Health IT for the Care Continuum Task Force
Draft Recommendations

May 13, 2019

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Robert Wah, co-chair
Health Information Technology Advisory Committee
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
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Dear Carolyn and Robert:

The Health Information Technology Advisory Committee (HITAC) asked the Health IT for the Care Continuum Task Force (HITCC TF or TF) to provide recommendations on: health IT supporting pediatric care and practice settings; data segmentation for privacy; and, input on a request for information on how health IT can support the treatment and prevention of opioid use disorder (OUD). This transmittal offers these recommendations, as informed by the deliberations among the Task Force subject matter experts.

1. Background

1.1 Overarching charge:

The Health IT for the Care Continuum Task Force will provide recommendations on ONC's approach, recommendations, and identified 2015 Edition certification criteria to support pediatric care and practice settings; related criteria to support multiple care and practice settings; and a request for information on how health IT can support the treatment and prevention of opioid use disorder.

1.2 Detailed charge:

Make specific recommendations on:

- The 10 ONC recommendations to support the voluntary certification of health IT for pediatric care, including whether to remove a recommendation;
- Identified 2015 Edition certification criteria for supporting the certification of health IT for pediatric care and practice settings and the pediatric technical worksheets *(which outlines existing, new or proposed certification criteria as correlated for the voluntary certification of health IT for pediatric care as well as correlated supplemental Children's EHR Format Requirements to specific ONC pediatric health IT recommendations);*
- 2015 Edition "DS4P" and "consent management for APIs" proposed certification criteria;
- How health IT can support the treatment and prevention of opioid use disorder in alignment with the HHS strategy to address the opioid crisis

2. Health IT for Pediatrics

The Task Force recommends to retain the ten ONC Pediatric Health IT Recommendations for the voluntary certification of health IT for pediatric care and to affirm the proposed rule identified existing and proposed certification criteria as relevant for the voluntary certification of health IT for pediatric care.

The Task Force also provides recommendations for the development of non-regulatory informational resources that can provide additional technical support for pediatric health IT implementation focused on the ten ONC Pediatric Health IT Recommendations and that this resource may be informed by the implementation considerations as identified by the Care Continuum Task Force.

The TF expressed great enthusiasm for the planned voluntary pediatric certification of EHRs as the members expect significant improvements in the care of children and a reduction in burden for providers caring for children. The TF further notes that these implementation considerations should be regarded as a starting point to achieving full pediatric functionality, and that future work is needed to improve and advance pediatric EHR functionality beyond these first requirements.

Below is a table referencing all the ONC Pediatric Health IT Recommendations with the aligned 2015 Edition Certification Criteria along with the aligned proposed new or updated certification criteria, as well as the Task Force recommendations and implementation considerations to inform future (potential) non-regulatory information resources such (e.g., implementation guides).

ONC Pediatric Health IT Recommendations HITCC Task Force Crosswalk			
ONC Pediatric Health IT Recommendation and Supplemental Children's EHR Format Requirements	**Alignment with 2015 Edition Certification Criteria**	**Alignment with Proposed New or Updated Certification Criteria**	**HITCC Task Force Draft Recommendations and Implementation Considerations to Inform Future (Potential) Non-Regulatory Informational Resource (e.g., Implementation Guide)**

Recommendation 1: Use biometric-specific norms for growth curves and support growth charts for children
 	
Supplemental Children's Format Requirements for Recommendation 1:
1. Allow unknown patient sex
2. Record Gestational Age Assessment and Persist in the EHR
3. Support growth charts for children
	• Common Clinical Data Set* (CCDS)
	• Demographic
	• Clinical Decision Support (CDS)
	• Application Programming Interfaces
		• United States Core Data for Interoperability (USCDI)
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Should include a visual display to serve as an alert
			  ○ Displayed value must be able to reference correct data sets (limit to data that are in the public domain and evidence based)
			• **Recommendation for Supplemental Requirements:** Retain all supplemental requirements as is for Recommendation 1

Recommendation 2: Compute weight-based drug dosage **Supplemental Children's Format Requirements for Recommendation 2:**	• Electronic Prescribing	• United States Core Data for Interoperability (USCDI) • Electronic Prescribing	• **Recommendation**: All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed • **Additional Implementation Considerations:**

1. Rounding for administrable doses 2. Alert based on age-specific norms			○ Minimum standard is limited to liquid, enteral medications that are dosed based on weight ○ Should be displayed in mL ○ Calculators – should not be able to round more than what is humanly measureable ○ Prescription final dose should be transmitted with metadata – additional information in text on how dose was derived ○ Include original weight for calculation ● **Recommendation for Supplemental Requirements:** Retain "Rounding for administrable doses" and remove "Alert based on age-specific norms" (pertains to medication dosing only due to the lack of availability of age specific dose ranges for pediatric medication in the public domain)
Recommendation 3: Ability to document all guardians and caregivers **Supplemental Children's Format Requirements for Recommendation 3:** 1. Ability to document parental (guardian) notification or permission 2. Record parental notification of newborn screening diagnosis 3. Authorized non-clinician viewers of EHR data 4. Document decision-making authority of patient representative	● Care Plan ● Transitions of Care ● Application Programming Interfaces ● Transitions of Care ● Demographic	● Unites States Core Data for Interoperability (USCDI) ● Data Segmentation for Privacy ● Application Programming Interfaces	● **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed ● **Additional Implementation Considerations:** ○ Guardian and caregiver information should be documented in a structured way (including role) ○ Encourage more robust nomenclature development towards a standard in the future to reference (e.g., through various paths including Standards Development Organizations, Interoperability Standards Advisory, USCDI) ○ Should have infinite ability to add list for all relevant contacts of the family (no limited fixed number) ○ Ability to manage list of active and historical participants (remove, archive, or start/end date) ● **Recommendation for Supplemental Requirements:** Retain all supplemental

			requirements for Recommendation 3 (with additional implementation consideration that the "Authorized non-clinician viewers of EHR data" requirements should not be provided as free text (allows user to choose from a vendor provided terminology of authorized non-clinician viewers)

Recommendation 4: Segmented access to information
 	
Supplemental Children's Format Requirements for Recommendation 4:
1. Problem-specific age of consent
	• Data Segmentation for Privacy
	• Transitions of Care
		• United States Core Data for Interoperability (USCDI)
		• Data Segmentation for Privacy
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Prevent what information gets sent out relevant to dependents on family based insurance (e.g., billing information)
			  ○ A user should be able to identify items that they want protected
			  ○ Prevent tagged data from showing in CDA, portal, or exit note given to another provider
			• **Future work considerations**: improvement in the transmission and sharing of data, and level of granularity involved with tagging
			• **Recommendation for Supplemental Requirements:**
			  ○ Remove "Problem-specific age of consent" requirement (due to challenges of varying state and local laws)

Recommendation 5: Synchronize immunization histories with registries
 	
Supplemental Children's Format Requirements for Recommendation 5:
1. Produce completed forms from EHR data
	• Transmission to Immunization Registries
	• View, Download, and Transmit to Third Party (VDT)
		• United States Core Data for Interoperability (USCDI)
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Needs future work into consolidating state immunization forecasting model into single resource
			  ○ Reduce amount of time to update forecasting

			○ Look into onboarding practices and resources for immunization forecasting ○ Clinicians should be able to verify source origins ○ The TF supports existing resources and investments by CDC and stakeholders for improving standards and interoperability of the Immunization Information Systems (IIS) including the voluntary testing and recognition program for EHRs and other clinical software, and the Immunization Collaborative convened by the Healthcare Information and Management Systems Society (HIMSS) and the American Immunization Registry Association (AIRA) ● **Recommendation for Supplemental Requirements:** ○ Retain supplemental requirements as is for Recommendation 5
Recommendation 6: Age and weight-specific single-dose range checking	● Clinical Decision Support (CDS) ● Application Programming Interfaces (API)	● United States Core Data for Interoperability (USCDI) ● Application Programming Interfaces (API)	● **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed ● **Additional Implementation Considerations:** ○ Consider similar limitations on dose calculations as seen in Recommendation 2 (Compute weight-based drug dosage) ○ Existing sources for dose range recommendations should be integrated into workflow ○ Allow user access to best practices or standards (demonstrating correct information source + element of shown work for clinician to verify) ○ Ability to test EHR accuracy ○ Include in QA/QI testing process

Recommendation 7: Transferrable access authority
 	
Supplemental Children's Format Requirements for Recommendation 7:
1. Age of emancipation
	• View, Download, and Transmit to Third Party (VDT)
	• Application Programming Interfaces
		• Data Segmentation for Privacy
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ more control needs to be at the end user (e.g., mark individuals with specific privileges until standard nomenclature can be developed)
			  ○ Distinguish authority to access patient's data vs. medical decision making authority
			  ○ Recommend an ad hoc limited standard or best practice paper to be developed in the meantime
			  ○ Need for nomenclature to be developed based on state/local laws
			  ○ Contradictory access – broad and vague at moment (EHR should be able to document via text field)
			• **Recommendation for Supplemental Requirements:**
			  ○ Retain supplemental requirements as is for Recommendation 7

Recommendation 8: Associate maternal health information and demographics with newborn	• Care Plan
	• Transitions of Care
	• Demographics
	• Family Health History
	• Social, Psychological, and Behavioral Data
		• United States Core Data for Interoperability (USCDI)
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Information should be available in a format that can be exported and easily digested by pediatric EHR
			  ○ Further integrate records between maternal and child (e.g., capability exists but mainly as text info such as family health history)
			  ○ Further research is needed on existing transmission of this type of data

Recommendation 9: Track incomplete preventative care opportunities	• Clinical Decision Support (CDS)
	• Clinical Quality Measures
	• Application Programming Interfaces
		• Application Programming Interfaces (APIs)	• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Generate lists for recall purposes
			  ○ Flag patients – create alert for when patient falls outside expected values

Recommendation 10: Flag special health care needs	• Problem List
	• Clinical Decision Support (CDS)
	• Clinical Quality Measures
		• United States Core Data for Interoperability (USCDI)
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Ability to determine generic flags
			  ○ Ability to transmit in coded way from system to system
			  ○ Ability to track mental health for children
			  ○ Would like to see incorporated into SNOMED or ICD

The last column as noted includes implementation considerations to inform future (potential) non-regulatory informational resource as identified by the TF. In addition to these considerations for specific pediatric recommendations, the TF members identified considerations that cut across these recommendations and, they believe, should help inform the future development of any implementation guide. This includes the importance of accounting for setting specific implementation guidance as pertains to both ambulatory and inpatient settings; and, it also includes the importance of identifying priority use cases to inform any future implementation resource. One such priority use case involves support for the long- term needs of pediatric survivors of complex conditions. The TF notes the value of a pediatric record that supports the needs of children with complex conditions through childhood and the transition to care in adult settings.

3. Opioid Use Disorder (OUD) Request for Information (RFI)

The TF recommends that ONC consider the following for any future activities related to the Opioid Use Disorder Request for Information.

3.1 Request for Information on Health IT and Opioid Use Disorder Prevention and Treatment

As part of our deliberations, the HITCC TF discussed various topics around how health IT can support the treatment and prevention of opioid use disorder in alignment with the HHS strategy to address the opioid crisis. Therefore we would like to provide feedback as per ONC's request for information.

We believe health IT can further clinical priorities, as well as public health goals, while offering more systematic coordinated approaches for OUD prevention and treatment. For example, health IT can support a clinician's ability to access and use community resource information and to make referrals for individuals with or at risk for OUD. We also believe that ideally the medication history in Prescription Drug Monitoring Programs (PDMPs) should be available "as a single point of entry" for clinicians to access without burden of having to log in to and use multiple portals. Having explored efforts to improve standards and interoperability involving the Immunization Information Systems (IIS) as pertains to the ONC Pediatric Health IT Recommendation on immunizations, the TF identified that in the context of PDMP interoperability- any national efforts to harmonize PDMP data could make state variations less likely to impede interoperability and integration efforts.

As a general sense and value, existing and new criteria can support clinical priorities and advance interoperability for OUD. The successful implementation of health IT can help support OUD and aid in the achievement of national and programmatic goals, especially where they may align with initiatives across the Department of Health and Human Services (HHS) and with stakeholder and industry led efforts.

The Task Force also discussed topics around health IT solutions and effective approaches to improve opioid prescription practices and clinical decision support (CDS) for OUD. We explored issues of burden, usability, and "trigger" for CDS Hooks from a clinician's perspective as pertains to workflow considerations and acknowledge the value of CDS tools, including CDS Hooks for the OUD use care, and recognize the importance of having underlying data available and of the United States Core Data for Interoperability (USCDI). We note that implementation should be made as simple as possible (possibly one click) to ease tracking and monitoring the desirable outcome. In addition, the TF recommends that these CDS Hooks should be functional at point of care, especially for rural areas where internet connection can be unreliable.

The TF also recommends the creation of a standardization order sets to more effectively and quickly bring decision support into the treatment of this disorder.

3.1.1 Data Segmentation for Privacy (DS4P) and Consent Management for APIs Certification Criteria

ONC proposes to remove the current 2015 Edition DS4P-send and receive certification criteria and replace them with three new DS4P criteria (two for C-CDA and one for FHIR). The Task Force supports this proposal and acknowledges that DS4P would help for opioid management and provide greater confidence in sharing OUD information. The TF also recognizes that the "consent management for APIs" proposal would also aid in furthering the exchange of information. The TF notes that, with appropriate protections in place, health IT can help providers electronically use and share data allowing providers to

appropriately share health information while both complying with laws/legal requirements[1] and respecting/honoring patient privacy preferences, often referred to as consent requirements.[2][3][4]

As an implementation consideration, the TF recommends that a user should be able to identify items that they want protected. The TF also acknowledges a need for the development of a minimal data set description to represent stakeholder consensus on what data is considered private. The TF notes that further work is needed to develop patient privacy best practices for universal adoption.

The TF identifies published resources to help inform on the development of these privacy practices as referenced below:

- Carequality Principles of Trust. Ratified Jan 2015. The Sequoia Project, 2017. https://sequoiaproject.org/wp-content/uploads/2017/08/Carequality_Principles-of-Trust_Final.pdf
- Carr JM., Chariperson, National Committee on Vital and Health Statistics. Letter to Secretary of Health and Human Services Kathleen Sebelius. 10 November 2010. https://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/101110lt.pdf
- CommonWell Health Alliance Member Services Agreement. 28 December 2018. https://www.commonwellalliance.org/wp-content/uploads/2019/01/CommonWell-MSA-28Dec2018-1.pdf
- Cuevas AG, O'Brien K, Saha S. Can patient-centered communication reduce the effects of medical mistrust on patients' decision making? *Health Psychol.* 2019 Apr;38(4):325-333.
- Hazin R, Brothers KB, Malin BA, *et al*. Ethical, legal, and social implications of incorporating genomic information into electronic health records. *Genet Med* 2013 Oct 15(10):810-816.
- Kilbride MK and Joffe S. The New Age of Patient Autonomy: Implications for the Patient-Physician Relationship. *JAMA* 2018 Nov 20;320(19):1973-1974.
- Minari J, Brothers KB, Morrison M. Tensions in ethics and policy created by National Precision Medicine Programs. *Hum Genomics* 2018 Apr 17;12(1):22. doi: 10.1186/s40246-018-0151-9.
- "Protecting Sensitive Health Information in the Context of Health Information Technology." Consumer Partnership for eHealth. June 2010. http://go.nationalpartnership.org/site/DocServer/Sensitive-Data-Final_070710_2.pdf?docID=7041
- Santana MJ, Manalili K, Jolley RJ, *et al.* How to practice person-centred care: a conceptual framework. *Health Expect*. 2018 Apr; 21(2): 429–440.
- The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. October 2015. https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf

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[1] *See HIPAA FAQs* https://www.hhs.gov/hipaa/for-professionals/faq/index.html *with noted specific example FAQs in subsequent footnotes*

[2] https://www.hhs.gov/hipaa/for-professionals/faq/264/what-is-the-difference-between-consent-and-authorization/index.html

[3] https://www.hhs.gov/hipaa/for-professionals/faq/488/does-hipaa-permit-a-doctor-to-discuss-a-patients-health-status-with-the-patients-family-and-friends/index.html

[4] https://www.hhs.gov/hipaa/for-professionals/faq/personal-representatives-and-minors/index.htm

- The Office of the National Coordinator for Health Information Technology. Trusted Framework and Common Agreement Draft 2. April 2019. https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf

Additional resources for historical purposes:

- The Office of the National Coordinator for Health Information Technology. Patient Consent for Electronic Health Information Exchange and Interoperability. https://www.healthit.gov/topic/interoperability/patient-consent-electronic-health-information-exchange-and-interoperability
- The Office of the National Coordinator for Health Information Technology. Health Information Privacy Law and Policy. https://www.healthit.gov/topic/health-information-privacy-law-and-policy
- The Office of the National Coordinator for Health Information Technology. Health Information Technology. https://www.healthit.gov/topic/health-information-technology

3.1.2 Health IT and Neonatal Abstinence Syndrome (NAS)

In its September 2018 report, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*, the HHS Office of the Surgeon General describes how the incidence of Neonatal Abstinence Syndrome (NAS), has increased dramatically in the last decade along with increased opioid misuse. ONC has requested public comment on these health IT policies, functionalities and standards to support providers engaged in the treatment and prevention of OUD including for the NAS use case.

The HITCC TF supports the idea of health IT policies, functionalities and standards to support providers engaged in the treatment and prevention of OUD. Specifically for the NAS use case, the TF recommends exploring broader ways to begin standardizing definitions with order sets. These order sets must be computable and identify specific language for EHRs to implement more accurately. In addition, we recommend that when such data sets are created, the data sets should not be used for punitive measures as it may discourage patients from receiving care when needed (e.g., child protection services and prosecution).