

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 July 10, 2024

Measure ID and Version: Interop_Clinical Care_1_v3

Measure Title: C-CDA Reconciliation and Incorporation Through Certified Health IT

Measure Description

for Health Information Technology

- Regulatory Reference: § 170.407(a)(3)(ii)
- Associated Certification Criteria: § 170.315(b)(2)
- This measure captures the use of health IT to obtain, reconcile, and incorporate C-CDA documents and constituent data elements including those reconciled and incorporated through manual and automated processes

Metrics

Metrics	Program Year
Number of encounters	Year 2
Number of unique patients with an encounter	Year 2
Number of unique patients with an encounter and associated C-CDA document	Year 2
Number of total C-CDA documents obtained	Year 2
Number of unique C-CDA documents obtained	Year 2
Number of total C-CDA documents obtained that were pre-processed	Year 2
Number of total C-CDA documents obtained that were not pre-processed	Year 2
Number of total C-CDA documents obtained that were pre-processed where data specified in § 170.315(b)(2) were reconciled and incorporated via manual processes performed by a clinician or their delegate	Year 3
Number of total C-CDA documents obtained that were pre-processed and determined to have no new data specified in § 170.315(b)(2) by manual processes performed by a clinician or their delegate	Year 3
Number of total C-CDA documents obtained that were pre-processed where data specified in § 170.315(b)(2) were reconciled and incorporated via fully automated processes	Year 3
Number of total C-CDA documents obtained that were pre-processed and determined to have no new data specified in § 170.315(b)(2) by pre-processes or fully automated processes	Year 3
Number of total C-CDA documents obtained that were not pre-processed where data specified in § 170.315(b)(2) were reconciled and incorporated via manual processes performed by a clinician or their delegate	Year 3
Number of total C-CDA documents obtained that were not pre-processed and determined to have no new data specified in § 170.315(b)(2) via manual processes performed by a clinician or their delegate only	Year 3
Number of select data specified in § 170.315(b)(2) obtained. For example, number of medications obtained.	Year 4
Number of select data specified in § 170.315(b)(2) reconciled and incorporated by any method. For example, number of medications reconciled and incorporated.	Year 4

Note: "Program Year" refers to the implementation year of the Insights Condition. "Year 1" measures start data collection in calendar year (CY) 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). The "Year 3" measures start data collection calendar year 2028, with reporting July 2029 (and annually thereafter). The "Year 4" measures start data collection calendar year 2029, with reporting July 2030 (and annually thereafter).



Definitions

• Encounter

Developers define relevant encounters based on their products' support for § 170.315(c)(1)-(4), which supports recording, importing, reporting or filtering clinical quality measures, and health IT certified to § 170.315 (g)(1), or (2), supports numerator recording and measure calculation for each Promoting Interoperability Program percentage-based measure.

C-CDA Documents

Any valid C-CDA document templates referred to in the standards adopted for certification to § 170.315(b)(2).

C-CDA Documents Obtained

- The total number of C-CDA documents obtained across all patients for the reporting period. The counts would not depend on whether information had previously been received for a patient prior to the reporting period.
- C-CDA documents obtained via all mechanisms (including from national networks, such as the Carequality
 framework, CommonWell, Direct Trust, and eHealth Exchange; Health IT Developer networks; EHR to EHR
 exchange; regional, local, and community HIE; and Direct Secure Messaging) should be counted in the measure.

• Unique C-CDA Documents

 Unique C-CDAs identified by document ID only, such that only one of multiple C-CDAs with the same document identifier will be included in the count of unique C-CDAs.

Unique Patients with an Encounter and an Associated C-CDA

- The number of unique patients with an encounter during the reporting period that have been matched to at least one C-CDA within the certified Health IT Module by automated or manual means in the reporting period and therefore have at least one associated C- CDA.
- Manual Processes Performed by a Clinician or Their Delegate
 - A manual process includes any action by a clinician or their delegate to reconcile or incorporate information obtained through a C-CDA in the patient's record. Manual processes also include affirmative action to indicate that reconciliation is complete or not necessary.

• Pre-Processes for Reconciliation and Incorporation

- Any automated process that uses methods beyond capabilities required as a part of certification to § 170.315(b)(2) to reduce the effort required to perform manual (by a clinician or their delete) or fully automated reconciliation and incorporation of information in the Health IT Module. This may include a method that: (1) deduplicates C-CDAs, for instance, based on document identifier, the information contained within multiple C-CDAs, or other means; (2) removes information for user review that is identical to information in the Health IT Module; (3) aggregates data across documents for bundled reconciliation; or (4) uses another means.
- Fully Automated Processes for Reconciliation and Incorporation
 - Any process by which proposed data specified in § 170.315(b)(2) contained within C-CDAs are automatically reconciled with information within certified health IT and incorporated into health IT without an action by a clinician end-user or their delegate. These processes include reconciling information from the C-CDA in the Health IT Module, for instance, by comparison of medication information in the Health IT Module and information in the C-CDA.
- Determined to Have No New Data Specified in § 170.315(b)(2)
 - Any process that determines that the C-CDA contains no new information. This includes manual processes where an
 end-user indicates that reconciliation is complete without adding new information to the patient record and automated
 process that verify the fact that information in the C-CDA is duplicative of existing information in the patient record.
- Reconciled and Incorporated via Any Method
 - Any approach to reconciling and incorporating information in the Health IT Module, including but not limited to manual processes performed by a clinician or their delegate only; a mix of manual and automated processes; or fully automated processes. This includes an affirmative action to: (1) reconcile information from the C-CDA in the Health IT Module, for instance, by comparison of medication information in the Health IT Module and information in the C-CDA; or (2) indicate that no information is incorporated into the Health IT Module.
- Select Data Specified in § 170.315(b)(2)
 - The data elements Substance (Medication) and Substance (Drug Class) in the Allergies and Intolerances data class.
 - The data elements Patient Goals and SDOH Goals in the Goals data class.
 - The data element Immunizations in the Immunizations data class.
 - The data element Values/Results in the Laboratory data class
 - The data element Medications in the Medications data class.
 - The data element Unique Device Identifier-Implantable for a patient's implantable device(s) in the Medical Devices data class.
 - The data element Assessment and Plan of Treatment in the Assessment and Plan of Treatment data class.
 - The data element Problems and SDOH Problems/Health Concerns in the Problems data class.



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., hospitals, individual clinician users) represented in the provided data for each metric response.
- Required: Developers shall submit documentation on the data sources and methodology used to generate these
 measures.
- Optional: Developers may also submit descriptive or qualitative information to provide context, including but not limited to:
 - If certified health IT identifies duplicate C-CDAs by analyzing the content of the C-CDA to determine if it is identical to another C-CDA's content, in addition to using the document identifier to determine duplicate C- CDAs; and
 - The number of C-CDAs obtained by different mechanisms, including but not limited to national networks; EHR to EHR exchange; regional, local, and community HIEs; and Direct Secure Messaging.

Implementation Information

- The measure applies to intra-system exchange, where specialists within the same provider organization do not have
 access to a "one patient one chart" health IT system, and inter-system exchange, where specialists across different
 provider organizations also do not have access to a "one patient one chart" health IT system; the measure is not
 limited to transitions of care.
- The act of viewing a C-CDA without an affirmative action verifying that information does not need to be incorporated into the patient's record (i.e., that it is either absent or duplicative) would not increment metrics.
- All C-CDAs that are either pre-processed or reconciled and incorporated through fully automated processes increment
 the metric on number of total C-CDA documents obtained that were pre-processed
- · C-CDA documents obtained, reconciled, and incorporated in the same reporting period increment the metrics.
- C-CDA documents obtained prior to the reporting period but reconciled and incorporated during the reporting period do
 not increment the metrics.
- For this measure, health IT developers are not required to:
 - Determine if a C-CDA is identical to another C-CDA by analyzing its content;
 - Parse or otherwise pre-process C-CDAs to evaluate whether the C-CDA contains data;
 - Exclude C-CDA documents without data; or
 - Deduplicate patients across different EHR instances.
- The metric "Number of total C-CDA documents obtained that were pre-processed where data specified in §
 170.315(b)(2) were reconciled and incorporated via fully automated processes" increments when data specified in §
 170.315(b)(2) from a C-CDA is reconciled and incorporated by automated processes even when some other data is incremented by manual processes.
- The metric "Number of total C-CDA documents obtained that were pre-processed where data specified in § 170.315(b)(2) were reconciled and incorporated via manual processes performed by a clinician or their delegate" increments when information is reconciled and incorporated through manual processes only. Other information in these C-CDAs may be removed by automated processes (e.g., identified as duplicative) prior to clinician review.

Exclusions

Products not certified to § 170.315(b)(2) would be excluded from reporting on this measure.

Measure Characteristics

- · Measure Area: Clinical Care 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

