# Data Standards, Data Quality, and Interoperability (Updated) - Retired

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*Editor's note: This update replaces the 2007 practice brief "Data Standards, Data Quality, and Interoperability."*

Data quality and consistency are critical to ensuring patient safety, communicating delivery of health services, coordinating care, and healthcare reporting. Assessing the quality and consistency of data requires data standards. This practice brief provides health information management (HIM) professionals with a clear understanding of data standards as a tool to enable interoperability and promote data quality.

The online version of this practice brief [...] is accompanied by an appendix that provides HIM professionals with a list of standards to reference in data dictionary development, electronic health records, the exchange of health information, and general data management processes to ensure information integrity and reliability. Evaluation of data validity, reliability, completeness, and timeliness are accomplished through a combination of human and machine processes in healthcare, and the list of data standard sources is a helpful reference guide when more detailed information is required.

## Data Standards and Regulatory Framework

Data standards are "documented agreements on representations, formats, and definitions of common data. Data standards provide a method to codify invalid, meaningful, comprehensive, and actionable ways, information captured in the course of doing business."[1] Rules to describe how the data is recorded to ensure consistency across multiple sources is another way to think of data standards. Without data standards and data quality, the future of interoperability is bleak. Data fields and the content of those fields need to be standardized.

Standards development organizations (SDOs) address a variety of aspects of health information and informatics. For example, the American Society for Testing and Materials (ASTM) and Health Level Seven (HL7) target clinical data standards. Insurance and remittance standards are a focus of the Accredited Standards Committee (ASC) X12. Standards to transmit diagnostic images are developed through Digital Imaging and Communications in Medicine (DICOM). The National Council for Prescription Drug Programs (NCPDP) represents pharmacy messages.

The Institute of Electrical and Electronics Engineers (IEEE), HL7, ASTM, and others develop data models and frameworks. See the table on page 65 for a breakdown of regulatory agencies responsible for working with the American National Standards Institute (ANSI) to drive data standards to achieve interoperability.

The AHIMA Leadership Model states that HIM professionals should serve as the leaders in healthcare organizations and in their professional community for ensuring that data content standards are identified, understood, implemented, and managed. As leaders, HIM professionals will need to collaborate with internal and external partners to meet interoperability and health information exchange agreements, influence the development of standards to meet organizational needs, and participate in the development of standards to address local and national industry needs.

Leadership actions for HIM professionals include but are not limited to:

- Increase knowledge and understanding of data content standards
- Assess organizational readiness
- Conduct a data content standards requirements analysis
- Develop a local data dictionary to support enterprise-wide interoperability

- Advance the development of data content standards
- Select integrated electronic systems that support data content requirements
- Contribute to domain knowledge by participating in relevant professional association work and mentoring others
- Contribute to the development and harmonization of industry and professional standards[3]

# Interoperability Ensures EHR Compatibility

The Office of the National Coordinator for Health IT (ONC) defines interoperability as ensuring that health-related information flows seamlessly. Information needs to follow the patient regardless of geographic, organizational, or vendor boundaries. Interoperability refers to the architecture or standards that make it possible for diverse EHR systems to work compatibly. The importance of interoperability goes far beyond the confines of the EHR. Information must flow into and out of health information exchanges—available to the patient at the right time, at the right place, and containing data that is accurate and complete.

ONC provides "building blocks" to bring awareness to maintaining and sustaining standard interoperability. These current initiatives are working to standardize:

- Meaning through the use of standardized healthcare vocabularies
- Structure by leveraging standards in HL7
- Transport using secure e-mail protocols
- Security through National Institute of Standards and Technology (NIST)-adopted encryption standards
- Services through open and accessible application programming interfaces (APIs)

There are many SDOs who are involved in the development and publishing of healthcare informatics standards at national and international levels. These standards are crucial to the capturing and sharing of clinical information in our electronic health information systems.

## Regulatory Agencies in Standard Development

Multiple regulatory agencies are currently responsible for working with the ANSI standard development organization to drive data standards that help achieve interoperability, including those listed in the table below.

| **Regulatory Agency** | **Data, Mapping, and Messaging Standards** |
|---|---|
| The Centers for Medicare and Medicaid Services (CMS) provides a list of data resources including standard terms and abbreviations that promotes naming and semantic consistency. | The "meaningful use" EHR Incentive Program was developed to allow care providers to implement EHR technology in three stages. Stage 1 focuses on data capture and sharing of data, stage 2 focuses on clinical processes such as information exchange and patient-controlled data, and stage 3 aims to focus on improving patient outcomes. The incremental phases allow care providers to adopt standards into their daily workflow. |

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| The Office of the National Coordinator for Health Information Technology (ONC) promotes flexible implementation standards that are able to change incrementally, emphasizing usability and workflow design to facilitate data exchange. | Meaningful use stage 2 EHR certification criteria delineates data standards. |
| The Agency for Healthcare Research and Quality (AHRQ) promotes the development of IT systems which identify specific criteria. | The National Strategy for Quality Improvement in Health Care (National Quality Strategy) is a nationwide effort to align public and private interests to improve the quality of health and healthcare for all Americans. Part of the Affordable Care Act, the National Quality Strategy is guided by three aims that provide better, more affordable care for an individual and the community.<br><br>The National Quality Strategy (NQS) promotes "national standards while supporting local, community, and state-level activities that respond to local circumstances."2 The NQS also works to align quality efforts among commercial and government activities, and across federal agencies. |

# Standards Development

In order to drive interoperability, the adoption of messaging standards is primarily driven by regulation. There are also stakeholder groups hard at work on harmonization efforts to manage information in standardized processes to enable data sharing. A consensus process gathers interested individuals from industry and consumer groups, specialty domains, agencies, professional organizations, and vendors to develop a concept and express it in a recommended course of action or standard. Then, a document is drafted to further refine the concept and work through details by an interactive voting process to assure that the completed standard has been accorded fair review prior to publishing.

ASTM publishes standard test methods, specifications practices, guides, terminologies, and classifications. ASTM E1384 and E31.25 (2013) Standard Practice for Content and Structure of the Electronic Health Record (EHR) describes a logical data organization and content (common data model) of an EHR. The model is used by an organization according to the major informational structures and content of the EHR. A patient's health record plays five unique roles:

1. It represents the patient's health history.
2. It provides a method for clinical communication and care planning among the individual healthcare practitioners serving the patient.
3. It serves as the legal document describing the healthcare services provided.
4. It is a source of data for clinical, health services, and outcomes research.
5. It serves as a major resource for healthcare practitioner education.[4]

HL7 is one organization that is developing international standards for interoperability and messaging including the Consolidated Clinical Document Architecture (C-CDA) and EHR functional model. HL7 develops international standards, which sometimes must be modified to meet the "meaningful use" EHR Incentive Program or reimbursement systems criteria unique to the United States. HL7 collaborates with the International Organization for Standardization (ISO) for international balloting.

ISO, the world's largest developer of voluntary standards, has many technical committees (TCs) that span a variety of products and services. ISO/TC 215 Health Informatics primarily develops voluntary standards in the field of information for health and health information and communication technology to promote interoperability. ISO/TC 215 includes standards for

areas such as healthcare delivery, disease prevention and wellness promotion, public health and surveillance, and clinical research related to health services.

Health informatics standards will play significant roles as electronic data management increases. It is important that HIM professionals learn about informatics in order to serve as a professional resource to healthcare organizations. HIM professionals can participate in the standards development process by evaluating proposed standards and recommending new ones. There has never been a greater need for input from the HIM perspective in the domain of data standards.

Areas for standardization in healthcare include health information exchanges (HIE), clinical data harmonization, and documentation.

## Data Standards for Health Information Exchange

Health information exchange organizations are an important part of improving efficiency and reducing cost for healthcare delivery, and global standards will make a difference in the way healthcare professionals capture and use health information worldwide.

To foster adoption of standardized language to meet the mandates of the meaningful use program, HL7 is offering free access to their standards. HL7's C-CDA is a library of templates that help facilitate exchange. While multiple record types fall under the C-CDA, they all provide a common format to assist in health information exchange. This library contains the following nine templates:

- Continuity of Care Document (CCD)
- Consultation Note
- Diagnostic Imaging Report (DIR)
- Discharge Summary
- History and Physical (H&P)
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

Each template has defined sections to harmonize the data across systems. This standard ensures the information integrity and reliability when sharing data across HIEs or between other health IT systems.

## The Role of Metadata in Standardization

Metadata is identified as a method to manage health information by indexing and applying attributes to a patient's record at the "granular" or data-element level. An emerging use of metadata is the processing of large amounts of data for data analytics. Being able to distill large amounts of data for specific data points will allow the metadata to be used to develop and improve quality care. Metadata will be critical for leveraging the volumes, velocity, and variety of healthcare data now available due to the increasing use of clinical information systems such as EHRs.

Though metadata will be critical for maintaining and preserving the healthcare record, there are currently no standards for the metadata schema. The proposed HL7 EHR-S RM-ES Functional profile will require the capture and retention of authors, data creation time stamps, modification, view, and deletion. HL7 standards are also not mandated at this time, but using the conformance criteria will benefit health information management professionals who are involved with the RFP process or are assessing an EHR system.

The schema varies by organization and within jurisdictions according to business needs. HIM professionals need to direct their organizations to consider specific business needs and the regulatory environment when making decisions about the maintenance and management of metadata. Understanding and managing metadata is not the sole responsibility of information technology (IT) professionals. HIM professionals should collaborate with IT to develop processes and procedures to ensure that metadata is managed effectively within their organizations.

Metadata captures information such as the date and time that an entry was made in the health record, who accessed the record and when, what changes have been made to the record and by whom, and the identity of staff who document sections of the record when this information is not collected by an authentication or signature, such as portions of a template that are completed by nursing or other allied healthcare staff. Metadata is an important tool that can be used to follow up on documentation or compliance issues, facilitate response to requests for an accounting of accesses of the medical record, or to meet internal or external reporting or analytics requirements.

# Clinical Data Standards Harmonization

Semantic interoperability is the ability of computer systems to interchange data and to interpret and use the data according to its meaning, rather than just its surface form. Problems arise when one term has multiple meanings or when two or more terms refer to the same concept but are not easily recognized as synonyms. Many multi-stakeholder workgroups are in existence today to address semantic interoperability. Examples include HL7, ISO, and the International Health Terminology Standards Development Organisation (IHTSDO)—the organization that maintains SNOMED CT.

Harmonizing disparate information systems requires data translation and mapping, as well as document and messaging standards with a regulatory framework that promotes their use. HIM professionals understand where data is created and distributed; this knowledge can be utilized to ensure harmonization between systems. There are multiple data models as they relate to health information exchange such as centralized, decentralized, and federated models. The type of model selected will determine how and where information will be collected and stored.

A centralized model collects data from local sources and stores the data in a central repository. A decentralized data model, also called a federated model, gives an organization control of the healthcare record, providing a quick and easy way to distribute data-sharing across regions. The hybrid model is a combination of the previous two models.

Along with developing standards for meaningful use interoperability, it is important to exchange information with standalone registry systems. When developing these standards, these systems should be considered in the forefront to eliminate manual data collection into disparate systems. Without standards there will be unstable and inconsistent data collection resulting in the inability to compare and improve outcomes.

When developing standards one also needs to consider the ability to connect clinical outcomes with billing data to help determine the value of healthcare provided. The value of healthcare is the quality over the cost. Every system has its own way of representing data. For example, relational databases have their own schema for defining tables and fields. Ontologies are one method of managing data and providing a mechanism for disparate systems to communicate. Although this is not a new term, it will be one that HIM professionals will hear in discussions related to interoperability and data standards. An ontology viewed with a data standards lens is a model of knowledge that serves as a semantic translator that is able to reconcile metadata standards, XML dialects, and database access methods.

# Data Standards and Documentation of Health Services

Employing data standards in health services documentation further entails consistent, accurate, and reproducible capture of clinical concepts using standardized terminology to describe diseases and procedures. This supports an environment conducive to the assessment of patient management, outcomes measures for quality and performance improvement, and clinical research. Current initiatives to measure quality and performance through data include the Joint Commission Core Measures, CMS' Present on Admission Indicator Reporting, CMS' Clinical Quality Measures, and the National Committee for Quality Assurance Healthcare Effectiveness Data and Information Set (HEDIS).

Documentation describes the methods and activities of collecting, coding, ordering, storing, and retrieving information to fulfill future tasks.[5] Whether the information is collected, stored, and read on paper or discrete data elements are recorded, electronically stored, and then displayed as traditional documents on a computer monitor, data content requirements remain the same. The appropriate recording of data for patient records is required for continuous treatment of patients. The quality and safety of medical decision making during the course of providing a health service relies on the timeliness and accuracy of the information available.

Observations, assessments, and plans made during the care of individual patients are all important elements of documentation.[6] There are a variety of messaging and data content standards related to clinical documentation capture, storage, retrieval, and use. Data structure and content standards create the framework for an optimal health record and effective information exchange between healthcare providers. A data content standard often leverages a terminology standard to simplify and unify the data presentation.[7]

With increasing focus on adoption of certified EHRs, along with financial incentives to demonstrate meaningful use and improve healthcare quality, there is increased urgency to develop definitions and standards. Specified terminology standards definitions and classifications of individual terms, coupled with content standards for uniform capture and collection, are essential framing structures to describe clinical concepts—such as the use of SNOMED CT for problem list identification. Effectively sending data back and forth between organizations is accomplished with messaging standards.

Commonly used guidelines for standards in EHR systems include:

- Continuity of Care Record/Document
- National Council for Prescription Drug Programs (NCPDP)
- Digital Imaging and Communications in Medicine (DICOM)
- SNOMED CT
- Logical Observation Identifiers Names and Codes (LOINC)
- ICD-9-CM
- ICD-10-CM/PCS
- RxNorm
- Current Procedural Terminology (CPT)

The National Library of Medicine's Unified Medical Language System links more than 100 terminologies available for a variety of use cases in healthcare.[8]

Describing clinical concepts in a standardized format allows for meaningful performance monitoring and outcomes measurement. In addition it supports consistent, evidence-based care through clinical decision support. The National Quality Forum's Quality Data Model (QDM) provides the potential for more precisely defined, universally adopted electronic quality measures to automate measurement and compare and improve quality using electronic health information.

# Recommendations for Promoting Standards

Priorities and emphasis on health informatics standards will set expectations for the healthcare industry. HIM professionals are in a position to advocate the application of standards and educate their colleagues. Standards contribute to the longitudinal view of health information within and among systems by calling for unified expectations about how data is defined, stored, and transferred to meet the users' needs. The ability to use this information to drive decisions through business intelligence is an emerging role for HIM professionals. HIM professionals can increase their knowledge and serve as a professional resource for their organization by:

- **Building knowledge in health informatics standards.** Remain well informed on standards that impact patient data and health information business processes. At a minimum, understand the relationship and major topic areas. Refer to Appendix A for a variety of standards development organizations and their websites. Refer to Appendix B for additional reading materials.
- **Investigate current data systems.** Verify HIM business processes that connect to these functions. Determine whether data definition or format changes need to be planned in preparation for regulatory implementation. See that related HIM processes are updated as necessary.
- **Access information on existing healthcare standards.** Review current standards and how they generally fit into the health information systems environment in healthcare organizations.
- **Determine if the current healthcare standards are used in your organization.** Note that although standards may be adopted in your organization, the manner in which the standards are used can be highly customized so those vendors can accommodate product variability, among other reasons. Investigate how your organization uses message standards.

- **Form or join a quality and data analytics team in your organization.** Become familiar with the types of information being requested and where it fits into the standards realm. Create a matrix to track what types of data are transmitted, how it is transmitted, and what standards are used.
- **Keep pace with the healthcare industry's standards development.** Professionally endorse these efforts.
- **Join a standards development organization.** HIM professionals' contribution to this work is essential to ensure comprehensive attention to health information business processes. Membership fees are often nominal and progress can be tracked through the standards website, organization's Wiki page, or through personal participation in development sessions.

# Appendices

# Appendix A: Data Standards Resource

Working independently, standards development organizations (SDOs), associations, government agencies, and nongovernmental organizations have developed an array of data standards that address multiple areas in healthcare. Different standards are required to implement electronic health records (EHRs) and facilitate interoperability.

Standards are developed both nationally and internationally. The American National Standards Institute (ANSI) coordinates the development and use of standards within the United States and represents the needs and views of US stakeholders in standardization forums around the globe. ANSI facilitates the development of American National Standards by accrediting the procedures of standards development organizations. ANSI accreditation signifies that the procedures used by the SDO meet ANSI's essential requirements for openness, balance, consensus, and due process.

The tables in this Practice Brief appendix outlines a sample of some of the common standards used today. Placing a standard in one category is difficult because various standards can be classified in more than one way, so in some instances, standards are repeated in multiple categories.

# Structure and Content Standards

Standards establish definitions for data elements in an EHR system. They specify the type of data to be collected in each data field and the attributes and values of each field, all of which are captured in data dictionaries.

| Resource | Description | Source |
|---|---|---|
| ASTM Continuity of Care Record (CCR)<br><br>Designation: E 2369-05 | Data content and document standard for relaying a patient's core data set upon transfer to support continuity of care. | ASTM |
| HL7 Standards: Primary Standards | Most frequently used HL7 standards | HL7 |
| Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2.0 | CDA Release 2.0 provides an exchange model for clinical documents such as discharge summaries and progress notes. By leveraging the use of XML, the HL7 Reference Information Models (RIMs), and coded vocabularies, the CDA makes documents both machine-readable (so they are easily parsed and processed electronically) and human-readable (so they can be easily retrieved | HL7 |

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| | and used by the people who need them). CDA documents can be displayed using XML-aware Web browsers or wireless applications such as cell phones. | |
| HL7 Continuity of Care Document (CCD) | The CCD was developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation of the ASTM Continuity of Care Record for those institutions or organizations implementing the HL7 Clinical Document Architecture. | HL7 |
| HL7 Communication Standard, Version 3 | Version 3 of the HL7 Communication Standard uses a methodology based on a reference information model (i.e., data). HL7's primary goal for Version 3 is to offer a standard that is definite and testable and provides the ability to certify vendor conformance. | HL7 |
| HL7 Version 2 Product Suite | Messaging standard for electronic data exchange. | HL7 |
| HL7 Version 3 Product Suite | Messaging standard driven by messages and electronic documents in XML syntax. | HL7 |
| National Council for Prescription Drug Programs (NCPDP) Data Dictionary | Data dictionary and data content standards for pharmacy data, developed by NCPDP. | NCPDP |

# Functional EHR Standards

Standards that define the components an EHR needs to support the functions for which it was designed.

| **Resource** | **Description** | **Source** |
|---|---|---|
| HL7 Standards: EHR Profiles | These standards provide functional models and profiles that enable the constructs for management of electronic health records. | HL7 |
| Public Health Data Standards Consortium (PHDCS ) Functional Standards | A reference list of functions that may be present in an EHR system. The function list is described from a user perspective with the intent to enable consistent expression of system functionality. Through the creation of functional profiles, this model enables a standardized description and common understanding of functions sought or available in a given setting (i.e., intensive care, cardiology, office practice in one country, or primary care in another country). | PHDSC |

# Technical/Interoperability Standards

Standards that complement other types of standards and make interoperability possible by providing the roles, or protocols, of how these data are actually transmitted from one computer system to another.

| Resource | Description | Source |
|---|---|---|
| Digital Imaging and Communications in Medicine (DICOM) | Messaging standard for digital images. DICOM is produced and managed by the DICOM standards committee, which consists of vendors, user organizations, government agencies, and trade associations. | DICOM |
| HL7 Arden Syntax for Medical Logic Systems (v2.0-v2.9) | This specification addresses the sharing of computerized health knowledge bases among personnel, information systems, and institutions. The scope has been limited to those knowledge bases that can be represented as a set of discrete modules. Each module, referred to as a Medical Logic Module (MLM), contains sufficient knowledge to make a single decision. | HL7 |
| HL7 Clinical Document Architecture (CDA) Release 2.0 | CDA Release 2.0 provides an exchange model for clinical documents such as discharge summaries and progress notes. By leveraging the use of XML, HL7 Reference Information Models (RIMs), and coded vocabularies, the CDA makes documents both machine-readable (so they are easily parsed and processed electronically) and human-readable (so they can be easily retrieved and used by the people who need them). CDA documents can be displayed using XML-aware Web browsers or wireless applications such as cell phones. | HL7 |
| HL7 Continuity of Care Document (CCD) | The CCD was developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation of the ASTM Continuity of Care Record for those institutions or organizations implementing the HL7 Clinical Document Architecture. | HL7 |
| HL7 Clinical Context Management (CCOW) | The CCOW standards specify technology-neutral architectures, component interfaces, and data definitions as well as an array of interoperable technology-specific mappings of these architectures, interfaces, and definitions. | HL7 |
| HL7 Version 3 Communication Standard | Version 3 uses a methodology based on a reference information model (i.e., data). HL7's primary goal for Version 3 is to offer a standard that is definite and testable and provides the ability to certify vendors' conformance. | HL7 |
| HL7 Version 2.5 Communication Standard | HL7 Version 2.5 introduced a number of new events, segments, and messages, as well as an expanded chapter on control. | HL7 |
| HL7 Version 2.4 Communication Standard | HL7 Version 2.4 introduces conformance query profiles in chapter 5 and adds messages for laboratory automation, application management, and personnel management. | HL7 |

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| HL7 Version 2.3.1 Communication Standard | HL7 Version 2.3.1 includes an updated timing/quantity data type to manage order occurrences, updates to facilitate public health surveillance reporting, segments and data types to accommodate international paradigms for reporting names and pharmacy orders, and the addition of a new field to satisfy the CMS Medical Necessity requirements for outpatient services and federal requirements for Level 2 modifiers. | HL7 |
| IEEE 1073 Point of Care Medical Device Communication | A family of medical device communications standards which allows hospitals and other healthcare providers to achieve plug-and-play interoperability between medical instrumentation and computerized healthcare information systems, especially in a manner that is compatible with the acute care environment. | IEEE |
| NCPDP Batch Transaction Standard | The NCPDP Batch Transaction Format provides practical guidelines and ensures consistent implementation throughout the industry of a file submission standard to be used between pharmacies and processors, or pharmacies, switches, and processors. | NCPDP |
| NCPDP Billing Unit Standard<br><br>NCPDP has many standards, should we list them | Due to the number of processors, fiscal intermediaries, plan administrators, and Medicaid programs, the NCPDP Billing Unit Standard was created to promote a "common billing unit language" for the submission of prescription claims. | NCPDP |
| NCPDP Formulary and Benefit Standard | This NCPDP Formulary and Benefit Standard provides a standard means for pharmacy benefit payers (including health plans and pharmacy benefit managers) to communicate formulary and benefit information to prescribers via technology vendor systems. | NCPDP |
| S&I Framework | A collaborative of public and private sectors focusing on tools, services, and guidance of health information exchange. | S&I Framework |

## Vocabulary, Terminology, and Classification Systems

Systems that facilitate the organization, storage, and retrieval of healthcare data.

## Standards Development Organizations

Private or government organizations involved in the development of healthcare informatics standards at a national or international level.

| Resource | Description | Source |
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| AIIM | AIIM is an ANSI (American National Standards Institute) accredited standards development organization. AIIM also holds the Secretariat for the ISO (International Organization for Standardization) committee focused on information management compliance issues, TC171. | AIIM |
| Accredited Standards Committee (ASC) X12 | ASC X12 is a designated committee under the Designated Standard Maintenance Organization (DSMO), which develops uniform standards for cross-industry exchange of business transactions through electronic data, interchange (EDI) standards. ASC X12 is an ANSI-accredited standards development organization. | ASC X12 |
| American Dental Association (ADA) | The ADA is an ANSI-accredited standards developing organization that develops dental standards that promote safe and effective oral healthcare. | ADA |
| ASTM International | Formerly the American Society for Testing and Materials, ASTM International is an ANSI-accredited standards development organization that develops standards for healthcare data security, standard record content, and protocols for exchange of laboratory data. | ASTM |
| European Committee for Standardization (CEN) | CEN contributes to the objectives of the European Union and European Economic Area with voluntary technical standards that promote free trade, the safety of workers and consumers, interoperability of networks, environmental protection, exploitation of research and development programs, and public procurement. | CEN |
| Clinical and Laboratory Standards Institute (CLSI) | A global nonprofit standards development organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. Its core business is the development of globally applicable voluntary consensus documents for healthcare testing. | CLSI |
| Clinical Data Interchange Standards Consortium (CDISC) | CDISC is an open, multidisciplinary nonprofit organization that has established worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. | CDISC |
| Designated Standard Maintenance Organization (DSMO) | The DSMO was established in the final HIPAA rule and is charged with maintaining the standards for electronic transactions, developing or modifying an adopted standard. | DSMO |
| Health Industry Business Communications Council (HIBCC) | HIBCC is an industry-sponsored and supported nonprofit organization. As an ANSI-accredited organization, its primary function is to facilitate electronic communications by developing standards for information exchange among healthcare trading partners. | HIBCC |
| Health Level 7 (HL7) | An ANSI-accredited standards development organization that develops messaging, data content, and document standards to support the exchange of clinical information. | HL7 |

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| Institute of Electrical and Electronic Engineers (IEEE) | A national organization that develops standards for hospital system interface transactions, including links between critical care bedside instruments and clinical information systems. | IEEE |
| International Organization for Standardization (ISO) | ISO is a nongovernmental organization and network of national standards institutes from 157 countries. | ISO |
| National Council for Prescription Drug Programs (NCPDP) | A designated committee under the Designated Standard Maintenance Organization (DSMO) that specializes in developing standards for exchanging prescription and payment information. | NCPDP |
| National Information Standards Organization (NISO) | An ANSI-accredited nonprofit association that identifies, develops, maintains, and publishes technical standards to manage information. NISO standards address areas of retrieval, re-purposing, storage, metadata, and preservation. | NISO |
| National Uniform Billing Committee (NUBC) | A designated committee under the Designated Standard Maintenance Organization (DSMO) that is responsible for identifying data elements and designing the CMS-1500. | NUBC |
| National Uniform Claim Committee (NUCC) | The national group that replaces the Uniform Claim Form Task Force in 1995 and developed a standard data set to be used in the transmission of non-institutional provider claims to and from third-party payers. | NUCC |

## Coordinators and Promoters of Standards Development

| Resource | Description | Source |
|---|---|---|
| AHIMA | AHIMA is the premier association of HIM professionals. AHIMA's 67,000 members are dedicated to the effective management of personal health information needed to deliver quality healthcare to the public. Founded in 1928 to improve the quality of medical records, AHIMA is committed to advancing the HIM profession in an increasingly electronic and global environment through leadership in advocacy, education, certification, and lifelong learning. | AHIMA |
| American National Standards Institute (ANSI) | ANSI coordinates the development and use of voluntary consensus standards in the United States and represents the needs and views of US stakeholders in standardization forums around the globe. It oversees the creation, promulgation and use of thousands of norms and guidelines that directly affect businesses in nearly every sector. ANSI is also actively engaged in accrediting programs that assess conformance to standards including globally recognized cross-sector programs such as the ISO 9000 (quality) and ISO 14000 (environmental) management systems. | ANSI |

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| Healthcare Information and Management Systems Society (HIMSS) | A membership organization exclusively focused on providing global leadership for the optimal use of healthcare information technology and management systems for the betterment of healthcare. | HIMSS |
| Workgroup for Electronic Data Interchange (WEDI) | A subgroup of Accreditation Standards Committee X12 that has been involved in developing electronic data interchange standards for billing transactions. | WEDI |

# Data Standards Initiatives and Resources

| Resource | Description | Source |
|---|---|---|
| National e-Health Collaborative (NeHC) | A federally chartered commission that provides input and recommendations to HHS on how to make health records digital and interoperable and ensure that the privacy and security of those records are protected in a smooth, market-led way. The mission of the National e-Health Collaborative (NeHC) is to help address barriers that could thwart the nation's progress toward interoperability. | NeHC |
| Certification Commission for Healthcare Information Technology (CCHIT) | CCHIT is an independent, voluntary, private-sector initiative organized to accelerate the adoption of robust, interoperable healthcare information technology throughout the United States by creating an efficient, credible, sustainable mechanism for the certification of healthcare IT products. | CCHIT |
| Health IT Policy Committee | The Health IT Policy Committee will make recommendations to the National Coordinator for Health IT on a policy framework for the development and adoption of a nationwide health information infrastructure, including standards for the exchange of patient medical information. | HIT Policy Committee |
| Health IT Standards Committee | The Health IT Standards Committee is charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. Initially, the Health IT Standards Committee will focus on the policies developed by the Health IT Policy Committee's initial eight areas. | HIT Standards Committee |
| Public Health Data Standards Consortium (PHDSC) | The Public Health Data Standards Consortium (The Consortium) is a national nonprofit member-based partnership of federal, state, and local health agencies; national and local professional associations; and public and private sector organizations and individuals. Its goal is to empower the | PHDSC |

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| | healthcare and public health communities with health information technology standards to improve individual and community health. | |
| National Institute on Standards and Technology(NIST) | An agency of the Department of Commerce that creates many of the federal government's security standards, which are mandated for use in government agencies and often by their contractors. | NIST |
| National Resource for Global Standards | A search engine that provides users with standards-related information from a wide range of developers, including organizations accredited by the American National Standards Institute (ANSI), other US private sector standards bodies, government agencies, and international organizations. | NSSN |
| Office of the National Coordinator for Health Information Technology (ONC) | ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009. The Office of the National Coordinator for Health Information Technology provides leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of healthcare and the ability of consumers to manage their care and safety. | ONC |
| Public Health Information Network (PHIN) | The Public Health Information Network (PHIN) is CDC's vision for advancing fully capable and interoperable information systems in the many organizations that participate in public health. PHIN is a national initiative to implement a multi-organizational business and technical architecture for public health information systems. | PHIN |
| Standards.gov | Maintained and operated by the National Institute of Standards and Technology (NIST), Standards.gov supports the requirements of the National Technology Transfer and Advancement Act (NTTAA), which became law in March 1996. The NTTAA directs federal agencies with respect to their use of private sector standards and conformity assessment practices. The objective is for federal agencies to adopt private sector standards, wherever possible, in lieu of creating proprietary, non-consensus standards. | NIST |
| Unified Medical Language System (UMLS) | A multipurpose resource that includes concepts and terms from many different source vocabularies developed. | UMLS |

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| United States Health Information Knowledgebase (USHIK) | USHIK is a publicly accessible registry and repository of healthcare-related data, metadata, and standards. USHIK is funded and directed by the Agency for Healthcare Research and Quality (AHRQ) with management support in partnership with the Centers for Medicare & Medicaid Services (CMS). | USHIK |
| Web Ontology Language (OWL) | A language designed for use by software applications that process the content of information instead of just presenting information to humans. There are three sublanguages currently available: OWL Lite, OWL DL, and OWL Full. | OWL |

| **Resource** | **Description** | **Source** |
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| Alternative Billing Concepts (ABC) Codes | ABC Codes contain more than 4,000 codes that describe what is said, done, ordered, prescribed, or distributed by providers of alternative medicine. Disciplines covered by this system include acupuncture, holistic medicine, massage therapy, homeopathy, naturopathy, ayurvedic medicine, chiropractors, and midwifery. | ABC Coders |
| Clinical Care Classification (CCC) System | A classification system consisting of two interrelated taxonomies: the CCC of Nursing Diagnoses and Outcomes, and the CCC of Nursing Interventions and Actions. Both taxonomies are classified by care components, or clusters of elements that represent behavioral, functional, physiological, or psychological care patterns. | CCC System |
| Current Dental Terminology (CDT) | CDT is a coding system developed to report services performed by the dental profession. CDT was formally called the Uniform Code on Dental Procedures and Nomenclature. | CDT |
| Current Procedural Terminology (CPT) | CPT is a comprehensive list of descriptive terms and codes published by the American Medical Association (AMA) and used for reporting diagnostic and therapeutic procedures and other medical services performed by physicians. | CPT |
| Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) | The DSM-5 is a nomenclature to standardize the diagnostic process for patients with psychiatric disorders. | DSM-5 |
| Global Medical Device Nomenclature (GMDN) | The GMDN is a collection of internationally recognized terms used to describe and catalog medical devices—in particular products used in | GMDN |

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| | the diagnosis, prevention, monitoring, treatment, or alleviation of disease or injury in humans. | |
| Healthcare Common Procedure Coding System (HCPCS) Code Set Level I | Level I of the HCPCS is comprised of CPT codes that are used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. These healthcare professionals use the CPT to identify services and procedures for which they bill public or private health insurance programs. Level I of the HCPCS, the CPT codes, does not include codes needed to separately report medical items or services that are regularly billed by suppliers other than physicians. | HCPCS |
| Healthcare Common Procedure Coding System (HCPCS) Code Set Level II | Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. | HCPCS |
| International Classification of Diseases for Oncology (ICD-O) | The ICD-O is the standard tool for coding diagnoses of neoplasms in tumor and cancer registrars and in pathology laboratories. ICD-O is a dual classification with coding systems for both topography and morphology. The topography code describes the site of origin of the neoplasm and uses the same three-character and four-character categories as in the neoplasm section of chapter II, ICD-10. | ICD-O |
| International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) | Classification system used in the United States to code and classify diagnoses from inpatient and outpatient records and to code inpatient procedures. ICD-9-CM is managed by the National Center for Health Statistics. | ICD-9-CM |
| International Classification of Functioning, Disability and Health (ICF) | The ICF is a health and health-related classification system that reports body functions and structures, activities, and participation. | ICF |
| International Classification of Primary Care, Second edition (ICPC-2) | ICPC is a reliable classification system for primary care physicians that enable the labeling of the most prevalent conditions that exist in the community as well as symptoms and complaints. | ICPC-2 |
| International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10) | The ICD-10 version of the disease classification system was developed by the World Health Organization and is used to report morbidity and mortality information worldwide. Effective with deaths occurring in 1999, the US replaced ICD-9 with ICD-10 for mortality report. | ICD-10 |

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| International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modification (ICD-10-CM) | ICD-10-CM is the future US coding classification system for healthcare professionals and institutions to report morbidity and mortality data. | ICD-10-CM |
| International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Procedure Coding System (ICD-10-PCS) | ICD-10-PCS is the future US coding classification for institutions to report procedure information. | ICD-10-PCS |
| Logical Observation Identifiers, Names and Codes (LOINC) | The LOINC coding system electronically exchanges laboratory and clinical information. | LOINC |
| MEDCIN | MEDCIN is a terminology and presentation engine. It includes more than 250,000 clinical data elements encompassing symptoms, history, physical examination, tests, diagnoses, and therapy. | MEDCIN |
| Medical Dictionary for Regulatory Activities (MedDRA) | MedDRA is a global standard medical terminology. It is expected to supersede or replace terminologies currently in use with the medical product development process. | MedDRA |
| National Drug Code (NDC) | NDC is a coding system for pharmacies to report services, supplies, drugs, and biologic information. | NDC |
| North American Nursing Diagnosis Association (NANDA) International Taxonomy II | Organization of the NANDA-International nursing diagnoses has evolved from an alphabetical listing in the mid-1980s to a conceptual system that guides the classification of nursing diagnoses in taxonomy. | NANDA |
| Nursing Interventions Classification (NIC) | NIC is a comprehensive, research-based, standardized classification of interventions that nurses perform. | NIC |
| Nursing Outcomes Classification (NOC) | NOC is a comprehensive, standardized classification of patient/client outcomes developed to evaluate the effects of nursing interventions. | NOC |
| Omaha System | The Omaha System is a research-based, comprehensive taxonomy designed to generate meaningful data following usual or routine documentation of client care. | Omaha System |

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| RxNorm | RxNorm is a clinical drug nomenclature that provides standard names for clinical drugs (active ingredient, strength, and dose form) and for dose forms as administered. | RxNorm |
| Systematized Nomenclature of Dentistry (SNODENT) | SNODENT is a systematized nomenclature of dentistry containing dental diagnoses, signs, symptoms, and complaints. | SNODENT |
| Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) | SNOMED CT is a comprehensive clinical terminology and infrastructure that enables a consistent way of capturing, sharing, and aggregating health data across specialties and sites of care. | SNOMED CT |
| Universal Medical Device Nomenclature System (UMDNS) | UMDNS is a standard international nomenclature and coding system used to facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. | ECRI<br><br>WHO |

# Appendix B: Recommended Reading

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## Prepared by

Kathy M. Johnson, RHIA
Annessa Kirby
Lesley Kadlec, MA, RHIA
Neysa I. Noreen, RHIA
Lisa Brooks Taylor, RHIA
Joy L. Updegrove, RHIA, CHC
Diana Warner, MS, RHIA, CHPS, FAHIMA

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Kathy Andersen, RHIT, CCS
Cecilia Backman, MBA, RHIA, CPHQ
Marlisa Coloso, RHIA, CCS

Julie Dooling, RHIA
Katherine Downing, MA, RHIA, CHP, PMP
Diana Reed, RHIT, CCS-P
Theresa Rihanek, MHA, RHIA, CCS
Cheryll Rogers, RHIA, CDIP, CCS, CTR
Angela Rose, MHA, RHIA, CHPS, FAHIMA
Terry J. Santana-Johnson, RHIT, CDIP, CCS, CCS-P
Patrice Spath, MA, RHIT, CHTS-IM
Lori McNeil Tolley, MEd, RHIA

## Original Authors

Susan Fenton, MBA, RHIA
Kathy Giannangelo, MA, RHIA, CCS
Crystal Kallem, RHIT
Rita Scichilone, MHSA, RHIA, CCS, CCS-P, CHC

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