



Health IT for Pediatric Care and Practice Settings

Dr. David Hunt, Office of Policy

Elisabeth Myers, Office of Policy

Samantha Meklir, Office of Policy

Dr. Albert Taylor, Office of Technology


The Office of the National Coordinator for
Health Information Technology



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Section 4001 of the 21st Century Cures Act

Section 4001(b) of the Cures Act includes two provisions related to supporting health IT across the care continuum.

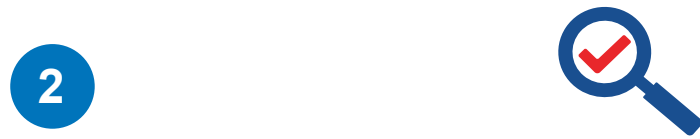
- The first instructs the National Coordinator to encourage, keep, or recognize through existing authorities the voluntary certification of health IT for use in medical specialties and sites of service where more technological advancement or integration is needed.
- The second outlines a provision related to the voluntary certification of health IT for use by pediatric health providers to support the health care of children.

ONC Three Part Approach

ONC's Approach For Identifying Health IT Certification Criteria and Standards To Support Multiple Care And Practice Settings, Including The Pediatric Care And Practice Settings



Analyze certification criteria in the ONC Health IT Certification Program to ensure broad applicability to multiple medical specialties and sites of service.



Focus on the real-time evaluation of standards to determine applicability to medical specialties and sites of service as well as to the broader care continuum, focusing on existing and emerging standards for inclusion in the [ONC Interoperability Standards Advisory \(ISA\)](#).



Work in collaboration with stakeholders to support the development of resources for medical specialties and sites of service for which ONC identifies a need to advance the effective implementation of certified health IT.

Health IT for Pediatric Care and Practice Settings

In response to the requirements set forth in the Cures Act, ONC has

1

Developed ten recommendations for the voluntary certification of health IT for pediatric care that does NOT include a separate certification program for pediatric care and practice settings.

2

Identified current and proposed new 2015 Edition certification criteria that support pediatric care and practice settings.

3

Focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.



We clarified in our final rule that we did not propose to adopt care- or practice-specific certification tracks, or additional program(s), in parallel to the existing voluntary ONC Health IT Certification Program.

ONC Stakeholder Collaboration

ONC Developed Recommendations Based on Stakeholder-Identified Clinical Priorities and the Children's EHR Format



Pediatric stakeholders
identified clinical priorities
and evaluated them with ONC.



[Access Children's EHR Format Here](#)



ONC Recommendations

ONC Recommendations for Health IT Supporting Pediatric Care

1. Use biometric-specific norms for growth curves and support growth charts for children
2. Compute weight-based drug dosage
3. Ability to document all guardians and caregivers
4. Segmented access to information
5. Synchronize immunization histories with registries
6. Age- and weight-specific single dose range checking
7. Transferrable access authority
8. Associate mother's demographics with newborn
9. Track incomplete preventative care opportunities
10. Flag special health care needs

ONC Recommendations - Technical Analysis

Our collaborative technical analysis involved engagement with stakeholders including through listening sessions, subject matter expert review panels, and the Federal Health IT Advisory Committee task force members.



The ONC Cures Act NPRM also included the technical analysis as an appendix to allow the public to review and submit public comment during the comment period on the proposed rule.

Appendix: Pediatric Technical Worksheets

These worksheets contain information on how each recommendation corresponds to the Children's EHR Format and to the existing or proposed new ONC certification criteria. We invite readers to use these worksheets to inform public comment on the recommendations, the inclusion of specific items from the Children's EHR Format¹⁹³, and the identified certification criteria as they relate specifically to use cases for pediatric care and sites of service.

We welcome public comment on the identified certification criteria for each recommendation.

Specifically, we seek comment for each recommendation on the following four broad questions:

- **Q1.** What relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) may impact or support feasibility of the recommendation in practice?
- **Q2.** How can the effective use of IT support each recommendation as involves provider training, establishing workflow, and other related safety and usability considerations?
- **Q3.** Should any of the recommendations not be included?
- **Q4.** Should any of the functional criteria listed under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification Criteria" be removed as a correlated item to support any of the recommendations?

Commenters are encouraged to reference the specific recommendation number (110) with the corresponding question number in their response. For example, "Recommendation 1. Q3."

Commenters are highly encouraged to use the template ONC has created to support public comment on the proposed rule.

¹⁹³ <https://healthit.hhs.gov/health-it-tool-and-resources/pediatric-economics/childrens-electronic-health-record-ehr-format>

Recommendation 1: Use biometric-specific norms for growth curves and support growth charts for children

Alignment with Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

- Title: Use biometric-specific norms for growth curves
- Children's EHR Format: Req-2044 - Release Package 2015 Priority List
- Topic(s): Primary Care Management, Well Child/Preventive Care
- Description: The system shall include the ability to use pediatric age-specific norms for weight, height/length, head circumference, and BMI to calculate and display growth percentiles and plot them over time on standardized Centers for Disease Control and Prevention/World Health Organizations (CDC/WHO) growth curves as appropriate.

Alignment with 2015 Edition Certification Criteria

ONC believes this recommendation is supported by the 2015 Edition definition and criteria listed below:

- **Common Clinical Data Set (CCDS)** including optional pediatric vital sign data elements with the reference range/scale or growth curve for BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than three years of age, and head occipital-frontal circumference for children less than three years of age
- **Demographic criterion** requires the ability to record birth sex in accordance with HL7 Version 3 ("Administrative Gender") and a null flavor value attributed as follows: male (M); female (F); and unknown (UNK)
- **Clinical Decision Support (CDS)** can be used to develop a variety of tools to enhance decision-making in the pediatric clinical workflow including contextually relevant reference information, clinical guidelines, condition-specific order sets, alerts, and reminders, among other tools.
- **Application Programming Interfaces** criteria including the "application access-patient selection", "application access-data category request", and "application access-all data request" which can help address many of the challenges currently faced by caregivers accessing pediatric health data.

Alignment with Proposed New or Updated Certification Criteria

ONC believes this recommendation is supported by the proposed new and updated certification criteria in this proposed rule:

- **United States Core Data for Interoperability (USCDI)**: The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference

ONC Recommendations - Technical Analysis

Health IT for Pediatric Care and Practice Settings

In response to the requirements set forth in section 4001 of the Cures Act, ONC has

- 1 Developed ten recommendations for the voluntary certification of health IT for pediatric care and a separate certification program for pediatric practice settings.
- 2 Identified current and proposed new 2015 Edition criteria that support pediatric care and practice settings.
- 3 Focused on non-regulatory initiatives that respond to stakeholders, including development of a new 2015 Edition criteria to support setting-specific implementation of the Health IT Certification Program.

Health IT for Pediatric Care and Practice Settings

ONC DEVELOPED RECOMMENDATIONS BASED ON STAKEHOLDER-IDENTIFIED CLINICAL PRIORITIES AND THE CHILDREN'S EHR FORMAT



Pediatric stakeholders identified clinical priorities and evaluated them with ONC.



Access Children's EHR Format Here

ONC RECOMMENDATIONS FOR PEDIATRIC HEALTH IT VOLUNTARY CERTIFICATION CRITERIA

1. Use biometric-specific norms for growth curves and support growth charts for children
2. Compute weight-based drug dosage
3. Ability to document all guardians and caregivers
4. Segmented access to information
5. Synchronize immunization histories with registries
6. Age- and weight-specific single dose range checking
7. Transferrable access authority
8. Associate mother's demographics with newborn
9. Track incomplete preventative care opportunities
10. Flag special health care needs

ONC CERTIFICATION CRITERIA TO SUPPORT PEDIATRIC CARE AND PRACTICE SETTINGS

CURRENT 2015 EDITION CRITERIA:

- Transitions of Care
- Care Plan
- View, Download, Transmit
- Application Programming Interface (API)
- Data Segmentation for Privacy
- Problem List
- Electronic Prescribing
- Common Clinical Data Set (CCDS)
- Social, Psychological, and Behavioral Data
- Clinical Quality Measure (CQM)
- Clinical Decision Support
- Immunizations
- Demographic data capture
- Family health history
- Patient health data capture
- Privacy and security

PROPOSED NEW 2015 EDITION CRITERIA:

- United States Core Data Set for Interoperability (USCDI)
- Electronic prescribing
- FHIR-based API
- Data segmentation for privacy

<https://www.healthit.gov/NPRM>

ONC Recommendations - Technical Analysis

- Relevant gaps, barriers, safety concerns, and resources (including available best practices, activities, and tools) that may impact or support feasibility of the recommendation in practice.
- Effective use of health IT itself in support of each recommendation as it relates to provider training, establishing workflows, and other related safety and usability considerations.



This enabled ONC to confirm all ten recommendations and the criteria identified as aligned with each.

- ✓ 10 Recommendations &
- ✓ Correlated Certification Criteria

ONC Certification Criteria to Support Pediatric Care and Practice Settings

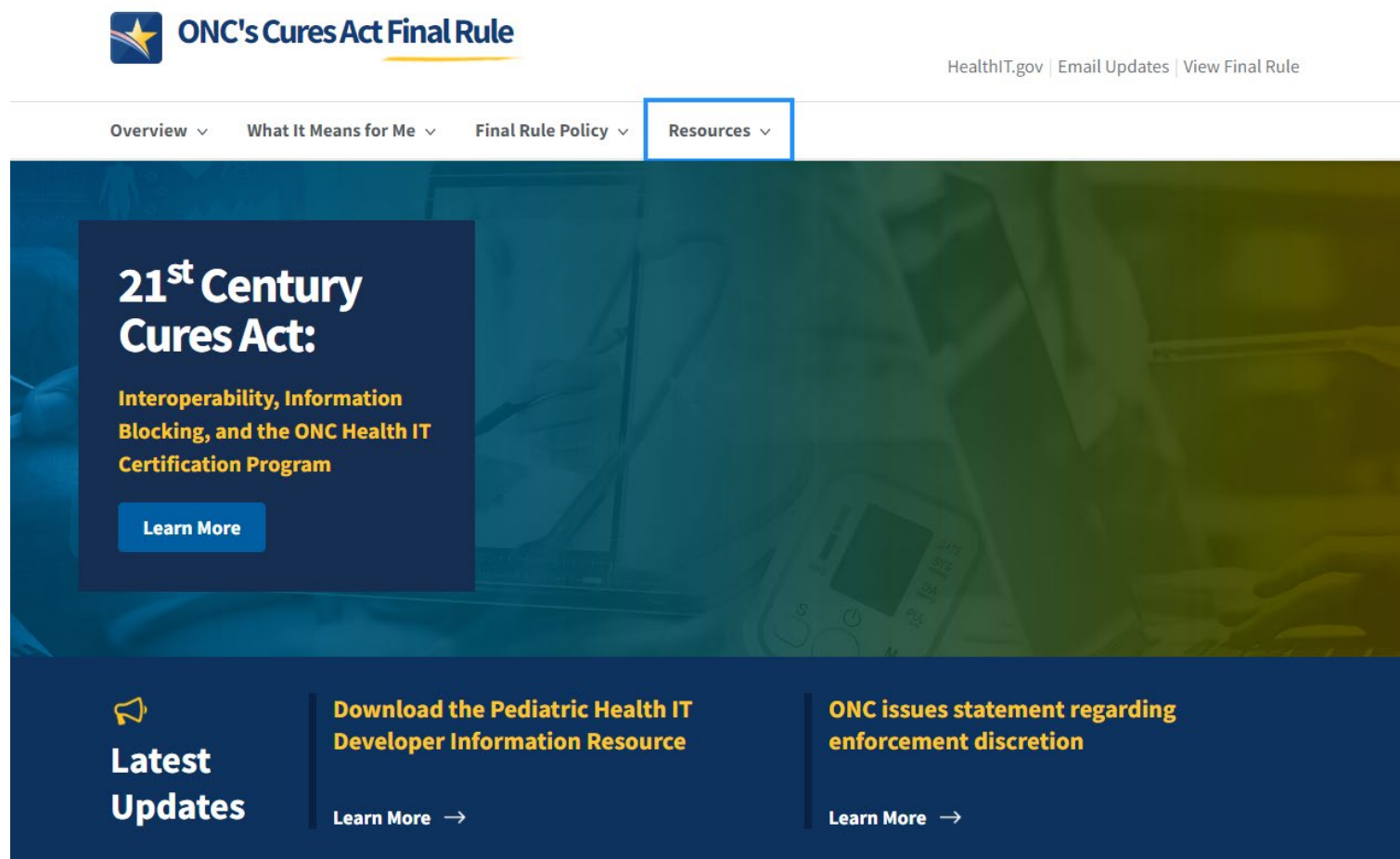
2015 Edition Cures Update

- Application Programming Interface (API)
- Care Plan
- Clinical Decision Support
- Clinical Quality Measure (CQM)
- Demographics
- Electronic Prescribing
- Family health history
- Immunizations
- Patient health data capture
- Privacy and security
- Security Tags – Send and Receive
- Social, Psychological, and Behavioral Data
- Transitions of Care
- United States Core Data Set for Interoperability (USCDI)
- View, Download, Transmit

ONC Certification Criteria to Support Pediatric Care and Practice Settings – Cures Rule

Health IT for the Care Continuum

www.HealthIT.gov/CuresRule



The screenshot shows the homepage of the ONC's Cures Act Final Rule website. At the top, there is a navigation bar with the ONC logo and the title "ONC's Cures Act Final Rule". To the right of the title are links for "HealthIT.gov", "Email Updates", and "View Final Rule". Below the navigation bar is a horizontal menu with four items: "Overview", "What It Means for Me", "Final Rule Policy", and "Resources". The "Resources" item is highlighted with a blue border. The main content area features a large blue banner with the text "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program". Below this text is a blue button labeled "Learn More". At the bottom of the page, there is a dark blue footer with three sections. The first section on the left is titled "Latest Updates" and includes a megaphone icon. The middle section is titled "Download the Pediatric Health IT Developer Information Resource" and includes a "Learn More" link with a right arrow. The right section is titled "ONC issues statement regarding enforcement discretion" and also includes a "Learn More" link with a right arrow.

ONC's Cures Act Final Rule

HealthIT.gov | Email Updates | View Final Rule

Overview ▾ What It Means for Me ▾ Final Rule Policy ▾ Resources ▾

21st Century Cures Act:
Interoperability, Information Blocking, and the ONC Health IT Certification Program

[Learn More](#)

Latest Updates

Download the Pediatric Health IT Developer Information Resource
[Learn More →](#)

ONC issues statement regarding enforcement discretion
[Learn More →](#)



Pediatric Health IT Developer Informational Resource

Pediatric Health IT and ONC Informational Resource (IR)



ONC developed an **Informational Resource (IR)** to help inform the technical and implementation specifications for developers of health IT products used by clinicians that provide health care for children.

- ONC's ten recommendations for health IT for pediatric care
- Relevant criteria within the ONC Health IT Certification Program
- Other technical information to support the implementation of health IT products for the safe and effective health care of children

Pediatric Health IT: Developer Informational Resource (IR)

- This IR is targeted to developers.
- A second related project is underway to create a tool for providers seeking to use the IR in working with their health IT developers
- Our goal with the next project is to create a user-friendly guide to the technical and implementation specifications for health care clinicians that is a companion to this developer IR aligned to the ten recommendations.



The Developer Information Resource – Recommendation Sections

The Informational Resource describes the ten ONC recommendations for an EHR to support care of children. Each recommendation has the following sections:

- Description
- 2015 Edition Cures Update Certification Criteria Alignment
- Implementation Resources
 - References to HL7 Child Health Functional Profile requirements and technical standards that are relevant to the recommendation.
- Other Technical Resources and Tools
 - Reference implementations, technical papers, or applications applicable to the recommendation.
- Children's EHR Format Clinical Recommendations
 - Requirements from AHRQ Children's EHR Format, developed to document gaps between the functions present in most EHRs and functions that would more optimally support the care of children.
- Other Considerations





Pediatric Health IT Developer IR Example

Recommendation Example from IR –

Recommendation 1: Use Biometric-Specific Norms for Growth Curves and Support Growth Charts for Children

Age and sex-specific weight, height/length, head circumference, and body mass index (BMI) percentile measurements are important for assessing normal growth or changes in growth pattern, and problems with growth and development such as obesity, failure to thrive, and certain hormone disorders. User-friendly displays that provide longitudinal information with automatic calculation of growth patterns and comparison with normal velocity are critical components of an EHR supporting care of children, on par with vital signs.

This recommendation aligns with the following 2015 Edition Cures Update Criteria:	
Clinical Decision Support	§170.315(a)(9)
Common Clinical Data Set*	§170.315(b)(4), (5)
Demographics	§170.315(a)(5)
Application Access – Data Category Request*	§170.315(g)(8)
Standardized API for Patient and Population Services*	§170.315(g)(10)
USCDI*	§170.213

* See the 21st Century Cures Act Final Rule and ONC guidance for information on effective dates, sunset dates, and other information on the certification criteria impacted by 2015 Edition Cures Update.

Recommendation Example from IR –

Recommendation 1: Use Biometric-Specific Norms for Growth Curves and Support Growth Charts for Children

Implementation Resources

- **HL7 EHRS-FM Release 2 Functional Profile: Child Health Functional Profile, Release 1; Developmental Screening and Reporting Services Derived Profile, Release 1 - US Realm**
 - The HL7 EHR System Function Model (EHRS-FM): Child Health Functional Profile Release 1; Developmental Screening and Reporting Services Derived Profile, Release 1 – US Realm identifies the critical EHR capabilities for pediatric developmental screening and reporting services. This standard references content and functions from the existing HL7 EHR-S Functional Model Release 2 and complements the HL7 Child Health Functional Profile Release 1.
 - Implementers should refer to section CP.3.1, “Conduct Assessments,” protocol 7.
- **HL7 FHIR Profile: Observation Vital Signs**
 - This profile is referenced by the HL7 FHIR US Core Profile and defines a consistent vocabulary and syntax for vital signs interoperability. It sets the minimum expectations for primary vital signs and additional measurements such as height, weight, and BMI percentile.
 - The profile includes key elements for this recommendation:
 - Head Circumference Observation. This profile constrains the Observations-Vital Signs profile for the measurement of head circumference.
 - Body Height (supplemented with Body height – lying [body length])
 - Body Weight
- **HL7 FHIR US Core Profile: Pediatric BMI per Age Observation**
 - This profile defines the minimum data required to record, search, and fetch pediatric BMI percentile per age and sex observations associated with a patient.
- **HL7 FHIR US Core Profile: Pediatric Weight for Height**
 - This profile defines the minimum data required to record, search, and fetch pediatric weight for height and age observations associated with a patient.
- **USCDI**
 - United States Core Data for Interoperability (USCDI) supports data collection to enable growth charts and defines the following elements as required:
 - Body Height
 - Body Weight
 - Date of Birth
 - Birth Sex
 - BMI percentile (2–20 years of age)
 - Weight for length percentile (Birth to 36 months)
 - Head occipital-frontal circumference percentile (Birth to 36 months)

Recommendation Example from IR –

Recommendation 1: Use Biometric-Specific Norms for Growth Curves and Support Growth Charts for Children

Other Technical Resources and Tools

The following resources and tools are supplemental resources for implementing this recommendation:

- [Boston Children's Hospital SMART Pediatric Growth Chart](#)
 - [Substitutable Medical Applications, Reusable Technologies \(SMART®\)](#) on FHIR application that demonstrates a high-performance, concise, minimal-click presentation of a child's growth over time.
- [SAS Program for the 2000 CDC Growth Charts Ages 0 to <20 Years](#)
 - Calculates percentiles and Z-scores (standard deviations) for a child's sex and age for BMI, weight, height, and head circumference based on the Centers for Disease Control and Prevention (CDC) growth charts.
- [SAS Program for the WHO Growth Charts Ages 0 to <20 Years](#)
 - Calculates percentiles and Z-scores (standard deviations) for a child's sex and age from birth up to 2 years of age for BMI, weight, height, skinfold thickness (triceps and subscapular), arm circumference, and head circumference based on the World Health Organization (WHO) growth charts.
- [WHO Anthro R Package Ages 0 to 5 Years](#)
 - Provides WHO child growth standards (Z-scores) with confidence intervals and standard errors around the prevalence estimates.
- [CDC Growth Charts for Children with Down Syndrome](#)
 - Growth charts for children with Down syndrome, in PDF format.
- [WHO Child Growth Standards](#)
 - Documentation describing the sample and methods used to construct the standards and present growth charts.
- [Fenton Preterm Growth Chart](#)
 - Preterm growth chart applications supporting the WHO growth standard to reflect actual age instead of completed weeks.
- [Olsen 2010 Growth Calculator for Preterm Infants](#)
 - Web interface with data entry, used to report percentiles and Z-scores for preterm infants, with integrated gestational age calculator and decision support.

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Children's EHR Format Recommendations

This recommendation corresponds to the following requirements from the Children's EHR Format:

- [Req-2009: Allow Unknown Patient Sex](#)
- [Req-2019: Record Gestational Age Assessment and Persist in the EHR](#)
- [Req-2042: Support Growth Charts for Children](#)
- [Req-2044: Use Biometric-Specific Norms for Growth Curves](#)

Recommendation Example from IR –

Recommendation 1: Use Biometric-Specific Norms for Growth Curves and Support Growth Charts for Children

Other Considerations

The following considerations should be of interest to the developer community and represent opportunities for future growth in the implementation of the recommendation.

Technical

- Further work is needed to appropriately identify provenance for the algorithm or standard used to present growth data compared to norms. Once identified, provenance should be displayed.
- There is a lack of standardized formats for growth chart data and calculations. Different standards and formats can add work or burden to implementers or users of implementations.


Technical and Clinical

- Children's EHR Format [Req-2045: Provide Alerts for Out-of-Range Biometric Data](#)
 - Alerts or notifications of growth data that are outside of an established norm may be provided to inform a clinician evaluating a growth chart.

Financial

- Some growth charts (particularly for specific pediatric populations) require a license for access/use. These may be cost prohibitive and administratively burdensome to purchase.

Resources and Questions



Interoperability Standards Advisory (ISA)

Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

Home | About the ISA | ISA Content | ISA Publications | Recent ISA Updates | 21st Century Cures

- Vocabulary/Code Set/Terminology +
- Content/Structure +
- Services/Exchange +
- Administrative +
- Appendices +
- Specialty Care and Settings -
- Interoperability for COVID-19 Novel Coronavirus Pandemic
- Opioids
- Pediatrics

Pediatrics

This page identifies interoperability needs, associated technical standards, and implementation specifications with including EHRs, for the delivery of healthcare to children. It is not exhaustive. These interoperability needs, stand practice settings. ONC welcomes feedback to add to this list, and improve these standards and specifications.

Vocabulary/Code Set/Terminology

Family Health History

Representing Patient Family Health History

Immunizations

Representing Immunizations – Historical
Representing Immunizations – Administered

Patient Clinical “Problems” (i.e., conditions)

Representing Patient Clinical “Problems”

Sex at Birth, Sexual Orientation and Gender

Representing Patient Sex (At Birth)

Social, Psychological, and Behavioral

Representing Alcohol Use
Representing Social Connection and Isolation
Representing Exposure to Violence (Intimate Partner Violence)
Representing Financial Resource Strain
Representing Level of Education
Representing Stress
Representing Depression
Representing Physical Activity

Health IT Feedback and Inquiry > Health IT Feedback

ONC Cures Act Final Rule

ONC Cures Final Rule

Questions or feedback about the ONC Cures Act Final Rule regarding:

- Conditions and Maintenance of Certification Requirements
- Updates to the 2015 Edition Certification Criteria
- Information Blocking
- Health IT for Pediatric Care and Practice Settings
- All Other Cures Act Final Rule General Inquiries

Providing User Information

- If you wish to receive a response to your inquiry from ONC and you don't have an account, please enter your first name, last name, and e-mail address so our team can create an account for you.

Create Cancel

Product List (CHPL) and Web Inquiries Standards

ONC

Recommendation 2: Compute Weight-Based Drug Dosage

Displaying a calculated medication dose and how the calculated dose was determined supports safe medication prescribing for pediatric patients by performing independent, redundant checking. Accurate and recently recorded height / length and weight are key inputs to dose calculation for pediatric patients when the medication dose varies based on these factors.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Criteria	Section
Electronic Prescribing*	\$170.315(b)(3)
USCDI*	\$170.213

* See the 21st Century Cures Act Final Rule and ONC guidance for information on effective dates, sunset dates, and other information on the certification criteria impacted by the 2015 Edition Cures Update.

Implementation Resources

Implementation Resources for Recommendation #2

[HL7 EHRS-FM Release 2 Functional Profile: Child Health Functional Profile, Release 1; Developmental Screening and Reporting Services Derived Profile, Release 1 – US Realm](#)

The HL7 EHR System Function Model (EHRS-FM): Child Health Functional Profile Release 1; Developmental Screening and Reporting Services Derived Profile, Release 1 – US Realm identifies the critical EHR capabilities for pediatric developmental screening and reporting services. This standard references content and functions from the existing HL7 EHR-5 Functional Model Release 2 and complements the HL7 Child Health Functional Profile Release 1. Implementers should refer to Sections CP.4.2.2, “Patient-Specific Medication Dosing and Warnings”; CP.4.2.3, “Medication Order Efficiency”; and CP.4.2.4, “Medication Alert Overrides.”

[HL7 FHIR Module: Clinical Reasoning \(Informative\)](#)

The HL7 FHIR Clinical Reasoning Module provides resources and operations to enable the representation, distribution, and evaluation of clinical knowledge artifacts such as Clinical Decision Support (CDS) rules, quality measures, public health indicators, order sets, and clinical protocols. In addition, the module describes how expression languages can be used throughout the specification to provide dynamic capabilities. The Clinical Decision Support Service, CDS Hooks component of the HL7 FHIR Clinical Reasoning Module provides the model to implement age- and weight-based dose checking.





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ONC Cures Rule

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