

**HL7 EHR TC –
Legal EHR-S Functional Profile
Workgroup**

**Legal Electronic Health
Record-System
Functional Profile**

**Registration Release 1 (v 1.0)
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Legal EHR-S Functional Profile Workgroup Co-Facilitators:

Michelle Dougherty, RHIA, CHP
American Health Information Management Association

Harry Rhodes, MBA, RHIA, CHPS, CPHIMS
American Health Information Management Association

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Preface

i. Notes to Readers

Version 1.0 of the Legal EHR-S (LEHR-S) Functional Profile has been registered with the HL7 EHR Technical Committee and is based on the HL7 EHR-S Functional Model Release 1, February 2007. In June 2007, the LEHR-S profile will be released for public comment. After reconciling the comments, the workgroup intends to release the profile for ballot later in 2007. Because of the special nature and scope of the LEHR-S profile, the workgroup decided to reach out to industry, care providers, healthcare organizations and other experts to solicit input through the public comment period before going through a ballot cycle.

The LEHR-S profile is a universal profile. It sets a foundation for other derived profiles to establish realm-specific language related to laws and regulation for the health record contained within the EHR-S. The profile is unique because it does not stand on its own. The profile should be coupled with a care setting profile, specifically care settings which are required by regulation or law to maintain health records. A care setting profile will identify the functionality and conformance criteria that support the collection of content for the required health record. The LEHR-S profile identifies the system functionality and conformance criteria that help organizations maintain a legally-sound electronic health record.

To reflect the universal applicability of the profile, a call for volunteers was published requesting workgroup members with a variety of expertise and from a variety of realms. The call resulted in a workgroup with members mainly from the U.S. and one member from Canada. The group referenced a variety of standards in developing the profile including ISO, ASTM, Canada Health Infoway, CCHIT and HL7 messaging standards. The review identified core concepts, many which were already in the EHR-S Functional Model and some that were new. Many of the concepts were consistent across the standards reviewed. The goal of this profile is to express those concepts in the framework of the EHR-S functional model through function statements and conformance criteria.

ii. Acknowledgements

The committee is indebted to the following workgroup facilitators, members, and expert guests for their contributions towards the Legal EHR-S domain and the materials presented in this profile.

Member Name & Credentials:	Affiliation
<i>Co-Facilitators:</i>	
Michelle Dougherty, RHIA, CHP	American Health Information Management Association
Harry Rhodes, MBA, RHIA, CHPS, CPHIMS	American Health Information Management Association
<i>Workgroup Members</i>	
Beth Acker, RHIA	Department of Veterans Affairs
Ellen M. Anderson, RHIA	Consultant (IT & HIM)
Kimberly Baldwin-Stried (Reich), MBA, MJ, RHIA, CHC, CPHQ	Consultant (Legal & HIM)
Reed Gelzer, MD, MPH, CHCC	Advocates for Documentation Integrity and Compliance
Sue Mitchell, RHIA	Omnicare Information Solutions
Sue Schneider, BA, CCHRA(C)	Canadian Health Information Management Association

Member Name & Credentials:	Affiliation
<i>Additional Workgroup Assistance:</i>	
Gary Dickenson	Consultant (IT & EHR Standards)
Wes Rishel	Gartner
Matt Greene	Department of Veterans Affairs

iii. Changes from Previous Release

Not applicable

Introduction

The Legal Electronic Health Record System (LEHR-S) Functional Profile, a project of the HL7 EHR Technical Committee, is aimed at developing a universally applicable *HL7 Informative Functional Profile* for EHR systems, conforming to the HL7 Electronic Health Record System (EHR-S) Functional Model. An EHR-S must be able to create, maintain, and manage records within a framework of ever-changing jurisdictional rules, regulations, and laws that are intended to assure electronic records are valid, accurate, and trustworthy. Therefore, the LEHR-S profile is a subset of requirements to assure data quality and integrity for all purposes and end-uses of health care data. Furthermore, since legal validity is at stake for all uses of electronic records as admissible business records, including admissibility as medical records, the LEHR-S is of primary importance to health care operations and to interoperability.

1 Background

The LEHR-S Workgroup was established to inform HL7 and other healthcare standards development organizations (SDOs) of the unique requirements necessary to create and maintain a legally sound electronic health record within an EHR-S. The LEHR-S Workgroup sought out members from a variety of realms and with a variety of backgrounds. Subject matter experts in the legal, technical and health information management fields participated with thoughtful insight and input. Membership in HL7 was not a prerequisite for participation.

2 Methods, Description and Project Plan

2.1 Description

An expert workgroup developed the Legal EHR-S Functional Profile building on the work completed by a previous group that identified EHR-S functionality for maintaining a legally sound electronic health record. The charge of this workgroup was to develop a profile for maintaining a legally-sound EHR within an EHR-S by completing the following:

- Review and update the work of the previous Legal Workgroup including a review of applicable standards, specifically, ISO, ASTM, HL7 Messaging, Canada Health Infoway, and electronic discovery.
- Develop a legal EHR-S functional profile (based on the most current version of the EHR-S functional model) including completion of applicable profile documents (i.e. profile registration), identification of applicable functionality, and development of conformance criteria.
- Determine connection, if any, between the EHR Technical Committee interoperability work/research being completed.

2.2 Scope of Project

The scope of this project was to address universal concepts in alignment with guidelines, standards, and requirements related to maintaining a legally sound EHR.

2.3 Out-of-scope for Project

Realm-specific requirements and laws, as well as principles that are not widely accepted, were out-of-scope for this project.

3 Legal EHR-S: Definition, Standards, Implementation and Interoperability

3.1 Definition

The EHR-S must be able to maintain a legally sound electronic health record that assures conformance to realm-specific rules, regulations, laws, and standards. A medical record contains data that captures the dynamic relationship between day to day clinical activities and the body of rules, regulations, laws, and standards that govern that data. This relationship is best served by careful and thoughtful consideration of EHR-S functions, assuring they are attentive to the purposes and intentions of those rules, regulations, laws, and standards as they protect the rights and the well-being of all patients by serving a broader purpose in support in data quality, integrity and trustworthiness.

3.2 Standards and Requirements

Some criteria and functions are based on widely accepted standards from such Standards Development Organizations (SDOs) such as the International Organization for Standardization (ISO), ASTM, Canada Health Infoway and HL7 messaging standards, as well as 2007 EHR product certification requirements from the Certification Commission for Healthcare Information Technology (CCHIT).

3.3 Implementation

It is recommended that the LEHR-S profile be coupled with a care setting profile, specifically care settings which are required by regulation or law to maintain health records. The care setting profile identifies the functionality that supports the content for the legal health record while the LEHR-S profile identifies foundational functionality that promotes data integrity and trustworthiness. This profile is not intended to stand alone, and the following options illustrate how it could be applied:

- LEHR-S profile paired with a care setting profile, with the care setting profile referencing the LEHR-S profile (examples of care setting profiles include the Emergency Department, Behavioral Health and Long Term Care – Nursing Home profiles),
- LEHR-S profile completely incorporated into the content of a care setting profile, or
- LEHR-S profile clarified through a realm-specific derived profile that specifies relevant jurisdictional laws, rules, and regulations (e.g. Canada could create a derived profile tailored to the realm). Care setting profiles developed in the realm could be paired with their realm specific LEHR-S profile.

A care setting profile will identify the functionality and conformance criteria which supports the collection of content for the required health record and relevant realm-specific jurisdictional laws, rules and regulations. The LEHR-S profile identifies universally the functionality and conformance criteria to support the maintenance of a legally-sound electronic health record within the EHR-S.

3.4 Interoperability

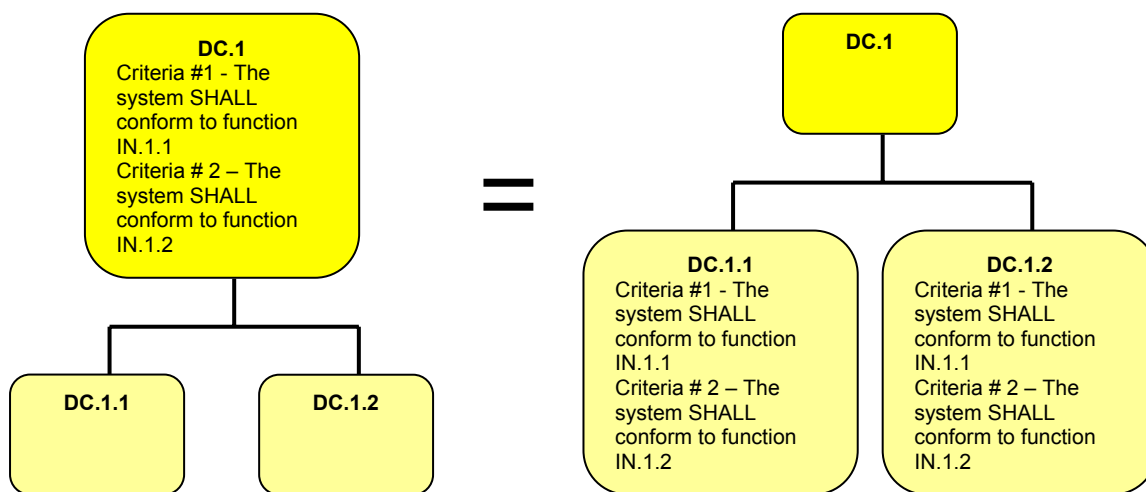
Each component, module or application within the LEHR-S must be interoperable to the degree required by the function description and conformance criteria specified in this profile. ISO 20514 states: “*The key to interoperability is through standardization of requirements for the EHR (record) architecture (e.g. ISO/TS 18308:2004) and ultimately the standardization of the EHR architecture itself (e.g. ENV 13606-1:2000)*”.

4 Organization of this Document

This profile is divided into three sections. Since the *Information Infrastructure* section contains the preponderance of requirements that drive a legal EHR, the Information Infrastructure functions will be listed first, followed by *Supportive* and *Direct Care* Functions.

Information Infrastructure	Functions that support the reliability, integrity, security and interoperability of the LEHR-S. These functions are not involved in the provision of healthcare, but are necessary to ensure that the EHR provides safeguards. The Information Infrastructure functions provide the foundation for maintaining a legally-sound electronic health record within an EHR-S.
Supportive Functions	Functions that support the delivery and optimization of care, but generally do not impact the direct care of an individual patient. These functions assist with the administrative and financial requirements associated with the delivery of healthcare, provide support for medical research and public health, and improve the global quality of healthcare. From a LEHR-S perspective only a handful of Supportive functions relate to maintaining a legally-sound electronic health record.
Direct Care	Functions employed in the provision of care to individual patients and collect information that will comprise the legal electronic health record. Direct care functions are the subset of functions that enable delivery of healthcare or offer clinical decision support.

Because the LEHR-S profile identifies the functionality to support a legally-sound EHR within an EHR-S, the Direct Care section is handled in a unique way. Since the EHR-S Functional Model is presented in a parent/child hierarchical outline, the LEHR-S profile has selected parent functions from the hierarchy whose children functions identify the collection of information that will comprise the legal health record. The conformance criteria in these parent functions require conformance with Information Infrastructure and Supportive functions that promote the maintenance of a legally-sound electronic health record. When a care setting profile selects any of the “child” functions in the Direct Care section, they are required to inherit the conformance criteria from the “parent” function, thereby assuring the content of the electronic health record is supported by Information Infrastructure and Supportive functions that maintain data integrity and trustworthiness (see diagram below).



5 Functional Priorities

The EHR TC and LEHR-S Workgroup recognize that clinical computing is an evolving field, and that many of the desired functions of EHR-S are not currently available. Nevertheless, it is important for functional profiles to outline major trends and articulate a vision for functionality (especially interoperability) for the future. Furthermore, the delineation of potential functions for future implementation and adoption should guide vendors in development, and help purchasers develop and articulate to vendors a strategic vision for future functional requirements.

Each function in the profile is assigned a single priority as follows:

EN Essential Now	Indicates that the implementation of the function is mandatory in all settings and SHALL be implemented in EHR systems claiming conformance to this profile.
EF Essential Future	Indicates that the function has significant importance in all settings but is not widely available. The function will become mandatory and SHALL be implemented in EHR systems claiming conformance to this profile within 24 months after the publication of this profile as a normative standard.

6 Conformance Clause

Key to the Functional Model and derived profiles is the concept of *conformance* which may be defined as “*verification that an implementation faithfully meets the requirements of a standard or specification*” [2]. In the functional model and in derived profiles, the general concept of conformance may be expressed in a number of forms. For instance, this profile can be said to conform to the functional model because it adheres to the conformance rules specified by the functional model. Similarly, an EHR-S may claim conformance to this profile if it meets all the requirements outlined in the profile.

6.1 Conformance of This Profile to the Functional Model

This profile conforms to the HL7 EHR-S Functional Model Release 1, February 2007.

6.2 Conformance of EHR Systems to This Profile

For a vendor or developer to claim conformance with the LEHR-S Functional Profile, a conformance statement SHALL be produced for all systems evaluated using this profile. As of the date registered, an EHR system claiming conformance to this profile SHALL include all functions designated as ‘Essential Now’, and each function SHALL satisfy the conformance criteria designated as ‘SHALL’.

Within the Direct Care section, the functions listed are header functions containing conformance criteria. These conformance criteria SHALL be inherited by all children functions under the named header direct care function. The children functions are listed in the HL7 EHR-S Functional Model, Release 1, February 2007 and labeled (F) for function. It is the purview of the vendor, developer or profile developers to select the appropriate direct care children functions for their systems and/or profiles. The inherited criteria provide a foundation for maintaining a legally-compliant health record. The LEHR-S profile does not identify the functionality that supports the collection of content for the patient record – care setting profiles will identify the appropriate content-related functions.

6.3 Conformance of Derived Profiles to This Profile

The LEHR-S Functional Profile Workgroup recognizes that realms, jurisdictions and other care setting profile developers MAY wish to develop their own LEHR-S profiles. In order for a derived profile to claim conformance with the LEHR-S Functional Profile, the profile SHALL include all functions with a priority of 'Essential Now'. Derived profiles SHALL NOT change the function ID, name or statement, and SHALL include all SHALL conformance criteria in all functions.

Derived profiles SHALL include the conformance criteria listed in the headers of the Direct Care section. These conformance criteria SHALL be inherited by all children functions under the named header direct care function. The children functions are listed in the HL7 EHR-S Functional Model, Release 1, February 2007 and labeled (F) for function. It is the purview of the profile developers to select the appropriate direct care children functions for their systems and/or profiles. The inherited criteria provide a foundation for maintaining a legally-compliant health record. The LEHR-S profile does not identify the functionality that supports the collection of content for the patient record – care setting profiles will identify the appropriate content-related functions.

6.4 Conformance Criteria

Each function defined in the model or profiles is associated with specific *conformance criteria* which are valuable statements used to determine if a particular function is met.

Conformance criteria have been developed in accordance with the standards set forth by the EHR Technical Committee. In order to ensure consistent, unambiguous understanding and application of the functional profile, the use of a consistent set of keywords (normative verbs defined in section 6.5) have been employed to describe conformance requirements.

6.5 Normative Language

The key words SHALL, SHALL NOT, SHOULD, and MAY in this document are to be interpreted as described in HL7 EHR-S Functional Model, Release 1, February 2007 Chapter 2: Conformance Clause:

SHALL – to indicate a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to' and 'must'.

SHALL NOT – to indicate a prohibited action. Synonymous with 'prohibited' and 'must not'.

SHOULD - to indicate an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.

MAY - to indicate an optional, permissible action. Synonymous with 'is permitted'.

Additional clarification is necessary to understand the standardized nomenclature used to describe the functions of a system. The following chart, adapted from the EHR-S FM *How to Guide for Creating Functional Profiles*, illustrates the hierarchy of nomenclature. For example, "capture" is used to describe a function that includes both direct entry "create" and indirect entry through another device "input". Similarly, "maintain" is used to describe a function that entails reading, updating, or removal of data.

MANAGE				
Capture		Maintain		
Input Device (Ext.)	Create (Int.)	Read (Present)	Update	Remove Access
		View Report Display Access	Edit Correct Amend Augment	Obsolete Inactivate Destroy Nullify Purge

7 Components of Legal EHR-S Functional Outline

Each function in the Legal EHR-S Functional Profile is identified and described using a set of elements or components as detailed below.

ID	Type	Priority	Name	Statement /Description	See Also	Conformance Criteria	Row #	FM Source		
								ID #	Criteria #	Criteria Status

Function ID

This is the unique outline identification of a function. Functions inherited from the HL7 EHR-S Functional Model retain the ID assigned in the model. New functions added by the authors of the Legal EHR-S Functional Profile bear a notation of "NEW" and are shown in italicized font.

Information Infrastructure functions are identified by an 'IN' followed by a number (Example IN.1.1; IN.1.2). Supportive functions are identified by an 'S' followed by a number (Example S.2.1; S.2.1.1). Direct Care functions are identified by 'DC' followed by a number (Example DC.1.1.3.1; DC.1.1.3.2).

Function Type

Indication of the line item as being a header (H) or function (F).

Function Priority

Indication that implementation of the function is Essential Now (EN) or Essential Future (EF). The definitions for these priorities are found above in Section 5.

Function Name

The name of the Function (*Example: Entity Authentication*). Functions inherited from the HL7 EHR-S Functional Model retain the Function Name as stated in the model. Names for new functions added by the authors of the Legal EHR-S Functional Profile are shown in italicized font.

Function Statement

Brief statement of the purpose of this function (*Example: Authenticate EHR-S users and/or entities before allowing access to an EHR-S*). Functions inherited from the HL7 EHR-S Functional Model retain the Function Statement as shown in the model. Statements for new functions added by the authors of the Legal EHR-S Functional Profile are shown in italicized font.

Description

Detailed description of the function, including examples if needed (*Example: Both users and applications are subject to authentication. The EHR-S must provide mechanisms for users and applications to be authenticated. Users will have to be authenticated when they attempt to use the application, the applications must authenticate themselves before accessing EHR information managed by other applications or remote EHR-S'...*) A 'Legal Rationale' has been added to the description of functions inherited from the HL7 EHR-S Functional Model, and is shown in italicized font. Descriptions for new functions added by the authors of the Legal EHR-S Functional Profile are also shown in italicized font.

See Also

This element is intended to identify relationships between functions.

Conformance Criteria

This element displays valuable statements used to determine if a particular function is met (*Example: The system SHALL authenticate principals prior to accessing an EHR-S application or EHR-S data*). Modifications to conformance criteria inherited from the HL7 EHR-S Functional Model are shown in italicized font. Conformance criteria for new functions added by the authors of the Legal EHR-S Functional Profile are also shown in italicized font.

Row #

This element is provided to help users when navigating the various sections (i.e. a user can reference row #38 of the IN section versus stating function IN.1.6, criterion #5).

FM Source – ID #

This element is intended to assist with tracing profile content back to the HL7 EHR-S Functional Model. The column displays the ID# for the source function from the model, or is blank if the function was added by the authors of the Legal EHR-S Functional Profile.

FM Source – Criteria #

This element is intended to assist with tracing profile content back to the HL7 EHR-S Functional Model. The column displays the number for the source criterion from the model, or is blank if the criterion was added by the authors of the Legal EHR-S Functional Profile.

FM Source – Criteria Status

This element is intended to assist with tracing profile content back to the HL7 EHR-S Functional Model. The following codes are used to convey the status of the profile's criteria in relation to the Functional Model:

- **N/C** (No Change) – the criterion is exactly the same as in the Functional Model
- **A** (Added) – the criterion was added by the Functional Profile authors and is not found in the Functional Model
- **M** (Modified) – the criterion has been modified and is not the same as in the Functional Model. Modifications to the Functional Model text are shown in italicized font.

Priority – EN = Essential Now, EF = Essential Future

FM Source - Criteria Status is either: N/C = no change, A=added, M=modify. For new children functions, the FM Source columns is blank.

ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
IN.1	H		Security	<p>Statement: Secure the access to an EHR-S and EHR information. Manage the sets of access control permissions granted within an EHR-S. Prevent unauthorized use of data, data loss, tampering and destruction.</p> <p>Description: To enforce security, all EHR-S applications must adhere to the rules established to control access and protect the privacy of EHR information. Security measures assist in preventing unauthorized use of data and protect against loss, tampering and destruction. An EHR-S must be capable of including or interfacing with standards-conformant security services to ensure that any Principal (user, organization, device, application, component, or object) accessing the system or its data is appropriately authenticated, authorized and audited in conformance with local and/or jurisdictional policies.</p> <p>An EHR-S should support Chains of Trust in respect of authentication, authorization, and privilege management, either intrinsically or by interfacing with relevant external services.</p> <p>Legal Rationale: The security practices of an organization support the integrity and trustworthiness of the health record maintained within the EHR system. In litigation, the organization's security practices may be called into question as a way to cast doubt on the validity of the record. The organizations adherence to realm-specific jurisdictional security laws and standards may also be called into question during litigation.</p>			1	IN.1		

Priority – EN = Essential Now, EF = Essential Future

FM Source - Criteria Status is either: N/C = no change, A=added, M=modify. For new children functions, the FM Source columns is blank.

ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
IN.1.1	F	EN	Entity Authentication	<p>Statement: Authenticate EHR-S users and/or entities before allowing access to an EHR-S. Description: Both users and applications are subject to authentication. The EHR-S must provide mechanisms for users and applications to be authenticated. Users will have to be authenticated when they attempt to use the application, the applications must authenticate themselves before accessing EHR information managed by other applications or remote EHR-S'. In order for authentication to be established a Chain of Trust agreement is assumed to be in place. Examples of entity authentication include:</p> <ul style="list-style-type: none"> - username/ password - digital certificate - secure token - biometrics <p>Legal Rationale: Authentication is a critical component to maintaining the legal integrity of the health record contained within the EHR-S.</p> <p>One of the foundational underpinnings of the validity of the record is identification of the users and assurances that they are accurately identified. As a result, the method used by the organization is very important.</p> <p>One of the most common and cost-effective methods of authentication is user ID and password. The legal profile incorporated additional criteria using the CCHIT certification criteria to strengthen the authentication process. Other methods of authentication are considered stronger than user ID and</p>		1. The system SHALL authenticate principals prior to accessing an EHR-S application or EHR-S data.	2	IN.1.1	1	N/C
						2. The system SHALL securely store authentication data/information (e.g. passwords, biometrics, etc.).	3			A
						3. The system SHALL prevent access to EHR-S applications or EHR-S data to all non-authenticated principals.	4	IN.1.1	2	N/C
						4. The system SHALL prevent viewing and access after a period of inactivity by terminating the session or by initiating a session lock that remains in effect until the user reestablishes access using appropriate identification and authentication procedures.	5			A
						5. The system SHALL enforce a limit of (configurable) consecutive invalid access attempts by a user and protect against further, possibly malicious, user authentication attempts using an appropriate mechanism (e.g. locks the account/node until released by an administrator, locks the account/node for a configurable time period, or delays the next login prompt according to a configurable delay algorithm).	6			A
						6. The system SHOULD provide the ability to implement a Chain of Trust agreement.	7	IN.1.1	3	N/C

Priority – EN = Essential Now, EF = Essential Future

FM Source - Criteria Status is either: N/C = no change, A=added, M=modify. For new children functions, the FM Source columns is blank.

ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
				password. Over time, as legal standards evolve, it is anticipated that the bar will be raised and stronger methods of authentication will need to be utilized by healthcare organizations to assure that their users are accurately identified in the system.		7. IF other appropriate authentication mechanisms are absent, THEN the system SHALL authenticate principals authentication using at least one of the following authentication mechanisms: username/password, digital certificate, secure token or biometrics.	8	IN.1.1	4	M
						8. IF passwords are used, THEN the system SHALL prevent the reuse of passwords previously used within a specific (configurable) timeframe (i.e., within the last X days, etc. - e.g. "last 180 days"), or shall prevent the reuse of a certain (configurable) number of the most recently used passwords (e.g. "last 5 passwords").	9			A
						9. IF username/passwords are used, THEN the system SHALL support password strength rules that allow for a minimum number of characters and inclusion of alpha-numeric complexity.	10			A
						10. The system SHALL support case-insensitive usernames that contain typeable alpha-numeric characters in support of ISO-646/ECMA-6 (aka ASCII).	11			A
						11. IF passwords are used, THEN the system SHALL NOT transport passwords in plain text.	12			A
						12. IF passwords are used, THEN the system SHALL NOT display passwords while being entered.	13			A

Priority – EN = Essential Now, EF = Essential Future

FM Source - Criteria Status is either: N/C = no change, A=added, M=modify. For new children functions, the FM Source columns is blank.

ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
IN.1.2	F	EN	Entity Authorization.	<p>Statement: Manage the sets of access-control permissions granted to entities that use an EHR-S (EHR-S Users).</p> <p>Enable EHR-S security administrators to grant authorizations to users, for roles, and within contexts. A combination of these authorization categories may be applied to control access to EHR-S functions or data within an EHR-S, including at the application or the operating system level.</p> <p>Description: EHR-S Users are authorized to use the components of an EHR-S according to their identity, role, work-assignment, location and/or the patient's present condition and the EHR-S User's scope of practice within a legal jurisdiction.</p> <p>- User based authorization refers to the permissions granted or denied based on the identity of an individual. An example of User based authorization is a patient defined denial of access to all or part of a record to a particular party for privacy related reasons. Another user based authorization is for a tele-monitor device or robotic access to an EHR-S for prescribed directions and other input.</p> <p>- Role based authorization refers to the responsibility or function performed in a particular operation or process. Example roles include: an application or device (tele-monitor or robotic); or a nurse, dietician, administrator, legal guardian, and auditor.</p> <p>- Context-based Authorization is defined by ISO 10181-3 Technical Framework for Access</p>	IN.1.3 S.1.3.1	1. The system SHALL provide the ability to create and update sets of access-control permissions granted to principals.	14	IN.1.2	1	N/C
						2. The system SHALL conform to function IN.2.2 (Auditable Records) for the purpose of recording all authorization actions.	15	IN.1.2	2	N/C
						3. The system SHALL provide EHR-S security administrators with the ability to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional law.	16	IN.1.2	3	N/C
						4. The system SHALL provide EHR-S security administrators with the ability to grant authorizations for roles according to scope of practice, organizational policy, or jurisdictional law.	17	IN.1.2	4	N/C

Priority – EN = Essential Now, EF = Essential Future

FM Source - Criteria Status is either: N/C = no change, A=added, M=modify. For new children functions, the FM Source columns is blank.

ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
				Control Standard as security-relevant properties of the context in which an access request occurs, explicitly time, location, route of access, and quality of authentication. For example, an EHR-S might only allow supervising providers' context authorization to attest to entries proposed by residents under their supervision.		5. The system SHALL provide EHR-S security administrators with the ability to grant authorizations within contexts according to scope of practice, organizational policy, or jurisdictional law.	18	IN.1.2	5	N/C
				In addition to the ISO standard, context authorization for an EHR-S is extended to satisfy special circumstances such as, work assignment, patient consents and authorizations, or other healthcare-related factors. A context-based example is a patient-granted authorization to a specific third party for a limited period to view specific EHR records.		6. The system SHALL provide the ability to define context for the purpose of principal authorization based on identity, role, work assignment, present condition, location, patient consent, or patient's present condition.	19	IN.1.2	6	M
				Another example is a right granted for a limited period to view those, and only those, EHR records connected to a specific topic of investigation.		7. The system SHALL provide the ability to define context based on legal requirements.	20	IN.1.2	7	M
				Legal Rationale: The authorization process is important legally because it provides the system rules and context for actions recorded within the EHR system. The actions and individuals may be called into question retrospectively. Authorization functionality is also important to constrain users to the system rules such as limiting printing or output capability. This is important legally to maintain controls on the location of outputs from the system.		8. <i>The system SHALL provide the ability to remove a user's privileges without deleting the user from the system (thereby maintaining a user history).</i>	21			A

Priority – EN = Essential Now, EF = Essential Future

FM Source - Criteria Status is either: N/C = no change, A=added, M=modify. For new children functions, the FM Source columns is blank.

ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						9. The system SHALL limit access to appropriately authorized users for EHR data that has been designated as confidential in accordance with function IN.1.9 (Patient Privacy and Confidentiality).	22			A
						10. The system MAY provide the ability to establish and enforce rules which prevent users with read and/or write privileges from printing or copying/writing to other media.	23			A
IN.1.3	F	EN	Entity Access Control	<p>Statement: Verify and enforce access control to all EHR-S components, EHR information and functions for end-users, applications, sites, etc., to prevent unauthorized use of a resource.</p> <p>Description: Entity Access Control is a fundamental function of an EHR-S. To ensure that access is controlled, an EHR-S must perform authentication and authorization of users or applications for any operation that requires it and enforce the system and information access rules that have been defined.</p> <p>Legal Rationale: Controls to limit access to only authorized users are important for supporting the authenticity and trustworthiness of the electronic health record.</p>		1. The system SHALL conform to function IN.1.1 (Entity Authentication).	24	IN.1.3	1	N/C
						2. The system SHALL conform to function IN.1.2 (Entity Authorization).	25	IN.1.3	2	N/C
						3. The system SHALL provide the ability to define system and data access rules.	26	IN.1.3	3	N/C
						4. The system SHALL enforce system and data access rules for all EHR-S resources (at component, application, or user level, either local or remote).	27	IN.1.3	4	N/C
						5. The system SHALL provide the ability for specified users to override the access control rules and request access to health information (“break the glass” functionality), record the reason for access and provide an administrative report.	28			A

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
IN.1.4	F	EN	Patient Access Management	<p>Statement: Enable a healthcare delivery organization to allow and manage a patient's access to the patient's personal health information.</p> <p>Description: A healthcare delivery organization will be able to manage a patient's ability to view his or her EHR based on scope of practice, organization policy or jurisdictional law. Typically, a patient has the right to view his or her EHR and the right to place restrictions on who can view parts or the whole of that EHR. For example, in some jurisdictions, minors have the right to restrict access to their data by parents/guardians.</p> <p>One example of managing a patient's access to his or her data is by extending user access controls to patients.</p> <p>Legal Rationale: Similar to access controls in IN.1.3, any controls on access, including patient access, are important for maintaining the electronic health record's integrity and trustworthiness.</p>		1. The system SHALL conform to function IN.1.3 (Entity Access Control) in order for a healthcare delivery organization to manage a patient's access to his or her healthcare information.	29	IN.1.4	1	N/C
IN.1.5	F	EN	Non-Repudiation	<p>Statement: Limit an EHR-S user's ability to deny (repudiate) the origination, receipt, or authorization of a data exchange by that user.</p> <p>Description: An EHR-S allows data entry and data access to a patient's electronic health record and it can be a sender or receiver of healthcare information. Non</p>		1. The system SHALL time stamp initial entry, modification, or exchange of data, and identify the actor/principal taking the action as required by users' scope of practice, organizational policy, or jurisdictional law.	30	IN.1.5	1	N/C

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								ID#	Criteria #	Criteria Status
				repudiation guarantees that the source of the data record can not later deny that it is the source; that the sender or receiver of a message cannot later deny having sent or received the message. For example, non-repudiation may be achieved through the use of a: - Digital signature, which serves as a unique identifier for an individual (much like a written signature on a paper document). - Confirmation service, which utilizes a message transfer agent to create a digital receipt (providing confirmation that a message was sent and/or received) and - Timestamp, which proves that a document existed at a certain date and time. Date and Time stamping implies the ability to indicate the time zone where it was recorded (time zones are described in ISO 8601 Standard Time Reference). Legal Rationale: Non-repudiation is a critical function in support of a legally-sound record. System functionality must support the integrity of the data and record and prevent against denial of origination or receipt.		2. The system SHALL provide additional non-repudiation functionality where required by users' scope of practice, organizational policy, or jurisdictional law.	31	IN.1.5	2	N/C
						3. The system SHALL conform to function IN.2.2 (Auditable Records) to prevent repudiation of data origination, receipt, or access.	32	IN.1.5	3	M
						4. The system SHALL conform to function IN.1.8 (Information Attestation) to ensure the integrity of data exchange and thus prevent repudiation of data origination or receipt.	33	IN.1.5	4	M
IN.1.6	F	EN	Secure Data Exchange	Statement: Secure all modes of EHR data exchange. Description: Whenever an exchange of EHR information occurs, it requires appropriate security and privacy considerations, including data obfuscation as well as both destination and source authentication when necessary. For example, it may be necessary to encrypt	IN.1.1 IN.2.2	1. The system SHALL secure all modes of EHR data exchange.	34	IN.1.6	1	N/C
						2. The system SHOULD conform to function IN.1.7 (Secure Data Routing).	35	IN.1.6	2	N/C

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								ID#	Criteria #	Criteria Status
				<p>data sent to remote or external destinations. A secure data exchange requires that there is an overall coordination regarding the information that is exchanged between EHR-S entities and how that exchange is expected to occur. The policies applied at different locations must be consistent or compatible with each other in order to ensure that the information is protected when it crosses entity boundaries within an EHR-S or external to an EHR-S.</p> <p>Legal Rationale: <i>It is important that the information received and used for patient care comes from a trusted source and that standards/protocols are in place to ensure that the data sent is the same as the data received.</i></p>		<p>3. The system MAY provide the ability to obfuscate data.</p> <p>4. The system SHALL encrypt and decrypt EHR data that is exchanged over a non-secure link.</p> <p>5. The system SHALL support standards-based encryption mechanisms when encryption is used for secure data exchange.</p>	36 37 38	IN.1.7 IN.1.6 IN.1.6	3 4 5	N/C N/C N/C
IN.1.7	F	EN	Secure Data Routing	<p>Statement: Route electronically exchanged EHR data only to/from known, registered, and authenticated destinations/sources (according to applicable healthcare-specific rules and relevant standards).</p> <p>Description: An EHR-S needs to ensure that it is exchanging EHR information with the entities (applications, institutions, directories) it expects. This function depends on entity authorization and authentication to be available in the system. For example, a physician practice management application in an EHR-S might send claim attachment</p>	IN.1.1 IN.1.2	1. The system SHALL automatically route electronically exchanged EHR data only from and to known sources and destinations and only over secure networks.	39	IN.1.7	1	N/C

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								ID#	Criteria #	Criteria Status
				<p>information to an external entity. To accomplish this, the application must use a secure routing method, which ensures that both the sender and receiving sides are authorized to engage in the information exchange. Known sources and destinations can be established in a static setup or they can be dynamically determined. Examples of a static setup are recordings of IP addresses or recordings of DNS names. For dynamic determination of known sources and destinations systems can use authentication mechanisms as described in IN.1.1. For example, the sending of a lab order from the EHRS to a lab system within the same organization usually uses a simple static setup for routing. In contrast sending a lab order to a reference lab outside of the organization will involve some kind of authentication process. In general, when the underlying network infrastructure is secure (e.g. secure LAN or VPN) the simple static setup is used.</p> <p>Legal Rationale: It is important that the information exchanged is from a trusted source.</p>		<p>2. The system SHOULD route electronically exchanged EHR data only to and from authenticated sources and destinations (conform to function IN.1.1 (Entity Authentication)).</p>	40	IN.1.7	2	N/C
						<p>3. The system SHOULD conform to function IN.2.2 (Auditable Records) to provide audit information about additions and changes to the status of destinations and sources.</p>	41	IN.1.7	3	N/C
IN.1.8	F	EN	Information Attestation	<p>Statement: Manage electronic attestation of information including the retention of the signature of attestation (or certificate of authenticity) associated with incoming or outgoing information.</p> <p>Description: The purpose of attestation is to show authorship and assign responsibility for an act, event, condition, opinion, or diagnosis. Every entry in the health record must be identified with the author and should not be made or signed by someone other than the</p>	IN.2.5.3.1	<p>1. The system SHALL conform to function IN.1.1 (Entity Authentication).</p>	42	IN.1.8	1	N/C
						<p>2. The system SHALL conform to function IN.1.2 (Entity Authorization).</p>	43	IN.1.8	2	N/C
						<p>3. The system SHALL provide the ability to associate any attestable content added or changed to an EHR with the content's author (for example by conforming to function IN.2.2 (Auditable Records)).</p>	44	IN.1.8	3	N/C

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								ID#	Criteria #	Criteria Status
				<p>author. (Note: A transcriptionist may transcribe an author's notes and a senior clinician may attest to the accuracy of another's statement of events.) Attestation is required for (paper or electronic) entries such as narrative or progress notes, assessments, flow sheets, and orders. Digital signatures may be used to implement document attestation. For an incoming document, the record of attestation is retained if included. Attestation functionality must meet applicable legal, regulatory and other applicable standards or requirements.</p> <p>Legal Rationale: Legally it is critical that the author of an entry (including all contributors or co-authors) be accurately identified and that every entry has an author who is responsible for the content. Over time it is anticipated that the bar will be raised and that stronger authentication/attestation processes will be required to prevent someone from refuting that they were the author.</p>		<p>4. The system SHALL provide the ability for attestation of attestable EHR content by the content's author <i>or authors</i>.</p> <p>5. The system SHALL indicate the status of attestable data which has not been attested.</p> <p>6. The system SHALL provide the ability for attestation of EHR content by properly authenticated and authorized users different from the author (e.g. <i>counter-signature</i>) as required by users' scope of practice, organizational policy, or jurisdictional law.</p> <p>7. <i>IF more than one author contributed to the EHR content, THEN the system SHALL maintain all authors/contributors.</i></p> <p>8. <i>IF EHR content was attested by someone other than the author, THEN the system SHALL maintain all authors/attesters and display in a hierarchical manner as defined by scope of practice, organizational policy, or jurisdictional law.</i></p> <p>9. <i>The system SHALL provide the ability to define and present a minimum data set of author information to be displayed with the entry as defined by organizational policy or jurisdictional law.</i></p> <p>10. <i>IF a record (e.g. a structured document) is completed by multiple authors, THEN the system SHALL allow for multiple-attestations linking the content completed to the appropriate author.</i></p> <p>11. The system SHOULD provide the ability to use digital signatures as the means for attestation.</p>	45	IN.1.8	4	M
							46	IN.1.8	5	N/C
							47	IN.1.8	6	M
							48			A
							49			A
							50			A
							51			A
							52	IN.1.8	7	M
IN.1.9	F	EN	Patient Privacy and Confidentiality	Statement: Enable the enforcement of the applicable jurisdictional and organizational patient privacy rules as they apply to various	IN.6	1. The system SHALL provide the ability to fully comply with the requirements for patient privacy and confidentiality in accordance with a user's	53	IN.1.9	1	N/C

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								ID#	Criteria #	Criteria Status
				<p>parts of an EHR-S through the implementation of security mechanisms.</p> <p>Description: Patients' privacy and the confidentiality of EHRs are violated if access to EHRs occurs without authorization. Violations or potential violations can impose tangible economic or social losses on affected patients, as well as less tangible feelings of vulnerability and pain. Fear of potential violations discourages patients from revealing sensitive personal information that may be relevant to diagnostic and treatment services. Rules for the protection of privacy and confidentiality may vary depending upon the vulnerability of patients and the sensitivity of records. Strongest protections should apply to the records of minors and the records of patients with stigmatized conditions. Authorization to access the most sensitive parts of an EHR is most definitive if made by the explicit and specific consent of the patient. Please see the definition of masking in the glossary.</p> <p>Legal Rationale: Organizational practices related to privacy and security jurisdictional laws could be called into question during a legal proceeding. Adherence to applicable laws supports the credibility and trustworthiness of the organization.</p>		scope of practice, organizational policy, or jurisdictional law.				
						2. The system SHALL conform to function IN.1.1 (Entity Authentication).	54	IN.1.9	2	N/C
						3. The system SHALL conform to function IN.1.2 (Entity Authorization).	55	IN.1.9	3	N/C
						4. The system SHALL conform to function IN.1.3 (Entity Access Control).	56	IN.1.9	4	N/C
						5. The system SHALL conform to function IN.1.5 (Non-Repudiation).	57	IN.1.9	5	M
						6. The system SHALL conform to function IN.1.6 (Secure Data Exchange).	58	IN.1.9	6	M
						7. The system SHALL conform to function IN.2.2 (Auditable Records).	59	IN.1.9	7	M
						8. The system SHALL provide the ability to maintain varying levels of confidentiality in accordance with users' scope of practice, organizational policy, or jurisdictional law.	60	IN.1.9	8	N/C
						9. The system SHALL provide the ability to mask parts of the electronic health record (e.g. medications, conditions, sensitive documents) from disclosure according to scope of practice, organizational policy or jurisdictional law.	61	IN.1.9	9	N/C
						10. The system SHALL provide the ability to override a mask in emergency or other specific situations according to scope of practice, organizational policy or jurisdictional law.	62	IN.1.9	10	N/C
IN.2	H		Health Record Information and Management	<p>Statement: Manage EHR information across EHR-S applications by ensuring that clinical information entered by providers is a valid</p>			63	IN.2		

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								ID#	Criteria #	Criteria Status
				representation of clinical notes; and is accurate and complete according to clinical rules and tracking amendments to clinical documents. Ensure that information entered by or on behalf of the patient is accurately represented. Description: Since EHR information will typically be available on a variety of EHR-S applications, an EHR-S must provide the ability to access, manage and verify accuracy and completeness of EHR information, maintain the integrity and reliability of the data, and provide the ability to audit the use of and access to EHR information. Legal Rationale: Adherence to sound electronic records management principles supports the maintenance of a legally-sound health record.						
IN.2.1	F	EN	Data Retention, Availability and Destruction	Statement: Retain, ensure availability, and destroy health record information according to scope of practice, organizational policy, or jurisdictional law. This includes: -Retaining all EHR-S data and clinical documents for the time period designated by policy or legal requirement; -Retaining inbound documents as originally received (unaltered); -Ensuring availability of information for the legally prescribed period of time to users and patients; and -Providing the ability to destroy EHR data/records in a systematic way according to policy and after the legally prescribed retention period. Description: Discrete and structured EHR-S	IN.1.7	1. The system SHALL provide the ability to store and retrieve health record data and clinical documents for the legally prescribed time. 2. The system SHALL provide the ability to retain inbound data or documents (related to health records) as originally received (unaltered, inclusive of the method in which they were received) for the legally organizationally prescribed time in accordance with users' scope of practice, organizational policy, or jurisdictional law. 3. The system SHALL retain the content of inbound data (related to health records) as originally received for the legally prescribed time.	64	IN.2.1	1	N/C
							65	IN.2.1	2	N/C
							66	IN.2.1	3	N/C

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				<p>data, records and reports must be:</p> <ul style="list-style-type: none"> -Made available to users in a timely fashion; -Stored and retrieved in a semantically intelligent and useful manner (for example, chronologically, retrospectively per a given disease or event, or in accordance with business requirements, local policies, or legal requirements); -Retained for a legally prescribed period of time; and -Destroyed in a systematic manner in relation to the applicable retention period. <p>An EHR-S must also allow an organization to identify data/records to be destroyed, and to review and approve destruction before it occurs. In such a case it should pass along record destruction date information along with existing data when providing records to another entity.</p> <p>Legal Rationale: Adherence to organizational retention and destruction policies that comply with jurisdictional law is critical in legal proceedings to prevent accusations of spoliation of evidence and establish that the organization destroyed records as part of their good faith practices.</p>		<p>4. The system SHALL provide the ability to retrieve both the information and business context data within which that information was obtained.</p>	67	IN.2.1	4	M
						<p>5. The system SHALL provide the ability to retrieve all the elements included in the definition of a legal medical record.</p>	68	IN.2.1	5	M
						<p>6. The system SHALL provide the ability to identify specific EHR data/records for destruction, review and confirm destruction before it occurs and implement function IN.2.2 (Auditable Records).</p>	69	IN.2.1	6	M
						<p>7. The system SHALL provide the ability to destroy EHR data/records so that all traces are irrecoverably removed according to policy and legal retentions periods.</p>	70	IN.2.1	7	M
						<p>8. The system SHALL pass along record destruction date information (if any) along with existing data when providing records to another entity.</p>	71	IN.2.1	8	M
NEW IN.2.1.1	F	EF	Legal Hold	<p>Statement: EHR systems must support a duty to preserve material evidence (suspend normal destruction practices) when the organization reasonably should know that the evidence (health information) may be relevant to anticipated litigation.</p> <p>Description/Legal Rationale: Organizations have a duty to preserve information that is or</p>	IN.2.2	<p>1. The system SHALL provide the ability to secure data/records for the purpose of suspending the normal destruction process for information considered relevant to potential or pending litigation.</p>	72			A
						<p>2. The system SHALL identify the locations of data/records and identify the associated custodian of the record.</p>	73			A

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								ID#	Criteria #	Criteria Status
				could be relevant to a legal proceeding whether litigation is threatened (the potential for) or impending. The organization must take steps to place a legal hold (suspend their normal destruction practices for all potentially relevant information) and prevent from loss, destruction, unauthorized use or alteration. Audit trail functionality will identify access and alterations to the record.		3. The system SHOULD provide the ability to identify the information involved in the legal hold by type, class or encounter (for example: medical record entry or report, e-mail, metadata, etc.).	74			A
						4. The system SHALL provide the ability to designate the status of information subject to legal hold as active, historical/archived or future data.	75			A
						5. The system SHALL provide the ability to monitor and age the ongoing status of a legal hold and provide reports for management.	76			A
						6. The system SHOULD provide a report which indicates file size, format, and retention of data on legal hold to be used for determining costs.	77			A
NEW IN.2.1.1.1	F	EF	Legal Hold Notice	Statement: Provide a notice to EHR-S users when records are on legal hold. Description/Legal Rationale: In an EHR-S records that are on legal hold will be available for review and/or patient care purposes. The notice tells the user that the records are on legal hold, who to contact for questions and the general reason for the hold. Key departments and staff must be notified when a legal hold has been lifted.	IN.6	1. The system SHALL provide the ability to generate a legal hold notice which 1) Identifies that a record/document is on legal hold; 2) Informs recipient who to contact for legal hold matters; 3) Describes the matter at issue; and 4) Identifies the potential sources of relevant information and legal obligation.	78			A
						2. The system SHOULD provide the ability to generate a notice to relevant personnel (HIM, IT, record custodian and others identified by the organization) to advise them when a legal hold has been lifted.	79			A
IN.2.2	F	EN	Auditable Records	Statement: Provide audit capabilities for system access and usage indicating the author, the modification (where pertinent), and the date and time at which a record was created, modified, viewed, extracted, or deleted. Date and Time stamping implies the ability to indicate the time zone where it was recorded (time zones are described in ISO 8601 Standard Time Reference). Auditable		1. The system SHALL audit capabilities for recording access and usage of systems, data, and organizational resources.	80	IN.2.2	1	N/C
						2. The system SHALL conform to function IN.1.1 (Entity Authentication).	81	IN.2.2	2	N/C
						3. The system SHALL provide audit capabilities indicating the time stamp for an object or data creation.	82	IN.2.2	3	N/C

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				<p>records extend to information exchange, to audit of consent status management (to support DC.1.3.3) and to entity authentication attempts. Audit functionality includes the ability to generate audit reports and to interactively view change history for individual health records or for an EHR-S.</p> <p>Description: Audit functionality extends to security audits, data audits, audits of data exchange, and the ability to generate audit reports. Audit capability settings should be configurable to meet the needs of local policies. Examples of audited areas include:</p> <ul style="list-style-type: none"> - Security audit, which logs access attempts and resource usage including user login, file access, other various activities, and whether any actual or attempted security violations occurred - Data audit, which records who, when, and by which system an EHR record was created, updated, translated, viewed, extracted, or (if local policy permits) deleted. Audit-data may refer to system setup data or to clinical and patient management data - Information exchange audit, which records data exchanges between EHR-S applications (for example, sending application; the nature, history, and content of the information exchanged); and information about data transformations (for example, vocabulary translations, reception event details, etc.) - Audit reports should be flexible and address various users' needs. For example, a legal authority may want to know how many 		<p>4. The system SHALL provide audit capabilities indicating the time stamp for an object or data modification in accordance with users' scope of practice, organizational policy, or jurisdictional law.</p> <p>5. The system SHALL provide audit capabilities indicating the time stamp for an object or data extraction in accordance with users' scope of practice, organizational policy, or jurisdictional law.</p> <p>6. The system SHALL provide audit capabilities indicating the time stamp for an object or data exchange.</p> <p>7. The system SHALL provide audit capabilities indicating the time stamp for an object or data view.</p> <p>8. The system SHALL provide audit capabilities indicating the time stamp for an object or data deletion in accordance with users' scope of practice, organizational policy, or jurisdictional law.</p> <p>9. The system SHALL provide audit capabilities indicating the author of a change in accordance with users' scope of practice, organizational policy, or jurisdictional law.</p> <p>10. The system SHALL provide audit capabilities indicating the viewer of a data set.</p> <p>11. The system SHALL provide audit capabilities indicating the data value before a change.</p> <p>12. The system SHALL provide audit capabilities to capture system events at the hardware and software architecture level. (See IN.2.2.1.2 System Metadata)</p> <p>13. The system SHALL conform to function IN.1.3 (Entity Access Control) to limit access to audit record information to appropriate entities in accordance with users' scope of practice, organizational policy, or jurisdictional law.</p>	83	IN.2.2	4	N/C
							84	IN.2.2	5	N/C
							85	IN.2.2	6	N/C
							86	IN.2.2	7	M
							87	IN.2.2	8	N/C
							88	IN.2.2	9	N/C
							89	IN.2.2	10	N/C
							90	IN.2.2	11	M
							91	IN.2.2	12	M
							92	IN.2.2	13	N/C

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				<p>patients a given healthcare provider treated while the provider's license was suspended. Similarly, in some cases a report detailing all those who modified or viewed a certain patient record</p> <p>- Security audit trails and data audit trails are used to verify enforcement of business, data integrity, security, and access-control rules</p> <p>-There is a requirement for system audit trails for the following events: >Loading new versions of, or changes to, the clinical system; >Loading new versions of codes and knowledge bases; >Taking and restoring of backup; >Changing the date and time where the clinical system allows this to be done; >Archiving any data; >Re-activating of an archived patient record; >Entry to and exiting from the clinical system; >Remote access connections including those for system support and maintenance activities.</p> <p>Legal Rationale: The audit functionality provides traceability to show the activities "behind the scenes." With traceability comes trustworthiness in the electronic records to be used in legal proceedings.</p>		14. The system SHALL provide the ability to generate an audit report.	93	IN.2.2	14	N/C
						15. The system SHALL provide the ability to view change history for a particular record or data set in accordance with users' scope of practice, organizational policy, or jurisdictional law.	94	IN.2.2	15	N/C
						16. The system SHALL provide the ability to record system maintenance events for loading new versions of, or changes to, the clinical system. (See IN.2.2.1.2 (System Metadata))	95	IN.2.2	16	M
						17. The system SHALL provide the ability to record system maintenance events for loading new versions of codes and knowledge bases.	96	IN.2.2	17	M
						18. The system SHALL provide the ability to record changing the date and time where the clinical system allows this to be done.	97	IN.2.2	18	M
						19. The system SHALL provide the ability to record system maintenance events for creating and restoring of backup. (See IN.2.2.1.2 (System Metadata))	98	IN.2.2	19	M
						20. The system SHALL provide the ability to record system maintenance events for archiving any data. (See IN.2.2.1.2 (System Metadata))	99	IN.2.2	20	M
						21. The system SHALL provide the ability to record system maintenance events for re-activating of an archived patient record. (See IN.2.2.1.2 (System Metadata))	100	IN.2.2	21	M
						22. The system SHALL provide the ability to record system maintenance events for entry to and exit from the EHR system.	101	IN.2.2	22	M
						23. The system SHALL provide the ability to record system maintenance events for remote access connections including those for system support and maintenance activities. (See IN.2.2.1.2 (System Metadata))	102	IN.2.2	23	M

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								ID#	Criteria #	Criteria Status
						24. The system SHALL utilize standardized time keeping (for example using the IHE consistent time profile).	103	IN.2.2	24	M
						25. The system SHALL provide the ability to record and report upon audit information using a standards-based audit record format (for example RFC 3881).	104	IN.2.2	25	M
NEW IN.2.2.1	H	EN	Metadata - General	<p>Statement: Metadata is an inextricable part of electronic records management and is utilized for a variety of functions and purposes. In a legal setting, metadata may be used to authenticate the evidentiary value of electronic information and/or describe contextual processing of a record.</p> <p>Description/Legal Rationale: Metadata (data about data) can validate and quantify the authenticity, reliability, usability and integrity of information over time and enable the management and understanding of electronic information (physical, analogue or digital). The metadata collected and retained may vary by organization and within jurisdictions according to: a) business needs; b) jurisdictional regulatory environment; c) risks affecting business operations.</p> <p>Effective utilization of metadata requires appropriate management of metadata information. All EHR applications must adhere to established standards which enable the</p>		1. The system SHALL capture and retain metadata as defined by organizational policy or jurisdictional law.	105			A
						2. The system SHALL maintain metadata that documents the business context in which records are created or captured, as well as the content, structure and appearance of those records;	106			A
						3. The system SHALL maintain metadata that documents records creation, records management and the business processes in which records are subsequently used, including any changes to the content, structure and appearance of the record.	107			A
						4. The system SHOULD maintain metadata which supports the technological environment in which digital records are created or captured.	108			A
						5. The system SHOULD utilize metadata to provide logical links between records and the context of their creation, and maintain them in a structured, reliable and meaningful way.	109			A

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								ID#	Criteria #	Criteria Status
				creation, registration, classification, access, preservation and disposition of records through time and within and across information systems. Metadata supports the interoperability strategies by enabling the authoritative capture of records created in diverse technical and business environments and is sustained for as long as required. (Reference - ISO 23081)		6. The system SHOULD utilize metadata to support the efficient and successful migration of records from one environment or computer platform to another or any other preservation method.	110			A
NEW IN.2.2.1.1	F	EN	Point of Record Metadata	<p>Statement: Metadata at the point of patient record capture includes information about the context of record creation, the business context, the agents involved and metadata about the content, appearance, structure and technical attributes of the record itself.</p> <p>Description/Legal Rationale: Metadata can ensure the authenticity, reliability, usability and integrity of information over time and enable the management and understanding of electronic information. (physical, analogue or digital) Effective utilization of metadata requires appropriate management of the information. Therefore, all EHR systems must adhere to established standards which enable the creation, registration, classification, access, preservation and disposition of records through time and within and across information systems. Some examples of metadata for the point of record include the audit record data, the header or footer of a structured document, the wrapper of an exchanged message, etc.</p>	IN.2.2	1. The system SHOULD produce metadata at the single record level which consists of: <ul style="list-style-type: none"> a) a description of the physical or technical structure of the record; b) a description of the logical structure of the record (i.e. description of the data elements which comprise the record) 	111			A
						2. The system SHOULD provide the ability to utilize metadata in such a way that it can document all processes performed upon a record, or on a group or aggregation of records.	112			A
						3. The system SHALL retain metadata records for as long as the original record exists, and/or in accordance with a legal hold or preservation order.	113			A
NEW IN.2.2.1.2	F	EN	System Metadata	<p>Statement: System metadata is information about the physical structure of the EHR system itself. This function includes defining, collecting and</p>	IN.2.2	1. The system SHALL provide the ability to define, collect and store database file creation data, unique file ID system, name, type, size, location, relationships between files.	114			A

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				<p>storing important data to describe the EHR architecture, hardware/ physical systems and the infrastructure in use over a definable time range.</p> <p>Description/Legal Rationale: System metadata topics include EHR system hardware components versions tracking, interfaces tracking, hyper linking, database product version tracking/structure/configuration and system architecture used over a definable time range.</p>		<p>2. The system SHOULD provide the ability to define hierarchical data stores (database).</p>	115			A
						<p>3. The system SHOULD provide the ability to define data conversion methods used.</p>	116			A
						<p>4. The system MAY generate system architecture definition/version tracking.</p>	117			A
						<p>5. The system SHALL generate data source definitions and archiving.</p>	118			A
						<p>6. The system MAY provide the ability to define data compaction methodology used in database.</p>	119			A
						<p>7. The system SHOULD provide the ability to define, collect and store interfaced messaging metadata (e.g., time sent, time received, source system, receipt system).</p>	120			A
NEW IN.2.2.1.3	F	EN	Software Application Metadata	<p>Statement: Software application metadata is information about the software/applications used in the EHR. This function includes defining, collecting and storing important data to describe the EHR software, its components, and their evolution over time.</p> <p>These software components fully serve as the basis for EHR-user interactions that generate the clinical patient data and display the clinical patient data.</p> <p>Description/Legal Rationale: Version control and archiving allows multiple</p>		<p>1. The system SHALL provide the ability to define, collect, and store product release version tracking.</p>	121			A
						<p>2. The system SHALL provide the ability to define, collect, and store product module install tracking</p>	122			A
						<p>3. The system SHALL provide the ability to define, collect, and store the creation/alternation/ deletion of direct data entry tools and tool components via version tracking.</p>	123			A
						<p>4. The system SHALL provide the ability to define, collect, and store the creation/alternation/ deletion of clinical data trending tools and tool components via version tracking.</p>	124			A

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				<p>sets or versions of the same software application modules and/or components and/or subcomponents to exist and be distinctly recognized over time. This accommodates changes to software/applications in both the vendor development and the client configuration cycles as the software product(s) undergoes a natural upgrade evolution. Some high-level categories of components are direct data entry tools, data display tools and reporting, both on-line and via print channels.</p> <p>It should be possible to retire depreciated software versions and components while supporting retrospective replication of the clinical view.</p>		<p>5. The system SHALL provide the ability to define, collect, and store the creation/alternation/deletion of data sets and set components via version tracking.</p> <p>6. The system SHALL provide the ability to define, collect, and store printing metadata, including what printed, who printed and the printing output.</p> <p>7. The system SHOULD standardize data entry tool status across all software modules tools/components;</p> <p>8. The system SHOULD lock all inactive versions and all active versions after creation/editing event.</p> <p>9. The system SHOULD limit any unique 'active' tool/component to one at a time.</p> <p>10. The system MAY provide the ability to use standardization & relationships of clinical concepts across all data entry tools and data display.</p> <p>11. The system SHOULD provide the ability to track hyperlink access associated with EHR (e.g., clinical knowledge base, PACs (Pictorial Archiving & Communications links).</p>	<p>125</p> <p>126</p> <p>127</p> <p>128</p> <p>129</p> <p>130</p> <p>131</p>			<p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p>
IN.2.3	F	EN	Synchronization	<p>Statement: Maintain synchronization involving:</p> <ul style="list-style-type: none"> -Interaction with entity directories; -Linkage of received data with existing entity records; -Location of each health record component; 		<p>1. The system SHALL conform to function IN.5.1 (Interchange Standards).</p>	132	IN.2.3	1	N/C

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				and -Communication of changes between key systems. Description: An EHR-S may consist of a set of components or applications; each application manages a subset of the health information. Therefore it is important that, through various interoperability mechanisms, an EHR-S maintains all the relevant information regarding the health record in synchrony. For example, if a physician orders an MRI, a set of diagnostic images and a radiology report will be created. The patient demographics, the order for MRI, the diagnostic images associated with the order, and the report associated with the study must all be synchronized in order for the clinicians to view the complete record. Legal Rationale: Maintenance of synchronization activities could be relevant during a legal proceeding.		2. The system SHOULD conform to function IN.3 (Registry and Directory Services) to enable the use of registries and directories.	133	IN.2.3	2	N/C
						3. The system SHOULD provide the ability to link entities to external information.	134	IN.2.3	3	N/C
						4. The system SHOULD store the location of each known health record component in order to enable authorized access to a complete logical health record if the EHR is distributed among several applications within the EHR-S.	135	IN.2.3	4	N/C
IN.2.4	F	EN	Extraction of Health Record Information	Statement: Manage data extraction in accordance with analysis and reporting requirements. The extracted data may require use of more than one application and it may be pre-processed (for example, by being de-identified) before transmission. Data extractions may be used to exchange data and provide reports for primary and ancillary purposes. Description: An EHR-S enables an authorized user, such as a clinician, to access and aggregate the distributed information, which corresponds to the health record or records that are needed for viewing, reporting, disclosure, etc. An EHR-S must support data	S.2.2	1. The system SHALL provide the ability to extract health record information.	136	IN.2.4	1	N/C
						2. The system SHOULD conform to function IN.1.6 (Secure Data Exchange) to provide secure data exchange capabilities.	137	IN.2.4	2	N/C
						3. The system SHALL provide the ability to de-identify extracted information.	138	IN.2.4	3	M
						4. The system SHOULD conform to function IN.5.1 (Interchange Standards) to enable data extraction in standard-based formats.	139	IN.2.4	4	N/C
						5. The system SHALL provide the ability to perform extraction operations across the complete data set that constitutes the health record of an individual within the system.	140	IN.2.4	5	M

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				<p>extraction operations across the complete data set that constitutes the health record of an individual and provide an output that fully chronicles the healthcare process. Data extractions are used as input to patient care coordination between facilities, organizations and settings. In addition, data extractions can be used for administrative, financial, research, quality analysis, and public health purposes.</p> <p>Legal Rationale: Extraction may also be needed in response to a request from the court of opposing party.</p>		<p>6. The system SHALL provide the ability to perform extraction operations whose output fully chronicles the healthcare process.</p> <p>7. The system SHALL provide the ability to extract data for administrative purposes.</p> <p>8. The system SHOULD provide the ability to extract data for financial purposes.</p> <p>9. The system SHOULD provide the ability to extract data for research purposes.</p> <p>10. The system SHOULD provide the ability to extract data for quality analysis purposes.</p> <p>11. The system SHOULD provide the ability to extract data for public health purposes.</p>	141	IN.2.4	6	M
							142	IN.2.4	7	M
							143	IN.2.4	8	N/C
							144	IN.2.4	9	N/C
							145	IN.2.4	10	N/C
							146	IN.2.4	11	N/C
NEW IN.2.4.1	F	EF	Search and Retrieve	<p>Statement: Automated search and retrieval technology is necessary and valuable in identifying and retrieving relevant EHR information.</p> <p>Description/Legal Rationale: When required to find all relevant information pertaining to litigation, human review of EHR information is impractical and costly. A defined approach to the search and retrieval of relevant information is more likely to result in accurate, complete, uniform and consistent production of relevant information for a legal proceeding. The EHR-S must support a structured method to search for relevant information from the system. This not only includes patient medical records, but also audit logs and metadata, decision support logic, e-mails and source systems. This function is the equivalent of "Google" for the EHR-S.</p>		<p>1. The system SHALL provide the ability to conduct key word searches of the EHR-S data base(s).</p> <p>2. The system SHALL retrieve and display information based on the search parameters (key words).</p> <p>3. The system MAY perform full text and metadata searching as a means of filtering data.</p> <p>4. The system MAY present a measure of how close the match meets the search criteria (i.e. 90% match).</p>	147			A
							148			A
							149			A
							150			A
IN.2.5	H		Store and Manage Health Record	<p>Statement: Store and manage health record information as structured and unstructured</p>			151	IN.2.5		

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			Information	<p>data Description: Unstructured health record information is information that is not divided into discrete fields AND not represented as numeric, enumerated or codified data.</p> <p>General examples of unstructured health record information include: - text - word processing document - image - multimedia</p> <p>Specific examples include: - text message to physician - patient photo - letter from family - scanned image of insurance card - dictated report (voice recording)</p> <p>Structured health record information is divided into discrete fields, and may be enumerated, numeric or codified.</p> <p>Examples of structured health information include: - patient address (non-codified, but discrete field) - diastolic blood pressure (numeric) - coded result observation - coded diagnosis - patient risk assessment questionnaire with multiple-choice answers</p> <p>Context may determine whether or not data are unstructured, e.g., a progress note might be standardized and structured in some EHR-S (e.g.,</p>						

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				<p>Subjective/Objective/Assessment/Plan) but unstructured in others.</p> <p>Managing healthcare data includes capture, retrieval, deletion, correction, amendment, and augmentation. Augmentation refers to providing additional information regarding the healthcare data, which is not part of the data itself, e.g. linking patient consents or authorizations to the healthcare data of the patient.</p> <p>Legal Rationale: Organizational policies on storage and maintenance of health record information may be called into question during legal proceedings. Adherence to organizational policy, standards of practice and jurisdictional law will be critical.</p>						
IN.2.5.1	F	EN	Manage Unstructured Health Record Information	<p>Statement: Create, capture, and maintain unstructured health record information.</p> <p>Description:</p>		1. The system SHALL capture unstructured health record information as part of the patient EHR.	152	IN.2.5.1	1	N/C
						2. The system SHALL retrieve unstructured health record information as part of the patient EHR.	153	IN.2.5.1	2	N/C
						3. The system SHALL provide the ability to update unstructured health record information.	154	IN.2.5.1	3	N/C
						4. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction) to provide the ability to inactivate, obsolete, or destroy unstructured health record information.	155	IN.2.5.1	4	N/C
						5. The system SHOULD provide the ability to report unstructured health record information.	156	IN.2.5.1	5	N/C
						6. The system MAY track unstructured health record information over time.	157	IN.2.5.1	6	N/C
						7. The system SHALL provide the ability to append corrected unstructured health record information to the original unstructured health record information <i>in conformance with IN.2.5.3.2.</i>	158	IN.2.5.1	7	M
						8. The system SHALL provide the ability to append	159	IN.2.5.1	8	M

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						unstructured health record information to the original unstructured health record information <i>in conformance with IN.2.5.3.2.</i>				
						9. The system SHALL provide the ability to append augmented unstructured health record information to the original unstructured health record information. A specific type of implementation is not implied.	160	IN.2.5.1	9	N/C
IN.2.5.2	F	EN	Manage Structured Health Record Information	<p>Statement: Create, capture, and maintain structured health record information. Description: Structured health record information is divided into discrete fields, and may be enumerated, numeric or codified.</p> <p>Examples of structured health information include: - patient address (non-codified, but discrete field) - diastolic blood pressure (numeric) - coded result observation - coded diagnosis - patient risk assessment questionnaire with multiple-choice answers</p> <p>Context may determine whether or not data are unstructured, e.g., a progress note might be standardized and structured in some EHRS (e.g., Subjective/Objective/Assessment/Plan) but unstructured in others.</p>		1. The system SHALL capture structured health record information as part of the patient EHR.	161	IN.2.5.2	1	N/C
						2. The system SHALL retrieve structured health record information as part of the patient EHR.	162	IN.2.5.2	2	N/C
						3. The system SHALL provide the ability to update structured health record information.	163	IN.2.5.2	3	N/C
						4. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction) to provide the ability to inactivate, obsolete, or destroy structured health record information.	164	IN.2.5.2	4	N/C
						5. The system SHOULD provide the ability to report structured health record information.	165	IN.2.5.2	5	N/C
						6. The system MAY track structured health record information over time.	166	IN.2.5.2	6	N/C
						7. The system SHOULD provide the ability to retrieve each item of structured health record information discretely within patient context.	167	IN.2.5.2	7	N/C
						8. The system SHALL provide the ability to append corrected structured health record information to the original structured health record information <i>in conformance with IN.2.5.3.2.</i>	168	IN.2.5.2	8	M
						9. The system SHALL provide the ability to append structured health record information to the original structured health record information <i>in conformance with In.2.5.3.2.</i>	169	IN.2.5.2	9	M
						10. The system SHALL provide the ability to append augmented structured health record information to	170	IN.2.5.2	10	N/C

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						the original structured health record information. A specific type of implementation is not implied.				
NEW IN.2.5.3	H		Manage Record States	<p>Statement: Manage health record information during the various states of completion.</p> <p>Description/Legal Rationale: Health record information may reside in various states that must be managed. This section uses the terms record, report, note, and documentation generically when describing the states and management issues. An important underlying principle for managing record states is the need to retain health information records that have been viewed for patient care purposes even if it has not been completed or attested. This principle has important legal impact because it provides a record of what the provider relied on for clinical decision-making.</p>			171			
NEW IN.2.5.3.1	F	EN	Pending State	<p>Statement: Health record information may be started, updated, but not completed. The records, although not complete, can represent an important piece of healthcare information particularly if viewed for patient care purposes.</p> <p>Description/Legal Rationale: To assure timeliness support, a system requires means to identify pending documents and to apply user-configured time limits for the system to close incomplete documents. The system should that notify the author or designee that a document has not been finalized and will be closed after a set period of inactivity or pending state. The author or surrogate should be notified prior to the note being closed and</p>	IN.1.8 IN.2.2 IN.2.5.3. IN.6	1. The system SHALL provide the ability to define business rules that establish a parameter (number of hours or days) for the length of time a document or note can be in a pending or inactive state before being administratively closed.	172			A
						2. The system SHALL provide a notification to the author or designate that a pending document will be administratively closed after a designated period of time.	173			A
						3. The system MAY display pending notes in accordance with the organization's business rules.	174			A
						4. IF the system displays pending notes, THEN it SHALL clearly identify that a note is pending (incomplete).	175			A

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				<p>allowed to update the status:</p> <p>A) complete the note if not viewed for patient care, B) complete the note if viewed for patient care, but retain the incomplete version, C) mark the note as erroneous and retain if used for patient care, or D) discard the note if erroneous or another entry was written if it was never used for patient care purposes.</p> <p>The system will then allow the automatically closed document, with the author identified, noting the author and dates of each update, to be available in the EHR.</p>		<p>5. The system SHALL allow the author the option to update the status: A) complete the note if not viewed for patient care, B) complete but retain the incomplete version the note if viewed for patient care, C) mark the note as erroneous and retain if never viewed for patient care purposes.</p>	176			A
						<p>6. The system MAY administratively close a note after a period of inactivity in accordance with its business rules and clearly identify that the note was administratively closed.</p>	177			A
						<p>7. The system SHALL apply a date/time stamp and identify the author each time the note was updated including when opened, when updated, with the signature event and when officially closed.</p>	178			A
NEW IN.2.5.3.2	F	EN	Amended, Corrected or Augmented State	<p>Statement: Updates to health record information made after finalization (or the signature event) will be handled as an amendment, correction or augmentation.</p> <p>Description/Legal Rationale: Clinicians need the ability to correct, amend or augment notes or documents once they have been completed. When an amendment, correction or augmentation has been made, principles for documentation practices require that the original documentation must be accessible, readable, and unobliterated. A user must have a clear indication that modifications have been made to the entry.</p>	IN.2.5.1 IN.2.5.2 IN.2.2 IN.2.2.1.2	<p>1. The system SHALL provide the author or a designee the ability to enter an amendment, correction or augmentation to a note or document.</p>	179			A
						<p>2. The system SHALL allow the author to indicate whether the change was an amendment (additional information), a correction of erroneous information and the reason, or an augmentation to supplement content.</p>	180			A
						<p>3. The system SHALL record and display with the amendment, correction or augmentation the date, time and user.</p>	181			A
						<p>4. The system SHALL display an indicator or flag that an amendment or correction has been made to a note or document when it is viewed or printed.</p>	182			A
						<p>5. The system SHALL retain the prior version(s) of a note or document before the amendment, correction or augmentation.</p>	183			A
						<p>6. The system SHALL provide a link or clear direction for accessing the original version of the note or document.</p>	184			A

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NEW IN.2.5.3.3	F	EN	Document Succession Management and Version Control	<p>Statement: A system shall retain previous versions of a document in accordance with the organization's business rules and manage document succession.</p> <p>Description/Legal Rationale: The organization must have the ability to establish business rules for identifying and handling of versions of documents and managing document succession. Succession management is based on a document's status change over time.</p> <p>A version of a document is:</p> <ol style="list-style-type: none"> 1) A completed document 2) A document completed and modified one or more times 3) A document that has been viewed for clinical decision-making purposes by an individual other than the author 4) A document that has been captured in an incomplete state per organization business rules and updated over time (i.e. a preliminary lab test). 5) A document that electively, according to the author, must be preserved in the current state at a given point in time (i.e. History and Physical). <p>Certain types of records are typically handled in versions, for example:</p> <ul style="list-style-type: none"> - Lab results (preliminary and final) - Dictated reports - Work ups (over course of days) 	IN.6 IN.2.2	1. The system SHALL provide the ability to establish business rules identifying the types of documents and notes that will be handled as a version when the record state changes (e.g. augmented, amended, corrected, etc.).	185			A
						2. The system SHALL provide the author or a designee the ability to revise a document or note and save it as a new version.	186			A
						3. The system SHALL record and display the original date, time and user and the new date, time and user for the updated version.	187			A
						4. The system SHALL manage the succession of documents by applying sequentially numbered versions.	188			A
						5. The system SHALL retain the prior version(s) of a note or document before the changes was made.	189			A
						6. The system SHALL display an indicator or flag that there is a prior version(s) when it is viewed.	190			A
						7. The system SHALL provide a link or clear direction for accessing the original version of the note or document.	191			A
						8. The system SHALL provide the ability to designate which version will be the final version for disclosure purposes.	192			A

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NEW IN.2.5.3.4	F	EN	Retracted State	<p>Statement: Remove a document from view if it is deemed erroneous and cite the reason.</p> <p>Description/Legal Rationale: Record retraction is used to reverse changes that have been made to an existing record/report. Once a record has been retracted, it is no longer visible in standard queries, though it remains accessible in EHR audit records should evidence ever be required for legal or other exceptional circumstances.</p> <p>There are times that a record is entered in an EHR and completed then found to be erroneous, i.e. the record may belong to another individual. In these cases, it is necessary to remove that record from view (storing it in case it may be needed for litigation or investigation purposes, etc.). After retracting an erroneous record, a user has the ability to resubmit a corrected record with no visible indication that there was ever a previous version.</p>	IN.2.2	1. The system SHALL provide the ability to retract a document from view so that it is no longer visible in standard queries.	193			A
						2. The system SHALL retain the retracted document and keep it accessible through EHR audit records to designated staff for legal purposes should the document be needed for litigation or internal investigation/quality assurance.	194			A
						3. The system SHALL provide the ability to submit a corrected record in the place of one removed from view when applicable.	195			A
						4. The system MAY provide the ability to identify the users who viewed the record prior to its removal and present them the new/corrected record that has been resubmitted.	196			A
						5. The system SHOULD provide the ability to identify the reason why the record was retracted.	197			A
NEW IN.2.5.4	F	EN	Redaction	<p>Statement: Remove from view (redact) for disclosure or reporting purposes portions of an EHR (at either the data or record level) and cite the authority for doing so.</p> <p>Description/Legal Rationale: Redaction is used to assure that information considered private or protected is not disclosed inappropriately. Systems must provide the ability to redact information at the data level or at the record level, provide a mechanism to capture the reason for redaction and retain a copy of the redacted records that were</p>	IN.2.2	1. The system SHALL provide the ability to redact (block from view) data elements or portions of a document	198			A
						2. The system SHOULD provide the ability to cite the reasons for redaction.	199			A
						3. The system SHALL store a copy of the redacted record.	200			A

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				disclosed. Redaction may be used for a variety of purposes such as protecting certain types of confidential or privileged information from being disclosed.						
NEW IN.2.5.5	F	EF	Health Record Completeness	<p>Statement: Support the ability to identify a report or record as complete and identify the status as defined by the organization.</p> <p>Description: The EHR-S must provide the ability for an organization to define minimum elements and timeframes for completion at the report level and at the record level. Provide a report that identifies completion and timeliness status by patient/ health record number or other specified parameters.</p> <p>Prior to disclosure for legal proceedings or other official purposes, an organization analyzes the health record for completeness. EHR systems must provide the ability to define a minimum set of content to be analyzed for timeliness and completeness and provide a report of the status.</p>	IN.6	1. The system SHALL provide the ability to define timeframes for completion of specified health record content (data, report or record level).	201			A
						2. The system SHOULD provide the ability to create a report or flag by patient/health record number indicating the completeness status of the report/health record and the specific deficiencies.	202			A
						3. The system MAY provide users a visual indication that indicates the content of a report or record is incomplete as defined by organization business rules.	203			A
NEW IN.2.5.6	F	EF	Chronology of Events	<p>Statement: Support the ability to view and disclose the patient care events that happened over a range of time in chronological order.</p> <p>Description: Functionality to support chronology of events allows the organization to display or disclose the patient care events in the sequence that they occurred. This view provides a beneficial retrospective look at the unfolding of events and timing of decision making which is important in the audit and review process and legal process.</p>		1. The system SHALL conform to function IN 2.2. (Auditable Records)	204			A
						2. The system SHALL provide the ability to configure sequencing of events (chronological and reverse chronological) and accommodate data ranges.	205			A
						3. The system SHALL maintain chronology data via user-centric data (e.g. all user-EHR interactions over time).	206			A
						4. The system SHALL maintain chronology data via patient-centric data (e.g. all events to patient over time)	207			A

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				<p>Chronology success is highly dependent upon systems integration, interfacing and intersystem time/date synchronization.</p> <p>The ability to create a chronology must be available in the EHR-S. External devices providing data (i.e. medical device) as well as any other potential data source that contributed to the patient's care must also have the ability to provide data in a way that supports chronology.</p>		<p>5. The system SHALL maintain chronology data via clinical-data centric (e.g. all lab work together) data.</p> <p>6. The system SHALL perform time/date synchronization checking across data sources for external source data.</p> <p>7. The system SHOULD retain module specificity (date/time/data source) chronology data from external sources</p> <p>8. The system SHOULD maintain the defined chronology via a legal hold (IN.2.1.1)</p>	<p>208</p> <p>209</p> <p>210</p> <p>211</p>			<p>A</p> <p>A</p> <p>A</p> <p>A</p>
<p>NEW IN.2.5.7</p>	F	EF	Replication of Views	<p>Statement: Supports the ability to replicate or recreate a view (both 'read' and 'write') to the extent possible from metadata.</p> <p>Description/Legal Rationale: Replication of views may be required for litigation to see information the way a clinician would have viewed/entered/used it at a given time.</p> <p>The replication process involved in an individual litigation may draw on system, application and patient record metadata, or, all of the above. The process by which this metadata is captured, stored and retrieved varies, but should be structured to fully support replication of view.</p> <p>Those handling litigation might expect the EHR system to capture a 'snapshot' of every EHR action taken by the clinician to diagnose and treat each given patient. For example, there currently is limited use of pdf technology to capture and then store such a 'snapshot'. Database management implications currently</p>	<p>IN.2.2 IN.2.2.1 IN.2.3 S.2.2.2 S.2.2.3</p>	<p>1. The system SHOULD provide audit capabilities for the data sets viewed (static, dynamic, multiple, customized)</p> <p>2. The system SHOULD maintain synchronization with the replication of views electronically and to other applicable health record output.</p> <p>3. The system SHOULD provide the ability to replicate electronic views of extracted health record information.</p> <p>4. The system SHALL conform to function IN.2.3 (Synchronization)</p> <p>5. The system SHALL provide the ability to generate reports of electronic views for replication purposes.</p>	<p>212</p> <p>213</p> <p>214</p> <p>215</p> <p>216</p>			<p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p>

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				<p>limit the 'snapshot' approach.</p> <p>'Best practice' replication of view approaches will evolve over time.</p> <p>The ability to produce a replicated view is not guaranteed and is limited to audit and metadata.</p>						
NEW IN.2.5.8	F	EN	Downtime Procedures, Storage & Back Up	<p>Statement: Provide reliable and consistent availability of the system and data at all times. Description/Legal Rationale: The system must be reliably and consistently available to users at all times. All transactions and changes are captured by redundant or backup systems as necessary to provide a reliable system. If the system fails, there is a goal of always having user access through redundant or backup systems and information.</p> <p>EHRs and/or data transmitted and retained in an interoperable HIT system must be stored and be secure from access by unauthorized and unidentified persons or users. This applies to data stored domestically and offshore. Records must be retained—unaltered, readable, and retrievable—and record retention must comply with all applicable laws and regulations. Records are to be readily available and in a readable format in the realm-specific language. Regardless of the physical location where the EHR is stored, the EHR must at all times be actually available, by legal process or as otherwise authorized by law, to patients, governmental and private payers, and law enforcement.</p>		1. The system SHALL provide the ability to capture data to multiple devices (such as redundant systems) and through multiple mechanisms (such as through database journals).	217			A
						2. The system SHALL trigger alarms/alerts for hardware failures.	218			A
						3. The system SHALL provide the ability to log interruption in availability.	219			A
						4. The system SHOULD provide the ability to repopulate data content with appropriate annotations of data capture occurring as a result of established downtime procedures.	220			A

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IN.3	F	EN	Registry and Directory Services	<p>Statement: Enable the use of registry services and directories to uniquely identify, locate and supply links for retrieval of information related to:</p> <ul style="list-style-type: none"> - patients and providers for healthcare purposes; - payers, health plans, sponsors, and employers for administrative and financial purposes; - public health agencies for healthcare purposes, and - healthcare resources and devices for resource management purposes. <p>Description: Registry and directory service functions are critical to successfully managing the security, interoperability, and the consistency of the health record data across an EHR-S. These services enable the linking of relevant information across multiple information sources within, or external to, an EHR-S for use within an application.</p> <p>Directories and registries support communication between EHR Systems and may be organized hierarchically or in a federated fashion. For example, a patient being treated by a primary care physician for a chronic condition may become ill while out of town. The new provider's EHR-S interrogates a local, regional, or national registry to find the patient's previous records. From the primary care record, a remote EHR-S retrieves relevant information in conformance with applicable patient privacy and confidentiality rules.</p>		1. The system SHALL provide the ability to use registry services and directories.	221	IN.3	1	N/C
						2. The system SHOULD provide the ability to securely use registry services and directories.	222	IN.3	2	N/C
						3. The system SHALL conform to function IN.5.1 (Interchange Standards) to provide standard data interchange capabilities for using registry services and directories.	223	IN.3	3	N/C
						4. The system SHOULD communicate with local registry services through standardized interfaces.	224	IN.3	4	N/C
						5. The system SHOULD communicate with non-local registry services (that is, to registry services that are external to an EHR-S) through standardized interfaces.	225	IN.3	5	N/C
						6. The system SHOULD provide the ability to use registries or directories to uniquely identify patients for the provision of care.	226	IN.3	6	N/C
						7. The system SHOULD provide the ability to use registries or directories to uniquely identify providers for the provision of care.	227	IN.3	7	N/C
						8. The system MAY provide the ability to use registries or directories to retrieve links to relevant healthcare information regarding a patient.	228	IN.3	8	N/C
						9. The system MAY provide the ability to use registries to supply links to relevant healthcare information regarding a patient.	229	IN.3	9	N/C
						10. The system MAY provide the ability to use registries or directories to identify payers, health plans, and sponsors for administrative and financial purposes.	230	IN.3	10	N/C

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				<p>An example of local registry usage is an EHR-S application sending a query message to the Hospital Information System to retrieve a patient's demographic data.</p> <p>Legal Rationale: As stated above in the description, the legal value of the registry and directory service functions are their support for successfully managing the security, interoperability, and the consistency of the health record data across an EHR-S.</p>		<p>11. The system MAY provide the ability to use registries or directories to identify employers for administrative and financial purposes.</p> <p>12. The system MAY provide the ability to use registries or directories to identify public health agencies for healthcare purposes.</p> <p>13. The system MAY provide the ability to use registries or directories to identify healthcare resources and devices for resource management purposes.</p>	231	IN.3	11	N/C
							232	IN.3	12	N/C
							233	IN.3	13	N/C
IN.4	H		Standard Terminologies and Terminology Services	<p>Statement: Support semantic interoperability through the use of standard terminologies, standard terminology models and standard terminology services.</p> <p>Description: The purpose of supporting terminology standards and services is to enable semantic interoperability. Interoperability is demonstrated by the consistency of human and machine interpretation of shared data and reports. It includes the capture and support of consistent data for templates and decision support logic.</p> <p>Terminology standards pertain to concepts, representations, synonyms, relationships and computable (machine-readable) definitions. Terminology services provide a common way for managing and retrieving these items.</p> <p>Legal Rationale: The mechanisms used to support the capture of data are potentially relevant in a legal proceeding. The on-going maintenance and ability to view historical</p>			234	IN.4		

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				<i>information (using the version applied at that time) will also be important in legal proceedings that will look retrospectively at health record information and system data.</i>						
IN.4.1	F	EN	Standard Terminologies and Terminology Models	<p>Statement: Employ standard terminologies to ensure data correctness and to enable semantic interoperability (both within an enterprise and externally).</p> <p>Support a formal standard terminology model.</p> <p>Description: Semantic interoperability requires standard terminologies combined with a formal standard information model. An example of an information model is the HL7 Reference Information model. Examples of terminologies that an EHR-S may support include: LOINC, SNOMED, ICD-9, ICD-10, and CPT-4.</p> <p>A terminology provides semantic and computable identity to its concepts.</p> <p>Terminologies are use-case dependent and may or may not be realm dependent. For example, terminologies for public health interoperability may differ from those for healthcare quality, administrative reporting, research, etc.</p> <p>Formal standard terminology models enable common semantic representations by</p>		<p>1. The system SHALL provide the ability to use standard terminologies to communicate with other systems (internal or external to the EHR-S).</p>	235	IN.4.1	1	N/C
						<p>2. The system SHALL provide the ability to validate that clinical terms and coded clinical data exists in a current standard terminology.</p>	236	IN.4.1	2	N/C
						<p>3. The system SHOULD provide the ability to exchange healthcare data using formal standard information models and standard terminologies.</p>	237	IN.4.1	3	N/C

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				describing relationships that exist between concepts within a terminology or in different terminologies, such as exemplified in the model descriptions contained in the HL7 Common Terminology Services specification. The clinical use of standard terminologies is greatly enhanced with the ability to perform hierarchical inference searches across coded concepts. Hierarchical Inference enables searches to be conducted across sets of coded concepts stored in an EHR-S. Relationships between concepts in the terminology are used in the search to recognize child concepts of a common parent. For example, there may be a parent concept, "penicillin containing preparations" which has numerous child concepts, each of which represents a preparation containing a specific form of penicillin (Penicillin V, Penicillin G, etc). Therefore, a search may be conducted to find all patients taking any form of penicillin preparation.		4. The system SHOULD provide the ability to use a formal standard terminology model.	238	IN.4.1	4	N/C
				Clinical and other terminologies may be provided through a terminology service internal or external to an EHR-S. An example of a terminology service is described in the HL7 Common Terminology Services specification.		5. The system SHOULD provide the ability to use hierarchical inference searches e.g., subsumption across coded terminology concepts that were expressed using standard terminology models.	239	IN.4.1	5	N/C
				Legal Rationale: Legally the use of standards to collect complete information will be beneficial to an organization when health record information is needed for litigation.		6. The system SHOULD provide the ability to use a terminology service (internal or external to the EHR-S).	240	IN.4.1	6	N/C
						7. IF there is no standard terminology model available, THEN the system MAY provide a formal explicit terminology model.	241	IN.4.1	7	N/C

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IN.4.2	F	EN	Maintenance and Versioning of Standard Terminologies	<p>Statement: Enable version control according to customized policies to ensure maintenance of utilized standards.</p> <p>This includes the ability to accommodate changes to terminology sets as the source terminology undergoes its natural update process (new codes, retired codes, redirected codes). Such changes need to be cascaded to clinical content embedded in templates, custom formularies, etc., as determined by local policy.</p> <p>Description: Version control allows for multiple sets or versions of the same terminology to exist and be distinctly recognized over time.</p> <p>Terminology standards are usually periodically updated, and concurrent use of different versions may be required. Since the meaning of a concept can change over time, it is important that retrospective analysis and research maintains the ability to relate changing conceptual meanings. If the terminology encoding for a concept changes over time, it is also important that retrospective analysis and research can correlate the different encodings to ensure the permanence of the concept. This does not necessarily imply that complete older versions of the terminology be kept in the EHR-S, only access to the changes needs to be maintained.</p> <p>It should be possible to retire deprecated versions when applicable business cycles are completed while maintaining obsolescent code sets. An example use of this is for</p>		1. The system SHALL provide the ability to use different versions of terminology standards.	242	IN.4.2	1	N/C
						2. The system SHALL provide the ability to update terminology standards.	243	IN.4.2	2	N/C
						3. The system SHALL relate modified concepts in the different versions of a terminology standard to allow preservation of interpretations over time.	244	IN.4.2	3	M
						4. The system SHOULD provide the ability to interoperate with systems that use known different versions of a terminology standard.	245	IN.4.2	4	N/C
						5. The system SHOULD provide the ability to deprecate terminologies.	246	IN.4.2	5	N/C
						6. The system MAY provide the ability to deprecate individual codes within a terminology.	247	IN.4.2	6	N/C
						7. The system SHALL provide the ability to cascade terminology changes where coded terminology content is embedded in clinical models (for example, templates and custom formularies) when the cascaded terminology changes can be accomplished unambiguously.	248	IN.4.2	7	N/C

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				possible claims adjustment throughout the claim's lifecycle. Legal Rationale: <i>The on-going maintenance and ability to view historical information (using the version applied at that time) will be important in legal proceedings that look retrospectively at health record information and system data.</i>		8. Changes in terminology SHALL be applied to all new clinical content (via templates, custom formularies, etc.).	249	IN.4.2	8	N/C
IN.4.3	F	EN when using more than one terminology with overlapping concepts	Terminology Mapping	<p>Statement: Map or translate one terminology to another as needed by local, regional, national, or international interoperability requirements</p> <p>Description: The ability to map or translate one terminology to another is fundamental to an organization in an environment where several terminologies are in play with overlapping concepts. It is a common occurrence that data is captured using one terminology, but is shared using another terminology. For example, within a healthcare organization there may be a need to map overlapping terminology concepts (e.g. between an EHRS and an external laboratory system, ore between an EHRS and a billing system). Realm specific (including local, regional, national or international) interoperability requirements can also determine the need for terminology mapping, and in many cases terminology mapping services can be used to satisfy these requirements.</p> <p>Legal Rationale: <i>The interaction and mapping of terminologies may be called into question when clinical decisions were documented and made based on concepts supported by standard terminologies.</i></p>		1. The system SHALL provide the ability to use a terminology map.	250	IN.4.3	1	N/C
						2. The system SHOULD provide the ability to use standard terminology services for the purposes of mapping terminologies.	251	IN.4.3	2	N/C
						3. The system MAY provide the ability for a user to validate a mapping.	252	IN.4.3	3	N/C
						4. The system MAY provide the ability to create a terminology map.	253	IN.4.3	4	N/C

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IN.5	H		Standards-based Interoperability	<p>Statement: Provide automated health care delivery processes and seamless exchange of clinical, administrative, and financial information through standards-based solutions.</p> <p>Description: Interoperability standards enable an EHR-S to operate as a set of applications. This results in a unified view of the system where the reality is that several disparate systems may be coming together. Interoperability standards also enable the sharing of information between EHR systems, including the participation in regional, national, or international information exchanges. Timely and efficient access to information and capture of information is promoted with minimal impact to the user.</p> <p>Legal Rationale: <i>When information exchanged becomes part of the formal medical record or is discoverable in a legal proceeding, the interoperability methods and underlying standards will be called into question.</i></p>			254	IN.5		

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IN.5.1	F	EN if interoperating with other systems (internal or external)	Interchange Standards	<p>Statement: Support the ability to operate seamlessly with other systems, either internal or external, that adhere to recognized interchange standards. "Other systems" include other EHR Systems, applications within an EHR-S, or other authorized entities that interact with an EHR-S.</p> <p>Description: An organization typically uses a number of interchange standards to meet its external and internal interoperability requirements. It is fundamental that there be a common understanding of rules regarding connectivity, information structures, formats and semantics. These are known as "interoperability or interchange standards". Data exchange which may be between internal systems or modules, or external to the organization, is to occur in a manner which is seamless to the user. For example, if data interchange involves double entry, or manual cut-and-paste steps by the user, it is not considered seamless. Representation of EHR content is transmitted in a variety of interchange formats such as: HL7 Messages, Clinical Document Architecture (CDA) and other HL7 Structured Documents, X12N healthcare transactions, and Digital Imaging and Communication in Medicine (DICOM) format.</p>		1. The system SHALL provide the ability to use interchange standards as required by realm specific and/or local profiles.	255	IN.5.1	1	N/C
						2. The system SHALL provide the ability to seamlessly perform interchange operations with other systems that adhere to recognized interchange standards.	256	IN.5.1		N/C

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				<p>Support for multiple interaction modes is needed to respond to differing levels of immediacy and types of exchange. For example, messaging is effective for many near-real time, asynchronous data exchange scenarios but may not be appropriate if the end-user is requesting an immediate response from a remote application.</p> <p>A variety of interaction modes are typically supported such as:</p> <ul style="list-style-type: none"> -Unsolicited Notifications, e.g. a patient has arrived for a clinic appointment -Query/Response e.g., Is Adam Everyman known to the system? Yes, MRN is 12345678. -Service Request and Response, e.g., Laboratory Order for "Fasting Blood Sugar" and a response containing the results of the test. -Information Interchange between organizations (e.g. in a RHIO, or in a National Health System) -Structured/discrete clinical documents, e.g., Clinical Note -Unstructured clinical document, e.g., dictated surgical note 		3. The system SHALL conform to functions under header IN.4 (Standard Terminologies and Terminology Services) to support terminology standards in accordance with a users' scope of practice, organizational policy, or jurisdictional law.	257	IN.5.1		N/C
						4. The system SHOULD provide the ability to exchange data using an explicit and formal information model and standard, coded terminology.	258	IN.5.1	4	N/C

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				Standard terminology is a fundamental part of interoperability and is described in section IN.4. Using a formal explicit information model further optimizes interoperability. An example of an information model is the HL7 Reference Information Model (RIM). Organizations typically need to deal with more than one information model and may need to develop a mapping or a meta-model.		5. IF there is no standard information model available, THEN the system MAY provide a formal explicit information model in order to support the ability to operate seamlessly with other systems.	259	IN.5.1	5	N/C
IN.5.2	F	EN if interoperating with other systems (internal or external)	Interchange Standards Versioning and Maintenance	<p>Statement: Enable version control according to local policies to ensure maintenance of utilized interchange standards. Version control of an interchange standard implementation includes the ability to accommodate changes as the source interchange standard undergoes its natural update process.</p> <p>Description: The life cycle of any given standard results in changes to its requirements. It is critical that an organization know the version of any given standard it uses and what its requirements and capabilities are.</p> <p>For example, if the organization migrates to an HL7 v2.5 messaging standard, it may choose to take advantage of new capabilities such as specimen or blood bank information. The organization may find that certain fields have been retained for backwards</p>		1. The system SHALL provide the ability to use different versions of interchange standards.	260	IN.5.2	1	N/C

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				<p>compatibility only or withdrawn altogether. The EHR-S needs to be able to handle all of these possibilities.</p> <p>Standards typically evolve in such a way as to protect backwards compatibility. On the other hand, sometimes there is little, or no, backwards compatibility when an organization may need to replace an entire standard with a new methodology. An example of this is migrating from HL7 v2 to HL7 v3.</p> <p>Interchange standards that are backward compatible support exchange among senders and receivers who are using different versions. Version control ensures that those sending information in a later version of a standard consider the difference in information content that can be interchanged effectively with receivers, who are capable of processing only earlier versions. That is, senders need to</p>		<p>2. The system SHALL provide the ability to change (reconfigure) the way that data is transmitted as an interchange standard evolves over time and in accordance with business needs.</p>	261	IN.5.2	2	N/C

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				be aware of the information that receivers are unable to capture and adjust their business processes accordingly. Version control enables multiple versions of the same interchange standard to exist and be distinctly recognized over time. Since interchange standards are usually periodically updated, concurrent use of different versions may be required. Large (and/or federated) organizations typically need to use different versions of an interchange standard to meet internal organizational interoperability requirements. For example, the enterprise-wide standard might use HL7 v2.5 for Lab messages, but some regions of the enterprise might be at a lower level. It should be possible to retire deprecated interchange standards versions when applicable business cycles are completed while maintaining obsolete versions. An		3. The system SHOULD provide the ability to deprecate an interchange standard.	262	IN.5.2	3	N/C

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				example use of this is for possible claims adjustment throughout the claim's life cycle. When interchange standards change over time, it is important that retrospective analysis and research correlate and note gaps between the different versions' information structures to support the permanence of concepts over time. An example use of this is the calculation of outcome or performance measures from persisted data stores where one version of a relevant interchange standard, e.g., CDA Release 1 captures the relevant data, e.g., discharge data, differently than CDA Release 2.		4. The system SHOULD provide the ability to interoperate with other systems that use known earlier versions of an interoperability standard.	263	IN.5.2	4	N/C
IN.5.3	F	EN if integrating with other systems	Standards-based Application Integration	<p>Statement: Enable standards-based application integration with other systems.</p> <p>Description: When an organization wishes to integrate its applications, they must use standardized methods. Standards-based application integration may be achieved in a variety of ways.</p> <p>For example:</p> <ul style="list-style-type: none"> -desktop visual integration may be achieved via HL7 Clinical Context Object Workgroup (CCOW) standards -workflow functions may be integrated via The Workflow Management Coalition (WfMC) standards -EHRS may be integrated in an Enterprise 		1. The system SHALL provide the ability to support standards-based application integration.	264	IN.5.3	1	N/C

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				Information System Architecture via Service Oriented Architecture (SOA) standards It is recognized that these examples are very disparate and used for very different purposes. The method used depends on the organization's approach to application integration. An organization could conceivably use multiple integration approaches.						
IN.5.4	F	EN if exchanging data	Interchange Agreements	Statement: Support interactions with entity directories to determine the address, profile and data exchange requirements of known and/or potential partners. Use the rules of interaction specified in the partner's interchange agreement when exchanging information. Description: Systems that wish to communicate with each other, must agree on the parameters associated with that information exchange. Interchange Agreements allow an EHR-S to describe those parameters/criteria. An EHR-S can use the entity registries to determine the security, addressing, and reliability requirements between partners. An EHR-S can use this information to define how data will be exchanged between the sender and the receiver. Discovery of interchange services and	IN.3	1. The system SHALL use interchange agreement descriptions when exchanging information with partners.	265	IN.5.4	1	N/C
						2. The system SHOULD use interchange agreement description standards (when available).	266	IN.5.4	2	N/C

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				<p>capabilities can be automatic.</p> <p>For example:</p> <ul style="list-style-type: none"> - A new application can automatically determine a patient demographics source using a Universal Description and Discovery Integration (UDDI) for source discovery, and retrieve the Web Services Description Language (WSDL) specification for binding details. - Good Health Hospital is a member of AnyCounty LabNet, for sharing laboratory results with other partners. Good Health Hospital periodically queries LabNet's directory (UDDI) to determine if additional information providers have joined LabNet. When new information providers are discovered, the Good Health IT establishes the appropriate service connections based upon the Service Description (WSDL). 		<p>3. The system MAY conform to function IN.3 (Registry and Directory Services) to interact with entity directories to determine the address, profile and data exchange requirements of known and/or potential partners.</p>	267	IN.5.4	3	N/C
						<p>4. The system MAY provide the ability to automatically discover interchange services and capabilities.</p>	268	IN.5.4	4	N/C
IN.6	F	EN	Business Rules Management	<p>Statement: Manage the ability to create, update, delete, view, and version business rules including institutional preferences. Apply business rules from necessary points within an EHR-S to control system behavior. An EHR-S audits changes made to business rules, as well as compliance to and overrides of applied business rules.</p> <p>Description: EHR-S business rule implementation functions include: decision support, diagnostic support, workflow control, and access privileges, as well as system and user defaults and preferences.</p> <p>An EHR-S supports the ability of providers and institutions to customize decision support</p>	DC.2.2 S.3.1 S.3.7 IN.2.5 IN.2.1	<p>1. The system SHALL provide the ability to manage business rules.</p>	269	IN.6	1	N/C
						<p>2. The system SHOULD provide the ability to create, import, or access decision support rules to guide system behavior.</p>	270	IN.6	2	N/C
						<p>3. <i>IF the system uses decision support rules, THEN</i> the system SHALL provide the ability to update decision support rules.</p>	271	IN.6	3	M
						<p>4. <i>IF the system uses decision support rules, THEN</i> the system SHALL provide the ability to customize decision support rules and their components.</p>	272	IN.6	4	M
						<p>5. <i>IF the system uses decision support rules, THEN</i> the system SHALL provide the ability to inactivate/obsolete <i>and archive per retention period as designated by organizational policy and jurisdictional law.</i></p>	273	IN.6	5	M

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				<p>components such as triggers, rules, or algorithms, as well as the wording of alerts and advice to meet realm specific requirements and preferences.</p> <p>Examples of applied business rules include:</p> <ul style="list-style-type: none"> - Suggesting diagnosis based on the combination of symptoms (flu-like symptoms combined with widened mediastinum suggesting anthrax); - Classifying a pregnant patient as high risk due to factors such as age, health status, and prior pregnancy outcomes; - Sending an update to an immunization registry when a vaccination is administered; - Limiting access to mental health information to authorized providers; - Establishing system level defaults such as for vocabulary data sets to be implemented.; and - Establishing user level preferences such as allowing the use of health information for research purposes. <p>Legal Rationale: The care delivery and documentation process captured within an EHR-S is based on system business rules. These rules will likely be called into question during a legal proceeding to understand the organization's good faith practices and when practices deviated from the norm.</p>		6. IF the system uses decision support rules, THEN the system SHALL provide the ability to destroy the decision support rules per retention period as designated by organizational policy and jurisdictional law.	274			A
						7. IF the system uses decision support rules, THEN the system SHALL conform to function IN.2.2 (Auditable Records) to audit all changes to decision support rules.	275	IN.6	6	M
						8. The system SHOULD provide the ability to create diagnostic support rules to guide system behavior.	276	IN.6	7	N/C
						9. IF the system uses diagnostic support rules, THEN the system SHALL provide the ability to update diagnostic support rules.	277	IN.6	8	M
						10. IF the system uses diagnostic support rules THEN the system SHALL provide the ability to customize diagnostic support rules and their components.	278	IN.6	9	M
						11. IF the system uses diagnostic support rules, THEN the system SHALL provide the ability to inactivate/obsolete and archive per retention period as designated by organizational policy and jurisdictional law.	279	IN.6	10	M
						12. IF the system uses diagnostic support rules, THEN the system SHALL provide the ability to destroy diagnostic support rules per retention period as designated by organizational policy and jurisdictional law.	280			A
						13. IF the system uses diagnostic support rules, THEN the system SHALL conform to function IN.2.2 (Auditable Records) to audit all changes to diagnostic support rules.	281	IN.6	11	M
						14. The system SHOULD provide the ability to create workflow control rules to guide system behavior.	282	IN.6	12	N/C
						15. IF the system uses workflow control rules, THEN the system SHALL provide the ability to update workflow control rules.	283	IN.6	13	M
						16. IF the system uses workflow control rules, THEN	284	IN.6	14	M

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						the system SHALL provide the ability to customize workflow control rules and their components.				
						17. <i>IF the system uses workflow control rules, THEN the system SHALL provide the ability to inactivate/obsolete and archive per retention period as designated by organizational policy and jurisdictional law.</i>	285	IN.6	15	M
						18. <i>IF the system uses workflow control rules THEN the system SHALL provide the ability to destroy workflow control rules per retention period as designated by organizational policy and jurisdictional law.</i>	286			A
						19. <i>IF the system uses workflow control rules THEN the system SHALL conform to function IN.2.2 (Auditable Records) to audit all changes to workflow control rules.</i>	287	IN.6	16	M
						20. The system SHOULD provide the ability to create access privilege rules to guide system behavior.	288	IN.6	17	M
						21. <i>IF the system uses access privilege rules, THEN the system SHALL provide the ability to update access privilege rules.</i>	289	IN.6	18	M
						22. <i>IF the system uses access privilege rules THEN the system SHALL provide the ability to customize access privilege rules and their components.</i>	290	IN.6	19	M
						23. <i>IF the system uses access privilege rules THEN the system SHALL provide the ability to inactivate/obsolete and archive per retention period as designated by organizational policy and jurisdictional law.</i>	291	IN.6	20	M
						24. <i>IF the system uses access privilege rules THEN the system SHALL provide the ability to destroy access privilege rules. per retention period as designated by organizational policy and jurisdictional law.</i>	292			
						25. <i>IF the system uses access privilege rules THEN the system SHALL conform to function IN.2.2 (Auditable Records) to audit all changes to access</i>	293	IN.6	21	M

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						privilege rules.				
						26. IF the system uses business rules, THEN the system SHALL conform to function IN.2.2 (Auditable Records) to audit all changes to other business rules.	294	IN.6	22	M
						27. The system SHALL support the ability to selectively export business rules.	295	IN.6	23	M
						28. IF the system uses access privilege rules THEN the system SHALL provide the ability to update access privilege rules.	289	IN.6	18	M
IN.7	F	EN	Workflow Management	<p>Statement: Support workflow management functions including both the management and set up of work queues, personnel lists, and system interfaces as well as the implementation functions that use workflow-related business rules to direct the flow of work assignments.</p> <p>Description: Workflow management functions that an EHR-S supports include:</p> <ul style="list-style-type: none"> -Distribution of information to and from internal and external parties; -Support for task-management as well as parallel and serial task distribution; -Support for notification and task routing based on system triggers; and -Support for task assignments, escalations and redirection in accordance with business rules. <p>Workflow definitions and management may be implemented by a designated application or distributed across an EHR-S.</p> <p>Legal Rationale: The workflow processes that support care delivery and documentation</p>	IN.2.1	1. The system SHOULD use workflow-related business rules to direct the flow of work assignments.	296	IN.7	1	N/C
						2. The system SHOULD provide the ability to create workflow (task list) queues.	297	IN.7	2	N/C
						3. The system SHOULD provide the ability to manage workflow (task list) queues.	298	IN.7	3	N/C
						4. The system MAY provide the ability to manage human resources (i.e., personnel lists) for workflow queues.	299	IN.7	4	N/C
						5. The system MAY use system interfaces that support the management of human resources (i.e., personnel lists).	300	IN.7	5	N/C
						6. The system MAY use system interfaces that support the management of workflow (task lists) queues.	301	IN.7	6	N/C
						7. The system MAY provide the ability to distribute information to and from internal and external parties.	302	IN.7	7	N/C
						8. The system MAY provide the ability to route notifications and tasks based on system triggers.	303	IN.7	8	N/C
						9. The system MAY dynamically escalate workflow according to business rules.	304	IN.7	9	N/C
						10. The system MAY dynamically redirect workflow according to business rules.	305	IN.7	10	N/C

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				capture within an EHR-S will likely be called into question during a legal proceeding to understand the organization's good faith practices and when practices deviated from the norm.		11. The system MAY dynamically reassign workflow according to business rules.	306	IN.7	11	N/C
						12. IF the system uses workflow (task list) queues THEN the system SHALL provide the ability to inactivate/obsolete and archive per retention period as designated by organizational policy and jurisdictional law.	307			A
						13. IF the system uses workflow (task list) queues THEN the system SHALL provide the ability to destroy the workflow queues. per retention period as designated by organizational policy and jurisdictional law.	308			A
						14. IF the system uses workflow (task list) queues THEN the system SHALL conform to function IN.2.2 (Auditable Records) to audit all changes to workflow (task list) queues.	309			A
						15. The system SHALL support the ability to selectively export rules related to workflow (task list) queues.	310			A

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S.1.3	H		Provider Information	Statement: Maintain, or provide access to, current provider information.	IN.1.3 IN.4		1	S.1.3		N/C
S.1.3.1	F	EN	Provider Access Levels	<p>Statement: Provide a current registry or directory of practitioners that contains data needed to determine levels of access required by the system.</p> <p>Description: Provider information may include any credentials, certifications, or any other information that may be used to verify that a practitioner is permitted to use or access authorized data.</p> <p>Legal Rationale: This function is relevant to the legal EHR because it establishes users and clinical personnel who are involved in patient care/encounter and supports the access control process.</p>	IN.2.3 IN.3	1. The system SHALL provide a registry or directory of all personnel who currently use or access the system.	2	S.1.3.1	1	M
						2. The system SHOULD contain, in the directory, the realm-specific legal identifiers required for care delivery such as the practitioner's license number	3	S.1.3.1	2	N/C
						3. The system SHALL provide the ability to add, update, and inactivate entries in the directory so that it is current.	4	S.1.3.1	3	M
						4. The system SHALL contain, in the directory, the information necessary to determine levels of access required by the system security functionality.	5	S.1.3.1	4	M
						5. The system SHOULD provide a directory of clinical personnel external to the organization that are not users of the system to facilitate documentation communication and information exchange.	6	S.1.3.1	5	M
S.1.3.7	F	EN	Provider Registry or Directory	<p>Statement: Provide access to a current directory, registry or repository of provider information in accordance with relevant laws, regulations, and organization or internal requirements.</p> <p>Description: A system maintains or has access to provider information needed in the provision of care. This is typically a directory, registry or repository. Information includes, but is not limited to; full name, specialty, credentials, address or physical location, and a 24x7 telecommunications address (e.g. phone or pager access number).</p>	IN.1.3 IN.2.1 IN.3	1. The system SHOULD conform to IN.3 (Registry and Directory Services), Conformance Criteria #7 (The system SHOULD provide the ability to use registries or directories to uniquely identify providers for the provision of care).	7	S.1.3.7	1	N/C
						2. The system SHALL contain provider information (such as full name, specialty, address and contact information), in accordance with scope of practice, organizational policy and jurisdictional law.	8	S.1.3.7	2	N/C
						3. The system SHALL provide the ability to add, update, and remove access to entries in the registry or directory so that it is current.	9	S.1.3.7	3	N/C

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				Views of the information are tailored to the user's security level and access need. For example, a nursing supervisor may need access to a provider's home phone. A member/patient wishing to select a primary care provider has a narrower view that would not include personal access information. <i>Legal Rationale: Provider registry information is important to identifying providers who were involved in the care delivery process.</i>		4. The system MAY provide a directory of clinical personnel external to the organization that are not users of the system to facilitate documentation.	10	S.1.3.7	4	N/C
						5. The systems SHOULD provide the ability to restrict the view of selected elements of the registry or directory information, subject to the user's security level and access needs.	11	S.1.3.7	5	N/C
S.2	H	EN	Measurement, Analysis, Research and Reports			1. The system SHALL conform to function IN.1.1 (Entity Authentication).	12	S.2	1	N/C
						2. The system SHALL conform to function IN.1.2 (Entity Authorization).	13	S.2	2	N/C
						3. The system SHALL conform to function IN.1.3 (Entity Access Control).	14	S.2	3	N/C
						4. The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality).	15	S.2	4	N/C
						5. The system SHALL conform to function IN.2.4 (Extraction of Health Record Information).	16	S.2	5	N/C
S.2.2	H	EN	Report Generation	Statement: Support the export of data or access to data necessary for report generation and ad hoc analysis. Description: Providers and administrators need access to data in the EHR-S for the generation of both standard and ad hoc reports. These reports may be needed for clinical, administrative, and financial decision-making, as well as for patient use. Reports may be based on structured data and/or unstructured text from the patient's health record. <i>Legal Rationale: Report generation functionality is important to provide an output of relevant information from EHR systems for legal proceedings. Reports are not limited to the formal medical record, but any kind of system</i>	DC.2.6.3 S.1.5 S.3.6	1. The system SHALL conform to function IN.2.2 (Auditable Records) in accordance with scope of practice, organizational policy and jurisdictional law.	17	S.2.2	1	N/C
						2. <i>The system SHALL conform to function IN.2.2.1.1 (Point of Record Metadata) in accordance with scope of practice, organizational policy and jurisdictional law.</i>	18			A
						3. <i>The system SHOULD conform to function IN.2.5.6 (Chronology of Events) in accordance with scope of practice, organizational policy and jurisdictional law.</i>	19			A
						4. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction).	20	S.2.2	2	N/C

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				<i>data/information that is relevant to the legal proceeding. Systems must have the ability to export the reports for disclosure purposes.</i>						
S.2.2.1	F	EN	Health Record Output	<p>Statement: Support the definition of the formal health record, a partial record for referral purposes, or sets of records for other necessary disclosure purposes.</p> <p>Description: Provide hardcopy and electronic output that fully chronicles the healthcare process, supports selection of specific sections of the health record, and allows healthcare organizations to define the report and/or documents that will comprise the formal health record for disclosure purposes. A mechanism should be provided for both chronological and specified record element output. This may include defined reporting groups (i.e. print sets). For example: Print Set A = Patient Demographics, History & Physical, Consultation Reports, and Discharge Summaries. Print Set B = all information created by one caregiver. Print Set C = all information from a specified encounter. An auditable record of these requests and associated exports may be maintained by the system. This record could be implemented in any way that would allow the who, what, why and when of a request and export to be recoverable for review. The system has the capability of providing a report or accounting of disclosures by patient that meets in accordance with scope of practice, organizational policy and jurisdictional law.</p>	<p>DC.1.1.4</p> <p>DC.1.4</p> <p>IN.1.2</p> <p>IN.2.5.1</p> <p>IN.2.5.2</p> <p>IN.4.1</p> <p>IN.4.3</p> <p>IN.5.1</p> <p>IN.5.4</p> <p>IN.6</p>	<p>1. The system SHALL provide the ability to generate reports consisting of all and part of an individual patient's record.</p> <p>2. The system SHALL provide the ability to define the records or reports that are considered the formal health record for disclosure purposes.</p> <p>3. The system SHALL provide the ability to generate reports in both chronological and specified record elements order.</p> <p>4. The system SHALL provide the ability to create hardcopy and electronic report summary information (procedures, medications, labs, immunizations, allergies, vital signs).</p> <p>5. The system SHOULD provide the ability to specify or define reporting groups (i.e. print sets) for specific types of disclosure or information sharing.</p> <p>6. The system SHALL provide the ability to include patient identifying information on each page of reports generated.</p> <p>7. The system SHALL provide the ability to customize reports to match mandated formats.</p> <p>8. <i>The system SHALL provide the ability to generate a report that includes the point of record metadata for disclosure purposes.</i></p>	21	S.2.2.1	1	N/C
							22	S.2.2.1	2	M
							23	S.2.2.1	3	M
							24	S.2.2.1	4	M
							25	S.2.2.1	5	M
							26	S.2.2.1	6	M
							27	S.2.2.1	7	M
							28			A
S.2.2.2	F	EN	Standard Report Generation	<p>Statement: Provide report generation features using tools internal or external to the system, for the generation of standard reports.</p> <p>Description: Providers and administrators need access to data in the EHR-S for clinical, administrative, financial decision-making, audit</p>	<p>IN.1.9</p> <p>IN.2.5.1</p> <p>IN.2.5.2</p> <p>IN.4.1</p>	<p>1. The system SHALL provide the ability to generate reports of structured clinical and administrative data using either internal or external reporting tools.</p> <p>2. The system SHOULD provide the ability to include information extracted from unstructured clinical and administrative data in the report generation</p>	29	S.2.2.2	1	M
							30	S.2.2.2	2	M

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				trail and metadata reporting, as well as to create reports for patients. Many systems may use internal or external reporting tools to accomplish this (such as Crystal Report). Reports may be based on structured data and/or unstructured text from the patient's health record. Users need to be able to sort and/or filter reports. For example, the user may wish to view only the diabetic patients on a report listing patients and diagnoses.	IN.4.3	process, using internal or external tools.				
						3. The system SHALL provide the ability to export reports generated.	31	S.2.2.2	3	M
						4. The system SHALL provide the ability to specify report parameters, based on patient demographic and/or clinical data, which would allow sorting and/or filtering of the data.	32	S.2.2.2	4	M
						5. The system (or an external application, using data from the system) SHALL provide the ability to save report parameters for generating subsequent reports.	33	S.2.2.2	5	M
						6. The system (or an external application, using data from the system) SHOULD provide the ability to modify one or more parameters of a saved report specification when generating a report using that specification.	34	S.2.2.2	6	M
S.2.2.3	F	EN	Ad Hoc Query and Report Generation	<p>Statement: Provide support for ad hoc query and report generation using tools internal or external to the system.</p> <p>Description: Providers and administrators need to respond quickly to new requirements for data measurement and analysis. This may be as a result of new regulatory requirements or internal requirements. This requires that users be able to define their own query parameters and retain them. The data may be found in both structured and unstructured data.</p> <p>Providers and administrators also need to query for the absence of specific clinical or administrative data. For example, the Quality Control department may be reviewing whether or not the protocol for management of Diabetes Mellitus is being followed. If the protocol calls for fasting blood sugars every 3 months at</p>	IN.2.5.1 IN.2.5.2	1. The system SHALL provide the ability to generate ad hoc query and reports of structured clinical and administrative data through either internal or external reporting tools.	35	S.2.2.3	1	M
						2. The system SHOULD provide the ability to include information extracted from unstructured clinical and administrative data in the report generation process, using internal or external tools.	36	S.2.2.3	2	M
						3. The system SHALL provide the ability to export reports generated.	37	S.2.2.3	3	M
						4. The system SHALL provide the ability to specify report parameters, based on patient demographic and/or clinical data, which would allow sorting and/or filtering of the data.	38	S.2.2.3	4	M
						5. The system SHALL provide the ability to save report parameters for generating subsequent reports.	39	S.2.2.3	5	M

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				minimum, the investigator might need to run an across-patient query locating patients with diabetes who do not show an FBS result within the last 3 months.		6. The system SHOULD provide the ability to modify one or more parameters of a saved report specification when generating a report using that specification.	40	S.2.2.3	6	M
						7. The system SHOULD provide the ability to produce reports, using internal or external reporting tools, based on the absence of a clinical data element (e.g., a lab test has not been performed in the last year).	41	S.2.2.3	7	M
S.3	H	EN	Administrative and Financial		IN.1.9, IN.2.4	1. The system SHALL conform to function IN.1.1 (Entity Authentication).	42			N/C
						2. The system SHALL conform to function IN.1.2 (Entity Authorization).	43			N/C
						3. The system SHALL conform to function IN.1.3 (Entity Access Control).	44			N/C
S.3.1	H		Encounter/Episode of Care Management	<p>Statement: Support the definition of Manage and document the health care needed and delivered during an encounter/episode of care.</p> <p>Description: Using data standards and technologies that support interoperability, encounter management promotes patient-centered/oriented care and enables real time, immediate point of service, point of care by facilitating efficient work flow and operations performance to ensure the integrity of: (1) the health record, (2) public health, financial and administrative reporting, and (3) the healthcare delivery process</p> <p>This support is necessary for direct care functionality that relies on providing user interaction and workflows, which are configured according to clinical protocols and business rules based on encounter specific values such as care setting, encounter type (inpatient, outpatient, home health, etc.), provider type, patient's EHR, health status, demographics, and the initial purpose of the encounter.</p>			45			

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
S.3.1.4	F	EN	Support Remote Healthcare Services	<p>Statement: Support remote health care services such as tele-health and remote device monitoring by integrating records and data collected by these means into the patient's record for care management, billing and public health reporting purposes.</p> <p>Description: Enables remote treatment of patients using monitoring devices, and two way communications between provider and patient or provider and provider. Promotes patient empowerment, self-determination and ability to maintain health status in the community. Promotes personal health, wellness and preventive care. For example, a diabetic pregnant Mom can self-monitor her condition from her home and use web TV to report to her provider. The same TV-internet connectivity allows her to get dietary and other health promoting information to assist her with managing her high-risk pregnancy.</p> <p>Legal Rationale: Data collected remotely must be incorporated into the electronic health record.</p>	DC.1.1 DC.1.3.3 DC.1.7.2.1 DC.1.7.2.2 DC.1.7.3 DC.3.2.1 DC.3.2.3 DC.3.2.5 IN.1.4 IN.1.6 IN.1.7 IN.2.2 IN.2.3 IN.2.5.1 IN.2.5.2	1. The system SHALL provide the ability to capture patient data from remote devices and integrate that data into the patient's record.	46	S.3.1.4	1	M
S.3.1.5	F	EN	Other Encounter and Episode of Care Support	<p>Statement: Where not covered above, provide the means to manage and organize the documentation of the health care needed and delivered during an encounter/episode of care.</p> <p>Description: Using data standards and technologies that support interoperability, encounter management promotes patient-centered/oriented care and enables real time, immediate point of service, point of care by facilitating efficient work flow and operations performance to ensure the integrity of: (1) the health record, (2) public health, financial and administrative reporting, and (3) the healthcare</p>	DC.3.1 DC.3.2 IN.2.3	1. The system SHALL provide the ability to organize patient data by encounter.	47	S.3.1.5	1	N/C
						2. The system SHOULD accept and append patient encounter data from external systems, such as diagnostic tests and reports.	48	S.3.1.5	2	N/C

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
				<p>delivery process. This support is necessary for direct care functionality that relies on providing user interaction and workflows, which are configured according to clinical protocols and business rules based on encounter specific values such as care setting, encounter type (inpatient, outpatient, home health, etc.), provider type, patient's record, health status, demographics, and the initial purpose of the encounter.</p> <p>Legal Rationale: <i>Legal proceedings may be limited to a specific encounter/episode therefore, it is important to manage and organize documentation by encounter.</i></p>		<p>3. The system SHALL provide the ability to create encounter documentation by one or more of the following means: direct keyboard entry of text; structured data entry utilizing templates, forms, pick lists or macro substitution; dictation with subsequent transcription of voice to text, either manually or via voice recognition system.</p>	49	S.3.1.5	3	N/C
						<p>4. The system SHOULD provide the ability to define presentation filters that are specific to the types of encounter. These specifics may include care provider specialty, location of encounter, date of encounter, associated diagnosis.</p>	50	S.3.1.5	4	N/C
S.3.4	F	EN	Manage Practitioner/Patient Relationships	<p>Statement: Identify relationships among providers treating a single patient, and provide the ability to manage patient lists assigned to a particular provider.</p> <p>Description: This function addresses the ability to access and update current information about the relationships between caregivers and the patients. This information should be able to flow seamlessly between the different components of the system, and between the EHR system and other systems. Business rules may be reflected in the presentation of, and the access to this information. The relationship among providers treating a single patient will include any necessary chain of authority/responsibility.</p> <p>Example: In a care setting with multiple providers, where the patient can only see</p>	<p>DC.2.6.3 S.1.3.4 S.2.2 IN.2.4</p>	<p>1. The system SHALL provide the ability to identify all providers by name associated with a specific patient encounter.</p>	51	S.3.4	1	N/C
						<p>2. The system SHALL provide the ability to specify the role of each provider associated with a patient such as encounter provider, primary care provider, attending, resident, or consultant.</p>	52	S.3.4	2	N/C
						<p>3. The system SHALL provide the ability to identify all providers who have been associated with any encounter for a specific patient.</p>	53	S.3.4	3	N/C
						<p>4. The system SHOULD provide authorized users the ability to add and update information on the relationship of provider to patient.</p>	54	S.3.4	4	N/C

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
				certain kinds of providers (or an individual provider); allow the selection of only the appropriate providers. Example: The user is presented with a list of people assigned to a given practitioner and may alter the assignment as required - to a group, to another individual or by sharing the assignment. <i>Legal Rationale: The identity and role/relationship a practitioner/provider has with a patient may be relevant during a legal proceeding.</i>		5. The system MAY provide the ability to view patient lists by provider.	55	S.3.4	5	N/C
						6. The system SHALL provide the ability to specify primary or principal provider(s) responsible for the care of a patient within a care setting.	56	S.3.4	6	N/C
S.3.5	H		Subject to Subject Relationship	Statement: Document relationships between patients and others to facilitate appropriate access to their health record on this basis if appropriate. Description: A user may assign the relationships between patients and others to facilitate access to their health record. Some example may include parent, relatives, a legal guardian, health care surrogate or payer.	S.1.4.1 IN.1.3 IN.1.5 IN.2.2		57			
S.3.5.1	F	EN	Related by Genealogy	Statement: Provide information on relationships by genealogy. Description: Relationships by genealogy may include genetic mother, next of kin, or family members. Appropriate consents must be acquired prior to the collection of use of this information. <i>Legal Rationale: Family and other relationships may have relevance during a legal proceeding.</i>	DC.1.1.3.1 DC.1.3.3	1. The system SHALL provide the ability to collect and maintain genealogical relationships.	58	S.3.5.1	1	N/C
						2. The system SHALL provide the ability to identify persons related by genealogy.	59	S.3.5.1	2	N/C
						3. The system SHOULD provide the ability to collect and maintain patient consents required to allow patient records to be viewed for the purposes of a genealogical family member's family medical history.	60	S.3.5.1	3	N/C
S.3.5.4	F	EN	Related by Other Means	Statement: Provide information on relationships by other means. Description: Other relationships that may need to be recorded would include but not be		1. The system SHALL provide the ability to identify persons with Power of Attorney for Health Care or other persons with the authority to make medical decisions on behalf of the patient.	61	S.3.5.4	2	M

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
				limited to surrogate mother, guardian, a person authorized to see health records, health care surrogate, and persons who may be related by epidemiologic exposure. Legal Rationale: It is important to identify who has legal clinical decision-making authority.			62			

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
DC.1	H	EN	Care Management	<p>Legal Profile Conformance: To achieve successful compliance with the LEHR-S Profile it is required that the systems SHALL comply with all overarching and inherited conformance criteria for all functions under DC.1 (DC.1.1 through DC.1.9).</p> <p><i>The overarching and inherited criteria provide a foundation for maintaining a legally-compliant health record. The LEHR-S profile will not identify the functionality that supports the collection of content for the patient record – care setting profiles will identify the appropriate content-related functions.</i></p> <p>Description: Care Management functions (i.e. DC.1.x functions) are those directly used by providers as they deliver patient care and create an electronic health record. DC.1.1.x functions address the mechanics of creating a health record and concepts such as a single logical health record, managing patient demographics, and managing externally generated (including patient originated) health data. Thereafter, functions DC.1.2.x through DC.1.9.x follow a fairly typical flow of patient care activities and corresponding data, starting with managing the patient history and progressing through consents, assessments, care plans, orders, results etc.</p> <p>Integral to these care management activities is an underlying system foundation that maintains the privacy, security, and integrity of the captured health information – the information</p>		1. The system SHALL conform to function IN.1.1 (Entity Authentication).	1	DC.1	1	N/C
						2. The system SHALL conform to function IN.1.2 (Entity Authorization).	2	DC.1	2	N/C
						3. The system SHALL conform to function IN.1.3 (Entity Access Control).	3	DC.1	3	N/C
						4. IF the system is used to enter, modify or exchange data, THEN the system SHALL conform to function IN.1.5 (Non-Repudiation), to guarantee that the sources and receivers of data cannot deny that they entered/sent/received the data.	4	DC.1	4	N/C
						5. IF the system exchanges data outside of a secure network, THEN the system SHALL conform to Function IN.1.6 (Secure Data Exchange), to ensure that the data are protected.	5	DC.1	5	N/C
						6. IF the system exchanges data outside of a secure network, THEN the system SHALL conform to Function IN.1.7 (Secure Data Routing), to ensure that the exchange occurs only among authorized senders and receivers.	6	DC.1	6	N/C
						7. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.1.8 (Information Attestation), to show authorship and responsibility for the data.	7	DC.1	7	N/C
						8. The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality).	8	DC.1	8	N/C
						9. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction).	9	DC.1	9	N/C
						10. <i>The system SHOULD conform to function IN.2.1.1 (Legal Hold).</i>	10			A
						11. <i>IF a legal hold is applied, THEN the system SHALL conform to function In.2.1.1.1 (Legal Hold Notice).</i>	11			A

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
				<p>infrastructure of the EHR-S. Throughout the DC functions, conformance criteria formalize the relationships to Information Infrastructure functions. Criteria that apply to all DC.1 functions are listed in this header (see Conformance Clause page six for discussion of “inherited” conformance criteria).</p> <p>In the Direct Care functions there are times when actions/activities related to "patients" are also applicable to the patient representative. Therefore, in this section, the term “patient” could refer to the patient and/or the patient’s personal representative (e.g. guardian, surrogate).</p>		12. The system SHALL conform to function IN.2.2 (Auditable Record).	12			A
						13. The system SHALL conform to function IN.2.2.1.1 (Point of Record Metadata).	13			A
						14. The system SHALL conform to function IN.2.2.1.2 (System Metadata).	14			A
						15. The system SHALL conform to In.2.2.1.3 (Software Application Metadata).	15			A
						16. The system SHOULD conform to function IN.2.3 (Synchronization).	16	DC.1	10	N/C
						17. IF the system is used to extract data for analysis and reporting, THEN the system SHALL conform to function IN.2.4 (Extraction of Health Record Information), to support data extraction across the complete health record of an individual.	17	DC.1	11	N/C
						18. The system SHALL conform to IN.2.4.1 (Search and Retrieve).	18			A
						19. IF the system stores unstructured data, THEN the system SHALL conform to function IN.2.5.1 (Manage Unstructured Health Record Information), to ensure data integrity through all changes.	19	DC.1	12	N/C
						20. IF the system stores structured data, THEN the system SHALL conform to function IN.2.5.2 (Manage Structured Health Record Information), to ensure data integrity through all changes.	20	DC.1	13	N/C
						21. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to IN.2.5.3.1 (Pending State).	21			A
						22. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.3.2 (Amended, Corrected or Augmented State).	22			A
						23. IF the system is used to manage versions of health record data/record, THEN the system SHALL conform to function IN.2.5.3.3 (Document Succession Management and Version Control).	23			A

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						24. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.3.4 (Retracted State).	24			A
						25. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.4 (Redaction).	25			A
						26. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.6 (Health Record Completeness).	26			A
						27. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.7 (Replication of Views).	27			A
						28. The system SHALL conform to function IN.2.5.8 (Downtime Procedures, Storage and Back Up).	28			A
						29. The system SHOULD conform to function IN.3 (Registry and Directory Services).	29	DC.1	14	N/C
						30. IF the system processes data for which generally accepted standard terminologies have been established, THEN the system SHALL conform to function IN.4.1 (Standard Terminologies and Terminology Models), to support semantic interoperability.	30	DC.1	15	N/C
						31. IF the system processes data for which generally accepted standard terminologies have been established, THEN the system SHALL conform to function IN.4.2 (Maintenance and Versioning of Standard Terminologies), to preserve the semantics of coded data over time.	31	DC.1	16	N/C
						32. The system SHOULD conform to function IN.4.3 (Terminology Mapping).	32	DC.1	17	N/C
						33. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.1 (Interchange Standards), to support interoperability.	33	DC.1	18	N/C

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						34. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.2 (Interchange Standards Versioning and Maintenance), to accommodate the inevitable evolution of interchange standards.	34	DC.1	19	N/C
						35. The system SHOULD conform to function IN.5.3 (Standards-based Application Integration).	35	DC.1	20	N/C
						36. IF the system exchanges data with other systems outside itself, THEN the system SHALL conform to function IN.5.4 (Interchange Agreements), to define how the sender and receiver will exchange data.	36	DC.1	21	N/C
						37. The system SHOULD conform to function IN.6 (Business Rules Management).	37	DC.1	22	N/C
						38. The system SHOULD conform to function IN.7 (Workflow Management).	38	DC.1	23	N/C
						39. The system SHALL conform to function S.2.2.1 (Health Record Output).	39	DC.1	24	N/C
DC.2	H	EN	Clinical Decision Support	<p><i>Legal Profile Conformance: To achieve successful compliance with the LEHR-S Profile it is required that the systems SHALL comply with all overarching and inherited conformance criteria for all functions under DC.2 (DC.2.1 through DC.2.6).</i></p> <p><i>The overarching and inherited criteria provide a foundation for maintaining a legally-compliant health record. The LEHR-S profile will not identify the functionality that supports the collection of content for the patient record – care setting profiles will identify the appropriate content-related functions.</i></p>		1. The system SHALL conform to function IN.1.1 (Entity Authentication).	40	DC.2	1	N/C
						2. The system SHALL conform to function IN.1.2 (Entity Authorization).	41	DC.2	2	N/C
						3. The system SHALL conform to function IN.1.3 (Entity Access Control).	42	DC.2	3	N/C
						4. IF the system is used to enter, modify or exchange data, THEN the system SHALL conform to function IN.1.5 (Non-Repudiation), to guarantee that the sources and receivers of data cannot deny that they entered/sent/received the data.	43	DC.2	4	N/C
						5. IF the system exchanges data outside of a secure network, THEN the system SHALL conform to function IN.1.6 (Secure Data Exchange), to ensure that the data are protected.	44	DC.2	5	N/C

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						6. IF the system exchanges outside of a secure network, THEN the system SHALL conform to function IN.1.7 (Secure Data Routing), to ensure that the exchange occurs only among authorized senders and receivers.	45	DC.2	6	N/C
						7. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.1.8 (Information Attestation), to show authorship and responsibility for the data.	46	DC.2	7	N/C
						8. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction).	47	DC.2	8	N/C
						9. <i>The system SHOULD conform to function IN.2.1.1 (Legal Hold).</i>	48			A
						10. <i>The system SHALL conform to function IN.2.2 (Auditable Record).</i>	49			A
						11. <i>The system SHALL conform to function IN.2.2.1.1 (Point of Record Metadata).</i>	50			A
						12. <i>The system SHALL conform to function IN.2.2.1.2 (System Metadata).</i>	51			A
						13. <i>The system SHALL conform to In.2.2.1.3 (Software Application Metadata).</i>	52			A
						14. The system SHOULD conform to function IN.2.3 (Synchronization).	53	DC.2	9	N/C
						15. IF the system is used to extract data for analysis and reporting, THEN the system SHALL conform to function IN.2.4 (Extraction of Health Record Information), to support data extraction across the complete health record of an individual.	54	DC.2	10	N/C
						16. <i>The system SHALL conform to IN.2.4.1 (Search and Retrieve).</i>	55			A
						17. IF the system stores unstructured data, THEN the system SHALL conform to function IN.2.5.1 (Manage Unstructured Health Record Information), to ensure data integrity through all changes.	56	DC.2	11	N/C

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						18. IF the system stores structured data, THEN the system SHALL conform to function IN.2.5.2 (Manage Structured Health Record Information), to ensure data integrity through all changes.	57	DC.2	12	N/C
						19. The system SHALL conform to function IN.2.5.8 (Downtime Procedures, Storage and Back Up).	58			A
						20. IF the system processes data for which generally accepted standard terminologies have been established, THEN the system SHALL conform to function IN.4.1 (Standard Terminologies and Terminology Models), to support semantic interoperability.	59	DC.2	13	N/C
						21. IF the system processes data for which generally accepted standard terminologies have been established, THEN the system SHALL conform to function IN.4.2 (Maintenance and Versioning of Standard Terminologies), to preserve the semantics of coded data over time.	60	DC.2	14	N/C
						22. The system SHOULD conform to function IN.4.3 (Terminology Mapping).	61	DC.2	15	N/C
						23. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.1 (Interchange Standards), to support interoperability.	62	DC.2	16	N/C
						24. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.2 (Interchange Standards Versioning and Maintenance), to accommodate the inevitable evolution of interchange standards.	63	DC.2	17	N/C
						25. The system SHOULD conform to function IN.5.3 (Standards-based Application Integration).	64	DC.2	18	N/C
						26. IF the system exchanges data with other systems outside itself, THEN the system SHALL conform to function IN.5.4 (Interchange Agreements), to define how the sender and receiver will exchange data.	65	DC.2	19	N/C

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						27. The system SHOULD conform to function IN.6 (Business Rules Management).	66	DC.2	20	N/C
						28. The system SHOULD conform to function IN.7 (Workflow Management).	67	DC.2	21	N/C
DC.3	H	EN	Operations Management and Communication	<p>Legal Profile Conformance: To achieve successful compliance with the LEHR-S Profile it is required that the systems SHALL comply with all overarching and inherited conformance criteria for all functions under DC.3 (DC.3.1 through DC.3.2.5).</p> <p>The overarching and inherited criteria provide a foundation for maintaining a legally-compliant health record. The LEHR-S profile will not identify the functionality that supports the collection of content for the patient record – care setting profiles will identify the appropriate content-related functions.</p>		1. The system SHALL conform to function IN.1.1 (Entity Authentication).	68	DC.3	1	N/C
						2. The system SHALL conform to function IN.1.2 (Entity Authorization).	69	DC.3	2	N/C
						3. The system SHALL conform to function IN.1.3 (Entity Access Control).	70	DC.3	3	N/C
						4. IF the system exchanges data across entity boundaries within an EHR-S or external to an EHR-S, THEN the system SHALL conform to function IN.1.6 (Secure Data Exchange) to ensure that the data are protected.	71	DC.3	4	N/C
						5. IF the system exchanges data with other sources or destinations of data, THEN the system SHALL conform to function IN.1.7 (Secure Data Routing) to ensure that the exchange occurs only among authorized senders and “receivers”.	72	DC.3	5	N/C
						6. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.1.8 (Information Attestation) to show authorship and responsibility for the data.	73	DC.3	6	N/C
						7. The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality).	74	DC.3	7	N/C
						8. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction).	75	DC.3	8	N/C
						9. The system SHOULD conform to function IN.2.1.1 (Legal Hold).	76			A
						10. The system SHALL conform to function IN.2.2 (Auditable Records).	77	DC.3	9	N/C
						11. The system SHALL conform to function IN.2.2.1.1 (Point of Record Metadata).	78			A
						12. The system SHALL conform to function IN.2.2.1.2 (System Metadata).	79			A

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						13. The system SHALL conform to In.2.2.1.3 (Software Application Metadata).	80			A
						14. The system SHOULD conform to function IN.2.3 (Synchronization).	81	DC.3	10	N/C
						15. IF the system is used to extract data for analysis and reporting, THEN the system SHALL conform to function IN.2.4 (Extraction of Health Record Information) to support data extraction across the complete health record of an individual.	82	DC.3	11	N/C
						16. The system SHALL conform to IN.2.4.1 (Search and Retrieve).	83			A
						17. IF the system stores unstructured data, THEN the system SHALL conform to function IN.2.5.1, (Manage Unstructured Health Record Information), to ensure data integrity through all changes.	84	DC.3	12	N/C
						18. IF the system stores structured data, THEN the system SHALL conform to function IN.2.5.2 (Manage Structured Health Record Information) to ensure data integrity through all changes.	85	DC.3	13	N/C
						19. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to IN.2.5.3.1 (Pending State).	86			A
						20. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.3.2 (Amended, Corrected or Augmented State).	87			A
						21. IF the system is used to manage versions of health record data/record, THEN the system SHALL conform to function IN.2.5.3.3 (Document Succession Management and Version Control).	88			A
						22. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.3.4 (Retracted State).	89			A
						23. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.4 (Redaction).	90			A

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ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						24. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.5 (Health Record Completeness).	91			A
						25. IF the system is used to enter or modify data in the health record, THEN the system SHALL conform to function IN.2.5.7 (Replication of Views).	92			A
						26. The system SHALL conform to function IN.2.5.8 (Downtime Procedures, Storage and Back Up).	93			A
						27. IF the system processes data for which generally accepted standard terminologies have been established, THEN the system SHALL conform to function IN.4.1 (Standard Terminologies and Terminology Models) to support semantic interoperability.	94	DC.3	14	N/C
						28. IF the system processes data for which generally accepted standard terminologies have been established, THEN the system SHALL conform to function IN.4.2 (Maintenance and Versioning of Standard Terminologies) to preserve the semantics of coded data over time.	95	DC.3	15	N/C
						29. The system SHOULD conform to function IN.4.3 (Terminology Mapping).	96	DC.3	16	N/C
						30. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.1 (Interchange Standards) to support interoperability.	97	DC.3	17	N/C
						31. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.2 (Interchange Standards Versioning and Maintenance) to accommodate the inevitable evolution of interchange standards.	98	DC.3	18	N/C
						32. The system SHOULD conform to function IN.5.3 (Standards-based Application Integration).	99	DC.3	19	N/C

Priority – EN = Essential Now, EF = Essential Future

FM Source - Criteria Status is either: N/C = no change, A=added, M=modify. For new children functions, the FM Source columns is blank.

ID#	Type	Priority	Name	Statement/Description	See Also	Conformance Criteria	Row #	FM Source		
								ID#	Criteria #	Criteria Status
						33. IF the system exchanges data with other systems outside itself, THEN the system SHALL conform to function IN.5.4 (Interchange Agreements) to define how the sender and receiver will exchange data.	100	DC.3	20	N/C
						34. The system SHOULD conform to function IN.6 (Business Rules Management).	101	DC.3	21	N/C
						35. The system SHOULD conform to function IN.7 (Workflow Management).	102	DC.3	22	N/C