

C.3. STATEMENT OF WORK

The mission of the Contractor must be exclusively the harmonization of relevant standards in the health care industry to enable and advance interoperability of health care applications, and the interchange of health care data, both supporting the delivery of care and public health.

The Contractor shall engage multiple stakeholders who are represented through an inclusive governance process to ensure an objective, open and consensus-driven process and credible result. All of the following stakeholder types shall be represented:

- Standards development organizations (SDOs);
- Clinicians and providers or their representative organizations;
- Safety net providers or their representative organization;
- Vendors that develop, market, install, and support health IT products or their representative organization;
- Health care purchasers or employers or their representative organization;
- Health care payers or health insurance companies or their representative organization;
- Health care consumers or their representative organization;
- Public health agencies or their representative organization;
- Clinical and health-services researchers or their representative organization; and
- Federal agencies and coordinating bodies representing various Federal agencies, as identified by the National Coordinator.

The Contractor shall have equal representation from greater than two-thirds (2/3) of the following SDOs or standards organizations:

- SDOs accredited by the American National Standards Institute (ANSI) in health informatics and implementation of EHR systems;

- SDOs or other organizations responsible for the standards chosen by the Consolidated Health Informatics (CHI) initiative within the Federal government;
- SDOs or other organizations put forth by the respondents to November 2004 HHS RFI on the development and adoption of a NHIN;
- SDOs under the Institute of Electrical and Electronics Engineers - Standards Association (IEEE-SA) with a focus on health care and health informatics;
- SDOs under the International Organization for Standardization (ISO) with a focus on health care and health informatics; and
- SDOs nominated by expert cross-agency sources in the Federal government.

The Contractor may include additional SDOs that are not represented through ANSI or the other sources indicated above, but such additions will be valid only with concurrence from the Project Officer. The SDO stakeholders must be selected and endorsed by the respective SDOs themselves. There are also a number of relevant standards that are owned or controlled by various agencies in the Federal government. Although none of these agencies are listed, the agency's interest will be represented to the Contractor by the CHI initiative and other Federal coordinating bodies.

The non-SDO stakeholders must be selected and endorsed by stakeholder organizations that have broad national membership constituencies. For example, a recognized national vendor association or clinician association should select and endorse the Contractor's representatives for vendors and clinicians respectively. There must be at least as many representatives from the non-SDO stakeholder types combined, as there are SDO representatives. These non-SDO stakeholders in the standards harmonization process should be represented equally relative to each other.

The contract is divided into three (III) phases. In Phase I, the Contractor shall:

Task 1: Develop and maintain a comprehensive work plan. The work plan shall provide a written description of a proposed process and strategy to execute all tasks and apply Earned Value Management (EVM - as referenced in section 300.4 of OMB Circular A-11) to the extent practicable. The work plan shall also provide the Project Officer with project activities; task prioritization; resource requirements, including person hours by task; interim milestones to achieve deliverables; interdependencies and intersections with other activities and risk mitigation strategies.

Task 2: Conduct a project start up meeting with the National Coordinator and Project Officer to review the contract, introduce contractor and Government staff, review and approve a comprehensive work plan, and identify and prioritize initial activities.

Task 3: Develop a minimum of three recommended use-cases, which are illustrations of the applicability and business need for all areas of standards for interoperability. The use-cases shall address specialized variations and extensions of the general case of patients receiving care from a health care provider or health care organization (e.g., a free standing lab) and requiring the exchange of their relevant health information with other providers or health care organizations to support the clinical delivery of care at a different time and/or setting. Additionally, use-cases shall be developed that illustrate health data transmission and/or exchange for public health purposes, such as bio-surveillance, outbreak management, alerting and communication with health providers, and public health detecting and reporting. The contractor shall discuss and develop a common set of use-cases in collaboration with HHS health IT contractors and appropriate stakeholders such as HHS, VA, DoD, DoC, DHS, EPA, NSF, and GSA, which shall be designated and convened by the Project Officer with assistance from a support contractor. The Contractor shall use the common set of use-cases in fulfilling all subsequent tasks in the contract. The Project Officer shall approve the common set of use-cases.

Task 4: Participate in meetings and related activities, which shall be designated and conducted by the Project Officer with assistance from a HHS support contractor, including: (1) attending the AHIC, a Federal advisory committee, that will develop advice and seek consensus-based recommendations for coordinating efforts in the public and private sectors for interoperable HHS health IT adoption and (2) participating with HHS health IT contractors and other stakeholders such as HHS, VA, DoD, DoC, DHS, EPA, NSF, and GSA to develop, apply and evaluate common use-cases, standards, definitions, priorities and other actions relevant to the development and evaluation of interoperable health IT. The Project Officer shall instruct the Contractor to attend all such meetings and related activities.

Task 5: Identify, analyze and resolve gaps and duplications within the standards industry, with proposed resolution strategies and timelines. The Contractor shall provide a thorough description of the gaps in the current standards landscape to meet the relevant use-cases, including missing standards, and incomplete or inadequate standards. Analogously, provide a thorough description of all duplications, overlap, or competition among standards for the relevant use-cases. The Contractor shall also maximize the use of existing processes where appropriate and review current projects to align and map standards supported by the National Library of Medicine and other Federal agencies to determine their applicability to the standards harmonization process.

Task 6: Select, test, and evaluate recommended standards to meet the relevant use-cases. The Contractor shall provide a thorough listing of all the standards that satisfy the requirements imposed by the relevant use-cases, as well as testing criteria that shall be used to test the standard to the relevant use-case. There may be more than one standard for a given area, and duplicative standards are allowed as long as they each satisfy the needs. The Contractor shall use as a starting point the health domains and standards adopted by the CHI initiative in the Federal government, unless they demonstrably do not meet the relevant requirements posed by the use-cases. The Contractor shall also discuss and agree on common

standards in collaboration with HHS health IT contractors and appropriate stakeholders such as HHS, VA, DoD, DoC, DHS, EPA, NSF, and GSA, which shall be designated and convened by the Project Officer with assistance from a support contractor. The Contractor shall use the common standards in fulfilling all subsequent tasks in the contract. The Project Officer shall approve the common standards.

Task 7: Prototype, test, and evaluate a standards change management process, dissemination vehicle and process, and release schedule for harmonized-standards versions, maximizing the use of existing processes where appropriate. The Contractor shall provide a thorough plan and schedule that describes how standards may be harmonized and maintained over time, and a recommended release schedule and publicly available dissemination process/channel of the standards relevant to the use-cases. After a process is developed for change management, it should be tested through actual execution on one or more of the use-cases, and released through the proposed dissemination channel(s).

Task 8: Prototype, test, and evaluate implementation guidelines for standards, including applicability criteria and adherence tests. The Contractor shall provide a thorough description of issues involved in implementing each selected standard, how to select the standard that applies to a given scenario, and how to verify correct implementation and use of the standards. The Contractor shall collaborate with NIST where appropriate as directed by the Project Officer. The Contractor shall also develop a plan to collaborate with NIST for approval by the Project Officer.

Task 9: Develop and evaluate a business plan for a self-sustaining standards harmonization process, including cost/revenue projections over a 6-year period. As part of the business plan, the Contractor shall include the appropriate organizational and operational constructs that underpin a sustainable business model.

Task 10: Submit written monthly status and financial reports describing progress against milestones,

potential risks and risk mitigation strategies, EVM to the extent practicable and planned activities for the coming month and report such status orally and in writing every month to the Project Officer.

Task 11: Assist the Project Officer in developing reports, briefings, and other analyses on an as needed basis in response to requests from internal/external entities.

During Phase II, the Contractor shall develop at least three additional recommended use-cases, and follow the procedures described in Tasks 3 through 8 described above.

During Phase III, the Contractor shall develop at least three additional recommended use-cases, and follow the procedures described in Tasks 3 through 8 described above.

If the Option Period is exercised, the Contractor shall develop at least three additional recommended use-cases, and follow the procedures described in Tasks 3 through 8 described above.

C.4. PERFORMANCE STANDARDS

The Contractor shall use HHS approved performance standards which were developed by the Contractor as part of the successful proposal to monitor overall performance of HHS initiatives and identify potential improvement opportunities. These performance standards shall be updated as necessary with the approval of the Government.

C.5. PLACE OF PERFORMANCE

Work will be performed primarily at the Contractor's facilities. However, the Contractor may be required to perform work in the National Coordinator's office located in HHS. Some work may be performed at other locations on an as-needed basis. All travel will be reimbursed in accordance with the Federal Travel Regulations.

C.6. GOVERNMENT FURNISHED EQUIPMENT AND INFORMATION

The Government shall provide office facilities to carry out the work if required at HHS and arrange for the Contractor

to have access to functioning required management tools, systems and infrastructure. The Project Officer will provide information, material and forms unique to the Department for supporting the tasks. The Contractor is not authorized to acquire any equipment without the prior written authorization from the Project Officer.