72810 Hedgehog Street • Palm Desert, CA 92260 • 858/538-2220 • 858/538-2209 (FAX)
info@hln.com • http://www.hln.com/

May 14, 2019

Dr. Don Rucker
Department of Health and Human Services,
National Coordinator for Health Information Technology
Mary E. Switzer Building, Mail Stop: 7033A
330 C St. SW
Washington, DC 20201

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

Dear Dr. Rucker,

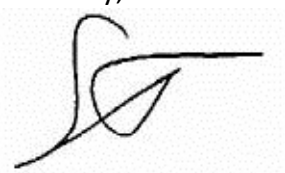
HLN Consulting is pleased to submit the attached comments in response to the above mentioned Notice of Proposed Rulemaking (NPRM). HLN is a leading public health informatics consulting company and as such our comments are offered from this public health perspective.

We are quite concerned about the ambiguities raised in this NPRM with respect to public health, as well as the potential adverse impacts (including unfunded mandates) that certain aspects of this NPRM may present to public health agencies, especially at the State, local and tribal levels.

We also support strongly the comments put forth under separate cover by the American Immunization Registry Association (AIRA) and other public health membership organizations and agencies.

HLN greatly appreciates the opportunity to comment on these proposed rules, and we look forward to continuing to collaborate to ensure high-value health IT interoperability with our many partners.

Sincerely,



Noam H. Arzt, PhD, FHIMSS, FAMIA
President

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

Note: Page numbers below are from the Federal Register version of the NPRM

Topic/Reference	Comments
USCDI (see earlier blog) p. 7440	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. 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. 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. We do not support this exemption as it reduces the transparency and participation for these important activities. At minimum, someone should represent public health on the USCDI Task Force.
EHI Export p. 7446	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	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

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	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. However, there is currently no organized activity or funding to add FHIR-based implementations to the national eCR project. 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. 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. We do not support this exemption as it reduces the transparency and participation for these important activities.
Encryption p. 7450	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

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	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. 7458	While many of the recommendations may affect children's health (and therefore public health), the most relevant recommendation for public health interoperability is **Recommendation 5: Synchronize immunization histories with registries**. 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 for immunization data submission or query/response and public health is not currently funded to provide this capability from IIS. It should be removed. 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 needs to study this suggestion and consider technical solutions to make these differing report formats more readily available.

Topic/Reference	Comments
RFI: Requiring TEFCA p. 7466	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 would need to be done only based on a clear understanding of where TEFCA has evolved since its original draft release. The new TEFCA 2.0 proposal was just released by ONC for comment on April 17, 2019 and comments with respect to TEFCA will be offered under separate cover in response to that document.
Communications about CEHRT p. 7467	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.
Real World Testing p. 7495	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. 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

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	that are already in place. 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.
Standards Version Advancement Process p. 7497	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. ONC should clarify the process for its selection of newer versions of standards that is a prerequisite for use by vendors, and ONC needs to explicitly indicate that public health will be actively involved in standards version selection.
Information Blocking p. 7508	This section of the NPRM will likely keep lawyers busy for months to come. The rules are long, detailed, complicated, and confusing; the impact on public health is not always clear. 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 or vendors adversely.

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	Here are a few suggestions for improving this section of the rule that affect public health agencies: • While a state-run HIEs is explicitly 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. • 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.
RFI: Registries p. 7553	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.

Topic/Reference	Comments
RFI: Patient Matching p. 7554	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 on the next page.

ONC NPRM (Feb 2019): Patient Matching RFI (p. 7555)

Public health has significant experience over a long period of time in patient matching strategies for records collected from diverse clinical locations. The following observations and suggestions are offered based on this experience:

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It is a common misconception that technology alone can solve the problem of poor data quality, but even the most advanced, innovative technical approaches are unable to overcome data quality issues. Thus, we seek input on the potential effect that data collection standards may have on the quality of health data that is captured and stored and the impact that such standards may have on accurate patient matching. We also seek input on other solutions that may increase the likelihood of accurate data capture, including the implementation of technology that supports the verification and authentication of certain demographic data elements such as mailing address, as well as other efforts that support ongoing data quality improvement efforts.	The quality of data used for patient matching is indeed a difficult problem which has plagued public health registries for some time. As we described in an article published in 2017, ONC convened a Patient Matching Community of Practice in 2014-15. We wrote, "Its major focus was developing a five-level data quality maturity model to try to characterize an organization's sophistication in using different common data elements to perform patient matching functions, as well as articulating value propositions for improved matching for different stakeholder types. The project released two documents, *Developing and Testing a Data Management Model and Maturity Scale Tailored to Improving Patient Matching Accuracy* and Guidelines for Pilot Testing of Data Management Maturity℠ Model for Individual Data Matching describing its work. The Data Quality Maturity Scale, included as Appendix B, highlights how systems across the healthcare community, at least as reflected in the core data elements, are at the high levels of maturity. In practice, however, the data elements needed for levels 4 and 5 are precisely the ones that are least consistently captured." We encourage ONC to draw on these documents and resources whose development ONC funded. External validation of key data elements used for matching can also be a big help. For example, in 2017 the American Immunization Registry Association (AIRA) arranged access to SmartyStreets, a cloud-based address cleansing service, for all Immunization

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	Information Systems (IIS) which chose to access it. By leveraging available CDC funding, for a modest amount this service is able to cover the *entire* IIS community and significantly increase the level of quality in address data which is often key for proper patient matching. AIRA maintains the license, provides documentation and coordination, and sponsors a monthly user group of interested IIS projects.
In concert with the GAO study referenced above, we seek input on what additional data elements could be defined to assist in patient matching as well as input on a required minimum set of elements that need to be collected and exchanged. We encourage stakeholders to review the Patient Demographic Record Matching section of the Interoperability Standards Advisory and comment on the standards and implementation specifications outlined. Public comments and subject matter feedback on all sections of the Interoperability Standards Advisory are accepted year round.	The Patient Demographic Record Matching Sections seems inadequate to address data elements for patient matching as it primarily focuses on IHE transactions which do not seem to focus normatively on *which* data elements might be best for matching. The Data Quality Maturity Scale, included as Appendix B in Guidelines for Pilot Testing of Data Management Maturity℠ Model for Individual Data Matching referenced above, provides detailed suggestions for data elements to be used for patient matching that were vetted through the community of practice that developed the guidelines. In addition, in January 2019 AIRA published its *IIS Functional Guide, Vol. 2: CDC Endorsed Data Elements*. This exhaustive document includes (in Appendix C) a list of data elements endorsed to fulfill the IIS functional standard of identifying, preventing and resolving duplicated and fragmented patient records using an automated process. This list is also worth consulting. Research in New York City by the Citywide Immunization Registry (CIR) has demonstrated that though matching is a complex activity, and it is difficult to tease apart factors affecting successful matching, the search success rate for the CIR was higher when more

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	search fields were sent, especially the internal ID assigned to each patient in the CIR and available to EHRs that query the system should they choose to store it. Studies such as this one should be replicated to help determine the most effective fields for searching and matching.
Also in alignment with the GAO study, we seek input on whether and what requirements for electronic health records could be established to assure data used for patient matching is collected accurately and completely for every patient. For instance, the adopted 2015 Edition ''transitions of care'' certification criterion (§ 170.315(b)(1)) currently includes patient matching requirements for first name, last name, previous name, middle name, suffix, date of birth, address, phone number, and sex. These requirement also include format constraints for some of the data.	Requiring specific data quality for is admirable but may not be practical, since in many (if not most) cases an EHR can only contain data as good as what is provided by the patient. To the degree that data formats can be enforced (like data formats for date of birth), or standard value sets maintained (like sex, race, and ethnicity), the quality of the data will naturally improve.
There are unique matching issues related to pediatrics and we seek comment on innovative and effective technical or non-technical approaches that could support accurate pediatric record matching.	The IIS community has worked in this domain specifically for more than twenty years. There are a number of specific patient matching issues that affect pediatric records, including: • Birth records that do not contain a true first name (but rather are populated with "baby boy" or "baby girl" as a first name was not available) can become difficult to match to future records. • Multiple births can sometimes present confusing matching problems, especially when first names are close or even identical. • Children do not usually have records in referential matching databases that are primarily drawn from financial/credit data sources (see below). • Though not unique to children, some data sources may include a patient's middle name embedded in the patient's first name field.

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	• Children may lack common identifiers that adults typically possess that may be used as primary or secondary matching fields (*e.g.,* driver's license number, social security number, cell phone number, e-mail address, unique Medicaid ID [which may be a family ID]). • On the other hand, children are often associated with parents/guardians and parent/guardian data can be used to supplement primary data for matching. There are no magic answers to addressing these issues; technology developers need to be sensitive to them when crafting solutions to pediatric matching challenges.
Recent research suggests that involving patients in patient matching may be a viable and effective solution to increase the accuracy of matching, and giving patients access to their own clinical information empowers engagements and improved health outcomes. We seek comment on potential solutions that include patients through a variety of methods and technical platforms in the capture, update and maintenance of their own demographic and health data, including privacy criteria and the role of providers as educators and advocates.	Public health registries are only just beginning to provide direct access to patients; IIS are probably leading the way given the broad usefulness of an up-to-date immunization history and forecast for school/child care/camp admission and preventive care. Many IIS also perform automated or semi-automated outreach services to encourage patients to complete missing immunizations ("Reminder") or to warn them of upcoming immunization needs ("Recall"). These services will often use text messages or e-mails to contact patients directly, yet IIS often do not have complete cell phone or e-mail records for their patients. Most IIS projects are somewhat reluctant to accept patient contact information (which could then also be available for matching) directly as opposed to soliciting this information from healthcare providers when they submit immunization records *to* the IIS. We do feel there is some potential for augmenting IIS contact information with patient-supplied data once patient access to IIS data becomes more prevalent.

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In addition, we seek input on standardized metrics for the performance evaluation of available patient matching algorithms. Health IT developers are each relying on a number of patient matching algorithms, however, without the adoption of agreed upon metrics for the evaluation of algorithm performance across the industry, existing matching approaches cannot be accurately evaluated or compared across systems or over time.	This has always been a difficult topic and we do not see any easy answers ahead. In 2017 ONC sponsored the Patient Matching Algorithm Challenge (PMAC) whose was to allow vendors to compete for the highest performance metrics for their matching algorithms by testing their software against a large set of test data provided by ONC. Cash prizes were awarded in a number of categories, and the winning vendors were featured in the discussion on the webinar. One of the main purposes of the challenge was to promote the use of standard metrics to evaluate algorithm products. We were a little concerned that the winners by their own admission "analyzed patterns in the data." This seems to call into question the applicability of their results to the "real world" where you don't get to see the data set; you have to adjudicate them as they come in. That means that these particular test runs were "tuned" for the data set and the measurable results might not hold up for other data sets. Over the years, several public health initiatives have attempted to provide comparative measures of matching algorithm performance or quality and have had less than successful results.
At the same time, we seek input on transparent patient matching indicators such as database duplicate rate, duplicate creation rate, and true match rate, for example, that are necessary for assessment and reporting. The current lack of consensus, adoption, and transparency of such indicators makes communication, reporting, and cross- provider or cross-organizational comparisons impossible, impedes a full and accurate assessment of the extent of the problem, prohibits informed decision making, limits	We have no comment on this important question.

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research on complementary matching methods, and inhibits progress and innovation in this area.	
There are a number of emerging private-sector led approaches in patient matching that may prove to be effective, and we seek input on these approaches, in general. A number of matching services that leverage referential matching technology have emerged in the market recently, yet evaluations of this type of approach has either not been conducted or has not been made public. Other innovative technical approaches such as biometrics, machine learning and artificial intelligence, or locally developed unique identifier efforts, when used in combination with non-technical approaches such as patient engagement, supportive policies, data governance, and ongoing data quality improvement efforts may enhance capacity for matching.	In an article published in 2017, we identified a set of distinct strategies for matching that seemed to be in play and the lack of any real consensus around any of them: 1. A "traditional" approach which leverages either deterministic and/or probabilistic techniques that continue to struggle with the lack of standardized data for input as discussed elsewhere in this response; 2. A unique identifier approach, either government sponsored or managed by the private sector, though this would likely be insufficient without corroborating data in a population as large and diverse as the US; 3. Health record banks which put the patient at the center of the problem but which have failed to gain any traction in the marketplace; 4. Biometrics, which still suffer from some limitations as well as privacy concerns; 5. Newer, innovative approaches such as referential matching which still have limitations in some segments of the population (like children) We believe that the public and private sectors need to get together to discuss and pilot various approaches and to encourage Congress to reexamine its current position on a national unique patient identifier.
Finally, ONC seeks input on new data that could be added to the United States Core Data for Interoperability (USCDI) or further constrained within it in order to support patient matching.	Refer to the Data Quality Maturity Scale, included as Appendix B in Guidelines for Pilot Testing of Data Management Maturity℠ Model for Individual Data Matching which provides detailed suggestions for data elements to be used for patient matching that were vetted through the community of practice that developed the guidelines.