Nationwide Health Information Network
Proposed Functional Requirements
Version 3
April 16, 2006

I. Overview

Functional requirements are traditionally used to define the workings of a system. As defined in requirements engineering, functional requirements identify specific behaviors of a system. In general, functional requirements designate specific "properties" (functions, services, behaviors, and technical and processing needs and capabilities) of "entities" (systems, services, networks and, at times, actors).

The Office of the National Coordinator for Health Information Technology (ONC) will work with you to collect and catalogue a list of functional requirements to help frame the conceptualization of the Nationwide Health Information Network. To that end, the functional requirements must define the:

- Complete workings of the "core" health information network: that is, the entities and properties which are necessary to unambiguously define general and use case specific network services, capabilities, behaviors and functions. The identification of entities and properties as "core" may vary depending on the specific architectural approach.

- The required entities and properties for "edge" systems (EMR's, Lab Information Management Systems, etc.) that must interface with the general and use case specific network functioning in the context of their connection to the health information network.

A typical functional requirement will be in the form of an <entity> shall, should or may <property>, where <property> is a clear and readable description of the required behavior. Each requirement should be unambiguous, specific, and verifiable. Typically these types of requirements may be more abstract than those used for the development of a particular software product, but the granularity of the functions will vary depending on the area being described. Similarly, these requirements will typically specify system-level interactions, services and functions (i.e., record locator service, data transformation service, etc.) as opposed to equipment level interactions (i.e., router, web server, etc.).

II. Cataloguing the Functional Requirements

In order to catalogue the range of technical requirements that could serve as a foundation for a Nationwide Health Information Network, ONC proposes a taxonomy that focuses on several axes:

- one axis delineating "entities" that may be services, systems, system components, or organizational or role based actors,

- a second axis that describes "functional categories" that represent common functions that cross different entities, and

- an axis to depict requirements that are principally for a specific use case or fall into a broader NHIN infrastructure bucket.

Below is specific guidance on the type of information needed to complete the "entity"-based functional requirements in the Functional Requirement Spreadsheet. In preparing the spreadsheet, we have developed a series of lists for proposed "entities", "functional categories" and others fields that serve as controlled vocabularies from which to pick. The terminology and descriptions below serve as your common definitions, to which we ask that you do not make changes. The exception is that you may create up to 5 additional items to the lists of entities or functional categories.

If you choose to create new items to the lists of entities or functional categories, please transmit the definition of the item and an example to Lammot, who will notify all the consortia of any changes.

Column	Guidance
Unique Requirement ID	You are free to use your own identification scheme, but it must include a unique number for all your submissions and include the abbreviation of your organization name (i.e., ACN, CSC, IBM, NGIT, ONC, other…) followed by a dash ("-") as the first part of the code so that we can uniquely identify all requirements (e.g., ONC-123). Each requirement row shall have an entry.
Functional Category	The functional category defines the general area of a requirement. Functional categories cross different entities and relate like requirements by the type of need they are addressing. Each requirement row shall have an entry. A proposed list and description of functional categories is provided at the end of this document in Appendix A.
Entity Name	An entity is a system or system component. Entity names will be descriptive and unique. Each requirement row shall have an entry. An entity is a portion of the statement <entity> SHALL, SHOULD, MAY <property>. A proposed list and description of entities is provided at the end of this document in Appendix B.
Entity – Property Relationship	"Shall", "Should" or "May" are allowable relationships between entities and properties. It is expected that the eventual product of harmonization, when refined to the minimum necessary requirements, will mostly include "shall"'s. Each requirement row shall have an entry.
Property	"Property" is a statement about the entity that describes a function or behavior that can be evaluated for conformance. As a practical matter, properties submitted at this level are expected to represent functions or attributes of the entity that are particularly relevant to the architecture of the Nationwide Health Information Network. Each requirement row shall have an entry.

Properties that some may consider "non-functional" (including such system qualities as availability, efficiency, flexibility, integrity, performance, reliability, reusability, scalability, usability) should only be provided where the property has a substantial impact on the architecture and capabilities of the Nationwide Health Information Network or a use case. For example, timeliness of transmissions by systems that are Biosurveillance sources or the response time required for a record retrieval should be cited although some may consider them "non-functional" attributes. |

Column	Guidance
Entity Role	Based on the proposed architectural design, entities may be classified as either "core" or "edge" systems. The entity role describes whether the ascribed functional requirement to be supported is part of the "core" nationwide health information network or a connected "edge" system with respect to the requirement.
Link to other requirements	Some requirements are specifically and concretely related to another requirement (such as the needs for the connection between a "core" Nationwide Health Information Network system and a connected "edge" system). Recognizing that many requirements are related, this field should contain references to other requirements that are fundamental and critical to the specific requirement in this row. This field may be empty for some requirements.
Principle Context	This field contains a choice of Nationwide Health Information Network "Infrastructure" or the specific use case to which this requirement is related. This field may be empty for some requirements.
Context Reference	If the requirement is linked to a specific "Event," "Action," or "Alternate Action" in a harmonized use case, the numerical code for the "Event," "Action," etc. the reference number(s) should be included here. This field may be empty for some requirements.
Comments / Rationale	This field should be used to add contextual information for the requirement and provide any descriptive information necessary to defend the need for the requirement. This field may be empty for some requirements.

Appendix A:
Proposed List of Functional and Non-Functional Categories

Below is the proposed list of categories of Nationwide Health Information Network's functional requirements.

Functional Categories

Audit and Logging – Functionality to support the recording of transactions and capability to review such recordings. For example, the functionality to support the identification and monitoring of activities within an application or system.

Authentication – The ability to uniquely identify and validate (to a reasonable degree) the identity of an entity. These requirements are applicable to systems, services, and organizational actors.

Authorization – The ability to determine and grant access to systems, services and data based on prescribed parameters (instantiated authorization/access policies). For example, the process of granting authority or delegation to specified actors.

Confidentiality – The ability to ensure that data are not disclosed (e.g., viewed, obtained or made known) to unauthorized individuals per organizational policies. Functionality to provide privacy, de-identification, anonymization and re-linking would be included in the confidentiality category.

Credentialing – The process of validating or confirming the qualifications of licensed professionals, e.g., clinical provider. These functional requirements are distinct from authentication and authorization.

Data Access and Update –The ability to retrieve, view, and modify data, within prescribed policies.

Data Content – There may exist requirements on data that constrain the context and use of data exchanged within the Nationwide Health Information Network. While many data requirements may be deferred to review of specifications or standards, there may be some high level data constraints that should be included within the Data Content functional category (e.g., requirement for structured or unstructured text).

Data Filtering – The functional requirements to support identifying and/or qualifying data that needs to be transmitted.

Data Mapping/Translation – The functional requirements to support reformatting or expressing data in different terms. These requirements may relate to terminology and/or message structure.

Data Quality/Data Integrity – The functional requirements to ensure data is correct and complete, including the ability to verify that data were transferred.

Data Rendering – The ability to present data.

Data Retrieval (Pull) – The functional requirements to support the request/retrieval of data.

Data Routing – The ability to identify a receiving system and ensure delivery of data.

Data Source – The functional requirements to support the identification of the data/information point of origin.

Data Transmission (Push) – The functional requirements to support the unsolicited sending of data.

Data Usage – There may exist requirements on data that constrain the context and use of data exchanged within the Nationwide Health Information Network. While many data requirements may be deferred to review of specifications or standards, there may be some high level data constraints that should be included within the Data Usage functional category.

Identity/Information Correlation – The ability to map information or entities with other entities (e.g., individuals or organizations, or necessarily a named system or network user). For example, correlating clinical information to the system or network-known identity of a patient where the patient. .

Persistent Data Storage – The ability of a system to function as a data repository.

Record Location – The ability to determine the location of data.

Transient Data – The ability of a systems to function as a data repository for a given entity for a given period of time or purpose.

Non-Functional Categories

Below is a proposed list of categories that include system qualities or "non-functional" requirements. As noted above, the expectation is that categories of non-functional requirements will only be designated where the property has a substantial impact on the architecture and capabilities of the Nationwide Health Information Network or a use case.

Accuracy – a measure of the application service quality - from the customer's perspective, the precision with which responses are provided to customer inquiries.

Business Rules – Policy driven dynamic requirements that may change during the operation of the system, requiring that the system adapt to the change without major rework.

Performance – a measure of the degree to which an entity satisfies its intended purpose.

Robustness – a measure of the ability of system to adjust to unanticipated conditions (i.e., the ability of a system to adjust to unanticipated conditions without losing its endurance and level of quality).

Scalability – a measure of the ability of system to adjust or extend to changing demands (user load, data load).

Appendix B:
Proposed List of Entities

The indentation below describes inheritance of requirements, so all the requirements that are common to every EMR would go under EMR, and only those requirements that are specific to the ambulatory settings would go under EMR-ambulatory.

Please note that some of the systems listed below may be components of a single application. For example, some Personal Heath Record Systems include registration information components, demographics components and medication history components.

Entity Name	Entity Description
1. Care Delivery Org (CDO) Systems	**Systems operated by care delivery organizations that participate in the NHIN. Note that some of the systems listed below may be components of one or more application. For example, some Electronic Health Systems can include registration, billing and clinical aspects of an EMR.**
Scheduling	CDO systems that include a scheduling capability.
Registration	CDO systems that maintain registration data about patients.
Billing	CDO systems that generate electronic bills or claims.
EMR	All EMR systems impendent of setting.
EMR – ambulatory	Requirements specific to EMRs in a ambulatory setting.
EMR – acute	Requirements specific to EMRs in a acute care setting.
EMR – ED	Requirements specific to EMRs in an Emergency Department setting.
LIS	Requirements for all laboratory information systems independent of setting.
LIS - reference lab	Requirements specific to LISs in the setting of an independent reference lab.
LIS - CDO lab	Requirements specific to LISs in the setting of a CDO.
Radiology	Requirements for all radiology systems independent of setting.
Pharmacy fulfillment	Requirements for all pharmacy systems independent of setting – includes pharmacy fulfillment modules integrated in an enterprise EMR.
Pharmacy independent	Requirements specific to pharmacy fulfillment systems in drugstores, chain stores and other free standing settings.
Pharmacy integrated	Requirements that are specific to pharmacy systems that are embedded in an enterprise EMR.
CDO NHIN Interface	Systems that exist specifically to interface with the NHIN – may include the enterprise application integration facilities of a healthcare stakeholder or brokering systems related to a particular application or service.
2. Consumer Systems	**Systems operated primarily for direct use by a consumer or the agent of a consumer. Note that some of the systems listed below may be s of a single application. For example, some Personal Heath Record Systems include registration information, demographics and medication history.**

Entity Name	Entity Description
Personal Health Record	Requirements for a Personal Health Record system that are not specific to the specification groups described below.
PHR - Registration info	Requirements for a Personal Health Record system that are specific to collecting and sharing registration information.
PHR - Med history	Requirements for a Personal Health Record system that are specific to collecting and sharing medication history.
PHR - other clinical	Requirements for a Personal Health Record system that are specific to collecting and sharing common clinical data.
Consumer NHIN Interface	Systems that exist specifically to interface with the NHIN – may include the enterprise application integration facilities of a healthcare stakeholder or brokering systems related to a particular application or service.
4. Data Analysis and Secondary Use Systems	**Systems that receive and derive value from analysis of aggregations of data received via the NHIN.**
Public Health	Systems that use data for surveillance of diseases and biological or chemical threats and other public health functions.
Quality Evaluation	Systems that use data for evaluation of the quality of care.
Clinical Trials	Systems that use data as part of clinical trials.
Adverse Events	Systems that receive data for adverse event reporting.
5. Payer Systems	**Requirements uniquely associated with NHIN participation by systems associated with healthcare payers.**
Enrollment/Eligibility	Requirements that are unique to enrollment eligibility systems.
Claims Processing	Requirements that are unique to claims processing eligibility systems.
Disease Management	Requirements that are unique to payer disease management eligibility systems.
Pharmacy benefits managers	Requirements that are unique to PBMs.
Claims aggregators	Requirements that are unique to claims aggregators.
Prescription aggregators	Requirements that are unique to systems that aggregate prescription data.
Formulary aggregators	Requirements that are unique to systems that aggregate formulary data.
6. Health Information Intermediaries	**Requirements that are unique to NHIN participant systems that facilitate the exchange of information among healthcare organizations, whether or not such participant systems conform to the HIPAA definition of a clearinghouse.**
7. Master Person Indices and other patient matching	**Requirements that are unique to NHIN participant systems that are used to match patients to their data.**
8. Repositories	**Requirements with respect to data retained within the NHIN.**
9. Record Locater	**Systems that contain information about and pointers to records.**
10. Terminology Servers	**Systems that support the management of sets of coded concepts and the mapping between alternate representations.**
11. Message handling	**Requirements that are unique to NHIN building block systems related to the formatting, parsing, translation or routing of messages that represent transactions.**

Entity Name	Entity Description
12. External user interfaces	**Requirements associated with systems within the NHIN that provide user interfaces to clinicians, consumers and other people including, but not limited to portals for viewing patient data or audit trails of transactions.**
13. Administrative	**Requirements associated with systems that support the administration of the NHIN**
Consumer Authorization	Requirements with respect accepting, tracking, and enforcing consumers permissions or declaration of prohibitions on the use of their data.
User Registration	Requirements with respect to user registration associated with systems that support the administration of the NHIN.
System Registration	Requirements with respect to system registration associated with systems that support the administration of the NHIN including but not limited to trading partner management functions.
Organization Registration	Requirements with respect to organization to system registration associated with systems that support the administration of the NHIN including but not limited to assertions by organizations of conditions under which information will be shared.
Audit trails	Requirements with respect to controlling, manipulating, searching or displaying audit trails.