ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

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June 3, 2019

Donald Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (RIN 0955-AA01)

Dear Dr. Rucker:

The Association of State and Territorial Health Officials (ASTHO) appreciates the opportunity to submit comments regarding the Office of the National Coordinator (ONC) Notice of Proposed Rulemaking on Interoperability, Information Blocking, and the ONC Health IT Certification Program. ASTHO and its state and territorial health official members welcome a strong partnership with ONC as it implements its guidance, rules, and related activities.

ASTHO is the national nonprofit organization representing the state and territorial public health agencies (S/THAs) of the United States, the U.S. Territories, and the District of Columbia. ASTHO's members, the chief health officials of S/THAs, are dedicated to formulating and influencing sound public health policy and to assuring excellence in state-based public health practice. S/THAs play a critical part in improving population health in their states—they assess community needs; design, implement, and evaluate programs that prevent or mitigate disease or injury; work to reduce health disparities; identify best practices in public health and evaluate their impacts; and convene and collaborate with stakeholders and communities. In addition, state and territorial health officials (S/THOs) have wide-ranging responsibilities and relationships with their state Medicaid agencies, ranging from statutory oversight, membership in an umbrella agency, or reporting separately to the governor or other state or territorial executive.[1] Thus, S/THAs have a unique role in coalitions, partnerships, and activities that improve population health.

S/THOs advance population health and adapt strategies to combat the evolving and leading causes of illness and poor health outcomes by utilizing informatics and multiple data sources to inform decisions. They develop an increasingly integrated health system by partnering with public health

[1] In five states (Kansas, Maryland, Montana, New York, and Utah), the S/THO has statutory oversight of Medicaid). In 14 states, the S/THA and Medicaid are part of an umbrella agency. In 31 states and Washington, D.C., the S/THA and Medicaid report separately to the governor (or, in Washington, D.C., to the mayor).

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and healthcare organizations and collaborating with diverse stakeholders and community leaders. Partnerships with stakeholders are essential to exchanging information and developing programs that address community needs and align programs or activities to reduce duplication or misalignment. Furthermore, partnering and exchanging information with sectors outside of health will be essential as greater recognition for collecting data relative to the social determinants of health expands.

Comments

Definitions

We recommend that ONC work with public health agencies to define public health's distinct and unique role instead of assuming or including them among the current list of defined actors: healthcare provider, health information network, health information exchange, and health IT developer.

Information Blocking

Much like patients and healthcare providers, public health agencies continue to face obstacles in mobilizing electronic health record (EHR) data and other electronic health information (EHI) to include resource and infrastructure needs for establishing and maintaining clinical to community connections and supporting national population health surveillance. Although ONC's proposed rule focuses on federal laws and their application to patients and providers, much of the information accrued from EHI has significance for informing public and population health activities that are state responsibilities. We recommend that ONC recognize the role of public and population health in the care continuum and fully support state and federal laws in EHI exchange.

The current definition of information blocking includes accessing, exchanging, or using EHI with public health authorities. While we support ONC's recognition of public health's data exchange needs within the definition of information blocking, we encourage ONC to engage S/THOs to clarify how "public health agencies" (i.e., public health entities that function in a similar role to health information exchanges, such as public health interface engines, public health agencies that offer clinical services or have a segment of the agency classified as a provider, and activities of vendors operating systems for public health) are classified among the four categories of actors. Until this engagement opportunity is available, we strongly encourage ONC to make public health agencies and their activities related to interoperability exempt from the list of actors held responsible for information blocking.

We also encourage ONC's support of state-mandated public health reporting to include language that specifically mentions that, based on state and federal public health laws, failing to report EHI is considered information blocking and is subject to information blocking penalties. While some S/THAs benefited from the Meaningful Use and Promoting Interoperability programs, many are still struggling to implement these programs due to a lack of necessary resources and infrastructure. As a result, these S/THAs are not able to reduce provider burden by automating their activities. We

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recommend that programs for automating EHI reporting and exchange be sufficiently supported in ONC's rule so that state agencies are able to advance their efforts and address provider burden as a result of manual reporting.

Further, ASTHO requests that ONC note that the failure of a certified product in being able to report to a public health registry should not only be determined as information blocking, but also serve as justification to suspend or terminate certification as an issue of public and population health safety.

Additionally, the proposed ONC rule currently does not distinguish data by its intended uses, and the rule language also solely references data in the context of individual clinical care. ASTHO suggests that ONC adjusts the rule language to reflect both issues, as once data is reported to public health agencies and integrated into both state and federal surveillance systems, that data informs population health outcomes and surveillance, and is no longer primarily intended to support individual clinical care.

Health IT for the Care Continuum

We suggest that the voluntary health IT certification for pediatric care include an additional recommendation that incorporates data of interest to public and population health surveillance. ASTHO also suggests that ONC work in coordination with public health agencies and organizations that are required to use this data to build upon existing certification criteria.

Exceptions to National Technology Transfer and Advancement Act

We recommend against the National Technology Transfer and Advancement Act (NTTAA) exceptions for the activities outlined in the proposed ONC rule and ask that the involved parties increase support for inclusive, consensus-based standards activities involving broad representation from health sectors, including S/THAs. We recommend this approach because, over the past several years, there has been a lack of adherence or attention to the consensus-based standards process with entities that seek exceptions (e.g., the Argonaut Project and the U.S. Core Data for Interoperability). We believe that NTTAA requirements help avoid siloed programs and one-off efforts for solutions and standards that impact the entire healthcare industry and, thus, public health's ability to respond adequately to public and population health needs.

U.S. Core Data for Interoperability

ASTHO appreciates ONC's work to establish the U.S. Core Data for Interoperability (USCDI) to ensure that core data elements and classes support nationwide interoperability and are available to providers and patients. We encourage ONC to list S/THAs among those entities able to access USCDI for public health reporting and surveillance purposes (e.g., for electronic case reporting, immunization registries, and syndromic surveillance), as S/THAs will be required to use the new USCDI data classes and elements which are replacing the common clinical data set. We also encourage ONC to require entities to adhere to federal law (i.e., the Health Insurance Portability and Accountability Act of 1996) and state laws in cases where profile data in USCDI is neither

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relevant nor appropriate for public health use. We recommend specifying that entities use USCDI data elements or classes according to program need and applicable state and federal law. Additionally, we recommend recognizing non-USCDI data as important to public health programs and including it in exchange standards, since some of that information is critical to public health.

Standards Advancement Process

ASTHO also requests that ONC explicitly engage S/THAs when selecting and developing new standards. We recommend that ONC develop a standards version advancement process with a more collaborative method for determining when standards are ready for implementation across organizational boundaries when there are two or more partners (including S/THAs) involved in the exchange. It is critical that one or more partners in the exchange not be able to implement new versions of interoperability standards that S/THAs and other trading partners are not yet prepared to support. In addition, we recommend that data exchange systems that adopt new versions retain support for previous versions, so as not to disrupt existing interoperability.

Application Programming Interfaces

We support health IT's goals of providing patients with greater access to their EHI and health data; however, the lack of standards in application programming interfaces (APIs) make compliance and adoption challenging. ASTHO and its members request that ONC engage S/THAs and confirm that Fast Healthcare Interoperability Resources (FHIR) APIs do not replace any existing public health interoperability standards that are currently being implemented through the 2015 EHR certification requirements and the Promoting Interoperability or Meaningful Use programs. (For example, Release 1.5 of the version 2 immunization implementation guide should still be accepted and required moving forward.)

Registries Request for Information

ASTHO appreciates that ONC has provided standards for public health registry reporting and that federal funding is provided through Health Information Technology for Economic and Clinical Health Act (HITECH) of the American Recovery and Reinvestment Act (ARRA) of 2009 to enable public health to electronically receive registry data. We again encourage that the rule clarifies that FHIR API support does not replace existing public health interoperability standards, as S/THAs currently do not have funding nor resources to make this shift.

Patient Matching Request for Information

ASTHO recommends patient matching as a critical tool for promoting improved patient safety, better care coordination, advanced interoperability, and improved public health surveillance in order to avoid information duplication or erroneous data. We encourage ONC to take an active role in standardizing operations and guidance for implementing master person indexing, with S/THA collaboration and involvement, to ensure interoperability between public health, insurance companies, and clinical providers.

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Trusted Exchange Framework and Common Agreement

ASTHO affiliates and partner organizations understand the Trusted Exchange Framework and Common Agreement (TEFCA) to be a voluntary framework for supporting information exchange and caution against issuing future rules that would require compliance, particularly from a subset of the health IT developer community. We do not recommend singling out this community as mandatory participants. Additionally, we note that requirements that fall on vendors contracted to operate public health registries may incur costs that public health is not prepared to support.

We encourage ONC to support the single on-ramp of S/THAs to interconnected health data networks, as these will support the plethora of information exchanges involved in public and population health surveillance. Furthermore, we recommend that ONC involve S/THAS in the development of standards for public health programs and suggest that agency data exchange transactions include both "push" data exchange and "query" for data. The ONC Interoperability Standards Advisory (ISA) currently lacks public health representation; therefore, we recommend a consensus-based standard process that includes S/THAs.

Real World Testing

In coordination with public health organizations and agencies, we support ONC's development of a directory of S/THAs that can be available to support real world testing of public health transactions and clinical care to public health transactions. If adopted, there is an opportunity for S/THAs and other organizations (e.g., Certified Electronic Health Record Transfer vendors) to collaborate, ensure more consistent national implementation, and potentially save costs by cost sharing between stakeholders (e.g., public health, healthcare providers, and other organizations involved) and using a common infrastructure that would be developed and deployed to support such testing.

Recommendations

In line with the above comments and suggestions, ASTHO and its members generally recommend the following:

- S/THA representation in the form of advisory body opportunities—in accordance with the Federal Advisory Committee Act—and/or stronger S/THA stakeholder engagement within working groups and national convenings designed to inform the creation of rules and guidance documents.
- For ONC to support and promote stronger collaboration among multiple sectors, to include S/THAs, healthcare, and health IT developers and vendors.
- A request for a stronger consensus-based standards process, which includes S/THAs.
- Resources in the form of funding opportunities, federal agency details, or regional coordinating/ technical assistance centers that can help S/THAs adopt standards and interoperability efforts.
- ONC ISA is lacking public health representation; therefore, we recommend a consensus-based standard process that includes S/THA input.

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- Development of a directory of S/THAs that can support or be leveraged for real-world testing of tools (if those are aligned with S/THA's experiences and population health outcome goals).

Thank you for the opportunity to submit comments to ONC's Notice of Proposed Rulemaking. ASTHO looks forward to working with the National Coordinator for Health IT, ONC, and the U.S. Department of Health and Human Services to support information exchange and health transformation activities that improve health outcomes in communities. If you have any questions or comments about the above recommendations, or should you provide any additional opportunities to share input—please email Mary Ann Cooney, chief of ASTHO's Center for Population Health Strategies, at mcooney@astho.org.

Sincerely,

Michael Fraser, PhD, MS, CAE, FCPP
Chief Executive Officer, ASTHO

cc: Mylynn Tufte, MBA, MSIM, BSN, North Dakota State Health Officer
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