

Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability Notice of Proposed Rulemaking

ONC Health IT Certification Program Insights Condition

Updated January 17,2025

Measure ID and Version: Interop_Public Health_1_v4

Measure Title: Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT

Measure Description

- Regulatory Reference: § 170.407(a)(3)(vi)
- Associated Certification Criteria: § 170.315(f)(1)
- This measure provides insights into the use of certified health IT to electronically send immunizations administered to immunization information systems (IIS), including by IIS and age.

Metrics and Reporting Timeline

Metric	Program Year
The number of immunizations administered overall	Year 1
The number of immunizations administered that were electronically submitted successfully to IISs overall	Year 1
The number of immunizations administered that were electronically submitted to IISs that returned with an acknowledgement with the error of severity level E overall	Year 2
The number of immunizations administered overall by age category and IIS	Year 2
The number of immunizations administered that were electronically submitted successfully to IISs overall by age category and IIS	Year 2
The number of immunizations administered that were electronically submitted to an IIS that returned with an acknowledgement with the error of severity level E overall by age category and IIS	Year 2

Note: "Program Year" refers to the implementation year of the Insights Condition. "Year 1" measures start data collection in calendar year 2026 (January 1st, 2026 - December 31st, 2026), with responses due in July 2027 (and annually thereafter). "Year 2" measures start data collection in calendar year 2027, with responses due in July 2028 (and annually thereafter).

Definitions

• Successful Submission: The total number of messages submitted to IISs, minus acknowledgements with

the error of severity level E.1

- Immunizations Administered: Immunizations newly administered during the reporting period.
- · Age Category:
 - Patients 19 years of age and older (adults)
 - Patients 18 years of age and younger (children and adolescents)

Supplemental Reporting Information

- Required: Measures and related metrics are due annually. The reporting period is one calendar year.
- Required: Measures and related metrics must be aggregated at the product level (across versions).
 - Note that health IT developers with integrated certified health IT products will only have to report one response for each metric for those products (rather than two or more individual responses).
- **Required**: Developers must provide percentage of total customers (e.g., hospital, individual clinician users) represented in the provided data for each metric response.
- <u>Required:</u> Developers will submit documentation on the data sources and methodology used to generate these measures.
- <u>Required</u>: 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.
- 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.

Implementation Information

- Jurisdictions vary in mandating IIS reporting for specific patient age groups and immunizations, therefore the
 measure will reflect existing practices for provider organizations to transmit this data in accordance with
 jurisdictional requirements.
- The measure counts immunizations administered at all health care provider organizations that have certified health IT eligible for reporting, including those that do not have an existing, active connection to electronically submit immunizations to an IIS.
- ONC will provide templates that will list the jurisdiction for each IIS to facilitate consistent reporting in a structured, electronic format.
- Patient Factors:
 - Age category: Patients should be counted based on age at time of administration.
 - 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 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

¹ Health Level (HL7®) 2.5.1 Implementation Guide for Immunization Messaging



category and IIS.

- Messages sent to IISs for the metrics, number of immunizations administered that were electronically submitted successfully to IISs overall, and number of immunizations administered that were electronically submitted successfully to IISs overall by age category and IIS:
 - Status of Submission: The metrics count the status of the final submission at the time the reporting period ends, rather than counting each attempt separately. This applies to replays, which should not count as separate submission attempts.
 - Update Message: In the instance where the initial message for an immunization administration is successful and a subsequent update in the EHR has an update message that fails, the metrics should reflect the final status of the immunization submission during the reporting period.
 - Severity Level: Acknowledgements with a severity level of E should count as a failed message and are the only severity level for messages that should be excluded from the metrics.
 - No Acknowledgement Received: Not all immunizations that are administered and submitted during the reporting period may receive a status of the submission acknowledgement message from an IIS during the reporting period. Where an acknowledgement from an IIS is not received, the immunization submission should be counted as successful.
 - Number of IIS Messages: Each successful submission an IIS to which a provider submits immunizations should be included and counted as a successful submission. An immunization that is successfully submitted to more than one IIS would be counted the number of times it was successfully submitted to each IIS.
- Immunizations Administered and Submitted:
 - Historical Immunizations: The metrics count immunizations newly administered during the reporting period and will not count historical immunizations previously administered that were recorded during the reporting period; this treatment of historical immunizations administered applies to data migrated from one EHR to another and immunizations that were previously administered by another provider site.
 - Immunizations Administered but not Submitted: ONC has provided two options regarding how to best select the IIS for those immunizations that are administered but not submitted: (1) based upon the primary IIS used by the client site, or (2) based upon the jurisdiction associated with client site's location.
 - Reporting Period: The metrics count immunizations administered and submitted during the reporting period; an immunization administered outside the reporting period and submitted during the reporting period would not count.
 - Submissions via Non-Certified Health IT: Immunizations administered but not electronically submitted via certified health IT to IISs via web portals or alternate mechanisms (e.g., manual submission of spreadsheets) would only be included in the metrics for number of immunizations administered overall, and number of immunizations administered overall by age category and IIS, given that these were administered, but not electronically submitted.
 - No Active Connection to Electronically Submit to an IIS: Immunizations administered at health care provider organizations that have certified health IT eligible for reporting, but do not have an existing, active connection to electronically submit immunizations to an IIS will count in the metrics for the number of immunizations administered (overall and by age category and IIS), while there will be no count in the metrics for the number of immunizations administered that were electronically submitted successfully to IISs (overall and by age category and IIS).
- Provider Type and Location: The measure is not constrained to the type of the health care provider who
 administered the immunization or the location the immunization was administered, provided the certified
 health IT is eligible for reporting.
- Regulatory Baselines: As these regulatory baselines (i.e., certification criteria) change in the future, so too would the measure specification.



Exclusions

• Products that are not certified to § 170.315(f)(1) are excluded from this measure.

Measure Characteristics

- Measure Area: Public Health Information Exchange
- Measure Category: Interoperability

Specification Sheet Version History

- Version 1 released April 14, 2023
- Version 2 released December 13, 2023
- · Version 3 released July 10, 2024
- Version 4 released January 17, 2025

