HL7 EHR-System Meaningful Use Functional Profile, Release 1 - US Realm

Based on HL7 EHR System Functional Model and Standard, Release 2.0
Based on ONC/NIST Test Procedures for EHR System Certification, 2014 Edition

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Notes to Balloters

Criteria that have high digit numbers (numbered in the range 80-99) are newly added for the purposes of the Meaningful Use Functional Profile and do not exist in base EHR-System functional Model release 2.

Functional Profile Components

The Function List includes the following components:

Function ID # (Normative)	This is the unique identifier of a function in the Function List (e.g. CP.1.1) and should be used to uniquely identify the function when referencing functions. The Function ID also serves to identify the section within which the function exists (CP = Care Provision Section) and the hierarchy or relationship between functions (CP.1.1 is a sibling to CP.1.2, parent of CP.1.1.1 and child of CP.1). In many cases the parent is fully expressed by the children.
Function Type (Reference)	Indication of the line item as being a header (H) or function (F) or conformance criteria.
Header/Function Name (Normative)	This is the name of the Function and whilst expected to be unique within the Function List; it is not recommended to be used to identify the function without being accompanied by the Function ID. Example: Manage Medication List
Function Statement (Normative)	This is a brief statement of the purpose of this function. Whist not restricted to the use of structured language that is used in the Conformance Criteria (see below); the Statement should clearly identify the purpose and scope of the function. Example: Create and maintain patient-specific medication lists.
Description (Reference)	This is a more detailed description of the function, including examples if needed. Example: Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, including medication start, modification, and end dates are stored. The entire medication history for any medication, 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/supply records, patient-reported medications and additional information such as age specific dosage.
Conformance Criteria (Normative)	Each function in the Function List includes one or more Conformance Criteria. A Conformance Criteria, which exists as normative language in this standard, defines the requirements for conforming to the function. The language used to express a conformance criterion is highly structured with standardized components with set meanings. The structured language used to define conformance clauses in the Function List are defined in the Glossary (Chapter 4).
Reference (Reference)	Reference to the Functional Model or Functional Profile the current Functional Profile was developed against.
Change Indicator	The change indicator shows the change from previous versions. This will be valued as follows: C - Changed D - Deleted N - New NC - No Change DEP - Deprecated
Priority	The priority for the implementation of the item. This will be valued as follows: EN - Essential Now EF - Essential Future O - Optional

1. Care Provision Section

Section Overview

The Care Provision Section contains those functions and supporting Conformance Criteria that are required to provide direct care to a specific patient and enable hands-on delivery of healthcare. The functions are general and are not limited to a specific care setting and may be applied as part of an Electronic Health Record supporting healthcare offices, clinics, hospitals and specialty care centers. The functions in this section are organized in general flow of an encounter; however, it is recognized that encounter flow varies considerably in different care settings and scopes of practice. All functions within the Care Provision Section have an identifier starting with “CP”.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CP.1 Header	Manage Clinical History	CP.1	NC	EN
	Statement: Manage the patient's clinical history lists used to present summary or detailed information on patient health history. **Description:** Patient Clinical History lists are used to present succinct "snapshots" of critical health information including patient history; allergy, intolerance and adverse reactions; medications; problems; strengths; immunizations; medical equipment/devices; and patient and family preferences.			
CP.1.1 Function	Manage Patient History	CP.1.1	NC	EN
	Statement: Manage medical, procedural/surgical, mental health, substance use, social and family history. This includes pertinent positive and negative histories, patient-reported or externally available patient clinical history. **Description:** The history of the current illness and patient historical data related to previous medical diagnoses, surgeries and other procedures performed on the patient, clinicians involved in procedures or in past consultations, and relevant health conditions of family members is captured through such methods as patient reporting (e.g., 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 may supplement locally captured documentation and notes wherever appropriate. Information regarding the patient's living situations may be an important means for a provider to uniquely identify a patient or to identify illnesses that may occur within a given proximity. Information regarding past or present living situations or environmental factors related to the patient or the fetal death may include a description of the father's type of occupation and occupational demographic information (such as the name and location of the employment). For example, it may be important for the clinician to know that the patient works in an occupation where lead exposure is common. It may also be important for the clinician to know that the patient lives in a household where asbestos routinely appears on clothing. **External References:** §170.314(a)(11) Smoking status Test Procedure_[PDF - 115 KB] §170.314(a)(13) Family health history Test Procedure_[PDF -467 KB]			
5.	The system SHALL provide the ability to manage family health history.	CP.1.1	C	EN
94.	The system SHALL provide the ability to manage an indication of the patient's smoking status based on the SNOMED CT smoking categories (e.g., current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; unknown if ever smoked; heavy tobacco smoker, light tobacco smoker).		N	EN
96.	The system SHALL provide the ability to manage family health history as structured data according to named standards.		N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CP.1.2 Function	Manage Allergy, Intolerance and Adverse Reaction List	CP.1.2	NC	EN

Statement: Manage patient-specific allergy, intolerance and adverse reaction lists.

Description: Allergens to substances, (including immunizations), are identified and the list of allergies is captured and maintained over time. Information regarding allergies may be coded or free text; coded information is preferred (where possible). In this function the term "allergy" is used to refer to allergies, intolerances, adverse reactions and sensitivities. All pertinent dates, including patient-reported events, are stored and the description of the patient allergy and adverse reaction is modifiable over time. The entire allergy history, including reaction, 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, food or environmental triggers. Notations indicating whether item is patient reported, and/or provider verified are maintained. The term 'true allergy' is defined by the US National Library of Medicine as: an allergy that is caused by a series of chemical steps in the body that produce the allergic reaction. The allergy information that should be captured may vary according to scope of practice, organizational policy, and/or jurisdictional law. For example, the documentation requirements regarding an allergic reaction to a substance that is reportable may require a higher level of data capture.

External References:

§170.314(a)(14) Patient list creation
Test Procedure_[PDF -490 KB]
§170.314(a)(2) Drug-drug, drug-allergy interaction checks
Test Procedure_[PDF -393 KB]
§170.314(a)(7) Medication allergy list
Test Procedure_[PDF - 140 KB]
§170.314(a)(8) Clinical decision support
Test Procedure_[PDF -473 KB]
§170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries
Test Procedure_[PDF -671 KB]
§170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries
Test Procedure_[PDF -671 KB]
§170.314(b)(4) Clinical information reconciliation
Test Procedure_[PDF -469 KB]
§170.314(b)(4) Clinical information reconciliation
Test Procedure_[PDF -469 KB]

1.	The system SHALL provide the ability to manage allergy, intolerance, and adverse reaction to drug, food, medical products (e.g., vaccines, biologics, devices, chemicals) or environmental triggers as unique, discrete entries.	CP.1.2	NC	EN
17.	The system SHALL provide the ability to manage allergy-information as standards-based coded data.	CP.1.2	C	EN
24.	The system SHALL provide the ability to render historical allergy information.	CP.1.2	C	EN
90.	The system SHALL provide the ability to capture and maintain the reconciled medication allergy list.		N	EN
91.	The system SHALL render the single reconciled medication allergy list.		N	EN
92.	The system SHALL provide the ability to remove a medication allergy from the single reconciled medication allergy list.		N	EN
93.	The system SHALL provide the ability to integrate identical medication allergies (from separate medication allergy lists) into one representation on the single reconciled medication allergy list.		N	EN
94.	The system SHALL provide the ability to integrate two or more medication allergy lists into a single reconciled medication list.		N	EN
95.	The system SHALL render the reconciliation medication allergy list including source of the medication allergy list, the last date each medication allergy was documented, updated, or edited.		N	EN
96.	The system SHALL render two or more medication allergy lists simultaneously in a single view		N	EN
97.	The system SHALL provide the ability to manage medication allergy lists from multiple sources for reconciliation.		N	EN
98.	The system SHALL provide the ability to manage the process of medication allergy list reconciliation according to scope of practice, organizational policy, and/or jurisdictional law.		N	EN
99.	The system SHALL provide the ability to determine and render clinical decision support rules applicable to medication allergy list updates.		N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CP.1.3 Function	Manage Medication List	CP.1.3	NC	EN

Statement: Create and maintain patient-specific medication lists.

Description: Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. The entire medication history for any medication including, over-the-counter products, alternative supplements and herbal medications, is viewable. Medication lists are not limited to provider orders/prescriptions but may also include, for example, pharmacy dispensed medications without prescription, over the counter medications and patient-reported medications, etc. All pertinent dates, including medication start, modification, and end dates are stored. Medication Lists may also include additional information such as age-specific dosage.

External References:
§170.314(a)(14) Patient list creation
Test Procedure_[PDF -490 KB]
§170.314(a)(5) Problem list
Test Procedure_[PDF - 125 KB]
§170.314(a)(6) Medication list
Test Procedure_[PDF - 118 KB]
§170.314(a)(8) Clinical decision support
Test Procedure_[PDF -473 KB]
§170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries
Test Procedure_[PDF -671 KB]
§170.314(b)(4) Clinical information reconciliation
Test Procedure_[PDF -469 KB]

1.	The system SHALL provide the ability to manage a patient-specific medication list based on current medication orders or prescriptions.	CP.1.3	NC	EN
2.	The system SHALL provide the ability to manage as discrete data the details of the medication information including name of the medication ordered, medication identifier (e.g., RxNORM), prescriber, ordering date, SIG (e.g., dose amount and quantity, timing, duration and route, and/or site of administration), quantity, formulation and ancillary instructions according to scope of practice, organizational policy, and/or jurisdictional law.	CP.1.3	NC	EN
5.	The system SHALL provide the ability to capture and maintain current and historical patient-specific medications in the Medication List.	CP.1.3	NC	EN
7.	The system SHALL provide the ability to render the medication history associated with a patient.	CP.1.3	NC	EN
11.	The system SHALL provide the ability to render a current medication list for patient use.	CP.1.3	NC	EN
28.	The system SHALL provide the ability to render active medications as defined by user requirements and according to scope of practice, organizational policy, and/or jurisdictional law (e.g., including medications that may still have a physiologic effect long after last administration).	CP.1.3	NC	EN
99.	The system SHALL provide the ability to determine and render clinical decision support rules applicable to medication list updates.		N	EN

CP.1.4 Function	Manage Problem List	CP.1.4	NC	EN

Statement: Create and maintain patient-specific problem lists.

Description: A problem list may include, but is not limited to chronic conditions, diagnoses, or symptoms, injury/poisoning (both intentional and unintentional), adverse effects of medical care (e.g., drugs, surgical), functional limitations, visit or stay-specific conditions, diagnoses, or symptoms. Problem lists are managed over time, whether over the course of a visit or stay or the life of a patient, allowing documentation of historical information and tracking the changing character of problem(s) and their priority. The source (e.g., the provider, the system id, or the patient) of the updates should be documented. All pertinent dates are stored, including date noted or diagnosed, dates of any changes in problem specification or prioritization, and date of resolution. This might include time stamps, where useful and appropriate. The entire problem history for any problem in the list is viewable.

External References:
§170.314(a)(14) Patient list creation
Test Procedure_[PDF -490 KB]
§170.314(a)(5) Problem list
Test Procedure_[PDF - 125 KB]
§170.314(a)(6) Medication list
Test Procedure_[PDF - 118 KB]
§170.314(a)(8) Clinical decision support
Test Procedure_[PDF -473 KB]
§170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries
Test Procedure_[PDF -671 KB]
§170.314(b)(4) Clinical information reconciliation
Test Procedure_[PDF -469 KB]

1.	The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient, using the SNOMED CT Terminology Standard.	CP.1.4	C	EN
2.	The system SHALL capture, maintain and render a history of all problems associated with a patient.	CP.1.4	NC	EN
10.	The system SHALL provide the ability to render only active problems.	CP.1.4	NC	EN
90.	The system SHALL provide the ability to capture and maintain the reconciled problem list.		N	EN
91.	The system SHALL render the single reconciled problem list.		N	EN
92.	The system SHALL provide the ability to remove a problem from the single reconciled problem list.		N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
93.	The system SHALL provide the ability to integrate identical problems (from separate problem lists) into one representation on the single reconciled problem list.		N	EN
94.	The system SHALL provide the ability to integrate two or more problem lists into a single reconciled problem list.		N	EN
95.	The system SHALL render the reconciliation problem list including source of the problem list, the last date each problem was documented or edited.		N	EN
96.	The system SHALL render two or more problem lists simultaneously in a single view		N	EN
97.	The system SHALL provide the ability to manage problem lists from multiple sources for reconciliation.		N	EN
98.	The system SHALL provide the ability to manage the process of problem list reconciliation according to scope of practice, organizational policy, and/or jurisdictional law.		N	EN
99.	The system SHALL provide the ability to determine and render clinical decision support rules applicable to problem list updates.		N	EN
CP.1.6 Function	Manage Immunization List	CP.1.6	NC	EN
	Statement: Create and maintain patient-specific immunization lists. **Description:** Immunization lists 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, manufacturer and lot number. The entire immunization history is viewable. **External References:** §170.314(f)(1) Immunization information Test Procedure_[PDF -381 KB]			
1.	The system SHALL provide the ability to manage all immunizations associated with a patient.	CP.1.6	C	EN
2.	The system SHALL provide the ability to maintain immunization details, as discrete data, including: - the immunization name/type, seqeunce number in the series & series identifier, strength and dose; - the date and time of administration; - manufacturer, lot number, expiration date, - route and site of administration; - administering provider; - observations, reactions and complications; - reason immunization not given, and/or immunization related activity not performed; according to scope of practice, organizational policy, and/or jurisdictional law.	CP.1.6	C	EN
3.	The system SHALL provide the ability to manage, as discrete elements, data associated with an immunization that was not given to a patient (e.g., due to a contraindication or a patient's refusal). Data associated with an immunization that was not given to a patient includes date-and-time, immunization type, series, exception reason, and immunization-withholding provider.	CP.1.6	NC	EN
4.	The system SHALL provide the ability to render (e.g., print or transmit) a report of a patient's immunization history (e.g., for appropriate authorities such as schools, day-care centers or public health immunization registries) according to scope of practice, organizational policy, and/or jurisdictional law.	CP.1.6	NC	EN
CP.1.8 Function	Manage Patient and Family Preferences	CP.1.8	NC	EN
	Statement: Capture and maintain patient and family preferences. **Description:** This function is focused on the capture and maintenance of facts on patient/family preferences. Patient and family preferences 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. Patient/Family preferences differ from social history and Advance Directives as follows: Social history refers primarily to elements of a patient's background that may impact on the patient's health (e.g., smoking, drinking, occupation, abuse, etc.). Advance Directives refers to requests regarding care when the patient is unable to competently make decisions about their own care (e.g., Do Not Resuscitate orders, living wills). **External References:** §170.314(a)(14) Patient list creation Test Procedure_[PDF -490 KB] §170.314(a)(3) Demographics Test Procedure_[PDF -395 KB]			
1.	The system SHALL provide the ability to manage patient preferences (e.g., language(s), religion, communications, spiritual and cultural practices).	CP.1.8	C	EN
CP.3 Header	Manage Clinical Documentation	CP.3	NC	EN
	Statement: Clinical Documentation must be managed including the capture of the documentation during an encounter, maintenance and appropriate rendering. **Description:** Clinical documentation includes all documentation that the clinician may capture during the course of an encounter with the patient or relevant to the patient. This includes assessments, clinical measurements, clinical documents and notes, patient-specific care and treatment plans. Management of clinical documentation also includes the acknowledgement and amendments of documentation provided by other providers.			

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CP.3.1 Function	Conduct Assessments	CP.3.1	NC	EN
	Statement: Create and maintain assessment information. **Description:** During an encounter with a patient, the provider will conduct an assessment that is germane to the age, gender, developmental or functional state, medical and behavioral condition of the patient, such as growth charts, developmental profiles, and disease specific assessments. Wherever possible, this assessment should follow industry standard protocols although, for example, an assessment for an infant will have different content than one for an elderly patient. When a specific assessment template does not exist, a new, locally-defined assessment can be created, using the format and data elements of similar assessments whenever possible. (NOTE: A new assessment may not necessarily be unique, since a facility may copy an assessment from another facility.) **External References:** §170.314(a)(12) Image results Test Procedure_[PDF -337 KB]			
6. The system SHALL provide the ability to receive assessment information from external sources (e.g., laboratory results and radiographic results) according to scope of practice, organizational policy, and/or jurisdictional law.		CP.3.1	C	EN
CP.3.2 Function	Manage Patient Clinical Measurements	CP.3.2	NC	EN
	Statement: Capture and manage patient clinical measures, such as vital signs, as discrete patient data. **Description:** Within the context of an episode of care, patient measures such as vital signs are captured and managed as discrete data to facilitate reporting and provision of care. Other clinical measures (such as expiratory flow rate, size of lesion, etc.) are captured and managed, and may be discrete data. **External References:** §170.314(a)(4) Vital signs, body mass index, and growth charts Test Procedure_[PDF - 135 KB] §170.314(a)(8) Clinical decision support Test Procedure_[PDF -473 KB]			
1. The system SHALL provide the ability to capture, maintain and render patient vital signs (e.g., blood pressure, temperature, heart rate, respiratory rate, height/length, weight and pain scale) as discrete elements of structured or unstructured data.		CP.3.2	C	EN
2. The system SHALL provide the ability to capture, maintain and render other clinical measures (e.g., peak expiratory flow rate, size of lesions, oxygen saturation, body mass index and severity of pain) as discrete elements of either structured or unstructured data.		CP.3.2	C	EN
3. The system SHALL provide the ability to determine and render additional values within an assessment based on discrete or atomic elements (e.g., Body Mass Index based on height and weight).		CP.3.2	C	EN
12. The system SHALL provide the ability to capture, maintain and render growth charts that include growth data (weight, length or height and head circumference) on a graph that includes normative data plotted against population-based normative curves by age ranges, gender and ethnicity of the respective normative data (e.g., females 0-36 months).		CP.3.2	C	EN
95. The system SHALL provide the ability to capture certain data elements (items, fields) constrained by data type (e.g., numeric, valid date/time) according to scope of practice, organizational policy or jurisdictional law.			N	EN
96. The system SHALL determine (calculate) and render body mass index.			N	EN
98. The system SHALL provide the ability to determine and render clinical decision support rules applicable to vital sign updates.			N	EN
99. The system SHALL capture height/length, weight and blood pressure as numeric values only.			N	EN
CP.3.3 Function	Manage Clinical Documents and Notes	CP.3.3	NC	EN
	Statement: Create, addend, amend, correct, authenticate, maintain, present and close, as needed, transcribed or directly-entered 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, graphic, audio, etc. The documents may also be structured documents that result from 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' responsibility, 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. **External References:** §170.314(a)(9) Electronic notes Test Procedure_[PDF -380 KB] §170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries Test Procedure_[PDF -671 KB]			
1. The system SHALL provide the ability to manage clinical documentation as 'structured' and/or 'unstructured' data		CP.3.3	C	EN
15. The system SHALL provide the ability to capture, maintain and render transition-of-care related information according to scope of practice, organizational policy, and/or jurisdictional law.		CP.3.3	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CP.3.4 Function	Manage Patient-Specific Care and Treatment Plans	CP.3.4	NC	EN

Statement: Provide templates and forms for clinicians to use for care plans, guidelines and protocols during provision of care and care planning.

Description: During the provision of care, the clinician reviews and uses templates and forms to ensure consistent quality patient care. Care plans, guidelines or protocols may contain goals or targets for the patient, specific guidance to the providers, suggested orders, and nursing interventions, among other items, including alerts. Information such as Order sets for care plans may arrive from an external institution and need to be approved locally before being inserted into the care plan. Tracking of implementation or approval dates, modifications and relevancy to specific domains or context is provided. Transfer of treatment and care plans may be implemented electronically using, for example, templates, or by printing plans to paper.

External References: §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries
Test Procedure_[PDF - 650 KB]

8. The system SHALL provide the ability to transmit care plans and treatment plans to other care providers.	CP.3.4	C	EN

CP.4 Function	Manage Orders	CP.4	NC	EN

Statement: Provide the ability to manage clinical orders and results including medication, non-medication, diagnostic tests, blood products, other biologics and referrals, using order sets as appropriate.

Description: The provision of clinical care includes the need to order from a variety of treatments using order sets as appropriate as well as reviewing the results of treatment. Orders for treatments may include medications, non-medication therapies (e.g., physical therapy, special diet, immunizations, non-allopathic regimens); diagnostic care (e.g., laboratory , radiology); blood products and other biologics (e.g., blood transfusions, human growth hormones). Patients are often referred to other health care providers for more specialized diagnostic workup, and/or treatment. An effective EHR-S must include support and management of these processes and associated documentation.

External References: §170.314(a)(1) Computerized provider order entry
Test Procedure_[PDF - 110 KB]
§170.314(a)(16) Inpatient setting only - electronic medication administration record
Test Procedure_[PDF -522 KB]
§170.314(a)(2) Drug-drug, drug-allergy interaction checks
Test Procedure_[PDF -393 KB]

2. The system SHALL provide the ability to manage the creation, renewal, modification and discontinuation of orders.	CP.4	NC	EN

CP.4.2 Function	Manage Medication Orders	CP.4.2	NC	EN

Statement: Create prescriptions or other medication orders with detail adequate for correct filling and administration. Provide information regarding compliance of medication orders with formularies. Provide drug utilization review functionality including alerts regarding drug interactions and allergies.

Description: Medications include prescribed and over the counter (OTC) drugs, allergy shots, oxygen, anesthetics, chemotherapy, and dietary supplements that were ordered, supplied, administered, or continued. Different medication orders, including new, discontinue, refill/continue, and renew require different levels and kinds of detail, as do medication orders placed in different situations. Administration or patient instructions are available for selection by the ordering clinician, 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 therapeutic regimen, e.g., Renal Dialysis, Oncology. When it comes to capturing the medication rationale, it is not mandatory that the provider always provide this information.

In addition, the system should present the clinician with clinical decision support functionality (such as the presentation of allergies, drug-drug interactions) during the medication ordering process. 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 ordering 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.

External References: §170.314(a)(1) Computerized provider order entry
Test Procedure_[PDF - 110 KB]
§170.314(a)(16) Inpatient setting only - electronic medication administration record
Test Procedure_[PDF -522 KB]
§170.314(a)(2) Drug-drug, drug-allergy interaction checks
Test Procedure_[PDF -393 KB]
§170.314(b)(3) Electronic prescribing
Test Procedure_[PDF -420 KB]

5. The system SHALL provide the ability to manage medication order details as discrete data for correct filling, dispensing and administration of drug (e.g., dose, route, physical form, duration, SIG).	CP.4.2	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CP.4.4 Function	Manage Orders for Diagnostic/Screening Tests	CP.4.4	NC	EN
	Statement: Enable the origination, documentation, transmission, tracking and maintenance of orders for diagnostic tests. **Description:** Orders for diagnostic tests (e.g., diagnostic radiology, laboratory) are captured and tracked including new, renewal and discontinue orders. Each order includes appropriate detail, such as order identification, instructions and clinical information necessary to perform the test. Orders and supporting detailed documentation shall be communicated to the service provider for completion of the diagnostic test(s).Some systems may contain instructions, but in some settings, instructions may be provided from external sources (e.g., handouts). **External References:** §170.314(a)(1) Computerized provider order entry Test Procedure_[PDF - 110 KB]			
1. The system SHALL provide the ability to manage orders for diagnostic tests.		CP.4.4	NC	EN
2. The system SHALL provide the ability to capture and render standard order detail for diagnostic test order fulfillment.		CP.4.4	NC	EN
CP.4.6 Function	Manage Orders for Referral	CP.4.6	NC	EN
	Statement: Enable the origination, documentation and tracking of referrals between care providers or healthcare organizations, including clinical and administrative details of the referral, and consents and authorizations for disclosures as required. **Description:** Documentation and tracking of a referral 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 particular patient is appropriate in a clinical context and with regard to administrative factors such as insurance may be provided to the care provider at the time the referral is created. The EHR-S provides the ability to receive and act upon referral responses from providers. The EHR-S may provide the ability to capture completion of the referral appointment. Referrals may be received electronically (i.e. e-Referrals); or may be received non-electronically. If non-electronic, the system needs to allow the user to capture the referral information and manage referral request. If the system supports e-Referrals, then the system will also need to support additional functionality to manage the receipt of the referral request. **External References:** §170.314(a)(12) Image results Test Procedure_[PDF -337 KB] §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB]			
1. The system SHALL provide the ability to manage outbound referral(s), whether internal or external to the organization.		CP.4.6	NC	EN
3. The system SHALL provide the ability to link (e.g., link to image stored in PACS) clinical details as necessary for the referral according to scope of practice of the referral recipient.		CP.4.6	NC	EN
CP.5 Function	Manage Results	CP.5	NC	EN
	Statement: Present, annotate, and route current and historical test results to appropriate providers for review. Provide the ability to filter and compare results. **Description:** Results of tests are presented in an easily accessible manner to the appropriate providers. For example, flow sheets, graphs, or other tools allow care providers to view or uncover trends in test data over time. The provider may desire to annotate, filter, and/ or compare results. In addition to making results viewable, it is often necessary to send results to appropriate providers using electronic messaging systems, pagers, or other mechanisms. In addition, the system may have the ability to redirect or copy specific test results to a specified individual. Documentation of notification is accommodated. Results may also be routed to patients electronically or non-electronically (e.g., by hard copy). Note: “Results” are understood as applying to any type of test, whether biological or psychological. Management of the results may also require the provider's communication of the results to the patient (see function CPS.8.4 (Support for Communications between Provider and the Patient, and/or the Patient's Representative)). There may also be a need to notify public health agencies based on the result. See function POP.2 (Support Population-based Epidemiological Investigation). **External References:** §170.314(a)(12) Image results Test Procedure_[PDF -337 KB] §170.314(a)(14) Patient list creation Test Procedure_[PDF -490 KB] §170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries Test Procedure_[PDF -671 KB] §170.314(b)(5)(A) Incorporate laboratory tests and values/results Test Procedure_[PDF -820 KB] §170.314(b)(5)(B) Incorporate laboratory tests and values/results Test Procedure_[PDF -685 KB] §170.314(b)(6) Inpatient setting only - transmission of electronic laboratory tests and values/results to ambulatory providers Test Procedure_[PDF - 828 KB]			
1. The system SHALL provide the ability to manage test results in according to scope of practice, organizational policy, and/or jurisdictional law.		CP.5	NC	EN
2. The system SHALL provide the ability to render numerical and non-numerical current and historical test results.		CP.5	NC	EN
3. The system SHALL provide the ability to render results for an identified patient or group of patients.		CP.5	NC	EN
19. The system SHALL provide the ability to link and render the results report to other data (e.g., images) with which it is associated.		CP.5	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
25.	The system SHALL provide the ability to render non-diagnostic quality images.	CP.5	NC	EN
26.	The system SHALL provide the ability to link with Radiology Information Systems (RIS) or Picture Archiving & Communication Systems (PACS) to enable the presentation of diagnostic quality images.	CP.5	C	EN
27.	The system SHALL provide the ability to link one or more images to a result report.	CP.5	NC	EN
90.	The system SHALL display the specimen source with test report information.		N	EN
91.	The system SHALL render any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability as part of the test report information.		N	EN
94.	The system SHALL render the test result and, if applicable, the units of measurement or interpretation, or both as part of the test report information.		N	EN
95.	The system SHALL render the specimen source, when appropriate, as part of the test report information.		N	EN
96.	The system SHALL render the test performed as part of the test report information.		N	EN
97.	The system SHALL render the test report date as part of the test report information.		N	EN
98.	The system SHALL render the name and address of the laboratory location where the test was performed as part of the test report information.		N	EN
99.	The system SHALL render patient identification (e.g., patient name, unique patient identifier) as part of the test report information.		N	EN
CP.5.1 Function	Manage Results of Diagnostic Tests	CP.5.1	NC	EN

Statement: Enable the receipt and display of results for diagnostics tests.

Description: Diagnostic test results are received and should be stored and displayed while linked to the original order in the system.

External References:
§170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries
Test Procedure_[PDF -671 KB]
§170.314(b)(6) Inpatient setting only - transmission of electronic laboratory tests and values/results to ambulatory providers
Test Procedure_[PDF - 828 KB]
§170.314(f)(4) Inpatient setting only - transmission of reportable laboratory tests and values/results
Test Procedure_[PDF - 1.05 MB]

1.	The system SHALL provide the ability to capture, maintain and render diagnostic results, including preliminary as well as final results.	CP.5.1	C	EN
CP.6 Header	Manage Medication, Immunization and Treatment Administration	CP.6	NC	EN

Statement: Provide the functionality required to support the management of medication and immunization administration.

Description: Provide the functionality required to support the safe administration of medications or immunizations to a patient based on medical requirement and orders within the system. This includes presenting providers with the list of medications or immunizations that are to be administered to a patient, necessary administration information, and capture all required and relevant administration details.

CP.6.1 Function	Manage Medication Administration	CP.6.1	NC	EN

Statement: Present providers with the list of medications that are to be administered to a patient, necessary administration information, and capture administration details.

Description: In a setting in which medication orders are to be administered by a provider rather than the patient, the necessary information is presented including: the list of medication orders that are to be administered; administration instructions, times or other conditions of administration; dose and route, etc. The system shall securely relate medications to be administered to the unique identity of the patient (see CPS.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.

The EHR system shall support the five "rights" - Right Patient, Right Drug, Right Dose, Right Route, Right Time.

The system should report medication administration, where appropriate, to public health or disease management authorities (e.g., oncology related medication orders should be communicated or transmitted to a cancer registry).

External References:
§170.314(a)(16) Inpatient setting only - electronic medication administration record
Test Procedure_[PDF -522 KB]

1.	The system SHALL provide the ability to render the list of medications that are to be administered.	CP.6.1	NC	EN
11.	The system SHALL provide the ability to capture, maintain and render medication administration details as discrete data, including:(1) the medication name, strength and dose;(2) date and time of administration;(3) route and site;(4) administering provider(5) observations, reactions and complications(6) reason medication not given, and/or medication related activity not performed; according to scope of practice, organizational policy, and/or jurisdictional law.	CP.6.1	NC	EN
98.	The system SHALL provide the ability to electronically, automatically, and simultaneously capture and store the date, time and user identification for each administered medication with the use of the assistive technology.		N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
99. The system SHALL provide the ability to determine and render, using assistive technology, if all of the "five rights" are correct, i.e., right patient, right medication, right dose, right route, right time, and any variance if not.			N	EN
CP.6.2 Function	Manage Immunization Administration	CP.6.2	NC	EN
Statement: Capture and maintain discrete data concerning immunizations given to a patient including date administered, type, manufacturer, lot number, and any allergic or adverse reactions. Facilitate the interaction with an immunization registry to allow maintenance of a patient's immunization history. **Description:** During an encounter, recommendations 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 immunization including date, type, immunization expiration date, 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 or other organization (e.g., military unit commander, refugee program leadership). This function should include the ability to use GTIN barcode scanners to capture vaccine information (NDC, lot number, expiration date). **External References:** §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB] §170.314(f)(1) Immunization information Test Procedure_[PDF -381 KB] §170.314(f)(2) Transmission to immunization registries Test Procedure_[PDF - 706 KB]			
1. The system SHALL provide the ability to capture immunization administration details as discrete data, including:(1) the immunization name/type, series, strength and dose;(2) date and time of administration;(3) manufacturer, lot number, expiration date,(4) route and site of administration; (5) administering provider;(6) observations, reactions and complications;(7) reason immunization not given, and/or immunization related activity not performed;according to scope of practice, organizational policy, and/or jurisdictional law.		CP.6.2	NC	EN
2. The system SHALL auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy, and/or jurisdictional law.		CP.6.2	C	EN
8. The system SHALL provide the ability to render a patient's immunization history upon request.		CP.6.2	C	EN
10. The system SHALL transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy, and/or jurisdictional law.		CP.6.2	C	EN
99. The system SHALL export the immunization information message using HL7 v2.5.1 Implementation Guide for Immunization Messaging and the HL7 Standard Code Set CVX - Vaccines and Administered Vocabulary Standard			N	EN
CP.8 Header	Manage Patient Education & Communication	CP.8	NC	EN
Statement: Provide the functionality to effectively communicate with the patient regarding their care and document the communication as part of the patient's medical record. **Description:** During an encounter with a patient or when any medical decision is made that affects the patient and requires action from the patient it is necessary to communicate effectively with the patient (or their representative) to ensure that they can participate appropriately in their care. This includes providing instructions pertaining to preparation for a procedure, self-administration of medications and self care.				
CP.8.1 Function	Generate, Record and Distribute Patient-Specific Instructions	CP.8.1	NC	EN
Statement: Generate and record patient-specific instructions related to pre- and post-procedural and post-treatment/discharge requirements. **Description:** When a patient is scheduled for a test, procedure, or discharge, specific instructions about diet, clothing, transportation assistance, convalescence, follow-up with physician, etc., may be generated and recorded, including the timing relative to the scheduled event. In an outpatient scenario, similar instructions for post-diagnosis, and/or post-treatment needs may also be generated and recorded (e.g., exercise instructions for low back pain, wound or burn care). **External References:** §170.314(a)(15) Patient-specific education resources Test Procedure_[PDF -98 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF -776 KB]			
1. The system SHALL provide the ability to determine and render standardized instruction sets pertinent to the patient condition, for procedures, or scheduled events.		CP.8.1	NC	EN
2. The system SHALL provide the ability to render instructions pertinent to the patient as selected by the provider.		CP.8.1	NC	EN
3. The system SHALL provide the ability to transmit instruction information in electronic format to be provided to the patient.		CP.8.1	C	EN
6. The system SHALL provide the ability to capture the actual instructions given to the patient or a reference to the document(s) containing those instructions.		CP.8.1	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
98.	The system SHALL provide the ability to render a patient educational information regarding patient problem list, medication list and laboratory tests/results.		N	EN
99.	The system SHALL provide the ability to render patient-specific educational materials based on HL7 Context-Aware Knowledge Retrieval Standard.		N	EN
CP.9 Header	Manage Care Coordination & Reporting	CP.9	NC	EN
	Statement: Provide the functionality required to coordinate care with other providers and report care provided. **Description:** During care provision it is necessary to coordinate care with other providers, internal or external to the organization, as well as to communicate the care provided.			
CP.9.1 Function	Produce a Summary Record of Care	CP.9.1	NC	EN
	Statement: Render a summarized review of a patient's episodic, and/or comprehensive EHR, subject to jurisdictional laws and organizational policies related to privacy and confidentiality. **Description:** Create summary views and reports at the conclusion of an episode of care. Create service reports at the completion of an episode of care such as, but not limited to, discharge summaries, specialist or consultation reports and public health reports, using information captured in the EHR and without additional input from clinicians. **External References:** §170.314(a)(15) Patient-specific education resources Test Procedure_[PDF -98 KB] §170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries Test Procedure_[PDF -671 KB] §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB] §170.314(b)(7) Data portability Test Procedure_[PDF -551 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF -776 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF -776 KB] §170.314(e)(2) Ambulatory setting only clinical summary Test Procedure_[PDF - 766 KB]			
1.	The system SHALL provide the ability to render summaries of the patient's comprehensive EHR that include at a minimum: problem list, medication list, allergy and adverse reaction list, and procedures.	CP.9.1	NC	EN
96.	The system SHALL provide the ability to select certain data for inclusion/exclusion before rendering the summary report.		N	EN
98.	The system SHALL render patient summaries that include the following US Meaningful Use Common Data Set Elements: 1) Patient name 2) Sex 3) Date of birth 4) Race 5) Ethnicity 6) Preferred language 7) Smoking status 8) Problems 9) Medications 10) Medication Allergies 11) Laboratory test(s) 12) Laboratory value(s)/result(s) 13) Vital signs – height, weight, blood pressure, BMI 14) Care plan field(s), including goals and instructions 15) Procedures 16) Care team member(s) 17) Provider's name 18) Provider's office contact information 19) Admission and discharge dates and locations 20) Discharge Instructions 21) Reason(s) for hospitalization 22) Encounter diagnoses 23) Immunizations 24) Cognitive status 25) Functional status 26) Reason for referral 27) Referring provider's name 28) Referring provider's contact information) Care team member(s)		N	EN
99.	The system SHALL provide the ability to display the Common MU Data Set data used in the transition of care/referral summary in their English representation if they associate with a vocabulary/code set.		N	EN
CP.9.2 Function	Capture Heath Service Report Information	CP.9.2	NC	EN
	Statement: Support the creation of health service reports to authorized health entities that a provider may be required to generate (e.g., the creation of an oncologist's report that must be submitted to a national cancer registry). **Description:** Providers are prompted to collect sufficient information in the course of care to avoid duplicate, retrospective or other additional data entry as part of supporting health management programs and reporting, for example public health, such as notifiable condition reports, immunization, cancer registry and discharge data. **External References:** §170.314(a)(3) Demographics Test Procedure_[PDF -395 KB] §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB]			
2.	The system SHALL provide the ability to render service reports at the completion of an episode of care (e.g., discharge summaries or public health reports) using data collected during the encounter.	CP.9.2	C	EN
3.	IF the patient is designated as deceased THEN the system SHALL provide the ability to capture (i.e., trigger), maintain and render the collection of death certificate data (e.g., date of death).	CP.9.2	C	EN

2. Care Provision Support Section

Section Overview

The Care Provision Support Section focusses on functions required to support the provision of care to a specific patient to enable hands-on delivery of healthcare. This section is organized generally in alignment with Care Provision Section. For example, CP.4 (Manage Orders) is supported directly by CPS.4 (Support Orders). This alignment is designed to assist in finding related support functions related to care provision functions but is not expected to be 100% matched as some Care Provision Functions do not require matching Support functions or vice-versa. All functions within the Care Provision Support Section have an identifier starting with “CPS”.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CPS.1 Header	Record Management	CPS.1	NC	EN
	Statement: Manage the patient record including all patient demographics, identifiers and other information to support the provision of care. **Description:** Management of the patient record includes creation through quick registration or through a captured referral request as well as managing the patient encounter information linked to the appropriate patient record. It is also critical to manage the patient's relationships through genealogy, insurance, living situation or other means. This section also includes support for the management of patient and family preferences including patient advance directives, consents and authorizations linked to the unique patient record. For those functions related to data capture, data should be captured using standardized code sets or nomenclature, depending on the nature of the data, or captured as unstructured data. Care-setting dependent data are entered by a variety of caregivers. Data may also be captured from devices or other tele-health applications.			
CPS.1.1 Function	Manage a Patient Record	CPS.1.1	NC	EN
	Statement: Manage a single logical record for each patient. **Description:** A single record is needed for legal purposes, as well as to organize it unambiguously for the provider. Health information is captured and linked to the patient record. Static data elements as well as data elements that will change over time are maintained. The patient is uniquely identified, after which the record is tied to that patient. Combining information on the same 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 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 them. **External References:** §170.314(a)(4) Vital signs, body mass index, and growth charts Test Procedure_[PDF - 135 KB] §170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries Test Procedure_[PDF -671 KB]			
12. The system SHALL provide the ability to render parts of a single patient's record using a primary identifier (e.g., Unique patient identifier, encounter number), secondary identifiers (e.g., Social Security Number), or other information, or combination of information, which are not identifiers, but could be used to help identify the patient (e.g., name or Date of Birth).		CPS.1.1	NC	EN
99. The system SHALL capture patient growth parameters: including weight, height or length, head circumference; and vital signs including (but not limited to): blood pressure, temperature, heart rate, respiratory rate, oxygen saturation, and severity of pain as discrete elements of structured data.			N	EN
CPS.1.2 Function	Manage Patient Demographics	CPS.1.2	NC	EN
	Statement: Manage patient demographic information. **Description:** Demographic information (including names, addresses, phone numbers, email addresses, date of birth, gender, race, and ethnicity) must be managed to support unique patient identification, reporting, care provision requirements. Patient Demographic information may also include information about the patient's contacts, methods of contact (e.g., email or telephone), and modes of contact (e.g., call secretary during the day, send text message on the weekend). Patient demographic data are captured and maintained as discrete fields and may be enumerated, numeric, or codified according to scope of practice, organizational policy, and/or jurisdictional law. Key patient identifiers (i.e., name and primary patient record identifier) often appear on patient information output (e.g., rendering of a patient's record). Patients may have multiple, and/or compound names, sometimes employing accent marks or special characters. To help parse patient names, discete fields are often used. **External References:** §170.314(a)(3) Demographics Test Procedure_[PDF - 395 KB] §170.314(a)(8) Clinical decision support Test Procedure_[PDF - 473 KB]			
1. The system SHALL provide the ability to manage demographic information as discrete data as part of the patient record (e.g., sex, race, ethnicity, date of birth).		CPS.1.2	C	EN
3. The system SHALL provide the ability to render demographic information as discrete data as part of the patient record.		CPS.1.2	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
4.	The system SHALL provide the ability to manage historic information for demographic data including prior names, addresses, phone numbers and email addresses.	CPS.1.2	NC	EN
9.	The system SHALL provide the ability to capture the patient's gender used for administrative purposes (as distinct from the clinical gender).	CPS.1.2	C	EN
13.	The system SHALL provide the ability to manage the date/time of birth, down to the minute, according to scope of practice, organizational policy and/or jurisdictional law.	CPS.1.2	C	EN
97.	The system SHALL provide the ability to capture the fact that a patient declined to specify their preferred language, race and/or ethnicity.		N	EN
98.	The system SHALL provide the ability to capture more than one race for a patient.		N	EN
99.	The system SHALL provide the ability to determine and render clinical decision support rules applicable to demographic updates.		N	EN
CPS.1.7 Function	Preferences, Directives, Consents and Authorizations	CPS.1.7	NC	EN
	Statement: Capture and manage patient preferences, advance directives, consents and authorizations. **Description:** In the Preferences, Directives, Consents and Authorizations 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 (i.e. guardian, surrogate, proxy, health care agent).			
1.	The system SHOULD conform to function CPS.1.7.1 (Support for Patient and Family Preferences).	CPS.1.7	NC	EN
CPS.1.7.1 Function	Support for Patient and Family Preferences	CPS.1.7.1	NC	EN
	Statement: Support the integration of patient and family preferences into clinical decision support. **Description:** Decision support functions should permit consideration of patient/family preferences and concerns, such as with language, religion, culture, medication choice, invasive testing, and advance 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 individual or set of treatment plans. Preferences may also be used to adjust patient information including labeling and medication instructions (e.g., for language and print size). **External References:** §170.314(a)(17) Advance directives Test Procedure_[PDF - 85 KB]			
7.	The system SHALL provide the ability to integrate necessary documentation of patient and family preferences (e.g., living wills, advance directives, healthcare proxies, and specific consents or releases).	CPS.1.7.1	C	EN
CPS.1.7.2 Function	Manage Patient Advance Directives	CPS.1.7.2	NC	EN
	Statement: Capture and maintain patient advance directives. **Description:** Patient advance directives and provider Do Not Resuscitate (DNR) orders are captured, as well as the date and circumstances under which the directives were received, and the location of any paper or electronic advance directive documentation. Advanced Directives may include for example living will, durable power of attorney, preferred interventions for known conditions, or the existence of a "Do Not Resuscitate" order. Circumstances is used to indicate where, how and when an advanced directive was captured (e.g., provided by the patient's parent during initial consultation visit). **External References:** §170.314(a)(17) Advance directives Test Procedure_[PDF - 85 KB]			
1.	The system SHALL provide the ability to manage advance directive information including the type of directive, relevant dates (e.g., received, reviewed, rescinded, updated), circumstances under which the directives were received (e.g., during initial consultation), and the location of any paper or electronic advance directive documentation.	CPS.1.7.2	NC	EN
CPS.2 Function	Support externally-sourced Information	CPS.2	NC	EN
	Statement: Capture and maintain a variety of information from multiple external sources. **Description:** External sources are those outside the EHR system, including clinical, administrative, and financial information systems, other EHR systems, Personal Health Record (PHR) systems, and data received through health information exchange networks.			

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CPS.2.1 Function	Support externally-sourced Clinical Documents	CPS.2.1	NC	EN

Statement: Incorporate clinical documentation (computable and scanned) from external (to the system) sources.

Description: Mechanisms for incorporating external clinical documentation (including identification of source) are available. External is considered anything that is external to the system - i.e. documents from the organization; but created in another system would be considered 'external' for the purposes of this function. Documentation incorporated through these mechanisms is presented alongside locally captured documentation and notes wherever appropriate. This covers all types of documents received by the provider that would typically be incorporated into a medical record, including but not limited to faxes, referral authorizations, consultant reports, and patient/resident correspondence of a clinical nature. Intrinsic to the concept of electronic health records is the ability to exchange health information with other providers of health care services. Health information from these external sources needs to be received, stored in the patient record, and displayed upon request.

External data and documents addressed in the function include:

1. Laboratory results received through an electronic interface - This information is to be received and stored in the resident record as discrete data, which means that each separate element of the data needs to be stored in its own field. Therefore, if laboratory results are received through an electronic interface, the results are received in the EHR and the laboratory test name, result (value), and unit of measure are correctly displayed as discrete data (vs. report format).

2. Scanned documents received and stored as images (e.g., power of attorney forms, Living wills) - These scanned documents are indexed and can be retrieved based on the document type, date of the original document, and the date of scanning.

3. Text-based outside reports (e.g., x-ray reports, hospital discharge summaries, history & physicals) - Any mechanism for capturing these reports is addendable: OCR, PDF, image file of report, etc.

4. Clinical images from an external source (e.g., radiographic images, digital images from a diagnostic scan or graphical images) – These images may be stored within the system or be provided through direct linkage to an external source such as a hospital PACS system.

5. Other forms of clinical results, such as wave files of EKG tracings.

6. Medication detail (e.g., a medication history) from an external source such as a pharmacy, the patient, payer, or another provider - While the medication detail includes the medication name, strength, and SIG, this does not imply that the data will populate the medication module.

7. Structured, text-based reports (e.g., medical summary text in a structured format).

8. Standards-based structured, codified data (e.g., a Continuity of Care Document (CCD) with SNOMED CT).

Data incorporated through these mechanisms is presented alongside locally captured documentation and notes wherever appropriate.

External References:
§170.314(a)(12) Image results
Test Procedure_[PDF - 337 KB]
§170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries
Test Procedure_[PDF - 671 KB]
§170.314(e)(1) View, download, and transmit to 3rd party
Test Procedure_[PDF - 776 KB]
§170.314(e)(1) View, download, and transmit to 3rd party
Test Procedure_[PDF - 776 KB]
§170.314(e)(2) Ambulatory setting only clinical summary
Test Procedure_[PDF - 766 KB]

1.	The system SHALL provide the ability to capture, store and render external documents.	CPS.2.1	NC	EN
3.	The system SHALL provide the ability to capture, store and render computable documents (e.g., CDA, C-CDA, HITSP/C32, ASTM CCR, ISO 13606, lab results or medication lists).	CPS.2.1	C	EN
4.	The system SHALL provide the ability to store imaged documents or link to the imaged documents in imaging systems.	CPS.2.1	C	EN
6.	The system SHALL provide the ability to receive from an external source structured, text-based documents and reports (e.g., C-CDA, HITSP/C32, and ASTM CCR formats).	CPS.2.1	C	EN
98.	The system SHALL provide the ability to display header(s) and individual sections of a conformant standards-based document (e.g., CCD, C-CDA) in human readable form.		N	EN
99.	The system SHALL provide the ability to view incoming messages or documents from external sources.		N	EN

CPS.2.3 Function	Support Emergency Medical System Originated Data	CPS.2.3	NC	EN

Statement: Provide the ability to capture and maintain patient information from an external Emergency Medical System (EMS).

Description: Emergency Medical Systems can provide care at the patient's location, prior to transport, or while enroute to medical facilities via ambulance, aeromedical evacuation and other transport mechanisms. Key parts of information about the patient can be gathered here, some of which is computable data (e.g., EKG and other telemetry), non-computable text-based and multimedia digital objects (e.g., images, audio reports and conversations).

External References:
§170.314(a)(4) Vital signs, body mass index, and growth charts
Test Procedure_[PDF - 135 KB]

1.	The system SHALL provide the ability to capture and store information transmitted from the Emergency Medical Services (EMS) (e.g., wound site, nature of the wound, vital signs).	CPS.2.3	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CPS.2.4 Function	Support externally-sourced Clinical Images	CPS.2.4	NC	EN
	Statement: Incorporate clinical images from external sources and support communication/presentation of images from medical and non-medical devices and entities. **Description:** Mechanisms for incorporating external clinical images (including identification of source) are available and communication with non-medical devices and entities is supported as appropriate to the care setting such as an office or a patient's home. Externally-sourced images may be presented with locally-sourced documentation and notes wherever appropriate. This covers all types of images received by the provider that would typically be incorporated into a medical record. These image documents are indexed and can be retrieved, e.g., based on the document type, date of the original document, and the date of scanning. Images may also be stored within the system or accessed by reference to an external system (e.g., a hospital's picture archiving and communication system). Examples of image formats include OCR, PDF, JPG or TIFF. Examples of externally-sourced images include: laboratory results report images 2. Radiographic images3. Images of power of attorney forms, living wills or birth certificates4. Graphs and charts5. Photographs or drawings of patient wounds6. Wave files of EKG tracings **External References:** §170.314(a)(12) Image results Test Procedure_[PDF - 337 KB]			
1.	The system SHALL provide the ability to capture, store and render clinical images (e.g., radiographs, pictures, video/audio, waveforms) received from external sources.	CPS.2.4	C	EN
2.	The system SHALL provide the ability to receive from an external source clinical result images (e.g., radiologic images).	CPS.2.4	C	EN
99.	The system SHALL provide the ability to render clinical images with associated narrative interpretations.		N	EN
CPS.3 Header	Support Clinical Documentation	CPS.3	NC	EN
	Statement: Standard assessments, guidelines and prompts are provided to facilitate decision support for the optimization of patient care based on specific medical conditions. **Description:** Provider support is offered for the consideration of issues that would help assure optimal patient management. These may include standard assessments, care plans and treatment protocols, with triggers and prompts to assist during the patient encounter. Recommendation for patient testing and follow-up is also included along with decision support for patient self-management of a condition between patient-provider encounters.			
CPS.3.11 Function	Support Other Encounter and Episode of Care Documentation	CPS.3.11	NC	EN
	Statement: Where not covered above, provide the means to manage and organize the documentation of the health care needed and delivered during an encounter/episode of care. **Description:** Using data standards and technologies that support interoperability, effective documentation of an encounter can promote patient- centered/oriented care and enables real-time, immediate point-of-service care delivery. Effective encounter and episode-of-care documentation can facilitate efficient work flow and improve operations performance. This can help to ensure the integrity of (1) the health record, (2) public health, financial and administrative reporting, and (3) the healthcare delivery process. **External References:** §170.314(f)(4) Inpatient setting only - transmission of reportable laboratory tests and values/results Test Procedure_[PDF - 1.05 MB]			
3.	The system SHALL provide the ability to capture encounter documentation by one or more of the following input methods: - direct keyboard entry of text; - structured data entry utilizing templates, forms, pick lists or macro substitution; and- dictation with subsequent transcription of voice to text, either manually or via voice recognition system.	CPS.3.11	NC	EN
CPS.3.9 Function	Clinical Decision Support System Guidelines Updates	CPS.3.9	NC	EN
	Statement: Capture and maintain updates of clinical decision support system guidelines and associated reference material. **Description:** System content such as discharge instructions, clinical guidelines, formularies, and other knowledge bases should be capable of being maintained and updated, independent of a particular encounter. Clinical decision support rules may be applied to the system using a manual process. As standards are developed to represent these rules, an automated update will be recommended. Any process to update decision support rules should include the verification of the appropriateness of the rules to the system. This may include but not be limited to authenticity of the source, the currency of the version, and any necessary approvals before updates can take place. **External References:** §170.314(a)(8) Clinical decision support Test Procedure_[PDF - 473 KB]			
1.	The system SHALL provide the ability to maintain the clinical content or rules utilized to generate clinical decision support reminders and alerts.	CPS.3.9	NC	EN
94.	The system SHALL provide the ability to manage clinical decision support rules using data singly, or in combination, from the patient problem list, medication list, medication allergy list, demographics, diagnostic tests and results/values and vital signs.		N	EN
95.	The system SHALL provide the ability to manage attributes associated with each diagnostic and therapeutic reference resource, including the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).		N	EN
96.	The system SHALL provide the ability to manage attributes associated with each clinical decision support intervention, including bibliographic citation of the intervention (clinical research/guideline), the developer of the intervention (translation from clinical research/guideline), the funding source of		N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
	the intervention development technical implementation, and the release (and, if applicable, revision date(s)) of the intervention.			
97.	The system SHALL provide the ability to manage the effective time frame (from/to dates/times) for each clinical decision support rule.		N	EN
98.	The system SHALL provide the ability to manage clinical and therapeutic reference information for clinical decision support rules (e.g., using HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard).		N	EN
99.	The system SHALL provide the ability to manage reference data categories for clinical decision support rules, singly or in combination, to include: problem list, medication list, medication allergy list, demographics, diagnostic test results and values and vital signs.		N	EN
CPS.4 Header	Support Orders	CPS.4	NC	EN
	Statement: Support for Orders is required to ensure that appropriate decision support and safety checks are conducted by the system at the time of ordering as well as at the time of dispensing medications or immunizations. **Description:** Support for orders includes the management of order set templates, the support for specific types of orders including medication, immunization, non-medication, diagnostic tests as well as blood products and biologicals. Decision Support for orders includes checking for allergies or adverse interactions, dosing checking and issuing the appropriate warnings. It may also include functions to increase ordering efficiency such as verifying all necessary information to fulfill the order is captured and making recommendations for supporting orders. A component of ordering medications and immunizations is the dispensing of those orders and, where applicable, this function will include criteria to support dispensing. Note: Administration of Orders is included in CPS.6 (Support for Treatment Administration).			
CPS.4.2 Function	Support for Medication and Immunization Ordering	CPS.4.2	NC	
	Statement: Provide functionality to alert providers to potential medication and immunization ordering errors (such as wrong patient, wrong drug, wrong dose, wrong route and wrong time). **Description:** During medication or immunization ordering it is critical to minimize potential errors that can cause adverse events. This is accomplished by the EHR system through the use of clinical decision support and prompting to validate the order at time of ordering. Whist many of these functions are more commonly associated with medication ordering; they also apply to ordering of immunizations when such ordering occurs. The support includes the checking for drug/drug interactions, checking against documented allergies or previous adverse events as well as validating patient-specific dosing and providing appropriate warnings. support for medial ordering efficiencies also ensures that orders are appropriate and contain all required supporting information. **External References:** §170.314(a)(2) Drug-drug, drug-allergy interaction checks Test Procedure_[PDF - 393 KB]			
10.	The system SHALL provide the ability to capture and maintain the severity level at which warnings are displayed.	CPS.4.2	C	EN
CPS.4.2.1 Function	Support for Medication Interaction and Allergy Checking	CPS.4.2.1	NC	EN
	Statement: Identify medication interaction warnings at the time of medication or immunization ordering, or prescribing, as well as at the time of dispensing. **Description:** The clinician is alerted to medication-medication, medication-allergy, medication-food, medication-supplement (herbal or dietary) interactions at levels appropriate to the health care setting and with respect to the patient condition. These alerts may be customized to suit the user or group. Note, medication may be affected by food or diatary choices; whist this is not considered an interaction it is consequently not included in this function; however, the provision of drug-food effectiveness in information to be provided to the patient is included in the function CP.8.1 (Generate, Record and Distribute Patient-Specific Instructions).If the patient's condition is one where, in order to view the necessary components of the health record, patient authorization or 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 situation, where all health information is required to provide the most effective treatment, and it is not possible to obtain an authorization or consent; the system should provide an override (e.g., "break the glass") function to allow access to the diagnosis or problem for which a medication was ordered, according to scope of practice, organizational policies, and/or jurisdictional law. **External References:** §170.314(a)(2) Drug-drug, drug-allergy interaction checks Test Procedure_[PDF - 393 KB]			
1.	The system SHALL determine and present the presence of interactions between medications ordered and medications already on the current medication list.	CPS.4.2.1	NC	EN
5.	The system SHALL determine and render the presence of interactions between medications ordered, medications on the current medication list as well as previous medications according to organization policy, and/or jurisdictional law.	CPS.4.2.1	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CPS.4.2.3 Function	Support for Medication Ordering Efficiencies	CPS.4.2.3	NC	EN
	Statement: Provide the tooling necessary to support efficient medication ordering. **Description:** Support efficient medication ordering workflows by allowing medications to be sorted and reviewed by key attributes, e.g., generic or trade names. Also support editing medication orders across multiple instances of an order and capturing medication orders in order sets. **External References:** §170.314(a)(10) Drug formulary checks Test Procedure_[PDF - 110 KB]			
1.	The system SHALL present a medication compendia or formulary content (e.g., drug, dose, route and SIG) and allow for automatic drug checking to be performed to facilitate the selection of the medication to be ordered.	CPS.4.2.3	C	EN
99.	The system SHALL provide the ability to manage the medication formulary or preferred drug list.		N	EN
CPS.4.2.5 Function	Support for Medication Reconciliation	CPS.4.2.5	NC	EN
	Statement: Review a patient's medication information (from more than one source) and reconcile conflicts. **Description:** Medication reconciliation is the process of comparing a patient's medication information (from all sources) to the medications that the patient is actually has been taking. Medication reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. Medication Reconciliation should be done at every episode or transition of care in which new medications are ordered or administered, existing orders are rewritten or where medications may influence the care given. Transitions in care include changes in setting, service, practitioner, or level of care. The Medication Reconciliation process comprises five includes several steps: (1) develop a list of current medication list of medications that the patient is taking, (2) develop a list of medications to be prescribed or recommended (3) compare the medication information from all sources; (4) make shared and informed clinical decisions based on the comparison and provide the ability to document the interaction; and (5) communicate the updated medication information to the healthcare teams, the patient and appropriate caregivers. For example: If a patient's pain, anticoagulation, hyperglycemia or other high risk therapy is being managed by a specialist, the healthcare team must be aware to avoid prescribing an additional equivalent of this medication.(6) Verify the patient's/caregiver's understanding and agreement to the patient's medication treatment plan.(7) Standardization of shared medication information (name, dose, instructions, indications, prescriber, etc) **External References:** §170.314(b)(4) Clinical information reconciliation Test Procedure_[PDF - 469 KB]			
1.	The system SHALL provide the ability to manage the process of medication reconciliation according to scope of practice, organizational policy, and/or jurisdictional law.	CPS.4.2.5	NC	EN
92.	The system SHALL provide the ability to capture and maintain the reconciled medication list.		N	EN
93.	The system SHALL render the single reconciled medication list.		N	EN
94.	The system SHALL provide the ability to maintain medications on the single reconciled medication list.		N	EN
95.	The system SHALL provide the ability to integrate identical medications (from separate medication lists) into one representation on the single reconciled medication list.		N	EN
96.	The system SHALL provide the ability to integrate two or more medication lists into a single reconciled medication list.		N	EN
97.	The system SHALL render the reconciliation medication list including source of the medication list, the last date each medication was documented, ordered, prescribed, refilled, or edited.		N	EN
98.	The system SHALL render two or more medication lists simultaneously in a single view		N	EN
99.	The system SHALL provide the ability to manage medication lists from multiple sources for reconciliation.		N	EN
CPS.5 Function	Support for Results	CPS.5	NC	EN
	Statement: Evaluate results and notify provider and patient of results within the context of the patient's healthcare data. **Description:** The system suggests result interpretations and notifications including those for, abnormal results, trending of results (such as discrete laboratory values over time), evaluation of pertinent results at the time of provider order entry (such as evaluation of laboratory results at the time of ordering a radiology exam), evaluation of incoming results against active medication orders. **External References:** §170.314(a)(8) Clinical decision support Test Procedure_[PDF - 473 KB]			
9.	The system SHALL provide the ability to determine and render decision support algorithms based upon result updates.	CPS.5	C	EN
CPS.8 Header	Support Patient Education & Communication	CPS.8	NC	EN
	Statement: Support for appropriate communication with the patient or the patient representatives. **Description:** Support for patient education and communication is critical to ensure that the patient can appropriately participate in his care. This includes providing access to relevant patient educational materials and reminders from internal, and/or external sources.			

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CPS.8.4 Function	Support for Communications Between Provider and Patient, and/or the Patient Representative	CPS.8.4	NC	EN

Statement: Facilitate communications between providers and patients, and/or the patient representatives.

Description: Providers are able to communicate with patients and others, capturing as specified by the business rules the nature and content of electronic communication, or the time and details of other communication.

Examples:

- When test results arrive, the clinician may wish to email the patient that test result was normal (details of this communication are captured).
- A patient may wish to request a refill of medication by emailing the physician.
- Patients with asthma may wish to communicate their peak flow logs/diaries to their provider.
- Hospital may wish to communicate with selected patients about a new smoking cessation program.
- Automated notification regarding annual flu shots

External References:
§170.314(e)(1) View, download, and transmit to 3rd party
Test Procedure_[PDF - 776 KB]
§170.314(e)(3) Ambulatory setting only secure messaging
Test Procedure_[PDF - 528 KB]

3.	The system SHALL provide the ability to receive and transmit information between providers and patients or their representative using a secure internet connection.	CPS.8.4	C	EN
98.	The System SHALL control access by allowing patients and their designated representatives to receive and transmit messages to providers.		N	EN
99.	The System SHALL control access to patient health information by their authorizated representatives.		N	EN

CPS.9 Header	Support Care Coordination & Reporting	CPS.9	NC	EN

Statement: Support exchange and reporting of information between participants in patient-centered care.

Description: Provide the support necessary to ensure that appropriate communication between providers is possible to coordinate the patient's care including, clinical communication between providers, standard and ad-hoc reporting and information views of the patient record.

CPS.9.1 Function	Clinical Communication Management and Support	CPS.9.1	NC	EN

Statement: Support exchange of information between participants in patient-centered care as needed, and the appropriate documentation of such exchanges. Support secure communication to protect the privacy of information as required by jurisdictional law.

Description: Healthcare requires secure communications among various participant in the patient's circle of care: patients, doctors, nurses, chronic disease care managers, public health authorities, pharmacies, laboratories, payers, consultants etc. An effective EHRS supports communication across all relevant participants, reduces the overhead and costs of healthcare-related communications, and provides automatic tracking and reporting. The list of communication participants is determined by the care setting and may change over time.

Because of concerns about scalability of the specification over time, communication participants for all care settings or across care settings are not enumerated here because it would limit the possibilities available to each care setting and implementation. However, communication between providers and between patients and providers will be supported in all appropriate care settings and across care settings. Implementation of the EHRS enables new and more effective channels of communication, significantly improving efficiency and patient care. The communication functions of the EHRS changes the way participants collaborate and distribute the work of patient care.

External References:
§170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries
Test Procedure_[PDF - 671 KB]
§170.314(e)(1) View, download, and transmit to 3rd party
Test Procedure_[PDF - 776 KB]
§170.314(e)(2) Ambulatory setting only clinical summary
Test Procedure_[PDF - 766 KB]
§170.314(f)(3) Transmission to public health agencies syndromic surveillance
Test Procedure_[PDF - 767 KB]

3.	The system SHALL have the ability to present an indication that a secure standards-based message/document has been transmitted or received, and present that message/document in human readable form.	CPS.9.1	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CPS.9.2 Function	Support for Inter-Provider Communication	CPS.9.2	NC	EN

Statement: Support exchange of information between providers as part of the patient care process, and the appropriate documentation of such exchanges. Support secure communication to protect the privacy of information as required by jurisdictional law.

Description: Communication among providers involved in the care process can range from real time communication (for example, communication between a therapist and nurse), to asynchronous communication (e.g., 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 be limited to consults, and referrals as well as possible exchanges within the office as part of the provision and administration of patient care (e.g., the communication of new information obtained within the office environment during the process of administration of a tetanus shot while the patient is in the exam room).The system should support the creation and acceptance of paper artifacts where appropriate.

External References:
§170.314(e)(3) Ambulatory setting only secure messaging
Test Procedure_[PDF - 528 KB]
§170.314(f)(6) Optional ambulatory setting only transmission to cancer registries
Test Procedure_[PDF - 473 KB]

2. The system SHALL provide the ability to integrate scanned documents from providers into the patient record.	CPS.9.2	NC	EN
3. The system SHALL provide the ability to receive and transmit messages or information in real time.	CPS.9.2	C	EN

CPS.9.3 Function	Health Record Output	CPS.9.3	NC	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.

Description: Provide hardcopy and electronic output that fully chronicles the healthcare process, supports selection of specific sections of the health record, and allows healthcare organizations to define the report, and/or documents that will comprise the formal health record for disclosure purposes. A mechanism should be provided for both chronological and specified record element output. This may include defined reporting groups (i.e. print sets). For example Print Set A = Patient Demographics, History & Physical, Consultation Reports, and Discharge Summaries. Print Set B = all information created by one caregiver. Print Set C = all information from a specified encounter. An auditable record of these requests and associated exports may be maintained by the system. This record could be implemented in any way that would allow the who, what, why and when of a request and export to be recoverable for review. The system has the capability of providing a report or accounting of disclosures by patient that meets in accordance with scope of practice, organizational policy, and jurisdictional law.

External References:
§170.314(a)(14) Patient list creation
Test Procedure_[PDF - 490 KB]
§170.314(a)(4) Vital signs, body mass index, and growth charts
Test Procedure_[PDF - 135 KB]
§170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries
Test Procedure_[PDF - 650 KB]
§170.314(b)(7) Data portability
Test Procedure_[PDF - 551 KB]
§170.314(d)(9) Optional accounting of disclosures
Test Procedure_[PDF - 113 KB]
§170.314(e)(1) View, download, and transmit to 3rd party
Test Procedure_[PDF - 776 KB]
§170.314(e)(2) Ambulatory setting only clinical summary
Test Procedure_[PDF - 766 KB]
§170.314(f)(6) Optional ambulatory setting only transmission to cancer registries
Test Procedure_[PDF - 473 KB]

1. The system SHALL provide the ability to render reports consisting of all and part of an individual patient's record according to scope of practice, organizational policy, and/or jurisdictional law.	CPS.9.3	NC	EN
3. The system SHALL provide the ability to render reports in both chronological and specified record elements order.	CPS.9.3	C	EN
4. The system SHALL provide the ability to maintain and render hardcopy and electronic report summary information (e.g., demographics, problems, procedures, medications, labs, immunizations, allergies, vital signs, patient communication preferences).	CPS.9.3	C	EN
7. The system SHALL provide the ability to update reports to match mandated formats.	CPS.9.3	C	EN
13. The system SHALL provide the ability to maintain a record of disclosure/release that includes the recipient and outbound content.	CPS.9.3	C	EN
15. The system SHALL provide the ability to render a record summary using the format specified by an organization to which a patient is transferred.	CPS.9.3	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
CPS.9.4 Function	Standard Report Generation	CPS.9.4	NC	EN

Statement: Provide report generation features using tools internal or external to the system, for the generation of standard reports.

Description: Providers and administrators need access to data in the EHR-S for clinical, administrative, financial decision-making, audit trail and metadata reporting, as well as to create reports for patients. Many systems may use internal or external reporting tools to accomplish this. Reports may be based on structured data, and/or unstructured text from the patient's health record.

Users need to be able to sort, and/or filter reports. For example:

-the user may wish to view only the diabetic patients on a report listing patients and diagnoses-the user may wish to view only male patients over 35 with a complaint of chest pain.

External References: §170.314(f)(3) Transmission to public health agencies syndromic surveillance
Test Procedure_[PDF - 767 KB]
§170.314(f)(6) Optional ambulatory setting only transmission to cancer registries
Test Procedure_[PDF - 473 KB]

1.	The system SHALL provide the ability to render reports of structured clinical and administrative data using either internal or external reporting tools.	CPS.9.4	C	EN
2.	The system SHALL provide the ability to extract unstructured clinical and administrative data for inclusion in the report generation process, using internal or external tools.	CPS.9.4	C	EN
3.	The system SHALL provide the ability to extract and transmit reports generated.	CPS.9.4	C	EN
7.	The system SHALL provide the ability to render automated reports as required by industry and regulatory bodies.	CPS.9.4	C	EN
99.	The system SHALL provide the ability to generate cancer case reports using HL7 CDA R2, CDA Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, IHTSDO CT International July 2012 Release and US Extension to SNOMED CT March 2012 Release and LOINC Database Version 2.40.		N	EN

CPS.9.5 Function	Ad Hoc Query and Rendering	CPS.9.5	NC	EN

Statement: Provide support for ad hoc query and report generation using tools internal or external to the system. Present customized views and summarized information from a patient's comprehensive EHR subject to jurisdictional laws and organizational policies related to privacy and confidentiality. The view may be arranged chronologically, by problem, or other parameters, and may be filtered or sorted.

Description: Providers and administrators need to respond quickly to new requirements for data measurement and analysis. This may be as a result of new regulatory requirements or internal requirements. This requires that users be able to define their own query parameters and retain them. The data may be found in both structured and unstructured data. Providers and administrators also need to query for the absence of specific clinical or administrative data. For example, the Quality Control department may be reviewing whether or not the protocol for management of Diabetes Mellitus is being followed. If the protocol calls for fasting blood sugars every 3 months at minimum, the investigator might need to run an across-patient query locating patients with diabetes who do not show an FBS result within the last 3 months. Emergency Department benchmarking reports - Key point of time include arrival time; treatment area entrance time, MD contact time; decision to admit, discharge or transfer time; and departure (left ED) time. Important intervals include, but are not limited to the “door to doctor time”, “doctor to diction time”, “admission to bed availability or departure” as well as overall length of stayA key feature of an electronic health record is its ability to support the delivery of care by enabling prior information to be found and meaningfully displayed. EHR systems should facilitate search, filtering (e.g., filtering by key word, tagged data, or diagnosis), summarization, and presentation of available data needed for patient care. Systems should enable views to be customized, for example, specific data may be organized chronologically, by clinical category, by consultant, depending on need. The views may be arranged chronologically, by problem, or other parameters, and may be filtered or sorted. Jurisdictional laws and organizational policies that prohibit certain users from accessing certain patient information must be supported.

External References: §170.314(a)(14) Patient list creation
Test Procedure_[PDF - 490 KB]

1.	The system SHALL provide the ability to render ad hoc query and reports of structured clinical and administrative data through either internal or external reporting tools.	CPS.9.5	C	EN
4.	The system SHALL provide the ability to capture and maintain report parameters, based on patient demographic, and/or clinical data, which would allow sorting, and/or filtering of the data.	CPS.9.5	C	EN
5.	The system SHALL provide the ability to save report parameters for generating subsequent reports.	CPS.9.5	C	EN
9.	The system SHALL provide the ability to present and transmit customized views of summarized information based on sort and filter controls for date or date range, problem, or other clinical parameters.	CPS.9.5	C	EN

3. Population Health Support Section

Section Overview

The Population Health Support Section focuses on those functions required of the EHR to support the prevention and control of disease among a group of people (as opposed to the direct care of a single patient), usually with something(s) in common, e.g., reside in the U.S., have diabetes, are under the age of 5, are treated by the same care provider, have pneumonia and are in a long-term care facility, etc. This section includes functions to support input to systems that perform medical research, promote public health, & improve the quality of care at a multi-patient level. Population health data must be managed carefully to avoid inadvertently breaching patient privacy and confidentiality. Individual patients may be identifiable within a population or aggregate based on information other than patient identifiers, e.g., age plus location, and/or based on a combination of public and population-based information. This section specifically addresses requirements related to patient privacy and consent for use of patient information for secondary uses, and/or reporting. All functions within the Population Health Support Section have an identifier starting with “POP”.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
POP.2 Header	Support Population-Based Epidemiological Investigation	POP.2	NC	EN

Statement: Support for population-based internal and external epidemiological investigations of clinical health of aggregate patient data for use in identifying health risks from the environment, and/or population in accordance with jurisdictional law.

Description: A care provider, public health expert, or organization may wish to analyze data from cohorts,(i.e., subpopulations defined by certain characteristics or conditions). For example, cohorts can be described in terms of demographics; education and social status; health status, diseases, or outcomes; industry and occupation; or injuries. Population health analysts, such as experts in public health departments, may compile individual, and/or population information reported or otherwise gathered from multiple EHRs within the jurisdictional area for surveillance and research. Populations of one or none also can be informative. By analyzing specified data for a cohort, public health experts and care providers can monitor disease prevalence and health-related trends; evaluate behavioral, socio-economical, occupational, and other impacts on health; and identify potential outbreaks and associated risk factors. Examples include:

- examining a cohort of patients with measles for a common (implied) exposure, such as attending the same school - following a cohort of diabetics with out-of-range markers, or analyze them from various perspectives, such as by occupation, blood sugar range, drugs that are being used and not being used.

- examining a cohort of bakers for a higher-than-expected prevalence of asthma.

- Upon suspicion of a flu outbreak, reviewing a cohort of patients who have presented in the Emergency Department in the last three days complaining of breathing difficulty.

- Examining cohorts of smokers with lung disease, sand-blasters with breathing disorders, adults with asthma, etc. A broad range of information is used for population health surveillance and analyses, including (but not limited to) health status/disease/outcomes, completion/results of recommended health screens, current or previous medical treatment data, demographics, education, marital status, social factors, family history of diseases, personal history (e.g., alcohol and tobacco use, reading capability, hearing deficiency), and environmental factors (such as occupation and industry, shift-work, hobby). The information may or may not be coded; the text may be structured or unstructured. Person-level data is used to identify persons with specified characteristics such as exposures, symptoms, risk factors, injuries, genetic markers, diseases or health outcomes that may require further care. Person-level data also is required to evaluate groupings of injuries, diseases or adverse health outcomes. Issues of access to person-level data while securing patient privacy are relevant. Data also may be monitored and analyzed in “aggregate” (for example, by age range, geographic location, socio-economic level, or education level), depicting the quantity of records, and/or content within each aggregate. Aggregates may be used to report de-identified data to public health, for example, cases of influenza-like-illness by age range.

Case and population information are subject to public health reporting. Care organizations may require population health reports, for example, to measure quality of care based on health improvements for populations under the care of their providers. Statistical analyses are a key component to analyzing population health data, such as epidemiological investigations to identify relationships between risks (such as exposures or behaviors) and health conditions. Individual clinicians or healthcare organizations may employ limited capabilities in EHR systems to analyze population health data. The EHR system also should be capable of interacting with, and leveraging, the capabilities of specialized external analytical systems.

The investigator may hide or mask certain aspects of epidemiological investigation information, as necessary according to scope of practice, policy, and/or law. The investigator may desire to tag or remove patients from the cohort who have relocated or died.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
POP.2.1 Function	Support for Epidemiological Investigation Data Collection	POP.2.1	NC	EN

Statement: Support for Person-Level and Aggregate-Level Queries to Generate Population Cohorts, and/or Aggregates to be used in epidemiologic investigations and reports.

Description: Population health analysts (investigators) examine health data for trends and conditions through the use of well-defined queries to create their data sets. Preparing such well-defined queries, i.e., selection criteria and parameters, used to generate a cohort can be a complex and iterative process. The investigator may desire to use pre-defined or self-constructed queries (which may be saved for reuse). During the process of defining a query, the investigator may desire to accumulate statistics regarding the results of interim queries (e.g., number of patients in the query result) to determine the suitability of the queries, and subsequently modify the final query.

The investigator maintains sets of queries by constructing names that depict the cohorts, the fields comprising the queries and, perhaps, values for those fields. The resultant data set generated should be validated against the intended purpose of the query. Queries may need to be saved to support future analysis of the same (or a similar) cohort. For example, the investigator may construct an "Insulin study for males age 65 and older" query that is used to review patients of a specific age, gender and drug usage, then also construct an “Insulin study for females age 65 and older” query by modifying a copy of the first one. Queries may identify “static” or “dynamic” cohorts. A “static cohort” query identifies and monitors certain patients within a given cohort over time (e.g., pregnant patients who arrived in the Emergency Department in January, 2012 and followed throughout their pregnancies).

A “dynamic cohort” query may identify new patients to be added periodically to a cohort (e.g., the number of pregnant patients who arrived in the Emergency Department during each month). Information compiled by using a query may need to be governed by applicable policies and regulations. For example, psychiatric data may need to be excluded from a given epidemiological investigation. The query may need to specify that subjects are de-identified or aggregates are created according to the requirements of the analysis or privacy restrictions. For example, queries may be made of de-identified aggregate subjects to evaluate possible medical products safety issues quickly and securely. Data aggregation may be used to de-identify subjects, to condense the cohort, or to sub-divide a given cohort into various "aggregates" (for example, by age range, geographic location, socio-economic level, or education level), depicting the quantity of records, and/or content within each aggregate. Aggregate data may need to be integrated or linked d within or across cohorts. The criteria for data aggregation also may be applied to different cohorts.

External References: §170.314(f)(3) Transmission to public health agencies syndromic surveillance
Test Procedure_[PDF - 767 KB]

1.	The system SHALL provide the ability to manage queries (e.g., criteria and parameters based on surveillance parameters, demographic, and/or clinical information) for use in extracting one or more cohorts, and/or aggregates according to scope of practice, organizational policy, and/or jurisdictional law.	POP.2.1	NC	EN
2.	The system SHALL provide the ability to capture and maintain pre-defined criteria and parameters (e.g., based on demographic, and/or clinical information) for use in extracting one or more cohorts, and/or aggregates.	POP.2.1	NC	EN
3.	The system SHALL provide the ability to capture and maintain ad hoc criteria and parameters specified by the user (e.g., based on demographic, and/or clinical information) for use in extracting one or more cohorts, and/or aggregates	POP.2.1	NC	EN
12.	The system SHALL provide the ability to manage case-reporting requirements defined by public health organizations as queries according to scope of practice, organizational policy, and/or jurisdictional law.	POP.2.1	NC	EN

POP.2.3 Function	Support for Cohort and Aggregate Data Sharing	POP.2.3	NC	EN

Statement: Support cohort and aggregate-level population data sharing within an organization, and/or with other organizations.

Description: Population health data needs to be shared in a number of formats. The cohort and aggregate data (query results) may need to be shared within a facility or transmitted to other organizations on an ad hoc or periodic (namely, regularly scheduled) basis. For example, public health surveillance, monitoring and research often rely on analysis of data from multiple sources, including EHR systems. The data may need to be prepared in user-defined formats or formats defined by external parties. The care provider, public health expert, or organization may need to transmit individual or aggregate data in multiple formats (e.g., to an external statistical analytic application or to public health agencies to meet reporting requirements). Query results may need to be viewed, saved, and/or printed in pre-defined or ad hoc report formats, (e.g., for quality reporting within the care organization). Some or all members of a cohort or population may need to be anonymized, depending on the rules governing the data sharing.

External References: §170.314(f)(3) Transmission to public health agencies syndromic surveillance
Test Procedure_[PDF - 767 KB]
§170.314(f)(6) Optional ambulatory setting only transmission to cancer registries
Test Procedure_[PDF - 473 KB]

1.	The system SHALL provide the ability to capture, maintain, and render a request for a population-based query result according to scope of practice, organizational policy, and/or jurisdictional law.	POP.2.3	NC	EN
2.	The system SHALL provide the ability to capture, maintain, and render pre-defined report criteria (e.g, fields to be included in the resulting report or dataset), parameters, formats, and metadata that specify use, and/or reuse of the reported data according to scope of practice, organizational policy, and/or jurisdictional law (e.g., the metadata may indicate that the report is intended for initial, confirmatory or other analyses).	POP.2.3	NC	EN
3.	The system SHALL provide the ability to enter, maintain, and render ad hoc (user-specified) report criteria (e.g., the fields to be included in the resulting report or dataset), parameters, formats, and metadata that specify use, and/or reuse of the reported data according to scope of practice, organizational policy, and/or jurisdictional law (e.g., the metadata may indicate that the report is intended for initial, confirmatory or other analyses).	POP.2.3	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
4.	The system SHALL provide the ability to maintain and render the results of a query (e.g., person-level lists, case reports, or aggregates) as specified by the requestors' report criteria using a recognized or a locally-defined standard (e.g., via reporting formats that are specified by public health guidelines).	POP.2.3	NC	EN
5.	The system SHALL provide the ability to capture, maintain, and render with reports the metadata that specify use, and/or reuse of the reported data according to scope of practice, organizational policy, and/or jurisdictional law (e.g., the metadata may indicate that the report is intended for preliminary, confirmatory or other analyses; or the metadata may also indicate that the data may only be used for surveillance purposes).	POP.2.3	NC	EN
6.	IF standardized transmission of the results of a query are required to/from a registry or directory, THEN the system SHALL conform to function TI.3 (Registry and Directory Services).	POP.2.3	NC	EN
9.	The system SHALL provide the ability to transmit information related to individual case reports, including clinical information (e.g., test results) from a care provider to public health organizations (e.g., public health notifiable, and/or reportable condition programs) according to scope of practice, organizational policy, and/or jurisdictional law (e.g., a care provider notifies the local public health authority of an individual case of a sexually-transmitted disease that was identified during the analysis of a related query).	POP.2.3	NC	EN
POP.6 Header	Measurement, Analysis, Research and Reports	POP.6	NC	EN
	Statement: Support the capture and subsequent export or retrieval of data necessary for the measurement, analysis, research and reporting. **Description:** Information from the EHR-S may be used to support measurement, analysis, research and reporting to improve the provision of care. Reporting may include: - reporting on patient outcome of care by population, facility, provider or community; - providing quality, performance, and accountability measurements for which providers, facilities, delivery systems, and communities are held accountable; - support process improvement measures and related initiatives; and- support health care organizational performance monitoring and improvement.			
POP.6.2 Function	Quality, Performance and Accountability Measures	POP.6.2	NC	EN
	Statement: Support the capture and subsequent export or retrieval of patient, and/or population data necessary to provide quality, performance, and accountability measurements for which providers, facilities, delivery systems, and communities are held accountable. **Description:** Many regions require regular reporting on the healthcare provided to individuals and populations. This reporting may include measures related to or addressing processes, outcomes, costs of care, quality of care, adherence to best practice guidelines, and credentialing and privileging monitoring. The system needs to provide the report-generating capability to easily create these reports or provide for the export of data to external report-generating software. **External References:** §170.314(c)(1-3) Clinical quality measures capture and export Test Procedure_[PDF - 1.75 MB] §170.314(g)(1-2) Automated numerator recording Test Procedure_[PDF - 1.6 MB]			
1.	The system SHALL provide the ability to render patient, and/or population data required to assess health quality, performance and accountability measures to appropriate organizations.	POP.6.2	C	EN
2.	The system SHALL provide the ability to capture and maintain multiple data sets required for health care quality, performance and accountability measurements (e.g., the number of flu shots given, or the number of pregnant women counseled to take folic acid).	POP.6.2	C	EN
3.	The system SHALL render patient, and/or population health care quality, performance and accountability measures data in a report format that can be displayed, transmitted electronically, or printed.	POP.6.2	C	EN
5.	The system SHALL determine and render patient, and/or population health care quality, performance and accountability measures in real-time, near real-time or just-in-time according to scope of practice, organizational policy, and/or jurisdictional law.	POP.6.2	C	EN
96.	The system SHALL render population health care quality, performance and accountability measures data including the numerator, denominator, and resulting percentage for each measure.		N	EN
97.	The system SHALL manage numerator and denominator for each discrete measure (of quality, performance and accountability).		N	EN
98.	The system SHALL render and export the patient-level QRDA Category I format for clinical quality measures.		N	EN
99.	The system SHALL render and export an aggregate report in the QRDA Category III format of the clinical quality measures.		N	EN

4. Administration Support Section

Section Overview

The Administrative Support Section focusses on functions required in the EHR-S to support the management of the clinical practice and to assist with the administrative and financial operations. This includes management of resources, workflow and communication with patients and providers as well as the management of non-clinical administrative information on patients and providers. All functions within the Administrative Support Section have an identifier starting with “AS”.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
AS.1 Header	Manage Provider Information	AS.1	NC	EN
	Statement: Maintain, or provide access to, current provider information. **Description:** Manage the information regarding providers within and external to an organization that is required to support care provision. This information includes a registry of providers (internal to the EHR-S or external), the provider's location, on-call information, and office information. Information regarding teams or groups of providers as well as individual patient relationships with providers is necessary to support care coordination and access to patient information.			
AS.1.1 Function	Manage Provider Registry or Directory	AS.1.1	NC	EN
	Statement: Provide a current registry or directory of practitioners that contains data needed to determine levels of access required by the system. **Description:** Provider information may include any credentials, certifications, or any other information that may be used to verify that a practitioner is permitted to use or access authorized data. **External References:** §170.314(d)(1) Authentication, access, control, and authorization Test Procedure_[PDF -357 KB] §170.314(d)(6) Emergency access Test Procedure_[PDF -88 KB]			
2. The system SHALL provide the ability to capture and maintain realm-specific legal identifiers required for care delivery (e.g., the provider's license number or national provider identifier).		AS.1.1	C	EN
4. The system SHALL link provider information in the registry or directory with the security function to determine or identify authorized levels of access.		AS.1.1	C	EN
6. The system SHALL provide the ability to update the provider's access to the requested patient's information when a patient-provider relationship is established in the system (e.g., when patient is cared for in Emergency, system enables emergency attending provider to access patient's information); according to scope of practice, organizational policy, and/or jurisdictional law.		AS.1.1	C	EN
99. The system SHALL manage (create) a unique identifier for each system user.			N	EN
AS.2 Function	Manage Patient Demographics, Location and Synchronization	AS.2	NC	EN
	Statement: Capture and management of patient administrative information across locations in order to support care, including directories, and/or registries. **Description:** A patient directory/registry may contain information including, but not limited to: full name, residence or physical location, alternate contact person, primary phone number, and relevant health status information. Various views of Patient Registry or Directory information may constructed to accommodate various user's needs. Examples of specific directory views are presented in the following functions. The patient administrative information also includes patient location information (within a facility as well as home care location(s)); as well as the patient's registration in healthcare programs.			
AS.2.6 Function	Manage Patient Privacy Consent Directives	AS.2.6	NC	EN
	Statement: Provide the ability to record and manage patient-specific privacy consent directive consistent with privacy policies. **Description:** The system enables the management of information access to support privacy policies. These policies allow patients to stipulate specific privacy preferences as a privacy consent directive. The consent may be issued for a specific disclosure, for a period of time, or until it is explicitly revoked. This function depends on infrastructure to enforce the privacy consent and any associated privacy policies using a combination of access control, secure messaging, secure data routing, and data segmentation. **External References:** §170.314(d)(9) Optional accounting of disclosures Test Procedure_[PDF - 113 KB]			
3. The system SHALL provide the ability to render disclosure events.		AS.2.6	C	EN
4. The system SHALL provide the ability to render an accounting of any patient identifiable information disclosed to other providers.		AS.2.6	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
AS.3 Header	Manage Personal Health Record Interaction	AS.3	NC	EN
	Statement: Provide the system support in managing the interaction with a patient's PHR. **Description:** The system can support interaction with the patient's PHR. It can also manage documentation related to the PHR-S consent and access directives.			
AS.3.2 Header	Manage Legal and Other Related PHR files	AS.3.2	NC	EN
	Statement: Manage legal and other related electronic documents that allow or restrict the use or disclosure of the PHR Account Holder's information. **Description:** The system should support the capture and management of files, and/or related electronic documents related to the use or disclosure of the patient's PHR information. These files, and/or documents may include scanned images or electronic images sent via attachment. The system does not judge the authenticity of the document. The system may allows for multiple instances of the same document (e.g., multiple authorizations). The system may allow for retiring but tracking of documents no long used. The system should support the removal of documents as request by the patient via their PHR system.			
AS.3.2.2 Function	Manage PHR End-of-Life Documents and Other Advance Directives	AS.3.2.2	NC	EN
	Statement: Manage Personal Health Record electronic documents that provide the patients direction for end-of-life care and manage other types of Advance Directives. **Description:** Advanced directives may need to be harmonized with external systems (e.g., Personal Health record system). **External References:** §170.314(a)(17) Advance directives Test Procedure_[PDF -85 KB]			
	1. The system SHALL provide the ability to manage Personal Health Record files and documents related to Advance Directives and end of life care directives (e.g., living will, do not resuscitate orders).	AS.3.2.2	C	EN
AS.4 Header	Manage Communication	AS.4	NC	EN
	Statement: Support communication to enable the exchange of information internally and between healthcare and non-healthcare organizations. **Description:** Communication among providers involved in the care process can range from real time communication (e.g., communication between a therapist and nurse), to asynchronous communication (e.g., 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 be limited to consults, and referrals as well as possible exchanges within the office as part of the provision and administration of patient care (e.g., the communication of new information obtained within the office environment during the process of administration of a tetanus shot while the patient is in the exam room).			
AS.4.1 Function	Manage Registry Communication	AS.4.1	NC	
	Statement: Enable the exchange of structured demographic and clinical information with registries (e.g., local disease-specific, notifiable, patient, provider, organization, and health services registries) for patient monitoring and subsequent epidemiological analysis. **Description:** The system can provide for automated or user-initiated exchange of individuals' health information to disease-specific registries or other notifiable registries (such as immunization registries). These exchanges should use standard data transfer protocols or messages. The systems should allow for updating and configuration of communication with new registries. **External References:** §170.314(f)(3) Transmission to public health agencies syndromic surveillance Test Procedure_[PDF -767 KB]			
	1. The system SHALL provide the ability to exchange structured demographic and clinical information with registries (e.g., local, disease specific, notifiable, patient, provider, organization, or health services registries).	AS.4.1	NC	EN
AS.4.2 Function	Support for Communications Within an Organization	AS.4.2	NC	EN
	Statement: Facilitate communications regarding patient data and status within a health care organization. **Description:** There needs to be an ability to communicate patient data and status (e.g., patient history, patient physical examination), discrete clinical data (e.g., blood pressure, pulse, temperature, pulse oximetry, laboratory data, microbiology data, radiology data), and orders between clinical systems in the facility (e.g., ambulatory, inpatient and ED).			
	1. The system SHOULD provide the ability to render patient status tracking data on patient status devices or other patient tracking systems.	AS.4.2	NC	EN
	2. The system SHOULD determine and render patient information appropriate to the care setting, and/or the patient's condition, on status/patient/tracking displays.	AS.4.2	NC	EN
	3. The system SHALL render patient information that can be used for status and patient tracking systems (e.g., tracking display, ED status board) that displays, as a minimum: patient identification, patient location, medical condition, care process status, study status, vital signs, and inter-staff communication notes as applicable.	AS.4.2	C	EN

5. Record Infrastructure Section

Section Overview

The Record Infrastructure Section consists of functions common to EHR System record management, particularly those functions foundational to managing record lifecycle (origination, attestation, amendment, access/use, translation, transmittal/ disclosure, receipt, de-identification, archive…) and record lifespan (persistence, indelibility, continuity, audit, encryption). RI functions are core and foundational to all other functions of the Model (CP, CPS, POP, AS). Note extensive reference to RI functions in Overarching Criteria. RI functions may be implemented within the architecture of a single system or across a tightly coupled suite of systems (applications).All functions within the Record Infrastructure Section have an identifier starting with “RI”.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
RI.1 Header	Record Lifecycle and Lifespan	RI.1	NC	EN

Statement: Manage Record Lifecycle and Lifespan

Description: Actions are taken to support patient health. Actions are taken in provision of healthcare to individuals. Actions are taken as the result of rules-based EHR System algorithms. Actors (i.e., patients, providers, users, systems) take Actions. (Actions broadly encompass tasks, acts, procedures or services performed or provided.) The EHR System captures Actions taken and creates corresponding Record Entries. Record Entries provide persistent evidence of Action occurrence, context, disposition, facts, findings and observations. From the point of Record Entry origination to the end of its lifespan, the EHR System manages each Entry consistent with and according to scope of practice, organizational policy, and jurisdictional law. In support of individual health and in provision of healthcare to individuals, Actors perform Actions and Actions have corresponding Entries in the EHR Record, (i.e., Action instances are documented by Record Entry instances). Record Entries may be captured during the course of the Action or sometime thereafter. The Actor (author/source) of the Record Entry may be the same as an Actor performing the Action or not. The EHRS Functional Model does not specify a particular relationship of Actions and corresponding Record Entries. It may be one to one, many to one or even one to many. Actions have associated metadata (e.g., who, what, when, where, why, how, under what conditions, in what context). The corresponding Record Entry captures this metadata along with other Action and Record Entry related information.

Each Record Entry also includes its own provenance metadata such as who (authoring Actor) and when (documented). Record Entries may be encapsulated to bind Actor (individual, organization, and/or system) signatures to data and metadata content and data/time of occurrence. Actions and related Record Entries capture a chronology of patient health and healthcare and also a chronology of operations and services provided in/by a healthcare enterprise. Record Entries reflect changes in health information from the time it was created, to the time it was amended, sent, received, etc. In this manner, each Record Entry serves as persistent evidence of an Action taken, enabling providers to maintain comprehensive information that may be needed for legal, business, and disclosure purposes. To satisfy these purposes, Record Entries must also be retained and persisted without alteration. Record Entries have both a lifecycle and a lifespan. Lifecycle Events include originate, retain, amend, verify, attest, access/view, de-identify, transmit/receive, and more. Lifecycle Events occur at various points in a Record Entry lifespan, always starting with a point of origination and retention (i.e., when the Entry is first created and stored). A Record Entry may have a pre and post Event state if content is modified. In this case, the original Record Entry is preserved (with signature binding) and a new Entry is created (with new signature binding). A Record Entry contains data and metadata, in multiple formats, following various conventions and standards. Included data may be tagged, and/or delimited, structured (concise, encoded, computable), or unstructured (free form, non-computable). Data may be encoded as text, document, images, audio, waveforms, in ASCII, binary or other encoding. Structured data may be characterized as being concise, encoded, computable, and may be divided into discrete fields.

Examples of structured health information include:

- patient residence (non-codified, but discrete field)
- diastolic blood pressure (numeric)
- coded laboratory result or observation
- coded diagnosis
- patient risk assessment questionnaire with multiple-choice answers.

Unstructured data may be characterized as being free form, and/or non-computable. Unstructured health record information is information that is not divided into discrete fields AND not represented as numeric, enumerated or codified data.

Examples of unstructured health record information include:

- text (text message to physician) - word processing document (a letter from a family member) - image (photograph of a patient or a scanned image of insurance card) - multimedia (dictated report or a voice recording).

Context may determine whether data are structured or unstructured. For example, a progress note might be standardized and structured in some systems (e.g., Subjective/Objective/Assessment/Plan) but unstructured in other systems. The EHR System manages Record Lifecycle Events for each Record Entry, including pre and post Event record states, continuity, persistence and related Record Audit Logs.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
RI.1.1 Function	Record Lifecycle	RI.1.1	NC	EN
Statement: Manage Record Lifecycle **Description:** As aboveReferences: - ISO 21089: Health Informatics – Trusted End-to-End Information Flows- HL7 EHR Interoperability Model DSTU- HL7 Electronic Health Record Lifecycle Model DSTU				
RI.1.1.1 Function	Originate and Retain Record Entry	RI.1.1.1	NC	EN
Statement: Originate and Retain a Record Entry (1 instance) **Description:** Occurs when Record Entry is originated typically during the course of an Action itself, to document the Action and context. Record Entry is persistent evidence of Action occurrence and includes an identified Author or Source is responsible for Record Entry content. Record Entry contains Metadata about the Action and its circumstances, e.g., who, what, when, where, facts, findings, observations, etc. An Audit Trigger is initiated to track Record Entry origination and retention. Reference: ISO 21089, Section 12.2.2. **External References:** §170.314(a)(1) Computerized provider order entry Test Procedure_[PDF - 110 KB] §170.314(a)(11) Smoking status Test Procedure_[PDF - 115 KB] §170.314(a)(16) Inpatient setting only - electronic medication administration record Test Procedure_[PDF - 522 KB] §170.314(a)(4) Vital signs, body mass index, and growth charts Test Procedure_[PDF - 135 KB] §170.314(a)(9) Electronic notes Test Procedure_[PDF - 380 KB] §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB] §170.314(d)(6) Emergency access Test Procedure_[PDF - 88 KB] §170.314(f)(5) Optional ambulatory setting only - cancer case information Test Procedure_[PDF - 353 KB] §170.314(f)(6) Optional ambulatory setting only transmission to cancer registries Test Procedure_[PDF - 473 KB]			
1. The system SHALL provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.		RI.1.1.1	NC	EN
RI.1.1.1.1 Function	Evidence of Record Entry Originate/Retain Event	RI.1.1.1.1	NC	EN
Statement: Maintain Evidence of Record Entry Originate/Retain Event **Description:** Evidence of Record Entry Originate/Retain Event includes key metadata, ensures health record integrity (and trust) and enables record audit. **External References:** §170.314(a)(16) Inpatient setting only - electronic medication administration record Test Procedure_[PDF - 522 KB] §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB]				
3. The system SHALL capture identity of the patient who is subject of Record Entry content.		RI.1.1.1.1	NC	EN
5. The system SHALL capture identity of the user who entered/authored Record Entry content.		RI.1.1.1.1	NC	EN
9. The system SHALL capture the type of Record Event trigger (i.e., originate/retain).		RI.1.1.1.1	NC	EN
10. The system SHALL capture the date and time of Action occurrence as evidenced by Record Entry content.		RI.1.1.1.1	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
RI.1.1.13 Function	Extract Record Entry Content	RI.1.1.13	NC	EN

Statement: Extract Record Entry content to produce subsets, derivations, summaries or aggregations (Multiple instances)

Description: Occurs when Record Entry content is extracted to render subsets, derivations, summaries or aggregations.

- Extraction of Record Entry content may be initiated by User command, and/or rules-based algorithm.

- Extraction of Record Entry content is the responsibility of the System – which invokes relevant rules.

- An Audit Trigger is initiated to track Record Entry content extraction. Reference: ISO 21089, Section 12.7. An EHR-S enables an authorized user, such as a clinician, to access and aggregate the distributed information, which corresponds to the health record or records that are needed for viewing, reporting, disclosure, etc. An EHR-S must support data extraction operations across the complete data set that constitutes the health record of an individual and provide an output that fully chronicles the healthcare process. Data extractions are used as input

to patient care coordination between facilities, organizations and settings. In addition, data extractions can be used for administrative, financial, research, quality analysis, public health purposes, and to enable re-creation of copies for importing into different EHR applications and enable the archiving of patients' data. Data may be extracted in order to meet analysis and reporting requirements. The extracted data may require use of more than one application and it may be pre-processed (for example, by being de-identified) before transmission. Data extractions may be used to exchange data and provide reports for primary and ancillary purposes.

External References:
§170.314(a)(9) Electronic notes
Test Procedure_[PDF - 380 KB]
§170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries
Test Procedure_[PDF - 650 KB]
§170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]

1. The system SHALL provide the ability to extract Record Entry content to produce subsets, derivations, summaries or aggregations according to scope of practice, organizational policy, and/or jurisdictional law.	RI.1.1.13	NC	EN
3. The system SHALL provide the ability to extract Record Entry content based on queries with selection criteria, for example, key words, date/time range, full text search.	RI.1.1.13	NC	EN

RI.1.1.13.1 Function	Evidence of Record Entry Extraction Event	RI.1.1.13.1	NC	EN

Statement: Maintain Evidence of Record Entry Extraction Event

Description: Evidence of Record Entry Extraction Events includes key metadata, ensures health record integrity (and trust) and enables record audit.

External References:
§170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]

3. The system SHALL capture identity of the patient who is subject of extracted Record Entry content.	RI.1.1.13.1	NC	EN
4. The system SHALL capture identity of the user extracting Record Entry content.	RI.1.1.13.1	NC	EN
6. The system SHALL capture the type of Record Event trigger (i.e., extract).	RI.1.1.13.1	NC	EN
7. The system SHALL capture the date and time Record Entry content is extracted.	RI.1.1.13.1	NC	EN

RI.1.1.16 Function	Destroy or Identify Record Entries as Missing	RI.1.1.16	NC	EN

Statement: Destroy or Identify Record Entries as Missing (1 or more instances)

Description: Occurs when Record Entries are destroyed or identified as missing.

- Destruction typically occurs after conclusion of the legal retention period.

- Destruction of Record Entries may be initiated by User command.

- Destruction of Record Entries is the responsibility of the System – which invokes relevant rules.

- An Audit Trigger is initiated to track Record Entry Destruction or Notation as Missing.

Reference: ISO 21089, Section 12.11.

External References:
§170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]

1. The system SHALL provide the ability to delete (destroy) Record Entries (e.g., those exceeding their legal retention period) according to scope of practice, organizational policy, and/or jurisdictional law.	RI.1.1.16	NC	EN

RI.1.1.16.1 Function	Evidence of Record Entry Destruction Event	RI.1.1.16.1	NC	EN

Statement: Maintain Evidence of Record Entry Destruction Event

Description: Evidence of Record Entry Destruction Event includes key metadata, ensures health record integrity (and trust) and enables record audit.

External References:
§170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]

3. The system SHALL capture identity of the patient who is subject of destroyed Record Entry content.	RI.1.1.16.1	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
4.	The system SHALL capture a destruction identifier for destroyed Record Entry content (e.g., nursing home inpatient stay from 3/15/2000 thru 6/10/2000).	RI.1.1.16.1	NC	EN
5.	The system SHALL capture identity of the user destroying Record Entry content.	RI.1.1.16.1	NC	EN
7.	The system SHALL capture the type of Record Event trigger (i.e., destroy).	RI.1.1.16.1	NC	EN
8.	The system SHALL capture the date and time Record Entry content is destroyed.	RI.1.1.16.1	NC	EN
RI.1.1.2 Function	Amend Record Entry Content	RI.1.1.2	NC	EN

Statement: Amend content of a Record Entry (1 instance)

Description: Occurs when Record Entry content is modified (from its original or previously retained state) – typically upon conclusion of an Action, to correct, update or complete content.

- Amended Record Entry content is the responsibility of authorized amendment Author(s).

- The amendment becomes part of the Act Record revision history, where the original content and any previous amendments are retained without alteration.

- After amendment, the System is responsible for retention of the Record Entry and its revision history.

- An Audit Trigger is initiated to track Record Entry amendment.

Reference: ISO 21089, Section 12.3.2

External References:
§170.314(a)(1) Computerized provider order entry
Test Procedure_[PDF - 110 KB]
§170.314(a)(11) Smoking status
Test Procedure_[PDF - 115 KB]
§170.314(a)(4) Vital signs, body mass index, and growth charts
Test Procedure_[PDF - 135 KB]
§170.314(a)(9) Electronic notes
Test Procedure_[PDF - 380 KB]
§170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]
§170.314(d)(4) Amendments
Test Procedure_[PDF - 352 KB]
§170.314(f)(5) Optional ambulatory setting only - cancer case information
Test Procedure_[PDF - 353 KB]

1.	The system SHALL provide the ability to update (amend) Record Entry content.	RI.1.1.2	NC	EN
2.	The system SHALL maintain the original and all previously amended versions of the Record Entry, retaining each version instance without alteration.	RI.1.1.2	NC	EN
3.	The system SHALL capture a new uniquely identifiable version of the Record Entry, incorporating amended content.	RI.1.1.2	NC	EN
RI.1.1.2.1 Function	Evidence of Record Entry Amendment Event	RI.1.1.2.1	NC	EN

Statement: Maintain Evidence of Record Entry Amendment Event

Description: Evidence of Record Entry Amendment Event includes key metadata, ensures health record integrity (and trust) and enables record audit.

External References:
§170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]
§170.314(d)(4) Amendments
Test Procedure_[PDF - 352 KB]

3.	The system SHALL capture identity of the patient who is subject of amended Record Entry content.	RI.1.1.2.1	NC	EN
4.	The system SHALL capture identity of the user who entered/authored Record Entry content amendment.	RI.1.1.2.1	NC	EN
5.	The system SHALL capture identity of the system application which amended Record Entry content.	RI.1.1.2.1	NC	EN
6.	The system SHALL capture the type of Record Event trigger (i.e., amendment).	RI.1.1.2.1	NC	EN
7.	The system SHALL capture the date and time Record Entry content is amended.	RI.1.1.2.1	NC	EN
8.	The system SHALL capture identity of the location (i.e., network address) where Record Entry content is amended.	RI.1.1.2.1	C	EN
9.	The system SHALL capture the rationale for amending Record Entry content.	RI.1.1.2.1	C	EN
11.	The system SHALL capture a reference (e.g., link, pointer) to pre-amendment data for each amended Record Entry.	RI.1.1.2.1	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
RI.1.1.4 Function	Attest Record Entry Content	RI.1.1.4	NC	EN
	Statement: Attest to content of Record Entry (1 instance) **Description:** Occurs when Record Entry content is attested for accuracy and completeness – typically during/after conclusion of an Action. - Attested Record Entry content is the responsibility of Attesting Author. The Attesting Author may be someone other than the originating Author, i.e., a supervisor, proctor, preceptor or other designated individual. - An Audit Trigger is initiated to track Record Entry attestation. The purpose of attestation is to show authorship and assign responsibility for an act, event, condition, opinion, or diagnosis. Every Record Entry must be identified with the author and should not be made or signed by someone other than the author unless they have authority to do so. For example, a resident may author Record Entry content but the person taking legal authority for the content is the “attester” – both individuals should be identified. (Note: A transcriptionist may transcribe an author's notes and a senior clinician may attest to the accuracy of another's statement of events.)- Author: All users who create or contribute content and have a role in the development of a Record Entry. Some entries may be created by an author whose role is a student, transcriber or scribe. - Attester: A user who takes legal authority for Record Entry content. The attester is often the same as the author, but they may also be an individual with authority to take responsibility for Record Entry content created in whole or in part by another author(s) (e.g., student, scribe, transcriptionist).Reference: ISO 21089, Section 12.2.2. **External References:** §170.314(d)(4) Amendments Test Procedure_[PDF - 352 KB]			
3. The system SHALL provide the ability to attest (approve and apply signature to) Record Entry content by the author.		RI.1.1.4	NC	EN
10. IF Record Entry content is attested by someone other than the author, THEN the system SHALL maintain and display the author(s) and attester.		RI.1.1.4	NC	EN
RI.1.1.5 Function	View/Access Record Entry Content	RI.1.1.5	NC	EN
	Statement: View/Access content of Record Entries (1 or more instances) **Description:** Occurs when Record Entry content is viewed or accessed. - Viewed Record Entry content is the responsibility of authorized User(s). - An Audit Trigger is initiated to track Record Entry views and access. Reference: ISO 21089, Section 12.5. **External References:** §170.314(a)(1) Computerized provider order entry Test Procedure_[PDF - 110 KB] §170.314(a)(11) Smoking status Test Procedure_[PDF - 115 KB] §170.314(a)(16) Inpatient setting only - electronic medication administration record Test Procedure_[PDF - 522 KB] §170.314(a)(4) Vital signs, body mass index, and growth charts Test Procedure_[PDF - 135 KB] §170.314(a)(9) Electronic notes Test Procedure_[PDF - 380 KB] §170.314(a)(9) Electronic notes Test Procedure_[PDF - 380 KB] §170.314(d)(4) Amendments Test Procedure_[PDF - 352 KB] §170.314(d)(6) Emergency access Test Procedure_[PDF - 88 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB] §170.314(e)(3) Ambulatory setting only secure messaging Test Procedure_[PDF - 528 KB] §170.314(f)(5) Optional ambulatory setting only - cancer case information Test Procedure_[PDF - 353 KB]			
2. The system SHALL provide the ability to render Record Entry content, including original version and any subsequent amendments.		RI.1.1.5	NC	EN
3. The system SHALL provide the ability to render Record Entry content down to the discrete element or item, including encoded fields.		RI.1.1.5	NC	EN
99. The system SHALL provide the ability to select one or more record entries.			N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
RI.1.1.5.1 Function	Evidence of Record Entry View/Access Event	RI.1.1.5.1	NC	EN
	Statement: Maintain Evidence of Record Entry View/Access Event **Description:** Evidence of Record Entry View/Access Event includes key metadata, ensures health record integrity (and trust) and enables record audit. **External References:** §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB]			
	1. The system SHALL audit each occurrence when Record Entry content is viewed/accessed.	RI.1.1.5.1	NC	EN
	7. The system SHALL capture the date and time Record Entry content is viewed/accessed.	RI.1.1.5.1	NC	EN
	10. The system SHALL capture the data, document or other identifier for the viewed/accessed Record Entry content.	RI.1.1.5.1	NC	EN
RI.1.1.6 Function	Output/Report Record Entry Content	RI.1.1.6	NC	EN
	Statement: Output/Report content of Record Entries (1 or more instances) **Description:** Occurs when Record Entry content is output or reported. - Output/reported Record Entry content is the responsibility of authorized User(s). - An Audit Trigger is initiated to track Record Entry content outputs and reports. Reference: ISO 21089, Section 12.5. **External References:** §170.314(a)(14) Patient list creation Test Procedure_[PDF - 490 KB] §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB] §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB]			
	1. The system SHALL provide the ability to output/report Record Entry content, retaining original, unaltered content and signature bindings, Action and Record Entry provenance and metadata.	RI.1.1.6	C	EN
	4. IF a specific recipient is known, THEN the system SHALL output/report protected Record Entry content based on established permissions and according to scope of practice, organizational policy, and/or jurisdictional law.	RI.1.1.6	C	EN
RI.1.1.6.1 Function	Evidence of Record Entry Output/Report Event	RI.1.1.6.1	NC	EN
	Statement: Maintain Evidence of Record Entry Output/Report Event **Description:** Evidence of Record Entry Output/Report Event includes key metadata, ensures health record integrity (and trust) and enables record audit. **External References:** §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB]			
	3. The system SHALL capture identity of the patient who is subject of the Record Entry(ies) populating the output/report generated.	RI.1.1.6.1	NC	EN
	4. The system SHALL capture identity of the user who generated the output/report of Record Entry content.	RI.1.1.6.1	NC	EN
	6. The system SHALL capture the type of Record Event trigger (i.e., output/report).	RI.1.1.6.1	NC	EN
	7. The system SHALL capture the date and time the output/report is generated.	RI.1.1.6.1	NC	EN
RI.1.1.7 Function	Disclose Record Entry Content	RI.1.1.7	NC	EN
	Statement: Disclose content of Record Entries **Description:** Occurs when Record Entry content is disclosed according to scope of practice, organizational policy or jurisdictional law. - Disclosed Record Entry content is the responsibility of authorized User(s). - An Audit Trigger is initiated to track Record Entry content disclosures. Reference: ISO 21089, Section 12.5. **External References:** §170.314(d)(9) Optional accounting of disclosures Test Procedure_[PDF - 113 KB]			
	1. The system SHALL identify the patient or individual subject of transmitted/disclosed Record Entry content.	RI.1.1.7	NC	EN
	2. The system SHALL capture a log entry for disclosure of protected Record Entry content, according to scope of practice, organizational policy, and/or jurisdictional law.	RI.1.1.7	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
RI.1.1.7.1 Function	Evidence of Record Entry Disclosure Event	RI.1.1.7.1	NC	EN
	Statement: Maintain Evidence of Record Entry Disclosure Event **Description:** Evidence of Record Entry Disclosure Event includes key metadata, ensures health record integrity (and trust) and enables record audit. **External References:** §170.314(d)(9) Optional accounting of disclosures Test Procedure_[PDF - 113 KB]			
1. The system SHALL audit each occurrence when Record Entry content is disclosed according to scope of practice, organizational policy, and/or jurisdictional law.		RI.1.1.7.1	NC	EN
2. The system SHALL capture identity of the organization from which Record Entry content is disclosed.		RI.1.1.7.1	NC	EN
3. The system SHALL capture identity of the patient who is subject of Record Entry content disclosed.		RI.1.1.7.1	NC	EN
4. The system SHALL capture identity of the user initiating disclosure of Record Entry content.		RI.1.1.7.1	NC	EN
7. The system SHALL capture the date and time Record Entry content is disclosed.		RI.1.1.7.1	NC	EN
9. The system SHALL capture the rationale for disclosing Record Entry content.		RI.1.1.7.1	C	EN
RI.1.1.8 Function	Transmit Record Entry Content	RI.1.1.8	NC	EN
	Statement: Transmit content of Record Entries (1 or more instances) **Description:** Occurs when Record Entry content is transmitted – typically to an external entity or system. - Transmittal may include original Record Entry content with subsequent amendment(s), if any. - Transmittal of Record Entries is the responsibility of the System – which invokes relevant rules. - An Audit Trigger is initiated to track Record Entry transmittal. Reference: ISO 21089, Section 12.8.1. **External References:** §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB] §170.314(e)(3) Ambulatory setting only secure messaging Test Procedure_[PDF - 528 KB]			
1. The system SHALL provide the ability to transmit Record Entry content to external systems, retaining original, unaltered content and signature bindings, Action and Record Entry provenance and metadata.		RI.1.1.8	C	EN
2. The system SHALL provide the ability to transmit Record Entry extracts to external systems, including content, context, provenance and metadata, according to scope of practice, organizational policy and jurisdictional law.		RI.1.1.8	C	EN
RI.1.1.9 Function	Receive and Retain Record Entries	RI.1.1.9	NC	EN
	Statement: Receive and retain/persist content of Record Entries (1 or more instances) **Description:** Occurs when Record Entry content is received – typically from an external system. - Receipt of Record Entries is the responsibility of the System – which invokes relevant rules. - An Audit Trigger is initiated to track Record Entry receipt and retention. Reference: ISO 21089, Section 12.8.1. **External References:** §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB] §170.314(e)(3) Ambulatory setting only secure messaging Test Procedure_[PDF - 528 KB]			
1. The system SHALL provide the ability to capture and maintain Record Entry content from external systems, retaining and persisting original unaltered content and signature bindings, Action and Record Entry provenance and metadata.		RI.1.1.9	C	EN
2. The system SHALL provide the ability to capture and maintain Record Entry extracts from external systems, retaining and persisting source, identity, record content, corresponding provenance and metadata.		RI.1.1.9	NC	EN
RI.1.1.9.1 Function	Evidence of Record Entry Receive/Retain Event	RI.1.1.9.1	NC	EN
	Statement: Maintain Evidence of Record Entry Receive/Retain Event **Description:** Evidence of Record Entry Receive/Retain Event includes key metadata, ensures health record integrity (and trust) and enables record audit. **External References:** §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB]			
1. The system SHALL audit each occurrence when externally-sourced Record Entry content is received and retained.		RI.1.1.9.1	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
9. The system SHALL capture the date and time Record Entry content is received.		RI.1.1.9.1	NC	EN
RI.2 Function	Record Synchronization	RI.2	NC	EN

Statement: Manage Record Synchronization

Description: An EHR-S may consist of a set of components or applications; each application manages a subset of the health information. Therefore it is important that, through various interoperability mechanisms, an EHR-S maintains all the relevant information regarding the health record in synchrony. For example, if a physician orders an MRI, a set of diagnostic images and a radiology report will be created. As a result, the patient demographic information, the order for MRI, the diagnostic images associated with the order, and the report associated with the study must all be synchronized in order for the clinicians to receive a synchronized view the complete record (with respect to time and geographic location).Date and time need to be consistent across the applications that are part of the EHR system.

Synchronization demonstrates a sequence and chain of events for reconstruction and is relevant during a legal proceeding. Maintenance of synchronization activities could be relevant during a legal proceeding.

Note: Standards exist for Consistent Date and Time.

External References: §170.314(a)(16) Inpatient setting only - electronic medication administration record
Test Procedure_[PDF - 522 KB]

5. The system SHALL provide the ability to manage date and time-related information between applications, components, services, systems, and devices.	RI.2	NC	EN

6. Trust Infrastructure Section

Section Overview

The Trust Infrastructure (TI) Section consists of functions common to an EHR System infrastructure, particularly those functions foundational to system operations, security, efficiency and data integrity assurance, safeguards for privacy and confidentiality, and interoperability with other systems. TI functions are core and foundational to all other functions of the Model (Care Provision, Care Provision Support, Population Health, Administrative Support and Record Infrastructure). Note extensive reference to TI functions in Overarching Criteria. TI functions may be implemented within the architecture of a single system or across a tightly coupled suite of systems (applications).All functions within the Trust Infrastructure Section have an identifier starting with “TI”.

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
TI.1 Header	Security	TI.1	NC	EN
	Statement: Manage EHR-S security. **Description:** EHR-S security consists of entity authentication, entity authorization, entity access control, patient access management, secure data exchange, attestation, patient privacy and confidentiality. EHR audit functions are described in TI.2.			
TI.1.1 Function	Entity Authentication	TI.1.1	NC	EN
	Statement: Authenticate EHR-S users, and/or entities before allowing access. **Description:** All entities accessing the EHR-S are subject to authentication. Examples of entity authentication, with varying levels of authentication rigor, include: - username/password; - digital certificate; - secure token; - biometrics. **External References:** §170.314(a)(2) Drug-drug, drug-allergy interaction checks Test Procedure_[PDF - 393 KB] §170.314(a)(8) Clinical decision support Test Procedure_[PDF - 473 KB] §170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries Test Procedure_[PDF - 671 KB] §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB] §170.314(d)(1) Authentication, access, control, and authorization Test Procedure_[PDF - 357 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB] §170.314(e)(3) Ambulatory setting only secure messaging Test Procedure_[PDF - 528 KB]			
	1. The system SHALL authenticate entities (e.g., users, organizations, applications, components, objects, and/or devices) accessing EHR-S protected resources (e.g., functions and data) according to scope of practice, organizational policy, and/or jurisdictional law, using an authentication mechanism such as an accredited Standards Development Organization-approved authentication standard (e.g., SAML, WS-Trust, Kerberos), username/password, digital certificate, secure token, biometric, or hardware-specific addressing mechanism. (See also ISO 22600.)	TI.1.1	NC	EN
	2. The system SHALL manage authentication data/information securely (e.g., passwords or biometric data).	TI.1.1	NC	EN
	97. The system SHALL manage (remove, delete) a unique identifier for each system user.		N	EN
	98. The system SHALL manage (create) a unique identifier for each system user.		N	EN
	99. The system SHALL manage (prevent re-assignment of) a unique identifier for each system user.		N	EN
TI.1.12 Function	Mobile Device Encryption		N	EN
	Statement: none **Description:** none **External References:** §170.314(d)(7) End-user device encryption Test Procedure_[PDF - 473 KB]			
	96. The system SHALL encrypt electronic health information locally stored on an end-user device after normal user stops.		N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
97.	The system SHALL encrypt electronic health information stored on end-user devices in conformance with the encryption algorithm(s) in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2.		N	EN
98.	The system SHALL manage end-user device settings ensuring encryption is enabled by default.		N	EN
99.	IF the encryption of electronic health information is a setting that can be disabled, THEN. the system SHALL control access to the encryption settings by a designated set of users.		N	EN
TI.1.2 Function	Entity Authorization	TI.1.2	NC	EN
	Statement: Manage set(s) of EHR-S access control permissions. **Description:** Entities are authorized to use components of an EHR-S in accordance with their scope of practice within local policy or legal jurisdiction. Authorization rules provide a proper framework for establishing access permissions and privileges for the use of an EHR system, based on user, role or context. A combination of these authorization categories may be applied to control access to EHR-S resources (i.e., functions or data), including at the operating system level. - User based authorization refers to the permissions granted to access EHR-S resources based on the identity of an entity (e.g., user or software component). - Role based authorization refers to the permissions granted to access EHR-S resources based on the role of an entity. Examples of roles include: an application or device (tele-monitor or robotic); or a nurse, dietician, administrator, legal guardian, and auditor. - Context-based Authorization refers to the permissions granted to access EHR-S resources within a context, such as when a request occurs, explicit time, location, route of access, quality of authentication, work assignment, patient consents and authorization. See ISO 10181-3 Technical Framework for Access Control Standard. For example, an EHR-S might only allow supervising providers' context authorization to attest to entries proposed by residents under their supervision. **External References:** §170.314(a)(8) Clinical decision support Test Procedure_[PDF - 473 KB] §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB] §170.314(d)(6) Emergency access Test Procedure_[PDF - 88 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB]			
1.	The system SHALL provide the ability to manage sets of access-control permissions granted to an entity (e.g., user, application, device) based on identity, role, and/or context according to scope of practice, organizational policy, and/or jurisdictional law.	TI.1.2	NC	EN
3.	The system SHALL provide the ability to manage roles (e.g., clinician versus administrator) and contexts (e.g., legal requirements versus emergency situations) for authorization according to scope of practice, organizational policy, and/or jurisdictional law.	TI.1.2	NC	EN
TI.1.3 Function	Entity Access Control	TI.1.3	NC	EN
	Statement: Manage access to EHR-S resources. **Description:** To ensure access is controlled, an EHR-S must authenticate and check authorization of entities for appropriate operations. **External References:** §170.314(a)(2) Drug-drug, drug-allergy interaction checks Test Procedure_[PDF - 393 KB] §170.314(a)(8) Clinical decision support Test Procedure_[PDF - 473 KB] §170.314(d)(1) Authentication, access, control, and authorization Test Procedure_[PDF - 357 KB] §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB] §170.314(d)(5) Automatic log-off Test Procedure_[PDF - 84 KB] §170.314(d)(6) Emergency access Test Procedure_[PDF - 88 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB] §170.314(e)(3) Ambulatory setting only secure messaging Test Procedure_[PDF - 528 KB]			
3.	The system SHALL provide the ability to manage system and data access rules for all EHR-S resources according to scope of practice, organizational policy, and/or jurisdictional law.	TI.1.3	NC	EN
4.	The system SHALL manage the enforcement of authorizations to access EHR-S resources.	TI.1.3	NC	EN
5.	The system SHALL control access to EHR-S resources after a configurable period of inactivity by terminating the session, or by initiating a session lock that remains in effect until the entity re-establishes access using appropriate identification and authentication procedures, according to organizational policy, and/or jurisdictional law.	TI.1.3	N	EN
6.	The system SHALL provide the ability to control-access to data, and/or functionality according to scope of practice, organizational policy, and/or jurisdictional law.	TI.1.3	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
TI.1.3.1 Function	Emergency Access Control	TI.1.3.1	NC	EN
	Statement: Manage emergency access to EHR-S resources. **Description:** The intent of Emergency Access Control is to mitigate the potential for impeding the provision of care in an emergency situation in accordance with organizational policy. For example, emergency access may include: 1) Single record entry (e.g., single laboratory results, single document, single view); 2) Single patient; 3) Single login session, multiple patients; 4) Site mode allowing simultaneous emergency access to all users. Logging of a user's activities should occur in the audit record/metadata. Reports of emergency access use for follow up are critical for compliance and monitoring. **External References:** §170.314(d)(6) Emergency access Test Procedure_[PDF - 88 KB]			
1.	The system SHALL provide the ability to define emergency access rules according to scope of practice, organizational policy, and/or jurisdictional law.	TI.1.3.1	NC	EN
3.	The system SHALL manage emergency access by individual users based on criteria (e.g., defined rules and categories) according to organizational policy, and/or jurisdictional law.	TI.1.3.1	NC	EN
TI.1.6 Function	Secure Data Exchange	TI.1.6	NC	EN
	Statement: Secure all modes of EHR data exchange. **Description:** Whenever an exchange of EHR information occurs, it requires appropriate security and privacy considerations, including data obfuscation as well as both destination and source authentication when necessary. For example, it may be necessary to encrypt data sent to remote or external destinations. **External References:** §170.314(b)(1) Transitions of care receive, display and incorporate transition of care/referral summaries Test Procedure_[PDF - 671 KB] §170.314(b)(2) Transitions of care create and transmit transition of care/referral summaries Test Procedure_[PDF - 650 KB] §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB] §170.314(d)(8) Integrity Test Procedure_[PDF - 97 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB] §170.314(e)(3) Ambulatory setting only secure messaging Test Procedure_[PDF - 528 KB]			
4.	The system SHALL encrypt and decrypt EHR data that is exchanged.	TI.1.6	C	EN
5.	IF encryption is used, THEN the system SHALL exchange data using recognized standards-based encryption mechanisms according to organizational policy, and/or jurisdictional law.	TI.1.6	NC	EN
6.	IF the EHR-S is the recipient of a secure data exchange, THEN the system SHALL provide acknowledgment of receipt.	TI.1.6	C	EN
7.	The system SHALL provide the ability to determine static or dynamic addresses for known and authorized sources and destinations.	TI.1.6	NC	EN
82.	The system SHALL provide the ability to exchange data in compliance with Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2 [170.210(f)]		N	EN
83.	The system SHALL manage the list of DIRECT recipients.		N	EN
84.	The system SHALL provide the ability to view incoming messages or documents from external sources.		N	EN
86.	The system SHALL provide the ability to exchange data in compliance with Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2 [170.210(f)]		N	EN
87.	The system SHALL render and export health information in HL7 C-CDA format.		N	EN
88.	The system SHALL render and export health information in human readable format.		N	EN
89.	The system SHALL provide the ability to manage message digests of health information sets exchanged.		N	EN
90.	The system SHALL provide the ability to manage hash values based on, and ensuring point-to-point integrity of, health information sets to be exchanged.		N	EN
91.	The system SHALL conform to the SOAP-Based Secure Transport RTM version 1.0, XDR, and XDR for transmitting health information in C-CDA formats.		N	EN
92.	The system SHALL conform to the Direct and the Cross-Enterprise Document Reliable Interchange (XDR) and Cross-Enterprise Document Media Interchange (XDM) for Direct Messaging Specification for transmitting health information in C-CDA formats.		N	EN
93.	The system SHALL provide the ability to manage address-bound or domain-bound certificates in either DNS CERT records or LDAP servers that are discoverable by other parties.		N	EN
94.	The system SHALL maintain certificates from other parties in DNS CERT records or LDAP servers.		N	EN
95.	The system SHALL render and export health information using the DIRECT transport standard, as specified by the US Office of National Coordinator.		N	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
96.	The system SHALL conform to the DIRECT transport standard for wrapped and unwrapped messages (according to RFC-5751).		N	EN
98.	The system SHALL provide the ability to reject DIRECT messages when sent using an invalid, or expired certificate or sent using an invalid trust store.		N	EN
99.	The system SHALL provide the ability to transmit a Message Disposition Notification (MDN) upon receipt of health information from an external source.		N	EN
TI.1.8 Function	Patient Privacy and Confidentiality	TI.1.8	NC	EN

Statement: Enable the enforcement of the applicable jurisdictional and organizational patient privacy rules as they apply to various parts of an EHR-S through the implementation of security mechanisms.

Description: Patients' privacy and the confidentiality of EHRs are violated if access to EHRs occurs without authorization. Violations or potential violations can impose tangible economic or social losses on affected patients, as well as less tangible feelings of vulnerability and pain. Fear of potential violations discourages patients from revealing sensitive personal information that may be relevant to diagnostic and treatment services. Rules for the protection of privacy and confidentiality may vary depending upon the vulnerability of patients and the sensitivity of records. Strongest protections should apply to the records of minors and the records of patients with stigmatized conditions. Authorization to access the most sensitive parts of an EHR is most definitive if made by the explicit and specific consent of the patient. Please see the definition of masking in the glossary.

Organizational practices related to privacy and security jurisdictional laws could be called into question during a legal proceeding. Adherence to applicable laws supports the credibility and trustworthiness of the organization.

External References: §170.314(d)(6) Emergency access
Test Procedure_[PDF - 88 KB]

10.	The system SHALL provide the ability to unmask (override a mask) in emergency or other specific situations in accordance with users' role, and according to scope of practice, organizational policy, and/or jurisdictional law.	TI.1.8	NC	EN
TI.2 Function	Audit	TI.2	NC	EN

Statement: Audit Key Record, Security, System and Clinical Events

Description: EHR Systems have built in audit triggers to capture key events in real-time, including events related to record management, security, system operations or performance or clinical situations.

Event details, including key metadata (who, what, when, where), are captured in an Audit Log.

Audit Review functions allow various methods of critical event notification as well as routine log review.

Audit functions implement requirements according to scope of practice, organizational policy, and jurisdictional law.

External References: §170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]

1.	The system SHALL conform to function TI.1.3 (Entity Access Control) to limit access to, or modification of, audit record information to appropriate entities according to scope of practice, organizational policy, and/or jurisdictional law.	TI.2	NC	EN
TI.2.1 Function	Audit Triggers	TI.2.1	NC	EN

Statement: Manage Audit Triggers

Description: EHR Systems have built in audit triggers to capture key events in real-time. Audit triggers signal key:

- Record management and lifecycle events;
- Security events related to system and data safeguards, both routine and exceptional;
- System events related to performance and operations, both routine and exceptional.
- Clinical events with special log requirements.

External References: §170.314(d)(2) Auditable events and tamper-resistance
Test Procedure_[PDF - 497 KB]
§170.314(e)(1) View, download, and transmit to 3rd party
Test Procedure_[PDF - 776 KB]

1.	The system SHALL audit key events, as specified in function TI.2.1 (Audit Triggers) and child functions, according to scope of practice, organizational policy, and/or jurisdictional law.	TI.2.1	NC	EN
2.	The system SHALL capture key Audit Metadata at each Audit Trigger, as specified in TI.2.1 (Audit Triggers) and child functions, according to scope of practice, organizational policy, and/or jurisdictional law.	TI.2.1	NC	EN
3.	The system SHALL capture an Audit Log Entry at each Audit Trigger as specified in TI.2.1 (Audit Triggers) according to scope of practice, organizational policy, and/or jurisdictional law.	TI.2.1	NC	EN
TI.2.1.2 Function	Security Audit Triggers	TI.2.1.2	NC	EN

Statement: Manage Security Audit Triggers

Description: Security Audit Triggers are designed to capture security related events, both routine and exceptional, including key metadata (who, what, when, where, why).

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
TI.2.1.2.2 Function	User Authentication to the System (Start user session) Security Audit Trigger	TI.2.1.2.2	NC	EN
	Statement: Manage Audit Trigger initiated to track user authentication to the system (start user session). **Description:** Capture user authentication to the system (start user session), both routine and exceptional, including key metadata (who, what, when, where, why). **External References:** §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB]			
1. The system SHALL audit each occurrence of user authentication at logon (start session).		TI.2.1.2.2	NC	EN
TI.2.2 Function	Audit Log Management	TI.2.2	NC	EN
	Statement: Manage Audit Log **Description:** Audit Triggers create Audit Log entries. Audit Log entries are typically managed as persistent evidence of events occurring over time, including events pertaining to record management, security, system operations and performance, key clinical situations. Audit log entries capture event details, including key metadata (who, what, when, where).Audit log functions fulfill log maintenance and persistence requirements according to scope of practice, organizational policy, and jurisdictional law. **External References:** §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB] §170.314(d)(3) Audit report(s) Test Procedure_[PDF - 395 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB]			
1. The system SHALL provide the ability to capture audit log entries using a standards-based audit record format according to scope of practice, organizational policy, and/or jurisdictional law (e.g., IETF RFC 3881 "Internet Engineering Task Force, Request For Comment, Security Audit and Access Accountability Message XML Data Definitions for Healthcare Applications").		TI.2.2	NC	EN
3. The system SHALL provide the ability to securely store audit log entries metadata including related metadata.		TI.2.2	C	EN
86. The system SHALL provide the ability to render an audit log report detailing patient data accessed.			N	EN
87. The system SHALL provide the ability to render an audit log report detailing any deletions (with a pointer to the deleted data).			N	EN
88. The system SHALL provide the ability to render an audit log report detailing any changes made (with pointer to the original data state).			N	EN
89. The system SHALL provide the ability to render an audit log report sorted by date and time of audit event, patient identification, user identification, type of audit action.			N	EN
91. The system SHALL capture the date and time encryption is disabled.			N	EN
92. The system SHALL capture identity of the user who disabled encryption.			N	EN
93. The system SHALL capture the date and time the audit log is disabled.			N	EN
94. The system SHALL capture identity of the user who disabled the audit log.			N	EN
95. The system SHOULD provide the ability to encrypt data at rest.			N	EN
96. The system SHALL audit changes to encryption status.			N	EN
97. The system SHALL manage encryption status, including enable, disable and setting default status.			N	EN
98. The system SHALL audit changes to audit log status.			N	EN
99. The system SHALL manage audit log status, including enable, disable and setting default status.			N	EN
TI.2.2.1 Function	Audit Log Indelibility	TI.2.2.1	NC	EN
	Statement: Manage Audit Log Indelibility **Description:** Audit logs must be maintained in a persistent and indelible form according to scope of practice, organizational policy, and jurisdictional law. **External References:** §170.314(d)(2) Auditable events and tamper-resistance Test Procedure_[PDF - 497 KB] §170.314(d)(3) Audit report(s) Test Procedure_[PDF - 395 KB] §170.314(e)(1) View, download, and transmit to 3rd party Test Procedure_[PDF - 776 KB]			
1. The system SHALL manage each Audit Log entry as a persistent, indelible (unalterable) data object including all metadata.		TI.2.2.1	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
TI.2.3 Function	Audit Notification and Review	TI.2.3	NC	

Statement: Notify of Audit Events, Review Audit Log

Description: EHR system functions allow various methods of critical event notification (from audit triggers) as well as routine log review.

Audit log notification and review functions implement requirements according to scope of practice, organizational policy, and jurisdictional law.

External References: §170.314(d)(3) Audit report(s)
Test Procedure_[PDF - 395 KB]

2.	The system SHALL provide the capability to render reports based on ranges of system date and time that audit log entries were captured.	TI.2.3	C	EN
TI.4 Function	Standard Terminology and Terminology Services	TI.4	NC	EN

Statement: Support semantic interoperability through the use of standard terminologies, standard terminology models and standard terminology services.

Description: The purpose of supporting terminology standards and services is to enable semantic interoperability. Interoperability is demonstrated by the consistency of human and machine interpretation of shared data and reports. It includes the capture and support of consistent data for templates and decision support logic.

Terminology standards pertain to concepts, representations, synonyms, relationships and computable (machine-readable) definitions. Terminology services provide a common way for managing and retrieving these items, including historically correct version interpretation. Terminology services need to support legal requirements for retrospective health record information and system data.

TI.4.1 Function	Standard Terminology and Terminology Models	TI.4.1	NC	EN

Statement: Employ approved standard terminologies to ensure data correctness and to enable semantic interoperability (both within an enterprise and externally).Support a formal standard terminology model.

Description: Semantic interoperability requires standard terminologies combined with a formal standard information model. An example of an information model is the HL7 Reference Information Model. Another example is the ISO/EN 13606 Electronic Health Record Communication.

A terminology provides semantic and computable identity to its concepts. Examples of terminologies that an EHR-S may support include: LOINC, SNOMED, ICD-9, ICD-10, and CPT-4.Terminologies are use-case dependent and may or may not be realm dependent. The key is that the standard be approved by all stakeholders. 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 relationships that exist between concepts within a terminology or in different terminologies, such as exemplified in the model descriptions contained in the HL7 Common Terminology Services specification.

The clinical use of standard terminologies is greatly enhanced with the ability to perform hierarchical inference searches across coded concepts. Hierarchical Inference enables searches to be conducted across sets of coded concepts stored in an EHR-S. Relationships between concepts in the terminology are used in the search to recognize child concepts of a common parent. For example, there may be a parent concept, "penicillin containing preparations" which has numerous child concepts, each of which represents a preparation containing a specific form of penicillin (Penicillin V, Penicillin G, etc.). Therefore, a search may be conducted to find all patients taking any form of penicillin preparation.

Clinical and other terminologies may be provided through a terminology service internal or external to an EHR-S.

External References: §170.314(b)(5)(A) Incorporate laboratory tests and values/results
Test Procedure_[PDF - 820 KB]
§170.314(b)(6) Inpatient setting only - transmission of electronic laboratory tests and values/results to ambulatory providers
Test Procedure_[PDF - 828 KB]
§170.314(e)(1) View, download, and transmit to 3rd party
Test Procedure_[PDF - 776 KB]
§170.314(f)(4) Inpatient setting only - transmission of reportable laboratory tests and values/results
Test Procedure_[PDF - 1.05 MB]

1.	The system SHALL provide the ability to exchange data with other systems(internal or external to the EHR-S) using approved standard terminologies.	TI.4.1	NC	EN
10.	The system SHALL have the ability to present standard terminology terms in a language which is appropriate for the user.	TI.4.1	C	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
TI.5 Header	Standards-Based Interoperability	TI.5	NC	EN

Statement: Provide automated health care delivery processes and seamless exchange of clinical, administrative, and financial information through standards-based solutions.

Description: Interoperability standards enable certain applications to be shared among EHR systems, resulting in a unified (logical) view of a given EHR system where several disparate systems may actually be participating transparently. Interoperability standards also enable certain information to be shared among EHR systems (including information that resides in regional, national, or international information exchanges). Interoperability standards also promote timely and efficient information capture, use, and re-use, often reducing the cumulative workload of the broad set of stakeholders.

When health-related information is exchanged -- or when external applications are used to extend an EHR system -- the interoperability methods and underlying standards that were used in the process may need to be disclosed during a legal proceeding (especially when the resulting information becomes part of the patient's medical record).

TI.5.1 Header	Application, Structured-Message, and Structured-Document Interchange Standards	TI.5.1	NC	EN

Statement: Support an EHR system's ability to operate seamlessly with systems that adhere to recognized application interchange standards. These systems include other EHR systems, subcomponents of an EHR system, or other (authorized, non-EHR) systems.

Description: Since a health care organization typically has various external and internal interoperability requirements, it must use a set of corresponding interoperability or interchange standards that will meet its connectivity and information structure, format, and semantic requirements. Information should be exchanged -- and applications should provide functionality -- in a manner that appears to be seamless to the user. To be specific, if data is received from an external source that requires a user to manually copy-and-paste that data into multiple parts of the system, the exchange is not considered to be "seamless".

Examples of standards-based EHR information content and exchange methods include: standards-based data extracts, standards-based messages, standards-based documents (e.g., HL7 Clinical Document Architecture (CDA) documents), standards-based healthcare transactions, and standards-based images (e.g., Digital Imaging and Communication in Medicine (DICOM) documents).

Support for multiple interaction modes is needed to respond to differing levels of immediacy and types of exchange. For example, messaging is effective for many near-real time, asynchronous data exchange scenarios but may not be appropriate if the end-user is requesting an immediate response from a remote application.

A variety of interaction modes are typically supported such as:

- Unsolicited Notifications (e.g., Adam Everyman has arrived at the clinic for his scheduled appointment);
- Query/Response (e.g., Query: Is Adam Everyman known to the system? Response: Yes, Adam's medical record number is 12345678);
- Service Request and Response (e.g., Request: Laboratory Order for “Fasting Blood Sugar”. Response: the results of the test);
- Information Interchange between organizations (e.g., in a regional health exchange or in a national health system);
- Structured/discrete clinical documents (e.g., a structured clinical note);
- Unstructured clinical document (e.g., dictated surgical note).

Standard terminology is a fundamental part of interoperability and is described in section TI.4. Using a formal explicit information model further optimizes interoperability. An example of an information model is the HL7 Reference Information Model (RIM). Organizations typically need to deal with more than one information model and may need to develop a mapping between information models, a meta-model (that helps to explain and organize the various information models), or both.

TI.5.1.1 Function	Application Interchange Standards	TI.5.1.1	NC	EN

Statement: Support the ability to operate seamlessly with other systems by using applications, and/or structured messages and documents that adhere to interchange standards.

Description: Placeholder - Not Defined at this time

External References:
§170.314(b)(3) Electronic prescribing
Test Procedure_[PDF - 420 KB]
§170.314(b)(5)(A) Incorporate laboratory tests and values/results
Test Procedure_[PDF - 820 KB]
§170.314(b)(6) Inpatient setting only - transmission of electronic laboratory tests and values/results to ambulatory providers
Test Procedure_[PDF - 828 KB]
§170.314(d)(8) Integrity
Test Procedure_[PDF - 97 KB]
§170.314(f)(3) Transmission to public health agencies syndromic surveillance
Test Procedure_[PDF - 767 KB]
§170.314(f)(4) Inpatient setting only - transmission of reportable laboratory tests and values/results
Test Procedure_[PDF - 1.05 MB]
§170.314(f)(6) Optional ambulatory setting only transmission to cancer registries
Test Procedure_[PDF - 473 KB]

1. The system SHALL provide the ability to receive and transmit information using interchange standards as required by realm / local -specific profiles, and/or by recognized jurisdictional authorities.	TI.5.1.1	NC	EN

Section/Id#: Type:	Header/Function Name Conformance Criteria	Reference	Chg Ind	Priority
2.	The system SHALL provide the ability to seamlessly perform interchange operations with other systems that adhere to interchange standards as required by realm / local -specific, and/or by recognized jurisdictional authorities.	TI.5.1.1	NC	EN
3.	The system SHALL conform to TI.4 (Standard Terminology and Terminology Services) including all child-functions, to support terminology standards according to scope of practice, organizational policy, and/or jurisdictional law.	TI.5.1.1	NC	EN
97.	The system SHALL conform to HL7 v2.5.1 Messaging Standard for exchange of Electronic Laboratory Reporting to Public Health information.		N	EN
98.	The system SHALL conform to HL7 v2.5.1 Messaging Standard for exchange of syndromic surveillance information.		N	EN
99.	The system SHALL manage prescription information messages using NCPDP SCRIPT and the RxNorm medication vocabulary standard.		N	EN
TI.5.1.3 Function	Structured-Message Interchange Standards	TI.5.1.3	NC	EN
	Statement: Support the management of structured messages. **Description:** Structured messages are an important method of facilitating the exchange of information to support care. Messages are often considered to be more transitory in nature; documents are often considered to be more permanent in nature. **External References:** §170.314(f)(3) Transmission to public health agencies syndromic surveillance Test Procedure_[PDF - 767 KB]			
1.	The system SHALL provide the ability to manage structured messages according to scope of practice, organizational policy, and/or jurisdictional law.	TI.5.1.3	NC	EN