Insights Measure Specifications Version 4:
Clarifications Fact Sheet

Overview

This fact sheet describes the Insights Measure Specifications Version 4 and associated clarifications for health IT developers participating in the ONC Health IT Certification Program (Certification Program). This resource is designed to assist Certified Health IT developers in meeting the Insights Condition and Maintenance of Certification requirements at 45 CFR 170.407.

Enforcement Discretion for the Insights Condition and Maintenance of Certification

In alignment with Executive Order (EO) 14192, ASTP/ONC is exercising enforcement discretion to reduce regulatory burden. Beginning July 1, 2027, Certified Health IT developers are only required to comply with reporting for the "use of FHIR in apps through certified health IT" measure (170.407(a)(3)(iv)), if applicable. Collection and reporting for all other measures under 45 CFR 170.407 is not required while enforcement discretion is in effect. Read more about the [Insights Condition Enforcement Discretion](#).

Version Flexibility for Reporting

Note that Certified Health IT developers must submit data using at least the version of the measure specification finalized as part of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule (Version 2). This means Certified Health IT developers may submit data using either Version 2 <u>or</u> Version 4 of the Insights Measure Specifications for reporting.

What are the differences between Insights Measure Specifications finalized in HTI-1 (Version 2) and Version 4 of the Insights Measure Specifications?

Use of FHIR® in Apps Through Certified Health IT ^(view spec sheet)

In the measure specifications, "user type" refers to the types of users the endpoint serves. A patient-facing endpoint serves patients accessing their EHI via certified API technology whereas a non-patient-facing endpoint enables other types of users to access EHI via certified API technology. In Version 2 of the measure specification, user type was defined by two categories: patient-facing and non-patient-facing. In Version 4, the definition for user type has been updated to include one additional category: patient-facing AND non-patient-facing. This update allows us to count the number of endpoints that serve <u>both</u> patients and other types of users, which was not previously possible with Version 2.

Collection and reporting for measures below are not required while enforcement discretion is in effect:

Individuals' Access to Electronic Health Information Through Certified Health IT (view spec sheet)

In Version 2 of the Individual Access measure specification, an individual's access to their electronic health information (EHI) was based upon an individual's authorization (via access token). Now, in Version 4 of the Individual Access measure specification, an individual's access is measured based on the return of at least one FHIR resource during the reporting period. The developer community brought to our attention that individuals may authorize access to their data (via an access token), but this does not necessarily indicate that a request was made to retrieve EHI. Given the intent is to measure individuals' access to EHI (rather than just authorizing access), we updated the definition of access to specify it should be measured by counting the number of individuals for whom at least one FHIR resource was returned during the reporting period.

Consolidated Clinical Document Architecture (C-CDA) Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT (view spec sheet)

Measuring patients with an encounter and associated C-CDA

In Version 2, there was a metric for capturing unique patients with an associated C-CDA document. In Version 4, this metric has been revised to capture the number of unique patients with an encounter and an associated C-CDA document during the reporting period. The revised metric is a direct subset of the existing metric "Number of Unique Patients with an Encounter." This change limits the count to C-CDAs associated with patients treated by a provider using the product during the reporting period, making the metric easier to interpret.

Pre-processing definition

In Version 2, the definition of "pre-processes" was any automated processes that deduplicated C-CDAs, removed information for user review that was identical to information in the health IT module, aggregated data across documents for bundled reconciliation, or used another method to process C-CDAs to facilitate reconciliation or incorporation of information into the health IT module. In Version 4, additional information was added to the definition for pre-processes that clarifies that pre-processes include any methods beyond capabilities required as a part of certification to § 170.315(b)(2) to reduce the effort required to perform manual or fully automated reconciliation. This is intended to clarify the purpose of the metric in addition to the four listed activities and to indicate that activities included in § 170.315(b)(2), like matching the C-CDA to the correct patient, are not included in the definition of pre-processing.

Definition of C-CDAs determined to have no new problems, medications or allergies and intolerances

In Version 2, the definition of C-CDAs determined to have no new problems, medications or allergies and intolerances was defined as any pre-process or fully automated process that determines that the C-CDA contains no new information. In Version 4, the definition of C-CDAs determined to have no new problems, medications or allergies and intolerances has been updated to include any automated processes that verify that information in a C-CDA is duplicative of information in the patient record. This clarifies that the metric encompasses comparison between the document and the patient record and is not limited to assessing whether the C-CDA contains problems, medications or allergies and intolerances.

Counting automated and pre-processed C-CDAs

In Version 2, it was ambiguous whether C-CDAs that were not pre-processed could then be reconciled and incorporated through fully automated processes. In Version 4, implementation information has been updated to clarify that both (1) C-CDAs that are reconciled and incorporated through fully automated processes and (2) those that are pre-processed increment the metric on C-CDAs that were pre-processed. This change was made to reduce ambiguity and because it is difficult to identify fully automated processes for reconciliation and incorporation that do not encompass pre-processes.

Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT ^(view spec sheet)

In Version 2 the measure specification captured the number of immunizations administered that were electronically submitted successfully to immunization information systems (IISs). In Version 4, metrics have been added to separately count the number of immunizations administered that were electronically submitted to IISs and returned an acknowledgement with the error of severity level E (overall, and by IIS and age category). These additional metrics will provide insights on potential issues associated with submissions to the IIS. We do not expect any additional burden associated with reporting this metric, as these metrics are a subset of the existing metric (number of immunizations administered that were electronically submitted successfully to IISs). Successful submission is defined as the total number of messages submitted to IISs, minus acknowledgements with the error of severity level E.

Immunization History and Forecasts Through Certified Health IT ^(view spec sheet)

In Version 2, the measure specification captured the number of query responses received successfully from IISs. In Version 4, we added metrics that report on the number of query responses received from IISs with acknowledgement with the error of severity level E (overall and by IIS). This should not represent additional burden, as these metrics are a subset of the original metric. These updates should enable monitoring the occurrence of communication failures between certified health IT and IIS more systematically.

Note: Only the "use of FHIR in apps through certified health IT" measure is currently subject to collection and reporting under enforcement discretion. If applicable, Certified Health IT developers may use either Insights Measure Specifications finalized in HTI-1 (Version 2) or Version 4 specifications for reporting.

Insights Condition Measure	Changes from Version 2 to Version 4
Individuals' Access to Electronic Health Information Through Certified Health IT	Changed definition of "access" from being based on an individuals' authorization (via access token) to actual data retrieval (i.e., at least one FHIR resource returned).
Applications Supported Through Certified Health IT	No change
Use of FHIR® in Apps Through Certified Health IT	Updated definition of "user type" to include one additional category (patient-facing AND non-patient facing).
Use of FHIR® Bulk Data Access Through Certified Health IT	No change

C-CDA Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT	• Revised metric to count unique patients with an encounter <u>and</u> C-CDA, instead of just C-CDA. • Clarified that pre-processes go beyond (b)(2) capabilities to reduce reconciliation effort. • Updated definition of C-CDAs with no new information to include automated duplication verification. • Clarified that both fully reconciled and pre-processed C-CDAs increment the metric.
Immunization Administrations Electronically Submitted to IIS Through Certified Health IT	Clarified a requirement to separately report the number of immunizations administered that were electronically submitted to immunization information systems (IISs) and returned an acknowledgement with the error of severity level E (overall, and by IIS and age category). This is a subset of the metric that counts successful submission to the IIS (which subtracts acknowledgements with the error of severity level).
Immunization History and Forecasts Through Certified Health IT	Clarified a requirement to separately report on the number of query responses received from IISs with acknowledgement with the error of severity level E (overall and by IIS). This is a subset of the original metric (the total number of immunization query responses received successfully from IISs, which minuses acknowledgements with the error of severity level E).