

Summary

Domain: Anatomy and Physiology

Standards Adoption Recommendation (Anatomy only):

Systematized Nomenclature of Medicine Clinical Terms[®] (SNOMED CT[®])
National Cancer Institute's (NCI) Thesaurus

SCOPE

Anatomy: To describe anatomical locations for clinical, surgical, pathological and research purposes.

Physiology: To describe or infer human physiology at least at the organ system, cellular, and biochemical levels

RECOMMENDATION

No standard is being recommended for Physiology.

SNOMED CT[®] and the NCI Thesaurus is recommended for Anatomy. It is not realistic to limit or change the anatomy component of current widely used clinical terminologies to adopted standards. Continued use with the required level of semantic understanding will require certified mappings. Hence, mapping is an essential requirement of the anatomy domain. It is the workgroup's recommendation that these mappings be developed, maintained, validated and distributed through the UMLS[®].

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Maintained and published by the National Institutes of Health/National Cancer Institute, the NCI Thesaurus contains the working terminology used in a growing number of NCI data systems. It covers vocabulary for clinical care, translational and basic research, and public information and administrative activities

APPROVALS AND ACCREDITATIONS

The CAP is an ANSI Standards Development Organization. The SNOMED CT[®] Healthcare Terminology Structure is ANSI approved.

ACQUISITION AND COST

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The NCI Thesaurus is covered by an open content license. The license allows free distribution and modification of the NCI Thesaurus content.

Summary

Domain: Billing / Financial

Standards Adoption Recommendation: HIPAA Transactions and Code Sets

SCOPE

The Billing/Financial standards are used to implement electronic exchange of health related information needed to perform billing/administrative functions in the Federal health care enterprise. It is assumed that the HIPAA transaction and code sets will serve as the basis for these standards.

RECOMMENDATION

The HIPAA approved transactions and codes set, both those currently approved as well as future updates, are recommended for adoption.

OWNERSHIP

Maintenance and control for the HIPAA approved codes sets are as follows:

NCHS maintains ICD-9-CM

FDA maintains NDC codes

CMS maintains HCPCS codes

AMA owns and maintains CPT-4[®] codes

ADA owns and maintains CDT[®] codes

Alternative Link owns and maintains ABC codes as well as the pilot participant registration logs

CMS maintains DRG codes

APPROVALS AND ACCREDITATIONS

Public Law 104-191, the Health Insurance Portability and Accountability Act of 1996 mandates the use of HIPAA code sets. Each agency/organization that owns or maintains a HIPAA approved transaction or code set has established their own approval/accreditation process for their standards. Only the ADA is an ANSI approved SDO with the CDT[®] being ANSI/ISO approved.

ACQUISITION AND COST

See <http://cms.hhs.gov/hipaa/hipaa2/education/infoserie/4-tcs.doc> for details on acquisition and accompanying information.

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).



Summary

Domain: Demographics

Standards Adoption Recommendation: Health Level Seven[®] (HL7[®]) Version 2.4+

SCOPE

The standard, as identified in the following section of this document, will be used to set the requirements for collecting and storing specific patient demographic data, to be used for various purposes, primarily that of unique patient identification.

RECOMMENDATION

Health Level Seven[®] (HL7[®]), Version 2.4 and higher. This recommendation complies with the OMB's Race and Ethnicity standards for reporting.

OWNERSHIP

Health Level Seven[®] (HL7[®]) holds the copyright, www.hl7.org

APPROVALS AND ACCREDITATIONS

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ACQUISITION AND COST

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Summary

Domain: Disability

Standards Adoption Recommendation:

No standard is recommended for adoption at this time for disability content needed by the Federal Government. However, recommendations are offered to guide research that will facilitate the development of (i) needed disability and functional content into existing terminologies and classification systems, and (ii) algorithms that can be used to equate the alternative scaling concepts used across federal classification systems. This research should be a collaborative effort between the disability community and terminology community.

RECOMMENDATION

There is no standard being recommended at this time. However, recommendations are included to guide future work in the area of disability content and questions.

OWNERSHIP

-NA-

APPROVALS AND ACCREDITATIONS

-NA-

ACQUISITION AND COST

-NA-

Summary

Domain: Diagnosis and Problem Lists

Standards Adoption Recommendation:

Systematized Nomenclature of Medicine Clinical Terms[®] (SNOMED CT[®])

SCOPE

Diagnosis/Problem List is broadly defined as a series of brief statements that catalog a patient's medical, nursing, dental, social, preventative and psychiatric events and issues that are relevant to that patient's health care (e.g. signs, symptoms, and defined conditions).

RECOMMENDATION

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Summary

Domain: Clinical Encounters

Standards Adoption Recommendation: Health Level Seven® (HL7®) Version 2.4+

SCOPE

An encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency-care, home health care, field and virtual (telemedicine).

RECOMMENDATION

Health Level Seven® (HL7®), Version 2.4 and higher.

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Summary

Domain: Genes and Proteins

Standards Adoption Recommendation:

Human Gene Nomenclature (HUGN) for genes. None for proteins.

SCOPE

To allow the federal health care sector to exchange information regarding the role of genes in biomedical research and healthcare, using a single unambiguous genetic nomenclature.

RECOMMENDATION

Human Gene Nomenclature (HUGN) sponsored by the Human Genome Organization (HUGO). No recommendation for Protein Nomenclature.

OWNERSHIP

HUGO is a non-profit body that is jointly funded by the UK Medical Research Council (40%) and the US National Institutes of Health, contract N01-LM-9-3533 (60%).

APPROVALS AND ACCREDITATIONS

-NA-

ACQUISITION AND COST

HUGN is free for nonprofit use, but requires a license for commercial use (see <http://www.gene.ucl.ac.uk/nomenclature/information/commercial.html>)

Summary

Domain: History and Physical

Standards Adoption Recommendation:

NONE: Work deferred to CHI Phase II

SCOPE

This domain is defined as the terminology that is used to identify, classify, and name the components incorporated into a patient's medical history and the physical exam process performed by a practitioner.

RECOMMENDATION

No recommendation. Work deferred to CHI Phase II.

OWNERSHIP

-NA-

APPROVALS AND ACCREDITATIONS

-NA-

ACQUISITION AND COST

-NA-

Summary

Domain: Non-Laboratory Interventions and Procedures

Standards Adoption Recommendation: Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)

SCOPE

This standard will be used to describe specific non-laboratory interventions and procedures performed / delivered. Interventions represent the purposeful activities performed in the provision of health care. Procedures are concepts that represent the purposeful activities performed in the provision of health care.

RECOMMENDATION

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Summary

Domain: Immunizations

Standards Adoption Recommendation: Health Level Seven[®] (HL7[®]) Version 2.3.1+

SCOPE

The implementation of a data standard for the storage and exchange of immunization data would provide an organized and streamlined means of communicating between Federal partners by offering a real-time means of transferring information regarding immunization encounters, vaccine events, patient records and other immunization-related information important to immunization registries.

RECOMMENDATION

Health Level Seven[®] (HL7[®]) for immunization registry terminology, more specifically the CVX (clinical vaccine formulation) and MVX (manufacturer) codes.

OWNERSHIP

The Immunization Data Transactions, Version 2.3.1 of the HL7[®] Standard Protocol, Version 2.0 has been promulgated as the primary standard for immunization data transactions by CDC in the National Immunization Program (NIP). HL7[®] has designated the CDC as the maintenance agency for the CVX and MVX codes.

APPROVALS AND ACCREDITATIONS

HL7[®] is an ANSI-accredited Standards Developing Organization. This standard has been approved by full organizational ballot voting.

ACQUISITION AND COST

There is no use license with this standard; it is available for any healthcare organization to use. An implementation guide for the HL7[®] standard with respect to immunization data transactions can be found on the National Immunization Program website: www.cdc.gov/nip/registry.

Summary

Domain: Laboratory Result Contents

Standards Adoption Recommendation: Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)

SCOPE

This standard will be used to exchange results of laboratory tests between facilities. These results are contained within a laboratory report that includes additional items such as patient and order demographics, laboratory test name (expressed as a LOINC® code as approved by CHI and adopted as a federal standard), specimen type and other items as may be required by business needs or messaging structures.

RECOMMENDATION

Systematized Nomenclature of Medicine Clinical Terms® (SNOMED CT®).

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Summary

Domain: Units

Standards Adoption Recommendation: Health Level Seven[®] (HL7[®]) Version 2.X +

SCOPE

This standard will be used to define common units of measure, such as Celsius or mg/ml, that are intended to be combined with a numeric value to accurately express a result.

RECOMMENDATION

HL7[®] codes for Units, Versions 2.X +, derived from the ISO 2955-83 standard (withdrawn by ISO in 2001) and ANSI X3.50.

OWNERSHIP

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APPROVALS AND ACCREDITATIONS

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Summary

Domain: Interventions & Procedures Laboratory Test Order Names

Standards Adoption Recommendation: Logical Observation Identifier Names and Codes (LOINC[®])

SCOPE

The representation of the names of laboratory test associated with an order within a computer system. Laboratory Results Naming, laboratory test result values, demographics, anatomy and physiology, and genes and proteins are not included in this domain and are the subjects of separate reports. The team recognizes that many of these vocabularies will also be incorporated in a comprehensive laboratory order system.

RECOMMENDATION

The work group recommends that LOINC[®] be adopted with identified gaps to be addressed to improve utility.

OWNERSHIP:

The Regenstrief Institute, Inc. owns LOINC[®].

APPROVALS AND ACCREDITATIONS:

LOINC[®] has been approved by full standard development organization vote by HL7[®] v2.4 as a coding system for observation identifiers.

ACQUISITION AND COST:

The LOINC[®] database and associated documents and programs are copyrighted, but the copyright permits all commercial and non-commercial uses in perpetuity at no cost. The LOINC[®] database can be obtained from the Regenstrief LOINC[®] website (<http://www.regenstrief.org/LOINC>). The website makes available a User's Guide, the free RELMA[®] (Regenstrief Logical Mapping Assistant) program, and the RELMA[®] User's Manual. RELMA[®] is a program for browsing the LOINC[®] database for mapping local test codes to LOINC[®] codes.

Summary

Domain: Medications

Sub-Domain: Clinical Drug

Standards Adoption Recommendation: Semantic Clinical Drug (SCD) of RxNorm

SCOPE

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

A “clinical drug” is a name for a pharmaceutical preparation consisting of its component(s), defined as active ingredients and their strength, together with the dose form of the drug as given to the patient. It expresses the equivalence of pharmaceutical preparations at a generic level, in the form in which medications are prescribed for the patient.

RECOMMENDATION

The CHI Medications subgroup has identified the Semantic Clinical Drug (SCD) of RxNorm, a portion of the UMLS[®] as the CHI standard for clinical drug nomenclature. .

OWNERSHIP

The National Library of Medicine has primary responsibility for the RxNorm terminology. As steward, NLM works in close collaboration with other governmental agencies (e.g. the VA, and the FDA, with the private sector (e.g. First Databank, Micromedex, Multum, Medispan) and other Nations (e.g. Britain, and Australia).

APPROVALS AND ACCREDITATIONS

RxNorm is a public domain system developed by the NLM in conjunction with the VA and the FDA, and in consultation with HL7[®].

ACQUISITION AND COST

RxNorm is distributed via UMLS[®] without restriction.

Summary

Domain: Medications

Sub-Domain: Special Populations

Standards Adoption Recommendation: Health Level Seven[®] (HL7[®]) Version 2.4

SCOPE

Sub-groups of the population using medications for the treatment or prevention of medical conditions can demonstrate difference in the safety and effectiveness of these products. (Gender, Age, Race/Ethnicity)

RECOMMENDATION

HL7[®] Version 2.4 gender, race & ethnicity codes—which covers the OMB guidelines as well as a more granular characterization hierarchically grouped according to the OMB categories. (Consistent with CHI demographics standards)

OWNERSHIP

Health Level Seven[®] (HL[®]7) holds the copyright, www.hl7.org

APPROVALS AND ACCREDITATIONS

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Summary

Domain: Medications

Sub-Domain: Drug Classifications

Standards Adoption Recommendation:

National Drug File Reference Terminology (NDF-RT)
(for Physiologic Effect & Mechanism of Action)

SCOPE

One of the desired qualities of a standardized medication terminology is the inclusion of hierarchical structures to categorize each medication, such as: mechanism of action, physiologic effects, intended therapeutic use, chemical structures, pharmacological properties, and FDA approved indications.

RECOMMENDATION

The National Drug File Reference Terminology (NDF-RT) classification scheme for the areas of Physiologic Effect and Mechanism of Action.

OWNERSHIP

The Veterans Administration developed the NDF-RT.

APPROVALS AND ACCREDITATIONS

ACQUISITION AND COST

May be obtained from the VA. Also available from the National Cancer Institute at

<http://nciterms.nci.nih.gov/NCIBrowser/Dictionary.do>

Will be in a near future release of the UMLS[®] (planned July 04)

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>

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. propranolol), or by a base substance – salt combination (e.g. propranolol hydrochloride). 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.

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.

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>

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.

Summary

Domain: Medications

Sub-Domain: Structured Product Labeling Sections

Standards Adoption Recommendation: Logical Observation Identifier Names and Codes (LOINC[®])

SCOPE

The major purpose of the SPL specification is to facilitate the submission, review, storage, dissemination, and access to product labeling information. It is intended to:

- Provide labeling information electronically, in a human readable text format that can be exchanged across systems without additional transformation steps.
- Improve dissemination of product labeling critical to improving risk management of regulated products.
- Use standards to improve integration of clinical data.
- Enhance patient safety by enhancing integration of labeling information with other technical and clinical applications.

RECOMMENDATION

LOINC[®] Clinical SPL section terminology upon gaining approval status by HL7[®] for the SPL specification and upon incorporation of the terminology into LOINC[®] (*Update April 04: approved and available*).

OWNERSHIP

LOINC[®] owns the standard. LOINC[®] is managed and documentation controlled by the Regenstrief Institute.

APPROVALS AND ACCREDITATIONS

Currently being balloted thru HL7[®] (Jan 2004) (*Update April 04: Ballot passed*)

ACQUISITION AND COST

The full LOINC[®] database and RELMA -- a program for searching and viewing the LOINC[®] database and mapping local files to LOINC[®] is available at no cost.

Summary

Domain: Multimedia

Standards Adoption Recommendation:

None: Work to continue in CHI Phase II

SCOPE

The primary application of this standard is for combining data from multiple media (e.g., images, photos, audios, videos, faxes, etc.) into patient records with the objective of ensuring interoperability and information exchange among federal agencies. This standard is useful throughout the federal healthcare system which employs a wide variety of medical records and patient information systems.

RECOMMENDATION

None. Work to continue in Phase II of CHI.

OWNERSHIP

-NA-

APPROVALS AND ACCREDITATIONS

-NA-

ACQUISITION AND COST

-NA-

Summary

Domain: Nursing

Standards Adoption Recommendation: Systematized Nomenclature of Medicine Clinical Terms[®] (SNOMED CT[®])

SCOPE

This domain is defined as a terminology that is used to identify, classify, and name the delivery of nursing care. Sub-domains are derived from the Nursing Process and ANA recognized Nursing Minimum Data Set (NMDS), emphasizing nursing assessment, diagnosis, interventions, and outcomes of nursing care.

RECOMMENDATION

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Summary

Domain: Population Health

**Standards Adoption Recommendation:
NONE**

SCOPE

To enumerate code sets used to report data to public health and for the purpose of population health statistics that were not specifically defined in other CHI domain reports.

RECOMMENDATION

None, additional work identified for CHI Phase II.

The diversity of terminology needs found in the workgroup's investigation of population health reporting needs lead to the conclusion that a specific CHI recommendation is inappropriate at this time.

The workgroup noted that in some circumstances, population health data is identical to clinical data such as reporting of infectious disease cases to public health departments or cancer rapid case ascertainment and other disease registry information to appropriate state registries. In those cases, the appropriate CHI domain recommendations for the underlying clinical data can be used. An example of this use is the Public Health Information Network (PHIN) electronic laboratory reporting standards from CDC that use LOINC[®] and SNOMED[®] codes within an HL7[®] message for public health reporting of infectious organisms identified by laboratories.

OWNERSHIP

-NA-

APPROVALS AND ACCREDITATIONS

-NA-

ACQUISITION AND COST

-NA-

Summary

Domain: Medical Devices and Supplies

Standards Adoption Recommendation:

None: Monitor Industry Work

SCOPE

This standard is used primarily to inventory medical devices and supplies and document their utilization by health services establishments and to regulate medical device and supply availability and utilization in the community by public health agencies. The regulation of medical devices and supplies involves premarket approval/classification and post market adverse event surveillance to ensure the safety and effectiveness of the product.

RECOMMENDATION

No one terminology is recommended, rather the recommendation is to encourage the Global Medical Device Nomenclature (GMDN) and the Universal Medical Device Nomenclature System (UMDNS[®]) to merge and to re-evaluate/adopt the resulting terminology.

OWNERSHIP

The GMDN is owned by the European Standards Body (CEN) and is a CEN/ISO standard. It was recently developed largely through the harmonization of six established medical device terminologies including a previous version of the UMDNS[®] and the terminology used by the Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA). The GMDN is managed and its content maintained by an international Maintenance Agency with significant FDA representation.

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APPROVALS AND ACCREDITATIONS

-NA-

ACQUISITION AND COST

-NA-

Summary

Domain: Text Based Reports

Standards Adoption Recommendation: Health Level Seven[®] (HL7[®]) CDA Release 1.0-2000

SCOPE

Identify standards and terminologies used to define the messaging architecture and syntax of clinical text documents

RECOMMENDATION

Health Level Seven[®] (HL7[®]) CDA Release 1.0-2000

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