ONC Final Rule: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (3/2020)

Public Health Issues, Impacts, and Opportunities (v1)

Final Rule: https://www.healthit.gov/curesrule/
Text: https://www.healthit.gov/cerus/sites/cerus/files/2020-03/ONC_Cures_Act_Final_Rule_03092020.pdf
Proposed to Final Rule Comparison (ONC): https://www.healthit.gov/cerus/sites/cerus/files/2020-03/NPRMvsFinalRule.pdf
Note: Page numbers in the first column are from the Federal Register version of the NPRM

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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. Data and corresponding code sets relevant to public health is scattered throughout the USCDI specification. For example, for immunization the USCDI references the CVX and NDC code sets in slightly newer versions than the ones in CCDS. Additional code sets relevant to	Public health has had little formal input to the development of USCDI. While it purports to identify a *minimum* data set for interoperability transactions, USCDI data classes and data elements are not uniformly required for all public health transactions and some of the data defined should *not* be sent to public health. Note that ONC is requesting an exemption for USCDI from The National Technology Transfer and Advancement Act (NTTAA) requirements that standards adopted by the Federal government must be developed or adopted by voluntary consensus standards bodies. At minimum,	Replaced CCDS with USCDI v1 and associated "Standards Version Advancement Process" (SVAP). ONC clarified that USCDI comes into effect *through* specific certification criteria and not in and of itself (p. 107). The certification criterion "transmission to public health agencies – electronic case reporting" (§ 170.315(f)(5)) would be subject to USCDI compliance. The discussion, however, seems to make it optional for public health to make use of data elements from USCDI that are not currently within eCR specifications (p. 110).

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	patient demographic (like race/ethnicity) are mentioned as well. The NPRM goes on to single out the Immunization and Syndromic Surveillance conformance criteria as ones for which they are considering, "changing the certification baseline versions of the code set for these criteria from the versions adopted in the 2015 Edition final rule to ensure complete interoperability alignment."	someone should represent public health on the USCDI Task Force. Electronic Case Reporting (eCR) is one of the certification criteria explicitly identified for use of the USCDI, but not all the data in USCDI is required (or even wanted) for an Electronic Initial Case Report (eICR), while some additional data *is* required. The code sets proposed for USCDI need to be examined to determine whether they are correct as proposed. In some cases, ONC is ambiguously considering revisions that are not clearly identified in the NPRM. Public health has an opportunity to make specific suggestions, for instance to update versions of the relevant code sets to be more current. 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	ONC did not update the code sets referenced for Immunization and Syndromic Surveillance conformance criteria (p. 116-17). ONC added some new demographic data elements to USCDI including more specific elements within patient address (p. 118), but chose not to require US Postal Service Addressing Standards (p. 119). Certain elements related to pediatric vital signs were added to USCDI (p. 124). ONC did not feel compelled by objections to the NTTAA exception (p. 100). *NOTE: Are additions to USCDI through this rulemaking a violation of the process set up within USCDI itself?*

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		Allergies" with "Substance Reactions" (likely the associated SNOMED-CT codes), which may have an impact on immunization or other adverse event reporting	
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.	This replacement was adopted by ONC (p. 143).
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).	ONC decided that the data set for data export would be "…the same ePHI that a patient would have the right to request a copy of pursuant to the HIPAA Privacy Rule" (p. 191) and would "…need to include the EHI that can be stored at the time of certification by the product" (p. 192). They expect variation between products as different products support different certification criteria. Note that ONC chose not to include this functionality as a certification criterion but to include it in Conditions and Maintenance of Certification (p. 195). ONC also clarified that this functionality is not required (or even meant) to be executed

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			directly by a patient (p. 205).
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. • 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	At least initially, public health reporting transactions do not appear to be directly impacted by this proposal, especially since most public health transactions are "push" transactions and the focus here seems to be on query/response transactions. 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. 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),	FHIR v4 API for both single and multiple patient focuses (p. 224). ONC did not feel compelled by objections to the NTTAA exception, but also did not recognize the selection of certain FHIR IGs as an exception (pp 100-102). The "ARCH" was *not* adopted but the HL7 US Core IG and SMART were (p, 380). ONC affirmed that the API requirements only apply to the specific API-focused certification criteria (p. 417). ONC affirmed the restrictions on fee imposed for API use and access. These restrictions may impact discounts that vendors might offer to government agencies (p. 431).

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	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)	though there is no such requirement being proposed in the NPRM. It seems appropriate for this rule to require FHIR R4 which is the first normative release. Prior releases are for trial use only and do not guarantee backward version compatibility as R4 will. Note that ONC is requesting an exemption from The National Technology Transfer and Advancement Act (NTTAA) requirements that standards adopted by the Federal government must be developed or adopted by voluntary consensus standards bodies for certain elements of the proposed FHIR strategy (*e.g.,* Argonaut, USCDI). The development of these artifacts has typically *not* involved public health representation.	
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.	This attestation was implemented with recognition that MFA may not be applicable in all situations. A "no" attestation can offer explanation (p 232).

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		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. 7458	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 interoperability is	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 standards or practices	Public health comments were acknowledged explicitly (p. 284). Work refining this voluntary area will continue.

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	Recommendation 5: Synchronize immunization histories with registries.	for immunization data submission or query/response and public health is not currently funded to provide this capability from 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.	Comments received under review by ONC (p. 292).
RFI: Requiring TEFCA p. 7466	ONC wonders whether rulemaking should require compliance with the Trusted Exchange Framework and	As previously described, TEFCA as originally proposed does little to further public health goals and does not seem	Comments received under review by ONC (p. 308).

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	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 services like clinical decision support (CDS). The impetus for this suggestion is related to preventing information blocking (see below).	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 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. It also should make it much easier for providers to discuss the operation of their CERHT products with public health and that will help promote successful interoperability. Public health should ensure that these new rules apply to its discussion of CEHRT as well.	ONC clarified that these provisions only relate to CEHRT (p. 316). ONC explicitly addresses comments about how communications with public health might be affected (p. 317). There is a somewhat confusing example related to screen shots (pp. 318-9), but later clarification that they are permitted under the copyright "fair use" doctrine subject to reasonable restrictions by a vendor for purposes permitted under the rule (p. 366). Clauses in vendor contracts that violate these rules would be grounds for product de-certification if enforced (p. 375).
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	Two types of CEHRT testing are currently in wide use by CEHRT vendors and users. First, the "laboratory environment" testing of EHRs is	ONC affirmed its proposal in this area, noting specifically that public health certification criteria should be included (p. 492-3). ONC

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	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.	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. In addition, public health organizations (like AIRA, APHL, ISDS, CSTE, and NAACCR) and most public health agencies have well-developed resources and processes to on-board provider organizations for interoperability transactions, test their interfaces with both hypothetical and real data, and ensure ongoing quality of the data being exchanged. At minimum, ONC needs to ensure that real-world testing requirements do not create infrastructure for testing of public health transactions *without* public health involvement. At best, public health needs to ensure that any new regulations do not interfere or detract from the well-established testing processes that are already in place. The ONC proposal includes all public health reporting certification criteria, including data formats, APIs, and	concluded that a test server and even synthetic data could be used for real-world testing with appropriate justification (p. 500). ONC concurred with comments that stressed the need to involve public health in real-world testing plans and to limit any additional burden on public health in participating (p. 502).

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		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.	
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.	No specific recognition of public health concerns in this area was noted in the Final Rule.

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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 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	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. One potential positive impact of this rule is that it may *help* public health enforce reporting requirements by accusing (or threatening to accuse) providers and vendors who do not report of information blocking. 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. Here are a few suggestions for improving this section of the rule that affect public health agencies: • While a state-run HIEs is explicitly	Enforcement of Information Blocking will not begin until additional rulemaking is proposed and finalize by the Office of the Inspector General of HHS. Community-based organizations were excluded from the definition of healthcare providers so long as they do not also conduct the activities identified in the definition (p. 595). ONC did not broaden the definition of HIT developer beyond CEHRT developers (p. 597), but included *offerors* of technology developed by others (p. 609). ONC also stated that public health infrastructure used to support public health reporting certification criteria would fall outside of this definition (p. 610). ONC also excluded providers who develop CEHRT for their own use *only* (p. 612). ONC combined the definitions of HIN and HIE, (pp. 622-3). Bilateral, 2-party exchanges were excluded

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	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.	within the definition, Public health interface engines (like an IIS or ELR transaction processor) that are not general purpose HIEs should be excluded as a covered activities under this rule. • Delays in on-boarding provider organizations for public health reporting should not be considered information blocking under this rule (e.g., a long on-boarding queue). • Similarly, public health preference for interfacing to certain types of organizations over others should not constitute information blocking (*e.g.,* connecting larger provider organizations before smaller ones, or pediatric practices over adult practices). • Obstacles (perceived or real) to primary or secondary use of data either possessed or transmitted by public health (other than those required by law) should not constitute information blocking. • Through the exclusions legal action by HHS against a government agency in relation to information blocking should not be expected or permitted.	(pp. 623-4). The focus of activity was also narrowed to HIPAA TPO (p. 624), but public health agencies were not explicitly excluded from this definition (p. 625). ONC has narrowed the definition of EHI to include HIPAA-associated ePHI regardless of whether the entity is a CE or not (p. 629). ONC refined the definitions of "access," "exchange," and "use" (pp. 636-8). ONC refined and expanded the final rule to include 8 exceptions. ONC determined that the routine delay of release of lab results to a patient was *not* an exception to information blocking (p. 780). ONC does not seem to make a similar statement about policies related to routine delay in release of other types of EHI (pp. 781-2). ONC affirmed that a patient's preference cannot be an obstacle

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		• The activities of IT vendors who fulfill contracts for products or services for public health agencies should not be subject to sanction under the rule. • Exceptions must not be used to justify failure to perform public health reporting.	to information sharing required by law unless the law allows for that preference (*e.g.,* opt-out; pp. 795, 847). ONC declined to exempt TEFCA-related exceptions at this time due to its newness (p. 886). ONC added a new "Content and Manner" exception which addresses potential exceptions based on *what* may be transmitted and *how* it is transmitted (beginning p. 912). ONC acknowledged the question about whether onboarding queue backlog could be exempted from information blocking but did not directly answer the question (pp. 1006-7).

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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. With respect to FHIR version, it seems appropriate for this rule to require FHIR R4 which is the first normative release. Prior releases are for trial use only and do not guarantee backward version compatibility as R4 will. 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.	ONC did not offer any comments on this RFI.

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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. See our detailed comments. 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 See our detailed comments.	ONC did not offer any comments on this RFI.