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Office of the National Coordinator (ONC)
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. Rucker:

We are writing on behalf of the undersigned national public health associations which represent the broad spectrum of public health policy and practice in the United States of America. We appreciate the opportunity to submit comments on the draft *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* in support of the requirements of the 21st Century Cures Act.

This proposed rule represents a major new effort to mobilize health data for patients and providers. It adds powerful tools to mobilize these data that range from controls on information blocking to the HL7 FHIR API. These tools join the legacy of *Meaningful Use,* the ongoing *Promoting Interoperability,* and the EHR certification program in striving to make electronic health data support a variety of outcomes.

We submit that while there are requirements placed on public health in this proposed rule, there is still limited attention to, and alignment for, mobilizing data for population health needs. Healthcare is a massive industry and powerful business which, when incentives are properly aligned, can drive major health IT activities. Public health, on the other hand, is dependent on government support and incentives, including regulations like this, to promote population health activities and outcomes. We hope the comments, below, will help to advance the population health components of this regulation.

The comments below are listed with page references based on the Microsoft Word copy of the rules posted at https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health:

Information Blocking of Public and Population Health Surveillance (pages 18-19, 24-26, 580-586)

Like patients and providers, public and population health continue to face obstacles in mobilizing clinical care / EHR data. Public health has needs for ongoing support to establish and to maintain clinical care connections that manifest the nation's health surveillance infrastructure. CMS and ONC have, to this point, focused principally on federal laws and on goals for patients and providers. But many of the benefits of health IT accrue in support of population health outcomes. And many of these public and population health activities are state and not federal responsibilities.

- Electronic data are now the *sine qua non* for health information exchange and the federal agencies need to ensure that state and local laws are now fully supported electronically. To point, information blocking regulations should specifically identify failures to electronically support state laws like those that require the reporting of specific conditions. These state laws should not be menu choices for providers or optional implementations for EHR vendors. Specific language should be included in this new regulation that indicates that the failure to support state mandated reporting can be considered information blocking and subject to information blocking penalties.

- Some public health programs benefited from *Meaningful Use* and some, to a much lesser degree, from *Promoting Interoperability*. However, many of these public health programs are still incompletely implemented and, resultantly, do not fully manifest opportunities to reduce provider burden from the automation of activities they seek to implement. In fact, legally mandated public health reporting was even cited in ONC's provider burden strategy. The programs for automating reporting need to be sufficiently supported in this regulation so that state laws are automatically addressed, and manual reporting is not otherwise considered a burden.

- While state law-driven activities are not fully considered by these regulations, the definitions included in this NPRM are broad enough that public health agencies and systems could actually be construed as being in-scope for the penalties of these regulations as perpetuating information blocking themselves. We strongly suggest that public health organizations and their activities related to interoperability be clearly excluded from consideration of blocking information.

Conditions and Maintenance of Certification (pages 293-294, 302-303)

- With the importance of public health surveillance, the failure of a certified product to support state laws and report to public health should not only be information blocking but should also be justification for suspension or termination of product certification. This is an issue of public health and safety as noted on page 316.

- Public health programs need reliable and ongoing inducements for clinical care to initiate and maintain electronic connections. The menu choices of *Promoting Interoperability* have greatly reduced the inducements to initiate connections and there are few ongoing drivers to re-connect when clinical care system changes inevitably happen. EHR upgrades should not mean that legally mandated reporting stops.

Standards Advancement Process (pages 12, 21-22, 63-66, 109, 143-147, 202-216, 272-287, 570, 627-640)

ONC is proposing to permit EHR health IT developers to use new versions of standards once these new versions are identified by the ONC. Many standards, however, involve data exchange between more than one organization. Without both sides of an exchange being able to operationalize a new standard, this suggested approach will be problematic.

- EHR vendors should not implement new versions of interoperability standards that public health agencies are not yet prepared to support.

- A more collaborative process that involves all the participants in determination of when a new standard is ready for implementation across organizational boundaries needs to be developed.

Exceptions to National Technology Transfer and Advancement Act (pages 58, 490)

ONC is seeking exceptions to the National Technology Transfer and Advancement Act (NTTAA) requirement to use voluntary consensus-based standards in several areas including the USCDI, the API Resource Collection in Health (ARCH), application programming interfaces (APIs) from consortia (like Argonaut), and more.

- We do not support NTTAA exceptions for the identified activities and instead ask that the involved programs increase their support for inclusive, consensus-based standards activities that involve broad representation of industry participants - including public health.

- In the past several years there has been an erosion of the consensus-based standards process with the advent of activities like some of those for which this regulation seeks exceptions (e.g. Argonaut, USCDI). Many of these activities do not have, or even allow, public health participation. Despite the lack of involvement, these processes can lead to HIT standards and infrastructure that non-participants, like public health, must then use.

- The full consensus-based standards development process required by the NTTAA helps public and population health needs be brought to bear on what can otherwise be siloed clinical care, payer, and government programs. Siloed programs are the real drivers of increased provider burden.

- The NTTAA requirements were established because Federal government programs and narrow constituent efforts are not usually the best determinants of industry-wide solutions or standards.

USCDI (pages 63-64, 144, 266-267, 528-531)

Electronic Case Reporting and, eventually, immunizations and syndromic surveillance are targeted to be required to use the new USCDI data classes and elements as they replace the Common Clinical Data Set.

- We fully support the concept of coordinated clinical data sets to align health IT programs, promote interoperability, maximize the use of extant EHR data, and minimize provider burden. The description and use of the CCDS and now the USCDI, however, has confused many people and our support for the USCDI depends on clearer communications regarding the following:

> ➢ There are some data in the USCDI that are not relevant to, nor appropriate for, public health programs such as electronic case reporting. In fact, these data cannot be received by state public health agencies in keeping with state laws. "Use" of any particular USCDI data element or class needs to be specified as "according to program need and applicable law."

> ➢ There are some critical data that public health requires that are not in the USCDI and will not be for some time. Therefore, while every effort should be made to use USCDI data where possible, some additional, non-USCDI data must be recognized as being important to programs and needed in involved exchange standards as well.

> ➢ As ONC itself points out, the USCDI itself is not an exchange standard. As such, the USCDI can be very helpful in coordinating data, but it is a complement to, and not a substitute for, well-developed and specified exchange standards and implementation guides.

- Public health also needs ongoing representation on the USCDI task force or in an appropriate consensus-based standards development organization preparing the USCDI if there are expectations that public health should use its products.

Application Programming Interfaces (page 620)

The consideration of Application Programming Interfaces (APIs) and the promising HL7 FHIR API is a laudable direction for health IT interoperability, but only if all participants can implement it.

- Public health needs support to inculcate this new standard and requisite supporting technology if it is to be a capable clinical care partner. Supporting public health partnership involves seeing that public health has the resources to implement the new standards and technology and that the standards and transactions that are important to public health are also advanced.

- Many of the references to these APIs focus exclusively on the technology of RESTful query and ignore the "push" elements of the FHIR API such as "Submit" ("POST" and "PUT") and "FHIR Messaging" that are critical to different kinds of public health reporting. In many respects, the relatively exclusive query focus represents the FHIR technology driving the program and ignores the clinical and public health programs and use cases, like: reporting, referrals, and others that need "push" transactions and messaging that can pass through intermediaries such as HIEs, HINs, and even the TEFCA QHINs.

- OpenID and OAuth are also laudable new technologies, but their specific use in circumstances such as the TEFCA, Health Data Networks, Health Information Exchanges, and other network intermediaries needs to be better elucidated and reconciled with existing infrastructure.

- As organizations external to clinical care, public health agencies' direct query access to EHR data has been historically limited and resisted by healthcare organizations. Many healthcare organizations do not even support selective authorization for their own clinical staff. Without a large amount of work in every healthcare organization to begin to manage selective authorizations for external organizations, it is not clear that external queries will be successful. Minimally, the full implications of these technologies need to be elucidated.

Registries Request for Information (pages 480-483)

ONC has asked for comments that stakeholders may have on implementation of the registry provisions of the Cures Act (Section 4005).

Public health has been working hard to breakdown silos, share EHR reporting infrastructure, and minimize provider burden. To that end, public health seeks to work hand in glove with the payer-related population activities in the CMS NPRM but cannot do so if these activities are isolated and resist public health participation. This has been the case with some of the activities listed in this regulation seeking National Technology Transfer and Advancement Act exceptions. Isolated reporting activities that do not share approaches or infrastructure with others are the source of a great deal of actual provider reporting burden.

- We applaud an effort by ONC to help harmonize the EHR reporting infrastructure and standards involved in reporting to registries and getting information from registries back to clinical care. ONC should support the consensus-based standards organizations existing efforts in this area including the "public health – Da Vinci reporting harmonization in FHIR" and the Common Clinical Registries Framework for data.

- EHR interface development can be greatly eased and mostly automated. It is also important that there be a focus on more than the data "what" of reporting so that standards and clinical infrastructure to automate the "when, where, and how" of registry population, reporting, and reducing provider burden are also available. Public health would strongly support ONC's participation in these ongoing efforts.

- It is important that data authorities and considerations for chronic diseases, reportable conditions, and other public health programs are well considered. For these reasons, it is critical that public health IT leadership be represented in these activities and that other reporting functions including quality reporting, pay for performance, and other reporting activities use and support common EHR infrastructure as well.

TEFCA (pages 158-160)

In this proposed guidance ONC asks whether rule making should require compliance with the Trusted Exchange Framework and Common Agreement (TEFCA). We have previously commented on the value of having a single on-ramp to interconnected health data networks to support the many-to-many exchanges involved in public health. We have these concerns about making TEFCA required:

- HIPAA should not become incumbent on public health agencies who are conducting activities that would otherwise be explicitly excluded from the HIPAA regulation already.

- Public health systems, like patient systems represent a different class of potential participants from clinical care systems and should not be subject to all the "individual access services" requirements.

- TEFCA exchange, more than just not violating state (and federal) laws, should explicitly require that "Participants," "Participant Members," and QHINs should comply with, and support, state laws.

- Public health should be excluded from paying QHIN transaction costs.

- Standards for public health programs / transactions need to be included in what is specified and permissible to exchange under TEFCA. And public health representatives need to be involved in the standards identification process. We support the use of consensus-based standards development for all standards used.

- We note that authentication and transaction approaches promoted in other places in these regulations (such as the basic FHIR API) do not contemplate or support the TEFCA and its exchange intermediaries in their use and need to be adjusted to do so.

Real World Testing (page 21)

The ONC proposal includes all public health reporting certification criteria, including data formats, APIs, and transport.

- Public health must be involved in real-world testing of public health transactions. Even more, 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 nationwide. 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.

- We vigorously support public health's inclusion in real-world testing tool development, use, and expertise, but only if public health's experience and goals are also central to tool development and relevant outcomes.

Voluntary HIT for Pediatric Care Settings (pages 16-17, 124-137, 669-690)

Consistent with the Cures Act, ONC is proposing voluntary certification for pediatric care settings that build upon existing certification criteria and add a few additional items. The proposal is based on the AHRQ Children's EHR Format.

- The reference to the inclusion of pediatric vital sign data elements in the USCDI is not relevant to immunization reporting or query.

- The requirement for FHIR is not currently consistent with CDC/AIRA standards or practices for immunization data submission or query/response and should be removed if public health is not funded to provide this capability from IIS.

- The supplemental requirement for production of a school, camp or childcare form from EHR data is not consistent with current IIS functionality or practice where such reports are generated from the IIS when required and should be removed.

Smoking status changes (page 48)

Public health agencies are commonly responsible for tobacco prevention work and are very concerned about the removal of smoking status from EMRs. Public health needs this information to be available to clinicians for patient care as well as for surveillance and population health work. Reducing tobacco and nicotine use is one of our greatest opportunities to help people live longer, healthier lives. Tobacco use remains the leading cause of preventable death in the nation.

Thank you very much for this opportunity to comment. We hope that this input helps to mobilize data for population needs in addition to the direct needs of patients and providers. Ultimately patients and providers benefit if population health needs are addressed.

Sincerely,

American Immunization Registry Association

Association of Public Health Laboratories

Association of State and Territorial Health Officials

Council of State and Territorial Epidemiologists

International Society for Disease Surveillance

National Association of County and City Health Officials