Consolidated Health Care Informatics

Standards Adoption Recommendation

Medications
Subdomain: Active Ingredients

Index

Summary

Domain: Medications

Sub-Domain: Active Ingredients

Standards Adoption Recommendation:

FDA Established Name for active ingredient &
FDA Unique Ingredient Identifier (UNII) codes.

SCOPE

The purpose of this standard is to enable the federal health care sector to share information regarding medication active ingredients. An active ingredient is a substance responsible for the effects of a medication. Frequently, an active ingredient is a known chemical substance. Known chemical substances may be called by the base substance (e.g. propanolol), or by a base substance – salt combination (e.g. propanolol hydrocloride). In certain instances the structure of the ingredient is not known precisely. For example, beef gelatin is a complex molecular mixture defined by the process used to create it.

RECOMMENDATION

FDA Established Name for active ingredient & FDA Unique Ingredient Identifier (UNII) codes.

OWNERSHIP

The recommended standards are in the public domain, and are administered by the FDA, supported by AHRQ and maintained by NCI.

APPROVALS AND ACCREDITATIONS

FDA

ACQUISITION AND COST

FDA Established Names and the UNII codes are free from FDA and will also be available from the NLM.

REVISION HISTORY

DATE	VERSION	COMMENT
2/13/2004	Public Document	Final Recommendation
2/24/2006	1.1	AHRQ reference added

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.

Medication Active Ingredients, a subdomain of Medications

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

An active ingredient is a substance responsible for the effects of a medication. Frequently, an active ingredient is a known chemical substance. Known chemical substances may be called by the base substance (e.g. propanolol), or by a base substance – salt combination (e.g. propanolol hydrocloride). In certain instances the structure of the ingredient is not known precisely. For example, beef gelatin is a complex molecular mixture defined by the process used to create it.

The purpose of this standard is to enable the federal health care sector to share information regarding medication active ingredients.

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.*

Medication active ingredients 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	June 2003

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

The CHI Medications subgroup recommends the following standards for medication active ingredients in order of priority

1. **Primary Standard:** FDA Established Name for active ingredient & FDA Unique Ingredient Identifier (UNII) codes. This selection was made because of the widespread use and free availability to the public of these names and the impending free availability of authoritative UNII codes that are in the public domain from the FDA through NLM. Until UNII Codes are available, the subgroup declines to recommend a code number scheme for active ingredients.

2. **Secondary Standards in order of precedence**
    a. USP-NF name& UNII codes
    b. USAN name and UNII code
    c. INN names & UNII codes
    d. IUPAC chemical names and UNII codes
    e. Common name and UNII codes

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

FDA Established Names

FDA Established Names are in the public domain, and are administered by the FDA with input from the manufacturer, the USAN council, and the USP.

USP Names

The United States Pharmacopeia (USP) is a non-government organization that establishes standards via a process of public involvement to ensure the quality of medicines and other health care technologies. Currently, USP provides standards (including names) for more than 3,400 prescription and non-prescription drugs, nutritional and dietary supplements, veterinary drug standards, and health care products. These standards are published in the United States Pharmacopeia and the National Formulary (USP-NF), which are officially recognized in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) About 650 elected scientists and practitioners comprise USP's scientific decision-making body by serving as members of the Council of Experts (COE) or on expert committees. About 400 members represent state associations and colleges of medicine and pharmacy; the federal government; national and international professional, scientific, and trade organizations; the pharmaceutical industry; and consumer organizations.

United States Adopted Names (USAN)

Every medication introduced to market since 1961 in the United States has been given a non-proprietary United States Adopted Name (USAN) by the USAN Council, a body composed of representatives from the United States Pharmacopoeia, the American Medical Association, the Food and Drug Administration, the American Pharmacists Association and an "at large" member. These names are known to virtually all health care providers and even lay citizens as "generic names", but are more properly referred to as "non-proprietary" names. USAN are in the public domain

UNII Codes

The FDA developing an electronic repository listing all medication ingredients used in the United States. Each will have a unique ingredient identifier (UNII) code based on molecular structure, manufacturing process, and/or other characteristics. The FDA and the NLM are collaborating to make the ingredient information repository, including all publicly available medication ingredients, structures, Molfiles, and names, available to the public at no cost. The NLM will also maintain mechanisms that will permit third parties to submit for potential inclusion information about ingredients used in products that are marketed or investigated outside the United States

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

FDA Established Names

Every active ingredient marketed in the US is given an "established" name by the FDA, with input from the manufacturer, the USAN council, and the USP. The established name may consist of up to 3 fields: active ingredient, dosage form, and route of administration. In practice, active ingredients named by the FDA Established Name, the USP Name, and the USAN name are, at the time of writing, identical for the same substances. It is theoretically possible however, that irreconcilable differences could arise between FDA, USP, and USAN. In this case, the medications group recommends that government standards respect legal authority in Sec 502(e)(3) FD&C Act. In other cases, a substance might have only 1 of these names in which case secondary recommendations should be followed.

USP-NF

The United States Pharmacopeia (USP) is a non-government organization that establishes standards via a process of public involvement to ensure the quality of medicines and other health care technologies. Currently, USP provides standards (including names) for more than 3,400 prescription and non-prescription drugs, nutritional and dietary supplements, veterinary drug standards, and health care products. These standards are

published in the United States Pharmacopeia and the National Formulary (USP-NF), which are officially recognized in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) The new annual edition is USP 26–NF 21

Of the 9,503 substances listed in the USP dictionary, some 3822 have USAN names. The USP Dictionary can be considered to be "complete" for medications marketed in the US regardless of when they were introduced. As mentioned in the USAN analysis, the coverage of USAN names does not necessarily include medications not marketed the United States. In addition, there are a number of marketed medication ingredients that were given non-USAN names prior to 1961

According to sources at USP, the non USP names can be used without restrictions.

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USAN non-proprietary names are a core component of RxNorm names, and are included in the offerings of each of the major US drug information vendors' products. NLM uses USAN non-proprietary names to index the world's medical literature and VA uses USAN non-proprietary names in its National Drug File. There is no competitor in the US for USAN non-proprietary names of marketed medications - USAN is the only official process, by legal mandate. USAN criteria are updated as comments are received, and have been in use for over 40 years.

USAN names have excellent content coverage for medications brought to market in the US since 1961 and are publicly available without intellectual property restrictions. Of the 9,503 substances listed in the USP dictionary, some 3822 have USAN names. The coverage of USAN names does not necessarily include medications not marketed the United States. In addition, there are a number of marketed medication ingredients that were given non-USAN names prior to 1961 (when USAN commenced) that have not ever been given a USAN. Examples include bubalbarbital sodium, cholorquine hydrochloride, and chlorphenaramine maleate. USAN names are organized in a uncoded, simple listing and thus fail to meet certain published criteria for good terminology practices.

UNII Codes

The FDA developing an electronic repository listing all medication ingredients used in the United States. Each will have a unique ingredient identifier (UNII) code based on molecular structure, manufacturing process, and/or other characteristics. When molecular structures are known, the ingredient's UNII code is based on the freely available and widely used Molecular Design Limited (MDL®) Molfile A Molfile is a unique electronic representation of molecular structure. When specific molecular structures of complex substances are not known, business rules established by an expert oversight committee will be applied; for example, beef gelatin, a complex molecular mixture, will be defined by the process used to create it.

The FDA and the NLM are collaborating to make the ingredient information repository, including all publicly available medication ingredients, structures, Molfiles, and names, available to the public at no cost. The NLM will also maintain mechanisms that will permit third parties to submit for potential inclusion information about ingredients used in products that are marketed or investigated outside the United States

The UNII code project is ongoing. As of early 2003, the FDA has acquired the Molfile software and is constructing electronic structural representations for all U.S. medication product ingredients. FDA and NLM will UNII codes and associated structural representations available to the public 2003.

Analysis for secondary recommendations is included below

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

Until UNII Codes are available, the subgroup declines to recommend a code number scheme for active ingredients. The group expects UNII codes to be available in 2004 via a joint effort of NLM and FDA

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 Established Names 2. United States Adopted Names (USAN) 3. United States Pharmacopoeia National Formulary of drug substances and pharmaceutical ingredients (USP-NF). 4. Chemical Abstracts Service (CAS) number 5. MolFile chemical structure representation and code 6. International Union of Pure and Applied Chemists (IUPAC) chemical name. *7.* Other approved names including British Approved Names (BAN), Japanese Approved Names (JAN) and International Nonproprietary Names (INN)

Option Analysis

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International Union of Pure and Applied Chemists (IUPAC) Name

Chemists internationally use the IUPAC names, and naming algorithms. The IUPAC does not provide a unique name, although it does provide an unambiguous name. IUPAC names are scientifically descriptive, and the naming algorithms are flexible and capable of representing virtually all chemicals known to be used in medications. IUPAC names cannot be generated for medication ingredients whose precise structures are not known. Furthermore, IUPAC names can be lengthy, and not easily understood by the uninitiated.

International Nonproprietary Names

http://www.who.int/medicines/organization/qsm/activities/qualityassurance/inn/innguide.shtml

International Nonproprietary Names (INN) identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name. To make INN universally available they are formally placed by WHO in the public domain, hence their designation as "nonproprietary". They can be used without any restriction whatsoever to identify pharmaceutical substances.

The INN system as it exists today was initiated in 1950 by a World Health Assembly resolution WHA3.11 and began operating in 1953, when the first list of International Nonproprietary Names for pharmaceutical substances was published. The cumulative list of INN now stands at some 7000 names designated since that time, and this number is growing every year by some 120-150 new INN.

British Approved Name, Japanese Approved Name, and other International Naming Schemes

Much like the US Adopted Names, other countries have developed naming schemes that allow laypersons within their countries to discuss active medication ingredients with complex chemical names. As a result of ongoing collaboration, national names such as British Approved Names (BAN), Dénominations Communes Françaises (DCF), Japanese Adopted Names (JAN) and United States Accepted Names (USAN) are nowadays, with rare exceptions, identical to the INN. These national naming schemes can be country specific. That is, they refer ingredients used in the particular country with names intended to meaningful to its citizens. As a result, there is significant overlap and yet some differences between various

national schemes. For example, differences exist between BAN and USAN names for the same substance (e.g. acetaminophen = paracetamol). In addition to having different names for the same substances, different countries permit the use of different medicinal ingredients. It is assured that all US medications do not have approved names under other countries' naming schemes. Likewise, these international naming schemes cover medications not currently employed in the US. Quantitative analysis of overlap and dissonance is beyond the scope of the current analysis. Given those caveats, the CHI group may wish to develop, or encourage the development of mappings to other international systems.

Chemical Abstracts Service (CAS) Registry Number

The Chemical Abstracts Service, established by the American Chemical Society, maintains an extensive listing of chemical substances and code numbers. CAS registry numbers are linked to chemical names expressed in several formats (e.g. USAN, IUPAC). CAS registry numbers used to index the chemical literature. The content coverage of CAS extends beyond medication active ingredients, although medications are an advertised use. CAS registry information is copyright protected and must be licensed. In addition, multiple "salt" forms of medications may share a single CAS registry number

Investigational "Lab" Names

When drug companies submit Investigational New Drug (IND) applications to the FDA for new molecular entities, they may not have yet decided upon a proprietary name, and the USP has not yet had an opportunity to create an adopted name (USAN) for the substance. Commonly, companies will refer to medications with a name composed of letters (representing the company) and numbers (representing the compound). An example of an investigational lab name is "RU 486" for the compound that was eventually given the USAN name "mifeprestone". Investigational lab names are used by the pharmaceutical industry, the FDA, and by centers conducting studies of the compounds. Investigational lab names are not necessarily restricted to compounds that have known chemical structures.

Current Deployment

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

FDA Established Name/USP Name/USAN Name – Too numerous to count
UNII Code - none

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

FDA Established Name/USP Name/USAN Name – Too numerous to count
UNII Code - none

What number or percentage of healthcare institutions have adopted the standard?
FDA Established Name/USP Name/USAN Name – Too numerous to count
UNII Code - none

What number or percentage of federal agencies have adopted the standard?
FDA Established Name/USP Name/USAN Name – Too numerous to count
UNII Code - none

Is the standard used in other countries?

FDA Established Name/USP Name/USAN Name – probably some, there is overlap resulting from harmonization efforts with INN and others

Are there other relevant indicators of market acceptance?

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.

FDA ESTABLISHED

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.

Of the 9,503 substances listed in the USP dictionary, some 3822 have USAN namesAll active ingredients in the US have an FDA established name

How often are terms updated?

FDA publishes the Orange Book quarterly
USAN adoptions are scheduled for the last Wednesday of each month
UNII codes – will be published via NLM as part of the DailyMed

Range of Coverage

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

All active ingredients marketed in the US have an FDA established name. FDA established names and the USP Dictionary can be considered to be "complete" for medications marketed in the US regardless of when they were introduced. Of the 9,503 substances listed in the USP dictionary, some 3822 have USAN names. As mentioned in the USAN analysis, the coverage of USAN names does not necessarily include medications not marketed the United States. In addition, there are a number of marketed medication ingredients that were given non-USAN names prior to 1961

UNII Codes – content will include all chemical substances marketed as medications in the US

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

FDA Established Names are in the public domain. Most active ingredient names are freely available in the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the NDC Directory. These active ingredient names should contain the active ingredient(s) as they appear on the latest approved labeling, both for RX and OTC drugs. The Orange Book is available in paper, and on-line at http://www.fda.gov/cder/ob/default.htm. The NDC Directory is only available on-line at http://www.fda.gov/cder/ndc/database/default.htm. The FDA may also be able to provide a separate list of active ingredient names. Lastly, the active ingredient names will be freely available through the DailyMed initiative through the NLM.

USP standards are published in the United States Pharmacopoeia and the National Formulary (USP-NF), which are officially recognized in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.). In 1906, with the enactment of the Pure Foods and Drug Act, the USP-NF achieved official status. It establishes legal standards for drugs manufactured in the U.S. The USP covers active ingredients and the NF covers inactive ingredients. The new annual edition is USP 26–NF 21

According to sources at USP, USAN are in the public domain; the non USAN USP names can be used without restrictions.

UNII Codes – free distribution via NLM

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.)

FDA Established Names – free from FDA and eventually via NLM along with UNII codes

According to the USP website
http://www.usp.org/cgi-bin/catalog/SoftCart.exe/catalog/frameset.htm?E+uspstore

2003 USP Dictionary
Online & Print Combination (Special Offer)
(2003 online license expires 3/31/04*)
Item Number: 3934322
Price: $ 319.00

UNII Codes – free distribution via NLM

Systems Requirements

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

none

Guidance:

See USP Website
UNII codes – under development

Maintenance:

FDA Established Names
Updates are issued quarterly to the FDA Orange Book**.**

USAN
See:
http://www.ama-assn.org/ama1/pub/upload/mm/365/timeprocessrqrd_0902.doc

What is the average time between versions?
USAN adoptions are scheduled for the last Wednesday of each month

What methods or tools are used to expedite the standards development cycle?
http://www.ama-assn.org/ama1/pub/upload/mm/365/timeprocessrqrd_0902.doc

How are local extensions, beyond the scope of the standard, supported if at all?
http://www.ama-assn.org/ama1/pub/upload/mm/365/timeprocessrqrd_0902.doc

UNII codes – processes under development

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.
Little to none for *FDA Established Name/USP Name/USAN Name*

UNII codes will be mapped to USAN and USP names by FDA

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

N/A

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.

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

FDA Established Name/USP Name/USAN Name – deployment is effectively done

UNII – FDA expects deployment 2004

Gaps

Identify the gaps in data, vocabulary or interoperability.

Need to be cautious referring to salt forms or base forms explicitly

Obstacles

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

None for FDA established names, USP Names or USAN,
UNII – under development