June 3, 2019

The Honorable Donald Rucker, M.D.
National Coordinator for Health Information Technology
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule,
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

RE: RIN 0955–AA01, Request for Comments, Notice of Proposed Rulemaking, *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*

Dear Dr. Rucker:

My name is Steve Eichner, and I currently serve as co-chair of the Public Health Promoting Interoperability Task Force (Task Force), a group of public health professionals focused on the impacts of electronic health records and health information exchange on public health agencies. Among other activities, we produce guides for public health agencies to use in implementing policies and practices to support the Centers for Medicare and Medicaid Services' *Promoting Interoperability Programs.*

On behalf of the Task Force, I am writing to you today with comments regarding the recent Notice of Proposed Rulemaking (NPRM) that implements provisions relating to the interoperability of electronic health record systems contained in the 21st Century Cures Act. We appreciate the effort that staff from the Office of the National Coordinator and other organizations have made in developing draft material,

The Task Force has some concerns regarding the proposed rule and its impact on public health agencies' ability to collect and appropriately share health information. Some of the provisions of the rule appear to require public health to redirect already scarce resources to activities that will not likely result in improved services. There are also many concepts in the NPRM that the Task Force supports.

NPRM Definitions and Information Blocking Provisions

Public health agencies currently provide a wide range of electronic services to health care providers, including supporting one-way electronic reporting of health conditions for population-level analysis such as trauma registries or syndromic surveillance as well as bi-directional services like immunization registries and prescription drug monitoring programs (PDMP), which are intended to support near-real-time services for coordinating care for individual patients. Unfortunately, the definitions provided in the NPRM are unclear. It would appear that services like an immunization registry or PDMP

could be considered (single issue) health information networks (HINs). Public health agencies also provide direct care services, qualifying them as health care providers, as defined in the NPRM. In some cases, public health agencies also appear to meet the definition of health information exchanges (HIEs). Public health agencies can also serve as health information technology vendors, supplying software and services to health care providers.

The proposed rule applies slightly different rules regarding information blocking to each category, and it is unclear when each of the different rules would apply to public health agencies. It may also be inappropriate to apply information blocking rules to public health in all categories. To address this issue, the Task Force recommends that an eighth exclusion from information blocking be established that includes all public health agencies/authorities established under state law, including state and local health departments.

As part of the exclusion, each agency/authority would be able to declare its readiness to support the information blocking provisions of the proposed rule on a program-by-program basis. The declaration would include what resource is available and the role (health care provider, HIN, HIE, vendor, etc.) the agency is serving in for that program. Functionally, the approach would be implemented in a manner like the declaration of readiness approach by public health agencies used under the *Promoting Interoperability* programs. This approach will help address the Task Force's concerns about accusations by other entities of information blocking by public health, even when no illegal information blocking is occurring.

An example of a situation where a public health agency could be (falsely) accused of information blocking may be illustrated by the example of a trauma registry operated by a state health department which collects information about all trauma incidents in a state and use the data on a de-identified basis, limited by state law in providing individually-identified information. Under the proposed rule, the agency could be accused of information blocking and would need to spend scarce resources in responding to the accusation. If the state could declare what programs were subject to information blocking provisions, the effort in responding to the accusation would not be necessary.

An example of where information blocking isn't occurring is when a public health agency is providing direct care, such as vaccination services, and is sharing that individually-identified information electronically with other care providers, either through an EHR or, perhaps, through resources like an immunization registry.

The Task Force proposes that, under the newly-added eighth exclusion rules, Entities wishing to access data maintained by a public health agency could go to the public health agency's web site and easily identify what information is available. The Task

Force is in an excellent position to help document required processes and communicate those processes to public health agencies, both directly and in conjunction with national public health-related associations.

The Task Force recommends that language be added to the exclusions that a health care provider being held in an onboarding or testing queue does not constitute information blocking. There may be a variety of reasons for a health care provider remaining in a queue including a change in technologies that requires retesting, the implementation of a new data exchange service, such as a new registry, that requires individualized attention, and staff shortages. As in the suggestion of adding a general exclusion for public health agencies above, including this specific exclusion reduces the burden on public health of responding to inappropriate accusations of information blocking.

The Task Force recommends including a failure to report data under existing public health laws as an example of information blocking. Since many exchanges with public health agencies occur as a result of “push-based” transactions initiated by the health care provider, the inclusion of this example demonstrate that information blocking can result from both “pull” and “push” data transactions.

The Task Force requests that vendors that release Certified Electronic Health Record Technology that is not able to actually report to a public health registry be considered to be information blocking and that any software found to not be able to actually report data have its certification suspended or terminated.

Response and Reporting Timeframes

Similarly, the Task Force recommends the addition of language addressing response and reporting timeframes as a component of information blocking. There needs to be clarity about what delays in reporting, or responding to a query, are acceptable. This can have a substantial impact on public health. For example, a notifiable condition is supposed to be reported within 24 hours of detection. If it is not reported within that time period, is that information blocking? Is it information blocking if not reported for 30 days? What happens if it is never reported electronically, from an information-blocking perspective?

Patient Authorization for Sharing Data

The Task Force is concerned about the NPRM’s current language that would appear to allow a health care provider to block the sharing of health information based on a request by a patient. The current language does not clearly and explicitly state that no request by an individual can override laws requiring public health reporting. The current language will confuse data reporters and potentially limit the timely reporting of critical information to public health.

Communications
The Task Force want to ensure that public health agencies have the same opportunities as health care providers regarding protected communication guidelines about health IT. Like private health care providers, public health agencies also interact with CEHRT developers. Explicitly including public health agencies in the NPRM's provisions regarding communications will facilitate public health agencies' sharing information about CEHRT that has limited success in meeting public health reporting requirements. Similar to the impact of providers sharing information with each other, including public health in the relevant provisions will enable improved collaboration between public health agencies.

Standards Development and Collaboration
The Task Force is a strong proponent of consensus-based decision-making and does not support ONC's request for National Technology Transfer and Advancement Act (NTTAA) exceptions for developing data and messaging standards within the NPRM. While the Task Force appreciates the speed at which decisions may be made within a closed group, it is critical that there be sufficient discussion and consideration of all stakeholders' concerns in adopting such critical technologies as the Fast Healthcare Interoperability Resources (FHIR), what other technologies may be used to support exchange under the federal guidelines, and the timeframes for adoption. Public health agencies have benefitted from these kinds of collaborative efforts, including the work of the Task Force itself.

The Standards Version Advancement Process must also use an open, collaborative to determine when standards are ready for implementation, and public health must be included as part of the decision-making body. No entity should be permitted to implement a new version of an interoperability standard that impacts public health that is not backwards-compatible and that public health agencies are not prepared to support. Any entity that adopts a new standard must retain support for the previous version until all trading partners can support the new standard.

The Task Force appreciates the work to establish the ensure that certain core data elements are available to providers and patients. While the goal of transitioning to United States Core Data for Interoperability (USCDI) has some benefits, use of voluntary consensus-based standards development organizations such as Health Level 7, that public health can and does participate in, is important.

Sending a full USCDI-based health record would include data elements such as discharge notes and cognitive status that should not usually be sent to public health, potentially violating HIPAA because the disclosure exceeds minimum necessary data standards. Clarification is also needed regarding the code set that would be utilized for each field (e.g., what values will be included in the definition of race?). Increasing the number of data fields may help with patient matching, a constant issue for many parties,

also as discussed above. The Task Force requests that the rule specifically call out public health agencies as a group that is included in the decision-making body and is able to formally vote on the adoption of core data elements.

FHIR

It is critical that any transition to FHIR take place incrementally, and the transition is not driven solely because FHIR is new technology. Public health is limited in its resources, has not invested in FHIR development, and has few resources to direct to new initiatives unless there is a substantial business reason for transitioning. The Task Force requests that the final rule include language that FHIR Application Programming Interfaces (API) *augment* but does not *replace* any existing public health interoperability standards included in *Promoting Interoperability* programs or in the 2015 Edition CEHRT certification requirements. The Task Force recommends adopting FHIR 4.0 for new transactions. The current, non-FHIR standards should be supported for at least five years after the rule is finalized.

Real World Testing

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 Task Force supports the NPRM's approach to ensuring CEHRT meets real-world requirements. Using real-world testing scenarios may assist with implementation across jurisdictions and may lead to cost savings. It is essential that public health be included in testing functionality, especially with respect to CEHRT's interfacing with public health's data resources. It is necessary, however to adequately address funding, perhaps establishing a public health testing center that has connections to applications operated by disparate public health agencies to facilitate testing without increasing the burden on public health staff.

Medication Lists and Smoking Status Removal

The Task Force agrees with ONC that medication lists are in virtually all EMRs but is concerned about eliminating the requirement that medication lists be maintained. Having ready access to a patient's medication history and current medications is critical in preventing potentially deadly medication interactions as well as when responding to disasters and the provision of mass-care or care outside of individuals' normal health care environment. Continuing the requirement to include a medication list is not adding an additional burden to providers but is documenting critical functionality.

Public health agencies are often responsible for tobacco prevention activities within their jurisdiction. Removing smoking status as a requirement from EMRs may make it more difficult to readily access patients' smoking status or limit providers' ability to update patient records.

Multi-factor Identity Validation
Multi-factor authentication identity validation assumes that there is a human accessing the data in real-time. Many transactions involving public health agencies focus on machine-to-machines transactions. These transactions cannot use multi-factor validation. The Task Force suggests that the rule language be modified to explicitly recognize that automated transactions, such as public health reporting, cannot support multi-factor authentication.

Pediatrics
The Task Force is concerned that the rule's language with Proposed New or Updated Certification Criteria presents some challenges. The requirement for FHIR support for immunization transactions, including query/response messages for vaccine forecasting is not in current Centers for Disease Control and Prevention standards. The proposed rule also seems to require the inclusion of pediatric vital sign data, which are also not relevant to current immunization messaging, and immunization information systems do not have fields available to store this data. Public health is not currently funded to modify its information systems (IIS) to support FHIR-based services for immunizations or include pediatric vital sign data in IIS.

The Task Force applauds the work ONC has accomplished to recognize the need for standards for public health registry reporting and the federal funding that has been provided through the Health Information Technology for Economic and Clinical Health Act (HITECH) to enable public health to electronically receive registry data. Unfortunately, funding through HITECH is about to expire, with no replacement funding source identified. Without federal support, public health agencies will be limited in their ability to make large investments in technology, such as the implementation of FHIR and API interfaces.

To help mitigate the loss of funds, the Task Force suggests that language of the proposed rule clarify that FHIR API support *augments* but does not *replace* existing public health interoperability standards currently included in *Promoting Interoperability* programs and 2015 Edition EHR certification requirements, allowing public health organizations to maintain current interfaces until sufficient funding is available to make necessary changes. Most public health organizations do not have available funds and cannot make changes within two years. If the transition to FHIR for public health moves forward, it must have public health participation, be accompanied by appropriate

funding, and provide time for public health agencies to develop and implement FHIR technology.

Patient Matching
Accurate patient matching is essential to coordinate care, understand patients' medical conditions, promote patient safety, and conduct accurate public health surveillance. The adoption of standards used to match patients will ensure consistency in the approach and serve as an important foundation for federal agencies policies, promoting consistency between programs. Public health's experience in patient matching, such as is used in cancer registries and immunization registry systems can be leveraged for use across the health care continuum. Collaborating with approaches developed in the private sector will allow for a universal approach that is agreeable to all. Developing a Medicaid-wide patient identifier and standardization of data elements used for patient matching would help a variety of programs. Ideally, Medicare would use the same algorithm and master patient index. The standard could be included in ONC's Interoperability Standards Advisory.

USCDI
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.

The Task Force strongly supports continued required immunization, syndromic surveillance, vital records, case report, disease and clinical registries, and other reporting. The suggestions in this letter are intended to and believes that, with the suggestions included in this letter, there will be significant improvements in data collection activities and the transformation of that data into actionable information through improved interoperability between public health agencies and their stakeholders.

Thank you for the opportunity to comment on the NPRM. Please feel free to contact me at steve.eichner@dshs.texas.gov with any questions you may have.

Sincerely,

Steve Eichner
Co-Chair, Public Health Promoting Interoperability Task Force