

External Standards Organizations

Healthcare Informatics Standards Development Organizations

Note to the HIMSS I&I reader:

The following pages cover healthcare informatics standards developers and regulatory bodies. For each organization, we need to determine at what level (if any) we need to be aware and/or involved in its work about standards and interoperability. Please note that this list is not exhaustive. There are many other organizations that are not included. If there are any ones missing that should be here, please let me know.

Siemens was a heavy contributor to this content based on a much larger compendium that was developed for internal use.

External Standards Organizations

ANSI-HISB

(American National Standards Institute Healthcare Informatics Standards Board)

Purpose/Business Justification:

ANSI HISB provides an open, public forum for the voluntary coordination of healthcare informatics standards among all United States' standard developing organizations. Many major developers of healthcare informatics standards in the United States participate in ANSI HISB. ANSI-HISB is underwritten by the US Department of Health and Human Services, and the Centers for Medicare and Medicaid Services are heavily represented on this board.

As of January 2003, ANSI HISB has 30 voting members and 41 non-voting observer members:

- Companies / Manufacturers - 2 voting, 17 observer
- Standards organizations - 11 voting ([AMA](#), [ADA](#), [ASC X12](#), [ASTM E31](#), [CAP](#), [HIBCC](#), [HL7](#), [IEEE 1073](#), [NCCLS](#), [NCPDP](#), [UCC](#)), 3 observer ([DISA](#), [INCITS](#), [JCAHO](#))
- Professional Societies - 2 voting, 4 observer
- Trade Associations - 2 voting, 4 observer
- US government agencies - 11 voting, 1 observer
- Standards users (providers, insurers) and other - 2 voting (Kaiser, Mayo), 12 observer

Attendance mainly is by standards organizations and US government representatives. There is only two healthcare IT vendor members, Per Se and Pfizer.

Deleted: one

Although ANSI HISB would *like* to be the required coordinator of US healthcare standards, they are not in reality. They recognize the existence of DICOM, IHE, and other non-ANSI groups with healthcare-relevant work but there is no strategy in effect to include them.

The US technical advisory group (TAG) serves as a bridge organization between ANSI-HISB and ISO/TC 215. ANSI has assigned the secretariat for the TAG to [HIMSS](#).

ASC X12

(Accredited Standards Committee X12)

Purpose/Business Justification:

ASC X12 is a Designated Standards Maintenance Organization (DSMO) for HIPAA. X12 is an Accredited Standards Committee (ASC), under the American National Standards Institute (ANSI). X12 developed the National EDI transaction standards for electronic commerce. EDI transaction standards developed by X12 cover such industries as automobile, banking, education,

External Standards Organizations

purchasing, materials management, government, and insurance. The X12 transactions are only used within the United States (and Canada).

As ASC X12 continues to enhance its EDI transaction sets, committee members are building next-generation e-business standards as demonstrated through its:

- Joint initiative with the UN/EDIFACT Working Group (EWG)
- Participation in the Electronic Business XML (ebXML) group
- Integration of business modeling and XML into the X12 standards development process using UML.

To drive the development of these two complementary standards, ASC X12 and EWG are creating a single set of business objects (core components) that are valid within the UN/EDIFACT and ASC X12 business processes. This single set of core business components will be the basis for future developments with XML and other emerging technologies.

[ASTM E31](#)

(ASTM International, Healthcare Informatics Committee)

Purpose/Business Justification:

ASTM E31 develops standards related to the architecture, content, storage, security, confidentiality, functionality, and communication of information used within healthcare and healthcare decision making, including patient-specific information and knowledge. The committee, with current membership of approximately 270 members, currently holds jurisdiction of over 30 approved standards and additional draft standards. Approved standards are published annually in June in the Annual Book of ASTM Standards, Volume 14.01.

ASTM work is widely referenced but not as widely implemented. This situation may change with the emergence of the Continuity of Care Record (CCR) standards from the E31.28 committee.

[Chaired by: Peter Weagermann](#)

[CDISC](#)

(Clinical Data Interchange Standards Consortium)

Purpose/Business Justification:

CDISC is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of

External Standards Organizations

clinical trials data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to lead the development of global, vendor-neutral, platform independent standards to improve data quality and accelerate product development in our industry. CDISC's core principles are:

- Lead the development of standard data models that improve process efficiency while supporting the scientific nature of clinical research.
- Recognize the ultimate goal of creating regulatory submissions that allow for flexibility in scientific content and are easily interpreted, understood, and navigated by regulatory reviewers.
- Acknowledge that the data content, structure and quality of the standard data models are of paramount importance, independent of implementation strategy and platform.
- Maintain a global, multidisciplinary, cross-functional composition for CDISC and its working groups.
- Work with other professional groups to encourage that there is maximum sharing of information and minimum duplication of efforts.
- Provide educational programs on CDISC standards, models, values and benefits.
- Accomplish the CDISC goals and mission without promoting any individual vendor or organization.

The CDISC data models will ultimately support the end-to end data flow of clinical trials, from the source(s) into an operational database, through analysis to regulatory submission. The sources of data that are relevant to CDISC vary among patient records (e.g., case report form data), clinical laboratory data, data from contract research organizations, shared data between companies with corporate mergers or development partners, and other sources.

CEN is the European Committee for Standardization similar to ISO which is Global.

Formatted: Index 1

CEN, the European Committee for Standardization, was founded in 1961 by the national standards bodies in the European Economic Community and EFTA countries.

Now CEN is contributing to the objectives of the European Union and European Economic Area with voluntary technical standards which promote free trade, the safety of workers and consumers, interoperability of networks, environmental protection, exploitation of research and development programmes, and public procurement.

There are over 250 technical committees, some in Healthcare. The committee listed below is for health informatics.

Deleted: ¶

Formatted: Normal

CEN/TC 251 Technical Committee

External Standards Organizations

(European Standardization of Health Informatics)

Purpose/Business Justification:

CEN/TC 251 promotes standardization in the field of Health Information and Communications Technology to achieve compatibility and interoperability between independent systems and to enable modularity.

[Chaired by: Gunnar Klein of Standards Institute in Sweden.](#)

[DICOM](#)

(Digital Imaging and Communications in Medicine)

Purpose/Business Justification:

The DICOM Standards Committee exists to create and maintain international standards for communication of biomedical diagnostic and therapeutic information in disciplines that use digital images and associated data. The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide. DICOM is a cooperative standard. Therefore, connectivity works because vendors cooperate in testing via scheduled public demonstration, over the Internet, and during private test sessions. Every major diagnostic medical imaging vendor in the world and many Information System vendors have incorporated the standard into their product design and most are actively participating in the enhancement of the standard. Most of the professional societies throughout the world have supported and are participating in the enhancement of the standard as well.

[HL7](#)

(Health Level Seven, Inc.)

Purpose/Business Justification:

HL7 is also one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. HL7 develops the most widely used specifications for messaging standards that enable disparate healthcare applications to exchange clinical and administrative data. HL7 members are known collectively as the Working Group, which is currently organized into Technical Committees (TC), and Special Interest Groups (SIG). The HL7 Working Group conducts three one-week external meetings each year. The technical committees are directly responsible for the content of the Standards. Special interest groups serve as a test bed for exploring new areas that may need coverage in HL7's published standards.

External Standards Organizations

HL7 standards work is international in scope. There are more than 40 HL7 international affiliates. As of the fall 2002 working group meeting the Memorandum of Understanding between HL7 and [CEN](#) has been revitalized. HL7 standards are also being adopted by [ISO](#), e.g. the HL7 Message Development Framework is recognized as ISO 17113 and HL7 v2.4, v3 data types (subset), and the v3 Reference information model are proposed standards.

[IEEE 1073](#)

(IEEE 1073 Point of Care Medical Device Communication Standards)

Purpose/Business Justification:

IEEE 1073 is the technical committee within [IEEE](#) concerned with standards for point-of-care medical device communications. IEEE 1073 is working closely with [ISO](#) and [CEN](#) to provide a common international set of standards in its subject matter domain.

[ISO/TC 215](#)

(ISO Healthcare Informatics Technical Committee)

Purpose/Business Justification:

ISO/TC 215 is concerned with standardization in the field of information for health, and Health Information and Communications Technology to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancies.

There are eight working groups:

- WG 1 Data Structure
- WG 2 Data Interchange
- WG 3 Semantic content
- WG 4 Security
- WG 5 Healthcards
- WG 6 Pharmacy and medication business
- WG 7 Devices
- WG 8 Business Requirements for an EHR

Deleted: six

Deleted: Health records and modeling coordination

Deleted: Messaging and communication

Deleted: Health concept representation

Deleted:

Deleted: E-p

Deleted: cines

Formatted: Bullets and Numbering

ISO is now adopting HL7, [IEEE](#) and [DICOM](#) standards:

External Standards Organizations

- The HL7 Message Development Framework is recognized as ISO 17113
- HL7 v2.4, v3 data types (subset) are proposed standards.
- HL7 v3 Reference information model will be re-published as an ISO and HL7 standard
- IEEE 1073 device standards are moving through this ISO committee
- DICOM is being proposed as a reference standard

Deleted: ,

Deleted: and the v3 Reference information model

Formatted: Bullets and Numbering

The Secretariats for ISOTC 215 and for the US Technical Advisory Group are held by [HIMSS](#)

[NCPDP](#)

(National Council of Prescription Drug Programs)

Purpose/Business Justification:

NCPDP is a non-profit, standards development organization working: to create and promote data interchange and processing standards to the **pharmacy services** sector of the health care industry, and to provide a continuing source of accurate and reliable information supporting the needs of their membership. Membership is comprised of individuals and organization representatives from all segments of the third-party prescription drug program industry, including drug manufactures, drug distributors, insurance carriers, prescription benefit managers, independent pharmacies, chain pharmacies, federal and state government agencies, computer companies, telecommunication system vendors, consultants, and mail service companies. Ninety percent of community pharmacies and nearly seventy percent of the nation's outpatient prescriptions use the NCPDP standard. NCPDP is working in conjunction with HL7 and X12 to assure better harmonization with the drug prescription messages of HL7 and the billing messages of X12.

[WEDI/SNIP](#)

(Workgroup for Electronic Data Interchange/Strategic National Implementation Process)

Purpose/Business Justification:

The WEDI mission is to foster widespread support for the adoption of electronic commerce within healthcare.

The WEDI/ HIPAA SNIP Task Group has been established to meet the immediate need to assess industry-wide HIPAA Administrative Simplification implementation readiness and to bring about the national coordination necessary for successful compliance. SNIP is a forum for coordinating the necessary dialog among industry implementers of the HIPAA standards. SNIP will identify industry "best practices" for implementation of HIPAA standards. SNIP will identify coordination issues leading toward their resolution as industry adopted "best practices."

External Standards Organizations

SNIP will adopt a process that includes an outreach to current industry initiatives, an information gap analysis, and recommendations on additional initiatives to gap-fill.

The WEDI/SNIP purpose is to promote general healthcare industry readiness to implement the HIPAA standards, identify education and general awareness opportunities for the healthcare industry to utilize, recommend an implementation time frame for each component of HIPAA for each stakeholder [Health Plan, Provider, Clearinghouse, Vendor] and identify the best migration paths for trading partners, establish opportunities for collaboration, compile industry input, and document the industry "best practices", and identify resolution or next steps where there are interpretation issues or ambiguities within HIPAA Administrative Simplification standards and rules.

External Standards Organizations

Cross-Industry Informatics Standards Development Organizations

The following pages cover cross-industry informatics standards development organizations and regulatory bodies. This is meant as comprehensive but not exhaustive data, as the informatics industry is always generating or revising standards.

External Standards Organizations

IEEE

(Institute of Electrical and Electronics Engineers)

Purpose/Business Justification:

The IEEE (Eye-triple-E) is a non-profit, technical professional association of more than 377,000 individual members in 150 countries. Through its members, the IEEE is a leading authority in technical areas ranging from computer engineering, biomedical technology and telecommunications, to electric power, aerospace and consumer electronics, among others.

Through its technical publishing, conferences and consensus-based standards activities, the IEEE

- Produces 30 percent of the world's published literature in electrical engineering, computers and control technology,
- Holds annually more than 300 major conferences, and
- Has nearly 900 active standards with 700 under development.

- Medical Device Standards 1073 series

Formatted: Bullets and Numbering

W3C

(Worldwide Web Consortium)

Purpose/Business Justification:

The World Wide Web Consortium (W3C) develops interoperable technologies (specifications, guidelines, software, and tools) to lead the Web to its full potential. W3C is a forum for information, commerce, communication, and collective understanding. Standards from W3C include HTML, XML, and related Internet messaging protocols and grammars.

External Standards Organizations

Healthcare Informatics Standards Advocates

The following pages cover healthcare informatics standards advocacy organizations that we must at least maintain awareness of in product development and marketing. This is meant as comprehensive but not exhaustive data, as the healthcare informatics arena often generates new advocacy organizations.

[AFEHCT](#)

(Association for Electronic Health Care Transactions)

Purpose/Business Justification:

AFEHCT is an association dedicated to supporting the use of EDI and standards in healthcare to improve efficiency, effectiveness, and quality of health information, while reducing the cost of health care. It is an industry group dedicated to effectively addressing detailed issues to meet the challenges of health care EDI, as well as an organization that addresses technical and policy issues. AFEHCT is a recognized leader by government health care and legislative organizations, and is recognized in Washington as the PRO-ACTIVE health care EDI Industry Association.

This organization has a very strong influence on capital hill in both congress and the executive branch. This organization represents HIS vendors, but in particular clearinghouses. AFEHCT has working relationships with CMS, DHHS, several Senate and House committees, and Senate and House members.

[AHIMA](#)

(American Health Information Management Association)

Purpose/Business Justification:

AHIMA is a professional association that represents specially educated health information management professionals who work throughout the healthcare industry. Health information management professionals serve the healthcare industry and the public by managing, analyzing, and utilizing data vital for patient care -- and making it accessible to healthcare providers when it is needed most.

To ensure that its members meet professional standards of excellence, AHIMA issues credentials in health information management. Members earn credentials through a combination of education and experience, and finally performance on national certification exams.

- **RHIA** Registered Health Information Administrator
- **RHIT** Registered Health Information Technician
- **CCS** Certified Coding Specialist

External Standards Organizations

- CCS-P Certified Coding Specialist - Physician-based
- CCA Certified Coding Associate
- **CHP Certified in Healthcare Privacy**

Formatted: Font: (Asian) Arial
Unicode MS

Formatted: Bullets and Numbering

Following their initial certification, AHIMA members must maintain their credentials and thereby the highest level of competency for their employers and consumers through rigorous continuing education requirements.

The [Foundation of Research and Education](#) (FORE) is the charitable affiliate organization of AHIMA that provides the financial and intellectual resources to support continuous innovation and advances in health information management through research, education, and public awareness initiatives.

AMIA

(American Medical Informatics Association)

Purpose/Business Justification:

The American Medical Informatics Association is a nonprofit organization of individuals, institutions, and corporations dedicated to developing and using information technologies to improve health care.

AMIA was formed in 1990 by the merger of three organizations - the American Association for Medical Systems and Informatics (AAMSI), the American College of Medical Informatics (ACMI), and the Symposium on Computer Applications in Medical Care (SCAMC). The 3,200 members of AMIA include physicians, nurses, computer and information scientists, biomedical engineers, medical librarians, and academic researchers and educators. AMIA is the official United States representative organization to the International Medical Informatics Association.

Relevant activities of the association include:

- The AMIA Annual Symposium is a five day conference on medical informatics, featuring scientific and applied papers, panels, work shops, tutorials, and systems demonstrations.
- The AMIA Spring Congress is a smaller meeting, focusing on specific themes within medical informatics, with recent and upcoming examples including medical informatics education, the role of informatics in quality improvement in health care, and informatics and public health.
- The Journal of the American Medical Informatics Association - JAMIA - is AMIA's professional journal.
- Public policy initiatives focusing on a variety of important issues and on how measures at the federal, legislative, and judicial levels affect the practice of health care. AMIA has been

External Standards Organizations

particularly involved in the complex issues surrounding the privacy and confidentiality of electronic medical records.

CCHIT

(Certification Consortium on Health Information Technology)

CCHIT was formed in July, 2004 by three leading industry associations in healthcare information management and technology – American Health Information Management Association ([AHIMA](#)), Healthcare Information and Management Systems Society ([HIMSS](#)), and The National Alliance for Health Information Technology (Alliance). The mission of CCHIT is 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's initial focus is on the certification of EHRs and related clinical IT products in the physician office and ambulatory setting. More information on the CCHIT is available at www.cchit.org.

Connecting for Health

Purpose/Business Justification:

Connecting for Health, a Public-Private Collaborative, an effort convened by the Markle Foundation, intends to address the challenges of mobilizing information to improve quality, conduct timely research, empower patients to become full participants in their care, and bolster the public health infrastructure. The purpose of the Collaborative is to catalyze specific actions on a national basis that will rapidly clear the way for an interconnected, electronic national health information infrastructure. The Collaborative plans to accomplish this by focusing on three key areas:

- Accelerating the rate of adoption of national clinical data standards throughout the nation's health care system in order to facilitate interoperability.
- Identifying practical strategies and solutions for developing an interconnected electronic infrastructure that will ensure the secure and private transmission of medical information and support the continuity of personal health information across plans and providers.
- Actively working to understand what consumers will need and expect from an interconnected health information system and identifying key steps for meeting their needs.

eHealth Initiative

The eHealth Initiative and the Foundation for eHealth Initiative are independent, non-profit affiliated organizations whose missions are the same: to drive improvement in the quality, safety, and efficiency of healthcare through information and information technology.

External Standards Organizations

Both organizations are focused on engaging multiple and diverse stakeholders -- including hospitals and other healthcare organizations, clinician groups, employers and purchasers, health plans, healthcare information technology organizations, manufacturers, public health agencies, academic and research institutions, and public sector stakeholders -- to define and then implement specific actions that will address the quality, safety and efficiency challenges of our healthcare system through the use of interoperable information technology.

HIMSS

(Healthcare Information and Management Systems Society)

Purpose/Business Justification:

HIMSS provides leadership in healthcare for the advancement and management of information technology. HIMSS provides services to IT health care corporations plus firms and professionals from around the globe. Through the collaboration of 41 chapters and 20 special interest groups, HIMSS directs and shapes the healthcare industry, encourages emerging technology and promotes public policies to improve healthcare delivery.

Note: As of January 2002, HIMSS has merged with the Center for Healthcare Information Management (CHIM). As of July, 2002, HIMSS also merged with CPRI-HOST.

In 2003 HIMSS became the Secretariat for [ISO/TC 215](#).

IHE

(Integrating the Healthcare Enterprise)

Purpose/Business Justification:

IHE is an joint initiative started by [HIMSS](#) and [RSNA](#). It is seen by medical specialists and other care providers, administrators, information technology professionals and industry to improve the way computer systems in healthcare share information. HIMSS is strongly promoting IHE as a means to help fulfill the national health information infrastructure projects in the US and in other countries.

IHE is seen as a certification authority in Europe, although it is not an SDO. IHE promotes coordinated use of established communications standards -- such as DICOM and HL7 plus cross-industry standards from IETF -- to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively.

Although IHE started with Radiology, it has expanded its scope to include IT Infrastructure,

External Standards Organizations

Cardiology, Laboratory, and HIS applications. This includes coordinating trade show demos with HL7 plus expanding the technical framework with applications and infrastructure elements that are common among healthcare IT systems and IT-enabled medical devices.

Interoperability Consortium

Purpose/Business Justification:

The Interoperability Consortium is a newly- formed consortium that includes eight of the largest technology companies including IBM, Microsoft, Intel, Oracle, Cisco, and HP. The major goal of the consortium is to “embrace open technology standards as the software building blocks for the NHIN.” The Interoperability Consortium has submitted its recommendations to the government and has recommended that the government establish a non-profit company called the National Health Technology Standards Corporation to be the arbitrator of technology standards, with its board members appointed by the HHS.

JHITA

(Joint Healthcare Information Technology Alliance)

Purpose/Business Justification:

AHIMA, AMIA, CHIM, CHIME and HIMSS joined together to form JHITA with the intent of pursuing a wide variety of objectives related to the common good of the Alliance membership. Two areas of focus for the Alliance are:

- "To provide appropriate advocacy for legislation/regulation promoting the effective use of technology and its management, telecommunications, and business process re-engineering."
- "To be a dynamic force in our industry by developing jointly sponsored offerings including educational programs, market focus groups, research, services and activities relating to information technology and management, telecommunications, and business process re-engineering."

The Alliance’s advocacy activities focus on identifying issues having the broadest impact on the Alliance membership. The Alliance monitors national legislative and regulatory activities and reports on those activities to the Alliance membership through routine summaries, Advocacy Papers on topics of particular interest to the membership, and presentations at selected Alliance member organization events. As issues of sufficient interest and concern arise, the Alliance pursues more advanced activities, to include meetings with legislators and regulators to convey the position of the Alliance membership.

External Standards Organizations

The Leapfrog Group

Purpose/Business Justification

Composed of more than 120 public and private organizations that provide health care benefits, The Leapfrog Group works with medical experts throughout the U.S. to identify problems and propose solutions that it believes will improve hospital systems that could break down and harm patients. Representing approximately 33 million health care consumers in all 50 states, Leapfrog provides important information and solutions for consumers and health care providers.

The case for Leapfrog, from the web site:

- American health care remains very far below obtainable levels of error prevention and overall customer value.
- Consumers have not been educated appropriately about the extent of preventable mistakes in health care, nor given information to help them select facilities that have key patient safety practices in place.
- Providers have not been given the rewards and incentives necessary to sustain the continuous process improvements that can lead to significant reductions in medical mistakes.
- Purchasing strategies need to champion superior overall value and focus on specific innovations offering scientifically validated "leaps" in reducing preventable medical mistakes.

By providing a viable forum through which each of these issues can be addressed, The Leapfrog Group aims to enhance the dialogue among purchasers, providers and consumers, and significantly impact the efforts to address the yearly death toll from preventable medical mistakes.

Medical Records Institute

Purpose/Business Justification:

The Medical Records Institute's mission is to promote and enhance the journey towards electronic health records, e-health, mobile health, and related applications of information technologies.

MRI achieve its mission by:

- Serving as an international forum for sharing knowledge, experience, and solutions
 - with the healthcare community at large, but especially with healthcare practitioners, as well as professionals in information system and health information management,

External Standards Organizations

- with vendors and vendor executives in regard to market strategies and technologies, and
- with patients, patient advocates and agents, and the general public, regarding the management of personal health information.
- Conducting international conferences, seminars, and other events, including [Toward an Electronic Patient Record](#) (TEPR), the annual conference on e-health and clinical IT issues.
- Publishing the Health IT Advisory Report and web sites
- Supporting, coordinating, and leading the process of creating healthcare information standards.

Peter Weageman, CEO, is the chair of [ASTM E31](#). He is past chair of [ANSI-HISB, US TAG for ISO/TC 215, and ISO/TC215 Task Force on Consumer Health Issues](#) and a member of the Information Management Workgroup of [JCAHO](#).

Deleted: ,

Deleted: the US TAG for [ISO/TC 215](#), and [ISO/TC215](#) Task Force on Consumer Health Issues.

Jeffrey Blair, Vice President, is vice-chair of the Subcommittee on Standards and Security of the [NCVHS](#) and is a member of [AMIA](#), the [ASTM E31](#) Committee on Health Informatics, the [HL7](#) Vocabulary technical committee, the [NHII](#) Task Force for [HIMSS](#), and the [NCVHS NHII](#) work group.

[NAHIT](#)

(National Alliance for Health Information Technology)

Purpose/Business Justification:

The mission of NAHIT is to "improve quality and performance through standards-based information systems." They believe this will require fundamental change driven by multiple stakeholders, through an inclusive and relentless process.

Critical guiding principles:

- Convening players in the Alliance committed to meaningful change and willing to participate in seeking better solutions.
- Targeting real, understandable benefits.
- Creating and implementing distinct projects will yield a viable health care information systems infrastructure accessible to all interested parties.

NAHIT's membership consists of:

- Provider-based Organizations - Hospitals, health systems, medical groups, associations, etc.
- Technology Companies/Vendors - MIS, consulting firms, technology software, etc.
- Aligned Stakeholders - Standards groups, government, payers, etc.

External Standards Organizations

The Alliance intends to promote voluntary standards to facilitate the interoperability of information systems.

External Standards Organizations

Federal Agencies: Standards Development and Advocacy

The following agencies either are directly involved in the development of standards or require compliance to recognized standards.

For each of the following we need to determine our role.

External Standards Organizations

[DHHS](#)

(US Department of Health and Human Services)

Purpose/Business Justification:

DHHS is responsible for a variety of healthcare standards:

- The [Centers for Medicare & Medicaid Services \(CMS\)](#) is responsible for Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIPError! Bookmark not defined.) programs. This includes the DRG and APC coding systems and related policies. CMS also regulates all laboratory testing (except research) performed on humans in the United States.
- CMS is responsible for the [Health Insurance Portability and Accountability Act \(HIPAA\)](#). Conformance with HIPAA's administrative simplification regulatory standards is mandatory for product acceptance in the US market. CMS maintains these standards in associations with its designated standards maintenance organizations (DSMOs).
- Commission on Systemic Interoperability (CMS Medicare Modernization Act)
- The [National Committee on Vital and Health Statistics \(NCVHS\)](#) serves as the statutory [42 U.S.C. 242k(k)] public advisory body to the Secretary of Health and Human Services in the area of health data and statistics. In that capacity, the Committee provides advice and assistance to the Department and serves as a forum for interaction with interested private sector groups on a variety of key health data issues. They have been tasked with reporting on HIPAA.
- Conformance with [Food and Drug Administration \(FDA\)](#) regulations is a requirement for some clinical IT systems.
- The [National Institute of Health \(NIH\)](#) is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

NIH is the parent organization for the [National Library of Medicine \(NLM\)](#). NLM's **Unified Medical Language System (UMLS)** project develops and distributes multi-purpose, electronic "Knowledge Sources" and associated lexical programs. System developers can use the UMLS products to enhance their applications -- in systems focused on patient data, digital libraries, Web and bibliographic retrieval, natural language processing, and decision support.

- The [National Health Information Infrastructure \(NHII\)](#) is "the set of technologies, standards, applications, systems, values, and laws that support all facets of individual health, health care, and public health." This is part of the Consolidated Health Informatics initiative (CHI). CHI is the health care component of President Bush's eGov Initiatives, created under

External Standards Organizations

the President's Management Agenda, to make it easier for citizens and businesses to interact with the government, save taxpayer dollars and streamline citizen-to-government transactions. Currently, under CHI, all federal agencies will adopt [HL7](#), [NCPDP](#), [IEEE 1073](#), [DICOM](#), and [LOINC](#) standards. For more information visit http://www.whitehouse.gov/omb/egov/gtob/health_informatics.htm

[NIST](#)

(National Institute of Standards and Technology)

Purpose/Business Justification:

NIST is a non-regulatory federal agency within the U.S. Commerce Department's Technology Administration. NIST's mission is to develop and promote measurements, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life. NIST carries out its mission in four cooperative programs:

- [NIST Laboratories](#), conducting research that advances the nation's technology infrastructure and is needed by U.S. industry to continually improve products and services. This includes the [Information Technology Laboratory](#), responsible for publishing [Federal Information Process Standards \(FIPS\)](#).
- [Baldrige National Quality Program](#), promotes performance excellence among U.S. manufacturers, service companies, educational institutions, and health care providers; conducts outreach programs and manages the annual Malcolm Baldrige National Quality Award which recognizes performance excellence and quality achievement.
- [Manufacturing Extension Partnership](#), a nationwide network of local centers offering technical and business assistance to smaller manufacturers; and
- [Advanced Technology Program](#), which accelerates the development of innovative technologies for broad national benefit by co-funding R&D partnerships with the private sector.

The [National Information Assurance Partnership \(NIAP\)](#), a joint agency of NIST and the National Security Agency (NSA), is a US Government initiative designed to meet the security testing, evaluation, and assessment needs of both information technology producers and consumers. In particular it is the US agency responsible for the Common Criteria (ISO 15048).

NIST is in partnership with [URAC](#) to form the [Security Health Care Accreditation and Certification Workgroup](#).