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February 27, 2026

The Honorable Thomas Keane, MD, MBA
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

RE: Request for Comments on Proposed Rule, "Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5)"

Dear Dr. Keane:

On behalf of the Washington State Department of Health (DOH), I am providing comments on the proposed rule published on December 29, 2025, in the Federal Register (Vol. 90, No. 245).

As a public health agency, DOH has many programs that receive and send data to clinical partners through their health IT systems. This exchange is mission critical for many of our agency's core responsibilities. DOH strives to make transacting data with public health as efficient as possible for all clinical partners. Our agency has embraced the interoperability standards set forth by ASTP/ONC for public health measures and believes this work has been essential to make public health data exchange more efficient, and to reduce burden, for both healthcare providers and public health agencies. DOH seeks to ensure proposed rules around interoperability support public health's need to carry on our essential work in protecting public health and patient safety.

While DOH supports some aspects of the proposed rule, there are several concerns outlined in our comments here. Our high-level concern is that many of the proposed removals of criteria do not make data exchange less burdensome, in that they open the door to variability in how or what standards are used and potentially move providers and public health back to manual data submission and data entry.

The department's specific comments are listed below based on page numbers in the PDF of the proposed rules posted at https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-astponc-deregulatory-actions-unleash-prosperity.

Model Card Transparency Requirement Removal (Page 60973)
DOH is concerned about the proposed removal of AI "model card" transparency requirements from the Decision Support Interventions certification criterion (§ 170.315(b)(11)). While ASTP states there is no publicly available evidence that these transparency requirements have led to positive impacts on patient care, the requirements have only been in effect since January 2025; insufficient time to evaluate their impact. State and local public health agencies increasingly rely on predictive algorithms and AI-enabled tools for disease surveillance, outbreak detection,

resource allocation, and population health management. Removing transparency requirements before alternative oversight mechanisms are established creates a gap in accountability precisely as AI adoption accelerates across the health system. We recommend that ASTP either retain or simplify the model card requirements or, at minimum, develop voluntary guidance frameworks for AI transparency that health IT developers and healthcare organizations can reference. Additionally, we are struggling to understand how the removal of these requirements aligns with the administration's stated goal of advancing "AI-enabled interoperability solutions," given that responsible AI deployment typically depends on understanding model provenance, training data characteristics, and performance limitations, which is the information contained in the current model card format.

Information Blocking: TEFCA Manner Exception (Page 60974)
DOH would prefer that the TEFCA Manner Exception be left in the rule and not removed. We see TEFCA as an important foundation to achieving national interoperability. This exception helps incentivize participation in the network. We also agree with ASTP that TEFCA and CMS Aligned Networks are complementary as stated in a recent healthIT.gov blogpost this year. This exception does not impose burden, since it is not required, but instead helps incentivize partners in moving interoperability forward.

Information Blocking: Artificial Intelligence Access and Use Definitions and Information Blocking (Pages 60970-60980)
WA DOH generally support HTI-5's clarification under Information Blocking Artificial Intelligence that access and use of electronic health information include automated means such as robotic process automation and autonomous AI systems as this reflects how public health reporting surveillance and analytics are increasingly conducted. Explicitly recognizing AI enabled access and use may improve the timeliness scalability and consistency of public health data exchange. At the same time expanding use to include autonomous AI systems raises unresolved operational and governance questions for public health authorities particularly regarding authentication role-based authorization minimum necessary access auditability and oversight when AI systems act on behalf of an agency or its contractors. HTI-5 does not specify how products should demonstrate appropriate controls or accountability for AI enabled use of electronic health information and existing information blocking frameworks were not designed with autonomous systems in mind. Additional HHS guidance specific to public health use cases such as surveillance e-case reporting and analytics would help ensure that the expanded definitions support responsible innovation while maintaining legal compliance, transparency, and public trust.

Clinical Certification Criteria: Patient Demographics (Page 60980)
Under the ONC health IT certification program and with the proposed adoption of USCDI v. 3.1, the collection of patient demographic data elements would be rolled back to support streamlined development and interoperability. The potential benefits of this change would be countered by the loss of this rich demographic data. These data are vital for monitoring public health, quality, and analytics for different populations. Even if the data elements are removed different vendors and health systems could interpret the changes differently which could lead to inconsistencies across the systems. Changes and inconsistencies could erode trust between patients and health systems. Any changes could raise question of confidentiality and consent, leading to a less healthy American population. Scaling back demographic data collection might also create gaps and make it harder for public health agencies to use electronic health data for population-level insights.

For LGBTQ+ patients, this deregulation is potentially harmful to the goals of interoperability and health system prosperity. The HHS proposal would remove critical data elements that are essential to the provision of high-quality, patient-centered care for LGBTQ+ individuals, including "name to use," "sex parameters for clinical use," "sexual orientation," "gender identity," and "pronouns." DOH advocates that these data elements not be removed.

Clinical Certification Criteria: Family Health History (Page 60982)
As a public health agency, family health history information is vitally important to several areas of our work. It can be critical in understanding the spread/prevalence of disease (both infectious and chronic – especially cancer risk screening). We have concerns about removing this criterion. While we understand this criterion has been in place for 12 years, we are hesitant to assume it will be correctly followed moving forward, especially by new EHR vendors who may seek certification. The proposed rule states: "Therefore, we expect that many developers of certified health IT will still conform to the SNOMED CT® U.S. Edition and the functionality to code family health history with SNOMED CT® U.S. Edition will remain in certified health IT adopted by hospitals and physicians." This information is vital to clinical care and public health, and we feel voluntary compliance is risky. We also are struggling to see how this reduces burden if it is widely adopted and used already. By requiring use of a standardized code set like SNOMED, we ensure we also get data coded in a way we expect which reduces our burden to process this data and make use of it.

Care Coordination Certification Criteria: Security Tags – Summary of Care (Page 60985)
Security tags provide an important feature in CEHRT to ensure extremely sensitive patient data is properly restricted. One example is the need to protect mental health and substance use disorder data under 42 CFR Part 2. These additional restrictions go beyond HIPAA and need to be properly accounted for, as not everyone involved in a patient's care is allowed to see that data. DOH is concerned about how these important privacy protections will be met if this criterion is removed. We do not support their removal without having an adequate replacement put into the rule at the same time.
Care Coordination Certification Criteria: Decision Support Interventions (Page 60986)
While DOH does see value in using AIto bolster decision support in both clinical and public health decision making, we have concerns about ensuring AI tools do not produce unintended consequences through undetected bias or flawed design and implementation. We advocate that ASTP retain key criteria that ensure that decision support interventions have source attribution, and intervention risk management. While many frontline providers may not have time to review such information, we believe it is vital for Chief Medical Informatics Officers, Chief Risk/Privacy Officers and Chief Information Officers to do so as they are the ones who are held responsible for ensuring technology used by their organizations is not causing patient harm. AI has as much ability to improve our lives as it does to harm it. Transparency and risk management requirements should be maintained in the rule. There needs to be a healthy balance of allowing AI to move forward while also mitigating the very serious risks it also possesses. DOH believes there are better ways to find a healthy balance with these criteria than removal.

Privacy and Security Certification Criteria (Page 60988)
Data held within a CEHRT is some of the most confidential and private data in the world. It is vital that it is properly protected. DOH takes great care in ensuring privacy and security requirements are met by any system that we choose to use or implement that holds such data. Especially with all of the breaches of healthcare systems today it feels vital to ensure CEHRT

products meet national privacy and security standards. DOH does not support removal of these critical criteria, especially as new vendors may come along and then there would be no security/privacy rules they have to follow. While DOH appreciates wanting to make the rules less burdensome, we encourage coming up with a replacement framework first and proposing it verses removing most of the privacy and security criteria as proposed in this rule.

Public Health Certification Criteria: Transmission to Cancer Registries (Page 60992)
As the state agency responsible for our cancer registry, we are concerned to see ASTP's proposal to remove this criterion. Our Cancer Registry is a mission-critical system mandated by state law and it has been valuable to have certification criteria for it in the ASTP rule. It has allowed us to offer it for promoting interoperability credit and we have active data transmissions coming in for this measure. We believe removing this would be detrimental to our ability to continue to move away from manual reporting and data entry to automation. We also note that in this proposal, ASTP states a reason for removal of the criterion is that the FHIR IG for cancer via the Helios project can replace the current CDA standard. We have been actively engaged with Helios and asked their leads about this. We believe there is a misunderstanding. The only cancer work done at Helios has been to look at it as a use case for a FHIR-based query/response for additional data after the initial cancer report has come in. While we are excited about the Cancer FHIR IG, it has yet to be adopted in any location that we are aware of and is still not far along in the HL7 balloting process (i.e., still in trial use). We ask that ASTP not remove this criterion and instead work with public health agencies in advancing the FHIR standard so that later we can move from CDA to FHIR.

Public Health Certification Criteria: Transmission to Public Health Agencies – Electronic Case Reporting (Page 60992)
Electronic Case Reporting (eCR) is growing in its use to meet state requirements for notifiable conditions reporting by providers. Having eCR criteria as part of CEHRT has been vital to advancing eCR. eCR provides immense opportunity to improve efficiency and reduce administrative burden not only for healthcare providers reporting to public health but also for public health manually entering data from emails, phone calls, and faxes. DOH is very concerned with the proposal to remove the standards-based requirements for eCR and reduce it to a functional requirement. Immense progress has been made by CDC in having many CEHRT products move to production for eCR using the standards currently listed in the regulation. Rolling back these standards-based requirements risks degrading the efficiency gains already achieved, introducing variability in implementations, and undermining the automation that eCR was designed to enable. While many public health agencies (PHA) may not yet be able to receive FHIR, functionality at APHL allows CEHRT to send either CDA or FHIR and convert it to CDA if needed for the PHA. We do not agree that there is an undue or large burden on CEHRT for eCR implementation given this capability and the wide adoption to date. If eCR is moved to a functional requirement only, we see undue burden being put on PHAs as we would have to be able to accept, validate, and process multiple non-standardized formats. This would reduce operational efficiency, increase manual review and reconciliation, and divert limited public health resources away from surveillance and response activities. The loss of clear standards will result in more providers reverting to or continuing to use fax-based reporting, further eroding efficiency and reversing progress toward timely, automated public health reporting. We encourage ASTP to include the CDA and FHIR standards to provide options for CEHRT during the transition to FHIR as proposed in HTI-2. This approach lowers burden while still ensuring interoperability.

Public Health Certification Criteria: Transmission to Public Health Agencies – Antimicrobial Use and Resistance Reporting (Page 60992)

While DOH appreciates that AUR data is only transmitted to CDC, it is also shared with states, so we do have some concerns about removing the standards from this criterion and making it a functional requirement only. When standards are not referenced this leaves it up to current and new CEHRT vendors to determine how to meet the functionality which can result in use of standards that are not well adopted or use of no standard format at all. This could create burden for CDC in having to accept data in multiple formats which impacts their ability to efficiently and effectively share that data with jurisdictions which is vital for our work in this space. We suggest that instead of removing the standard that multiple standards (CDA and FHIR) are listed or at least refer to the current one in use and leverage SVAP to allow for advancement. Another idea is to consider is to reference the Interoperability Standards Advisory (ISA) in the rule so vendors use balloted standards that are being used in production and can use FHIR sooner when available in the ISA. By at least referring to the ISA in the rule we can avoid vendors (especially new ones) using proprietary formats which add cost and do not decrease burden, and it allows ASTP to not have outdated standards in regulation. If ISA is explored, we encourage the rule to indicate use of only standards with a good standards process maturity, implementation maturity and adoption level as the ISA contains many trial use and emerging standards that would not be appropriate to require.

Public Health Certification Criteria: Transmission to Public Health Agencies – Health Care Surveys (Page 60992)

Health Care Surveys are also solely submitted to the CDC. That said, states use the data for public health planning, evaluating care disparities, tracking trends, and meeting federal quality reporting requirements (like Promoting Interoperability), to understand their unique health system, identify regional issues, and improve care quality and access for their residents. Given the value we see from these surveys, we have concerns about the proposal to remove them from the rule. We see in your comments that the rationale is based on reducing burden, encouraging use of FHIR, and that these requirements have been met for a long time. Given the value of this data, we propose a better solution is to add a FHIR standard in addition to the current CDA available. We often must support a current and a replacement standard simultaneously to help raise all boats. In addition, we have concerns that if this criterion is removed, that new CEHRT will not have to be able to submit this important data. If this capability is already in place and well established with most CEHRT vendors today, then we do not see much burden in keeping it. Another option would be to reference the ISA in the rule so that as new standards get well adopted, they can be moved to more freely/easily rather than listed specific standards in the rule. If ISA is explored, we encourage the rule to indicate use of only standards with a good standards process maturity, implementation maturity and adoption level as the ISA contains many trial use and emerging standards that would not be appropriate to require.

Design and Performance Certification Criteria: Automated Measure Calculation (Page 60994)

Through efforts like USCDI+ for Public Health USCDI + for Quality, and the Helios FHIR Accelerator (and others), we have seen more need and interest from public health in utilizing quality measures. Examples include situational awareness measures that help assess hospital bed capacity (such as the SAFR IG) and eCQM for conditions like hypertension and diabetes, where the measure meets a CMS clinical quality reporting requirement and the underlying data can be reused for more modern public health approaches to understanding the prevalence of these diseases in our population. DOH has been exploring how such reuse of these CMS measures could aid our chronic disease work to enhance traditional surveys like BRFSS. If again, these

measures are widely adopted already, how does removing the requirement to automate significantly reduce burden? Automating the process of measure calculation reduces the burden of manually processing data. This is exponentially true for use cases like near real-time bed tracking (with the use of standards) is difficult to implement widely without automation. DOH encourages ASTP to keep these criteria as we believe a better way to reduce burden is to continue strong collaboration across HHS (CDC, CMS, HRSA, ASPR, etc.) to find ways to reuse measures across various HHS domains. We have found very real value and benefit from our work in this space already.

Conditions and Maintenance of Certification Requirements for Health IT Developers: Application Programming Interfaces (Page 61002)

While DOH appreciates the retention of § 170.404(b)(2), (3) and (4) without timelines, as it is understandable that the time needed may vary and that the given timelines are outdated, it is important that the API documentation is available via easily accessible links. Additionally, with reference to 170.315 g (7), providing distinct parameters for selecting the patients supports the clarity of the process and decreases risks of ambiguity in uniquely identifying the individuals. Also (9), data requests made through the APIs for pre-agreed data sharing agreements would increase the efficiency and decrease the burden of manual processes needed for fulfilling the requests. Keeping these would help enhance and maintain the efficiency of DOH and would strongly recommend retaining them.

Conditions and Maintenance of Certification Requirements for Health IT Developers: Real World Testing (Page 61002)

DOH appreciates real world testing as often simply attesting to meeting a criterion without being able to prove it results in real world problems during implementation. Testing is where you find out if you built it properly or not and what you missed. PHAs often find data structure and data quality issues during our onboarding of providers using CEHRT. This is often the case because a CEHRT vendor has attested to meeting criteria for public health exchange but has not done the real-world testing to ensure it works properly. This leads to extra delays in onboarding that could be avoided. We encourage ASTP to keep the real-world testing requirements for these reasons.

Conditions and Maintenance of Certification Requirements for Health IT Developers: Insights (Page 61003)

We appreciate ASTP wanting to move the nation forward with FHIR adoption and we see that reflected in the proposal for Insights. WA DOH supports movement to FHIR and is in the process of establishing a FHIR server and FHIR capabilities. We also feel that to have more FHIR adoption we need to see more incentives for public health in terms of funding for this modernization. Many PHAs still do not have this capability and will not without investment. We would like to see the insight conditions specifically for immunizations be kept as there is no FHIR IG yet for immunizations exchange and we see the importance of having measures for the performance of CEHRT. Currently, the two immunization measures are the only public health related ones in the rule, and we do not want to see them removed. Data quality is so critical for our work in public health and in the case of immunizations it is also critical for the provider who is querying the immunization registry to make important clinical care decisions.

Unfunded Mandates Reform Act of 1995

While we appreciate efforts to reduce burden and applaud ASTP for looking to find ways to do so, we are concerned that this proposed rule does impose unfunded mandates on state, territorial,

local and tribal governments and the private sector. When standards are no longer required in the rule it can result in CEHRT vendors using any number of standards (from SDOs or propriety) that result in PHAs having to support them all. This does create a cost burden in terms of potential new development and in operational costs for supporting multiple standards. At most, we feel no more than two standards should be supported simultaneously (the current most adopted standard and the one seen as its successor). We also stress again that if new CEHRT is created and standards are not in place in the rule, then those vendors of new CEHRT could do any number of things to meet a functional requirement. We also have concerns about the unfunded costs of removing criteria like the cancer registry reporting. If CEHRT vendors and providers are not incentivized or required to report by federal rules, and a state still has a general reporting requirement (not electronic reporting), this potentially pushes a provider back to paper and faxing. If a CEHRT doesn't have to support something like cancer reporting, they likely will not or charge providers additional money to have that capability.

As an illustrative example, we received 101,995 electronic cancer event reports last year from one of our largest healthcare systems (we have 422 state HIE healthcare systems). If providers faxed each record at $2.50 per fax that costs nearly $255,000. Data entry, estimated at $4.25 per form (15 minutes to enter a form at $17/hour) would cost over $433,000 and assuming a 2% error rate at an estimated cost of $50 per error (estimate to find and edit each error) to correct it would cost nearly $102,000. This example illustrates a cost of over $790,000 to have providers fax and public health manually enter and correct errors at this number of records (approximately $7.75 per health record). For context, we collected over 260 million records electronically using standards via our HIE in 2025. Extending this example to every provider, including state, local, tribal and territory health departments, would add up fast, and this is only one of the data sources impacted by the proposed rule. We ask ASTP to carefully consider the changes and the impact they could have. We feel many of our proposed changes above would mitigate these unfunded potential costs of implementing this proposal.

Conclusion

DOH strongly supports continued required reporting in the areas of immunization, syndromic surveillance, vital records, case reports, disease and clinical registries and other public health domains. 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. DOH looks forward to partnering with HHS to further this important work. Thank you for the opportunity to provide comments on the proposed rules.

Sincerely,

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