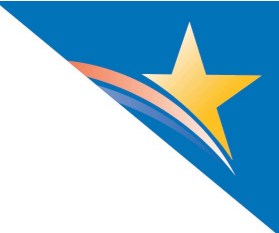The Office of the National Coordinator for
Health Information Technology

Pediatric Health Information Technology: Developer Informational Resource

JUNE 2020

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

PEDIATRIC HEALTH INFORMATION TECHNOLOGY: DEVELOPER INFORMATIONAL RESOURCE

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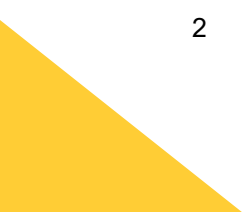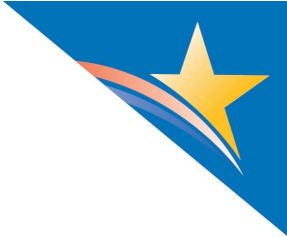
Introduction

PURPOSE AND METHODOLOGY

The dynamic and evolving health information technology (IT) landscape for pediatric settings presents unique challenges and informational needs. There are critical functionalities, data elements, and other requirements that should be present in health IT products to address healthcare needs specific to the care of children.

This Informational Resource (IR) is part of a broader ONC effort to advance interoperable health IT across the care continuum[1] and promote the availability of certified health IT for medical specialty care providers and care settings.[2] It is intended to help inform the technical and implementation specifications for developers of health IT products used by clinicians that provide healthcare for children. This IR identifies ONC's ten recommendations for health IT for pediatric care,[3] relevant certification criteria within the ONC Health IT Certification Program (Program), and other technical information to support the implementation of health IT products to support the safe and effective healthcare of children.

While this IR is primarily intended to support the role of health IT developer, it could interest a wider audience. For example, providers could use the Pediatric Health Information Technology: Provider Informational Resource for information regarding the implementation of health IT products to support pediatric care settings.

In developing this IR, ONC collaborated with various stakeholders to incorporate their input on clinical priorities in pediatric care settings. ONC also conducted a technical analysis to evaluate how developers can use relevant resources to support the health IT needs for pediatric care and sites of service. These resources include, but are not limited to, Department of Health and Human Services (HHS) adopted standards, emerging standards under review, and the ONC Program's health IT certification criteria. We note that in this IR we refer to the Program criteria as the 2015 Edition Cures Update, which is inclusive of both the 2015 Edition Certification Criteria and the 2015 Edition Cures Update criteria. This approach assures both versions are available during the transition between one set of standards and the updated

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[1]   Department of Health and Human Services, *supra* note 1, Section VI., Health IT for the Care Continuum, at 85 FR 25713. Available at https://www.federalregister.gov/d/2020-07419/p-842.

[2]   Id.

[3]   Department of Health and Human Services, Office of the National Coordinator for Health Information Technology. 45 CFR Parts 170 and 171 RIN 0955-AA01, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. Final Rule. Available at https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

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version. Existing 2015 Edition certification criteria are applicable for up to 24 months[4] after the publication date of the final rule; beyond that point, the 2015 Edition Cures Update criteria apply.

The ten recommendations in this document are informed by the American Academy of Pediatrics (AAP) clinical priorities and build on federal and stakeholder activities to date, including efforts supported by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS).

In many cases, the 2015 Edition Cures Update criteria and interoperability standards are broadly supportive across various settings and use cases, including for pediatrics. This IR addresses any gaps with information on other technical resources and available tools.

CONSIDERATIONS FOR USE OF THIS RESOURCE

This IR focuses on the priority functionalities and standards that pediatricians consider critical for health IT to support the safe and effective healthcare of children.

- The IR explores how developers can use the 2015 Edition Cures Update criteria, adopted and emerging standards, and other relevant implementation and technical resources and tools to support the health IT needs for pediatric care and practice settings.
- It identifies other technical resources and tools to support the successful implementation in health IT of pediatric clinical priorities in practice to help address gaps with the existing certification criteria and interoperability standards that are broadly supportive across various settings and use cases.

The following content is relevant to developers. It is incorporated, as applicable, throughout this document.

Available FHIR resources and implementation guidance: It is important to note that some, but not all, of the ten recommendations are supported by a Health Level Seven International® (HL7®) Fast Healthcare Interoperability Resource® (FHIR®)[5] Implementation Guide (IG) or profile. Where there is no IG, the IR provides references to existing HL7 FHIR profiles or other functional specifications. The health IT developer may encounter gaps while implementing these recommendations, and in such instances, ONC encourages developers to leverage existing technology to best meet the recommendations.

Children's EHR Format: This IR builds on previous federal and stakeholder activities, including the Children's Electronic Health Record Format supported by AHRQ and CMS. The AAP supported AHRQ's development of the Children's EHR Format to help bridge the gap between functions present in most EHRs and functions that would provide optimal support for the care of children. The Children's EHR Format

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[4]   ONC is exercising enforcement discretion to waive compliance timelines in order to provide flexibility for health IT developers supporting healthcare providers with the Covid-19 response.

[5]   HL7® and FHIR® are registered trademarks owned by Health Level Seven International and registered with the United States Patent and Trademark Office.

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expands on the hierarchy created by HL7 for the EHR- System Functional Model and incorporates the HL7 Child Health Functional Profile.

Guidance on usability by the National Institute of Standards and Technology Interagency or Internal Report (NISTIR): A Human Factors Guide to Enhance EHR Usability of Critical User Interactions when Supporting Pediatric Patient Care (NISTIR 7865) is an additional resource that may be informative to developers seeking to implement pediatric-specific health IT. This NISTIR guide highlights critical user interactions that can help increase the functionality of pediatric EHRs and prioritize patient safety.

Pediatric care industry resources including Bright Futures™: Many recommendations in this IR are a result of ongoing AAP and AHRQ efforts to provide guidance and standards in pediatric care and pediatric health IT. This IR therefore also suggests additional clinical or technical resources—many of which derive from stakeholders—to aid developers with implementation. Specifically, the AAP develops and stewards the Bright Futures Guidelines, a framework for all pediatric preventive care screenings and well-child visits, and the foundation of pediatric care in the US. Bright Futures™ is a national health promotion and prevention initiative funded by HHS, the Health Resources & Services Administration (HRSA), and HRSA's Maternal and Child Health Bureau (MCHB).

HOW TO USE THIS INFORMATIONAL RESOURCE

This IR includes ten recommendations for an EHR to support care of children. Each recommendation has the following sections:

Description

Text providing details about the recommendation.

2015 Edition Cures Update Certification Criteria Alignment

References to relevant certification criteria that support the recommendations.

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

Requirements from AHRQ's 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.

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Other Considerations

Information to supplement the references.

ONC suggests developers use this information to learn about the significance of each recommendation and review the resources available to guide implementation.

LIMITATIONS

Medicine, clinical practice, and health IT are continually advancing. To optimize care for pediatric patients, health IT developers should update their systems to keep pace with best practices in EHR design. Developers should rely on this IR only as a starting point.

This IR is not intended to serve as legal advice, medical advice, or recommendations to fit a provider's or professional's specific circumstances, including variations in federal, state, or local laws. ONC encourages developers to seek expert advice when evaluating the use of this IR.

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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:

Criteria	Section
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 the 2015 Edition Cures Update.

Implementation Resources
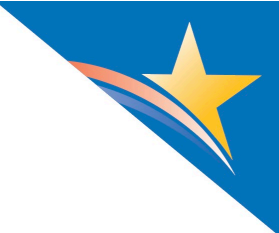
Implementation Resources for Recommendation #1

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.

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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

- Body Height
- Body Weight
- Date of Birth
- Birth Sex
- BMI Percentile (2–20 years)
- Weight for Length Percentile (Birth–36 months)
- Head Occipital-frontal Circumference Percentile (Birth–36 months)
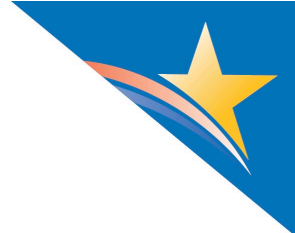
Other Technical Resources and Tools

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

Resource / Tool	Description
Boston Children's Hospital SMART Pediatric Growth Chart	Substitutable Medical Applications, Reusable Technologies (SMART®)6 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.

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6   SMART™ and the SMART logos are trademarks of The Children's Medical Center Corporation.

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Resource / Tool	Description
SAS Program for the WHO Growth Charts Ages 0 to <2 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.
Boston Children's Hospital SMART Pediatric Growth Chart	Substitutable Medical Applications, Reusable Technologies (SMART®)6 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 <2 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.

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Children's EHR Format

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

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.

Last updated May 2020.

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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
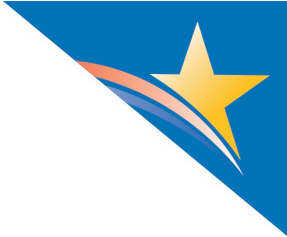
The HL7 EHR System Function Model (EHRS-FM): Child Health Functional Profile Release 1; Developmental Screening and Reporting Services Derived Profile, Release 1 – US Realm identifies the critical EHR capabilities for pediatric developmental screening and reporting services. This standard references content and functions from the existing HL7 EHR-S 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 Efficiencies"; 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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HL7 FHIR Profile: Observation Vital Signs

The Observation Vital Signs profile defines a core set of vital signs observations, including vocabulary Logical Observation Identifier Name and Codes (LOINC®)[7] and Unified Code for Units of Measure (UCUM). Body height, body weight, and BMI are supported in this profile and are required inputs to age- and weight-based single-dose checking. This profile is referenced in the HL7 FHIR US Core IG.

The profile includes key elements for this recommendation:

- Body Height (supplemented with Body height – lying [body length])
- Body Weight
- Body Mass Index

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.

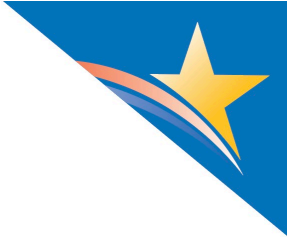## HL7 FHIR US Core Profile: Medication Request

The Medication Request profile is used to record a prescription or order for a medication. This profile sets minimum expectations for the Medication Request resource to record, search, and fetch medications associated with a patient.

USCDI

USCDI supports data collection for weight-based dose checking and defines the following data elements as required:

- Body Height
- Body Weight
- Date of Birth
- Birth Sex
- BMI Percentile (2–20 years)

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[7] LOINC® is a registered trademark owned by Regenstrief Institute, Inc. and registered with the United States Patent and Trademark Office.

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- Weight for Length Percentile (Birth–36 months)
- Head Occipital-frontal Circumference Percentile (Birth–36 months)

NCPDP SCRIPT Standard, Implementation Guide

National Council for Prescription Drug Programs (NCPDP) standard for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities.

Other Technical Resources and Tools

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

Resource / Tool	Description
SCRIPT Implementation Recommendations	This document provides requirements and best-practice guidance for implementation when transmitting NCPDP SCRIPT transactions, including specific guidance for prescribing in pediatric populations.
SMART Health IT Medication Management Applications	SMART catalog of medication management applications.
STEPStools	Safety Through Enhanced e-Prescribing Tools (STEPStools) is an AHRQ-funded project to create a knowledge base that supports an algorithm for rounding of medication doses and applies compounded medication knowledge.

Children's EHR Format

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

- Req-2012: Medication Management, Compute Weight-Based Drug Dosage
- Req-2035: Medication Management, Rounding for Administrable Doses

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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

- The HL7 FHIR US Core IG Medication Request profile states that *dosageInstruction* must be supported but it is not required. There is no guidance that *dosageInstruction* be valued appropriately based on patient factors.

- The SCRIPT specification supports age, weight, and height but not Pediatric Weight for Height as defined by US Core or Pediatric BMI per Age and Sex profile. The HL7 FHIR Observation Vital Signs profile supports LOINC codes for body height (8302-2) or body height – lying (8306-3) and body weight, (29463-7, in kilograms). The body height codes do not specify a unit of measure that would have to be constrained to centimeters. SCRIPT supports LOINC and UCUM.

- Medical devices lag in the adoption of FHIR and may not be able to support this requirement.

Technical and Clinical

- Obesity can result in physiologic alterations that may be important to drug disposition. Dosing recommendations for hospitalized children with obesity remain limited, which can lead to variability in prescribing practices for children with obesity and pose risk of under- or over-exposure to medications. Although sources for CDS related to weight-based dosing exist, there is no IG specific to this recommendation.

- [Children's EHR Format Req-2013: Alert based on Age-Specific Norms](). Req-2013 has not been listed as a specific resource because the recommendation does not include alerts. Alerts to a clinician may be of value when, for example, the patient's weight or height is not within age-specific norms.

Financial

- None of the sources for dose calculations, rounding rules, etc. are free for use. Cost may pose a barrier to adoption / usage.

Last updated May 2020.

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RECOMMENDATION 3: ABILITY TO DOCUMENT ALL GUARDIANS AND CAREGIVERS

Due to the unique caregiver and guardianship scenarios for pediatric patients, such as adoption, foster care, and extended or stepfamilies, maintaining an accurate and structured record of a patient's Care Team has been identified as a critical component of an EHR supporting pediatric patients.

A Care Team includes all the people, teams, and organizations who participate in the coordination and delivery of care for a single patient or group of patients. Care Team members may have access to a patient's data and/or have authority to make medical decisions. The composition of a Care Team is dynamic over time and members may be transient.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Criteria	Section
Care Plan	§170.315(b)(9)
Demographics	§170.315(a)(5)
Transitions of Care	§170.315(b)(1)
Application Access – Data Category Request*	§170.315(g)(8)
Standardized API for Patient and Population Services*	§170.315(g)(10)
Security Tags – Summary of Care– Send*	§170.315(b)(7)
Security Tags – Summary of Care – Receive*	§170.315(b)(8)
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 #3

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

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.1.1, "Manage Patient History" and specifically protocols 2–8.

HL7 FHIR US Core Implementation Guide STU 3: Care Team Profile

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The HL7 FHIR US Core Care Team profile sets the minimum requirements to identify Care Team members associated with a patient. The profile identifies the data that must be valued, optional data items, and the vocabularies and value sets to support coded data.

Other Technical Resources and Tools

ONC has not identified any resources or other tools as supplemental resources for implementing this recommendation.

Children's EHR Format

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

- Req-2006: Ability to Access Family History, Including All Guardians and Caregivers
- Req-2016: Record Parental Notification of Newborn Screening Diagnosis
- Req-2032: Authorized Non-Clinician Viewers of EHR Data

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.

Clinical

- The ability to document parental or guardian notification or permission has been identified as an important component of Care Team management. *See* Children's EHR Format: Req-2008: Ability to Document Parental (Guardian) Notification or Permission.

Technical and Regulatory

- USCDI does not include a detailed definition of a Care Team.

Last updated May 2020

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RECOMMENDATION 4: SEGMENTED ACCESS TO INFORMATION

This recommendation addresses the need for privacy of certain services by segmenting information and providing access to specific segments of the record to specific users. If this recommendation is not accomplished, disparities in care may result when information cannot be appropriately protected.

For example, adolescents may be allowed by law or practice to sequester access to information, such as sexual and behavioral health history in their health record. Some jurisdictions require sequestering a child's record of sexual history or abuse. Sequestering patient-selected information from parental, billing, or insurance communications may be required to protect an adolescent or pediatric patient's privacy.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Criteria	Section
Transitions of Care	§170.315(b)(1)
Security Tags – Summary of Care – Send*	§170.315(b)(7)
Security Tags – Summary of Care – Receive*	§170.315(b)(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 the 2015 Edition Cures Update.
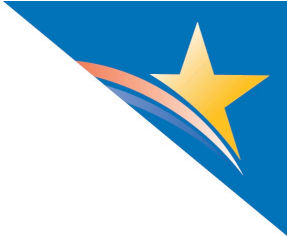
Implementation Resources

Implementation Resources for Recommendation #4

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 Sections CP.9.1, "Produce a Summary Record of Care" and TI.1.8, "Patient Privacy and Confidentiality."

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HL7 C-CDA R2.1 Implementation Guide: Templates for Clinical Notes

This IG, HL7 Consolidated Clinical Document Architecture (C-CDA®) Templates for Clinical Notes, in conjunction with the HL7 CDA Release 2 standard, guides implementation of the following CDA [8] documents and header constraints for clinical notes: Care Plan including Home Health Plan of Care (HHPoC), Consultation Note, Continuity of Care Document (CCD), Diagnostic Imaging Reports (DIR), Discharge Summary, History and Physical (H&P), Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, Unstructured Document, and Patient Generated Document (US Realm Header)

HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P) Release 1

This IG enables the exchange of protected / sensitive personal health information and supports secure exchange of health information and privacy annotations applied to documents, messages, or atomic data elements. This standard supports certification criterion §170.205(o)(1).

HL7 Healthcare Privacy and Security Classification System (HCS), Release 1 (Informative)

This informative guide describes a Healthcare Privacy and Security Classification System (HCS) suitable for automated privacy and security labeling and segmentation of protected health information (PHI) for privacy policy enforcement through security access control services. This is an American National Standards Institute (ANSI®)[9] standard.

Implementation Guide: Direct Edge Protocols

This IG provides guidance for standardizing Direct Edge Protocols (protocols between clients and Health Information Service Providers [HISP]) and improving interoperability between HISPs and Edge Systems (HISP clients). It complements current Direct project specifications.

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[8] CDA® is a registered trademark owned by Health Level Seven International and registered with the United States Patent and Trademark Office.

[9] "ANSI," the ANSI logo, and numerous other identifiers containing "ANSI" are registered trademarks, service marks, and accreditation marks of the American National Standards Institute® (ANSI®).

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Other Technical Resources and Tools

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

Resource / Tool	Description
HL7 FHIR Resource: Consent	The HL7 FHIR Consent resource is a record of a healthcare consumer's choices to permit or deny identified recipients or recipient roles to perform one or more actions within a given policy context.
Test Script: Consent Management for APIs[10]	Developed by ONC to guide implementation of SMART on FHIR Consent2Share profile.
SMART on FHIR Application: Consent2Share	Open source software application sponsored by the United States Substance Abuse and Mental Health Services Administration (SAMHSA). It is designed to support behavioral health data integration with FHIR servers.
HL7 FHIR Resource: Consent	The HL7 FHIR Consent resource is a record of a healthcare consumer's choices to permit or deny identified recipients or recipient roles to perform one or more actions within a given policy context.

Children's EHR Format

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

- Req-2039: Problem-Specific Age of Consent
- Req-2041: Segmented Access to Information

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

- Technical standards to allow alignment with state-specific privacy laws would support this recommendation.

Last updated May 2020.

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[10] 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.

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RECOMMENDATION 5: SYNCHRONIZE IMMUNIZATION HISTORIES WITH REGISTRIES

Access to accurate and up-to-date pediatric immunization information is critical for comprehensive, age-based, preventive care. EHR synchronization with Immunization Information Systems (IIS) and Health Information Exchanges (HIE) is necessary to confirm current immunization status both during and between visits to avoid unnecessary and missed immunizations. Interoperability with IIS allows EHRs to take advantage of the immunization forecasting features provided by many of the state registries. This feature removes the burden from developers of health IT modules to maintain immunization forecasting rules.

Messaging standards established through Meaningful Use requirements remain in place to confirm bidirectional communication and reconciliation function.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Criteria	Section
View, Download, and Transmit to Third Party*	§170.315(e)(1)
Transmission to Immunization Registries	§170.315(f)(1)
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 the 2015 Edition Cures Update.

Implementation Resources

Implementation Resources for Recommendation #5

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 Sections POP.2.1, "Support for Epidemiological Investigation/Surveillance Data Collection" and POP.6, "Measurement, Analysis, Research and Reports."

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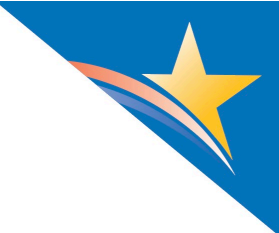
HL7 FHIR Implementation Guide: CDS Immunization Forecast

This IG standardizes the use of CDS to support immunization forecasting in a clinical workflow.

HL7 FHIR Profile: US Core Immunization

Minimum expectations for the HL7 FHIR Immunization resource to record, fetch, and search immunization history associated with a patient.

HL7 Version 2.5.1 Implementation Guide: Immunization Messaging, Release 1.5 and **July 2015 Addendum**

This IG is intended to facilitate the exchange of immunization records between different systems. In addition, it addresses the need to specify usage requirements for data elements that are not included in the standard HL7 usage designations.

See Children's EHR Format Req-2028: Use Established Immunization Messaging Standards.

Other Technical Resources and Tools

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

| Resource / Tool	Description
CDC Clinical Decision Support for Immunization (CDSi)	CDC-maintained logic specification and data definitions supporting the implementation of immunization CDS, aligning with Advisory Committee on Immunization Practices (ACIP) recommendations.
AIRA Tool Sets	The American Immunization Registry Association (AIRA) supports the use of immunization information to ensure healthy communities by supporting IIS with the Aggregate Analysis Reporting Tool (AART) and Message Quality Evaluation Tool (MQE).

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Resource / Tool	Description
HIMSS Immunization Integration Program	Healthcare Information and Management Systems Society (HIMSS)-sponsored public / private initiative to advance immunization interoperability to improve patient care and outcomes. The initiative includes recognition program, test plans, voluntary testing and recognition program, and usability guidance.
CDC: HL7 Standard Code System CVX	CDC-maintained vaccine code system. Health systems and IIS must use concepts from this code system to record vaccine administration.
IIS Functional Standards, v 4.0	CDC-authored standard that describes the operations, data quality, and technology needed by IIS to support immunization programs, vaccination providers, and other stakeholders.
The Immunization Information System Landscape	National Center for Immunization and Respiratory Diseases (NCIRD) overview of the immunization information system landscape.

Children's EHR Format

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

- Req-2011: Synchronize Immunization Histories with Registry
- Req-2027: Produce Completed Forms from EHR Data
- Req-2028: Use Established Immunization Messaging Standards
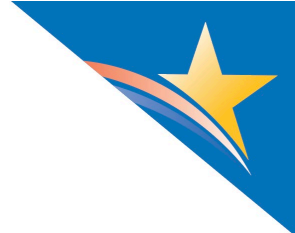
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Other Considerations

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

Technical

- Some EHRs consume messages from immunization registries and do not display them, or only display them to an administrator. Clinicians need access to the registry data at point of care for complete patient information.
- At present, there is no specific HL7 FHIR IG for communication with immunization registries but there is a US Core Immunization profile referenced as part of the US Core IG.
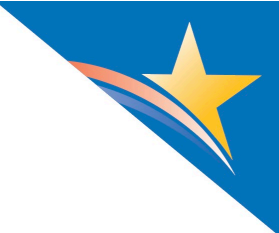
Regulatory

- The recommendation requires bidirectional interoperability between EHRs and jurisdictions; however, the jurisdictions do not use a single standard for immunization data.

Other

- Immunization registries recommended against[11] the requirement to change the interoperability model from HL7 Version 2 (V2) messages to FHIR. Differences in standards will impede communication.

Last updated May 2020.

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[11] *See, e.g.*, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology. 45 CFR Parts 170 and 171 RIN 0955-AA01, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. Final Rule.

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RECOMMENDATION 6: AGE- AND WEIGHT-SPECIFIC SINGLE-DOSE RANGE CHECKING

Single dose treatment for definitive therapy or a loading dose puts pediatric patients at unique risk of subtherapeutic or toxic doses. Evaluation of the age and weight of a pediatric patient is critical to ensure a single dose will not cause harm. EHRs supporting the care of children should reflect this capability by providing alerts where appropriate and displaying normal pediatric ranges for reference and weight-based dose calculations.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Criteria	Section
Clinical Decision Support	§170.315(a)(9)
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 the 2015 Edition Cures Update.

Implementation Resources

Implementation Resources for Recommendation #6

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

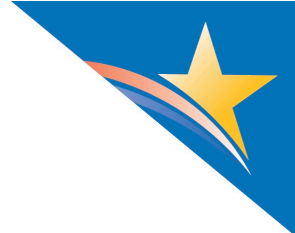The HL7 EHR System Function Model (EHRS-FM): Child Health Functional Profile Release 1; Developmental Screening and Reporting Services Derived Profile, Release 1 – US Realm identifies the critical EHR capabilities for pediatric developmental screening and reporting services. This standard references 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 Sections CP.4.2.2, "Patient-Specific Medication Dosing and Warnings"; CP.4.2.3, "Medication Order Efficiencies"; 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 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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HL7 FHIR Profile: Observation Vital Signs

The Observation Vital Signs profile defines a core set of vital signs observations, including code systems, LOINC, and UCUM. Body height, body weight, and BMI are supported in this profile and are required inputs to age- and weight-based single dose checking. This profile is referenced in the HL7 FHIR US Core IG.

The profile includes key elements for this recommendation:

- Body Height (supplemented with Body height – lying [body length])
- Body Weight
- Body Mass Index

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

USCDI supports data collection for weight-based dose checking and defines the following elements as required:
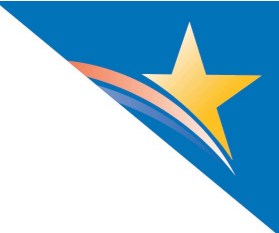
- Body Height
- Body Weight
- Date of Birth
- Birth Sex
- BMI Percentile (2–20 years)
- Weight for Length Percentile (Birth to 36 months)
- Head Occipital-frontal Circumference Percentile (Birth to 36 months)

HL7 FHIR Profile: US Core Medication Request

The Medication Request profile is used to record a prescription or order for a medication. This profile sets minimum expectations for the Medication Request resource to record, search, and fetch medications associated with a patient.

NCPDP SCRIPT Standard, Implementation Guide

National Council for Prescription Drug Programs standard for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities.

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Other Technical Resources and Tools

Certain additional references are relevant to this recommendation:

Criteria	Section
STEPStools	STEPStools is an AHRQ-funded project to create a knowledgebase that supports an algorithm for rounding of medication doses and application of compounded medication knowledge.
SCRIPT Implementation Recommendations	This document provides requirements and best-practice guidance for implementation when transmitting NCPDP SCRIPT transactions, including specific guidance for prescribing in pediatric populations.
SMART Health IT Medication Management Applications	SMART catalog of medication management applications.
ISMP Guidelines for Safe Electronic Communication of Medication Information	The Institute for Safe Medication Practices defines conventions for communicating medication information electronically, including units of measure for height and weight, as well as infant weight.

Children's EHR Format

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

- Req-2037: Age- and Weight-Specific Single Dose Range Checking

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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

- General HL7 FHIR-based testing and acceptance is not evident. Although HL7 FHIR resources, such as Dosage, have data elements for dose range and range rate, there is no clear HL7 FHIR Connectathon validation evidence for this resource.

- The HL7 FHIR US Core IG includes the Medication Request resource and *dosageInstruction* that must be supported but is not required. In addition, there is no guidance that *dosageInstruction* is valued appropriately based on patient factors.

- The SCRIPT specification supports age, weight, and height but not Pediatric Weight for Height as defined by US Core or Pediatric BMI per Age and Sex profile. The HL7 FHIR Observation Vital Signs profile supports LOINC codes for body height (8302-2) or body height – lying (8306-3) and body weight, (29463-7, in kilograms). The body height codes do not specify a unit of measure that would have to be constrained to centimeters. SCRIPT supports LOINC and UCUM.

- HL7 FHIR US Core defines profiles for Pediatric BMI per Age and Sex, and Pediatric Weight for Length and Height. Use of these profiles may provide more accurate, patient- specific dosing information.

Financial

- Cost may be a barrier to adoption and/or usage because few or none of the sources for dose calculations, rounding rules, etc., are free.

Other

- Not all medical devices such as infusion pumps have enough range checking for dosing and may not be able to support this recommendation. There are sources for CDS related to weight-based dosing (noted in references for Recommendation 2); however, there is no IG specific to this recommendation.

Last updated May 2020.

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RECOMMENDATION 7: TRANSFERRABLE ACCESS AUTHORITY

The Care Team members allowed to access a pediatric patient's health record may change due to family dynamics (e.g., foster care, adoption, and divorce) or patient emancipation. Capturing relationships and roles associated with the patient (see Recommendation 3), including a mechanism to manage transitions of access authority, is necessary to support transfer of access authority.

For example, a minor patient becomes emancipated either by attaining a certain age or entering a designated condition (such as pregnancy, experiencing abuse, or active military status). State law or court order determines when emancipation occurs. Transition of a pediatric patient to emancipated minor status may be automatically or manually controlled and enable features for the patient to define access rights.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Criteria	Section
View, Download, and Transmit to Third Party (VDT)*	§170.315(e)(1)
Application Access – Data Category Request*	§170.315(g)(8)
Standardized API for Patient and Population Services*	§170.315(g)(10)
Security Tags – Summary of Care– Send*	§170.315(b)(7)
Security Tags – Summary of Care – Receive*	§170.315(b)(8)

* 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.

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Implementation Resources

Implementation Resources for Recommendation #7

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 TI.1.3, "Entity Access Control."

SMART on FHIR Application: Consent2Share

SMART Consent2Share is an open source software application sponsored by SAMHSA. It is designed to support behavioral health data integration with FHIR servers.

HL7 FHIR Resource: Consent

There are four anticipated uses for the Consent Resource, all of which are written or verbal agreements by a healthcare consumer (grantor) or a personal representative, made with an authorized entity (grantee) concerning authorized or restricted actions, and with any limitations on purpose of use and handling instructions to which the authorized entity must comply.

Consent Management for APIs[12]

Certification test script aligned with HL7 FHIR Consent2Share Profile.

HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P) Release 1

This IG defines the exchange of protected / sensitive personal health information and supports secure exchange of health information and privacy annotations applied to documents, messages, or atomic data elements. This standard supports certification criteria §170.205(o)(1).

HL7 Healthcare Privacy and Security Classification System (HCS), Release 1 (Informative)

This IG describes a Healthcare Privacy and HCS suitable for automated privacy and security labeling and segmentation of PHI for privacy policy enforcement through security access control services. This is an ANSI standard.

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[12] 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.

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HL7 C-CDA R2.1 Implementation Guide: Templates for Clinical Notes

This IG, HL7 Consolidated Clinical Document Architecture Templates for Clinical Notes, in conjunction with the HL7 CDA Release 2 standard, is used to implement CDA documents and header constraints for clinical notes that may be created when transferring access authority, such as HHPoC, CCD, Discharge Summary, H&P, Progress Note, Referral Note, and Transfer Summary.

Other Technical Resources and Tools

ONC has not identified any resources or other tools as supplemental resources for implementing this recommendation.

Children's EHR Format

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

- Req-2026: Transferrable Access Authority
- Req-2040: Age of Emancipation

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

- The test script defined by ONC for Consent Management for APIs (in Implementation Resources for this Recommendation) references HL7 FHIR STU3, which is not the most recent version.[13]
- US Core does not include the HL7 FHIR Consent resource, which along with the HL7 FHIR Clinical Reasoning Module, would support this recommendation.
- Although no IG supports this recommendation, existing infrastructure could support its creation.

Last updated May 2020.

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[13] 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.

RECOMMENDATION 8: ASSOCIATE MATERNAL HEALTH INFORMATION AND DEMOGRAPHICS WITH NEWBORN

Point-of-care access to some maternal health and demographic information is critical for the care of a newborn patient. Critical health information may include but is not limited to maternal infections, immunizations, blood type, maternal substance use that can affect babies (tobacco, alcohol, opiates), behavioral health disorders, and heritable genetic conditions.

Associating maternal information with a newborn is important to the well-being of children in inpatient hospitals and upon transfer to an outpatient pediatric setting or another hospital.

This recommendation suggests that a minimum set of data related to maternal health and demographics is available to an authorized care team member.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Criteria	Section
Care Plan	§170.315(b)(9)
Demographics	§170.315(a)(5)
Family Health History	§170.315(a)(12)
Transitions of Care	§170.315(b)(1)
Social, Psychological, and Behavioral Data	§170.315(a)(15)
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 the 2015 Edition Cures Update.

Implementation Resources

Implementation Resources for Recommendation #8

HL7 EHRS-FM Release 2 Functional Profile: Child Health Functional Profile, Release 1

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 Sections CP.1.1, "Manage Patient History" and Section CPS.2, "Support Externally-Sourced Information."

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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 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 the association and de-association of a mother's health record with her baby's health record.

HL7 FHIR Resource: Patient

This resource contains demographic and other information about a patient and includes an ability to link to another patient's resource (mother) that concerns the original patient (child).

HL7 FHIR Resource: Related Person

A Related Person resource is primarily used for information attribution because Related Persons are often a source of information about the patient.

HL7 FHIR Resource: Family Member History

This resource records significant health conditions for a person (mother) related to the subject (child).

Please refer to the note in Other Considerations, Technical.

HL7 FHIR Profile: Family Member History for Genetics

This profile adds additional information to a family member history supporting observations necessary to enable genetics-based risk analysis for patients.

HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1

The HL7 Clinical Genomics Family Health History (Pedigree) Model is a data standard for capturing family histories within a system and transmitting family histories between systems. This includes describing a patient's full pedigree (family and familial relationships) with diseases and conditions, and the option to link genetic data and risk analysis. The model can transmit complete family history information for clinical decision support and risk assessment.
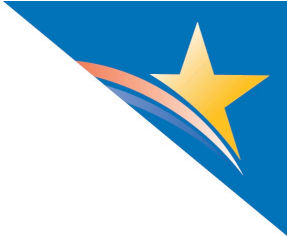
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Other Technical Resources and Tools

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

Resource / Tool	Description
USHIK Mother's Medical Record Number	Mother's medical record number is a metadata item in the United States Health Information Knowledgebase (USHIK) metadata repository.
IHE Patient Care Coordination Technical Framework Supplement Perinatal Workflow	Integrating the Healthcare Enterprise (IHE) specification that defines a profile for integrating perinatal care into an EHR workflow.
IHE Patient Care Coordination Technical Framework Supplement: Labor and Delivery Profiles	This specification defines a profile for integrating labor and delivery care into an EHR workflow.
IHE Quality, Research and Public Health Technical Framework Supplement: Newborn Admission Notification Information	This specification defines a profile for integrating newborn admission notifications into an EHR workflow.
A Granular Ontology Model for Maternal and Child Health Information System	National Center for Biotechnology Information (NCBI) publication describing an HL7 FHIR-based data access model for maintaining maternal and child health data to enable the effective exchange of healthcare data.

Children's EHR Format

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

- Req-2001: Link Maternal and Birth Data to Child Health Record
- Req-2021: Associate Mother's Demographics with Newborn

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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

- There is some implementation guidance on how maternal and newborn records should be connected; however, there is no HL7 FHIR IG that addresses the complete picture, including Care Team. For example, maternal records can be linked where records exist in the same hospital. In a use case where the baby is treated at another hospital, though, it is essential to have aspects of a mother's record in the baby's record.

- There are multiple ways to represent family history in HL7 FHIR. The HL7 FHIR US Core IG requires a supporting Care Team, which includes the use of the Participant Role value set that could identify the mother. A more constrained IG is needed to dictate the use of the fixed code of biological mother.

- Existing standards supporting the documentation of family history are not comprehensive nor have they been tested in a connectathon. For example, the family history-related resources in HL7 FHIR support documentation of conditions and not laboratory test results. The family history-related resources identify the related family member by name only—there is no linkage to a specific patient or encounter. The vocabulary to define the relationships is not aligned with that of Care Team member relationships.

Clinical

- The recommendation does not specify natural biological mother / surrogate versus adoptive or foster mother or biological, adoptive / foster father for demographics.

Technical and Clinical

- The Children's EHR Format requirements list the name of many maternal data elements that could be useful; however, specific maternal data items (and associated standards) that are critical to travel with the newborn's record are not clearly identified.

Last updated May 2020.

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RECOMMENDATION 9: TRACK INCOMPLETE PREVENTATIVE CARE OPPORTUNITIES

Clinical guidelines for the care and treatment of pediatric patients are well established and regularly updated to incorporate new evidence. Pediatric clinical guidelines include age-specific preventive care encounters and procedures such as vaccinations and well visits. Identifying preventive care that is overdue or expected soon is key to maintaining a pediatric patient's health.

This recommendation addresses the need to alert pediatricians when a child presenting at a visit has not received or is due for preventive care services, including age-based well child visits, immunizations, and screening tests. Alerts visible at point of care support a clinician's review of the preventive care schedule with the guardian.

Aligning with this recommendation may include re-purposing the retrospective quality reporting infrastructure to provide a list of patients who have missed preventive services to support patient outreach, prospective reporting to provide a list of patients who should be scheduled for preventive services, and implementation of integrated workflow notifications.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Resource / Tool	Description
Clinical Decision Support	§170.315(a)(9)
Clinical Quality Measures (CQMs)	§170.315(c)(1-4)
Application Access – Data Category Request*	§170.315(g)(8)
Standardized API for Patient and Population Services*	§170.315(g)(10)

* 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 #9

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 Sections CPS.3.1, "Support for Standard Assessments"; CPS.3.3, "Support for Standard Care Plans, Guidelines, Protocols"; CPS 9.4, "Standard Report Generation"; POP.1.1,

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"Support for Health Maintenance, Preventative Care and Wellness"; and POP.1.2, "Present Notifications and Reminders for Preventative Services and Wellness."

HL7 FHIR Module: Clinical Reasoning

The HL7 FHIR Clinical Reasoning module provides resources and operations to enable the representation, distribution, and evaluation of clinical knowledge artifacts such as 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 notification of a patient with either a missed or upcoming preventive care event.

The Quality Reporting component of the HL7 FHIR Clinical Reasoning Module provides the model to implement the reporting aspects of retrospective and prospective identification of patients who have missed preventive care or who are scheduled soon.

Children's Health Care Quality Measures

Established by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) to strengthen the quality of care provided and health outcomes of children in the Medicaid and Children's Health Insurance Program (CHIP).

HL7 FHIR Resource: Flag

An HL7 FHIR Flag resource may be created as the result of patient inclusion in a query or report. Examples of EHR data that could provide input to a decision to flag a patient as at risk for missed preventive care include overdue well-child visit and upcoming well-child visit.

Other Technical Resources and Tools

Resource / Tool	Description
Bright Futures Recommendations for Preventive Pediatric Health Care Periodicity Schedule	Preventive care schedule in PDF form, from infancy through adolescence (21 years).

Children's EHR Format

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

- Req-2024: Track Incomplete Preventive Care Opportunities
- Req-2047: Identify Incomplete Preventive Care Opportunities

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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

- An HL7 FHIR Implementation Guide to identify potential and actual missed preventive care does not exist. Supporting resources, such as Care Plan, Service Request, Activity Definition, Procedure, as well as supporting vocabulary, are available.

Last updated May 2020.

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RECOMMENDATION 10: FLAG SPECIAL HEALTH CARE NEEDS

All pediatric practices provide care for individuals or groups of patients whose needs cannot always be accurately captured by using standard code systems. The definition of special needs can also vary significantly by the type of practice; for example, a specialty care clinic may define special needs differently from a primary care practice.

Tools that allow flexible, customizable identification of patients with special needs, including medical complexity, may be necessary to support this recommendation. The tools should support accurate and timely reporting and allow the designation to be communicated in a clear and intuitive manner. Patients with special needs may also be identified by evaluating a problem list, laboratory results, or inclusion in a patient cohort such as a registry.

Information in a patient's record may be used to prospectively identify children with special needs and/or medical complexity. Flags identifying this information may be added during clinician workflow or as a result of a CDS rule.

This recommendation aligns with the following 2015 Edition Certification Criteria:

Resource / Tool	Description
Clinical Decision Support	§170.315(a)(9)
Clinical Quality Measures (CQMs)	§170.315(c)(1-4)
Problem List*	§170.315(a)(6)
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 the 2015 Edition Cures Update.

Implementation Resources

Implementation Resources for Recommendation #10

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 POP.2.1, "Support for Epidemiological Investigation/Surveillance Data Collection."

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HL7 FHIR Module: Clinical Reasoning

The HL7 FHIR Clinical Reasoning Module provides resources and operations to enable the representation, distribution, and evaluation of clinical knowledge artifacts such as 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 special needs and medical complexity population identification.

The Quality Reporting component of the HL7 FHIR Clinical Reasoning Module provides the model to implement the reporting aspects of special needs and medical complexity population identification.

Children's Health Care Quality Measures

Established by the Children's Health Insurance Program Reauthorization Act of 2009 to strengthen the quality of care provided and improve health outcomes of children in the Medicaid and Children's Health Insurance Program.

HL7 FHIR Resource: Flag

An HL7 FHIR Flag resource may be created as the result of a CDS rule or hook. The flag value may be derived in various ways. HL7 has not yet identified a vocabulary for flag values. Examples of EHR data that could provide input to a decision to flag a patient as having special needs are:

- Problem list entries
- Enrollment in a registry or cohort
- Lab result values
- Findings

Other Technical Resources and Tools

ONC has not identified any resources or other tools as supplemental resources for implementing this recommendation.

Children's EHR Format

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

- Req-2014: Flag Special Health Care Needs

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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

- There is structural support for a confidentiality vocabulary, functional requirements, and exemplar implementations; however, there is no specific FHIR implementation guide that addresses the workflow to flag patients with special needs.

Clinical

- The American Academy of Pediatrics' 2016 Clinical Report: Recognition and Management of Medical Complexity.
- The pediatrics community has identified medically complex patients as among the highest risk of all children for adverse medical, developmental, psychosocial, and family outcomes. EHR support for this recommendation enables identification of medically complex patients and promotes proactive care.

Last updated May 2020.

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Acronym Definitions

Acronym Definitions	
Term	**Definition**
AAP	American Academy of Pediatrics
AART	Aggregate Analysis Reporting Tool
ACIP	Advisory Committee on Immunization Practices
AHRQ	Agency for Healthcare Research and Quality
AIRA	American Immunization Registry Association
ANSI®	American National Standards Institute
BMI	Body Mass Index
CCD	Continuity of Care Document
CCDS	Common Clinical Data Set
C-CDA®	Consolidated Clinical Document MQE Architecture
CDA®	Clinical Document Architecture
CDA® R2	Clinical Document Architecture Release 2
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Program Reauthorization Act of 2009
CMS	Center for Medicare & Medicaid Services
CQM	Clinical Quality Measure
Cures Act	21st Century Cures Act of 2016
DERS	Drug Libraries and Dose Error Reduction Systems
DIR	Diagnostic Imaging Reports
DS4P	Data Segmentation for Privacy
EHR	Electronic Health Record
EHRS-FM	Electronic Health Record System Function Model
FHIR®	Fast Healthcare Interoperability Resource
H&P	History and Physical
HCS	Healthcare Privacy and Security Classification System

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Acronym Definitions	
HHPoC	Home Health Plan of Care
HHS	Health and Human Services
HIE	Health Information Exchanges
HIMSS	Healthcare Information and Management Systems Society
HISP	Health Information Service Providers
HITAC	Health Information Technology Advisory Committee
HL7®	Health Level Seven
HRSA	Health Resources & Services Administration
IG	Implementation Guide
IHE	Integrating the Healthcare Enterprise
IIS	Immunization Information Systems
IR	Informational Resource
ISMP	Institute for Safe Medication Practices
IT	Information Technology
LOINC®	Logical Observation Identifier Name and Codes
MCHB	Maternal and Child Health Bureau
MQE	Message Quality Evaluation Tool
NCBI	National Center for Biotechnology Information
NCIRD	National Center for Immunization and Respiratory Diseases
NCPDP	National Council for Prescription Drug Programs
ONC	Office of the National Coordinator for Health Information Technology
PHI	Protected Health Information
SAMHSA	Substance Abuse and Mental Health Services Administration
SMART®	Substitutable Medical Applications, Reusable Technologies
STEPStools	Safety Through Enhanced e-Prescribing Tools
UCUM	Unified Code for Units of Measure
USCDI	United States Core Data for Interoperability
USHIK	United States Health Information Knowledgebase
VDT	View, Download, and Transmit to Third Party
WHO	World Health Organization

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