AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

October 4, 2024

Dr. Micky Tripathi
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC)
Attention: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule
Mary E. Switzer Building, 7033A
330 C Street SW
Washington, DC 20201

RE: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule

(Comments to be uploaded at: https://www.federalregister.gov/documents/2024/08/05/2024-14975/health-data-technology-and-interoperability-patient-engagement-information-sharing-and-public-health#open-comment)

Dear Dr. Tripathi,

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on the proposed rule on Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2). These comments are a compilation of our members' input, including over 80 organizations representing Public Health Immunization Information Systems (IIS), IIS implementers and other technology vendors, stakeholder organizations and sponsors, and other partners. Immunization Information Systems interface with a broad range of stakeholders, including health care providers using electronic health record systems, pharmacists, schools, childcare facilities, health plans and payors, among others.

As with HTI-1, HTI-2 will greatly support further standardization and interoperability across the health IT ecosystem. We appreciate your leadership in advancing regulation focused on improving the nation's health and urge ASTP/ONC to finalize provisions in the proposed rule intended to strengthen data exchange between healthcare providers using certified health information technology and public health agencies.

Several prominent themes emerged during our members' review; we have captured these for your consideration below.

1) We greatly appreciate the focus on uniform standards, including the measurement and testing to ensure alignment with standards. AIRA has actively partnered with the IIS, federal partners, and EHR communities regarding measurement and testing. In collaboration with CDC, AIRA launched the IIS Measurement and Improvement Initiative (M&I) in 2015, to measure IIS alignment with standards and to support this alignment through guidance and technical assistance. Similarly, in 2018, we have partnered with CDC and HIMSS to expand the Immunization Integration Program (IIP), a program that tests and recognizes EHRs for their immunization-related functionality. Both M&I and IIP have demonstrated significant successes over the years, and credit can be attributed to these programs for improving immunization interoperability and driving IIS to be leaders in public and private health information exchange.

   Over the years, AIRA and the IIS community have learned the critical importance of measurement and continuous improvement work in strengthening IIS systems. Regularly assessing performance through system evaluations and benchmarking helps identify areas where IIS programs can enhance accuracy, timeliness, and completeness of immunization records. Measurement efforts provide actionable insights that guide system upgrades, policy changes, and best practices across jurisdictions. By focusing on improvement, AIRA has been able to promote consistent, evidence-based enhancements that build trust in IIS data, making it more reliable for public health decision-making. This ongoing commitment to measurement not only drives technical advancements but also reinforces accountability, ensuring that IIS systems are optimized to meet the evolving needs of immunization programs and public health goals.

   We encourage ASTP/ONC to leverage AIRA's expertise and experience in measurement as HTI-2 is finalized and eventually operationalized. We hope that our organization and member knowledge, coupled with our broad partnerships across the public and private health IT environment, will serve as valuable resources as these certification efforts unfold.

2) We strongly encourage ASTP/ONC to consider extending the positive impact of EHR certification to other settings where immunizations are provided. Pharmacies, long-term care facilities, and schools are all active partners in the provision of immunizations and other public health efforts and contribute broadly to the shared goal of high vaccine coverage for the population. Stronger standards adoption supported by certification programs would help these settings to use and/or share immunization

information more thoroughly, for the benefit of their patients, residents, or students, respectively.

Similarly, consumer access applications could benefit from a certification process that supports the adoption of unform immunization interoperability standards. HTI-2's callout of the SMART Health Cards Framework is positive, but much work remains to truly standardize and promote these and other consumer-facing efforts to make consolidated immunization records available to all individuals. We strongly encourage ASTP/ONC to continue exploring opportunities to promote certification and standards-based interoperability across all of health care and human services.

3) As strong proponents of standards and interoperability across public health, we support ASTP/ONC's efforts to create a certification program for public health products. However, it is critically important that these initial testing efforts are supported with dedicated funding, and that sustainable funds are available to bolster the continued enhancements needed to truly modernize public health in general, and immunization information systems specifically. According to the Trust for America's Health, while the United States spends an estimated $3.6 trillion annually on health, less than 3 percent is directed toward public health and prevention. Considering this statistic, it is not difficult to understand why public health systems fall behind other areas of health IT in reaching modernization goals. Sustained multi-year funding will allow public health to continue to raise the bar in meeting technological changes and supporting providers, consumers, and others who need access to accurate, complete, and timely immunization information.

Our detailed comments in response to the regulation and the questions in the proposal are in table form on the following pages, marked as comments, questions, and/or suggested wording changes. Our comments focus on the measures for immunization administrations electronically submitted to IIS, as well as the proposed certification of public health IT products and Insights Condition. Where page numbers are noted, they refer to the Federal Register version of the proposed rule, published August 5, 2024.

The World Health Organization lauds immunizations as one of modern medicine's greatest achievements and estimates that they save up to 2.5 million lives every year. Promoting and facilitating the exchange of accurate, timely, and complete immunization information will allow this invaluable data to be available to public and private health professionals, schools, consumers, and others, improving health for all.

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Thank you for your commitment to improving health care and health information technology. We appreciate your consideration of these comments and look forward to continuing to collaborate with ASTP/ONC. Please feel free to contact me with any questions at mbkurilo@immregistries.org.

Sincerely,

Mary Beth Kurilo, MPH, MSW
Senior Director of Health Informatics
American Immunization Registry Association (AIRA)

Table of Comments

High Level Order of Comments by Section:

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(f)(21)
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Multifactor Authentication (MFA)
Insights Condition

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(f)(1)	Page 63542	We propose to update the Immunization Messaging Implementation Guide (IG) standard in § 170.205(e) to the HL7 v2.5.1 IG for Immunization Messaging, Release 1.5, Published October 2018, which is a compilation of the Release 1.5 version and the Addendum from 2015 referenced in the current Program, and incorporate it by reference in § 170.299	Comment: We support the adoption of the 2018 update to the immunization IG currently referenced in the § 170.315(f) criteria. Several of the currently referenced standards date back to the 2012 certification criteria and have been improved by later iterations of the standards and other clarifying documents through the inclusion of real-world lessons learned. We feel that the inclusion of updated standards will improve the quality of data received by public health. Question: We want to clarify whether Appendix C of the 2018 guide is part of the normative (e.g., enforceable) part of the IG or not. Appendix C incorporates additional guidance in which has been identified as important during real-world implementation of the original Release 1.5 standard, and we support its inclusion.
(f)(1)	Page 63543	Specifically, we request feedback on the standard referenced in § 170.205(e) and whether we should consider adopting that soon-to-be most current version in a final	Comment: Although it would be ideal to reference the Immunization IG in development, we support the focus on the 2018 IG, as the next version of the IG is not likely

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		rule, as we are aware that an updated version of the standard is due to be published in mid-2024.	to be through the balloting process until mid-2025. We do however encourage the authors of future proposed rules to consider incorporating future versions of HL7 balloted immunization implementation guides. Similarly, the future immunization IG may be a good candidate for the Standards Version Advancement Process (SVAP).
(f)(1)	Page 63542	We also propose that adoption of the standard in § 170.205(e)(4) expires on January 1, 2028. Additionally, as described in the "Minimum Standards Code Sets Updates" section (III.B.5), we propose to update the vocabulary standards in § 170.207(e) that are referenced in § 170.315(f)(1) and thus are proposing to update § 170.315(f)(1)(i)(B) to reference the new proposed § 170.207(e)(5) and to update § 170.315(f)(1)(i)(C) to reference the new proposed § 170.207(e)(6).	Comment: We support this change as it is critical to regularly update code sets and advance minimum standards in regulation.
(f)(1)	Page 63542	We propose to add a functional requirement in § 170.315(f)(1)(iii) to receive incoming patient-level immunization-specific query or request from external systems and respond.	Question: • Is this a requirement for the Health IT Module to receive a query, just as the IIS does in current data exchange? • If so, what system is expected to query Health IT Modules? We have not heard of any IIS wanting this functionality to date. We also do not have standards set for how a query might be sent from an IIS system to an EHR.

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			• If this functionality is intended for use by the IIS community, we recommend the removal of this functional requirement • We also believe this may be covered by the existing (g)(10) requirement for FHIR APIs (which include the Immunization resource); if there is a difference, it would be helpful to have that explained. To that point, we recommend that the ability for a provider to respond to an immunization query be supported by 170.315(g)(10) and (g)(20) using a common FHIR based approach rather than requiring implementation of an HL7 v2 based query, as we are not aware of any parties interested in such queries and alignment with already available FHIR based queries should be our approach moving forward. • We are also unclear on the use of the term "immunization-specific query", as we lack a specification based on that term.
(f)(1)	Page 63542	We propose to add a functional requirement in § 170.315(f)(1)(iii) to receive incoming patient-level immunization-specific query or request from external systems and respond.	We have recommended this section not be carried forward. However, if it is, we would also like to note that this standard includes profiles for two different types of queries: 1. Z34/Z32 profiles to Request Complete Immunization History 2. Z44/Z42 profiles to Request Evaluated History and Forecast

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			While the Z34/Z32 profiles simply require the return of known patient immunization events, the use of the Z44/Z42 profiles requires the responding system (certified HIT in the case of the new functional criterion) to perform decision support in order to evaluate the patient history against a specific set of recommendations (typically provided by the CDC Advisory Committee on Immunization Practices (ACIP)) in order to provide a customized set of immunization recommendations. We expect that not all certified HIT may provide this type of decision support as other criteria in this section require certified HIT to be able to query an Immunization Information System (IIS) at a local jurisdiction for a set of recommendations. That is, certified HIT may have chosen not to provide their own decision support and instead rely on that of the local immunization program. Required certified HIT to respond with an evaluated history and forecast as part of the new requirement in § 170.315(f)(1)(iii) may be a significant burden for some systems. We strongly recommend that the rule authors clarify which profile sets certified HIT must support as part of this requirement.
(f)(1)	Page 63542	We propose to revise the name of the certification criterion in § 170.315(f)(1) to "Immunization registries – Bi-directional exchange" to more accurately represent the capabilities included in the certification criterion. We note that we additionally propose a requirement in support of requests for multiple patients' data as a	Proposed Wording: We propose defining bidirectional exchange more fully as "Immunization information systems; submission and/or query". The (f)(1) section is highlighting the certification expectations for certified EHR technology, so it is helpful to center them as the "actor" in this portion of exchange. Alternatively, "Interoperability with

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		group using an application programming interface in § 170.315(g)(20)(ii) and direct readers to section III.B.13.f for further information on that related proposal, in addition to our proposed revisions to § 170.315(g)(10) which includes capabilities to support multiple patients' data as a group using an application programming interface (section III.B.19). We expect these changes to enable more approaches for bidirectional exchange of immunization information.	Immunization Information Systems" may be a simpler and clearer option to consider to avoid confusion.
(f)(1)	Page 63542	We also propose that adoption of the standard in § 170.205(e)(4) expires on January 1, 2028	Question: This suggests a slightly different and later date; is the true expectation for Certified EHR Technology to expire on January 1, 2027 or January 1, 2028?
(f)(1)	Page 63542	We note that we additionally propose a requirement in support of requests for multiple patients' data as a group using an application programming interface in § 170.315(g)(20)(ii) and direct readers to section III.B.13.f for further information on that related proposal, in addition to our proposed revisions to § 170.315(g)(10) which includes capabilities to support multiple patients' data as a group using an application programming interface (section III.B.19).	Question: Can you explain the difference is between multiple patients (population) and public health bulk query?
(f)(1)	Page 63542	Further, we propose patient access to their immunization information stored in Health IT Modules using SMART Health Cards	Comment: We support the promotion of the SMART Health Cards methodology, but we have concerns that this

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		"verifiable health records" in proposed § 170.315(g)(10) and direct readers to section III.B.19 for further information on that proposal.	technology is not feasible for producing and sharing a consumer version of the full lifespan immunization record, given the limited space on a 2D barcode. We propose that the rule reference the adoption of both SMART Health Cards and SMART Health Links functionality to offer flexibility for implementers to provide consumers with the most functional data (using SMART Health Card for a subset of the full record (e.g., a record of immunizations received that day), and using SMART Health Links to provide the full consolidated patient immunization record). We also support the strong recommendation that providers using Certified EHR Technology to query the IIS prior to providing the patient/consumer with their full immunization record, to ensure the consolidated record is as complete as possible.
(f)(1)	Page 63542	We propose the new and revised certification criteria in § 170.315(f)(1)(ii) and (iii) to replace the existing certification criterion in § 170.315(f)(1)(i) beginning on January 1, 2027.	Comment: We believe this timeline for most of this functionality, although ambitious, is reasonable for providers using Certified EHR Technology as well as IIS. However, because (iii) includes functionality to receive an external query request (EHRs responding to a QBP), then that is a major change for them to develop and roll out, and the timeline may need to be extended.
(f)(1)	Page 63542	We propose to revise the certification criterion in § 170.315(f)(1) to include revised minimum standard code set requirements, updated implementation specifications, and new functionality. We propose that, for the time period up to and including December 31, 2026, a Health IT	Question and Proposed Wording: The references to what functionality sunsets and what functionality persists for EHR exchange with IIS is ambiguous. • (i) is clearly VXU submission

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		Module may continue to be certified to the existing version of the certification criterion as described in § 170.315(f)(1)(i), with proposed modifications for clarity and with a proposed revision to include the minimum standard code set updates for representation of historic and administered vaccines proposed for adoption in § 170.207(e), or it may be certified to the newly proposed certification criteria in § 170.315(f)(1)(ii) and (iii). We propose the new and revised certification criteria in § 170.315(f)(1)(ii) and (iii) to replace the existing certification criterion in § 170.315(f)(1)(i) beginning on January 1, 2027.	• (ii) is ambiguous – see below bullets for potential ambuguity. • (iii) is clearly an EHR receiving a QBP and responding with an RSP. If (i) is going away, it's critical that we understand what is/isn't included in (ii). Per the cost table included in this section, (ii) is focused only on Query to IIS – which implies we lose the requirement for EHRs to submit data to the IIS via a VXU (since that is (i) and it's going away). On the topic of sunsetting the current HTI-1 rule, the (f)(1)(i) is clearly submission and (f)(1)(ii) is clearly query. We suspect ONC is trying to expand (ii) to be submission and query in the new proposed rule, but we believe ONC needs to be much more explicit. "Create immunization information for electronic transmission" doesn't necessarily evoke submission to IIS, especially when the standard referenced (the IG in 170.205(e)(4)) includes VXUs and QBPs. We recommend modifying the wording to ensure it is clear that both submission and query persist as expectations for CEHRT after January 1, 2027. Proposed Wording: We propose the new and revised certification criteria in § 170.315(f)(1) (i), (ii), and (iii) to replace the existing certification criterion in § 170.315(f)(1)(i) beginning on January 1, 2027.

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(f)(1)	Page 63780	(C) Receive incoming patient-level immunization-specific query or request from external systems and respond in accordance with paragraph (f)(1)(ii)(A) of this section. (iii) Receive incoming patient-level immunization-specific query or request from external systems and respond.	Comment: Again, we are recommending ASTP does not move forward with this query expectation, and rather supports a FHIR-based solution for accessing EHR data in (g)(10) and (g)(20). However, if this query expectation for EHRs is maintained, these two bullets appear to be saying the same thing. We recommend maintaining (C) and deleting (iii).
(f)(1)	Page 63780	(A) Create immunization information for electronic transmission and support request, access, and display in accordance with the standards in paragraphs (f)(1)(ii)(A)(1) through (3) of this section;	Please clarify the meaning of "support request, access, and display" in § 170.315(f)(1)(ii)(A) or remove it if the intent of this is covered in § 170.315(f)(1)(ii)(B).
(f)(21)	Page 63552	We propose to adopt a new certification criterion for health IT for public health that would focus on immunization information—receipt, validation, parsing, and filtering—adhering to the same standard as required in § 170.315(f)(1). We further propose a requirement for responding to queries from external systems, as well as seek comment on patient access as a complement to the proposed updated requirements in § 170.315(f)(1).	Comment/Question: As an Immunization/IIS community, we support the definition and adoption of standards. We have long known that it is critical that both sides of an electronic exchange have the standards, technology and resources in place to implement interoperability. Common expectations on both sides speeds understanding and implementation. However, we have questions about how the certification criterion for Health IT for public health will be implemented, and in particular, what entity will conduct the testing and report on results. In addition, we want to emphasize the need for sustainable funding needed for IIS to participate in the initial and ongoing testing and in making enhancements or modifications to their systems to meet standards.

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(f)(21)	Page 63537	In this proposed rule, we use the phrase "health IT for public health" to mean hardware, software, integrated technologies or related licenses, IPs, upgrades, or packaged solutions sold as services that are designed to support public health use cases for the electronic creation, maintenance, access, or exchange of public health information, which is consistent with the "health IT" definition in section 13101(5) of the HITECH Act and 45 CFR 170.102. In 2020, CDC launched the Data Modernization Initiative (DMI) to modernize public health data and surveillance infrastructure.	Question: Within the immunization vendor community, this definition likely only fits a small number of vendor products. This definition would not fit Awardee Developed, or even WIR (Wisconsin Immunization Registry)-based systems supported by a number of vendors. We have concerns with the focus on "related licenses, IPs, upgrades or packaged solutions **SOLD** as services that are designed to support public health". Would this preclude many vendor products within the IIS community from being certified? What advantages might that create for an unproven vendor product that meets interoperability requirements, but not the many other functions of an IIS?
(f)(21)	Page 63542	We propose to update the Immunization Messaging Implementation Guide (IG) standard in § 170.205(e) to the HL7 v2.5.1 IG for Immunization Messaging, Release 1.5, Published October 2018, which is a compilation of the Release 1.5 version and the Addendum from 2015 referenced in the current Program, and incorporate it by reference in § 170.299	Comment: We support the move to the October 2018 IG, but must acknowledge that there will be work on the part of the IIS community (programs and vendors) to integrate some of the guidance, including the new requirements on the National Set of Error Codes (ERR-5). Coordination will be needed to ensure that all partners across the ~150,000 EHR-IIS interfaces are coordinated to re-onboard, test, and go live by the end of 2026. if compliance with the HL7 v2.5.1 IG for Immunization Messaging, Release 1.5, Published October 2018 standard is required of HIT support public health, we strongly recommend that specific profiles be called out in the final rule as required or optional to support. This

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			will ensure that both trading partners support the same query type (Request Complete Immunization History or Request Evaluated History and Forecast) and provide guidance to HIT module developers as to the need to offer decision support functionality to generate evaluated histories and forecasts.
(f)(21)	Page 63552	We believe these proposed requirements, coupled with the proposed § 170.315(g)(20) and updates to § 170.315(f)(1), can move the nation closer to this ideal state.	Comment: Because this is within the (f)(21) section for IIS certification, we assume this means IIS will also have to certify to 170.315(g)(20) [(g)(20) is the ability to support FHIR access to EHR data for Public Health Purposes and include bulk]. If this reasoning holds, we believe this means IIS would be required to be a client to query for EHR data in bulk, which would be a significant and costly lift for IIS development. We do not believe there is currently a strong use case for this functionality.
(f)(21)	Page 63552	"...and technical capability to respond to incoming patient-level and/or immunization-specific queries from external systems. We request feedback on the functional requirement to respond to patient-level, immunization-specific queries from external systems and request comment on if the standard referenced in § 170.205(e) is sufficient for the proposed functional requirement to respond to incoming patient-level and immunization-specific queries."	Comment/Proposed Wording: The standard in 170.205(e) is not sufficient for the proposed functional requirement to respond to incoming patient-level and immunization-specific queries. The current standard only supports patient-level queries. There is no functional requirement in the standard for immunization-specific queries. When a provider queries for a patient, the receiving system returns the entire consolidated immunization history for the patient. That said, there has not been a need or desire for immunization-specific queries. We recommend removal of the phrase "immunization

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			specific queries" throughout HTI-2 as it relates to this standard.
(f)(21)	Page 63552	"We seek comment on if we should also require health IT for public health to share immunization information on a population of patients using the standard specified in § 170.315(g)(20)(ii) in our proposals in section III.B.16, and whether health IT for public health should also be able to support patient access using SMART Health Cards for Immunization Criteria according to § 170.315(j)(22). We specifically request comment on readiness and feasible timelines for these capabilities."	Comment: We are in support of IIS implementing the standard for Bulk FHIR query, but we are unsure IIS can reasonably implement this in the timeframe allotted and with the current funding limitations to build, maintain, and support operations. We also believe that the IIS community would benefit from an IIS specific IG for bulk FHIR, or at the very least, more formal guidance to support implementation. We also support the concept of SMART Health Cards, but have several concerns about this being included as a requirement: 1) The QR code does not have enough space for a full lifespan immunization record, which is what is typically queried from an IIS, so we suggest focusing on SMART Health Links instead (noting that this methodology is earlier in its development, and likely not yet ready for regulation) 2) Like the comments above re: Bulk FHIR Query, this has a funding aspect to build, maintain, and support operations. 3) Similarly, there is also a local policy aspect. Some jurisdictions may need more lead time to work through policy and law to requirements to offer

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			this in their jurisdiction. Requiring all vendors to support this would put undo cost onto a jurisdiction that may have to pay for something they can't use.
(f)(21)	Page 63552	"Additionally, we recognize that due to the work and collaboration of state immunization programs, IIS vendors, CDC's National Center for Immunization and Respiratory Diseases (NCIRD), and the American Immunization Registry Association (AIRA), immunization systems can do much of what is described above already. Through these NCIRD sponsored and established programmatic requirements and optional testing programs conducted by AIRA, many IISs already meet most of, if not all, of the requirements in the proposed certification criterion."	Comment: We appreciate the recognition of the IIS community's hard work, and this is true for most of the adoption of the 2018 updated HL7 V2 IG, However, it is important to acknowledge that most IIS do not support – nor have they been tested against – newer functions such as bulk FHIR query or SMART health cards. They also do not currently support, nor have they been tested against, the optional transport methods proposed in the rule.
(f)(21)	Page 63552	"We propose requirements in § 170.315(f)(21)(i) to enable health IT for public health to receive electronic immunization information transmitted through a method that conforms to Simple Object Access Protocol (SOAP)-based transport. Optionally, to meet the received requirements, a developer (serving as a Participant or Subparticipant of a Qualified Health Information NetworkTM (QHINTM), or who is a QHIN) may demonstrate receipt through a connection governed by the	Proposed Wording: As written, it sounds like the IIS vendor could do any single one of these to meet the requirements of (f)(21)(i). We believe the first sentence should include a "Must" or the second and additional sentences could say "additionally" rather than "Optionally". Alternatively, the rule could strike the secondary methods as they are not currently in the use by IIS but note the importance of monitoring their use for future consideration. Comment:

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		Trusted Exchange Framework and Common Agreement, receipt through a method that conforms to the standard specified in § 170.205(p)(1) when the technology is also using an Simple Mail Transfer Protocol (SMTP)-based edge protocol, or receipt via an application programming interface in accordance with the standard specified in § 170.215(a)(1) or at least one of the versions of the standard specified in § 170.215(d)."	Additionally, we request clarification if this requirement is specific to the implementation of the specification for Transport for Immunization Submission and Query/Response as outlined in the Interoperability Standards Advisory (ISA) and/or the Transport (SOAP) topic on the CDC website. If a specific SOAP specification is intended, we suggest incorporation the specification by reference in the update rule.
(f)(21)	Page 63782	(i) Receive. Receive electronic immunization information transmitted. (A) Required. Through a method that conforms to Simple Object Access Protocol (SOAP)-based transport; (B) Optional. (1) Receive through a connection governed by the Trusted Exchange Framework and Common Agreement; (2) Through a method that conforms to the standard specified in § 170.205(p)(1) when the technology is also using a Simple Mail Transfer Protocol (SMTP)-based edge protocol; or (3) Via an application programming interface in accordance with the standard specified in § 170.215(a)(1) or at least one of the versions of the standard specified in § 170.215(d).	The topic reference above appears again later in the rule, and the language is clearer. We do suggest removing (i)(B)(2), as SMTP is not used in this space and is unlikely to be adopted at this late stage.

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(f)(21)	Page 63552	"We propose requirements in § 170.315(f)(21)(ii) to demonstrate the ability to detect valid and invalid electronic immunization information received and formatted in accordance with the standards specified in § 170.207(e)(5) and § 170.207(e)(6). In order to meet the validate requirements, the health IT for public health must include the capability to identify valid electronic immunization information received and process the data elements required for the standards specified in § 170.207(e)(5) and § 170.207(e)(6). Processing must include any necessary data mapping to enable use as discrete data elements, aggregation with other data, and parsing and filtering in accordance with the parse and filter requirements in the proposed § 170.315(f)(21)(iii). Additionally, in order to meet the validate requirements, the health IT for public health must correctly interpret empty sections and null combinations; detect errors in immunization information received, including invalid vocabulary standards and codes not specified in the standards specified in § 170.207(e)(5) and § 170.207(e)(6); and record errors encountered allowing a user to be notified of the errors produced, to review the errors produced, and to store or maintain	Comment: We support this addition. AIRA has Measurement and Improvement test cases and content under the Submission and Data Quality Incoming/Ongoing Content Areas that could support this effort.

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		error records for audit or other follow up action."	
(f)(21)	Page 63553	"We propose that Health IT Modules certified to § 170.315(f)(21)(iii) support users to parse and filter immunization information received and validated in accordance with validate requirements in the proposed § 170.315(f)(21)(ii) according to the standard specified in § 170.207(e)(5) or § 170.207(e)(6)."	Comment: It is not clear what the true requirement is here so it would be impossible to test. We would request more clear expectations from ONC on this.
(f)(21)	Page 63553	"We propose functional requirements in § 170.315(f)(21)(iv) to respond to both incoming patient-level and immunization-specific queries from external systems."	Comment: Neither the current standard nor AIRA's measurement effort supports immunization-specific queries. We recommend removing this wording.
(f)(21)	Page 63783	"(iii) Parse and filter. Enable a user to parse and filter immunization information received and validated in accordance with paragraph (f)(21)(ii) of this section according to the standard specified in § 170.207(e)(5) or (6)."	Comment: We request that the rule better define "parse" and "filter" as it relates to each domain throughout the rule. For example, "filter" may mean something different to ELR than it means to immunization. It would be helpful to have clear definitions to better understand the implications and expectations of these requirements, to ensure not only uniform implementation, but also to support clear testing methods for certification.
	Page 63710	Table 42, Estimated Labor Hours	Comment: We recommend ASTP reconsider the cost estimates listed in section 170.315(f)(21) Table 42, as we suspect the true costs for certification will be much higher. The estimate of $63.91/hour for developers seems low, given the specialized market, and this does not appear to include costs for project management, business analysis, testing, etc. Similarly, given the number of roles

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			likely to be involved, the benchmark of 1000 hours seems low as well.
(g)(20)	Page 63501	As discussed in section III.B, adopting USCDI v4 and the proposals in § 170.315(g)(20) are intended to facilitate core public health missions including detecting and monitoring, investigating and responding, informing and disseminating, and being response-ready.	Comment: There are several references to the public health API being the foundation of future IGs, pilot work, etc., and yet, the guidance still feels early in its development for being referenced in a federal requirement. Additionally, all of this would likely need a testing program. Question: Would "Health IT systems for public health" have to certify some technology solution to query for this data via an EHR's public health API? If so, the data they would be querying would likely be extremely unique to the public health systems (e.g., IIS won't be querying for AODA services or lab results but could potentially query for pregnancy status). Further, the current IGs are very foundational/broad. I'm not sure these would be helpful to certify a public health system. Question: Similarly, we have a question about which parts of the overall certification requirements HIT for public health must meet? Would public health be required to implement FHIR APIs, for example?
USCDI v4	Page 63500	"The proposed adoption of the United States Core Data for Interoperability Standard Version 4 (USCDI v4) would promote the establishment and use of interoperable data sets of EHI for	Although we support the move to USCDI v4, we strongly recommend that ASTP review past comments regarding data elements to consider for inclusion in future versions. For example, immunizations would support the inclusion of Vaccine Administration Date,

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		interoperable health data exchange. As discussed in section III.B.1, USCDI v4 would facilitate the collection, access and exchange of data for use in public health and emergency response (*e.g.,* the COVID-19 pandemic) by capturing and promoting the sharing of key data elements related to public health."	Vaccination Event Record Type, MRN (and other IDs), Mother's Maiden Name and Multiple Birth Indicator and Birth Order (for minors).
	Page 63561	"In addition to the support for the framework, subscription topics, and filters in § 170.315(j)(23), we propose in § 170.315(g)(20)(iii)(C)(1) that a Health IT Module certified to § 170.315(g)(20) enable a client to subscribe to notifications filtered according to the conditions "Encounter.reasonCode," and "Encounter.subject" when a patient encounter starts and the conditions "Encounter.reasonCode," and "Encounter.subject" when a patient encounter ends."	Question: How would an IIS operationalize subscriptions across X,000 providers based on Encounter.subject (person) and Encounter.reasonCode? How might we prescribe to IIS how to subscribe to every provider so that nothing is missed?
(g)(20)	Page 63559	"The consistent functionalities established in the combination of § 170.315(g)(10) and § 170.315(g)(20) would support the creation or revision of health IT for public health IGs necessary to advance interoperability for specific use cases, such as cancer pathology reporting, which has a draft FHIR IG, or immunization reporting, which is currently only supported by a HL7 v2-based IG. Using HL7 FHIR-based APIs, PHAs	Comment: Although this testing was innovative, we have some concerns that it was fairly primitive (as reported by the individuals sharing about the work), and we worry that this could fast-track this topic into regulation. It is also difficult to think about if/how this would function in the immunization use case, after an immunization was already reported – perhaps for pregnancy status or risk factor data?

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		and healthcare partners could create an ecosystem where health IT for public health can securely query data directly from the source, in real time, when needed, based on an initial push of relevant data. Helios tested this approach and participants were able to successfully query EHRs for additional patient-level information after an initial trigger, and we are working with CDC to pilot and scale this approach."	
(g)(20)	Page 63559	"Third, we believe that the proposed certification criterion in § 170.315(g)(20) would serve as a glidepath towards an eventual transition to broader HL7 FHIR-based reporting for public health data exchange. We propose that Health IT Modules certified to § 170.315(g)(20) would support modular and foundational capabilities and standards, such server support for subscriptions in § 170.315(j)(23), and support a public health specific set of HL7 FHIR profiles that extend the requirements in § 170.315(g)(10) to support a public health transition to HL7 FHIR."	Comment: This appears to be a direct reference to Public Health transitioning to FHIR. Although we support the evolution of standards and the support of FHIR across health IT, this would be an enormous legacy lift for immunization interoperability, and would likely require significant and sustained investment, given the volume of HL7 V2 connections today.
(j)(20) and (j)(21)	Page 63571	"We propose to adopt the CDS Hooks IG v2 at § 170.215(f)(1). We propose two certification criteria to support workflow triggers using the CDS Hooks IG v2:	Comment: We support this proposal to adopt CDS Hooks IG v2 and appreciate that it does not define or propose specific workflows.

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		(j)(20) criterion includes requirements for "clients" participating in API-based workflow triggers for decision support (j)(21) criterion includes requirements for "services" providing decision support services to clients. We note that the proposed workflow triggers criteria in (j)(20) and (j)(21) do not define or propose specific workflows associated with decision support, including how and when clinicians use decision support capabilities. Rather, we propose to include standards-based interfaces in (j)(20) and (j)(21) to enable clinical systems to call other systems offering decision support services in a standardized manner to support the exchange and use of these services."	
(j)(23) and (j)(24)	Page 63746	"We propose that Health IT Modules certified to § 170.315(j)(23) and § 170.315(j)(24) demonstrate support for FHIR-based API subscriptions according to the HL7 FHIR Subscriptions Framework. We specifically propose the adoption of the Subscriptions R5 Backport Implementation Guide version 1.1.0 (Backport IG) in § 170.215(h)(1) as a baseline standard conformance requirement in § 170.315(j)(23) and § 170.315(j)(24)."	Comment: We conceptually support the concept of subscriptions, but we believe there is a lot of complexity in how they could be implemented. If IIS were to implement subscriptions, we would need to have a very extensive guide to describe what types of subscriptions the IIS must support and how they work. This feels very aspirational and abstract, and it may be too early to include it in rule. Although we support the continued evolution of functions such as bulk FHIR query and subscriptions, a key issue in the HTI-2 regulation is the contrast between

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			the established National IG for Immunizations and newer standards. The National IG provides a detailed, well-defined framework for IIS and EHR systems, making it suitable for certification and assessment. In contrast, the newer standards such as bulk query and subscriptions are still under active development and lack mature, immunization-specific guidance. While there has been some preliminary work and thought on applying these technologies to immunization, no definitive implementation guides exist. Thus, requiring immunization systems to support these standards at this stage would be premature, as there is no established basis for certification or assessment. The difference between the specificity of the National IG and the current state of these emerging FHIR standards highlights the need for further development and consensus within the immunization community. Until clear, immunization-specific standards are established, these new technologies should not be regulated as mandatory requirements.
XVII. Multi-factor Authentication Criterion	Page 63747	"As explained in section III.B.17, we propose to revise the "multi-factor authentication" (MFA) certification criterion in § 170.315(d)(13) and accordingly update the privacy and security (P&S) certification framework in § 170.550(h). The proposed update would revise our MFA certification criterion by replacing our current "yes" or "no" attestation requirement with a specific requirement to support multi-factor	Comment: The proposed movement from a "yes or no" attestation to a specific criterion for MFA support applies to numerous other criteria where authentication is necessary. While MFA is a current industry best practice, history will tell us that this won't be the industry best practice for a long time. On the horizon are passwordless authentication models (https://www.microsoft.com/en-us/security/business/solutions/passwordless-

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		authentication and configuration for three certification criteria on and after January 1, 2028. We propose to apply the updated MFA requirements by revising each of the certification criteria in § 170.315(b)(3), (e)(1), (g)(10), and (g)(30) to require that a Health IT Module certified to these criteria also be certified to § 170.315(d)(13)(ii) on and after January 1, 2028. Given our proposal to embed § 170.315(d)(13) references into each applicable certification criterion, § 170.315(d)(13) does not need to be referenced again in § 170.550(h)(3), therefore, we propose to expire all the references to § 170.315(d)(13) in § 170.550(h)(3) by December 31, 2027. We believe these updates would match industry best practices for information security, particularly for important authentication use cases in certified health IT."	authentication) which may become the industry best practice at a pace faster than regulation can move. Furthermore, it is noted in 17.A that MFA has previously expressed concern regarding increased provider burden. We encourage ONC to consider criterion that would be more flexible to accommodate the ever-evolving world of authentication.
Insights Condition in the rule	Page 63600	"We also intend to make another technical update to the measure specification sheet by adding metrics to separately count the number of immunizations administered that were electronically submitted to IIS where an acknowledgement from an IIS is not received by certified health IT overall, and by IIS and age category. The current measure specification sheet indicates health IT developers optionally report on	We strongly support real world reporting of aggregate data that provides visibility into how much immunization data EHR vendor products are providing to IIS. Additionally, we have some feedback and recommendations regarding the measures that are addressed below.

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		number of submissions that did not receive acknowledgement as part of the supplemental documentation. These separate metrics would enable monitoring the occurrence of these communication failures between certified health IT and IIS more systematically. We do not expect substantive additional burden associated with this metric. We also request comment on the value and burden associated with reporting a count of the subset of messages sent to third party intermediaries where the third-party intermediary does not provide an acknowledgement that the message was sent to an IIS."	
Insights Condition - Immunization Administrations Electronically Submitted to Immunization Information Systems through Certified Health IT	Measurement Spec Sheet on the Proposed Rule: Immunization Administrations Electronically Submitted to Immunization Information Systems through Certified Health IT, Page 1	"The number of immunizations administered that were electronically submitted successfully to IISs overall by age category and IIS - Year 2"	Comment: AIRA strongly recommends stratification "by IIS" in Year 1. Without this, a certified Health IT vendor will submit a single number for each of the 4 metrics and the results will be heavily skewed by the volume of administrations in heavily populated jurisdictions. This may obscure other successes or gaps in other jurisdictions, noting that the top 5 jurisdictions (CA, TX, FL, NY, PA) account for 36% of the U.S. population.

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Insights Condition - Immunization Administrations Electronically Submitted to Immunization Information Systems through Certified Health IT	Measurement Spec Sheet: Page 2	Supplemental Reporting Information: "Required: Developers will indicate the method used to select the IIS for immunizations that are administered but not submitted either: (1) based upon the primary IIS used by the client site, or (2) based upon the jurisdiction associated with client site's location."	Comment In nearly all, if not all cases, the client site must report to the IIS based upon the jurisdiction associated with the client site, so option 1 and 2 seem redundant. We would recommend modifying the language to read: "Required: Developers will indicate the method used to select the IIS for immunizations that are administered but not submitted based upon the jurisdiction associated with client site's location."
Insights Condition - Immunization Administrations Electronically Submitted to Immunization Information Systems through Certified Health IT	Measurement Spec Sheet: Page 2	"Optional: Developers may also submit descriptive or qualitative information to provide context, including but not limited to: ◦ Counts of replays (see Implementation Information below); ◦ The number of submissions that did not receive acknowledgement; ◦ The volume of immunizations administered but not electronically submitted via certified health IT (if available); and ◦ Count of error and acknowledgement codes on messages returned.	Comment: The optional measure of "The number of submissions that did not receive an acknowledgement" in the list of optional measures seems the same as Metric 4 for year 1 (and 8 for year 2): "The number of immunizations administered that were electronically submitted to an IIS where an acknowledgement from an IIS is not received by certified health IT overall". Unless there is something to differentiate it, we recommend removing this measure from the optional list.
Insights Condition - Immunization Administrations Electronically	Measurement Spec Sheet: Page 2	"Opt-out: Patients who have been administered an immunization and opt-out of submitted their data to an IIS should count in the metrics for number of immunizations administered overall, and	Comment: We believe this should actually read: "Patients who have been administered an immunization and opt-out of **submitting** their data…"

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Submitted to Immunization Information Systems through Certified Health IT		number of immunizations administered by age category and IIS, but not in the metrics for number of immunizations administered that were electronically submitted successfully to IISs overall, and number of immunizations administered that were electronically submitted successfully to IISs by age category and IIS."	Clarification is needed to better address opted-out patients (as understood by the EHR system to keep it simple) entirely from all measures, or keep in metric 1 and create a metric 1a to count just opted-out patients and then exclude them from Metrics 2, 3, 4 related to interoperability. The latter (a measure 1a approach) would highlight local law on opt-out rates. At present, for example, opt-out patients are included in metric 3 which could be a significant number of rejections in a jurisdiction like Texas where providers are encouraged to submit all records, but rejections occur if the patient hasn't opted-in.
Insights Condition - Immunization Administrations Electronically Submitted to Immunization Information Systems through Certified Health IT	Measurement Spec Sheet: Page 1	Metrics: 1. The number of immunizations administered overall 2. The number of immunizations administered that were electronically submitted successfully to IISs overall 3. The number of immunizations administered that were electronically submitted to IISs that returned with an acknowledgement with the error of severity level E overall 4. The number of immunizations administered that were electronically submitted to an IIS where an acknowledgement from an IIS is not received by certified health IT overall	Comment: Given the limitations of these measures, each measure on its own will provide a piece of the story, but it is impossible to confidently come up with something like a success rate (e.g., Metric 2/Metric 1 * 100). If the goal is to strive for a measure of success, it may be worth considering adding a Metric 1a of "Immunizations that were administered and were attempted to be submitted to the IIS via a certified health IT module.", removing opt out patients from this measure. We recommend that ASTP review inclusion/exclusion by metric: As written, the measures will not result in metrics 2 + 3+ 4 = metric 1. Each Metric has distinct inclusion and exclusion criteria. This will result in 4 unique metrics of raw counts which are hard to make inferences from. It will not be clear what 3.4 million successful submissions means if it's not clear what the denominator is. A health system using CEHRT that

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			submits each vaccination event to two IIS could potentially have a Metric 2 (successful submissions) that is larger than total administrations (Metric 1).
Insights Condition: Immunization History and Forecasts Through Certified Health IT	Measurement Spec Sheet on the Proposed Rule: Immunization History and Forecasts Through Certified Health IT, Page 1	The number of immunization queries sent to IISs overall	Comment: Please consider stratifying "by IIS" in Year 2. Without this, a certified Health IT vendor will submit a single number for each of the 4 metrics and the results will be heavily skewed by the volume of administrations in heavily populated jurisdictions and may mislead other successes or gaps in other jurisdictions. The top 5 jurisdictions (CA, TX, FL, NY, PA) account for 36% of the U.S. population.
	Measurement Spec Sheet on the Proposed Rule: Immunization History and Forecasts Through Certified Health IT, Metrics, Page 1	1. The number of immunization queries sent to IISs overall 2. The number of query responses received successfully from IISs overall 3. The number of query responses received from IISs with acknowledgement with the error of severity level E overall 4. The number of queries sent but no acknowledgement from the IIS was received overall	Comment: The metrics do not account for an outcome of "Not Found", "List of Patients", "Too Many", or "Protected Patient". If any of those conditions happen, they will not show up in Metrics 2 (Patient Found), 3 (Query Rejected with "E"), or 4 (No RSP returned) which are focused on the response from an IIS but would be counted in Metric one which focuses on the queries sent to an IIS. This will lead to Metric 2 + 3 + 4 not equaling Metric 1. Please consider another metric to address "Successful response where a single patient was not returned".