MD FIRE Contracting Language **Medical Device Free Interoperability Requirements for the Enterprise**	**October 2014** V 2.1 *First Version Released October 2008*

Medical Device Plug-and-Play (MD PnP) Program
Massachusetts General Hospital / Partners HealthCare System
Johns Hopkins Medicine
Kaiser Permanente
Veterans Administration

This document contains five sections:

1. Overview (this page)
2. Background and Clinical Context
3. Sample RFI Language (Appendix A)
4. Sample RFP and Contract Language (Appendix B)
5. Sample Standards Table (Appendix C)

Section 1: Overview

Medical Device "Free Interoperability Requirements for the Enterprise", or MD FIRE, is an open international collaborative project to improve patient safety through the adoption of fully interoperable medical devices and systems. The term "Medical Device" in this document includes traditional stand-alone devices, software-only medical devices, and Health Information Technology (HIT) systems that receive or transmit medical device data, whether or not regulated by the FDA or other authorities. This includes, but is not limited to mobile applications (apps), Electronic Health Records (EHRs), and Clinical Decision Support (CDS) systems.

MD FIRE has two synergistic goals. The first is to promote the awareness and knowledge of medical device interoperability throughout the medical and healthcare community. To that end, MD FIRE has resulted from fourteen clinical societies (including the American Medical Association) and the FDA endorsing the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency." The second goal of MD FIRE is to enable healthcare delivery organizations to acquire and use interoperable medical devices. To that end, MD FIRE has created sample RFI, RFP and contracting language that may be re-used to aid in the purchase and maintenance of fully interoperable medical devices and systems in support of patient safety.

MD FIRE is a living document; updates to the MD FIRE contracting language are posted on the www.mdpnp.org website. The MD FIRE document may be shared under the Creative Commons Attribution-Share Alike license. The August 2012 version 2.0 reflects input from several sources, including the VA Medical Devices Interoperability Program Council. The October 2014 version 2.1 clarifies the MD FIRE definition of medical devices and connected HIT systems.

We welcome your collaboration, endorsement, and proposals for changes or enhancements to the MD FIRE document. Please contact Julian M. Goldman, MD (jgoldman@mdpnp.org).

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Section 2: Background and Clinical Context

This section discusses the requirements for medical device interoperability in the modern healthcare environment. These requirements are changing the way in which we procure and use medical devices. The Appendices provide examples of sharable language for Requests for Information (RFIs), Requests for Proposal (RFPs), and contracts.

Background

Medical devices, essential for the practice of modern medicine, have been designed traditionally to operate independently using proprietary protocols and interfaces for integration into both the Healthcare Delivery Organization's (HDO's) existing medical devices and Systems (as defined below) and a vendor's products or Systems. With the increasing complexity of the healthcare environment, stand-alone and/or proprietary medical devices and Systems no longer provide an acceptable solution. To improve patient safety, medical devices and Systems of medical devices and other Information Technology (IT) products and Systems must easily integrate with other vendors' equipment, software and Systems that have been or will be installed at the HDO.[1]

Essential improvements in patient safety and healthcare efficiency in clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and Systems.[1] Clinical societies (including the American Medical Association) and the FDA endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency."[2] [3]

Our collaboration through the Medical Device Plug-and-Play (MD PnP) Interoperability program leads us to conclude that HDOs must lead a call to action for interoperability of medical devices with various HDO legacy or new Systems. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.

We HDOs intend to adopt and implement interoperability standards for medical device interconnectivity via our procurement actions. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and associated Systems (i) will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; (ii) will improve the quality of medical devices; (iii) will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; (iv) will release HDO resources now used to maintain customized interfaces; and (v) will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual, institutional, and national goals for improved healthcare quality and outcomes.

Our goals are to (i) educate the medical community; (ii) facilitate compliance by medical device manufacturers; (iii) encourage the implementation of interoperability by compiling and

[1] *For purposes of this paper and the Appendices, "System" is defined as a collection of (i) multiple medical devices that are interconnected or (ii) one or more medical devices, which may or may not be directly interconnected, that are connected to other equipment. A System may be a newly created System, an HDO legacy System, or the combination of a new System and a legacy System.*

presenting the evidence of present and projected clinical demand for the interoperability of medical devices; and (iv) encourage and facilitate the development and adoption of medical device interoperability standards and related technologies through HDO procurement actions.

Clinical Context

Why is medical device interoperability necessary to improve patient safety? As an example, when taking an x-ray in the Intensive Care Unit, the ability to synchronize the x-ray with the patient's breathing cycle has been demonstrated to improve image quality.[4] Similarly, a safety interlock that would stop the flow of opioid pain medication from an infusion pump and call the nurse if a patient showed signs of respiratory distress could save lives.[5] There are numerous other examples whereby medical device interoperability and medical System integration, if available, will improve patient safety.[6] [7] Unfortunately, the capability of interconnecting and synchronizing medical devices from multiple manufacturers is not available today.

Standards-based medical device interoperability can provide real-time comprehensive population of a patient's Electronic Health Record (EHR), and in the future will permit the creation of integrated error-resistant medical Systems that will support advanced capabilities such as (i) automated System readiness assessment; (ii) physiologic closed loop control of medication delivery, ventilation, and fluid delivery; (iii) decision support; (iv) safety interlocks; (v) monitoring of device performance; (vi) plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; and (vii) other innovations to improve patient safety, treatment efficacy, and workflow efficiency.[6] [8]

Recommendations

We strongly encourage HDOs to adopt medical device interoperability as an essential element of their procurement process.

We have drafted sample medical device and Systems interoperability requirements and encourage HDOs and vendors to use such requirements in their procurement process, including their RFPs, RFIs and contracts for the procurement of medical devices, whether stand-alone or in Systems, and any associated services. Sample language is included in the Appendices of this document, and is also available at http://www.mdpnp.org/mdfire.php. In addition, we have included text that describes the possible uses of those clauses and how they can be implemented by the HDO in an RFI, RFP, or contract. We also hope and expect that sample language regarding medical devices and Systems interoperability will continue to evolve over time. For that reason, this document and the sample language are available under shareware license through the www.mdpnp.org web site.

We believe that including requirements for interoperability in the language which HDOs utilize to procure medical devices will provide a way for all HDOs to ensure patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information.

References:

[1] Connectivity to Improve Patient Safety: Making Medical Device "Plug-and-Play" Interoperability a Reality. *Patient Safety & Quality Healthcare* 7:1, 26-30, Jan-Feb 2010. (http://mdpnp.org/publications_UN9U.html)

[2] http://mdpnp.org/interopendorsements_.html

[3] "FDA Perspective," 2007 Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS-MD PnP 2007), pp xii-xiii, 2007. (http://mdpnp.org/uploads/FDA_Kessler-Tillman_position_letter.pdf)

[4] Synchronization of Radiograph Film Exposure with the Inspiratory Pause Effect on the Appearance of Bedside Chest Radiographs in Mechanically Ventilated Patients. *American J of Resp and Crit Care Med*, V160, p2067, 1999.

[5] Dangers of Postoperative Opioids. *APSF Newsletter*, V21, No4, Winter 2006-2007. (http://mdpnp.org/publications_UN9U.html)

[6] ASTM International standard F2761-2009 on the Integrated Clinical Environment, Annex B: "Clinical Context and Clinical Scenarios".

[7] Once a Tech Fantasy, Plug-and-Play OR Edges Closer to Reality. *Anesthesiology News*, V33, No1, January 2007, pp 1, 15. (http://mdpnp.org/publications_UN9U.html)

[8] Summary of the August 2011 Symposium on "The Role and Future of Health Information Technology in an Era of Health Care Transformation." (http://www.gwumc.edu/sphhs/healthit/HITSymposium2011.pdf)

Appendix A

MD FIRE Sample RFI Language

Background: Request for Information (RFI)

A Request for Information (RFI) is an open request to the broader market intended to gather information to be used as part of an acquisition process. An RFI may also be used to prepare the market or specific vendors for the actual RFP, or to identify products that are superior to those currently in use.[2] RFIs may include a detailed list of products/services for which pricing is requested.

If the sender of the RFI wishes to purchase/acquire products or services after analyzing the RFI response, it is usual to proceed to issuing a Request for Proposal (RFP) or Request for Quote (RFQ).

A good RFI enables the buyer to collect information on:

- Existing suppliers and vendors, the depth and breadth of their products, and their strategic focus
- The current state of the market
- Research trends or dynamics in the market
- Current pricing for products and services (note: pricing data collected should not be considered final or necessarily used to select or reject vendors, since responding vendors will expect a formal follow-up RFP or RFQ, and then a negotiation phase)[3]

The RFI text below is not intended to be complete, but only to provide sample text that can be re-purposed to an HDO's official RFI template and framework.

MD FIRE text incorporated into HDO's procurement documents should be reviewed and approved by the appropriate HDO governance and acquisition professionals, in accordance with applicable HDO policies.

The following section discusses the need for medical device interoperability in the modern healthcare environment. It is intended as the introduction and background section of an HDO RFI for interoperable devices and systems.

[2] http://www.negotiations.com/articles/procurement-terms/
[3] http://en.wikipedia.org/wiki/Request_for_information

RFI TEMPLATE TEXT

Note: This introductory text is included to inform potential responders of the HDO's motivations and needs, and provides context for the specific terms and language.

Medical Device and Healthcare Industry Background

Medical devices, essential for the practice of modern medicine, have been designed traditionally to operate independently using proprietary protocols and electronic data interfaces for integration into both the Healthcare Delivery Organization's (HDO's) existing medical devices and Systems[4] and a vendor's products or Systems. With the increasing complexity of the healthcare environment, stand-alone and/or proprietary medical devices and Systems no longer provide an acceptable solution. To improve patient safety, medical devices and Systems comprised of medical devices and other IT products and Systems must easily integrate with multiple vendors' equipment, software and Systems that have been or will be installed at the HDO.

Clinical Need Background

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and Systems.[1] Clinical societies (including the American Medical Association) and the FDA endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency."[2] [3]

Clinical Vision

Standards-based medical device interoperability can provide real-time comprehensive population of a patient's electronic medical record (EMR), and in the future will permit the creation of integrated error-resistant medical Systems that will support advanced capabilities such as (i) automated System readiness assessment; (ii) physiologic closed loop control of medication delivery, ventilation, and fluid delivery; (iii) decision support; (iv) safety interlocks; (v) monitoring of device performance; (vi) plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; and (vii) other innovations to improve patient safety, treatment efficacy, and workflow efficiency.[6] [8]

Objectives

We [the HDO] intend to adopt and implement interoperability standards for medical device interconnectivity via our procurement actions. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and associated Systems (i) will enable the development of innovative approaches to improve patient safety, healthcare

[4] *For purposes of this document, "System" is defined as a collection of (i) multiple medical devices that are interconnected or (ii) one or more medical devices, which may or may not be directly interconnected, that are connected to other equipment. A System may be a newly created System, an HDO legacy System, or the combination of a new System and a legacy System.*

quality, and provider efficiency for patient care; (ii) will improve the quality of medical devices; (iii) will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; (iv) will release HDO resources now used to maintain customized interfaces; and (v) will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual and institutional goals for improved healthcare quality and outcomes.

Our goals are to (i) encourage the implementation of interoperability by compiling and presenting the evidence of present and projected clinical demand for the interoperability of medical devices; and (ii) encourage and facilitate the development and adoption of medical device interoperability standards and related technologies through HDO procurement actions.

We are therefore including medical device interoperability as an essential element in our procurement process and in future vendor selection criteria.

Sample RFI Text

This section of the document provides examples of sharable language for RFIs. The language is to be used in an RFI that is an initial step in selecting vendors in a competitive bidding process. Include in the RFI the examples below if it is the intention of the Healthcare Delivery Organization (HDO) to utilize them for the contract. It is anticipated that one or more of the sections below would be included as part of the product specifications or other contract language in any contract that would be entered into by the HDO. Each of the sample sections below may be included in any combination in any document.

"Product" refers to the medical device(s) or Systems that will be acquired by the HDO's procurement action.

"Company" refers to the supplier of the Product.

"System" is defined as a collection of (i) multiple medical devices that are interconnected or (ii) one or more medical devices, which may or may not be directly interconnected, that are connected to other equipment. A System may be a newly created System, an HDO legacy System, or the combination of a new System and a legacy System.

RFI Text Example A: Request for Specific Functionality and Interoperability Capabilities

Requests a complete description of specific functionality and interoperability capabilities. The text shown is only an example and would be expanded by the HDO in a detailed specification. This text may be used if the HDO knows what interoperability capabilities it is seeking, what Product functions support that interoperability, and which standards are to be implemented. Language in square brackets [this or that] represents options or sample text. The actual content should be selected by the HDO as appropriate for their clinical, business, or technical requirements.

Current Interoperability Functionality by Specific Capability
Describe the extent to which the product conforms to the following requirements:

- The Product must have the following capabilities:

- Pulse oximeter sends % oxygen saturation and pulse rate data to other clinical Systems in compliance with [IEEE 11073 Data Information Model].
- Pulse oximeter sends clinical and technical (equipment) alarms, and upper and lower oxygen saturation and pulse rate alarm settings to other clinical Systems using standard [IEEE 11073 Data Information Model].
- Pulse oximeter interfaces with clinical Systems and accepts data and control to set alarm limits [and averaging time and sensitivity mode].

Current Interoperability Functionality by Use Case
Describe the extent to which the product conforms to the following requirements:

The Product must implement the HITSP Lab Results Reporting (EHR) Use Case, which is HITSP Interoperability Specification 1 (IS 01) Version 3.1, recognized 2009, as described at http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01

- The HITSP Lab Results Reporting (EHR) Use Case requires partial or complete compliance and implementation of the following standards:
  - Health Level 7 (HL7) Versions 2.5 and 2.5.1
  - HL7 Clinical Document Architecture (CDA) Release 2.0
  - IETF RFC 2818: Hypertext Transfer Protocol (HTTP) over Transport Layer Security (TLS)
  - HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1
  - HL7 Version 3.0 Privacy Consent related specifications
  - IETF RFC 1305: Network Time Protocol (Version 3)
  - IHTSDO Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)
  - Logical Observation Identifiers Names and Codes (LOINC)
  - OASIS Security Assertion Markup Language (SAML) Version 2.0
  - OASIS WS-Federation Version 1.1
  - OASIS WS-Trust Version 1.3
  - OASIS eXtensible Access Control Markup Language (XACML) Version 2.0
  - Unified Code for Units of Measure (UCUM)

Future Interoperability Functionality by Use Case
Describe the extent to which the product conforms to the following requirements:

[By January 1, 2014, Within 12 months of contract award] the Product must implement the HITSP Lab Results Reporting (EHR) Use Case, which is HITSP Interoperability Specification 1 (IS 01) Version 3.1, recognized 2009, as described at http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01

- The HITSP Lab Results Reporting (EHR) Use Case requires partial or complete compliance and implementation of the following standards:
  - Health Level 7 (HL7) Versions 2.5 and 2.5.1
  - HL7 Clinical Document Architecture (CDA) Release 2.0
  - IETF RFC 2818: Hypertext Transfer Protocol (HTTP) over Transport Layer Security (TLS)
  - HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1

- HL7 Version 3.0 Privacy Consent related specifications
- IETF RFC 1305: Network Time Protocol (Version 3)
- IHTSDO Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)
- Logical Observation Identifiers Names and Codes (LOINC)
- OASIS Security Assertion Markup Language (SAML) Version 2.0
- OASIS WS-Federation Version 1.1
- OASIS WS-Trust Version 1.3
- OASIS eXtensible Access Control Markup Language (XACML) Version 2.0
- Unified Code for Units of Measure (UCUM)

RFI Text Example B: Interoperability Using Interfaces and Standards

Describe product and development plans for interoperability of your Product(s), including:

- List all external electronic data interfaces for each Product
- For each of these interfaces, describe:
  - The unique identifier or name for the interface, including version number if applicable
  - The applicable standard. Examples include, but are not limited to: ANSI (http://www.ansi.org/), ASTM (http://www.astm.org/Standard/index.shtml), NEMA (http://www.nema.org/stds/), ISO (http://www.iso.org/iso/specific-applications_health), DICOM (http://medical.nema.org/), IEEE (http://standards.ieee.org/findstds/standard/healthcare_it.html), IHE (http://www.ihe.net/profiles/), USB (http://www.usb.org/home), WiFi (http://standards.ieee.org/about/get/802/802.11.html), ZigBee (http://www.zigbee.org/Standards/Overview.aspx), Bluetooth (https://www.bluetooth.org/apps/content/), HL7 (http://www.hl7.org/implement/standards/index.cfm)
  - The standard name and version if applicable, e.g., HL7 2.3
  - The domain, subset, and profile of the interface as applicable, e.g., IHE Radiology Profile
  - Any internal company identifier or name or title of the interface requirements, specification, or implementation. This could include published requirements specifications, API version numbers, etc.
  - Any externally developed interface specification or design guideline, for example:
    - Continua Design Guidelines (and version number)
    - HDO-developed specifications such as the Intermountain Health CEM (Clinical Element Model)
    - Published, open, but company-owned interface specifications such as the *Agilent Series 50 Fetal Monitors Digital Interface Protocol Specifications Programmer's Guide*
  - Whether its classification is "proprietary & closed", "proprietary & open", "standard" (i.e., HL7 or DICOM), "standard with a third party implementation guideline or profile" (e.g., IHE Radiology) or "standard with a third party implementation guideline and third party certification" (e.g., Continua or USB or WiFi)
  - Whether it is currently in operational use at HDO sites, developed but not in use, in development, or planned for development

- References to the interface's specification – these could be external links to Standards Development Organizations or the Company's own documentation, as applicable
- A description of the Product functions supported by the interface
- Disclosure of license fees, if any, to use the implemented standard

Note: To the extent possible at the RFI stage, the HDO should include detailed specifications for the Product and identify the other products and/or Systems with which the Product should be interoperable and/or integrated.

If the HDO determines that it will contract for the item or items above after receiving the information in response to the RFI, that information should be included in the terms of the contract (see Appendix B).

A table illustrating the information required above is shown in Appendix C at the end of this document.

RFI Text Example C: Description of All Current and Planned Interoperability Capabilities and Related Functionality

Requests a complete description of the Product's "Current" (as defined below) interoperability capabilities, but does not call for any particular function or standard. This example also includes language anticipating the possibility that to the extent that a respondent must engage in Product development to satisfy the HDO's requirements, some portion of that development work could be funded by the HDO. The terms of such funding and development would be defined by the RFP and contract.

Please include in the RFI response the approach and plans for interoperability of your Product(s), specifically:

- All interoperable interface standards, technology standards, terminology standards, communication standards, and design guidelines that the Products will implement and comply with (including but not limited to USB, WiFi, ZigBee, Bluetooth, HL7, Continua). For each standard and guideline, describe:
  - The current and proposed scope of compliance with each standard and guideline, including but not limited to the exact specifications and guideline versions.
  - A description of the current and proposed Product functions that are interoperable and supported by the standards and guidelines.
  - An estimate of the [Not to Exceed, Time and Materials] cost and schedule to implement the proposed capabilities and standards listed above. If updates or compliance are included in the regular maintenance agreement, please describe those terms.
    Note: this clause would be inserted only if the HDO intends to fund some or all of the Company's Product development work that is necessary to meet actual Contract or RFP requirements. However, this clause would not be included in any contract that also included Company-funded Product development.
- Describe your process for demonstration, acceptance testing, and certification and validation of the Product's interoperability for the standards listed above. If you propose to provide independent validation and verification of capability, the full price of that effort should be described.

- Describe your processes for Product maintenance and upgrades to accommodate new interface technology, new interface standards, updated interface standards, or new Product functionality.
- Describe the supported proprietary, customized, standards-based, and interoperable interfaces, electronic data interfaces, and data transfer functions supported by the Product.
- Describe the Product's current and proposed functions that are available or fully functional only when (i) the System is interfacing with Company's Products or other products and Systems that would be provided by subcontractors to the Company or companies that are collaborating with, but are not under the control of the Company; and (ii) the Company would have systems integration responsibility for the Products and any legacy and other Systems.
- List the Product's current and proposed interfaces that are fully supported only when interoperating with Company's Products or the products of companies that are collaborating with, but are not under the control of the Company.
- "Current" means functions, features, and compliance that are currently marketed by Company and in use by its customers.

For all of the above items, please describe all the resources required from the HDO and third parties, including costs and dependencies, where known.

RFI Text Example D: Description of Technology Supporting Interoperability

Requests a complete description of the Product technology. This should be used only if the HDO intends to evaluate the Product's technology and implementation.

Please describe Company's implementation of technology relevant to interoperability with other medical devices and Systems, including:

- Description of the current and proposed system architecture, including interfaces
- Description of the current and proposed software architecture, including interfaces
- Description of the current and proposed hardware architecture, including interfaces
- Description of the current and proposed application architecture, including interfaces

RFI Text Example E: Description of Company's Past Support for Interoperability

Requests a complete description of the Company's corporate activities related to interoperability, but not directly related to the Product itself. This should be used only if the HDO intends to evaluate a Company's past commitment and contributions to interoperability.

Please describe the efforts and contributions that Company has made to achieving medical device interoperability for your products in particular or the industry in general. The response may take any form, but as an example it could include:

- Company's participation in interoperability standards consortiums, societies, or other similar organizations developing or promoting interoperability
- Any relevant public demonstrations, plug-fests, or product implementations that show the interoperability of Company's products

RFI Text Example F: Complete Interoperability

The purpose of this section is to provide an example of terms for a procurement action that seeks complete Product interoperability. Language in square brackets [this or that] should be

selected as appropriate by the Healthcare Delivery Organization (HDO). The term "Supplier" refers to the vendor that is entering into the contract for a Product. All other terms mean the same as indicated in the earlier sections of this Appendix.

Describe the Product's ability to meet the following requirements:

During the Term of the Agreement and any subsequent period during which HDO is purchasing support and maintenance services from Supplier for Products, Supplier will implement federally ratified interoperability standards and interoperability specifications for all interfaces described below:

- The HITSP Lab Results Reporting (EHR) Use Case, which is HITSP Interoperability Specification 1 (IS 01) Version 3.1, recognized 2009, as described at http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01
- Applicable certification criteria published by the Certification Commission for Health IT (CCHIT): http://www.cchit.org/
- Applicable specifications recognized by the Secretary of US Health and Human Services and required under the federal contracting provisions of US Executive Order 13410
- Other interoperability standards and specifications recognized or required in applicable laws, rules, regulations, and legislation from the federal government and states and districts where HDO operates

Note: This requirement would also need to be supported in the Agreement by (i) detailed descriptions of the timelines for implementation, (ii) the allocation of costs, (iii) the other product and System dependencies, and (iv) the consequences (i.e., potentially liquidated damages or other adverse consequences) that the Supplier will incur if those obligations are not met in a satisfactory manner.

Supplier will implement these standards and specifications in accordance with HDO Project Timeline Exhibit (see Example K).

As part of the HDO's acceptance testing process, Supplier shall demonstrate in the HDO's own test and operational environments that the Products successfully interoperate with the HDO's existing third party equipment and Systems in accordance with the requirements in this Exhibit and with the use cases [described in this Agreement, mutually agreed upon by the parties].

RFI Text Example G: Independent Lab Testing of Interfaces

Describe the Product's ability to meet the following requirements:

Supplier agrees to have each interface tested and verified by an independent lab approved by Supplier and HDO.[5] All costs from the Supplier and other third parties for independent lab testing and certification shall be listed separately [and paid by Supplier]. Supplier also agrees to obtain any applicable consortia certification for Product interfaces, including without limitation, USB, WiFi, ZigBee, Bluetooth, HL7, and Continua.

[5] Such as the Medical Device Plug-and-Play Interoperability Lab at the Center for Integration of Medicine and Innovative Technology (CIMIT) or the Kaiser Garfield Center

RFI Text Example H: Connectivity by Clinical Domain

This section provides a means to add requirements by clinical domain. HDO should consider specifying domains as needed.

Describe the Product's ability to meet the following requirements:

Product and all subsequent releases and replacement Products shall comply with applicable interoperability standards, guidelines, and certifications in the following domains:

- acute care documentation systems
- physiological monitors
- monitoring of chronic disease [diabetes, CHF level III] in the patient's home
- ventilators
- patient care beds
- etc.

RFI Text Example I: Request for Conformance to Specific Standards

This section provides a means to add conformance to specific standards not required by other sections.

Describe the Product's ability to meet the following requirements:

Product and all subsequent releases and replacement Products shall demonstrate conformance with the following standard(s):

- ASTM F2761-2009: Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model
- IEC 60601-1: Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance
    - IEC 60601-1-2: Medical Electrical Equipment: General Requirements for Safety – Electromagnetic Compatibility
    - IEC 60601-1-6: Medical Electrical Equipment: General Requirements for Safety – Usability
    - IEC 60601-1-8: Medical Electrical Equipment: General Requirements for Safety – Tests and Guidance for Alarm Systems in Medical Electric Equipment and Medical Electrical Systems

RFI Text Example J: Commitment to Work towards Interoperability

This section is to be used when the Supplier is expected to make commercially reasonable efforts to achieve interoperability and at the same time to inform the HDO of any issues, barriers, or problems with the current set of standards. However, it is preferable to have the contract establish some deadlines or other incentives for the Supplier's attainment of a specified level of interoperability, along with any allocation of costs among the parties and the consequences if the deadlines are not met by the Supplier.

Describe the Product's ability to meet the following requirements:

At every release of a Product's software, either for implementation or maintenance, Supplier shall use *commercially reasonable efforts* to implement applicable [federally ratified] interoperability standards. Supplier and HDO shall meet quarterly [in-person or by

teleconference by mutual agreement] to discuss Supplier's progress towards implementing and conforming to applicable standards. At each meeting, Supplier shall provide the following information:

- For each interface, a description of the progress and accomplishments made towards conformance with standards
- For each interface, a list of issues, objections, and problems encountered with the Supplier's Products, third party products, and the HDO's or standards' specifications that prevent or delay conformance

RFI Text Example K: HDO Project Timeline Exhibit

This is a placeholder for the HDO to define its own program/project timeline with respect to identifying the requirements for interoperable interfaces that would be referenced in the RFI, RFP, or Contract. This Exhibit should at a minimum specify:

- When requirements will be delivered from the HDO to the Supplier
- When the Supplier is expected to complete development of interfaces
- When the Supplier is expected to complete testing, validation, and certification of interoperable interfaces

Note: The actual content of this Exhibit should be created by the HDO.

RFI Text Example L: RFI Example for Implementation of a Specific Technical Standard: Network Time Protocol

Requests a complete description of specific functionality and interoperability capabilities. The text shown is only an example and would be expanded by the HDO in a detailed specification.

Describe the Product's ability to meet the following requirements:

Current Interoperability Functionality: The Product must have the following capabilities:

- A reliable system clock in UTC that includes a full implementation of either Network Time Protocol version 4 (NTPv4) or Simple Network Time Protocol version 4 (SNTPv4) as specified by IETF RFC 5905 (see http://www.ntp.org/rfc.html).
- If the product supports manual or automatic local time zones, then the local time shall be based on an algorithm that utilizes UTC.
- If the product utilizes automatic or manual daylight savings time, then the local time shall be based on an algorithm that utilizes UTC.
- The product shall use local time or UTC for all user and electronic interfaces.
- If the product is unable to synchronize on UTC though the implementation of NTPv4 or SNTPv4, then the product will inform the user in an appropriate manner.

RFI Text Example M: Demonstrating IHE Compatibility

This section references external documents. Note that the referenced documents may have changed since this document was approved and published.

The *IHE PCD User Handbook* was assembled by the IHE Patient Care Device (PCD) Planning and Technical committees. It describes how and why to acquire and implement systems and devices with IHE capabilities for device interaction. IHE capabilities outside of device interactions are not addressed.

The *IHE PCD User Handbook* can be found at
http://www.ihe.net/Resources/upload/IHE_PCD_User_Handbook_2011_Edition.pdf

The *IHE PCD User Handbook* includes recommended text to require specific IHE Profiles in RFPs. This language can also be used for RFIs. An HDO would include this level of specificity as desired for the procurement of relevant products.

Note*:* The *IHE PCD User Handbook* states on page 31:

> [*The IHE RFP] Structure only solves one part of integration: a vendor could support an IHE profile (i.e., information is present and in the right order) but use terms that connected systems can't understand, requiring either the supplier or the facility to perform the translation. To identify cases in which a system under consideration does not support standardized nomenclature and terminologies, purchasers must ask suppliers to specify their level of terminology and nomenclature support when responding to an RFP.*

Therefore the HDO may want to supplement this material with other terms as appropriate and desired.

RFI Text Example N: Continua Health Alliance Compliance

Note: Only the version 1 Continua Design Guidelines are publicly available. At this time, compliance with a later version requires that the vendor become a member of the Continua Health Alliance in order to have access to those Design Guidelines (see http://www.continuaalliance.org/static/cms_workspace/External_Guidelines_Order_Form_2010.pdf).

The Continua Health Alliance Design Guidelines apply to only some healthcare use cases and are not universal.

There are several possible combinations of Continua Compliance. There are currently two Continua Interfaces (PAN and xHR) and two transport standards that are certified by USB and Bluetooth, respectively, and not by Continua (see http://www.continuaalliance.org/static/cms_workspace/Continua_Certification_Public.pdf for more information).

Continua Health Alliance Design Guideline Version 1
Continua Interface Compliance terms:

- PAN
  - Vendor's product will be certified compliant by the Continua Health Alliance for the PAN interface
  - Vendor's product will be certified compliant by the Continua Health Alliance for the xHR interface

Continua Transport Standard Compliance terms:

- BlueTooth
  - Vendor's product will fully comply with and pass BlueTooth HDP/MCAP Self-Qualification tests
- USB

- Vendor will be certified compliant by USB for the USB Interface transport standard (see http://www.usb.org/developers/compliance/labs/ for more information)

RFI Text Example O: Vendor Compliance Verification

Note: It is in the HDO's interest that every requirement be verified. This can be done through demonstration of the capability by the Supplier, the HDO's acceptance test process, specific test processes, third-party testing, certification testing, or with a combination of any of these processes.

Describe the extent to which the requirements of this RFI and the Product's capabilities can be verified through the following processes. List any requirements or product capabilities which cannot be verified through any of the following processes:

Demonstration

- [All, specific operational requirement, specific functional requirement] will be demonstrated by the Supplier in the Supplier's environment in accordance with the [mutually agreed-upon terms in the contract, specification YYY, standard XXX]

Customer Test

- [All, specific operational requirement, specific functional requirement] will be verified in the HDO's own test and operational environments in accordance with the [mutually agreed-upon terms in the contract, specification YYY, standard XXX]

Supplier Test

- [All, specific operational requirement, specific functional requirement] will be verified in Supplier-provided test and operational environments in accordance with the [mutually agreed-upon terms in the contract, specification YYY, standard XXX]

Third-Party Test

- [All, specific operational requirement, specific functional requirement] will be verified by [third-party testing organization, mutually agreed-upon testing organization] operational environments in accordance with the [mutually agreed-upon terms in the contract, specification YYY, standard XXX]

Certification

- [All requirements, specific operational requirement, specific functional requirement] of the Product will be certified compliant with standard [XXX] by [UL, other certification body]

Conformance

- The vendor shall provide verification that that the software and hardware deliverables conform to performance, interoperability, functionality, reliability, and safety assessment standards as defined by Standard [XXX] by [AAMI/UL JC 2800, or other appropriate conformance standards body]

FDA Compliance

- The vendor shall list, and provide evidence, that the product is in compliance with applicable FDA recognized standards in this list (http://www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf)
- The vendor shall provide evidence that the product is in compliance with applicable FDA Guidance Documents, Draft Guidance Documents, and Rules.
- [For example:
    - FDA Mobile Medical Device Guidance Document (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)
    - Content of Pre-Market Submissions for Management of Cybersecurity in Medical Devices (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf)]

Please note that Appendix B duplicates the information just presented in Appendix A, with the language changed to reflect the differences between an RFI and an RFP.

Appendix B

MD FIRE Sample RFP and Contract Language

Background: Request for Proposal (RFP)

A Request for Proposal (RFP) is a document issued during a procurement process as an invitation for suppliers to submit proposals on specific products or services. The RFP may follow an RFI (Request for Information). The RFP brings structure and objectivity to the procurement process, and is intended to enable measured comparison of the risks and benefits of the acquisition.[6]

The RFP provides to potential suppliers the buyer's strategy, short-term and long-term business objectives. This enables suppliers to create offerings that match the described needs of the buyer. A broadly distributed RFP may also identify suppliers that the buyer was not aware of. An RFP informs the market of the needs and strategy of the buyer, which also helps less competitive suppliers to develop future products and services for the buyer.

A good RFP:

- Informs suppliers that a buyer is seeking specific products and services, signals that the purchase will be competitive and will be scoped by the described time frame, budget, volume, and geography
- Describes in detail the requirements of the buyer, ideally at a level of detail that can be incorporated into the supplier's proposal
- Leads to clear and unambiguous proposals that can be scored objectively relative to each other and to the buyer's performance, financial, schedule, technical, business, and clinical goals
- Is structured for clear and objective evaluation by the buyer, enabling impartial selection decisions; this encourages new suppliers to make offers, and is an essential component of transparent public sector procurement

RFP text in this Appendix defines requirements that are interchangeable with Contract terms.

The following text is recommended as a template introduction in the RFP itself in order to communicate the HDO's justifications and motivations for requesting interoperability in general, and the RFP terms in particular.

The RFP text below is not intended to be complete, but only to provide example text that can be re-purposed to an HDO's official RFP template and framework.

MD FIRE text incorporated into HDO's procurement documents should be reviewed and approved by the appropriate HDO governance and acquisition professionals, in accordance with applicable HDO policies.

[6] http://en.wikipedia.org/wiki/Request_for_proposal

This section discusses the need for medical device interoperability in the modern healthcare environment. It is intended as the introduction and background section of an HDO RFP for interoperable devices and systems.

RFP TEMPLATE TEXT

Note: This introductory text is included to inform potential responders of the HDO's motivations and needs, and provides context for the specific terms and language.

Medical Device and Healthcare Industry Background

Medical devices, essential for the practice of modern medicine, have been designed traditionally to operate independently using proprietary protocols and electronic data interfaces for integration into both the Healthcare Delivery Organization's (HDO's) existing medical devices and Systems[7] and a vendor's products or Systems. With the increasing complexity of the healthcare environment, stand-alone and/or proprietary medical devices and Systems no longer provide an acceptable solution. To improve patient safety, medical devices and Systems comprised of medical devices and other IT products and Systems must easily integrate with multiple vendors' equipment, software and Systems that have been or will be installed at the HDO.

Clinical Need Background

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and Systems.[1] Clinical societies (including the American Medical Association) and the FDA endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency."[2] [3]

Clinical Vision

Standards-based medical device interoperability can provide real-time comprehensive population of a patient's electronic medical record (EMR), and in the future will permit the creation of integrated error-resistant medical Systems that will support advanced capabilities such as (i) automated System readiness assessment; (ii) physiologic closed loop control of medication delivery, ventilation, and fluid delivery; (iii) decision support; (iv) safety interlocks; (v) monitoring of device performance; (vi) plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; and (vii) other innovations to improve patient safety, treatment efficacy, and workflow efficiency.[6] [8]

Objectives

We [the HDO] intend to adopt and implement interoperability standards for medical device interconnectivity via our procurement actions. We also recognize that the necessary standards

[7] *For purposes of this document, "System" is defined as a collection of (i) multiple medical devices that are interconnected or (ii) one or more medical devices, which may or may not be directly interconnected, that are connected to other equipment. A System may be a newly created System, an HDO legacy System, or the combination of a new System and a legacy System.*

are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and associated Systems (i) will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; (ii) will improve the quality of medical devices; (iii) will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; (iv) will release HDO resources now used to maintain customized interfaces; and (v) will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual and institutional goals for improved healthcare quality and outcomes.

Our goals are to (i) encourage the implementation of interoperability by compiling and presenting the evidence of present and projected clinical demand for the interoperability of medical devices; and (ii) encourage and facilitate the development and adoption of medical device interoperability standards and related technologies through HDO procurement actions.

We are therefore including medical device interoperability as an essential element in our procurement process and vendor selection criteria.

Sample RFP Text

This section of the document provides examples of sharable language for RFPs. The language is to be used in an RFP that is an initial step in selecting vendors in a competitive bidding process. Include in the RFP the examples below if it is the intention of the Healthcare Delivery Organization (HDO) to utilize them for the contract. It is anticipated that one or more of the sections below would be included as part of the product specifications or other contract language in any contract that would be entered into by the HDO. Each of the sample sections below may be included in any combination in any document.

"Product" refers to the medical device(s) or Systems that will be acquired by the HDO's procurement action.

"Company" refers to the supplier of the Product.

"System" is defined as a collection of (i) multiple medical devices that are interconnected or (ii) one or more medical devices, which may or may not be directly interconnected, that are connected to other equipment. A System may be a newly created System, an HDO legacy System, or the combination of a new System and a legacy System.

RFP Text Example A: Request for Specific Functionality and Interoperability Capabilities

Requests a complete description of specific functionality and interoperability capabilities. The text shown is only an example and would be greatly by the HDO in a detailed specification. This text may be used if the HDO knows what interoperability capabilities it is seeking, what Product functions support that interoperability, and which standards are to be implemented. Language in square brackets [this or that] represents options or sample text. The actual content should be selected by the HDO as appropriate for their clinical, business, or technical requirements.

Current Interoperability Functionality by Specific Capability
Describe the extent to which the product conforms to the following requirements:

- The Product must have the following capabilities:
    - Pulse oximeter sends % oxygen saturation and pulse rate data to other clinical Systems in compliance with [IEEE 11073 Data Information Model].
    - Pulse oximeter sends clinical and technical (equipment) alarms, and upper and lower oxygen saturation and pulse rate alarm settings to other clinical Systems using standard [IEEE 11073 Data Information Model].
    - Pulse oximeter interfaces with clinical Systems and accepts data and control to set alarm limits [and averaging time and sensitivity mode].

Current Interoperability Functionality by Use Case
Describe the extent to which the product conforms to the following requirements:

The Product must implement the HITSP Lab Results Reporting (EHR) Use Case, which is HITSP Interoperability Specification 1 (IS 01) Version 3.1, recognized 2009, as described at http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01

- The HITSP Lab Results Reporting (EHR) Use Case requires partial or complete compliance and implementation of the following standards:
    - Health Level 7 (HL7) Versions 2.5 and 2.5.1
    - HL7 Clinical Document Architecture (CDA) Release 2.0
    - IETF RFC 2818: Hypertext Transfer Protocol (HTTP) over Transport Layer Security (TLS)
    - HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1
    - HL7 Version 3.0 Privacy Consent related specifications
    - IETF RFC 1305: Network Time Protocol (Version 3)
    - IHTSDO Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)
    - Logical Observation Identifiers Names and Codes (LOINC)
    - OASIS Security Assertion Markup Language (SAML) Version 2.0
    - OASIS WS-Federation Version 1.1
    - OASIS WS-Trust Version 1.3
    - OASIS eXtensible Access Control Markup Language (XACML) Version 2.0
    - Unified Code for Units of Measure (UCUM)

Future Interoperability Functionality by Use Case
Describe the extent to which the product conforms to the following requirements:

[By January 1, 2014, Within 12 months of contract award] the Product must implement the HITSP Lab Results Reporting (EHR) Use Case, which is HITSP Interoperability Specification 1 (IS 01) Version 3.1, recognized 2009, as described at http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01

- The HITSP Lab Results Reporting (EHR) Use Case requires partial or complete compliance and implementation of the following standards:
    - Health Level 7 (HL7) Versions 2.5 and 2.5.1
    - HL7 Clinical Document Architecture (CDA) Release 2.0
    - IETF RFC 2818: Hypertext Transfer Protocol (HTTP) over Transport Layer Security (TLS)

- HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1
- HL7 Version 3.0 Privacy Consent related specifications
- IETF RFC 1305: Network Time Protocol (Version 3)
- IHTSDO Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)
- Logical Observation Identifiers Names and Codes (LOINC)
- OASIS Security Assertion Markup Language (SAML) Version 2.0
- OASIS WS-Federation Version 1.1
- OASIS WS-Trust Version 1.3
- OASIS eXtensible Access Control Markup Language (XACML) Version 2.0
- Unified Code for Units of Measure (UCUM)

RFP Text Example B: Interoperability Using Interfaces and Standards

Describe product and development plans for interoperability of your Product(s), including:

- List all external electronic data interfaces for each Product
- For each of these interfaces, describe:
  - The unique identifier or name for the interface, including version number if applicable
  - The applicable standard. Examples include, but are not limited to: ANSI (http://www.ansi.org/), ASTM (http://www.astm.org/Standard/index.shtml), NEMA (http://www.nema.org/stds/), ISO (http://www.iso.org/iso/specific-applications_health), DICOM (http://medical.nema.org/), IEEE (http://standards.ieee.org/findstds/standard/healthcare_it.html), IHE (http://www.ihe.net/profiles/), USB (http://www.usb.org/home), WiFi (http://standards.ieee.org/about/get/802/802.11.html), ZigBee (http://www.zigbee.org/Standards/Overview.aspx), Bluetooth (https://www.bluetooth.org/apps/content/), HL7 (http://www.hl7.org/implement/standards/index.cfm)
  - The standard name and version if applicable, e.g., HL7 2.3
  - The domain, subset, and profile of the interface as applicable, e.g., IHE Radiology Profile
  - Any internal company identifier or name or title of the interface requirements, specification, or implementation. This could include published requirements specifications, API version numbers, etc.
  - Any externally developed interface specification or design guideline, for example:
    - Continua Design Guidelines (and version number)
    - HDO-developed specifications such as the Intermountain Health CEM (Clinical Element Model)
    - Published, open, but company-owned interface specifications such as the *Agilent Series 50 Fetal Monitors Digital Interface Protocol Specifications Programmer's Guide*
  - Whether its classification is "proprietary & closed", "proprietary & open", "standard" (i.e., HL7 or DICOM), "standard with a third party implementation guideline or profile" (e.g., IHE Radiology) or "standard with a third party implementation guideline and third party certification" (e.g., Continua or USB or WiFi)
  - Whether it is currently in operational use at HDO sites, developed but not in use, in development, or planned for development

- References to the interface's specification – these could be external links to Standards Development Organizations or the Company's own documentation, as applicable
- A description of the Product functions supported by the interface
- Disclosure of license fees, if any, to use the implemented standard

Note: To the extent possible at the RFI stage, the HDO should include detailed specifications for the Product and identify the other products and/or Systems with which the Product should be interoperable and/or integrated.

If the HDO determines that it will contract for the item or items above after receiving the information in response to the RFP, that information should be included in the terms of the contract.

A table illustrating the information required above is shown in Appendix C at the end of this document.

RFP Text Example C: Description of All Current and Planned Interoperability Capabilities and Related Functionality

Requests a complete description of the Product's "Current" (as defined below) interoperability capabilities, but does not call for any particular function or standard. This example also includes language anticipating the possibility that to the extent that a respondent must engage in Product development to satisfy the HDO's requirements, some portion of that development work could be funded by the HDO. The terms of such funding and development would be defined by the RFP and contract.

Please include in the RFI response the approach and plans for interoperability of your Product(s), specifically:

- All interoperable interface standards, technology standards, terminology standards, communication standards, and design guidelines that the Products will implement and comply with (including but not limited to USB, WiFi, ZigBee, Bluetooth, HL7, Continua). For each standard and guideline, describe:
  - The current and proposed scope of compliance with each standard and guideline, including but not limited to the exact specifications and guideline versions.
  - A description of the current and proposed Product functions that are interoperable and supported by the standards and guidelines.
  - An estimate of the [Not to Exceed, Time and Materials] cost and schedule to implement the proposed capabilities and standards listed above. If updates or compliance are included in the regular maintenance agreement, please describe those terms.
    Note: this clause would be inserted only if the HDO intends to fund some or all of the Company's Product development work that is necessary to meet actual Contract or RFP requirements. However, this clause would not be included in any contract that also included Company-funded Product development.
- Describe your process for demonstration, acceptance testing, and certification and validation of the Product's interoperability for the standards listed above. If you propose to provide independent validation and verification of capability, the full price of that effort should be described.

- Describe your processes for Product maintenance and upgrades to accommodate new interface technology, new interface standards, updated interface standards, or new Product functionality.
- Describe the supported proprietary, customized, standards-based, and interoperable interfaces, electronic data interfaces, and data transfer functions supported by the Product.
- Describe the Product's current and proposed functions that are available or fully functional only when (i) the System is interfacing with Company's Products or other products and Systems that would be provided by subcontractors to the Company or companies that are collaborating with, but are not under the control of the Company; and (ii) the Company would have systems integration responsibility for the Products and any legacy and other Systems.
- List the Product's current and proposed interfaces that are fully supported only when interoperating with Company's Products or the products of companies that are collaborating with, but are not under the control of the Company.
- "Current" means functions, features, and compliance that are currently marketed by Company and in use by its customers.

For all of the above items, please describe all the resources required from the HDO and third parties, including costs and dependencies, where known.

RFP Text Example D: Description of Technology Supporting Interoperability

Requests a complete description of the Product technology. This should be used only if the HDO intends to evaluate the Product's technology and implementation.

Please describe Company's implementation of technology relevant to interoperability with other medical devices and Systems, including:

- Description of the current and proposed system architecture, including interfaces
- Description of the current and proposed software architecture, including interfaces
- Description of the current and proposed hardware architecture, including interfaces
- Description of the current and proposed application architecture, including interfaces

RFP Text Example E: Description of Company's Past Support for Interoperability

Requests a complete description of the Company's corporate activities related to interoperability, but not directly related to the Product itself. This should be used only if the HDO intends to evaluate a Company's past commitment and contributions to interoperability.

Please describe the efforts and contributions that Company has made to achieving medical device interoperability for your products in particular or the industry in general. The response may take any form, but as an example it could include:

- Company's participation in interoperability standards consortiums, societies, or other similar organizations developing or promoting interoperability
- Any relevant public demonstrations, plug-fests, or product implementations that show the interoperability of Company's products

RFP Text Example F: Complete Interoperability

The purpose of this section is to provide an example of terms for a procurement action that seeks complete Product interoperability. Language in square brackets [this or that] should be

selected as appropriate by the Healthcare Delivery Organization (HDO). The term "Supplier" refers to the vendor that is entering into the contract for a Product. All other terms mean the same as indicated in the earlier sections of this Appendix.

Describe the Product's ability to meet the following requirements:

During the Term of the Agreement and any subsequent period during which HDO is purchasing support and maintenance services from Supplier for Products, Supplier will implement federally ratified interoperability standards and interoperability specifications for all interfaces described below:

- The HITSP Lab Results Reporting (EHR) Use Case, which is HITSP Interoperability Specification 1 (IS 01) Version 3.1, recognized 2009, as described at http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01
- Applicable certification criteria published by the Certification Commission for Health IT (CCHIT): http://www.cchit.org/
- Applicable specifications recognized by the Secretary of US Health and Human Services and required under the federal contracting provisions of US Executive Order 13410
- Other interoperability standards and specifications recognized or required in applicable laws, rules, regulations, and legislation from the federal government and states and districts where HDO operates

Note: This requirement would also need to be supported in the Agreement by (i) detailed descriptions of the timelines for implementation, (ii) the allocation of costs, (iii) the other product and System dependencies, and (iv) the consequences (i.e., potentially liquidated damages or other adverse consequences) that the Supplier will incur if those obligations are not met in a satisfactory manner.

Supplier will implement these standards and specifications in accordance with HDO Project Timeline Exhibit (see Example K).

As part of the HDO's acceptance testing process, Supplier shall demonstrate in the HDO's own test and operational environments that the Products successfully interoperate with the HDO's existing third party equipment and Systems in accordance with the requirements in this Exhibit and with the use cases [described in this Agreement, mutually agreed upon by the parties].

> *Note: There could be non-disclosure and other restrictions on the access to third-party equipment and Systems that Supplier may need to address. Thus, there could be significant negotiations and additional contract language detailing how the tests will be run (including whether they will be run under "live" conditions, scheduling, access/use of the HDO's data, equipment and Systems), and how the costs will be allocated between the Supplier and the HDO for the acceptance tests and any remedial actions, as further described below. To the extent that any data or other output will result, it also should be made clear that the HDO will own it.*

RFP Text Example G: Independent Lab Testing of Interfaces

Supplier agrees to have each interface tested and verified by an independent lab approved by Supplier and HDO.[8] All costs from the Supplier and other third parties for independent lab testing and certification shall be listed separately [and paid by Supplier]. Supplier also agrees to obtain any applicable consortia certification for Product interfaces, including without limitation, USB, WiFi, ZigBee, Bluetooth, HL7, and Continua.

RFP Text Example H: Connectivity by Clinical Domain

This section provides a means to add requirements by clinical domain. HDO should consider specifying domains as needed.

Describe the Product's ability to meet the following requirements:

Product and all subsequent releases and replacement Products shall comply with applicable interoperability standards, guidelines, and certifications in the following domains:

- acute care documentation systems
- physiological monitors
- monitoring of chronic disease [diabetes, CHF level III] in the patient's home
- ventilators
- patient care beds
- etc.

RFP Text Example I: Request for Conformance to Specific Standards

This section provides a means to add conformance to specific standards not required by other sections.

Product and all subsequent releases and replacement Products shall demonstrate conformance with the following standard(s):

- ASTM F2761-2009: Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model
- IEC 60601-1: Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance
    - IEC 60601-1-2: Medical Electrical Equipment: General Requirements for Safety – Electromagnetic Compatibility
    - IEC 60601-1-6: Medical Electrical Equipment: General Requirements for Safety – Usability
    - IEC 60601-1-8: Medical Electrical Equipment: General Requirements for Safety – Tests and Guidance for Alarm Systems in Medical Electric Equipment and Medical Electrical Systems

RFP Text Example J: Commitment to Work towards Interoperability

This section is to be used when the Supplier is expected to make commercially reasonable efforts to achieve interoperability and at the same time to inform the HDO of any issues, barriers, or problems with the current set of standards. However, it is preferable to have the

[8] Such as the Medical Device Plug-and-Play Interoperability Lab at the Center for Integration of Medicine and Innovative Technology (CIMIT) or the Kaiser Garfield Center

contract establish some deadlines or other incentives for the Supplier's attainment of a specified level of interoperability, along with any allocation of costs among the parties and the consequences if the deadlines are not met by the Supplier.

At every release of a Product's software, either for implementation or maintenance, Supplier shall use *commercially reasonable efforts* to implement applicable [federally ratified] interoperability standards. Supplier and HDO shall meet quarterly [in-person or by teleconference by mutual agreement] to discuss Supplier's progress towards implementing and conforming to applicable standards. At each meeting, Supplier shall provide the following information:

- For each interface, a description of the progress and accomplishments made towards conformance with standards
- For each interface, a list of issues, objections, and problems encountered with the Supplier's Products, third party products, and the HDO's or standards' specifications that prevent or delay conformance

RFP Text Example K: HDO Project Timeline Exhibit

This is a placeholder for the HDO to define its own program/project timeline with respect to identifying the requirements for interoperable interfaces that would be referenced in the RFI, RFP, or Contract. This Exhibit should at a minimum specify:

- When requirements will be delivered from the HDO to the Supplier
- When the Supplier is expected to complete development of interfaces
- When the Supplier is expected to complete testing, validation, and certification of interoperable interfaces

Note: The actual content of this Exhibit should be created by the HDO.

RFP Text Example L: RFP Example for Implementation of a Specific Technical Standard: Network Time Protocol

Requests a complete description of specific functionality and interoperability capabilities. The text shown is only an example and would be expanded by the HDO in a detailed specification.

Current Interoperability Functionality: The Product must have the following capabilities:

- A reliable system clock in UTC that includes a full implementation of either Network Time Protocol version 4 (NTPv4) or Simple Network Time Protocol version 4 (SNTPv4) as specified by IETF RFC 5905 (see http://www.ntp.org/rfc.html).
- If the product supports manual or automatic local time zones, then the local time shall be based on an algorithm that utilizes UTC.
- If the product utilizes automatic or manual daylight savings time, then the local time shall be based on an algorithm that utilizes UTC.
- The product shall use local time or UTC for all user and electronic interfaces.
- If the product is unable to synchronize on UTC though the implementation of NTPv4 or SNTPv4, then the product will inform the user in an appropriate manner.

RFP Text Example M: Demonstrating IHE Compatibility

This section references external documents. Note that the referenced documents may have changed since this document was approved and published.

The *IHE PCD User Handbook* was assembled by the IHE Patient Care Device (PCD) Planning and Technical committees. It describes how and why to acquire and implement systems and devices with IHE capabilities for device interaction. IHE capabilities outside of device interactions are not addressed.

The *IHE PCD User Handbook* can be found at http://www.ihe.net/Resources/upload/IHE_PCD_User_Handbook_2011_Edition.pdf

The *IHE PCD User Handbook* includes recommended text to require specific IHE Profiles in RFPs. This language can also be used for RFIs. An HDO would include this level of specificity as desired for the procurement of relevant products.

Note*:* The *IHE PCD User Handbook* states on page 31:

> [*The IHE RFP] Structure only solves one part of integration: a vendor could support an IHE profile (i.e., information is present and in the right order) but use terms that connected systems can't understand, requiring either the supplier or the facility to perform the translation. To identify cases in which a system under consideration does not support standardized nomenclature and terminologies, purchasers must ask suppliers to specify their level of terminology and nomenclature support when responding to an RFP.*

Therefore the HDO may want to supplement this material with other terms as appropriate and desired.

RFP Text Example N: Continua Health Alliance Compliance

Note: Only the version 1 Continua Design Guidelines are publicly available. At this time, compliance with a later version requires that the vendor become a member of the Continua Health Alliance in order to have access to those Design Guidelines (see http://www.continuaalliance.org/static/cms_workspace/External_Guidelines_Order_Form_2010.pdf).

The Continua Health Alliance Design Guidelines apply to only some healthcare use cases and are not universal.

There are several possible combinations of Continua Compliance. There are currently two Continua Interfaces (PAN and xHR) and two transport standards that are certified by USB and Bluetooth, respectively, and not by Continua (see http://www.continuaalliance.org/static/cms_workspace/Continua_Certification_Public.pdf for more information).

Continua Health Alliance Design Guideline Version 1
Continua Interface Compliance terms:

- PAN
  - Vendor's product will be certified compliant by the Continua Health Alliance for the PAN interface
  - Vendor's product will be certified compliant by the Continua Health Alliance for the xHR interface

Continua Transport Standard Compliance terms:

- BlueTooth
  - Vendor's product will fully comply with and pass BlueTooth HDP/MCAP Self-Qualification tests
- USB
  - Vendor will be certified compliant by USB for the USB Interface transport standard (see http://www.usb.org/developers/compliance/labs/ for more information)

RFI Text Example O: Vendor Compliance Verification

Note: It is in the HDO's interest that every requirement be verified. This can be done through demonstration of the capability by the Supplier, the HDO's acceptance test process, specific test processes, third-party testing, certification testing, or with a combination of any of these processes.

Demonstration

- [All, specific operational requirement, specific functional requirement] will be demonstrated by the Supplier in the Supplier's environment in accordance with the mutually agreed-upon terms in the contract

Customer Test

- [All, specific operational requirement, specific functional requirement] will be verified in the HDO's own test and operational environments in accordance with the [mutually agreed-upon terms in the contract, specification YYY, standard XXX]

Supplier Test

- [All, specific operational requirement, specific functional requirement] will be verified in Supplier-provided test and operational environments in accordance with the [mutually agreed-upon terms in the contract, specification YYY, standard XXX]

Third-Party Test

- [All, specific operational requirement, specific functional requirement] will be verified by [third-party testing organization, mutually agreed-upon testing organization] operational environments in accordance with the [mutually agreed-upon terms in the contract, specification YYY, standard XXX]

Certification

- [All requirements, specific operational requirement, specific functional requirement] of the Product will be certified compliant with standard [XXX] by [UL, other certification body]

Conformance

- The vendor shall provide verification that that the software and hardware deliverables conform to performance, interoperability, functionality, reliability, and safety assessment standards as defined by Standard [XXX] by [AAMI/UL JC 2800, or other appropriate conformance standards body]

FDA Compliance

- The vendor shall list, and provide evidence, that the product is in compliance with applicable FDA recognized standards in this list (http://www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf)
- The vendor shall provide evidence that the product is in compliance with applicable FDA Guidance Documents, Draft Guidance Documents, and Rules.
- [For example:
    - FDA Mobile Medical Device Guidance Document (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)
    - Content of Pre-Market Submissions for Management of Cybersecurity in Medical Devices (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf)]

Appendix C
Sample Standards Table

This table contains **examples** of the expected level of detail to be provided by Supplier for its external interfaces.

Example Interface Standard Table								
Scope / Domain / Purpose	**Standard**	**Domain**	**Type**	**In use?**	**Scope of Conformance**	**Plans**	**Reference to Interface Specification**	**Functions Supported**
Patient demographics	HL7 2.3	Demographics	Open standard, not validated	In operational use	Partial implementation	No plans to discontinue	www.hl7.org	Receive and display patient demographic data
Patient lab data	Proprietary	Laboratory	Proprietary, open	In operational use	Full	Will be maintained for existing products, but eventually replaced by CCHIT certification	Example: www.vendorname.com/productsupport/interfacess	Send patient lab data
Patient lab data	HL7 2.3	Laboratory	Open standard, CCHIT certification	Planned for development	Planned to be lab data	Will replace lab data interface within 12 months of ratification of the specification and adoption by the US government	www.hl7.org	Send patient lab data to the EMR
Patient weight	IEEE 11073 Continua V2 Guidelines	Disease Management	Open validated standard, Continua guidelines, Continua validation	No	Full & certified	Planned for delivery in 20xx products	http://www.continuaalliance.org/products/cert-process.html	Receive CHF patient's weight
Contrast injectors	CIA425, Part 2: Injector	CANOpen Application Profile for Medical Diagnostic, Add-on Modules, Part 2: Injectors	Standard	Yes	Full	No plans to change	http://www.can-cia.org	Connect injectors to CANOpen network for x-ray contrast injections
Pulse oximeter	IEEE P11073-10404	Pulse oximeter	Standard	Yes	Full	No plans to change	https://development.standards.ieee.org/pub/active-pars?n=12	Acquire pulse oximeter data
Integrated Clinical Environment	ASTM F2761 ICE Part II	ICE system data	In process	No	N/A	All products will conform	http://www.astm.org/Standards/F2761.htm	Log data continuously from devices in

(ICE) data logger		logging						the ICE
Disease taxonomy	ICD-11	All	Standard	No	None	Will implement within 18 months of ratification and publication by WHO	http://www.who.int/classifications/icd/revision/en/index.html	All functions support clinical documentation
Clinical Element Model	CEM of HL7 RIM	EHR structured Data					http://www.hl7.org/documentcenter/public/wg/java/20110519_RIMBAA_Stan_Huff.ppt	Representation and coding of structured patient data
HITSP Lab Results Reporting (EHR) HITSP IS 01, Version 3.1	Healthcare Information Technology Standards Panel (HITSP) Interoperability Specifications (Recognized 16 Jan 2009)	Lab Results Reporting to EHR	Open, Published, Recognized	Yes	Full	Will implement in compliance with HITSP Use Case; will implement other standards defined by the Use Case as necessary to comply with the Use Case	http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01	The Electronic Health Records Laboratory Results Reporting Interoperability Specification defines specific standards to support the interoperability between electronic health records and laboratory systems and secure access to laboratory results and interpretations in a patient-centric manner

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Andy DelGesso	10/08	1.0
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Michael Robkin, MBA	10/08, 10/09, 12/09, 10/11, 3/12, 10/14	1.0, 1.1, 1.2, 1.3, 1.6, 1.7,2.1
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