Consolidated Health Informatics

Standards Adoption Recommendation

Chemicals

Index

Summary

Domain: Chemicals

Standards Adoption Recommendation:
Conditional: Substance Registry System (SRS)

SCOPE
To provide codes for chemicals of importance to health care outside of medications, which were covered in the CHI Medication standard. The workgroup feels that for health care purposes these chemicals will be those found in the workplace or the environment that might be related to health. Commonly the first, and perhaps only use, of a chemical code would be during a first encounter and perhaps be part of a History and Physical.

RECOMMENDATION
Conditional: The Environmental Protection Agency's (EPA) Substance Registry System (SRS).

- Establishing interagency communication so that medical needs are addressed in a timely and coordinated fashion.
- Developing a mechanism so that similar tables from other agencies can be matched against the SRS table and missing elements added.
- Investigate availability of a subset or view of information from the database in an acceptable format for healthcare use as a no or low-cost distribution item.
- Requirement for registering an Object Identifier (OID) if it is to be used in HL7 messaging.

OWNERSHIP
The Substance Registry System (SRS) is the Environmental Protection Agency's (EPA) central system for information about regulated and monitored substances.

APPROVALS AND ACCREDITATIONS
-NA-

ACQUISITION AND COST
Free & no license is required.

Included is a download feature that lets you receive information about the contents the registry. There is a download section included at the bottom of each detail page. File formats include text report, Oracle (SQL* Loader), and comma-separated text files (for use in MS Access, MS Excel). Download files are available in a nonstandard, compressed file format that requires decompression software, such as WinZip or PKZip.

The registry data can also be accessed using the Environmental Metadata Gateway (EMG, http://www.epa.gov/emg/), a search engine that enables users to search the metadata registry content using a Universal Resource Locators (URL) with integrated

search capabilities. It enables users to search and seamlessly navigate to the detail pages meeting the search criteria. An EMG Search has been developed that enables system developers to build URLs to automatically query various substance data and display the appropriate detail information from EPA's application, the Substance Registry System (SRS).

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.

Chemicals

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

To provide codes for chemicals of importance to health care outside of medications, which were covered in the CHI Medication standard. The workgroups feels that for health care purposes these chemicals will be those found in the workplace or the environment that might be related to health. Commonly the first, and perhaps only use, of a chemical code would be during a first encounter and perhaps be part of a History and Physical.

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.*

Domain/Sub-domain	In-Scope (Y/N)
Non-medicine chemicals	Y
Medication ingredients	N

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

Case Management Information
Customer Risk Factors
Population Member Health Data
Population Risk Reduction Plan

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

Name	Agency/Department
Steven J Steindel, PhD (Team Lead)	**CDC/HHS**
William A Hess	FDA/HHS
John Harmon	EPA
Richard W Niemeier	CDC/HHS

Work Period *Dates work began/ended.*

Start	End
11/3/03	01/27/04

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended*

Conditional - below

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

The standard is owned and maintained by Environmental Protection Agency. It is part of the EPA System of Registries (ww.epa.gov/sor). The System of Registries (SoR) provides a gateway and search capability to several registries and repositories residing in the Environmental Protection Agency's (EPA) Office of Environmental Information (OEI). These registries comprise a critical link in EPA's information architecture and are a vital component to the National Environmental Information Exchange Network (Network). Specifically, the SoR was developed to support the Agency's data standards program and numerous Agency information technology initiatives, including the Agency architecture and data exchange with stakeholders through network nodes.

The registries provide identification information for objects of interest to EPA, Network trading partners, including states and tribal entities, and the public. These objects consist of data elements, XML tags, data standards, substances (chemicals, biological organisms, and physical properties), terms, facilities, regulations, and data sets that the Agency uses in its core business processes.

The Substance Registry System (SRS) is the Environmental Protection Agency's (EPA) central system for information about regulated and monitored substances. The system provides a common basis for identification of chemicals, biological organisms, and other substances listed in EPA regulations and data systems, as well as substances of interest from other sources, such as publications. The SRS supports and conforms to EPA's Chemical Identification Data Standard and the EPA's Biological Identification Data Standard.

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

Literally thousands of directories of chemicals exist for many purposes. The EPA SRS as chosen because it is reasonably complete, readily available, in current wide-spread use and already has a structure that allows linkage to other data sources. As a federal government resource, there is no cost associated with access or use.

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

US Environmental Protection Agency (EPA) Substance Registry System (SRS) (www/epa.gov/srs)

- Establishing interagency communication so that medical needs are addressed in a timely and coordinated fashion. (It is the Workgroup's understanding that this

communication has started.)
- Developing a mechanism so that similar tables from other agencies can be matched against the SRS table and missing elements added. (Note: this will require new, unidentified resources.)
- Investigate availability of a subset or view of information from the database in an acceptable format for healthcare use as a no or low-cost distribution item. (EPA is willing to provide this view as a periodically updated, perhaps every six-months, compressed file for Internet download.)

Requirement for registering an Object Identifier (OID) if it is to be used in HL7 messaging.

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 CT® must be specifically discussed.*

SNOMED CT®: Was not specifically reviewed by the Workgroup. SNOMED CT® was reviewed as a means of identifying ingredients as part of the Medication Workgroup and found inadequate. A brief look at the Chemicals area by the Workgroup Chair indicated it was also not adequate for this domain.

CDC NIOSH Registry of Toxic Effects of Chemical Substances® (RTECS®): A database of 152,970 toxic chemicals (January 2001). The database is now privately maintained and available at a modest (starting at approximately $275 for a CD) subscription price. While this database appeared complete and was well targeted for toxicological information of medical importance, the subscription price and availability of a federally maintained system eliminated it from consideration. (See mapping below).

Chemical Abstract Service (CAS) Numbers: were investigated as they are the primary identification number assigned in the US. Approximately 22 million chemicals are registered with CAS. Licensing restrictions were viewed as preventing us of CAS Numbers for medical messaging. Note that CAS Numbers may be used freely for regulatory purposes and appear in many chemical databases for that reason.

The workgroup noted the existence of many Chemical lists for various purposes and felt the domain was too large to adequately review in depth. A review of the content and requirements of the EPA SRS indicated that it meet the needs of a CHI Validation study.

Current Deployment

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

Widespread use by those impacted by the EPA.

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.

Data as of 11/10/03:
Number of substances currently in the SRS: 87707

Number of submitting organizations represented in the SRS: 37
Number of information resources included in the SRS: 965

The SRS contains substance identification information and listings of substances in EPA regulations and Agency programs. Substances are identified by common identifiers such as Chemical Abstracts Service Registry Number (CASRN) and name (systematic or scientific). Each substance is linked to regulations in which it is referenced and program systems where it has been reported. Searches can also be done by specific regulation or program system.

How often are terms updated?

The data in the SRS is periodically updated with new EPA regulations and program system lists. Future plans include expanded reference information for regulations and an improved user interface. Other enhancements may include adding identification information and linking to other information resources such as toxicology and health information.

Data may be added by directly contacting the EPA as well (http://oaspub.epa.gov/sor/reg$.startup). Any additional chemicals to SRS must be approved by the EPA contractor to ensure accuracy (e.g., ensuring accurate matches between Chemical Abstract Service (CAS) numbers and names). Contemplated is a process by which an EPA program office, whenever it makes a change to its list of regulated chemicals (e.g., a chemical newly regulated under the Clean Water Act), that change is automatically communicated to SRS and reviewed by the EPA contractor to see if the chemical already exists in SRS or if a new chemical record (with all the associated metadata) must be created.

Range of Coverage

Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)
The Standard in this new format and in previous formats has been widely used, maintained and available from the EPA for a number of years. The Standard has information for STOrage RETrieval for Water Quality Data (STORET), Air Quality System (AQS), National Emission Inventory (NEI), and EPA Registry Names, substance lists for Green Chemistry Expert System (GCES), Chemical on Reporting Rules (CORR), Emergency Response Notification System (ERNS), Federal Insecticide, Fungicide, and Rodenticide Act Inert Ingredients in Pesticide Products (FIFRA-Inerts), Integrated Taxonomic Information System (ITIS), Safe Drinking Water Information System-Enviro (SDWIS-Enviro), OPP Registration Eligibility Decisions (OPP-REDS), Permit Compliance System-Enviro (PCS-Enviro), and Pesticide Product Information System (PPIS). Previous EPA registries, the Chemical Registry System (CRS) and the Biology Registry System (BioRS) have been retired with full function included in this standard.

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

Included is a download feature that lets you receive information about the contents the registry. There is a download section included at the bottom of each detail page. File formats include text report, Oracle (SQL* Loader), and comma-separated text files (for use in MS Access, MS Excel). Download files are available in a nonstandard, compressed file format that requires decompression software, such as WinZip or PKZip. Download of the complete database does not appear to be available at this time.

The registry data can also be accessed using the Environmental Metadata Gateway (EMG, http://www.epa.gov/emg/), a search engine that enables users to search the metadata registry content using a Universal Resource Locators (URL) with integrated search capabilities. It enables users to search and seamlessly navigate to the detail pages meeting the search criteria. An EMG Search has been developed that enables system developers to build URLs to automatically query various substance data and display the appropriate detail information from EPA's application, the Substance Registry System (SRS).

No license is required.

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.)

None.

Systems Requirements

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

No

Guidance: *What public domain and implementation and user guides, implementation tools or other assistance is available and are they approved by the SDO?*
All EPA information is found on the above noted websites. No formal training programs were noted.

Maintenance: *How do you coordinate inclusion and maintenance with the standards developer/owners?*

Contractor maintained – see above.

What is the average time between versions?

Varies depending on regulatory changes and requests for additions. An email subscription service is available to advise people of changes that impact them (http://oaspub.epa.gov/sor/subscribe$.startup)

How are local extensions, beyond the scope of the standard, supported if at all?

EPA is presently looking at options for introducing web services to allow states/tribes or whomever to access SRS to feed their own local systems. The idea is that the local mini-SRS and then periodically contact SRS to determine if there have been any updates.

How do you coordinate inclusion and maintenance with the standards developer/owners?
See above – contractor coordinated.

What is the process for adding new capabilities or fixes?

See above.

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

Not know.

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

Not known.

Mapping Requirements

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

Two existing federal databases were identified that would require mapping to the SRS:
The FDA UNII Code System (CHI Medicine Ingredient Standard); and
The NIOSH Registry of Toxic Effects of Chemical Substances (RTECS®, now externally maintained).
It is anticipated that others might exist as well.

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

The EPA has indicated a willingness to work with federal partners to include missing needed terms or the mapping information when these terms currently exist. The SRS is

currently formatted to include links to related database information and would require no structural change. They also see a clear need to link to toxicological information such as that contained in RTECS®. While the Workgroup did not evaluate the extent of overlap, it was felt that many of the chemicals in both the above databases are already in the SRS, with the exception of some drugs.

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.

Already in wide-spread use. Time for a new deployment is not known.

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

NA

Gaps

Identify the gaps in data, vocabulary or interoperability.

Essential gaps that need resolution before removing conditional recommendation:

- Establishing interagency communication so that medical needs are addressed in a timely and coordinated fashion. . (It is the Workgroup's understanding that this communication has started.)
- Developing a mechanism so that similar tables from other agencies can be matched against the SRS table and missing elements added. (Note: this will require new, unidentified resources.)
- Investigate availability of a subset or view of information from the database in an acceptable format for healthcare use as a no or low-cost distribution item. (EPA is willing to provide this view as a periodically updated, perhaps every six-months, compressed file for Internet download.)
- Requirement for registering an Object Identifier (OID) if it is to be used in HL7® messaging.

*Gaps identified that need addressing but **do not prevent acceptance**:*

- A task EPA is still undertaking is a review of the commonly regulated chemicals and the selection from the many synonyms available of an EPA Preferred Name. In the process we're identifying ambiguities in naming (the same name applied to multiple chemicals) or in some instances a program used a name that is not appropriate for a particular chemical (e.g., its a name used by a completely different chemical). These kind of problems really highlight the need for an Agency-wide system like SRS and the need for someone to review any changes to chemical content in SRS.
- Introduction of common chemical download format such as the MOLFIL or developing CXML (Chemical XML).

Obstacles

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

None – widely used.

Appendix A

Information Exchange Requirements (IERs)

Information Exchange Requirement	Description of IER
Beneficiary Financial / Demographic Data	Beneficiary financial and demographic data used to support enrollment and eligibility into a Health Insurance Program.
Beneficiary Inquiry Information	Information relating to the inquiries made by beneficiaries as they relate to their interaction with the health organization.
Beneficiary Tracking Information	Information relating to the physical movement or potential movement of patients, beneficiaries, or active duty personnel due to changes in level of care or deployment, etc.
Body of Health Services Knowledge	Federal, state, professional association, or local policies and guidance regarding health services or any other health care information accessible to health care providers through research, journals, medical texts, on-line health care data bases, consultations, and provider expertise. This may include: (1) utilization management standards that monitor health care services and resources used in the delivery of health care to a customer; (2) case management guidelines; (3) clinical protocols based on forensic requirements; (4) clinical pathway guidelines; (5) uniform patient placement criteria, which are used to determine the level of risk for a customer and the level of mental disorders (6) standards set by health care oversight bodies such as the Joint Commission for Accreditation of Health Care Organizations (JCAHO) and Health Plan Employer Data and Information Set (HEDIS); (7) credentialing criteria; (8) privacy act standards; (9) Freedom of Information Act guidelines; and (10) the estimated time needed to perform health care procedures and services.
Care Management Information	Specific clinical information used to record and identify the stratification of Beneficiaries as they are assigned to varying levels of care.
Case Management Information	Specific clinical information used to record and manage the occurrences of high-risk level assignments of patients in the health delivery organization..
Clinical Guidelines	Treatment, screening, and clinical management guidelines used by clinicians in the decision-making processes for providing care and treatment of the beneficiary/patient.

Cost Accounting Information	All clinical and financial data collected for use in the calculation and assignment of costs in the health organization .
Customer Approved Care Plan	The plan of care (or set of intervention options) mutually selected by the provider and the customer (or responsible person).
Customer Demographic Data	Facts about the beneficiary population such as address, phone number, occupation, sex, age, race, mother's maiden name and SSN, father's name, and unit to which Service members are assigned
Customer Health Care Information	All information about customer health data, customer care information, and customer demographic data, and customer insurance information. Selected information is provided to both external and internal customers contingent upon confidentiality restrictions. Information provided includes immunization certifications and reports, birth information, and customer medical and dental readiness status
Customer Risk Factors	Factors in the environment or chemical, psychological, physiological, or genetic elements thought to predispose an individual to the development of a disease or injury. Includes occupational and lifestyle risk factors and risk of acquiring a disease due to travel to certain regions.
Encounter (Administrative) Data	Administrative and Financial data that is collected on patients as they move through the healthcare continuum. This information is largely used for administrative and financial activities such as reporting and billing.
Improvement Strategy	Approach for advancing or changing for the better the business rules or business functions of the health organization. Includes strategies for improving health organization employee performance (including training requirements), utilization management, workplace safety, and customer satisfaction.
Labor Productivity Information	Financial and clinical (acuity, etc.) data used to calculate and measure labor productivity of the workforce supporting the health organization.
health organization Direction	Goals, objectives, strategies, policies, plans, programs, and projects that control and direct health organization business function, including (1) direction derived from DoD policy and guidance and laws and regulations; and (2) health promotion programs.
Patient Satisfaction Information	Survey data gathered from beneficiaries that receive services from providers that the health organization wishes to use to measure satisfaction.

Patient Schedule	Scheduled procedure type, location, and date of service information related to scheduled interactions with the patient.
Population Member Health Data	Facts about the current and historical health conditions of the members of an organization. (Individuals' health data are grouped by the employing organization, with the expectation that the organization's operations pose similar health risks to all the organization's members.)
Population Risk Reduction Plan	Sets of actions proposed to an organization commander for his/her selection to reduce the effect of health risks on the organization's mission effectiveness and member health status. The proposed actions include: (1) resources required to carry out the actions, (2) expected mission impact, and (3) member's health status with and without the actions.
Provider Demographics	Specific demographic information relating to both internal and external providers associated with the health organization including location, credentialing, services, ratings, etc.
Provider Metrics	Key indicators that are used to measure performance of providers (internal and external) associated with the health organization.
Referral Information	Specific clinical and financial information necessary to refer beneficiaries to the appropriate services and level of care.
Resource Availability	The accessibility of all people, equipment, supplies, facilities, and automated systems needed to execute business activities.
Tailored Education Information	Approved TRICARE program education information / materials customized for distribution to existing beneficiaries to provide information on their selected health plan. Can also include risk factors, diseases, individual health care instructions, and driving instructions.