HL7 EHR-System for a Pharmacist/ Pharmacy Electronic Health Record Implementation Guide for Community Practice





Pharmacy Health Information Technology Collaborative



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Implementation Guide for Community Practice

he HL7 EHR-S Functional Model defines a standardized model of the functions that may be present in electronic health record (EHR) systems. A "functional profile" is a specification that uses the functional model to indicate those functions that are required for certain EHR systems and health care delivery settings. The Pharmacist/ Pharmacy Provider Functional Profile is designed to facilitate capturing of clinical medication-related data at the point of care in a single logical health record. The functional profile specifies the requirements needed to support messaging among prescribers, pharmacists or pharmacy providers, and other health care entities benefiting from medication-related information.

The Functional Profile, Release 1, was reviewed by the Pharmacist Services Technical Advisory Coalition (PSTAC) Workgroup 4 with the goal of publishing an implementation guide specific to an EHR for a community pharmacy practice setting. Based on findings from a survey of system vendors, the implementation guide's focus was narrowed from the functional profile's scope, which had encompassed all pharmacy practice settings. It was decided that reducing the work necessary to develop a community pharmacy practice EHR would shorten the software development cycle and gain system vendor support for earlier implementation.



This implementation guide represents the content of the following chapters of the HL7 Functional Profile.

Chapter 3: Direct Care Functions

Chapter 4: Supportive Functions

Chapter 5: Information Infrastructure Functions

The implementation guide follows the format of the functional profile, which is as follows:

- Identification Number of the Specific Function
- Name of the Function
- Statement/Description of the Function
- Conformance Criteria

The functional profile divides the conformance criteria into the following categories:

- Those functions that the EHR shall have or that are required
- Those functions that the EHR should have but are not required
- Those functions that the EHR may have but are not required

Functions that were designated as optional are not included in this implementation guide, because they were not considered essential to the EHR at this time.

The PSTAC workgroup established timelines for the conformance criteria. The required conformance criteria (SHALL) within a functional area, which were given an implementation date of Jan. 1, 2015, are included in this implementation guide. The PSTAC Workgroup 4 identified additional criteria (SHOULD or MAY) for conformance in 2017 and 2018 or beyond. Those criteria will be published in a future guide.

ID#	Туре	Name	Statement/Description	Conformance Criteria
DC.1	н	Care Management	Management	1. The system SHALL conform to function IN.1.1 (Entity Authentication).
		EN	ly 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	2. The system SHALL conform to function IN.1.2 (Entity Authorization).
			health record and concepts such as a single logical health record, managing patient demographics,	3. The system SHALL conform to function IN.1.3 (Entity Access Control).
			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	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.
			plans, orders, results etc. Integral to these care management activities is an underlying system foundation that maintains the privacy, security, and integrity of the captured health information – the	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.
			information infrastructure of the EHR-S. Through- out the DC functions, conformance criteria formalize the relationships to Information Infrastructure func- tions. Criteria that apply to all DC.1 functions are listed in this header (see Conformance Clause page	6. IF the system exchanges data outside of a secure net- work, 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.
		six for discussion of "inherited" conformance cri- teria). 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). Registry and directory	teria). In the Direct Care functions there are times when actions/activities related to "patients" are also applicable to the patient representative. Therefore,	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.
			patient and/or the patient's personal representative (e.g. guardian, surrogate). Registry and directory services are not essential to a standalone electronic prescribing system. However, if provided, the crite-	8. The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality).
				9. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction).
				10. The system SHOULD conform to function IN.2.3 (Syn- chronization).
				11. 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.
			12. 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.	
				13. 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.
				15. 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.
				16. 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.
			18. IF the system exchanges data for which generally ac- cepted interchange standards have been established, THEN the system SHALL conform to function IN.5.1 (Interchange Standards), to support interoperability.	

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				 19. 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. 21. 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. 22. The system SHALL conform to function IN.6 (Business
				Rules Management). 23. The system SHOULD conform to function IN.7 (Work- flow Management).
DC.1.1	Н	Record Management EN	Statement: Description: For those functions related to data capture, data may be captured using stan- dardized code sets or nomenclature, depending on the nature of the data, or captured as unstructured data. Care-setting dependent data is entered by a variety of caregivers. Details of who entered data and when it was captured should be tracked. Data may also be captured from devices or other tele- health applications.	
DC.1.1.1	F	Identify and Maintain	Statement: Identify and maintain a single patient re- cord for each patient. Description: A single record	1. The system SHALL create a single logical record for each patient.
		a Patient Record EN		2. IF the identity of a patient is unknown, THEN the system SHALL provide the ability to create a record for the un- known patient according to scope of practice, organizational policy, or jurisdictional law.
				3. The system SHALL provide the ability to store more than one identifier for each patient record.
			patient, or separating information where it was inadvertently captured for the wrong patient, helps maintain health information for a single patient. In the process of creating a patient record, it is at times	4. The system SHALL associate key identifier information (e.g., system ID, medical record number) with each patient record.
		advantageous to replicate identical information across multiple records, so that such data does no have to be re-entered. For example, when a paren registers children as new patients, the address, guarantor, and insurance data may be propagated	advantageous to replicate identical information across multiple records, so that such data does not have to be re-entered. For example, when a parent registers children as new patients, the address, guarantor, and insurance data may be propagated in the children's records without having to re-enter	5. The system SHALL provide the ability to uniquely identi- fy a patient and tie the record to a single patient.
				6. The system SHALL provide the ability, through a controlled method, to merge or link dispersed information for an individual patient upon recognizing the identity of the patient.
				7. IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to mark the information as erroneous in the record of the patient in which it was mistakenly associated and represent that information as erroneous in all outputs containing that information.
				8. IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to associate it with the correct patient.
			9. The system SHALL provide the ability to retrieve parts of a patient record using a primary identifier, secondary identifiers, or other information which are not identifiers, but could be used to help identify the patient.	
				12. The system SHALL conform to function IN.2.2 (Audit- able Records).

DC.1.1.2	F	Manage Patient De-	Statement: Capture and maintain demographic information. Where appropriate, the data should be clinically relevant and reportable. Description: Contact information including addresses and phone numbers, as well as key demographic information	1. The system SHALL capture demographic information as part of the patient record.
		mographics EN		2. The system SHALL store and retrieve demographic information as discrete data.
			such as gender, and other information is stored and maintained for unique patient identification, report-	3. The system SHALL provide the ability to retrieve demo- graphic data as part of the patient record.
			ing purposes and for the provision of care. Patient demographics are captured and maintained as discrete fields (e.g., patient names and addresses)	4. The system SHALL provide the ability to update demo- graphic data.
			and may be enumerated, numeric or codified. Key patient identifiers are shown on all patient informa-	7. The system SHALL present a set of patient identifying information at each interaction with the patient record.
			tion output (such as name and ID# on each screen of a patient's record). The system will track who updates demographic information, and when the demographic information is updated.	9. The system SHALL conform to function IN.2.2 (Audit- able Records).
				11. The system SHOULD provide the ability to capture and maintain multiple addresses.
				12. The system SHOULD provide the ability to capture and maintain multiple phone numbers.
DC.1.1.3	н	Data and Documen- tation from External Sources EN	Description: External sources are those outside the EHR system, including clinical, administrative, and financial information systems, other EHR systems, PHR systems, and data received through health information exchange networks.	2. The system SHALL conform to function IN.2.2 (Audit- able Records).
DC.1.1.3.1	F	F Capture Data and Docu- mentation from Exter- nal Clinical Sources EN	d Docu- entationtation from external sources. Description: Mech- anisms for incorporating external clinical data and documentation (including identification of source) such as image documents and other clinically relevant data are available. Data incorporated	1. The system SHALL provide the ability to capture exter- nal data and documentation.
				2. IF lab results are received through an electronic inter- face, THEN the system SHALL receive and store the data elements into the patient record.
				3. IF lab results are received through an electronic inter- face, THEN the system SHALL display them upon request.
				9. The system SHALL provide the ability to receive, store and present medication details from an external source.
DC.1.1.4	F	F Produce a Summary Record of Care EN		 The system SHALL present summarized views and reports of the patient's comprehensive EHR.
			Care related to privacy and confidentiality. Description:	5. The system SHALL conform to function IN.2.2 (Audit- able Records).

DC.1.2	F	Manage Pa- tient History EN	ht History dural/surgical, social and family history including the capture of pertinent positive and negative histo- ries, patient-reported or externally available patient clinical history.	 The system SHALL provide the ability to capture, update and present current patient history including pertinent pos- itive and negative elements, and information on clinicians involved. The system SHALL capture the complaint, presenting 	
			Description: The history of the current illness and patient historical data related to previous med- ical diagnoses, surgeries and other procedures performed on the patient, clinicians involved in pro- cedures or in past consultations, and relevant health conditions of family members is captured through such methods as patient reporting (for example interview, medical alert band) or electronic or non- electronic historical data. This data may take the form of a pertinent positive such as: "The patient/ family member has had" or a pertinent negative such as "The patient/family member has not had" When first seen by a health care provider, patients typically bring with them clinical information from past encounters. This and similar information is captured and presented alongside locally captured	problem or other reason(s) for the visit or encounter.7. The system SHALL conform to function IN.2.2 (Auditable Records).	
DC.1.3	H	Preferences, Directives, Consents and Authori- zations EN		2. The system SHALL conform to function IN.2.2 (Audit- able Records).	
DC.1.3.1	F	Manage Patient and Family Preferences EN	Statement: Capture and maintain patient and family preferences. Description: Patient and family prefer- ences regarding issues such as language, religion, spiritual practices and culture – may be important to the delivery of care. It is important to capture these so that they will be available to the provider at the point of care. NOTE: This function is focused on the capture and maintenance of facts on patient/family preferences. For issues related to death and dying see DC.1.3.2	 The system SHALL provide the ability to capture, present, maintain and make available for clinical decisions patient preferences such as language, religion, spiritual practices and culture. The system SHALL provide the ability to capture, present, maintain and make available for clinical decisions family preferences such as language, religion, spiritual practices and culture. 	
DC.1.3.3	F	Manage Consents and Authori- zations EN	Statement: Create, maintain, and verify patient de- cisions such as informed consent for treatment and authorization/consent for disclosure when required. Description: Decisions are documented and include the extent of information, verification levels and exposition of treatment options. This documentation helps ensure that decisions made at the discretion of the patient, family, or other responsible party, govern the actual care that is delivered or withheld. There may be several documents active at any one time that may govern a patient's care. Both clinical and administrative consents and authorizations are considered part of this function. A consent or authorization includes patient authorization for re- disclosure of sensitive information to third parties. Consents/Authorizations for printing should include appropriate standardized forms for patients, guard- ians, foster parents. The system must appropriately present forms for adolescents according to privacy rules. Some states may mandate assent. Assent is agreement by the patient to participate in services when they are legally unable to consent (e.g., an adolescent, an adult with early dementia).	 The system SHALL provide the ability to indicate that a patient has completed applicable consents and authorizations. The system SHALL provide the ability to indicate that a patient has withdrawn applicable consents and authorizations. The system SHALL provide the ability to document the source of each consent, such as the patient or the patient's personal representative if the patient is legally unable to provide it. 	
DC.1.4	H	Summary Lists EN		2. The system SHALL conform to function IN.2.2 (Audit- able Records).	

DC.1.4.1	F	Manage Allergy, Intolerance and Adverse Reaction List EN	Statement: Create and maintain patient-specific allergy, intolerance and adverse reaction lists. Description: Allergens, including immunizations, and substances are identified and coded (whenever possible) and the list is captured and maintained over time. All pertinent dates, including patient-re- ported events, are stored and the description of the patient allergy and adverse reaction is modifiable over time. The entire allergy history, including reac- tion, for any allergen is viewable. The list(s) includes all reactions including those that are classifiable as a true allergy, intolerance, side effect or other adverse reaction to drug, dietary or environmen- tal triggers. Notations indicating whether item is patient reported and/or provider verified are maintained.	 The system SHALL provide the ability to capture true allergy, intolerance, and adverse reaction to drug, dietary or environmental triggers as unique, discrete entries. The system SHALL provide the ability to capture the reaction type. The system SHALL provide the ability to capture a report of No Known Allergies (NKA) for the patient. The system SHALL provide the ability to deactivate an item on the list. The system SHALL provide the ability to capture the reason for deactivation of an item on the list. They system SHALL provide the ability to capture and display the date on which allergy information was entered.
DC.1.4.2	F	Medication List ENmedication lists. Description: Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, includ- ing medication start, modification, and end dates are stored. The entire medication history for any medi-	Medication List ENmedication lists. Description: Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, includ- ing medication start, modification, and end dates are stored. The entire medication history for any medi- cation, including alternative supplements and herbal medications, is viewable. Medication lists are not limited to medication orders recorded by providers, but may include, for example, pharmacy dispense/	 The system SHALL provide the ability to capture patient-specific medication lists. The system SHALL display and report patient-specific medication lists. The system SHALL provide the ability to capture the details of the medication when known such as ordering date, medication identifier (RxNorm/NDC/UNII), dose, route, and SIG (directions on the prescription). The system SHALL provide the ability to capture medications not reported on existing medication lists or medication histories.
			 6. The system SHALL provide the ability to capture non-prescription medications including over the counter and complementary medications such as vitamins, herbs and supplements. 7. The system SHALL present the current medication lists associated with a patient. 9. The system SHALL present the details of the medi- cation, when known, such as prescriber, and medication ordering dates. 10. The system SHALL provide the ability to mark a med- ication as erroneously captured and excluded from the presentation of current medications. 11. The system SHALL provide the ability to print a current medication list for patient use. 13. The system SHALL maintain coded list of medications 	
				including a unique identifier for each medication. 15. The system SHALL provide the ability to query (for ex- ample a plan, payer or pharmacy) for a medication history.

DC.1.4.3	F	Manage Problem List EN	Statement: Create and maintain patient- specific problem lists. Description: A problem list may include, but is not	 The system SHALL capture, display and report all active problems associated with a patient. The system SHALL capture, display and report a history
			limited to: Chronic conditions, diagnoses, symp- toms, or functional limitations.	of all problems associated with a patient.
			Problem lists are managed over time, whether over the course of a visit or stay or the life of a patient,	3. The system SHALL provide the ability to capture onset date of problem.
			allowing documentation of historical information and tracking the changing character of problem(s) and their priority. The source (e.g. the provider, the	5. The system SHALL provide the ability to capture the source, date and time of all updates to the problem list.
				6. The system SHALL provide the ability to deactivate a problem.
DC.1.4.4	F	Manage Immuniza-	Statement: Create and maintain patient-specific immunization lists. Description: Immunization lists	1. The system SHALL capture, display and report all immunizations associated with a patient.
		tion List EN	are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. Details of immunizations administered are captured as discrete data elements including date, type, man- ufacturer and lot number. The entire immunization history is viewable.	2. The system SHALL record as discrete data elements data associated with any immunization given including date, type, lot number and manufacturer.
DC.1.4.5	5	Manage Medication Associated Diagnosis List EN From eRx DC.1.4.3	Statement: Create and maintain medication — spe- cific diagnosis lists for a patient. Description: Diagnosis lists are managed over time to serve as basis for the prescribing of specific medications.	1. The system SHALL provide the ability to create, display and report diagnoses associated with medications to be prescribed.
				4. The system SHALL provide the ability to capture and display the diagnoses associated with medications previously prescribed for the specific patient.
DC.1.5	F	F Manage Assess- ments EN	Description: During an encounter with a patient, the provider will conduct an assessment that is	1. The system SHALL provide the ability to create assessments.
				11. The system SHALL conform to function IN.2.2 (Audit- able Records).
				12. The system SHALL provide the ability to link data from a standard assessment to a medication list.
DC.1.6	H	Care Plans, Treatment Plans, Guidelines and Proto- cols EN		
DC.1.6.1	F	Present Guide- lines and Protocols for Planning Care ENStatement: Present organizational guidelines for patient care as appropriate to support planning of care as appropriate to support planning of care, including order entry and clinical documenta- tion.	1. The system SHALL provide the ability to present cur- rent guidelines and protocols to clinicians who are creating plans for treatment and care.	
			4. IF decision support prompts are used to support a spe- cific clinical guideline or protocol, THEN the system SHALL conform to function DC.1.8.6 (Manage Documentation of Clinician Response to Decision Support Prompts).	
				5. The system SHALL conform to function DC.2.2.1.2 (Support for Context-Sensitive Care Plans, Guidelines, Protocols).

DC.1.6.2	F	Manage Patient-	ient- care organizations to build care plans, guidelines	 The system SHALL provide the ability to capture pa- tient-specific plans of care and treatment.
		Specific Care and Treat- ment Plansand protocols for use during patient care planning and care. Description: Care plans, guidelines or protocols may contain goals or targets for the patient, specific guidance to the providers, suggest- ed orders, and nursing interventions, among other 	2. The system SHALL conform to DC.1.6.1 (Present Guidelines and Protocols for Planning Care) and provide the ability to use locally or non-locally developed templates, guidelines, and protocols for the creation of patient-specific plans of care and treatment.	
			or approval dates, modifications and relevancy to specific domains or context is provided. Transfer of treatment and care plans may be implemented	3. The system SHALL provide the ability to use previously developed care plans as a basis for the creation of new plans of care and treatment.
			electronically using, for example, templates, or by printing plans to paper.	4. The system SHALL provide the ability to track updates to a patient's plan of care and treatment including authors, creation date, version history, references, local sources and non-local sources in accordance with scope of practice, organizational policy and jurisdictional law.
				8. The system SHALL provide the ability to transfer plans of care and treatment to other care providers.
				12. The system SHALL conform to function IN.2.2 (Audit- able Records).
DC.1.7	H	Orders and Referrals Management EN		1. The system SHALL conform to function IN.2.2 (Audit- able Records).
DC.1.7.1	F	F Manage Medication Orders EN Statement: Create prescriptions or other medica- tion orders with detail adequate for correct filling and administration. Provide information regarding compliance of medication orders with formularies. Description: Different medication orders, including discontinue, refill, and renew, require different levels and kinds of detail, as do medication orders placed in different situations. The correct details are recorded for each situation. Administration or patient instructions are available for selection by the ordering clinicians, or the ordering clinician is facilitated in creating such instructions. The system may allow for the creation of common content for prescription details. Appropriate time stamps for all medication related activity are generated. This includes series of orders that are part of a therapeu- tic regimen, e.g. Renal Dialysis, Oncology. When a clinician places an order for a medication, that order may or may not comply with a formulary specific to the patient's location or insurance coverage, if applicable. Whether the order complies with the formulary should be communicated to the order- ing clinician at an appropriate point to allow the ordering clinician to decide whether to continue with the order. Formulary-compliant alternatives to the medication being ordered may also be presented. In some pharmacy practice settings the sharing of formulary and benefit information from the PBM with the pharmacy is not possible.	Medication Orderstion orders with detail adequate for correct filling and administration. Provide information regarding	1. The system SHALL provide the ability to create prescription or other medication orders with the details adequate for correct filling and administration captured as discrete data.
			discontinue, refill, and renew, require different	2. The system SHALL capture user and date stamp for all prescription related events.
			placed in different situations. The correct details are recorded for each situation. Administration or patient instructions are available for selection by	3. The system SHALL conform to function DC.1.4.2 (Man- age Medication List) and update the appropriate medication list with the prescribed medications (in case of multiple medication lists).
			may allow for the creation of common content for	4. The system SHALL provide a list of medications to search, including both generic and brand name.
			5. The system SHALL provide the ability to maintain a discrete list of orderable medications.	
			clinician places an order for a medication, that order may or may not comply with a formulary specific to the patient's location or insurance coverage, if applicable. Whether the order complies with the	6. The system SHALL conform to function DC.1.7.2.1 (Man- age Non-Medication Patient Care Orders) and provide the ability to order supplies associated with medication orders in accordance with scope of practice, organizational policy or jurisdictional law.
			15. The system SHALL provide the ability to re-prescribe a medication from a prior prescription using the same dosage but allow for editing of details adequate for correct filling and administration of medication (e.g. dose, frequen- cy, body weight).	
				16. The system SHALL conform to function DC.2.3.1.1 (Support for Drug Interaction Checking) and check and re- port allergies, drug-drug interactions, and other potential adverse reactions, when new medications are ordered.
				17. The system SHALL conform to function DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) and check and report other potential adverse reactions, when new medications are ordered.
			18. The system SHALL provide the ability to create pre- scriptions in which the weight-specific dose is suggested.	

DC.1.7.2.1	F	Manage Non-Medica-	Statement: Capture and track patient care orders. Enable the origination, documentation, and tracking	1. The system SHALL provide the ability to capture non-medication patient care orders for an action or item.
		tion Patient Care Orders EN		2. The system SHALL provide the ability to capture ade- quate order detail for correct order fulfillment.
			ing new, renewal and discontinue orders.	3. The system SHALL track the status of the ordered action or item.
				7. The system SHALL conform to DC.2.4.2 (Support for Non-Medication Ordering)
DC.1.7.2.4	F	Manage Referrals EN	Statement: Enable the origination, documentation and tracking of referrals between care providers or healthcare organizations, including clinical and	1. The system SHALL provide the ability to capture and communicate referral(s) to other care provider (s), whether internal or external to the organization.
			administrative details of the referral, and consents and authorizations for disclosures as required. Description: Documentation and tracking of a refer-	2. The system SHALL provide the ability to capture clinical details as necessary for the referral.
			ral from one care provider to another is supported, whether the referred to or referring providers are internal or external to the healthcare organization. Guidelines for whether a particular referral for a	3. The system SHALL provide the ability to capture admin- istrative details (such as insurance information, consents and authorizations for disclosure) as necessary for the referral.
			particular patient is appropriate in a clinical context and with regard to administrative factors such as in- surance may be provided to the care provider at the time the referral is created. In the pharmacy setting referrals may be condition based, e.g. for smoking cessation counseling or diabetes related medication therapy management (MTM) services. They may also be for medication use instruction and monitoring.	4. The system SHALL present captured referral informa- tion.
				8. The system SHALL provide the ability to document transfer of care according to organizational policy, scope of practice, and jurisdictional law.
DC.1.7.3	F	Order Sets input or system prompt. EN Description: Order sets, which may include medication and non-medication orders, allow a care provider to choose common orders for a particular circumstance or disease state according to standards or other criteria. Recommended order sets may be presented based on patient data, medication or other contexts.	 The system SHALL provide the ability to present order set(s). 	
			EN Description: Order sets, which may include med- ication and non-medication orders, allow a care provider to choose common orders for a particular circumstance or disease state according to stan-	 The system SHALL provide the ability to order at the patient level from presented order sets.
				3. The system SHALL provide the ability to record each component of an order set that is ordered.
				4. The system SHALL conform to function DC.2.4.1 (Support for Order Sets).
DC.1.8	H	Documenta- tion of Care, Measure- ments and Results EN		1. The system SHALL conform to function IN.2.2 (Audit- able Records)

DC.1.8.1	Н	Manage Medication	Statement: Present providers with the list of medications that are to be administered to a patient,	1. The system SHALL present the list of medications to be administered.
		Administra- tion Optional	administration details Description: In a setting in which medication orders are to be administered by a provider (e.g. pharmacist) rather than the patient, the necessary information is presented including: the list of med- ication orders that are to be administered; admin-	2. The system SHALL display the timing, route of adminis- tration, and dose of all medications on the list.
		optionat		7. The system SHALL provide the ability to capture medication administration details – including timestamps, observations, complications, and reason if medication was not given – in accordance with organizational policy, scope of practice, and jurisdictional law.
	administration; dose and route, etc. The system shall securely relate medications to be administered to the unique identity of the patient [see DC.1.1.1]. Additionally, the provider can record what actually was or was not administered, whether or not these facts conform to the order. Appropriate time stamps for all medication related activity are generated. For some settings that administer complete sets of medications from a variety of providers' orders, it may be useful to provide an additional check for possible drug-drug or other interactions. If the pharmacist administers drugs, then the system	8. The system SHALL securely relate interventions to be administered to the unique identity of the patient.		
DC.1.8.2	munization Administra- cerning immunizations given to a patient includir date administered, type, manufacturer, lot numb	Statement: Capture and maintain discrete data con- cerning immunizations given to a patient including date administered, type, manufacturer, lot number, and any allergic or adverse reactions. Facilitate the	1. The system SHALL provide the ability to recommend required immunizations, and when they are due, during an encounter based on widely accepted immunization schedules.	
		EN	interaction with an immunization registry to allow maintenance of a patient's immunization history. Description: During an encounter, recommenda- tions based on accepted immunization schedules are presented to the provider. Allergen and adverse reaction histories are checked prior to giving the immunization. If an immunization is administered, discrete data elements associated with the immu- nization including date, type, manufacturer and lot number are recorded. Any new adverse or allergic reactions are noted. If required, a report is made to the public health immunization registry.	3. The system SHALL perform checking for potential adverse or allergic reactions for all immunizations when they are about to be given.
				4. The system SHALL provide the ability to capture immunization administration details, including date, type, lot number, expiration date, route of administration site of administration and manufacturer.
				5. The system SHALL provide the ability to capture other clinical data pertinent to the immunization administration (e.g. vital signs).
				6. The system SHALL record as discrete data elements data associated with any immunization.
				8. The system SHALL provide the ability to update the immunization schedule.
				10. The system SHALL conform to function DC.1.4.1 (Man- age Allergy, Intolerance and Adverse Reaction Lists).
				13. The system SHALL display the timing, route of adminis- tration, and dose of all immunizations on the list.
				14. The system SHALL provide the ability to capture im- munization administration details – including timestamps, observations, complications, and reason if medication was not given – in accordance with organizational policy, scope of practice, and jurisdictional law.
DC.1.8.4	F	Manage Pa- tient Clinical Measure- ments EN	t Clinical asure- ontsmeasures, such as vital signs, as discrete patient data. Description: Within the context of an episode of care,	1. IF required by the scope practice, THEN the system SHALL capture patient vital signs such as blood pressure, temperature, heart rate, respiratory rate, and severity of pain as discrete elements of structured or unstructured data.
			and managed as discrete data to facilitate reporting and provision of care.	2. IF required by the scope of practice, THEN the system SHALL capture psychiatric symptoms and daily functioning as structured or unstructured data.

DC.1.8.5	F	Manage Clinical Documents and Notes EN	Statement: Create, addend, correct, authenticate and close, as needed, transcribed or directly-en- tered clinical documentation and notes. Description: Clinical documents and notes may be unstructured and created in a narrative form, which may be based on a template, graphical, audio, etc. The documents may also be structured documents that result in the capture of coded data. Each of these forms of clinical documentation is important and appropriate for different users and situations. To facilitate the management and documentation on how providers are responding to incoming data on orders and results, there may also be some free text or formal record on the providers' responsi- bility and/or standard choices for disposition, such as: Reviewed and Filed, Recall Patient, or Future Follow Up. The system may also provide support for documenting the clinician's differential diagnosis process.	 The system SHALL provide the ability to capture clinical documentation (henceforth "documentation") including original, update by amendment in order to correct, and addenda. The system SHALL provide the ability to capture free text documentation. The system MAY present documentation templates (structured or free text) to facilitate creating documentation. The system SHALL provide the ability to view other documentation within the patient's logical record while creating documentation. The system SHALL provide the ability to update documentation prior to finalizing it. The system SHALL provide the ability to finalize a document or note. The system SHALL provide the ability to attribute record and display the identity of all users contributing to or finalizing a document or note, including the date and time of entry (see appropriate criteria in IN.2.2 (Auditable Records). The system SHALL present captured documentation.
DC.1.8.6	F	Manage Doc- umentation of Clinician Response to Decision Support Prompts	Statement: Capture the decision support prompts and manage decisions to accept or override decision support prompts. Description: Clinician actions in response to decision support prompts are captured and can be managed at the patient level or aggregated for organizational trending.	 The system SHALL provide the ability to capture clinical decision support prompts and user decisions to accept or override those prompts. The system SHALL provide the ability to record the reason for variation from the decision support prompt. The system SHALL provide the ability for the pharma-
DC.2	H	EN Clinical Deci- sion Support EN		 cist to record interventions on medication orders. 1. The system SHALL conform to function IN.1.1 (Entity Authentication). 2. The system SHALL conform to function IN.1.2 (Entity Authorization). 3. The system SHALL conform to function IN.1.3 (Entity
				 Access Control). 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. 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. 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.
				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.
				 8. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction). 10. 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.

				 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. 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.
				 13. 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.
				14. 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.
				16. IF the system exchanges data for which generally ac- cepted interchange standards have been established, THEN the system SHALL conform to function IN.5.1 (Interchange Standards), to support interoperability.
				17. IF the system exchanges data for which generally ac- cepted 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.
				19. 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.
DC.2.1	н	Manage Health		2. The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality).
		Information to Provide Decision Support EN		3. The system SHALL conform to function IN.2.2 (Audit- able Records).
DC.2.1.2	F	Support for Patient	Statement: Offer prompts based on patient-specific data at the point of information capture for assess-	1. The system SHALL provide the ability to access health assessment data in the patient record
		Context- Driven Assess-	ment purposes. Description: When a clinician fills out an assess- ment, data entered is matched against data already	6. The system SHALL conform to function DC.1.5 (Manage Assessments)
		ments EN	in the system to identify potential linkages. For example, the system could scan the medication list and the knowledge base to see if any of the symptoms are side effects of medication already prescribed. Important diagnoses could be brought to the doctor's attention, for instance ectopic pregnancy in a woman of child bearing age who has abdominal pain.	7. The system SHOULD conform to function DC.1.4.3 (Man- age Problem List)
DC.2.1.4	F	Support for Patient and	Statement: Support the integration of patient and family preferences into clinical decision support.	1. The system SHALL conform to DC.1.3.1 (Manage Patient and Family Preferences).
	Family Preferences EN Description: Decision support functions should per mit consideration of patient/family preferences and concerns, such as with language, religion, culture, medication choice, invasive testing, and advance	2. The system SHALL provide for the ability to capture and manage patient and family preferences as they pertain to current treatment plans.		
			directives. Such preferences should be captured in a manner that allows for their integration with the health record and easy retrieval from the health record. Preferences may be specified across all treatment plans or specifically to a treatment plan.	8. The system SHALL conform to function DC.1.3.2 (Manage Patient Advance Directives).

DC.2.2	н	Care and Treatment Plans,		 The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality). The system SHALL conform to function IN.2.2 (Audit-
		Guidelines and Protocols EN		able Records).
DC.2.2.1	н	Support for Condition		1. The system SHOULD conform to function IN.1.4 (Patient Access Management).
		Based Care and Treatment Plans, Guidelines, Protocols EN		2. The system SHOULD conform to function IN.3 (Registry and Directory Services).
DC.2.2.1.1	2.1.1FSupport for Standard Care Plans, Guidelines, ProtocolsStatement: Support the use of appropriate standard care plans, guidelines and/or protocols for the man- agement of specific conditions. Description: Before they can be accessed upon request (e.g., in DC 1.6.1), standard care plans,	1. The system SHALL conform to function DC.1.6.1 (Pres- ent Guidelines and Protocols for Planning Care) and provide the ability to access standard care plans, protocols and guidelines when requested within the context of a clinical encounter.		
		EN	protocols, and guidelines must be created. These documents may reside within the system or be provided through links to external sources, and can	5. The system SHALL conform to DC.2.2.1.2 (Support for Context-Sensitive Care Plans, Guidelines, Protocols).
			be modified and used on a site specific basis. To facilitate retrospective decision support, variances from standard care plans, guidelines, and protocols can be identified and reported.	6. The system SHALL conform to DC.2.1.1 (Support for Standard Assessments).
DC.2.2.1.2	F	Support for Context- Sensitive	Statement: Identify and present the appropriate care plans, guidelines and/or protocols for the management of patient specific conditions that are	 The system SHALL provide the ability to access care and treatment plans that are sensitive to the context of patient data and assessments.
		Care Plans, Guidelines, Protocols	identified in a patient clinical encounter. Description: At the time of the clinical encounter (problem identification), recommendations for med-	6. The system SHALL conform to function DC.2.2.1.1 (Support for Standard Care Plans, Guidelines, and Protocols).
		EN	ications, immunizations, referrals and evaluations are presented based on evaluation of patient specific	7. The system SHALL conform to function DC.2.1.1 (Support for Standard Assessments).
			data such as age, gender, developmental stage, their health profile, and any site-specific considerations. These may be modified on the basis of new clinical data at subsequent encounters.	8. The system SHALL conform to function DC.2.1.2 (Support for Patient Context-Driven Assessments).
DC.2.3	н	Medication and		1. The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality).
		Immuniza- tion Management EN		2. The system SHALL conform to function IN.2.2 Auditable Records).
DC.2.3.1	H	Support for Medication and Immuni- zation Ordering EN		

DC.2.3.1.1	F	Support for Drug Interaction	Statement: Identify drug interaction warnings at the time of medication ordering/prescription. Description: The clinician is alerted to drug-drug,	1. The system SHALL check for and alert providers to interactions between prescribed drugs and medications on the current medication list.
		Checking EN		2. The system SHALL relate medication allergies to med- ications to facilitate allergy checking decision support for medication orders.
			to suit the user or group. If the patient's condition is one where, in order to view the necessary compo- nents of the health record, patient authorization or	3. The system SHALL provide the ability to document that a provider was presented with and acknowledged a drug interaction warning.
			consent is required, then the system should show the medication but mask the condition for which the medication is prescribed until the required consent or authorization is available. In an emergent	 The system SHALL provide the ability to prescribe a medication despite alerts for interactions and/or allergies being present.
			situation, where all health information is required to provide the most effective treatment, and it is	5. The system SHALL provide the ability to set the severity level at which warnings should be displayed.
			not possible to obtain an authorization or consent, the system should provide an override function to allow access to the diagnosis or problem for which	6. The system SHOULD provide the ability to check for duplicate therapies.
			a medication was ordered. This may vary based on jurisdictional law.	7. The system SHALL conform to DC.1.8.6 (Manage Documentation of Clinician Response to Decision Support Prompts) and provide the ability to document why a drug interaction warning was overridden.
				8. The system MAY check for interactions between pre- scribed drugs and food detailing changes in a drug's effects potentially caused by food (including beverages) consumed during the same time period.
				11. The system SHALL identify contraindications between a drug and patient conditions at the time of medication ordering.
DC.2.3.1.3	F	Support for Medication Recommen- dations EN	Statement: The system should provide recommen- dations and options in medication and monitoring on the basis of patient diagnosis, cost, local formular- ies or therapeutic guidelines and protocols. Description: Offer alternative medications on the basis of practice standards (e.g. cost or adherence to guidelines), a generic brand, a different dosage, a different drug.	 The system SHOULD conform to function DC 2.3.1.2 (Support for Patient-Specific Dosing and Warnings).
				2. The system SHOULD present recommendations for medication regimens based on findings related to the patient diagnosis.
				3. The system SHALL present alternative treatments in medications on the basis of practice standards, cost, formularies, or protocols.
				4. The system SHOULD present suggested lab monitoring as appropriate to a particular medication.
				5. The system SHOULD conform to function IN.1.4 (Patient Access Management).
DC.2.4.2	F	Support for Non-	Statement: Display and request provider valida- tion of information necessary for non-medication	1. The system SHALL identify required order entry components for non-medication orders.
		Medication Ordering EN	orders that make the order pertinent, relevant and resource-conservative at the time of provider order entry. Description: Possible order entry support includes, but is not limited to warnings for orders that may be inappropriate or contraindicated, phones for the hearing impaired • groups of supplies or kits common to an orga- nization • simple durable medical equipment (DME) such as crutches or walkers • complex DME such as wheelchairs and hospital beds • therapies and other services that may require a	2. The system SHALL present an alert at the time of order entry, if a non-medication order is missing required information.
			referral and/or an authorization for insurance coverage	

DC.2.4.3	F	Support for Result Interpreta- tion EN	Statement: Evaluate results and notify provider of results within the context of the patient's healthcare data. Description: Possible result interpretations include, but are not limited to: abnormal result evaluation/ notification, trending of results (such as discrete lab values), evaluation of pertinent results at the time of provider order entry, evaluation of incoming results against prescriptions/medication orders	 The system SHALL present alerts for a result that is outside of a normal value range.
DC.2.4.4	Н	Support for Referrals EN		
DC.2.4.4.1	F	Support for Referral Process	a patient's healthcare data. Description: When a healthcare referral is made, health information, including pertinent clinical and behavioral health results, demographic and insur- ance data elements (or lack thereof) are presented to the provider. Standardized or evidence based	1. The system SHALL provide the ability to include clinical and administrative data (e.g. insurance information) as part of the referral process.
		EN		2. The system SHALL provide the ability to include test and procedure results with a referral.
				5. The system SHALL conform to function S.2.2.1 (Health Record Output).
DC.2.4.4.2	F	Support for Referral	Statement: Evaluate patient data and recommend that a patient be referred based on the specific	 The system SHALL present recommendations for potential referrals based on diagnosis(es).
		Recommen- dations EN	patient's healthcare data. Description: Entry of specific patient conditions may lead to recommendations for referral e.g. for smok- ing cessation counseling if the patient is prescribed a medication to support cessation screening or	2. The system SHALL present recommendations for potential referrals based on patient condition (e.g. for smoking cessation counseling if the patient is prescribed a medication to support cessation).
			assessment for behavioral health conditions.	4. If the system receives referrals, THEN the system shall conform to function DC.1.7.2.4 "Manage Referrals".
DC.2.5	н	Support for Health		2. The system SHALL conform to function IN.1.9 (Patient Privacy and Confidentiality).
		Mainte- nance: Preventive Care and Wellness EN		3. The system SHALL conform to function IN.2.2 (Audit- able Records).

DC.3	н	Operations Management	1. The system SHALL conform to function IN.1.1 (Entity Authentication).
		and Communica- tion	2. The system SHALL conform to function IN.1.2 (Entity Authorization).
		EN	3. The system SHALL conform to function IN.1.3 (Entity Access Control).
			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.
			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".
			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.
			8. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction).
			9. The system SHALL conform to function IN.2.2 (Audit- able Records).
			11. 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.
			12. IF the system stores unstructured data, THEN the sys- tem SHALL conform to function IN.2.5.1, (Manage Unstruc- tured Health Record Information), to ensure data integrity through all changes.
			13. 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.
			14. IF the system processes data for which generally accepted standard terminologies have been established, THEN the system SHALL conform to function IN.4.1 (Stan- dard Terminologies and Terminology Models) to support semantic interoperability.
			15. 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.
			17. IF the system exchanges data for which generally ac- cepted interchange standards have been established, THEN the system SHALL conform to function IN.5.1 (Interchange Standards) to support interoperability.
			18. IF the system exchanges data for which generally ac- cepted 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.
			20. 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.

DC.3.1.1	.3.1.1 F	Clinical Task Assignment and Routing	Statement: Assignment, delegation and/or trans- mission of tasks to the appropriate parties. Description: Tasks are at all times assigned to at	 The system SHALL provide the ability for users to create manual clinical tasks. The system SHALL provide the ability to automate
		EN	least one user or role for disposition. Whether the task is assignable and to whom the task can be	clinical task creation.
			assigned will be determined by the specific needs of practitioners in a care setting. An example would be in medication therapy management.	3. The system SHALL provide the ability to manually mod- ify and update task status (e.g. created, performed, held, canceled, pended, denied, and resolved).
				10. IF the system is used to enter, modify, or exchange data, THEN the system SHALL conform to IN.1.5 (Non-Repudi- ation) to guarantee that the sources and receivers of data cannot deny that they entered/sent/received the data.
DC.3.1.2	F	Clinical Task Linking EF	Statement: Linkage of tasks to patients and/or a relevant part of the electronic health record. Description: Clinical tasks must include information	1. The system SHALL provide the ability to link a clinical task to the component of the EHR required to complete the task.
		2015	or provide an electronic link to information that is required to complete the task. For example, this may include a patient location in a facility, a patient's contact information, or a link to new lab results in the patient's EHR. An example of a well defined task is "Dr. Jones must review Mr. Smith's blood work re- sults." Efficient workflow is facilitated by navigating to the appropriate area of the record to ensure that the appropriate test result for the correct patient is reviewed. Other examples of tasks might involve fulfillment of orders or responding to patient phone calls.	2. The system SHALL conform to function IN.1.5 (Non-Re- pudiation).
DC.3.1.3	F	Clinical Task Tracking	Statement: Track tasks to facilitate monitoring for timely and appropriate completion of each task.	1. The system SHALL provide the ability to track the status of tasks.
		EN	Description: In order to reduce the risk of errors during the care process due to missed tasks, the provider is able to view and track un-disposed tasks, current work lists, the status of each task, unassigned tasks or other tasks where a risk of omission exists. The timeliness of certain tasks can be tracked, or reports generated, in accordance with relevant law and accreditation standards. For example, a provider is able to create a report to show test results that have not been reviewed by the ordering provider based on an interval appropriate to the care setting.	2. The system SHALL provide the ability to notify providers of the status of tasks.
				6. IF the system is used to enter, modify, or exchange data, THEN the system SHALL conform to IN.1.5 (Non-Repudi- ation) to guarantee that the sources and receivers of data cannot deny that they entered/sent/received the data.
DC.3.2.1	F	Support for Inter- Provider	Statement: Support exchange of information be- tween providers as part of the patient care process, and the appropriate documentation of such ex-	 The system SHALL provide the ability to document in the patient record verbal/telephone communication between providers.
		Communica- tion EN	Communica- tionchanges. Support secure communication to protect the privacy of information as required by federal or jurisdictional law.	2. The system SHALL provide the ability to incorporate scanned documents from external providers into the patient record.
			Description: Communication among providers in- volved in the care process can range from real time communication, to asynchronous communication (for example, consult reports between physicians). Some forms of inter-practitioner communication will be paper based and the EHR-S must be able to produce appropriate documents. The system should provide for both verbal and written communication. These exchanges would include but not limited to consults, and referrals as well as possible exchang- es.	6. The system SHALL conform to function IN.1.5 (Non-Re- pudiation).

DC.3.2.2	F	Support for Provider - Pharmacy	ovider - bi-directional communication of information elec- tronically between practitioners and pharmacies	1. The system SHALL conform to function DC.1.7.1 (Man- age Medication Orders) and provide the ability to order medications.
		Communica- tion EN	or between practitioner and intended recipient of pharmacy orders. Description: When a medication is prescribed, the order is routed to the pharmacy or other intended	2. The system SHALL electronically communicate orders between the prescriber, provider and pharmacy, as necessary, to initiate, change, or renew a medication order.
			recipient of pharmacy orders. This information is used to avoid transcription errors and facilitate detection of potential adverse reactions. If there is a question from the pharmacy, that communi- cation can be presented to the provider with their other tasks. The transmission of prescription data between systems should conform to realm accept- able messaging standards. As an example, specific standards in the United States include the most	3. The system SHALL receive any acknowledgements, prior authorizations, renewals, inquiries and fill notifica- tions provided by the pharmacy or other participants in the electronic prescription and make it available for entry in the patient record.
				8. IF the system is used to enter, modify, or exchange data, THEN the system SHALL conform to IN.1.5 (Non- Repudi- ation) to guarantee that the sources and receivers of data cannot deny that they entered/sent/received the data.

ID#	Туре	Name	Statement/Description	Conformance Criteria
S.1	н	Clinical Support EN		1. The system SHALL conform to function IN.1.1 [Entity Authentication].
				2. The system SHALL conform to function IN.1.2 (Entity Authorization).
				3. The system SHALL conform to function IN.1.3 [Entity Access Control].
S.1.1	F	Registry Notification EF 2015	Statement: Enable the automated transfer of formatted demographic and clinical information to and from local disease specific registries (and other notifiable registries) for patient monitoring and subsequent epidemiological analysis. Description: The user can export personal health information to disease specific registries, other notifiable registries such as immunization registries, through standard data transfer protocols or messages. The user can update and configure communication for new registries.	1. The system SHALL provide the ability to trans- fer formatted demographic and clinical informa- tion to local disease specific registries (and other notifiable registries).
S.1.3	H	Provider Information EN	Statement: Maintain, or provide access to, current provider information.	
S.1.3.1	F	Provider Access Levels	Statement: Provide a current registry or directory of practi- tioners that contains data needed to determine levels of ac- cess required by the system. Description: Provider informa-	1. The system SHALL provide a registry or direc- tory of all personnel who currently use or access the system.
			tion 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.	3. The system SHALL provide the ability to add, update, and inactivate entries in the directory so that it is current.
S.2.2	H	Report Generation EN	Statement: Support the export of data or access to data nec- essary 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	1. The system SHALL conform to function IN.2.2 (Auditable Records) in accordance with scope of practice, organizational policy and jurisdictional law.
			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.	2. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction).
S.2.2.1	F	Health Record Output EN	Statement: Support the definition of the formal health record, a partial record for referral purposes, or sets of records for other necessary disclosure purposes as it relates to medica- tion. Description: Provide hardcopy and electronic output that fully chronicles the prescribing process, supports selection of specific sections of the health and medication record, and allows healthcare organizations to define the report and/or documents that will comprise the formal health and medica- tion record Including allergy and adverse reactions for dis- closure 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 exam- ple: Print Set A = Patient Demographics, History & Physical, Consultation Reports, and Discharge Summaries. 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.	1. The system SHALL provide the ability to generate reports consisting of all and part of an individual patient's health and medication record.

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S.3	н	Administrative and Financial		1. The system SHALL conform to function IN.1.1 [Entity Authentication].
		EN		2. The system SHALL conform to function IN.1.2 (Entity Authorization).
				3. The system SHALL conform to function IN.1.3 (Entity Access Control).
5.3.1	H	Encounter/ Episode of Care Management EN	Statement: Support the definition of Manage and document the health care needed and delivered during an encounter/ episode of care. Description: Using data standards and technologies that support interoperability, encounter management promotes patient-centered/oriented care and enables real time, im- mediate 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 admin- istrative reporting, and (3) the healthcare 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.), pro- vider type, patient's EHR, health status, demographics, and the initial purpose of the encounter.	
3.1.2	F	Encounter Spe- cific Function- ality EN	Statement: Provide assistance in assembling appropriate data, supporting data collection and processing output from a specific encounter. Description: Workflows, based on the encounter management settings, will assist (with triggers alerts and other means) in determining and supporting the appropriate data collection, import, export, extraction, linkages and transformation. As an example, a pediatrician is presented with diagnostic and procedure codes specific to pediatrics. Business rules enable automatic collection of necessary data from the patient's health record and patient registry. As the provider enters data, workflow processes are triggered to populate appro- priate transactions and documents. For example, data entry might populate an eligibility verification transaction or query the immunization registry.	1. The system SHALL provide workflow support for data collection appropriate for care setting.
3.1.5	F	Other Encounter and Episode of	Statement: Where not covered above, provide the means to manage and organize the documentation of the health care	1. The system SHALL provide the ability to orga- nize patient data by encounter.
		Care Support EN	needed and delivered during an encounter/episode of care. Description: Using data standards and technologies that support interoperability, encounter management promotes patient-centered/oriented care and enables real time, im- mediate 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 admin- istrative reporting, and (3) the healthcare 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.	3. The system SHALL provide the ability to cre- ate 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.

3.3	H	Administrative Transaction Processing EN	 Statement: Support the creation (including using external data sources, if necessary), electronic interchange, and processing of transactions listed below that may be necessary for encounter management during an episode of care. Description: Support the creation (including using external data sources, if necessary), electronic interchange, and processing of transactions listed below that may be necessary for encounter management during an episode of care. verification of eligibility The EHR system shall capture the patient health-related information needed for administrative and financial purposes including reimbursement. Captures the episode and encounter information to pass to administrative or financial processes (e.g. triggers transmissions of charge transactions as by-product of on-line interaction including order entry, order statusing, result entry, documentation nervy, medication administration charting). Clinical information needed for billing is available on the date of service. Clinical teams do not perform additional data entry / tasks exclusively to support administrative or financial processes. 	
3.3.4	F	Support of Service Requests and Claims EN	Statement: Support interactions with other systems, appli- cations, and modules to support the creation of health care attachments for submitting additional clinical information in support of service requests and claims. Description: Retrieves structured and unstructured data, including but not limited to lab data, imaging data, device monitoring data, and text based data, based on rules or requests for additional clinical information, in support of service requests or claims, at the appropriate juncture in the encounter workflow.	 The system SHALL provide the ability to view available, applicable clinical information to sup- port service requests. The system SHALL provide the ability to view available, applicable clinical information to support claims.
S.3.3.5	F	Claims and Encounter Reports for Reimbursement EN	Statement: Support interactions with other systems, appli- cations, and modules to enable the creation of claims and encounter reports for reimbursement. Description: Retrieves information needed to support claims and encounter report- ing. This reporting occurs at the appropriate juncture in the encounter workflow in a manual or automated fashion. For example this could occur at an initial, interim or final billing. The system may also present the information that is provided for audit and review by local authorities.	 The system SHALL provide the ability to view available, applicable information needed to enable the creation of claims and encounter reports for reimbursement. The system SHALL provide the ability to capture and present available, applicable data as required by local authority for audit and review.
S.3.4	F	Manage Practitioner/ Patient Rela- tionships EN	Statement: Identify relationships among providers treating a single patient, and provide the ability to manage patient lists assigned to a particular provider. 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 seam- lessly 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. Example: In a care setting with multiple providers, where the patient can only see certain kinds of providers (or an in- dividual 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 assign- ment.	 The system SHALL provide the ability to identify all providers by name associated with a specific patient encounter. 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. The system SHALL provide the ability to iden- tify all providers who have been associated with any encounter for a specific patient. The system SHALL provide the ability to speci- fy primary or principal provider(s) responsible for the care of a patient within a care setting.

S.3.7	Н	Supportive Function Maintenance EN	Statement: Update EHR supportive content using a manual or automated process. Description:	
5.3.7.1	F	Clinical Decision Support System Guideline Updates	Statement: Facilitate and/or perform updates of clinical decision support system guidelines and associated reference material including drug utilization review (DUR) information.	1. The system SHALL provide the ability to update the clinical content or rules utilized to generate clinical decision support reminders and alerts.

Chapter 5 - Information Infrastructure Functions to Certify by January 1, 2015

ID#	Туре	Name	Statement/Description	Conformance Criteria
IN.1	H	Security EN	Statement: Secure the access to an EHR-S and EHR informa- tion. Manage the sets of access control permissions granted within an EHR-S. Prevent unauthorized use of data, data loss, tampering and destruction. 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. 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.	 The system SHALL provide the ability to encrypt stored user passwords in accordance with scope of practice, organizational policy or jurisdictional law The system SHALL log off user after speci- fied period of inactivity.
IN.1.1	F	Entity Authentication EN Authentication for updates and changes	Statement: Authenticate EHR-S users and/or entities before allowing access to an EHR-S. Description: Both users and applications are subject to au- thentication. 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: - username/ password - digital certificate - secure token - biometrics	 The system SHALL authenticate principals prior to accessing an EHR-S application or EHR-S data. The system SHALL prevent access to EHR-S applications or EHR-S data to all non-authenticated principals. IF other appropriate authentication mech- anisms are absent, THEN the system SHALL authenticate principals using at least one of the following authentication mechanisms: username/password, digital certificate, secure token or biometrics.

IN.1.2	F	Entity Authorization EN	Statement: Manage the sets of access-control permissions granted to entities that use an EHR-S [EHR-S Users]. 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. 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 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 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 Context-based Authorization is defined by ISO 10181-3 Technical Framework for Access 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 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 right granted for a limited period to view those, and only those, EHR records connected to a specific topic of investigation.	 The system SHALL provide the ability to create and update sets of access-control per- missions granted to principals. The system SHALL conform to function IN.2.2 (Auditable Records) for the purpose of recording all authorization actions. The system SHALL provide EHR-S security administrators with the ability to grant autho- rizations to principals according to scope of practice, organizational policy, or jurisdictional law. The system SHALL provide EHR-S security administrators with the ability to grant authori- zations for roles according to scope of practice, organizational policy, or jurisdictional law. The system SHALL provide EHR-S security administrators with the ability to grant authori- izations for roles according to scope of practice, organizational policy, or jurisdictional law. The system SHALL provide EHR-S security administrators with the ability to grant autho- rizations within contexts according to scope of practice, organizational policy, or jurisdictional law.
IN.1.3	F	Entity Access Control EN	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. 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.	 The system SHALL conform to function IN.1.1 (Entity Authentication). The system SHALL conform to function IN.1.2 (Entity Authorization). The system SHALL provide the ability to define system and data access rules. The system SHALL enforce system and data access rules for all EHR-S resources (at component, application, or user level, either local or remote).

IN.1.5	F	Non-Repudia- tion EN	Statement: Limit an EHR-S user's ability to deny (repudiate) the origination, receipt, or authorization of a data exchange by that user. Description: An EHR-S allows data entry and data access to a patient's electronic health record and it can be a sender or re- ceiver of healthcare information. Non 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 cer- tain 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).	 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, organiza- tional policy, or jurisdictional law. The system SHALL provide additional non-repudiation functionality where required by users' scope of practice, organizational policy, or jurisdictional law.
IN.1.6	F	Secure Data Exchange EN	Statement: Secure all modes of EHR data exchange. Description: Whenever an exchange of EHR information occurs, it requires appropriate security and privacy consider- ations, including data obfuscation as well as both destination and source authentication when necessary. For example, it may be necessary to encrypt 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.	 The system SHALL secure all modes of EHR data exchange. The system SHALL encrypt and decrypt EHR data that is exchanged over a non-secure link. IF encryption is used for secure data exchange, THEN the system SHALL support standards-based encryption in accordance with organizational policy or juris- dictional law.
IN.1.7	F	Secure Data Routing EN	Statement: Route electronically exchanged EHR data only to/from known, registered, and authenticated destinations/ sources (according to applicable healthcare-specific rules and relevant standards). 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 au- thorization and authentication to be available in the system. For example, a physician practice management application in an EHR-S might send claim attachment 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 informa- tion exchange. Known sources and destinations can be estab- lished 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 authenti- cation mechanisms as described in IN.1.1. For example, the sending of a lab order from the EHR-S 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 authen- tication process. In general, when the underlying network infrastructure is secure (e.g. secure LAN or VPN) the simple static setup is used.	1. The system SHALL automatically route electronically exchanged EHR data only from and to known sources and destinations and only over secure networks or in an encrypted format when using a non-secure network.

IN.1.8	F	Information Attestation EN	Statement: Manage electronic attestation of information including the retention of the signature of attestation (or cer- tificate of authenticity) associated with incoming or outgoing	1. The system SHALL conform to function IN.1.1 (Entity Authentication).
			information. Description: The purpose of attestation is to show authorship and assign responsibility for an act, event,	2. The system SHALL conform to function IN.1.2 (Entity Authorization).
			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 author. (Note: A transcriptionist may transcribe an author's notes and a senior clinician may attest to the accuracy of another's statement	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).
			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,	4. The system SHALL provide the ability for attestation of attestable EHR content by the content's author.
			the record of attestation is retained if included. Attestation functionality must meet applicable legal, regulatory and other applicable standards or requirements.	5. The system SHALL indicate the status of attestable data which has not been attested.
IN.1.9 F	F	Patient Privacy and Confidenti- ality EN	Statement: Enable the enforcement of the applicable ju- risdictional and organizational patient privacy rules as they apply to various parts of an EHR-S through the implementa- tion of security mechanisms. Description: Patients' privacy and the confidentiality of EHRs	1. The system SHALL provide the ability to fully comply with the requirements for patient privacy and confidentiality in accordance with a user's scope of practice, organizational policy, or jurisdictional law.
			are violated if access to EHRs occurs without authoriza- tion. Violations or potential violations can impose tangible economic or social losses on affected patients, as well as less	2. The system SHALL conform to function IN.1.1 (Entity Authentication).
			tangible feelings of vulnerability and pain. Fear of potential violations discourages patients from revealing sensitive	 The system SHALL conform to function IN.1.2 (Entity Authorization). The system SHALL conform to function IN.1.3 (Entity Access Control).
			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 protect should apply to the records of minors and the records of patients with stigmatized conditions. Authorization to ac	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	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.
				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.
				10. The system SHALL provide the ability to override a mask in emergency or other specific situations according to scope of practice, orga- nizational policy or jurisdictional law.

IN.2.1	F	Data Retention, Availability and Destruction	Statement: Retain, ensure availability, and destroy health record information according to scope of practice, organiza- tional policy, or jurisdictional law. This includes:	1. The system SHALL provide the ability to store and retrieve health record data and clini- cal documents for the legally prescribed time.
		EN	 -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 	2. The system SHALL provide the ability to retain inbound data or documents (related to health records) as originally received (unal- tered, 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.
			EHR-S data, records and reports must be: -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 applica- ble retention period. An EHR-S must also allow an organization to identify data/re- cords 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.	3. The system SHALL retain the content of inbound data (related to health records) as originally received for the legally prescribed time.
IN.2.2	F	Auditable Records EN	Statement: Provide audit capabilities for system access and usage indicating the author, the modification (where perti- nent), 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 records extend to information	 The system SHALL provide audit capabili- ties for recording access and usage of systems, data, and organizational resources.
			exchange, to audit of consent status management (to support DC.1.3.3) and to entity authentication attempts. Audit func- tionality includes the ability to generate audit reports and to interactively view change history for individual health records or for an EHR-S. Description: Audit functionality extends to security audits, data audits, audits of data exchange, and the ability to gener-	2. The system SHALL conform to function IN.1.1 (Entity Authentication).
			ate audit reports. Audit capability settings should be configurable to meet the needs of local policies. Examples of audited areas include: - Security audit, which logs access attempts and resource usage including user login, file access, other various activi- ties, and whether any actual or attempted security violations	3. The system SHALL provide audit capabil- ities indicating the time stamp for an object or data creation.
			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 manage- ment data	4. The system SHALL provide audit capabil- ities indicating the time stamp for an object or data modification in accordance with users' scope of practice, organizational policy, or jurisdictional law.
			- Information exchange audit, which records data exchanges between EHR-S applications (for example, sending appli- cation; the nature, history, and content of the information exchanged); and information about data transformations (for example, vocabulary translations, reception event details,	5. The system SHALL provide audit capabil- ities indicating the time stamp for an object or data extraction in accordance with users' scope of practice, organizational policy, or jurisdic- tional law.
			etc.)	6. The system SHALL provide audit capabil- ities indicating the time stamp for an object or data exchange.

IN.2.2	F	Auditable Records EN	- Audit reports should be flexible and address various users' needs. For example, a legal authority may want to know how many 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 previder because	8. The system SHALL provide audit capabil- ities indicating the time stamp for an object or data deletion in accordance with users' scope of practice, organizational policy, or jurisdic- tional law.
			patient record - Security audit trails and data audit trails are used to verify enforcement of business, data integrity, security, and ac- cess-control rules -There is a requirement for system audit trails for the follow- ing events:	9. The system SHALL provide audit capabili- ties indicating the author of a change in accor- dance with users' scope of practice, organiza- tional policy, or jurisdictional law.
			 →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; 	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.
			 →Archiving any data; →Re-activating of an archived patient record; →Entry to and exiting from the clinical system; 	14. The system SHALL provide the ability to generate an audit report.
			→Remote access connections including those for system support and maintenance activities	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.
IN.2.3	F	Synchronization EN	Statement: Maintain synchronization involving: -Interaction with entity directories; -Linkage of received data with existing entity records; -Location of each health record component; 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 rel- evant 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 asso- ciated with the order, and the report associated with the study must all be synchronized in order for the clinicians to view the complete record.	1. The system SHALL conform to function IN.5.1 (Interchange Standards).
IN.2.4	F	Extraction of Health Record Information EN	Statement: Manage data extraction in accordance with analy- sis 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 informa- tion, which corresponds to the health record or records that are needed for viewing, reporting, disclosure, etc. An EHR-S must support data 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 coordina- tion between facilities, organizations and settings. In addition, data extractions can be used for administrative, financial, research, quality analysis, public health purposes, and to enable re-creation of copies for importing into different EHR applications and enable the archiving of patients' data.	1. The system SHALL provide the ability to extract health record information.

IN.2.5.1	Manage Unstructured Health	Statement: Create, capture, and maintain unstructured health record information. Description:	1. The system SHALL capture unstructured health record information as part of the patient EHR.
	Information EN		2. The system SHALL retrieve unstructured health record information as part of the patient EHR.
			3. The system SHALL provide the ability to update unstructured health record information.
			4. The system SHALL conform to function IN.2.1 (Data Retention, Availability and De- struction) to provide the ability to inactivate, ob- solete, or destroy unstructured health record information.
			7. The system SHALL provide the ability to append corrected unstructured health record information to the original unstructured health record information. A specific type of imple- mentation is not implied.
			8. The system SHALL provide the ability to append unstructured health record information to the original unstructured health record information. A specific type of implementation is not implied.
			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 imple- mentation is not implied.
			10. The system SHALL provide the ability to capture and transmit as free text (manual entry, import and export) structured, encoded data, not currently in the SCRIPT Standard, but required for correct dispensing and adminis- tration of medication.

IN.2.5.2	F	Manage Structured Health Record Information EN	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 codi- fied. 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 Context may determine whether or not Context may deter- mine 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 unstruc- tured in others.	 The system SHALL capture structured health record information as part of the patient EHR. The system SHALL retrieve structured health record information as part of the patient EHR. The system SHALL provide the ability to update structured health record information. The system SHALL conform to func- tion IN.2.1 (Data Retention, Availability and Destruction) to provide the ability to inactivate, obsolete, or destroy structured health record information. The system SHALL provide the ability to append corrected structured health record information. A specific type of imple- mentation is not implied. The system SHALL provide the ability to append structured health record information to the original structured health record informa- tion. A specific type of imple- mentation is not implied. The system SHALL provide the ability to append structured health record informa- tion. A specific type of imple- mentation is not implied. The system SHALL provide the ability to append structured health record informa- tion. A specific type of implementation is not implied. The system SHALL provide the ability to append augmented structured health record information. A specific type of imple- mentation is not implied.
IN.3	F	Registry and Directory Services EN 2015	Statement: Enable the use of registry services and directo- ries to uniquely identify, locate and supply links for retrieval of information related to: - patients and providers for healthcare purposes; - payers, health plans, sponsors, and employers for adminis- trative and financial purposes; - public health agencies for healthcare purposes, and - healthcare resources and devices for resource management purposes. Description: Management of security and interop- erability are critical to use of registry and directory service functions. These services enable the linking of relevant information across multiple information sources within, or external to, an EHR-S for use within an application. 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 previ- ous records. From the primary care record, a remote EHR-S retrieves relevant information in conformance with applica- ble patient privacy and confidentiality rules. An example of local registry usage is an EHR-S application sending a query message to the Hospital Information System to retrieve a pa- tient's demographic data. Registry and directory services are not essential to a standalone electronic prescribing system. However, if provided, the criteria would apply.	 The system SHALL provide the ability to use registry services and directories. The system SHALL conform to function IN.5.1 (Interchange Standards) to provide stan- dard data interchange capabilities for using registry services and directories.

IN.4.1	F	Standard Terminology Models EN	Statement: Employ standard terminologies to ensure data correctness and to enable semantic interoperability (both within an enterprise and externally). Support a formal stan- dard terminology model. Description: Semantic interoperability requires standard terminologies combined with a formal standard information model. A terminology provides semantic and computable identity to its concepts. Terminologies are use-case depen- dent 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. Formal standard terminology models enable common semantic representations by describing relation- ships that exist between concepts within a terminology or in different terminologies, such as exemplified in the model descriptions contained in the HL7 Common Terminology Ser- vices specification. The clinical use of standard terminologies is greatly enhanced with the ability to perform hierarchical In- ference searches across coded concepts. Hierarchical Infer- ence 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 commo 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 Preparation. Clinical and other terminologies may be provided through a terminology service internal or external to an EHR-S. An example of a terminologies sup form of penicillin preparation. Clinical and other terminologies may be provided through a terminology service internal or external to an EHR-S. An examples of other HL7 and non-HL7 standards include: Standard information models: - HL7 Clinical Document Architecture Release 2 - ISO/EN 13606 Electronic Health Record Communication NCPDP SCRIPT Standard terminologies: - LOINC - SNOMED - ICD-9, ICD	 The system SHALL provide the ability to use standard terminologies to communicate with external systems. The system SHALL provide the ability to validate that clinical terms and coded clinical data exists in a current standard terminology. The system SHALL provide the ability to manage terminology assets and supporting tools (internal or external to the EHR-S).
11.5	n	Stan- dards-based Interoperability EN	Statement: Provide automated health care delivery process- es and seamless exchange of clinical, administrative, and financial information through standards- based solutions. 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 interna- tional information exchanges. Timely and efficient access to information and capture of information is promoted with minimal impact to the user.	

IN.5.1	F	Interchange Standards EN	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.	1. The system SHALL provide the ability to use interchange standards as required by realm specific and/or local profiles.
			Description: An organization typically uses a number of inter- change standards to meet its external and internal interoperability requirements. It is fundamental that there be a common understanding of rules regarding connectivity,	2. The system SHALL provide the ability to seamlessly perform interchange operations with other systems that adhere to recognized interchange standards.
			exchange which may be between internal systems or mod- ules, 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	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.
			tion of EHR content is transmitted in a variety of interchange formats such as: ISO 13606 extracts, HL7 Messages, Clinical Document Architecture (CDA) and other HL7 Structured Documents, X12N healthcare transactions, NCPDP transactions and Digital Imaging and Communication	6. The system SHALL provide the ability to dis- play structured documents, such as CCD and/ or CCR, for results information and file them as intact documents in the EHR.
			in Medicine (DICOM) format. 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 sce- narios but may not be appropriate if the end-user is request- ing an immediate response from a remote application. A variety of interaction modes are typically supported such as:	7. The system SHALL provide the ability to generate and format specified CCD and/or CCR documents with narrative sections and struc- tured entries (discrete fields) and specified Terminology and value sets.
			 Unsolicited Notifications, e.g. a patient has arrived for a clinic appointment Query/Response e.g., Is Adam Everyman known to the sys- tem? 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 Standard terminology is a fundamental part of interopera- bility 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 Infor- mation Model (RIM). Organizations typically need to deal with	
			more than one information model and may need to develop a mapping or a meta-model.	

IN.5.2	F	Interchange Standards Versioning and	Statement: Enable version control according to local policies to ensure maintenance of utilized interchange standards. Version control of an interchange standard implementation	 The system SHALL provide the ability to use different versions of interchange stan- dards.
		Maintenance EN	includes the ability to accommodate changes as the source interchange standard undergoes its natural update process. Description: The life cycle of any given standard usually results from 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. Standards typically evolve in such a way as to protect back- wards compatibility. However, sometimes there is little, or no, backwards compatibility when an organization may need to replace an entire standard with a new methodology. 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 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 feder- ated) organizations typically need to use different versions of an interchange standard to meet internal organizational interoperability requirements. 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 con- cepts over time.	2. The system SHALL provide the ability to change (reconfigure) the way that data is trans- mitted as an interchange standard evolves over time and in accordance with business needs.
IN.6	F	Business Rules and Manage- ment EN	Statement: Manage the ability to create, update, delete, view, and version business rules including institutional preferenc- es. 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 over- rides of applied business rules. 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. An EHR-S supports the ability of providers and institutions to customize decision support com- ponents such as triggers, rules, or algorithms, as well as the wording of alerts and advice to meet realm specific require- ments and preferences. Examples of applied business rules include: - Suggesting diagnosis based on the combination of symp- toms (flu-like symptoms combined with widened mediasti- num 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 vac- cination 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.	 The system SHALL provide the ability to manage business rules.



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