The Office of the National Coordinator for Health Information Technology

2015 Edition Final Rule:

Overview of the 2015 Edition Health IT Certification Criteria & ONC Health IT Certification Program Provisions

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Agenda

- Goals of the Final Rule
- Highlights of the ONC Health IT Certification Program
- Final 2015 Edition – Changes Compared to the Proposed 2015 Edition and the 2014 Edition
- Certification to the 2015 Edition Use Cases (MU & Beyond)

Overview of the 2015 Edition Final Rule

- Supports HHS-wide goals to achieve better care, smarter spending, and healthier people
- Builds on the foundation established by the 2011 and 2014 Editions and addresses stakeholder feedback by **reducing burden as compared to the 2015 Edition proposed rule**
- Focuses on health IT components necessary to establish an interoperable nationwide health information infrastructure
- Incorporates changes designed to foster innovation, open new market opportunities, and provide more provider and patient choices in electronic health information access and exchange
- Addresses information blocking and the continued reliability of certified health IT

2015 Edition Final Rule Health IT Goals

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- Improve Interoperability
- Facilitate Data Access and Exchange
- Ensure Privacy and Security Capabilities
- Improve Patient Safety
- Reduce Health Disparities
- Improve the Reliability and Transparency of Certified Health IT
- Use the ONC Health IT Certification Program to Support the Care Continuum
- Support Stage 3 of the EHR Incentive Programs

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ONC Health IT Certification Program

Supporting the Broader Care Continuum

A more accessible ONC Health IT Certification Program supportive of:

- Diverse health IT systems, including but not limited to EHR technology ("Health IT Module" instead of "EHR Module")

  Remember: There is no "Complete EHR" certification to the 2015 Edition or future editions

- Health IT across the care continuum, including long-term and post-acute care (LTPAC) settings

Supporting the Broader Care Continuum: How It Will Work

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The Past (2011 and 2014 Editions)	The Future (2015 and Future Editions)

• ONC included **policy** that supported the EHR Incentive Programs in its previous Editions
  • Defined the Certified EHR Technology (CEHRT) definition on behalf of CMS
  • Required "meaningful use measurement" criteria
  • Specified the minimum number of clinical quality measures developers must certify to in order to participate in the EHR Incentive Programs
  • Specified criteria as "ambulatory" or "inpatient"
	• ONC does not include **policy** to support the EHR Incentive Programs in its Editions
	  • Each program sets its own requirements (e.g., CMS defines the CEHRT definition in its final rule)
	  • **The ONC Health IT Certification Program is "agnostic" to settings and programs, but can support many different use cases and needs**
	  • This allows the ONC Health IT Certification Program to support multiple program and setting needs, for example:
	  • EHR Incentive Programs
	  • Long-term and post-acute care
	  • Chronic care management
	  • Behavioral health
	  • Other public and private programs

Programs Beyond MU that are Using the ONC Health IT Certification Program

A number of programs currently point to certified health IT and/or the the ONC Health IT Certification Program. Here are a few:

- Physician Self-Referral Law exception and Anti-kickback Statute safe harbor for certain EHR donations
- CMS chronic care management services (included in 2015 and 2016 Physician Fee Schedule rulemakings)
- Department of Defense Healthcare Management System Modernization Program
- The Joint Commission for performance measurement initiative ("ORYX vendor" – eCQMs for hospitals)

There are also other HHS rulemakings encouraging the use of certified health IT or proposing required alignment with adopted standards. These rulemakings are mentioned in more detail in the 2015 Edition final rule.

Transparency Requirements – Part 1

ONC-ACBs must ensure health IT developers conspicuously disclose in plain language on their website, in all marketing materials, communication statements, and other assertions related to certified heath IT:

- ❑ Additional types of costs users may incur to implement or use health IT for any purpose within the scope of its certification (not just for achieving MU objectives)
- ❑ Limitations (including contractual, technical, or other limitations) that are likely to limit a user's ability to implement or use health IT for any purpose within the scope of its certification

Transparency Requirements – Part 2

Health IT developers will be required to:

- ❑ Provide a hyperlink for all disclosures, which will be published via ONC's CHPL
- ❑ Make a "transparency attestation" indicating whether or not they will provide the required information (prior slide) to other persons and organizations (e.g., customers, prospective customers, and associations representing consumers or providers) upon request

"Open Data"
Certified Health IT Products List (CHPL)

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- Converting the CHPL to an open data file to make the reported product data (e.g., test results) more accessible for product analysis
- Require that ONC-Authorized Certification Bodies (ONC-ACBs) report an expanded set of information about health IT products for increased product transparency

Improve the Reliability and Transparency of Certified Health IT

Privacy and Security Certification Framework

- A Health IT Module will need to meet applicable privacy and security certification criteria, which is based on the other capabilities included in the Health IT Module

- Removes the responsibility from the provider to ensure that they possess technology certified to all the necessary privacy and security criteria

Ensure Privacy and Security Capabilities

Privacy and Security Certification Framework, continued

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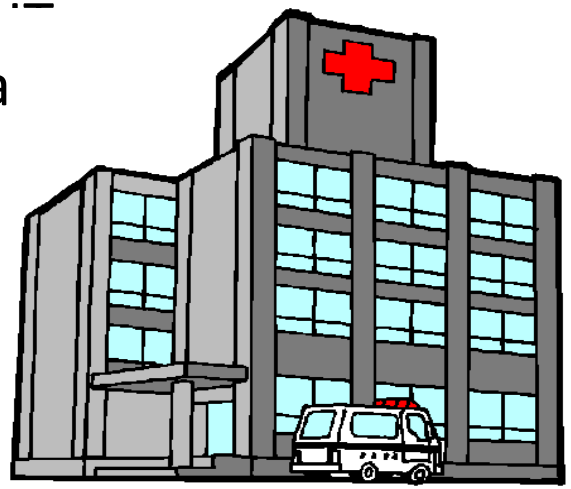
Final 2015 Edition Privacy and Security Certification Framework		
If the Health IT Module includes capabilities for certification listed under:	It will need to be certified to approach 1 or approach 2 for each of the P&S certification criteria listed in the "approach 1" column	
	Approach 1	**Approach 2**
§ 170.315(a)	§ 170.315(d)(1) (authentication, access control, and authorization), (d)(2) (auditable events and tamper resistance), (d)(3) (audit reports), (d)(4) (amendments), (d)(5) (automatic log-off), (d)(6) (emergency access), and (d)(7) (end-user device encryption)	For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation sufficiently detailed to enable integration with external services necessary to meet the criterion.
§ 170.315(b)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8) (integrity)	
§ 170.315(c)	§ 170.315(d)(1) through (d)(3) and (d)(5)*	
§ 170.315(e)(1)	§ 170.315(d)(1) through (d)(3), (d)(5), (d)(7), and (d)(9)(trusted connection)*	
§ 170.315(e)(2) and (3)	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(9)*	
§ 170.315(f)	§ 170.315(d)(1) through (d)(3) and (d)(7)	
§ 170.315(g)(7), (8) and (9)*	§ 170.315(d)(1) and (d)(9); and (d)(2) or (d)(10) (auditing actions on health information)*	
§ 170.315(h)	§ 170.315(d)(1) through (d)(3)	
***Emphasis added to identify additions to the framework as compared to the Proposed Rule.**		

Ensure Privacy and Security Capabilities

Surveillance of Certified Health IT

- New requirements for "in-the-field" surveillance under the ONC Health IT Certification Program
- ONC-ACBs should ensure that certified Health IT Modules can perform certified capabilities in a production environment (when implemented and used)
  - ❑ Reactive surveillance (e.g., complaints)
  - ❑ Randomized surveillance
    (2% of annually certified health IT at one or more location)
- Enhanced surveillance of <u>mandatory transparency requirements</u>
- Non-conformity and corrective action reported to the CHPL beginning in CY 2016



Improve the Reliability and Transparency of Certified Health IT

Improve Patient Safety

Final 2015 Edition: Comparison to the Proposed 2015 Edition and to the 2014 Edition

Standards Adoption

New and updated vocabulary, content, and transport standards for the structured recording and exchange of health information

- 2015 Edition Base EHR Definition
- Common Clinical Data Set
- Other uses are supported, for example:
  - ❑ Public Health
  - ❑ Social, Psychological, and Behavioral Health

Improve Interoperability

2015 Edition Base EHR Definition

- Focuses, at a minimum, on the functionalities that all users of certified Health IT should possess
- Ensures that the minimum functionalities required by the HITECH Act remain in the Base EHR Definition
- Reminder: The requirements can be met using a combination of certified Health IT Modules

Facilitate Data Access and Exchange

Improve Patient Safety

2015 Edition Base EHR Definition

** Red Italic - New to the Base EHR Definition as compared to the 2014 Edition*

** Privacy and security removed – now attached to the applicable certification criteria

Base EHR Capabilities	Certification Criteria
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.315(a)(5) Problem List § 170.315(a)(6) Medication List § 170.315(a)(7) Medication Allergy List § 170.315(a)(8) *Smoking Status § 170.315(a)(11) (*NEW)* *Implantable Device List § 170.315(a)(14) (*NEW)*
Capacity to provide clinical decision support	Clinical Decision Support § 170.315(a)(9)
Capacity to support physician order entry	Computerized Provider Order Entry (medications, laboratory, or diagnostic imaging) § 170.315(a)(1), (2) or (3)
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures – Record and Export § 170.315(c)(1)
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.315(b)(1) Data Export § 170.315(b)(6) *Application Access – Patient Selection § 170.315(g)(7) (*NEW)* *Application Access – Data Category Request § 170.315(g)(8) (*NEW)* *Application Access – All Data Request § 170.315(g)(9) (*NEW)* Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2)

Common Clinical Data Set

- Renamed the "Common MU Data Set." This does not impact 2014 Edition certification.
- Includes key health data that should be accessible and available for exchange.
- Data must conform with specified vocabulary standards and code sets, as applicable.

Patient name	Lab tests
Sex (NS)	Lab values/results
Date of birth	Vital signs (changed from proposed rule) (NS)
Race (NS)	Procedures
Ethnicity (NS)	Care team members
Preferred language (NS)	*Immunizations (NEW)*
Problems	*Unique device identifiers for implantable devices (NEW)*
Smoking Status	*Assessment and plan of treatment (NEW)*
Medications	*Goals (NEW)*
Medication allergies	*Health concerns (NEW)*

ONC Interoperability Roadmap Goal

2015-2017 Send, receive, find and use priority data domains to improve health and health quality

Red Italic = New data added to data set (+ standards for immunizations) *(NEW)*
Blue Underlined = Only new standards for data (NS)

2015 Edition:
A Numbers Overview

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The 2015 Edition:
68 Proposed Certification Criteria **(including CQM reporting criterion from IPPS rule)** **and** **6 "Additional" Certification Criteria in the Final Rule** • The number of criteria is reflective of flexibility and optionality. • In response to stakeholder feedback, we have and continue to split capabilities out into separate criteria instead of including all the capabilities in a single criterion. For example, see CPOE criteria (formerly 1 criterion; now 3 criteria) and the API and associated privacy and security criteria (formerly 1 criterion; now 5 criteria).
60 Adopted Certification Criteria
14 Proposed Criteria were Not Adopted
2015 Edition as Compared to the 2014 Edition:
16 Unchanged Criteria **(gap certification eligible)**
25 Revised Criteria
19 New Criteria

Key for Following Tables/Slides

The tables on the following slides focus on comparing the adopted 2015 Edition certification criteria with the proposed 2015 Edition certification criteria. The tables also provide two other relevant points of information:

1. They identify whether the adopted 2015 Edition certification criterion is associated with the EHR Incentive Programs (meaningful use/MU) or solely supports other settings and use cases.
2. They compare the adopted 2015 Edition certification criteria to the 2014 Edition certification criteria on the basis of whether the 2015 Edition certification are unchanged, revised, or new compared to the 2014 Edition. This comparison is accomplished by categorizing the 2015 Edition certification criteria into sections based on whether they are unchanged, revised, or new. These three categories are identified by headings at the top of each slide/table. For reference, the meaning and relevance of unchanged, revised, and new are as follows:

   "Unchanged" certification criteria are those that include the same capabilities as compared to prior certification criteria of adopted editions; and to which a Health IT Module presented for certification to the 2015 Edition could have been previously certified to all of the included capabilities.

   "Revised" certification criteria are those that include within them capabilities referenced in a previously adopted edition of certification criteria as well as changed or additional new capabilities; and to which a Health IT Module presented for certification to the 2015 Edition could not have been previously certified to all of the included capabilities.

   "New" certification criteria are those that as a whole only include capabilities never referenced in previously adopted certification criteria editions and to which a Health IT Module presented for certification to the 2015 Edition could have never previously been certified. As a counter example, the splitting of a 2014 Edition certification criterion into two criteria as part of the 2015 Edition will not make those certification criteria "new" for the purposes of a gap certification eligibility analysis.

   Of importance, "unchanged" criteria are eligible for gap certification. This means that the certification of a Health IT Module to an "unchanged" 2015 Edition criterion can be done using the test results from the certification of the Health IT Module to the 2014 Edition version of the criterion. This creates efficiencies and substantially reduces burden.

Not Adopted Certification Criteria

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Not Adopted Criterion Associated with the EHR Incentive Programs (1)
Family Health History – Pedigree
Not Adopted Criteria for Other Settings and Use Cases (13)
Vital Signs
Image Results
Patient List Creation
Electronic Medication Administration Record
Decision Support – Knowledge Artifact
Decision Support – Service
Incorporate Laboratory Tests and Values/Results
Transmission of Laboratory Test Reports
Accessibility Technology
SOAP Transport and Security Specification and XDR/XDM for Direct Messaging
Healthcare Provider Directory – Query Request
Healthcare Provider Directory – Query Response
Electronic Submission of Medical Documentation
Requested Comment; Not Adopted
Work and Industry Occupation Data
U.S. Uniformed/Military Service Data
Pharmacogenomics Data

Unchanged Criteria

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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Unchanged Criteria Associated with the EHR Incentive Programs (15)	
CPOE – Medications	Different than proposed - Adopted with additional optional "reason for order" field
CPOE – Laboratory	Different than proposed • Adopted with additional optional "reason for order" field • Did not adopt CLIA requirements and LOI + eDOS standards • We still strongly support lab interoperability (e.g., we will focus efforts on piloting standards)
CPOE – Diagnostic Imaging	Different than proposed - Adopted with additional optional "reason for order" field
Drug-drug, Drug-allergy Interaction Checks for CPOE	Different than proposed - Did not adopt "user response documentation" proposal
Medication List	Adopted as proposed
Medication Allergy List	Adopted as proposed
Drug-formulary and Preferred Drug List Checks	Different than proposed • Did not adopt the proposed NCPDP Formulary and Benefit standard • We will continue to support efforts to coalesce around a real-time standard
Smoking Status	Different than proposed - Adopted as functional (no standard)

Unchanged Criteria - Continued

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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Unchanged Criteria Associated with the EHR Incentive Programs (15)	
Authentication, Access Control, Authorization	Different than proposed – Replaced the term "person" with "user"
Audit Report(s)	Adopted as proposed
Amendments	Adopted as proposed
Automatic Access Time-Out	Adopted as proposed
Emergency Access	Adopted as proposed
End-User Device Encryption	Adopted as proposed
Transmission to Public Health Agencies – Reportable Lab Tests and Values/Results	Different than proposed - Did not adopt proposed standard; rather, adopted the 2014 Edition standards
Unchanged Criterion that Supports Other Settings and Use Cases (1)	
Accounting of Disclosures	Adopted as proposed

Improve Interoperability

Ensure Privacy and Security Capabilities

Revised Criteria

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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Revised Criteria Associated with the EHR Incentive Programs (25)	
Demographics	Different than proposed - Added sexual orientation and gender identity data
Problem List	Adopted as proposed - Potential attestation for prior certified products
Clinical Decision Support	Different than proposed • Removed lab tests and values/results references from CDS configuration • Did not adopt "user response documentation" proposal • Did not include preferred language for identifying reference information • Reordered the regulation text to align with testing (non-substantive change)
Family Health History	Adopted as proposed - Potential attestation for prior certified products
Patient-Specific Education Resources	Different than proposed - Do not require preferred language (adopted as optional)
Transitions of Care	Different than proposed • Adopted updated C-CDA Release 2.1 standard with only CCD, Referral Note, and (for inpatient setting only) Discharge Summary templates • Health IT must receive and validate both C-CDA Release 1.1 and 2.1 documents for interoperability (not create C-CDA Release 1.1) • More specific requirements for C-CDA section display to improve clinical relevance of displayed data • Adopted patient match data for creation of C-CDA documents with standards

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Facilitate Data Access and Exchange

Revised Criteria - Continued

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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Revised Criteria Associated with the EHR Incentive Programs (25)	
Clinical Information Reconciliation and Incorporation	Different than proposed • Updated to C-CDA Release 2.1 standard and 3 templates • Create a CCD based on the data reconciled and incorporated
ePrescribing	Different than proposed • Did not adopt structured Sig • Added field for "reason for prescription" using ICD-10 • Clarified "all oral liquid medications" in only metric (mL)
Data Export	Different than proposed • Changed name of criterion from "data portability" • Updated to C-CDA Release 2.1 standard and 3 templates • Clarified configuration requirements, including not adopting the 3-year look back period
CQMs – Record and Export	Different than proposed - Adopted newer QRDA I standard, Release 3
CQMs – Import and Calculate	Different than proposed - Adopted newer QRDA I standard, Release 3
CQMs – Report	Different than proposed ***(proposed in FY2016 IPPS proposed rule, but finalized in this final rule)*** • Adopted with newer QRDA I standard, Release 3 • QRDA III DSTU Release 1 with September 2014 Errata

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Revised Criteria - Continued

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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Revised Criteria Associated with the EHR Incentive Programs (25)	
Auditable Events and Tamper-Resistance	Different than proposed ***(proposed as unchanged)*** - Revised to require auditing of user privileges
Integrity	Different than proposed ***(proposed as unchanged)*** - Revised to SHA-2
View, Download, and Transmit to 3rd Party	Different than proposed • Updated to C-CDA Release 2.1 standard and only CCD template • Adopted two ways for transmitting patient health information (email and another encrypted method, which could be Direct) • Removed API – providers have it via the 2015 Edition Base EHR definition • Adopted date and time filtering capabilities similar to "Data Export" criterion • Embedded security requirement is now part of the overall P&S framework
Secure Messaging	Different than proposed • Embedded security requirements are now part of the overall P&S framework • Require SHA-2 as the minimum standard for creating hashes
Immunization Registries	Different than proposed - Adopted a newer version of the proposed standard
Syndromic Surveillance	Different than proposed • Adopted a newer version of the standard and addendum • No certification requirement for the ambulatory setting
Cancer Registries	Different than proposed - Adopted a newer version of the proposed standard

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Facilitate Data Access and Exchange

Revised Criteria - Continued

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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Revised Criteria Associated with the EHR Incentive Programs (25)	
Automated Numerator Recording	Adopted as proposed
Automated Measure Calculation	Adopted as proposed
Safety-enhanced Design	Different than proposed • Added only demographics, problem list, and IDL; removed eMAR • Adopted with a minimum test participant threshold (10) • Alternative user satisfaction measurement may be permitted
Quality Management System	Adopted as proposed – Clarified the requirement is the identification of the QMS
Direct Project	Different than proposed ***(proposed as unchanged)*** • Adopted the updated Applicability Statement (primary Direct protocol) • Require use of the Direct delivery notification specification • Required to send/receive messages in "wrapped" format
Direct Project, Edge Protocol, and XDR/XDM	Different than proposed ***(proposed as unchanged)*** • Adopted the updated Applicability Statement (primary Direct protocol) • Require use of the Direct delivery notification specification • Required to send/receive messages in "wrapped" format • Must support both the XDS Metadata profiles (Limited and Full)

Improve Interoperability

Facilitate Data Access and Exchange

New Criteria

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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New Criteria Associated with the EHR Incentive Programs (12)	
Application Access – Patient Selection Application Access – Data Category Request Application Access – All Data Request	Different than proposed (proposed as 1; now 5 criteria with 3 focused on API) • A standards-based approach is intended for the next appropriate rulemaking • Updated to C-CDA Release 2.1 standard and only CCD template • Adopted date and time filtering capabilities similar to "Data Export" criterion • Removed requirements that the API must include a means for requesting application to register with the data source (will not meet end goal) • Removed XML or JSON requirement, but require computable format • Security requirements – see below
Trusted Connection	***Not proposed - new criterion*** (1 of 5 criteria) • Pulled security requirement out of the proposed API criterion and made it part of the P&S certification framework to apply back to the API criteria • Requires establishment of a trusted connection at either the message-level or transport-level using specified encryption and hashing standards
Auditing Actions on Health Information	***Not proposed - new criterion*** (1 of 5 criteria) • Pulled the security requirement out of the proposed API criterion and made it part of the P&S certification framework to apply back to the API criteria • Similar to the audit criterion (170.315(d)(2)), but without recording of audit log or encryption status (locally stored on end-user devices)

Improve Interoperability

Facilitate Data Access and Exchange

New Criteria - Continued

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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New Criteria Associated with the EHR Incentive Programs (12)	
Implantable Device List	Different than proposed • Added "Distinct Identification Code" to the identifiers for parsing • Revised and expanded the attributes for association with a UDI to comprise key identifying and patient safety-related data about implantable devices • Provided flexibility for developers utilizing the FDA and NLM's GUDID web services to use the SNOMED CT® terminology in lieu of GMDN • Clarified display requirements for allowing users to "change" the active UDIs in a patient's list of implantable devices
Patient Health Information Capture	Different than proposed • Combined capabilities to be "enable a user to identify, record, and access information directly and electronically shared by a patient…." • Clarified that the criterion *supports* the Stage 3 associated measure, but the goal was to set a foundation for accepting information directly from patients
Case Reporting	Different than proposed • No content standard required • Focuses on trigger codes, patient match, and data ("ToC" data + trigger)
Antimicrobial Use and Resistance Reporting	Adopted as proposed

Improve Interoperability

Facilitate Data Access and Exchange

New Criteria - Continued

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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New Criteria Associated with the EHR Incentive Programs (12)	
Health Care Surveys	Adopted as proposed and clarified that the implementation guide consist of three surveys: National Hospital Care Survey, National Ambulatory Medical Care Survey, and National Hospital Ambulatory Medical Care Survey
Accessibility-centered Design	Adopted as proposed
Consolidated CDA Creation Performance	Different than proposed • C-CDA Release 2.1 and applicable templates, depending on presented health IT • Added "completeness" testing requirement per request for comment
New Criteria that Support Other Settings and Use Cases (7)	
Social, Psychological, and Behavioral Data	Different than proposed - Adopted all proposed measures in one criterion (with LOINC codes), except SO/GI (moved to demographics)
Common Clinical Data Set Summary Record – create	***Not proposed - new criterion based on response to request for comment*** • Same "ToC" C-CDA creation, Common Clinical Data Set (and other data), and patient matching requirements • **No** transport standards requirements
Common Clinical Data Set Summary Record – receive	***Not proposed - new criterion based on response to request for comment*** • Same "ToC" C-CDA receive, Common Clinical Data Set and other data, and validate and display requirements • **No** transport standards requirements

Improve Interoperability

Facilitate Data Access and Exchange

New Criteria - Continued

As Compared to the 2014 Edition; and Compared to the Proposed Rule

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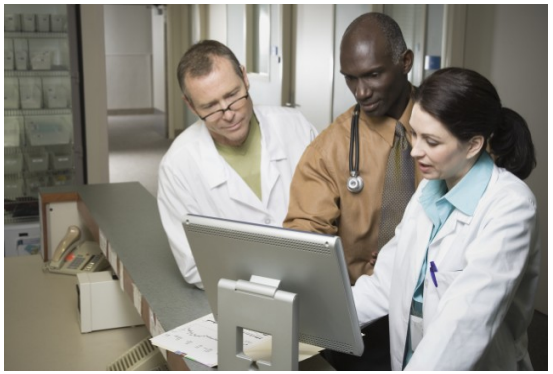
New Criteria that Support Other Settings and Use Cases (7)	
Data Segmentation for Privacy – Send	Different than proposed • Clarified in regulation text that it only applies to document-level tagging • Adopted C-CDA Release 2.1
Data Segmentation for Privacy – Receive	Different than proposed • Clarified in regulation text that it only applies to document-level tagging • Adopted C-CDA Release 2.1
Care Plan	Different than proposed • Adopted C-CDA Release 2.1 standard • Specifically require Health Status Evaluations and Outcomes Section and Interventions Section (V2) for certification based on request for comment
Clinical Quality Measures – Filter	Different than proposed • Adopted QRDA I Release 3 for patient-level; and QRDA III DSTU Release 1 with September 2014 Errata for aggregate-level reports • Health IT must also be able to display the filtered data results in human readable format • Adopted Healthcare Provider Taxonomy (CMS Crosswalk) standard for provider type • Adopted Payment Typology Code Set for patient insurance

Improve Interoperability

Facilitate Data Access and Exchange

Patient Safety Provisions

- Patient matching for transitions of care/referral summaries
- Record and exchange Unique Device Identifiers
- Safety-enhanced Design
  - ❑ A conditional certification requirement (depends on the other capabilities in the Health IT Module) for an expanded set of certification criteria compared to the 2014 Edition
  - ❑ Health IT developers must submit specific information about the user-centered design processes used and applied
  - ❑ Minimum 10 test participants for summative testing
- Quality Management System (QMS)
  - ❑ A mandatory requirement for certification of a Health IT Module to the 2015 Edition
  - ❑ Health IT developers must identify the QMS used to develop, test, implement, and maintain capabilities of certified health IT
  - ❑ The identified QMS system must be:
    - Established by the federal government or SDO; or
    - Mapped to one or more QMS established by the federal government or SDO
  - ❑ Attesting that a QMS was not used is no longer permitted



Improve Patient Safety

Addressing Health Disparities

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Certification Criteria Capabilities	What the Capabilities Provide
More granular recording and exchange of patient race and ethnicity	Allows providers to better understand health disparities based on race and ethnicity, and improve patient care and health equity
Record sexual orientation and gender identity	Represents a crucial first step forward to improving care for lesbian, gay, bisexual, and transgender communities
Record social, psychological, and behavioral data (e.g., education level, stress, depression, and alcohol use)	Allows providers and other stakeholders to better understand how this data can affect health, reduce disparities, and improve patient care and health equity
Filtering for clinical quality measures	Filtering on demographics, problem lists and other data, which will assist providers in identify disparities and opportunities for care improvement
Exchange of sensitive health information (data segmentation for privacy)	Allows for the exchange of sensitive health information (e.g., behavioral health, substance abuse, and genetic information), in accordance with federal and state privacy laws, for more coordinated and efficient care
Record and access information directly and electronically shared by a patient	Addresses health disparities in populations that are less likely to execute care planning documents or provide health information to providers
Accessibility of health IT	• Transparency for the accessibility standards used in development • Web content accessibility for the capabilities of the VDT criterion

Reduce Health Disparities

Certification to the 2015 Edition Use Cases (MU & Beyond)

Certification Program Requirements*				
2015 Edition Mandatory Certification Criteria (n=2)	**2015 Edition Conditional Certification Criteria (n= 12)**	**2015 Edition Certification Criteria Associated with EHR Incentive Programs Stage 3 (n=38)**		**2015 Edition Certification Criteria Supporting the Broader Care Continuum (n=8)**
Quality Management System - (g)(4) (REV)	*Authentication, Access Control, Authorization -(d)(1) (UN)*	*CPOE – Medications - (a)(1) (UN)*	CQM – Record and Export - (c)(1) (REV)	Social, Psychological, and Behavioral Data - (a)(15) (NEW)
Accessibility-Centered Design - (g)(5) (NEW)	Auditable Events and Tamper-Resistance - (d)(2) (REV)	*CPOE – Laboratory - (a)(2) (UN)*	CQM – Import and Calculate - (c)(2) (REV)	DS4P – Send - (b)(7) (NEW)
	Audit Report(s) - (d)(3) (UN)	*CPOE Diagnostic Imaging - (a)(3) (UN)*	CQM – Report - (c)(3) (REV)	DS4P – Receive - (b)(8) (NEW)
	Amendments - (d)(4) (UN)	*Drug-Drug, Drug-Allergy Interaction Checks for CPOE - (a)(4) (UN)*	View, Download, and Transmit to 3rd Party - (e)(1) (REV)	Care Plan - (b)(9) (NEW)
	Automatic Access Time-Out - (d)(5) (UN)	Demographics - (a)(5) (REV)	Secure Messaging - (e)(2) (REV)	CQM Filter - (c)(4) (NEW)
	Emergency Access - (d)(6) (UN)	Problem List - (a)(6) (REV)	Patient Health Information Capture - (e)(3) (NEW)	*Accounting of Disclosures - (d)(11) (UN)*
	End-User Device Encryption - (d)(7) (UN)	*Medication List - (a)(7) (UN)*	Transmission to Immunization Registries -(f)(1) (REV)	Common Clinical Data Set Summary Record – Create -(b)4) (NEW)
	Integrity - (d)(8) (REV)	*Medication Allergy List - (a)(8) (UN)*	Transmission to PHA – Syndromic Surveillance - (f)(2) (REV)	Common Clinical Data Set Summary Record – Receive -(b)(5) (NEW)
	Trusted Connection - (d)(9) (NEW)	CDS - (a)(9) (REV)	*Transmission to PHA – Reportable Laboratory Tests and Values/Results - (f)(3) (UN)*	
	Auditing Actions on Health Information - (d)(10) (NEW)	*Drug-Formulary and Preferred Drug List Checks - (a)(10) (UN)*	Transmission of Cancer Registries - (f)(4) (REV)	
	Safety Enhanced Design - (g)(3) (REV)	*Smoking Status - (a)(11) (UN)*	Transmission to PHA – Electronic Case Reporting - (f)(5) (NEW)	
	Consolidated CDA Creation Performance - (g)(6) (NEW)	Family Health History - (a)(12) (REV)	Transmission to PHA – Antimicrobial Use and Resistance Reporting - (f)(6) (NEW)	
		Patient-Specific Education Resources - (a)(13) (REV)	Transmission to PHA – Health Care Surveys - (f)(7) (NEW)	
		Implantable Device List - (a)(14) (NEW)	Automated Numerator Recording - (g)(1) or Automated Measure Calculation - (g)(2) (REV)	
		Transitions of Care - (b)(1) (REV)	Application Access – Patient Selection - (g)(7) (NEW)	
		Clinical Information Reconciliation and Incorporation - (b)(2) (REV)	Application Access – Data Category Request - (g)(8) (NEW)	
		Electronic Prescribing - (b)(3) (REV)	Application Access – All Data Request -(g)(9) (NEW)	
		Data Export - (b)(6) (REV)	Direct Project - (h)(1) (REV)	
			Direct Project, Edge Protocol, and XDR/XDM - (h)(2) (REV)	

KEY: Criteria are "new," "unchanged," and "revised" as compared to the 2014 Edition

Black Underlined Font/Green Background = NEW to the 2015 Edition (NEW)

Red Italic Font/Gray Background = UNCHANGED criteria (eligible for gap certification) (UN)

Black Font/Gray Background = "REVISED" criteria (REV)

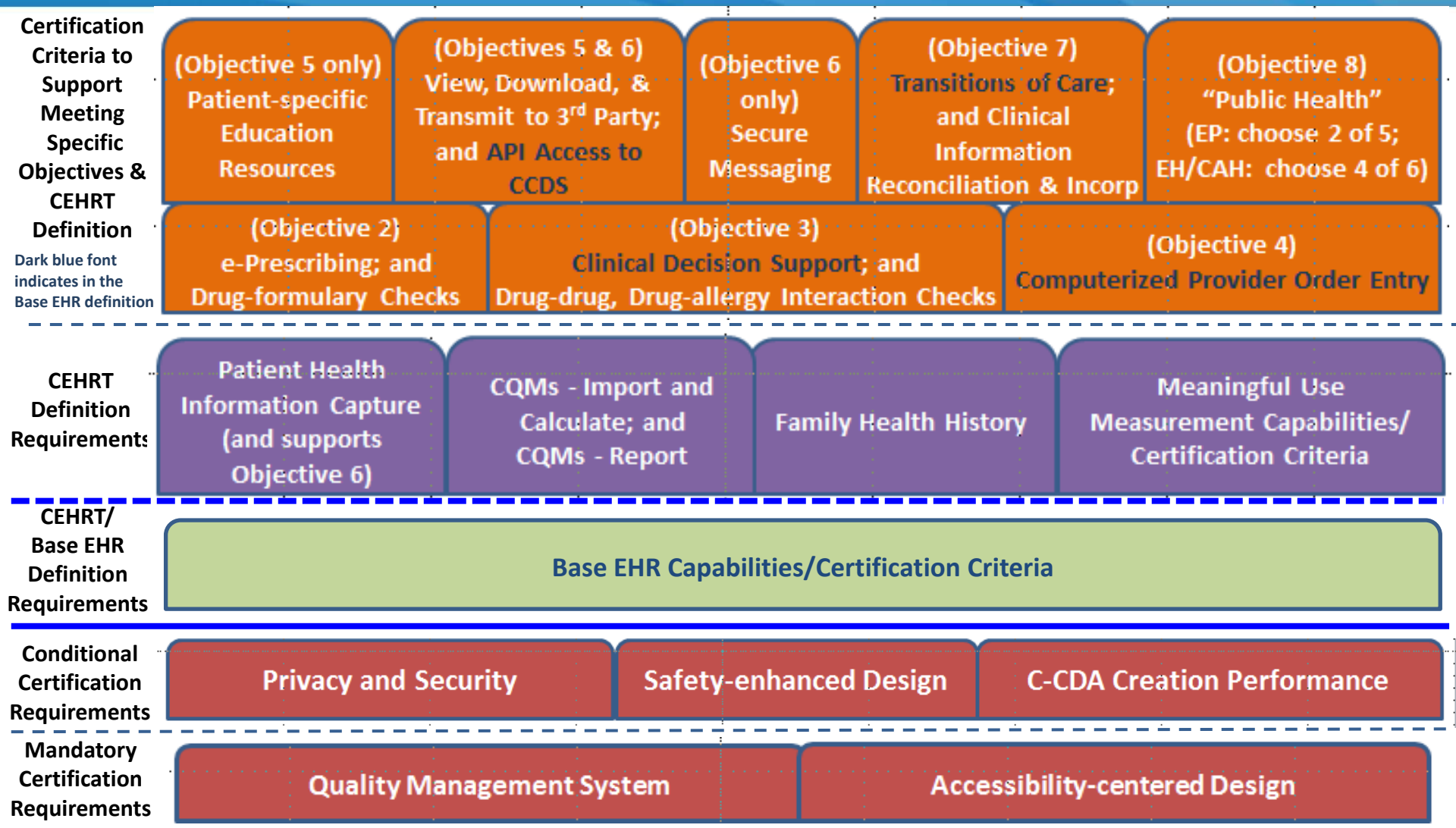
*** These columns identify mandatory and conditional certification requirements (i.e., the application of certain certification criteria to Health IT Modules) that Health IT Modules presented for certification must meet regardless of the setting or program the Health IT Module is designed to support.**

EHR Incentive Programs
Stage 3 Meaningful Use Objectives

- **Objective 1:** Protect Patient Health Information
- **Objective 2:** Electronic Prescribing
- **Objective 3:** Clinical Decision Support
- **Objective 4:** Computerized Provider Order Entry
- **Objective 5:** Patient Electronic Access to Health Information
- **Objective 6:** Coordination of Care through Patient Engagement
- **Objective 7:** Health Information Exchange
- **Objective 8:** Public Health and Clinical Data Registry Reporting

Certified Health IT Module(s) to Support the EHR Incentive Programs Stage 3 in 2018 and Beyond

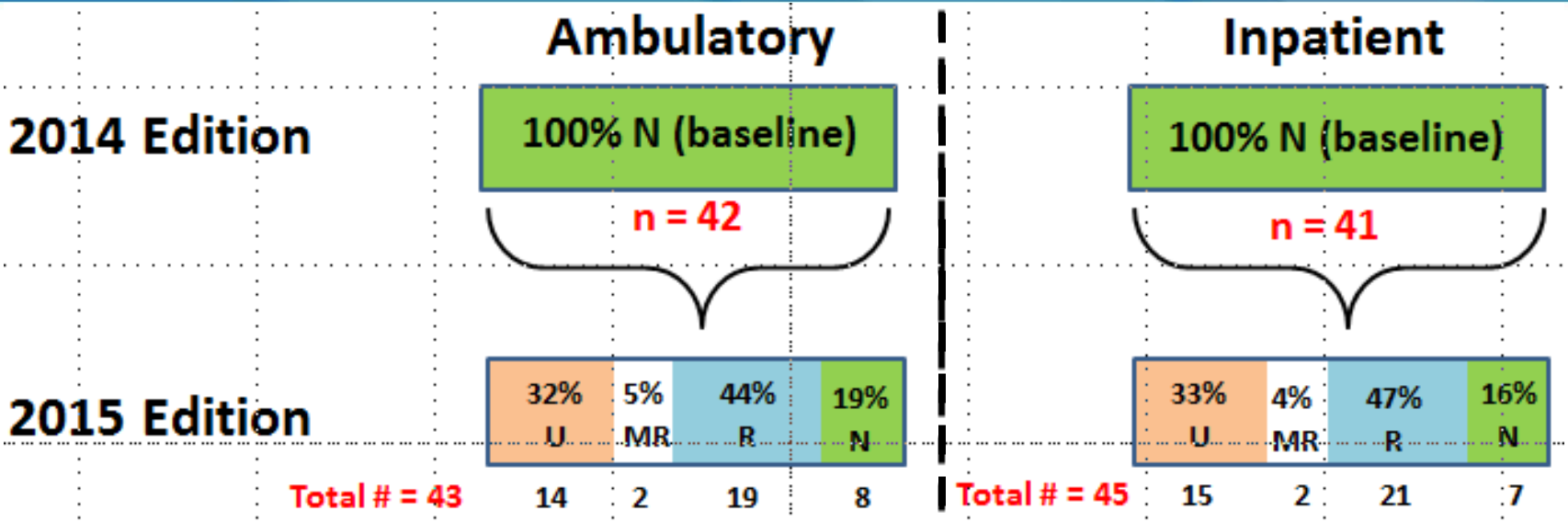
Putting the I in HealthIT
www.HealthIT.gov



Support Stage 3 of the EHR Incentive Programs

What is Minimally Required for Stage 3 in 2018 and Beyond?

2014 Edition vs. 2015 Edition



Bottom Line

- More criteria for certification flexibility (e.g., CPOE and API = 6 criteria).
- 37% of criteria are unchanged or minimally revised for the ambulatory setting.
- 38% of criteria are unchanged or minimally revised for the inpatient setting.
- The total minimum number of criteria needed to participate in Stage 3 is about the same for EPs and slightly more for EHs/CAHs as compared to Stage 2.

Notes: 1. This analysis does not account for potential exclusions. 2. A mix of health IT certified to the 2014 and 2015 Editions may be used to meet Stage 3 in 2017 as long as it does not prohibit an EP, EH, or CAH from meeting a measure. Please see the CMS "Stage 3 and Modifications" final rule.

U = Unchanged criteria R = Revised N = New
MR = Minimally revised criteria (Problem List and Family Health History)

*Note: For public health criteria, EPs choose 2 of 5 measures and EHs/CAHs choose 4 of 6 measures.

Certified Health IT Module(s) to Support Other Health Care Settings (LTPAC Example)

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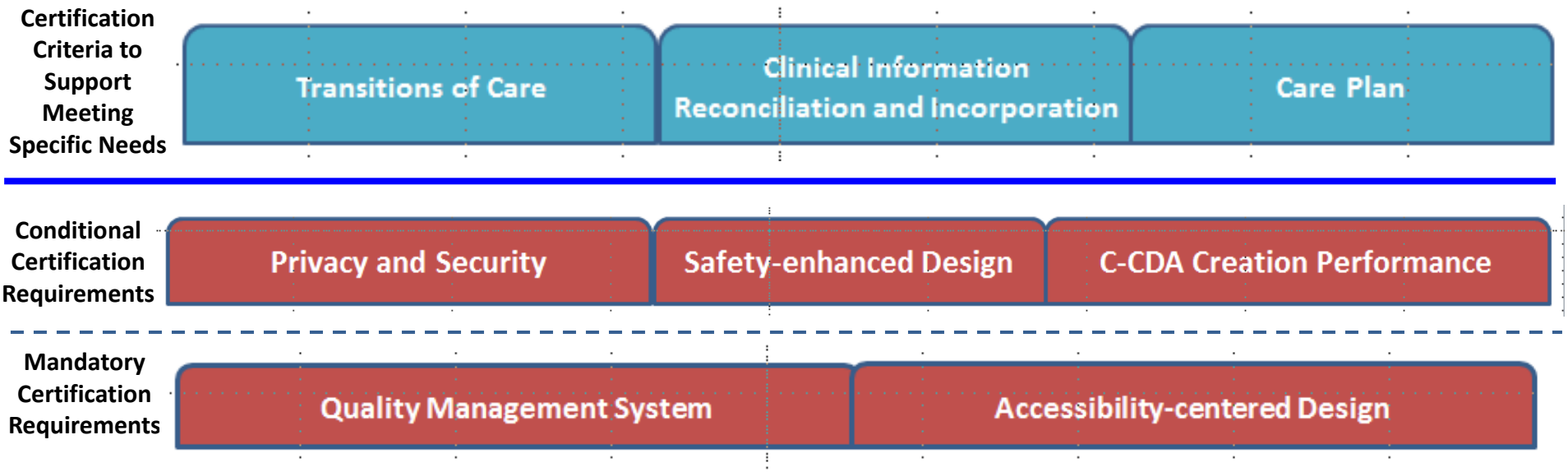
Long-Term and Post-Acute Care Certification (example only)



Use of the ONC Health IT Certification Program to Support the Care Continuum

Certified Health IT Module(s) to Support Other Health Care Settings (Behavioral Health Example)

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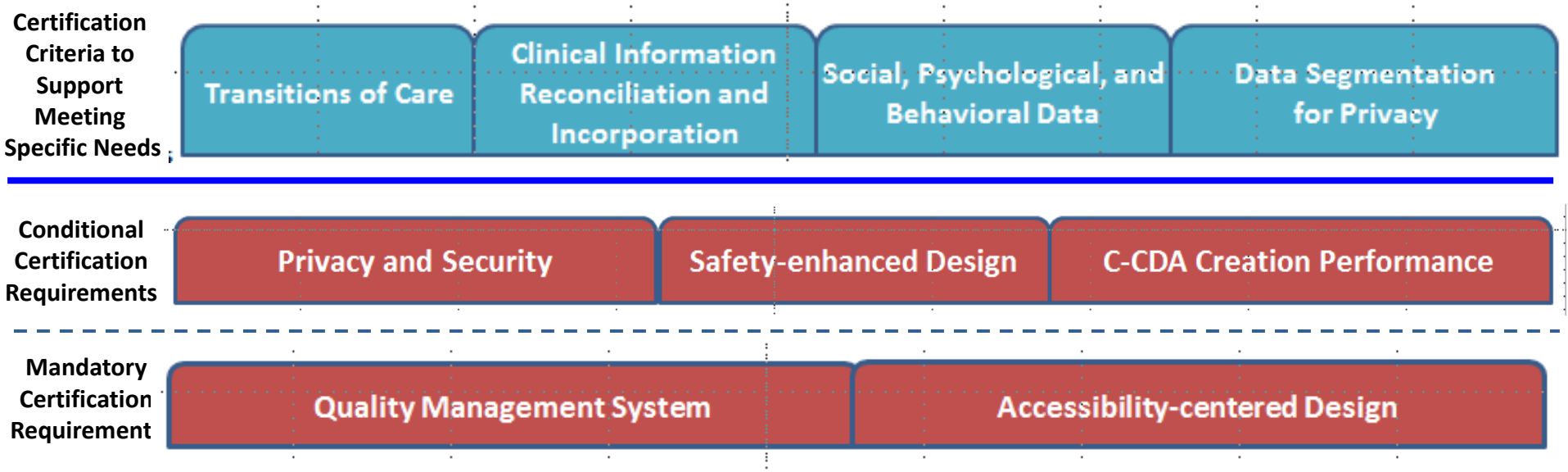
Behavioral Health Certification (example only)



Use of the ONC Health IT Certification Program to Support the Care Continuum

Additional Information and Resources

- **2015 Edition Final Rule**: https://www.federalregister.gov/articles/2015/10/16/2015-25597/2015-edition-health-information-technology-certification-criteria-2015-edition-base-electronic
  - The 2015 Edition final rule provisions become **effective on January 14, 2016**, except for § 170.523(m) (adaptations/updates reporting) and (n) (complaints reporting), which are **effective on April 1, 2016**.
  - There is **no** comment period for this final rule.
- **For more information and guidance on the 2015 Edition Final Rule, please visit**: https://www.healthit.gov/policy-researchers-implementers/2015-edition-final-rule
- **2015 Edition Final Rule Test Procedures and Certification Companion Guides**: The 2015 Edition final test procedures are available for a 30-day comment period. The Certification Companion Guides are not undergoing a formal public comment period, but ONC encourages stakeholders to review the Certification Companion Guides during the public comment period of the 2015 Edition final test procedures. https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method
- **ONC Regulations**: https://www.healthit.gov/policy-researchers-implementers/health-it-regulations