October 4, 2024

The Honorable Micky Tripathi, Ph.D., M.P.P.
Assistant Secretary for Technology Policy and National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, D.C. 20201

SUBJECT: RE: Request for Comments on Proposed Rule, "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)"

Dear Dr. Tripathi:

The Washington State Department of Health (WA-DOH) and the Washington State Health Care Authority (HCA) have reviewed the proposed rulemaking for "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)" and submit the following joint comments as they relate to our agencies.

WA-DOH and HCA have many programs that receive and send data to clinical partners through health IT systems. We strive to make transacting data with public health as seamless and efficient as possible for all partners. WA-DOH and HCA embrace the interoperability standards set forth by Assistant Secretary for Technology Policy (ASTP)/ Office of the National Coordinator of Health IT (ONC) for public health measures and believe this work has been essential to make public health reporting more efficient for both healthcare providers and public health agencies.

We seek to ensure new rules around interoperability support public health's need to carry on our essential work in protecting public health and patient safety. WA-DOH and HCA support the overall goal of the proposed HTI-2 rules to advance interoperability. The following highlight our key comments:

- **Some standards and criterion are not ready yet for certification (e.g. birth reporting).** We are not aware of a state public health agency that has this capability in production.

- **More time and funding are needed to complete this important modernization work for our nation's public health system**. The Health Information Technology for Economic and Clinical Health Act (HITECH) provided more than $25 billion to incentivize the digitization of the United States health care system over a decade. Public health agencies will need reasonable time and funding to achieve data modernization. The Healthcare Information and Management System Society (HIMSS) produced a report recommending that $36.7 billion be provided to public health over 10 years for public health data infrastructure. In the meantime, additional support from federal agencies advocating for public health agencies' direct access to electronic medical records

(EMR) can improve many of these issues and is relatively quick to implement. Unfortunately, some healthcare organizations often cite HIPAA as a barrier to this access inappropriately, as public health is a HIPAA-exempt entity. Direct advocacy from ONC within this rule, or future rules from ONC regarding direct access to EMRs for public health, would go a long way to improving information sharing in the short term while more efficient data modernization efforts are developed in the coming years.

- We support work done around the new protecting care access exception. Addition of the exception would increase public confidence that the nationwide health information technology infrastructure will improve interoperability rather than create new privacy concerns for patients, specifically patients in need of access to reproductive healthcare.

- We respectfully request that ONC work with partners to mature standards to improve interoperability between healthcare and public health through robust standards development and piloting.

- We strongly support continued required reporting in the areas of immunization, syndromic surveillance, vital records, case reports, disease and clinical registries and others. Federal support for public health reporting must remain strong including the provision of additional funding to ensure public health registries can become and remain interoperable. WA-DOH and HCA look forward to partnering with HHS to further this important work.

The following highlight specific comments based on page numbers in the PDF of the proposed rules.

Definition of "health IT for public health"
We appreciate the need to improve interoperability between public health systems and healthcare. While the definition for "health IT for public health" seems comprehensive, the definitions create a lot of new requirements that come with initial and ongoing cost to public health agencies. While certification is a voluntary program, based on what the Centers for Medicare and Medicaid Services (CMS) has done to require use of certified EHR technology (CEHRT) for providers, it seems logical that the same will happen to public health agencies from HHS funding. The given timeline for meeting these new certification requirements is not feasible. The number of systems that WA-DOH has built and the number hosted by vendors that would be impacted is large. More time and funding are needed to complete this important modernization work.

Revised and Additional (f) criteria (f)(1) to (f)(5) and (f)(21) to (f)(25)
We appreciate the approach to enhancing the certification criteria to include the systems necessary at public health agencies in order to accept and meaningfully use the data produced by CEHRT at healthcare organizations. We recognize the nature of this approach produces parity between the submitters and receivers of the data, building off previous investments. This juncture provides us an opportunity to reshape some of how we discuss HealthIT for public health, and we could create more long-standing opportunities if we built foundational requirements based on core public health activities. For example, casting public health activities in the following categories would allow true extensibility and modularization:

- Surveillance; including syndromic surveillance, reportable lab tests and results, antimicrobial use and resistance reporting
- Case management; including electronic case management, field work, and contact tracing
- Registry management; including immunization registry, cancer registry, and prescription registries
- Vital records; including birth reporting and in the future death reporting

Specifically, for the expansion of existing f criteria 1-5, we appreciate the push towards new standards and creating more explicit functional requirements.

- January 1, 2028 is an aggressive timeframe for the implementation of the Fast Healthcare Interoperability Resources (FHIR) and Laboratory Order Interface (LOI) standards, and would support an implementation runway with gradual goals similar to how Meaningful Use and Promoting Interoperability were iterated over several years.
- We believe there is a benefit to working towards consolidation around FHIR standards, to limit the number of different FHIR standards required for different reporting from healthcare organizations to public health agencies. One organization maintaining multiple FHIR standards depending on which form of registry they are reporting can be cumbersome and prohibitive.
- We fully support the inclusion of requirements around standardized coding, such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine (SNOMED). Additional specificity regarding where within the lab reports these standardized codes are included, and a national framework for mappings would be helpful. For example, an individual hospital may work with multiple lab test vendors who map LOINC codes differently, increasing workload and producing confusion.
- While we agree that higher adoption of LOI and Laboratory Result Interface (LRI) standards may lead to increased data quality, submitters are currently struggling with meeting existing standards. Specific requirements about data quality and how to monitor or measure data quality would be needed to achieve meaningful results. We recommend changing the LOI/LRI standard from only version 4 to version 4 or later. This would resolve the issue of determining the best version of Health Level Seven (HL7) for Newborn Screening Labs data exchange at this time since there is not clarity on which version is optimal. This could then be moved to a singular standard in a future federal rulemaking.
- For syndromic surveillance, we support revising referenced standards to the most recent implementation guide: HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use, July 2019.
- We would appreciate seeing more language regarding submitting error corrections; public health agencies traditionally receive one transmission of data, and later corrections are not transmitted.
- For registry reporting, including Cancer registries, we recommend supporting both FHIR and V2 Clinical Data Architecture (CDA), as we have heard from multiple vendors that V2 messages are preferable in instances of a scheduled "push" of data.
    - The North American Association of Central Cancer Registries (NAACCR) publishes guidance for electronic lab reporting for cancer registries that further clarifies expected content that we believe would be a meaningful standard to include for cancer registry reporting.
    - WA-DOH requests clarification regarding on the effective dates for LOI and LRI IGs within the rule. The LOI IG appears to be dated October 2022 rather than December 3, 2013, and the LRI IG appears to be dated October 2022 rather than July 16, 2012, as stated in the proposed rule.

For the new f criteria 21-25, we appreciate the inclusion of the technology requirements for public health agencies in this rule. We believe creating and supporting these common technologies will improve the marketplace for public health technologies.

- We appreciate the push for newer, more modern terminologies, but ask that the standards include support for previous versions in parallel to newer adoptions. Public health agencies will need to

support submitters which cannot, or will not, migrate to newer standards while also supporting modern systems and terminologies.

- Similar to above, WA-DOH believes January 1, 2028 to be an aggressive timeframe for the implementation of many of these standards without adequate and predictable funding. State health departments like WA-DOH will require a long-term funding plan in order to put a request to their state legislature, for example.
- We appreciate comments regarding validation of files to existing requirements in multiple sections and agree that validation is increasingly important to ensure accurate and timely exchange. We would appreciate additional specificity about what federal tools will be created to support these uniform validations, and how they will be kept up to date to ensure accurate and timely submissions to agencies. There will be many challenges regarding what submitters are validated against, the certification criteria compared to implementation guides, and consistent usage of standard terminologies. These challenges increase for complicated documents such as electronic initial case reports (eICR).
- We would appreciate focusing on registries as a central public health activity, and providing requirements for individual registries as needed. As mentioned earlier, while the registries addressed in this standard are extremely important, we have the opportunity to create an extensible software environment which allows for additional public health registries to follow the same framework.
- We request that receiving reports over FHIR/APIs and Trusted Exchange Framework and Common Agreement (TEFCA) not be specified as the only transport and exchange mechanisms for any key public health transactions at this time as many agencies are not ready to even begin looking at TEFCA.
- We would appreciate more information on the implementation plans for the new capabilities required to send Electronic Laboratory Reporting (ELR) with LOI from healthcare organizations, and the requirements for public health agencies to receive, and in particular, filter these messages. Filtering does not appear to be specified within the current implementation guides.
- We have a concern regarding the requirement within the Syndromic Surveillance data exchange section to require the use of Secure File Transfer Protocol (SFTP), and make the use of other technologies optional. We believe that this is too narrow with multiple secure solutions currently in use and may interfere with FHIR adoption.
- We have several questions regarding changes in the Electronic Case Reporting (eCR) requirements for public health agencies. Will it be a requirement for public health agencies to generate Reportability Response (RR) receipts, and will these RRs require a trigger condition which is not currently included in the RR?
- We do not believe that the terms “receive”, “validate”, “parse” and “filter” are adequately defined or described in the rule. We ask for clarity or definitions to be added in order to reduce complexity and cost.

<u>Birth reporting (f)(8) and (f)(28)</u>

WA-DOH is supportive of the move to digital birth reporting as it would save resources in birth centers from doing manual data entry and could improve data quality in the registry, however we have not seen any successful implementation yet in the United States and think some pilot reference implementations are needed before certification criteria can be developed.

<u>Prescription Drug Monitoring Program (PDMP) – (f)(9) and (f)(29)</u>

We are concerned about the proposed rules in § 170.315(f)(29), which would impose an unnecessary financial burden on already overstretched public health systems by requiring public health IT systems to unclearly support Health IT modules under § 170.315(f)(9). First, two national networks, RxCheck and PMPi, already manage interstate sharing of PDMPs. Requiring public health data systems to take on

additional interstate data sharing would be costly and intentionally redundant — this would only provide benefit in systems that frequently handle out-of-state care. Second, the proposal to allow patients direct access to PDMPs under § 170.315(f)(29)(iv) conflicts with state laws. WA-DOH is not aware of any state that currently allows patients direct access to PDMP data, which would introduce significant legal and technical challenges and further strain public health data systems. An alternative would be to allow patient access via CEHRT to any data that has been stored there from a PDMP as part of their record. Lastly, without a clear data exchange standard, requiring public health data systems in § 170.315(f)(29) to process and exchange electronic prescription data for controlled substances and support PDMP queries would severely hinder interoperability. Public health data systems would need to support multiple data formats and methods, creating unnecessary complexity and costs. We recommend that the ONC prioritize working with PDMP interested parties on finding a common set of standards to use (with proper funding and timeline to implement), improving care coordination for people with substance use disorder by implementing electronic consent management and ensuring justice system health records are interoperable with other health systems.

New Standardized API for Public Health Data Exchange

We are supportive of New Standardized Application Programming Interface (API) for public health and agrees that it is the necessary first step for developing and furthering FHIR based ecosystem. One of the primary steps for the standardized API is to have standard sets of profiles for use in the exchange of data in Public Health. The expansion of Public Health Profiles Library to include all current use cases pertaining to public health would be an essential step in the process of standardization.

The rule proposes the use of SMART-on-FHIR technology, that uses OAuth 2.0, and this will very much be a paradigm shift with regards to the transport and security method used by the public health domain. The use cases currently being implemented at WA-DOH (VRDR FHIR IG) is using OAuth 2.0 as a standalone service. However, the matter needs to be approached with the implementation of SMART on FHIR platform at the enterprise level. The platform shall be used for connectivity with services inside and outside the organization.

Bulk data API and subscriptions mentioned in the proposed rule has great potential in the public health interoperability space. However, the use of technology is in very primitive stages and we are not aware of real use case in production in any public health agencies in the nation. Therefore, more time and technical and financial resources need to be invested in development, testing and quality assurance of these resources. Once all the different technologies in the ecosystem that supports development and exchange of FHIR based data gets implemented and is networked through Qualified Health Information Networks (QHIN) under TEFCA, the public health systems will be well positioned to proactively collect and analyze data in near real time thus enabling public health to better collaborate with the health care systems in prevention, containment and control of public health threats and management of emergencies.

The standard API for Public Health is assumed to also have support for the standard US Core API as part of it for supporting the use cases like clinical data exchange for services the data for which stewarded by state health agencies and by community information exchanges.

Verifiable Health Records 170.315(j)(22)

We recommend that the final rule reference the optional adoption of SMART health cards and SMART health link functionality using the HL7 FHIR SMART Health Cards and Links Framework. Washington State (WAverify.org) has successfully developed reference prototypes and implementations in how this technology can help the public to make more portable their own critical personal health information. Canada and other countries are advancing the adoption of International Patient Summary and ASTP/ONC should add this standard to the certification program if we are to stay part of the global ecosystem.

Bulk Data Enhancements

We are very supportive of advancing bulk query/response capabilities as they are needed for many important use cases. Currently, we recommend that ASTP/ONC resolve patient matching in context of bulk data queries. For example, HELIOS identified the need for substantive changes before it is ready for use in immunization focused queries. While for a Provider API that may work in context of established attribution lists, in other use cases bulk data would not be as ready. We also recommend additional testing of bulk data Access implementation prior to certification.

New Certification Criteria for Modular API Capabilities

We are generally supportive of a more modular approach for clarity and reduced ambiguity. In combination with role-based criteria, the certification criteria can be adopted in a more targeted fashion. This more modular approach should also be considered in (g)(10) and (g)(20) criteria and reconciled with the relevant information blocking requirements in that the certification program should enable more HIT to be certified by focusing on the data that the HIT actually manages, thus supporting the much more modular HIT ecosystem. We also request care be taken to ensure these criteria aligns with CMS certification for health IT systems. WA-DOH is considering how to leverage CMS funding for sustainability of our DMI efforts and it would be very costly if they do not align.

Revised Computerized Provider Order Entry (CPOE) – Laboratory Criterion

WA-DOH would like clarity from ASTP/ONC on this criterion as it is not clear on its intent for CPOE in relationship to public health when public health is the performing lab. We request clarification if the intent is that providers working in hospitals would be able to enter orders directly into a Public Health Lab Web Portal or rather that PHL software LIMS would be able to receive provider entered orders from EMR and other "Non-PHL" applications via HL7 messaging.

Environmental Public Health

We appreciate the inclusion of environmental public health in the proposed rule. Environmental public health data is important to include and consider since program work often includes syndromic surveillance (e.g. wildfire smoke exposure, food born illnesses, vibrio and biotoxin illnesses, illnesses caused by harmful algal blooms, pesticide exposure illnesses), electronic data transfer, etc. Additionally, WA-DOH think that in ASTP/ONC's new elevated role there could be more coordination in the adoption of interoperable standards for environmental health. Traditionally, the Environmental Protection Agency uses very different data formats, we encourage the use of FHIR to a bridge the worlds of health and environment.

USCDI Data Elements

We support the direction of moving towards USCDI V4 as the new minimum floor and appreciate the alignment with the new OMB race/ethnicity standards. We recommend that the patient demographic 'Language' data element may be better separated by 'written' and 'verbal'. Certain new data elements such as 'average blood pressure' and 'results reference range' should be system generated so not to add unnecessary provider administrative burden.

Prior Authorization APIs

We support ONC's new provider recertification requirement moving towards mandating the HL7 Da Vinci Project implementation guides which align with CMS requirements for payers to establish Prior Authorization APIs.

New Protecting Care Access Exception

The Protecting Care Access Exception will apply to acts or omissions likely to interfere with access, exchange, or use of particular EHI that an actor believes could create a risk of exposing patients, care

providers, and other persons who assist in access or delivery of health care to potential administrative, civil, or criminal investigations or other actions on certain bases. The rule would add a new information blocking exception, and the stated purpose of the exception is to create certainty for actors that certain practices for which no other exception would apply will not be considered ‘‘information blocking’’ under the information blocking statute (PHSA section 3022) and regulations (45 CFR part 171).

Protecting patient healthcare data and eliminating barriers to access to reproductive healthcare are top priorities for Washington. We support the new exception because it may offer actors certainty that limiting sharing of EHI will not be considered information blocking. We agree that the exception may help assure patients and providers that the information blocking regulations support actors limiting EHI sharing in response to privacy risks that arise over time, while also continuing to support patients' own access to their EHI and other sharing of EHI consistent with applicable law and patient preferences that foster better patient care.

We agree that the addition of the exception would increase public confidence that the nationwide health information technology infrastructure and will improve interoperability rather than create new privacy concerns for patients, specifically patients in need of access to reproductive healthcare.

Requestor preferences exception

The proposed rule creates an additional information blocking exception, which is referred to as the "Requestor Preferences Exception'' in § 171.304. The proposed rule intends to offer actors certainty that it would not be considered ‘‘information blocking’’ to honor an information requestor's preferences for: (1) limitations on the scope of EHI made available to the requestor; (2) the conditions under which EHI is made available to the requestor; and (3) the timing of when EHI is made available to the requestor.

WA-DOH supports the rule because it offers actors certainty that honoring a request to limit the sharing of EHI will not be considered information blocking. This rule creates a new method for actors to honor providers and patients requests for additional privacy protections.

Information Blocking Enhancements

WA-DOH is involved in many data exchanges that are critical to public health work with laboratories and pharmacies. We support ASTP/ONC inclusion of laboratories (ELR needs for public health) and pharmacists (immunizations and PDMP needs for public health) in the definition of "healthcare provider" as an actor subject to information blocking. We encourage ASTP/ONC and HHS to find ways to incentivize and eventually also certify laboratory information management systems and pharmacy dispensing and sales systems to complete the interoperability eco-system that is needed for healthcare.

Estimated Costs to PHAs to Meet New Requirements

We conducted internal cost estimates to assess and compare the proposed rule's funding allocations for f criteria improvements. Given the quick turnaround, we focused solely on project staffing costs, as vendor, infrastructure, and implementation partner expenses are unknown without rigorous consultation and can vary significantly depending on the specific needs of each project.

We estimate that staffing costs alone average $1 million per system. This excludes infrastructure, vendor expenses, potential implementation partner costs, and additional certification expenses (like paying an ASTP/ONC approved 3rd party do perform the certification). These estimates clearly demonstrate that the proposed cost estimate in the rule is significantly insufficient. Costs escalate rapidly due to the broad range of specialized roles required for successful implementation, including informatics specialists, IT developers, security experts, business analysts, and project managers. It would also likely cost more given the implementation deadlines being recommended.

With multiple systems and components needing updates—such as the public health API, Bulk FHIR, and SMART Health Card components—the current funding is grossly insufficient to cover these resource-intensive requirements. WA-DOH estimates that the total cost for all systems will approach $10 million. To successfully implement these updates and ensure sustainable operations, significant additional funding will be required.

HIMSS produced a report recommending that $36.7 billion be provided to public health over 10 years for public health data infrastructure. The investment to meet these important requirements has not been provided. Much of the current DMI investment needs to go, and has gone already, to other very vital pieces of improving public health infrastructure. While interoperability is a piece of DMI it is not all of it. We need additional funding to not only become certified but to meet all of the maintenance requirements that also come with certification. It is difficult to commit to this type of certification when we have no way of sustainably maintaining it. Again, we understand that this is a voluntary program and we want to make it clear that if the desire is for public health agencies to go through certification, more implementation and operational funding is required.

We strongly support continued required reporting in the areas of immunization, syndromic surveillance, vital records, case reports, disease and clinical registries and others. Federal support for public health reporting must remain strong including the provision of additional funding to ensure public health registries can become and remain interoperable. We look forward to partnering with HHS to further this important work. Thank you for the opportunity to provide comments on the proposed rules.

If you have any questions, please contact WA-DOH's Federal and Regulatory Affairs Director, Michael Ellsworth at Michael.Ellsworth@doh.wa.gov or Governor Inslee's Director of Federal & Inter-State Affairs, Rose Minor at rose.minor@gov.wa.gov.

Sincerely,

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