy, and patient are currently being considered. In addition, there are hundreds of international dosage form terms that are missing from the current HL7<sup>®</sup> dosage form standard (e.g., "spirit"). Finally, the current HL7<sup>®</sup> dosage form terms sometimes precoordinates a "route of administration" term with a dosage form term, and uses the "route of administration" term as a proxy for describing a dosage form's formulation. For example, the HL7<sup>®</sup> dosage form term "rectal solution" to describe a solution that has been formulated for rectal use (containing no buffers and no flavors), rather than formulated for ophthalmic (containing buffers) or oral (containing flavors) use. While this level of granularity is necessary for some use cases, it is well beyond the need for most use cases. An HL7<sup>®</sup> special interest group is working upon the HL7<sup>®</sup>

dosage forms, and it is the anticipation of that group that future iterations will be much more acceptable. HL7<sup>®</sup> dosage form standards are generally not peer-reviewed for acceptability or synonymy (e.g., HL7<sup>®</sup> has both “rectal solution” and “enema” dosage forms), and revisions usually require a lengthy vetting process. It is freely available at: <http://www.hl7.org/>

### **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 Orange Book, which is also published by USP DI, and which is used in every pharmacy nationwide as a basis for generic substitution. The FDA/CDER Data Standards Manual is routinely referenced in regulatory litigation. The FDA/CDER Data Standards Manual was also used as a basis for some HL7<sup>®</sup> dosage form terms and their definitions, and those HL7<sup>®</sup> dosage form terms are currently being revised to include those FDA/CDER Data Standards Manual dosage form terms that were missing.

*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?*

Unknown

*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)

<b>Department/Agency</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>
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 141 dosage form terms 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 dosage form terms are complete and can be immediately implemented.

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

All dosage form 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 conformity 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.*

Need to be cautious so that the vocabulary does not refer to proprietary dosage forms.

**Obstacles**

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

Direct-to-consumer drug advertising using dosage form misrepresentation.