

C.2. PURPOSE

The responses to the November 2004 RFI on the development and adoption of a NHIN provided options for how widespread interoperability of health information could be achieved. Cumulatively, the 512 responses yielded nearly 5,000 pages of information. The responses provided an extraordinarily rich and descriptive set of thoughts on interoperability and health information exchange. A key refrain from the responses was the call for the harmonization of standards used in health information exchange, and the Federal government's role to facilitate it happening.

Standards are foundational to interoperability. Interoperability, for the purposes of this contract, means the ability of different information systems, software applications and networks to communicate and exchange information in an accurate, effective, useful, and consistent manner. The current landscape of standards does not ensure interoperability due to many factors, such as conflicts and gaps. Further, for true interoperability to be realized, many standards need to be harmonized, including standards that do not traditionally fall into the commonly accepted health care standards arena (e.g., broader technology standards for data interchange). For the purposes of this contract, harmonized or harmonization means the function of developing, reconciling, setting and maintaining standards required to achieve interoperability. For the purposes of this contract, the scope of the term standards is restricted to the structure and content of health care data, information, or concepts that are usefully exchanged or provided between and among care providers and public health authorities, and the interchange methods used to facilitate these exchanges. Further:

- "Structure," as used in this contract, means a format, method, or language whose purpose is representing or using information so that it may be exchanged electronically; it excludes such formats, methods, or languages whose purpose is security or low-level transmission. An example of structure for representation and usage might be XML (eXtensible Markup Language) or a specific schema for XML. An example of structure or format for other purposes

might be MD5 (message digest 5) for determining the integrity of data for purposes of security.

- "Content," as used in this contract, means terms or codes used to describe procedures, items, diagnoses, or similar aspects of health care; it excludes items that have a prescriptive or normative aspect. An example of a descriptive item would be a code, such as an ICD-9 diagnosis code, or a NDC code for pharmaceutical products. An example of a prescriptive item might be a medical practice guideline from a recognized source, such as the American College of Cardiology (ACC).
- The "interchange methods" might include such technological considerations such as web services or remote messaging, infrastructure for metadata or semantic brokering, or other such means to facilitate data relay, translation, and interpretation.

The purpose of this contract is to develop, prototype, and evaluate a harmonization process for achieving a widely accepted and useful set of standards targeted specifically to enable and support widespread interoperability among health care software applications, particularly EHRs. The Contractor shall develop and evaluate a standards harmonization process that includes the following:

- Recommended use-cases that illustrate applicability and business need for all areas of recommended standards;
- Identification of gaps and duplications within the universe of standards relevant to the use-cases, with proposed mitigation strategies and timelines;
- Standards change management process, a release and dissemination process, and release schedule for standards versions;
- Implementation guidelines for standards, including how to recognize when given standards are applicable, and tests of adherence to the specified standards;
- Recommended standards to meet the relevant use-cases; and

- Models for perpetuation of the standards-harmonization activity.

The Contractor shall maximize the use of existing processes where appropriate and work collaboratively with other HHS health IT contractors developing and evaluating a compliance certification process and NHIN prototypes. The contractors shall meet and collaborate because there are various tasks within each contract that are interdependent and require a coordinated and systematic approach. For example, the contractors will independently recommend use-cases that illustrate interoperability scenarios to support their respective contract deliverables. The contractors and appropriate stakeholders such as representatives from the Department of Health and Human Services (HHS), Department of Veterans Affairs (VA), Department of Defense (DoD), Department of Commerce (DoC), Department of Homeland Security (DHS), Environmental Protection Agency (EPA), National Science Foundation (NSF) and General Services Administration (GSA) shall convene to discuss the recommended use-cases and agree to a common set of use-cases that shall be used by all contractors in fulfilling their respective contract deliverables. Additional interdependent activities among the contracts that require a coordinated approach are described in the specific tasks of each contract. The Project Officer shall designate and convene the meetings among the contractors with assistance from a HHS support contractor. See the Federal Business Opportunities (FedBizOpps) and the HHS website for information on the solicitations for the other contracts.

Additionally, within the Federal government, the NIST will develop a process to take output from the standards harmonization process and consider them as Federal Information Processing Standards (FIPS) relevant to Federal agencies. NIST's issuance of FIPS shall also be based on recommendations from public and private sector coordination efforts through the AHIC, a Federal advisory committee, as accepted by the Secretary of HHS. The FIPS will be consistent with the standards adopted by the harmonization process so that Federal and private sector standards are aligned and so that widespread interoperability among health care software applications, particularly EHRs, will exist.