ONC Notice of Proposed Rulemaking to Improve the Interoperability of Health Information (2/2019)

Public Health Issues, Impacts, and Opportunities (v8)

NPRM: https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health
Text: https://www.healthit.gov/sites/default/files/nprm/ONCCuresActNPRM.pdf
ONC Summary: https://www.healthit.gov/sites/default/files/page/2019-02/HITACNPRMPresentation.pdf
Note: Page numbers below are from the Federal Register version of the NPRM

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
USCDI (see earlier blog) p. 7440	ONC proposes to replace the Common Clinical Data Set (CCDS) with a new standard which subsumes the CCDS data and adds some additional data classes. It includes minimum standard code sets for many data elements. This would likely include a process for annual update of the standard. This would take effect 24 months after the publication of the final rule.	Electronic Case Reporting (eCR) is one of the certification criteria explicitly identified for use of the USCDI. The impact on the HL7 Electronic Initial Case Report (eICR) specification needs to be examined. Immunization and syndromic surveillance data submission code sets are explicitly identified for compliance. The code sets proposed for USCDI need to be examined to determine whether they are correct as proposed. The NPRM asks for advice on several items which may have a public health impact: • Pediatric vital signs • Eight specific types of clinical notes, structured or unstructured • Provenance data elements • Replacement of "Medication Allergies" with "Substance Reactions" (likely the associated SNOMED-CT codes), which may have an impact on immunization or other adverse event reporting

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
NCDPD SCRIPT 2017017 p. 7444	Replacement of NCPDP SCRIPT version 10.6 with NCPDP SCRIPT 2017071 for ePrescribing, but not fully until Medicare Part D phases out the older version.	State PDMP projects need to assess whether their systems are compatible with this new version, or will be by the effective date of the final rule.
EHI Export p. 7446	Within 24 months, replacement of an existing C-CDA data export capability with a new, more general one until APIs mature enough for this capability to be unnecessary. Key elements include: • Single patient at patient's request and patient panel for EHR migration • All available data, new or old, even in PDF format, though the NPRM asks if a time filter should be optionally specified (*e.g.,* only data from the past year) • No proscribed format, but format must be published hoping that a few common formats will dominate • Needs to be timely, but not real time (to avoid potential for information blocking – see below)	This may be an opportunity for public health to benefit from more standardized and comprehensive formats for EHR data export that may facilitate public health registry data *import.* While we are not suggesting that this data import replace *routine* public health registry reporting, there are some cases where a more complete patient history (or subset of a history) may be desired (*e.g.,* most IIS only requires *new* vaccine administrations to be sent though retrospective vaccine histories are also desired).
FHIR API p. 7476	Consistent with the Cures Act and its definition of interoperability "without special effort," the NPRM is embracing the deployment of the FHIR API, initially as a read-only method of implementing seamless and consistent interoperability. Though this section is long and complicated, here are the salient points: • Both single patient and multiple patient queries would be supported.	At least initially, public health reporting transactions do not appear to be directly impacted by this proposal. However, as FHIR becomes more pervasive in the clinical community, some public health registry activities (*e.g.,* IIS query/response) may come under pressure to support FHIR. Currently, there is no organized activity in the IIS community in this regard.

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
	• ONC seems uncertain of which version of FHIR to mandate, feedback is requested on several proposals including R2, both R2 and R3, both R2 and R4, or just R4. • Proposes adopting a bundle of specific profiles to be referred to as "API Resource Collection in Health" or "the ARCH" aligned with USCDI: AllergyIntolerance; CarePlan; Condition; Device; DiagnosticReport; Goal; Immunization; Medication; MedicationOrder; MedicationStatement; Observation; Patient; Procedure; Provenance; DocumentReference (for clinical notes). • Proposes use of OpenID/OAuth for authentication. • Proposed use of SMART Standalone Launch and EHR Launch • Applies *only* to specifically-identified "API-focused" certification criteria: o Select a patient o Respond to requests for patient data in specific data categories o Respond to requests for patient data in all data categories • FHIR endpoints must be published • Very complicated rules proposed for charging fees for these capabilities so as not to engage in data blocking (see below)	One potential side effect is that vendors who provide public health applications (like IIS) as well as CEHRT software/modules would find that *all* of their products (CEHRT or not) subject to these regulations. This may or may not impact their public health products adversely. Electronic case reporting (eCR) standards development *is* currently pursuing a parallel set of activities for the eICR using both C-CDA as well as FHIR technologies and may be better positioned in the near future. More ancillary public health activities, such as provision of clinical decision support (CDS) services for immunization evaluation and forecasting or determining reportable conditions may also benefit from consideration of FHIR-based technologies (like CDS Hooks), though there is no such requirement being proposed in the NPRM.

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
Encryption p. 7450	ONC is proposing better reporting of the ability of Health IT encrypt of authentication credentials and utilize multi-factor authentication within six month of publishing the final rule.	Any health IT module – including modules that support public health reporting – would need to attest as to whether they encrypt their authentication credentials. As it has been good practice for many years, this effectively sets a new floor of compliance for public health registries. As proposed in the NPRM, the discussion of multi-factor authentication tacitly presumes that the interoperability is *interactive* between the user and the data source, as opposed to being an automated transaction. It is important that public health request explicit recognition in the final rule that *automated* transactions such as public health reporting cannot support multi-factor authentication.
Voluntary HIT for Pediatric Care Settings p. 7457	Consistent with the Cures Act, ONC is proposing voluntary certification for pediatric care settings that build upon existing certification criteria and add just a few additional items. The proposal is based on the AHRQ Children's EHR Format. The appendix to the NPRM contains a worksheet and RFI asking for feedback about the ten recommendations that ONC has developed based initially on a review of the Children's EHR Format by the American Academy of Pediatrics back in 2017. While many of the recommendations may affect children's health (and therefore public health), the most relevant recommendation for public health	With respect to recommendation 5, • The noted alignment with the Children's EHR Format seems appropriate. • The noted alignment with 2015 Edition Certification Criterion seems appropriate. • The noted alignment with Proposed New or Updated Certification Criteria does *not* seem appropriate and needs comment: o The reference to the inclusion of pediatric vital sign data elements in the USCDI is not relevant to immunization reporting or query. o The requirement for FHIR is not currently consistent with CDC/AIRA

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
	interoperability is **Recommendation 5: Synchronize immunization histories with registries**.	standards or practices for immunization data submission or query/response and public health is not currently funded to provide this capability from with IIS. o The supplemental requirement for production of a school, camp or child care form from EHR data is not consistent with current IIS functionality or practice where such reports are generated from the IIS when required. It is worth noting that the format of official reports tends to differ across jurisdictions and it may not be reasonable for EHR vendors to maintain reports for all jurisdictions used by their products. The IIS community should study this requirement and consider technical solutions to make these differing report formats more readily available.
RFI: Opioid Use Disorder Prevention and Treatment p. 7461	ONC is seeking comment and suggestion on how existing certification criteria support opioid use disorder prevention and treatment, and how additional criteria might improve the situation.	State PDMP projects should carefully review this section of the NPRM and related certification criteria and make recommendations for changes and additions.
RFI: Requiring TEFCA p. 7466	ONC wonders whether rulemaking should require compliance with the Trusted Exchange Framework and Common Agreement (TEFCA, see earlier blog), when (and if) it is released. The requirement would only be on vendors who support interoperability and not, for instance, on vendors who support ancillary	As previously described, TEFCA as originally proposed does little to further public health goals and does not seem to propose strategies or technologies that are at the heart of public health data interoperability. It was always purported to be a voluntary activity and any substantial change to that understanding

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
	services like clinical decision support (CDS). The impetus for this suggestion is related to preventing information blocking (see below).	would need to be done only based on a clear understanding of where TEFCA has evolved since its original draft release.
Communications about CEHRT p. 7467	Many EHR vendors have restrictive clauses in their contracts with provider organizations that prohibit discussion or display of EHR experiences to the public. ONC proposes clarifying a CEHRT user's right to communicate privately or publically about his or her experience with products, including the display of screen shots to exemplify that experience.	If adopted, this provision may provide an opportunity for public health to speak more openly about CEHRT that does not meet public health reporting requirements well and to facilitate exchange of information between agencies about their experiences with various CEHRT products and vendors.
Real World Testing p. 7495	ONC is proposing to require real-world testing for interoperability which would require CEHRT vendors annually to publish publicly formal test plans as well as test results for their products. Testing could be done with real or synthetic data (or a mix) and would have to cover certified products whether they are in use or not.	Two types of CEHRT testing are currently in wide use by CEHRT vendors and users. First, the "laboratory environment" testing of EHRs is conducted as part of the certification process itself. Second, for interoperability, the National Institute of Standards and Technology (NIST) provides interoperability testing tools for vendors and users of HIT. The ONC proposal includes all public health reporting certification criteria, including data formats, APIs, and transport. If adopted, this represents an opportunity for public health agencies and organizations to coordinate the real-world testing of CEHRT to ensure more consistent implementation across the country. There is also the potential for significant cost savings for both public health and CEHRT vendors in leveraging common infrastructure that might be deployed to support this testing.

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
Standards Version Advancement Process p. 7497	ONC has recognized that the process of including specific standards and versions of standards in formal rulemaking prevents easy adoption of newer versions of standards as they become available due to the onerous nature of rulemaking itself. ONC is proposing to permit health IT developers to voluntarily use in their certified Health IT Modules newer versions of adopted standards once the new version is certified by ONC. Likely ONC would certify new versions through an annual process tied to the Interoperability Standards Advisory (ISA). Vendors would have to warn users with sufficient time and with a plan, and would be able to self-certify the version if NIST testing facilities did not support it yet.	While adoption of newer standards is laudable and can enable richer functionality, there is risk here that vendors will be able to implement new versions of interoperability standards that public health agencies are not prepared to support. Conversely, this is also an opportunity for public health to adopt and promote newer versions of standards more quickly than current rulemaking allows. Public health should request that ONC clarify the process for its selection of newer versions of standards that is a prerequisite for use by vendors, and that ONC needs to explicitly indicate that public health will be actively involved in standards version selection.
Information Blocking p. 7508	This is one of the main sections of the NPRM. That is a potentially huge new process for both the government and healthcare community. Here are just a few of the salient points as we understand them: • Defined as a practice that must be *likely* to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI). • Applies to vendors developing CEHRT and their products, whether certified or not. • Also applies to health information exchanges and networks, apparently regardless of their CEHRT status. Seems to include vendors who hold property rights	This section of the NPRM will likely keep lawyers busy for months to come. The rules are long, detailed, complicated, and confusing. Public health will also need to struggle with understanding how these proposed rules affect its activities and ask lots of questions in any comments related to this section. Here are just a few questions public health agencies might ponder: • While a state-run HIEs is explicitly within the definition, does a public health interface engine qualify as a covered activities under this rule? • Would delays in on-boarding provider organizations for public health reporting be considered information blocking under

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
	to vocabularies as well. • Covers *identifiable* EHI of all types, including clinical, administrative and even pricing data; de-identified data is excluded. • ONC proposes seven exceptions to the rule. A key exception relevant to public health is promoting the privacy of EHI by abiding by Federal, state and local law. • There is an extensive discussion about consent and how consent laws might affect information blocking. • There is an extensive discussion about the limitations on charging fees for fear of engaging in information blocking activities which generally contain fees to the recovery of reasonable costs in developing and deploying relevant technology in a non-discriminatory way. • Finally, ONC asks whether activities required to support TEFCA should be exempt from these rules. It appears that anyone would be able to make claims against a covered organization which would have to "defend" those claims to HHS.	this rule (*e.g.,* a long on-boarding queue)? • Would *obstacles* to primary or secondary use of data either possessed or transmitted by public health (other than those required by law) constitute information blocking? • Could legal action be taken by HHS against a government agency that it determined *might* be engaged in information blocking? • Would public health *preference* for interfacing to certain types of organizations over others constitute information blocking (*e.g.,* connecting larger provider organizations before smaller ones, or connecting pediatric practices over adult practices)? • Would IT vendors who fulfill contracts for products or services based on public health requirements be subject to sanction under the rule if the activities they are being instructed to conduct are determined to be information blocking?
RFI: Registries p. 7553	ONC is asking questions specifically about the suitability of FHIR R4 for supporting improved exchange between a provider and a registry in several very discreet ways. Additionally, ONC asks for "any other comments stakeholders may have on implementation of the registries provisions" of the Cures Act (Section 4005).	This RFI is not exclusively directed at public health registries but includes clinician-led clinical data registries. For its portion, public health needs to make clear the current limitations in consideration, let alone deployment, of any version of FHIR to support registry reporting and activities.

Topic w/ONC Fact Sheet Link	Brief Description	Issues, Impact, or Opportunities
		With respect to the broader question of public health registries, Section 4005 of the Cures Act has only very general language that requires EHRs to "…be capable of transmitting to, and where applicable, receiving and accepting data from, registries in accordance with standards recognized by the Office of the National Coordinator for Health Information Technology…." Any comments related to this broad requirement are acceptable and this may be a good opportunity for public health to provide some education and opinion.
RFI: Patient Matching p. 7554	A nine-question RFI is included in the NPRM asking a wide variety of questions about patient matching, referencing a recent Cures Act-required GAO report (see recent blog) on this topic. Topics include: • Data elements available for matching • Unique pediatric matching requirements • Notion of involving patients themselves in matching • Metrics for measuring matching • Measures of database duplication level • Input on private sector emerging techniques, including referential matching and biometrics • Additions to or constraints on USCDI that might enable or facilitate matching	Public Health is in a strong position to offer comments and suggestions from its experience with patient matching and should launch a specific effort to respond to this RFI. In addition, the CMS Interoperability and Patient Access NPRM contains a slightly different RFI to which public health should also respond (p. 7656). Topics include: • Use of a patient matching algorithm with a proven success rate • Use of a particular software solution for patient matching • Requiring a CMS-wide identifier • Standardization of data elements for matching across CMS • Sources for data proofing • Use of patient-generated data