Office of the National Coordinator for Health IT
Proposed Rule Public Comment Template

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule

Preface

This public comment template supports a specific proposed rule that would implement certain provisions of the 21st Century Cures Act. This proposed rule would also make several updates to certification criteria and implementation specifications recognized by the Program. The template is not intended to substitute for review of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule published in the *Federal Register* at 88 FR 23746. A PDF copy of the official version of the rule is available from the FederalRegister.gov website at: https://www.govinfo.gov/content/pkg/FR-2023-04-18/pdf/2023-07229.pdf.

This template is intended to provide a simple way to organize and present comments on the new and modified provisions in 45 CFR Parts 170 and 171, as well as responses to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of unstructured comments, or to use it as an addendum to narrative cover pages.

To further enhance the public comment experience, in complement to this public comment template, an unofficial copy of the proposed rule is also available in Microsoft Word format on ONC's website at www.healthIT.gov/proposedrule. We believe having a copy of the rule available in Microsoft Word will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments.

The following tables are organized according to the table of contents of the proposed rule, and the order in which proposed new and revised provisions are discussed in the preamble of the rule rather than the order in which the proposals would be codified in regulatory text. Tables pertaining to proposals include the *Federal Register* page(s) of the proposed rule where the regulatory impact analysis related to the proposal can be found. All tables include the *Federal Register* page(s) of the proposed rule where the preamble discussion of the proposal can be found. Each table provides a field for submitting comments on the proposals or requests for information, including, but not limited to, responses to specific questions or requests for comment posed in the preamble. This field can be expanded as necessary for commenting.

To be considered, all comments (including comments organized using this document) must be submitted according to the instructions in the proposed rule. Electronic submissions are strongly encouraged and can be easily completed through the regulations.gov website (the proposed rule's docket is at: https://www.regulations.gov/document/HHS-ONC-2023-0007-0001). Look for the "Comment" button on the left.

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule

Section III – ONC Health IT Certification Program Updates

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing - General Comments
Preamble FR Citation: 88 FR 23746
Public Comment Field: Enter comments on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing – General Comments.

"The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"
We propose to rename all criteria within the Program simply as "ONC certification criteria for health IT."
Preamble FR Citation: 88 FR 23757 **Specific questions in preamble?** No
Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.
Public Comment Field: Enter comments on "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions".

§ 170.102 - Definitions Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

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Revised certification criterion (or criteria) means a certification criterion that meets at least one of the following:

(1) Has added or changed the capabilities described in the existing criterion in 45 CFR part 170;

(2) Has an added or changed standard or implementation specification referenced in the existing criterion in 45 CFR part 170; or

(3) Is specified through notice and comment rulemaking as an iterative or replacement version of an existing criterion in 45 CFR part 170.

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Preamble FR Citation: 88 FR 23759 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.102 - Definitions related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions".

§ 170.524 - Principles of Proper Conduct for ONC-ATLs – Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

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(f)* * *

(1) Retain all records related to the testing of Complete EHRs and/or Health IT Modules to the ONC Certification Criteria for Health IT beginning with the codification of those certification criteria in the Code of Federal Regulations through a minimum of three years from the effective date of the removal of those certification criteria from the Code of Federal Regulations; and

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Preamble FR Citation: 88 FR 23761 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.524 - Principles of Proper Conduct for ONC-ATLs – Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions".

§ 170.524 - Principles of Proper Conduct for ONC-ATLs – Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

§ 170.523 - Principles of Proper Conduct for ONC-ACBs – Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

* * * * *

(g)* * *

(1) Retain all records related to the certification of Complete EHRs and Health IT Modules to the ONC Certification Criteria for Health IT beginning with the codification of those certification criteria in the Code of Federal Regulations through a minimum of 3 years from the effective date of the removal of those certification criteria from the Code of Federal Regulations; and

* * * * *

(k)* * *

(1)* * *

(i) The disclaimer "This Health IT Module is compliant with the ONC Certification Criteria for Health IT and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services."

(ii) For a Health IT Module certified to the ONC Certification Criteria for Health IT, the information specified by paragraphs (f)(1)(i), (vi) through (viii), (xv), and (xvi) of this section as applicable for the specific Health IT Module.

Preamble FR Citation: 88 FR 23761 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.523 - Principles of Proper Conduct for ONC-ACBs – Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions".

§ 170.550 - Health IT Module Certification - Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

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(g) *Health IT Module dependent criteria.* When certifying a Health IT Module to the ONC Certification Criteria for Health IT, an ONC-ACB must certify the Health IT Module in accordance with the certification criteria at:

* * * * *

and

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§ 170.550 - Health IT Module Certification - Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

(m) *Time-limited certification and certification status for certain ONC Certification Criteria for Health IT.* An ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for:
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Preamble FR Citation: 88 FR 23759 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.550 - Health IT Module Certification – Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions".

§ 170.213 - The United States Core Data for Interoperability Standard (USCDI) v3

The USCDI standard is currently cross-referenced to § 170.213 in certain certification criteria, each of which could currently be certified using either USCDI v1 or USCDI v2 because USCDI v2 is approved for SVAP. With our proposal to add the USCDI v3 in § 170.213, these criteria may also be certified using USCDI v3. We propose to continue allowing USCDI v1 or USCDI v2 under SVAP, and to also allow USCDI v3 through December 31, 2024. We propose to allow only USCDI v3 after this date for the criteria using USCDI. The criteria cross-referencing to USCDI § 170.213 are as follows:

- "Care coordination - Transitions of care - Create" (§ 170.315(b)(1)(iii)(A)(*1*));
- "Care coordination - Clinical information reconciliation and incorporation - Reconciliation" (§ 170.315(b)(2)(iii)(D)(*1)* through (*3*));
- "Patient engagement - View, download, and transmit to 3rd party - View" (§ 170.315(e)(1)(i)(A)(*1*));
- "Design and performance - Consolidated CDA creation performance" (§ 170.315(g)(6)(i)(A));
- "Design and performance - Application access – all data request – Functional requirements" (§ 170.315(g)(9)(i)(A)(*1*)); and
- "Design and performance - Standardized API for patient and population services – Data response" (§ 170.315(g)(10)(i)(A) and (B)).

§ 170.213 United States Core Data for Interoperability.

The Secretary adopts the following versions of the United States Core Data for Interoperability standard:

(a) *Standard*. United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2025.

(b) *Standard.* United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (incorporated by reference, see § 170.299).

§ 170.213 - The United States Core Data for Interoperability Standard (USCDI) v3

Preamble FR Citation: 88 FR 23762 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.213 - The United States Core Data for Interoperability Standard (USCDI) v3.

§ 170.205(a)(5) - C-CDA Companion Guide Updates

We propose to adopt the HL7 CDA® R2 IG: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 Realm in § 170.205(a)(6) (''C–CDA Companion Guide R3''). However, it is our understanding that HL7 is working on updating the C-CDA R2.1 Companion Guide (Release 4) for USCDI v3. If the C–CDA Companion Guide Release 4 (R4) is published before the date of publication of the final rule, it is our intention to consider adopting the updated Companion Guide R4 that provides guidance and clarifications for specifying data in USCDI v3 since we propose to adopt USCDI v3 as the baseline in this proposed rule.

We propose to revise § 170.205(a)(5) to add that the adoption of the standard in § 170.205(a)(5) expires on January 1, 2025. Developers of certified health IT with Health IT Modules certified to criteria that reference § 170.205(a)(5) would have to update those Health IT Modules to § 170.205(a)(6) and provide them to customers by January 1, 2025.

Further, we propose that Health IT Modules certified to the certification criteria below would need to update to the HL7 CDA® R2 IG: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 in § 170.205(a)(6) by January 1, 2025:

- ''transitions of care'' (§ 170.315(b)(1)(iii)(A));
- ''clinical information reconciliation and incorporation'' (§ 170.315(b)(2)(i), (ii), and (iv));
- ''care plan'' (§ 170.315(b)(9)(ii));
- ''view, download, and transmit to 3rd party'' (§ 170.315(e)(1)(i)(A) and (B));
- ''consolidated CDA creation performance'' (§ 170.315(g)(6)(i)); and
- ''application access—all data request'' (§ 170.315(g)(9)(i)).

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

(a)* * *

(5) *Standard.* HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion

§ 170.205(a)(5) - C-CDA Companion Guide Updates
Guide, Release 2 (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2025**.** (6) *Standard.* HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide, Release 3 - US Realm (incorporated by reference, see § 170.299). * * * * *
Preamble FR Citation: 88 FR 23767 **Specific questions in preamble?** No
Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.
Public Comment Field: Enter comments on § 170.205(a)(5) - C-CDA Companion Guide Updates.

§ 170.207 - "Minimum Standards" Code Sets Updates

We propose to adopt newer versions of the following minimum standards code sets:

(a)* * *

(1) *Standard*. IHTSDO SNOMED CT®, U.S. Edition, March 2022 Release (incorporated by reference, see § 170.299).

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(c)* * *

(1) *Standard*. Logical Observation Identifiers Names and Codes (LOINC®) Database Version 2.72, February 16, 2022, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference, see § 170.299).

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(d)* * *

(1) *Standard*. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, July 5, 2022 Full Monthly Release (incorporated by reference, see § 170.299).

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(4) *Standard.* The code set specified at 45 CFR 162.1002(b)(2).

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(e)* * *

(1) *Standard*. HL7 Standard Code Set CVX - Vaccines Administered, updates through June 15, 2022 (incorporated by reference, see § 170.299).

(2) *Standard*. National Drug Code Directory (NDC) - Vaccine NDC Linker, updates through July 19, 2022 (incorporated by reference, see § 170.299).

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(f)* * *

(3) *Standard*. CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021) (incorporated by reference, see § 170.299).

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(m)* * *

(1)* * *

(2) *Standard*. The Unified Code of Units of Measure, Revision 2.1, November 21, 2017 (incorporated by reference, see § 170.299).

(n)* * *

(1) *Standard.* Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see § 170.299), up until the adoption of this standard expires January 1, 2026, attributed as follows:

(i) Male. M; (ii) Female. F; (iii) Unknown. nullFlavor UNK.

(2) *Standard*. Sex must be coded in accordance with, at a minimum, the version of SNOMED CT ® codes specified in § 170.207(a)(1).

(3) *Standard.* Sex for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC ® codes specified in § 170.207(c)(1).

(o) *Sexual orientation and gender information*--(1) *Standard*. Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED-CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see § 170.299), up until the adoption of this standard expires on January 1, 2026, for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

(i) *Lesbian, gay or homosexual.* 38628009

(ii) *Straight or heterosexual.* 20430005

(iii) *Bisexual.* 42035005

(iv) *Something else, please describe.* nullFlavor OTH

(v) *Don't know.* nullFlavor UNK

(vi) *Choose not to disclose.* nullFlavor ASKU

(2) *Standard*. Gender identity must be coded in accordance with, at a minimum, the version of SNOMED-CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), up until the adoption of this standard expires January 1, 2026, for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

(i) *Male.* 446151000124109

(ii) *Female.* 446141000124107

(iii) *Female-to-Male (FTM)/Transgender Male/Trans Man.* 407377005

(iv) *Male-to-Female (MTF)/Transgender Female/Trans Woman.* 407376001

(v) *Genderqueer, neither exclusively male nor female.* 446131000124102

(vi) *Additional gender category or other, please specify.* nullFlavor OTH

(vii) *Choose not to disclose.* nullFlavor ASKU

(3) *Standard*. Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in § 170.207(a)(1).

(4) *Standard.* Pronouns must be coded in accordance with, at a minimum, the version of LOINC codes specified in 170.207(c)(1).

(p)* * *

(1) *Financial resource strain.* Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC ® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC ® code 76513-1 and LOINC ® answer list ID LL3266-5.

(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® code 63504-5 and

LOINC® answer list ID LL1069-5.

(3) *Stress.* Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3.

(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL361-7), 44255-8 (with LOINC® answer list ID LL361-7), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

(5) *Physical activity.* Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2).

(6) *Alcohol use.* Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

(7) *Social connection and isolation.* Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76511-5 (with LOINC answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: Intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

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(r)* * *

(2) *Standard*. Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, October 29, 2021 (incorporated by reference, see § 170.299).

(s)* * *

(2) *Standard*. Public Health Data Standards Consortium Source of Payment Typology Code Set Version 9.2 (December 2020) (incorporated by reference, see § 170.299).

§ 170.207 - "Minimum Standards" Code Sets Updates

Preamble FR Citation: 88 FR 23768 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23880 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.207 - "Minimum Standards" Code Sets Updates.

§ 170.315(f)(5) - Electronic Case Reporting

Included in Base EHR Definition? No

(5) *Transmission to public health agencies – electronic case reporting.* (i) Enable a user to create an electronic case report for transmission meeting the requirements described in paragraphs (f)(5)(i)(A) through (C) of this section for the time period up to and including December 31, 2024; or meet the requirements described in paragraph (f)(5)(ii) of this section.

(A) Consume and maintain a table of trigger codes to determine which encounters may be reportable.

(B) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.

(C) Create a case report for electronic transmission based on a matched trigger from paragraph (f)(5)(i)(B) of this section and including at a minimum:

(*1*) The data classes expressed in the standards in § 170.213.

(*2*) Encounter diagnoses information formatted according to the standard specified in § 170.207(i) or the version of the standard specified in § 170.207(a)(1).

(*3*) The provider's name, office contact information, and reason for visit.

(*4*) An identifier representing the row and version of the trigger table that triggered the case report.

(ii) Enable a user to create a case report for electronic transmission in accordance with the following:

(A) Consume and process electronic case reporting trigger codes and parameters and identify a reportable patient visit or encounter based on a match from the Reportable Conditions Trigger Code value set in § 170.205(t)(4) received from the eRSD profiles as specified in the HL7 FHIR eCR IG in § 170.205(t)(1).

(B) Create a case report consistent with at least one of the following standards:

(*1*) The eICR profile of the HL7 FHIR eCR IG in § 170.205(t)(1), or

(*2*) The eICR profile of the HL7 CDA eICR IG § 170.205(t)(2).

(C) Receive, consume, and process a case report response that is formatted to either the reportability response profile of the HL7 FHIR eCR IG in § 170.205(t)(1) or the HL7 CDA RR IG in § 170.205(t)(3).

(D) Transmit a case report electronically to a system capable of receiving an electronic case report.

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§ 170.315(f)(5) - Electronic Case Reporting	
Preamble FR Citation: 88 FR 23769	**Specific questions in preamble?** Yes
Regulatory Impact Analysis: Please see 88 FR 23886 for estimates related to this proposal.	
Public Comment Field: ONC did a good job of defining new certification criteria to help move eCR forward. Inclusion of consuming and processing the Electronic Reporting and Surveillance Distribution (eRSD) Specification Library and the eRSD Supplemental Library for trigger code processing is useful, while recognizing that though certification criteria need to identify a specific eRSD version, in reality these code sets can change rapidly, especially in an emergency. Across the board, both CDA and FHIR-based specifications for eRSD, as well as eICR and RR, need to continue to be supported for the foreseeable future as proposed. Of course, a clinical site must provide an eICR in the format required by the appropriate agency (CDA or FHIR), not simply pick one of these formats on its own. These criteria must reference the appropriate implementation guides which stipulate the required and optional data elements regardless of what USCDI might indicate more broadly. ONC also suggests that EHR technology needs to be recertified once these new criteria go into effect and we support clinical sites being required to use this newly-certified technology. **Recognition by ONC of the role of the eCR Now application (or its functional equivalent in the future) might also be useful. As a nuance, ONC might stipulate more precisely that not only does a certified EHR need to support either CDA or FHIR-based files as proposed, but that the file format of the RR should match the format of the eICR originally generated (for example, if an EHR supports only CDA-based eCIR generation it should support acceptance of CDA-based RRs).** **It is worth noting that while the NPRM recognizes that decision support for eCR is part of the workflow and process, the use of AIMS as the transport intermediary and RCKMS as the proscribed CDS strategy are not part of the recommendation even though it is the dominant architecture for eCR today. I do have mixed feelings about this. Likely ONC wants to ensure that standards-based case reports are transmitted as required by public health agencies that are receiving them. Since AIMS and RCKMS are not required by all public health agencies, I suppose it is consistent that ONC would not create a new requirement through this regulation.**	

§ 170.205(t) – Public Health – Electronic Case Reporting Standards

(t) *Public health – electronic case reporting* – (1) *Standard.* HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) - US Realm 2.1.0 – STU 2 US (HL7 FHIR eCR IG) (incorporated by reference, see § 170.299).

(2) *Standard.* HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1 - US Realm (HL7 CDA eICR IG) (incorporated by reference, see § 170.299).

(3) *Standard.* HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1 - US Realm (HL7 CDA RR IG) (incorporated by reference, see § 170.299).

(4) *Standard*. Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting. RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022 (incorporated by reference, see § 170.299).

Preamble FR Citation: 88 FR 23769 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23886 for estimates related to this proposal.

Public Comment Field: Click or tap here to enter text.

ONC did a good job of defining new certification criteria to help move eCR forward. Inclusion of consuming and processing the Electronic Reporting and Surveillance Distribution (eRSD) Specification Library and the eRSD Supplemental Library for trigger code processing is useful, while recognizing that though certification criteria need to identify a *specific* eRSD version, in reality these code sets can change rapidly, especially in an emergency. Across the board, both CDA and FHIR-based specifications for eRSD, as well as eICR and RR, need to continue to be supported for the foreseeable future as proposed. Of course, a clinical site must provide an eICR in the format required by the appropriate agency (CDA or FHIR), not simply pick *one* of these formats on its own. These criteria must reference the appropriate implementation guides which stipulate the required and optional data elements regardless of what USCDI might indicate more broadly. ONC also suggests that EHR technology needs to be recertified once these new criteria go into effect and we support clinical sites being required to use this newly-certified technology.

Recognition by ONC of the role of the eCR Now application (or its functional equivalent in the future) might also be useful. As a nuance, ONC might stipulate more precisely that not only does a certified EHR need to support *either* CDA or FHIR-based files as proposed, but that the file format of the RR should *match* the format of the eICR originally generated (for example, if an EHR supports only CDA-based eCIR generation it should support acceptance of CDA-based RRs).

§ 170.205(t) – Public Health – Electronic Case Reporting Standards

It is worth noting that while the NPRM recognizes that decision support for eCR is part of the workflow and process, the use of AIMS as the transport intermediary and RCKMS as *the* proscribed CDS strategy are not part of the recommendation even though it is the dominant architecture for eCR today. I do have mixed feelings about this. Likely ONC wants to ensure that standards-based case reports are transmitted as required by public health agencies that are receiving them. Since AIMS and RCKMS are not *required* by all public health agencies, I suppose it is consistent that ONC would not create a new requirement through this regulation.

§ 170.315(b)(11) – Decision Support Interventions (DSI)

Included in Base EHR Definition? Yes

(11) *Decision support interventions*--(i) *Decision support intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.

(ii) *Decision support configuration.* (A) Enable interventions and reference resources specified in paragraphs (b)(11)(iii) and (iv) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) Enable interventions:

(*1*) Based on the following data expressed in the standards in § 170.213, at a minimum:

(*i*) Problems;

(*ii*) Medications;

(*iii*) Allergies and Intolerances;

(*iv*) At least one demographic specified in paragraph (a)(5)(i) of this section;

(*v*) Laboratory;

(*vi*) Vital Signs;

(*vii*) Unique Device Identifier(s) for a Patient's Implantable Device(s).; and

(*viii*) Procedures.

(*2*) When a patient's medications, allergies and intolerance, and problems are incorporated from a transition of care or referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

(C) Enable end users to provide electronic feedback based on information displayed through the intervention and make available such feedback data for export, in a computable format, including but not limited to the intervention, action taken, user feedback provided (if applicable), user, date, and location.

(iii) *Evidence-based decision support interventions.* Enable a limited set of identified users to select (i.e., activate) electronic decision support interventions (in addition to drug-drug and drug-allergy

contraindication checking) based on any of the data referenced in paragraphs (b)(11)(ii)(B)(*1*)(*i*) through (*vii*) of this section.

(iv) *Linked referential DSI.* (A) Identify for a user diagnostic and therapeutic reference information in accordance with at least one of the following standards and implementation specifications:

(*1*) The standard and implementation specifications specified in § 170.204(b)(3).

(*2*) The standard and implementation specifications specified in § 170.204(b)(4).

(B) For paragraph (b)(11)(iv)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (b)(11)(ii)(B)(*1*)(*i*), (*ii*), and (*iv*) of this section.

(v) *Predictive decision support interventions attestation.* Health IT developers must make one of the following attestations:

(A) Yes – the Health IT Module enables or interfaces with one or more predictive decision support interventions as defined in § 170.102 based on any of the data expressed in the standards in § 170.213.

(B) No – the Health IT Module does not enable or interface with one or more predictive decision support interventions as defined in § 170.102 based on any of the data expressed in the standards in § 170.213.

(vi) *Source attributes.* Enable a user to review a plain language description of source attribute information as indicated and at a minimum via direct display, drill down, or link out from a Health IT Module:

(A) For evidence-based decision support interventions under paragraph (b)(11)(iii) of this section:

(*1*) Bibliographic citation of the intervention (clinical research or guideline);

(*2*) Developer of the intervention (translation from clinical research or guideline);

(*3*) Funding source of the intervention development technical implementation; and

(*4*) Release and, if applicable, revision dates of the intervention or reference source;

(*5*) Use of the patient demographics and observations data specified in paragraph (a)(5)(i) of this section;

(*6*) Use of Social Determinants of Health data as expressed in the standards in § 170.213; and

(*7*) Use of Health Status Assessments data as expressed in the standards in § 170.213.

(B) For linked referential DSI in paragraph (b)(11)(iv) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research or guideline).

(C) For Health IT Modules that enable or interface with one or more predictive decision support interventions, as described in paragraph (b)(11)(v)(A) of this section, source attributes in paragraph (b)(11)(vi)(A) of this section and the following:

(*1*) Intervention details:

(*i*) Output of the intervention;

(*ii*) Intended use of the intervention;

(*iii*) Cautioned out-of-scope use of the intervention;

(*2*) Intervention development:

(*i*) Input features of the intervention including description of training and test data;

(*ii*) Process used to ensure fairness in development of the intervention;

(*iii*) External validation process, if available;

(*3*) Quantitative measures of intervention performance:

(*i*) Validity of prediction in test data;

(*ii*) Fairness of prediction in test data;

(*iii*) Validity of prediction in external data, if available;

(*iv*) Fairness of prediction in external data, if available;

(*v*) References to evaluation of use of the model on outcomes, if available;

(*4*) Ongoing maintenance of intervention implementation and use:

(*i*) Update and continued validation or fairness assessment schedule;

(*ii*) Validity of prediction in local data, if available;

(*iii*) Fairness of prediction in local data, if available.

(D) A Health IT Module must clearly indicate when a source attribute listed in paragraphs (b)(11)(vi)(A), (B), or (C) of this section, as applicable, is not available for the user to review, including when:

(*1*) The source attribute includes the "if available" phrase; or

(*2*) The decision support intervention, enabled by or interfaced with the Health IT Module, is developed by other parties that are not developers of certified health IT.

(E) Enable a limited set of identified users to author and revise source attributes and information beyond source attributes listed in paragraphs (b)(11)(vi)(A) and (b)(11)(vi)(C) of this section, as applicable.

(vii) *Intervention Risk Management.* By December 31, 2024, a health IT developer that attests "yes," in § 170.315(b)(11)(v)(A) must:

(A) Employ or engage in the following intervention risk management practices for all predictive decision support interventions, as defined in § 170.102, that the Health IT Module enables or interfaces with:

(*1*) *Risk analysis*. Analyze potential risks and adverse impacts associated with a predictive decision support intervention for the following characteristics: validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy.

(*2*) *Risk mitigation*. Implement practices to mitigate risks, identified in accordance with § 170.315(b)(11)(vii)(A)(*1*), associated with a predictive decision support intervention; and

(*3*) *Governance*. Establish policies and implement controls for predictive decision support intervention governance, including how data are acquired, managed, and used in a predictive decision support intervention.

(B) Compile detailed documentation regarding the intervention risk management practices listed in paragraph (b)(11)(vii)(A) of this section and upon request from ONC, make available such detailed documentation for any predictive decision support intervention, as defined in § 170.102, that the Health IT Module enables or interfaces with.

(C) Submit summary information of the intervention risk management practices listed in paragraph (b)(11)(vii)(A) of this section to its ONC-ACB via publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

§ 170.315(b)(11) – Decision Support Interventions (DSI)
(D) Review annually and, as necessary, update documentation described in paragraphs (b)(11)(vii)(B) and (b)(11)(vii)(C) of this section.
Preamble FR Citation: 88 FR 23774 **Specific questions in preamble?** Yes
Regulatory Impact Analysis: Please see 88 FR 23889 for estimates related to this proposal.
Public Comment Field: Enter comments on § 170.315(b)(11) – Decision Support Interventions (DSI).

§ 170.315(a)(9) – Clinical Decision Support Interventions
Included in Base EHR Definition? Yes
In keeping with the proposal to modify the Base EHR definition in § 170.102, we propose that the adoption of § 170.315(a)(9) as part of the Program would expire January 1, 2025. This would effectively remove § 170.315(a)(9) from the Program. We note that if we finalize these proposals, developers of certified health IT with Health IT Modules certified to § 170.315(a)(9) would need to certify to § 170.315(b)(11) to support customers that are required to use certified technology that meets the Base EHR definition by December 31, 2024, which is the effective date we propose elsewhere in this preamble to modify the Base EHR definition to include § 170.315(b)(11). (9)* * * (vi) *Expiration of Criterion.* The adoption of this criterion for purposes of the ONC Health IT Certification Program expires on January 1, 2025. * * * * *
Preamble FR Citation: 88 FR 23783 **Specific questions in preamble?** No
Regulatory Impact Analysis: Please see 88 FR 23889 for estimates related to this proposal.
Public Comment Field: Enter comments on § 170.315(a)(9) – Clinical Decision Support Interventions.

§ 170.405 - Real World Testing - Proposed Updates to Real World Testing Condition Related to Decision Support Interventions and Predictive Models

(a) *Condition of Certification requirement*. A health IT developer with one or more Health IT Module(s) certified to any one or more of the ONC Certification Criteria for Health IT in § 170.315(a)(9), (b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h) must successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C.300jj(9) and § 170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

Preamble FR Citation: 88 FR 23808 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23889 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.405 - Real World Testing - Proposed Updates to Real World Testing Condition Related to Decision Support Interventions and Predictive Models.

§ 170.102 – Definitions Related to Decision Support Interventions and Predictive Models

Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality;

(iv) To exchange electronic health information with, and integrate such information from other sources; and

(3) Has been certified to the certification criteria adopted by the Secretary in—

(i) Section 170.315(a)(1), (2), or (3); (a)(5), (a)(14), (b)(1), (c)(1), (g)(7), (9), (10), and (h)(1) or (2);

(ii) Section 170.315(a)(9) or (b)(11) for the period up to and including December 31, 2024; and

(iii) Section 170.315(b)(11) on and after January 1, 2025.

ONC certification criteria for health IT means the certification criteria in § 170.315.

* * * * *

Predictive decision support intervention means technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis.

* * * * *

Preamble FR Citation: 88 FR 23782 **Specific questions in preamble?** No

§ 170.102 – Definitions Related to Decision Support Interventions and Predictive Models

Regulatory Impact Analysis: Please see 88 FR 23889 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.102 – Definitions Related to Decision Support Interventions and Predictive Models.

§ 170.523 - Principles of Proper Conduct for ONC-ACBs Related to DSI Proposals

(f)* * *

(1) For the ONC Certification Criteria for Health IT:

* * * * *

(xxi) Where applicable, all of the information required to be submitted by the health IT developer to meet intervention risk management requirements in § 170.315(b)(11)(vii)(C).

* * * * *

Preamble FR Citation: 88 FR 23805 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23889 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.523 - Principles of Proper Conduct for ONC-ACBs – Related to DSI Proposals.

Synchronized Clocks Standards

We propose to remove the current named specification for clock synchronization, which is Network Time Protocol (NTP v4 of RFC 5905), in § 170.210(g), based on public feedback and reflective of contemporary norms within the industry. Additionally, we propose to keep the requirement for any network time protocol (NTP) standard to be present, though any NTP standard could be used.

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

*****

(g) *Synchronized clocks*. The date and time recorded utilize a system clock that has been synchronized using any Network Time Protocol (NTP) standard.

*****

Preamble FR Citation: 88 FR 23811 **Specific questions in preamble?** No

Synchronized Clocks Standards

Regulatory Impact Analysis: Please see 88 FR 23893 for estimates related to this proposal.

Public Comment Field: Enter comments on Synchronized Clocks Standards.

§ 170.315(g)(10) - Standardized API for Patient and Population Services

Included in Base EHR Definition? Yes

(10)* * *

(i)* * *

(A) Respond to requests for a single patient's data according to the standards and implementation specifications adopted in 170.215(a) and in § 170.215(b)(1), including the mandatory capabilities described in "US Core Server CapabilityStatement," for each of the data included in the standards adopted in § 170.213. All data elements indicated as "mandatory" and "must support" by the standards and implementation specifications must be supported.

(B) Respond to requests for multiple patients' data as a group according to the standards and implementation specifications adopted in § 170.215(a), (b)(1), and (d), for each of the data included in the standards adopted in § 170.213. All data elements indicated as "mandatory" and "must support" by the standards and implementation specifications must be supported.

(ii)* * *

(A) Respond to search requests for a single patient's data consistent with the search criteria included in the implementation specifications adopted in § 170.215(b)(1), specifically the mandatory capabilities described in "US Core Server CapabilityStatement."

* * * * *

(iv)* * *

(A) Establish a secure and trusted connection with an application that requests data for patient and user scopes in accordance with the implementation specifications adopted in § 170.215(b)(1) and (c).

* * * * *

(v)* * *

(A)* * *

(*1*)* * *

(*ii*) A Health IT Module's authorization server must issue a refresh token valid for a period of no less than three months to applications using the "confidential app" profile according to an implementation specification adopted in § 170.215(c).

* * * * *

(*2*)* * *

(*ii*) A Health IT Module's authorization server must issue a refresh token valid for a new period of no less than three months to applications using the "confidential app" profile according to an implementation

§ 170.315(g)(10) - Standardized API for Patient and Population Services

specification adopted in § 170.215(c).

* * * * *

(vi) *Patient authorization revocation*. A Health IT Module's authorization server must be able to revoke and must revoke an authorized application's access at a patient's direction within 1 hour of the request.

(vii) *Token introspection*. A Health IT Module's authorization server must be able to receive and validate tokens it has issued in accordance with an implementation specification in § 170.215(c).

* * * * *

Preamble FR Citation: 88 FR 23812 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23894 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.315(g)(10) - Standardized API for Patient and Population services.

§ 170.215 – Application Programming Interface Standards

The Secretary adopts the following standards and associated implementation specifications as the available standards for application programming interfaces (API):

(a) *API base standard*. The following are applicable for purposes of standards-based APIs.

(1) *Standard*. HL7® Fast Healthcare Interoperability Resources (FHIR ®) Release 4.0.1 (incorporated by reference, see § 170.299).

(2) [Reserved]

(b) *API constraints and profiles*. The following are applicable for purposes of constraining and profiling data standards.

(1) *United States Core Data Implementation Guides*.

(i) *Implementation specification*. HL7 FHIR® US Core Implementation Guide STU 3.1.1 (incorporated by reference in § 170.299). The adoption of this standard expires on January 1, 2025.

(ii) *Implementation Specification*. HL7 FHIR® US Core Implementation Guide STU 5.0.1 (incorporated by reference, see § 170.299).

(2) [Reserved]

(c) *Application access and launch*. The following are applicable for purposes of enabling client applications to access and integrate with data systems.

(1) *Implementation specification*. HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the “SMART Core Capabilities” (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2025.

(2) *Implementation specification*. HL7 SMART Application Launch Framework Implementation Guide

§ 170.215 – Application Programming Interface Standards
Release 2.0.0, including mandatory support for the "Capability Sets" of "Patient Access for Standalone Apps" and "Clinician Access for EHR Launch"; all "Capabilities" as defined in "8.1.2 Capabilities;" "Token Introspection" as defined in "7 Token Introspection" (incorporated by reference, see § 170.299). (d) *Bulk export and data transfer standards*. The following are applicable for purposes of enabling access to large volumes of information on a group of individuals. (1) *Implementation specification*. FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1), including mandatory support for the "group-export" "OperationDefinition" (incorporated by reference, see § 170.299). (2) [Reserved] (e) *API authentication, security, and privacy*. The following are applicable for purposes of authorizing and authenticating client applications. (1) *Standard*. OpenID Connect Core 1.0, incorporating errata set 1 (incorporated by reference, see § 170.299). (2) [Reserved]
Preamble FR Citation: 88 FR 23812 **Specific questions in preamble?** Yes
Regulatory Impact Analysis: Please see 88 FR 23894 for estimates related to this proposal.
Public Comment Field: Enter comments on § 170.215 – Application Programming Interface Standards.

§170.315(a)(5) Patient Demographics and Observations Certification Criterion

Included in Base EHR Definition? Yes

(a)* * *

(5) Patient demographics and observations. (i) Enable a user to record, change, and access patient demographic and observations data including race, ethnicity, preferred language, sex, sex for clinical use, sexual orientation, gender identity, name to use, pronouns, and date of birth.

(A)* * *

(*1*) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify race.

(*2*) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify ethnicity.

* * * * *

(C) *Sex.* Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1) for the time period up to and including December 31, 2025; or § 170.207(n)(2).

(D) *Sexual orientation.* Enable sexual orientation to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(1) for the time period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify sexual orientation.

(E) *Gender identity.* Enable gender identity to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(2) for the time period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify gender identity.

(F) *Sex for Clinical Use.* Enable a patient's sex for clinical use to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(3). Conformance with this paragraph is required by January 1, 2026.

(G) *Name to Use.* Enable a patient's preferred name to use to be recorded. Conformance with this paragraph is required by January 1, 2026.

(H) *Pronouns*. Enable a patient's preferred pronouns to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(4). Conformance with this paragraph is required by January 1, 2026.

* * * * *

Preamble FR Citation: 88 FR 23819 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23895 for estimates related to this proposal.

Public Comment Field: Enter comments on §170.315(a)(5) Patient Demographics and Observations Certification Criterion.

§ 170.315(b)(1) Transitions of Care Certification Criterion

Included in Base EHR Definition? Yes

(b)* * *

(1)* * *

(iii)* * *

(A)* * *

(1) The data classes expressed in the standards in § 170.213 and in accordance with § 170.205(a)(4), (5), and paragraphs (b)(1)(iii)(A)(3)(i) through (iii) of this section for the time period up to and including December 31, 2024, or

(2) The data classes expressed in the standards in § 170.213 and in accordance with § 170.205(a)(4), (6), and paragraphs (b)(1)(iii)(A)(3)(i) through (iii) of this section, and

* * * * *

(B)* * *

(2) At a minimum, the version of the standard specified in § 170.207(a)(1).

* * * * *

(G) *Patient matching data*. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, current address, phone number, and sex. The following constraints apply:

* * * * *

(3) *Sex Constraint*: Represent sex with the standards adopted in § 170.213.

Preamble FR Citation: 88 FR 23821 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23897 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.315(b)(1) Transitions of Care Certification Criterion.

§ 170.315(d)(14) - Patient Requested Restrictions Certification Criterion

Included in Base EHR Definition? No

(d)* * *

(14) Patient requested restrictions.

(i) For any data expressed in the standards in § 170.213, enable a user to flag whether such data needs to be restricted from being subsequently used or disclosed as set forth in 45 CFR § 164.522; and

(ii) Prevent any data flagged pursuant to paragraph (d)(14)(i) of this section from being included in a use or disclosure.

§ 170.315(d)(14) - Patient Requested Restrictions Certification Criterion	
Preamble FR Citation: 88 FR 23821	**Specific questions in preamble?** Yes
Regulatory Impact Analysis: Please see 88 FR 23898 for estimates related to this proposal.	
Public Comment Field: Enter comments on § 170.315(d)(14) - Patient Requested Restrictions Certification Criterion.	

§ 170.550(h) - Health IT Module Certification – Privacy and Security Framework Related to Patient Requested Restrictions Certification Criterion
* * * * * (h) * * * (1) General rule. When certifying a Health IT Module to the ONC Certification Criteria for Health IT, an ONC-ACB can only issue a certification to a Health IT Module if the privacy and security certification criteria in paragraphs (h)(3)(i) through (ix) of this section have also been met (and are included within the scope of the certification). (3)* * * (iii) Section 170.315(b)(1) through (3) and (6) through (9) are also certified to the certification criteria specified in § 170.315(d)(1) through (3), (d)(5) through (8), (d)(12) and (13), and, by January 1, 2026, (d)(14); (v) Section 170.315(e)(1) is also certified to the certification criteria specified in § 170.315(d)(1) through (3), (5), (7), (9), (12), (13), and, by January 1, 2026, (d)(14); (viii) Section 170.315(g)(7) through (10) is also certified to the certification criteria specified in § 170.315(d)(1), (9), (12), (13), and, by January 1, 2026, (d)(14); and (d)(2)(i)(A) and (B), (d)(2)(ii) through (v), or (d)(10); * * * * *
Preamble FR Citation: 88 FR 23822 **Specific questions in preamble? No**
Regulatory Impact Analysis: Please see 88 FR 23898 for estimates related to this proposal.
Public Comment Field: Enter comments on § 170.550(h) - Health IT Module Certification – Privacy and Security Framework Related to Patient Requested Restrictions Certification Criterion.

§ 170.315(e)(1) - View, Download, and Transmit to 3rd party
Included in Base EHR Definition? No
* * * * * (iii) *Request for restrictions* – Patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in the standards in § 170.213. Conformance with this paragraph is required by January 1, 2026.
Preamble FR Citation: 88 FR 23822 **Specific questions in preamble?** No
Regulatory Impact Analysis: Please see 88 FR 23898 for estimates related to this proposal.
Public Comment Field: Enter comments on § 170.315(e)(1) - View, Download, and Transmit to 3rd party.

§ 170.205(o) - Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information.
(o) * * * (2) *Standard*. HL7 FHIR® Data Segmentation for Privacy Implementation Guide: Version 1.0.0 – current – ci-build, December 1, 2022 (incorporated by reference, see § 170.299). * * * * *
Preamble FR Citation: 88 FR 23877 **Specific questions in preamble?** No
Regulatory Impact Analysis: N/A
Public Comment Field: Enter comments on § 170.205(o) - Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information.

Requirement for Health IT Developers to Update their Previously Certified Health IT Modules
We propose to add introductory text in § 170.315: **§ 170.315. ONC Certification Criteria for Health IT.** The Secretary adopts the following certification criteria for health IT. Health IT must be able to electronically perform the following capabilities in accordance with applicable standards and implementation specifications adopted in this part. For all criteria in this section, a health IT developer with a Health IT Module certified to any revised certification criterion, as defined in § 170.102, shall update the Health IT Module and shall provide such update to their customers in accordance with the dates identified for each revised certification criterion and for each applicable standard in 45 CFR part 170 subpart B.
Preamble FR Citation: 88 FR 23826 **Specific questions in preamble?** No
Regulatory Impact Analysis: N/A
Public Comment Field: Enter comments on Requirement for Health IT Developers to Update their Previously Certified Health IT Modules.

Assurances Condition and Maintenance of Certification Requirements
§ 170.402 Assurances. (a)* * * (5) A health IT developer must not inhibit its customer's timely access to interoperable health IT certified under the Program. (b)* * * (3)(i) *Update*. A health IT developer must update a Health IT Module, once certified to a certification criterion adopted in § 170.315, to all applicable revised certification criteria, including the most recently adopted capabilities and standards included in the revised certification criterion. (ii) *Provide*. A health IT developer must provide all Health IT Modules certified to a revised certification criterion, including the most recently adopted capabilities and standards included in the revised certification criterion, to its customers of such certified health IT. (iii) *Timeliness*. Unless expressly stated otherwise in this part, a health IT developer must complete the actions specified in paragraphs (b)(3)(i) and (ii) of this section: (A) By no later than December 31 of the calendar year that falls 24 months after the effective date of the final rule adopting the revised criterion or criteria; or (B) If the developer obtains new customers of health IT certified to the revised criterion after the effective date of the final rule adopting the revised criterion or criteria, then the health IT developer must provide the health IT certified to the revised criterion to such customers within whichever of the following timeframes that expires last: (1) The timeframe provided in paragraph (b)(3)(iii)(A) of this section; or (2) No later than 12 months after the purchasing or licensing relationship has been established between the health IT developer and the new customer for the health IT certified to the revised criterion.
Preamble FR Citation: 88 FR 23828 **Specific questions in preamble?** No
Regulatory Impact Analysis: N/A
Public Comment Field: Enter comments on Assurances Condition and Maintenance of Certification Requirements.

§ 170.102 – Definitions Related to Assurances
Provide means the action or actions taken by a health IT developer of a certified Health IT Modules to make the certified health IT available to its customers. *****
Preamble FR Citation: 88 FR 23829 **Specific questions in preamble?** No
Regulatory Impact Analysis: N/A
Public Comment Field: Enter comments on § 170.102 – Definitions Related to Assurances.

Real World Testing – Inherited Certified Status

(a) *Condition of Certification requirement*. A health IT developer with Health IT Module(s) certified to any one or more of the ONC certification criteria for health IT in § 170.315(a)(9), (b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h) must successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C.300jj(9) and § 170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

(b)* * *

(2)* * *

(ii) For real world testing activities conducted during the immediately preceding calendar year, a health IT developer must submit to its ONC-ACB an annual real world testing results report addressing each of its certified Health IT Modules that include certification criteria referenced in paragraph (a) of this section by a date determined by the ONC-ACB that enables the ONC-ACB to publish a publicly available hyperlink to the results report on CHPL no later than March 15 of each calendar year, beginning in 2023. For certified Health IT Modules included in paragraph (a) of this section that are updated using Inherited Certified Status after August 31 of the year in which the plan is submitted, a health IT developer must include the newer version of the certified Health IT Module(s) in its annual real world testing results report. The real world testing results must report the following for each of the certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

* * * * *

Preamble FR Citation: 88 FR 23830 **Specific questions in preamble?** No

Regulatory Impact Analysis: N/A

Public Comment Field: Enter comments on Real World Testing – Inherited Certified Status.

§ 170.407 Insights Condition and Maintenance of Certification

(a) *Condition of Certification.* A health IT developer must submit responses in accordance with the established Insights Condition of Certification requirements with respect to all applicable certified health technology a health IT developer offers under the ONC Health IT Certification Program. A health IT developer must provide responses to an independent entity on behalf of the Secretary with the following Insights Condition measure(s) requirements:

(1) *Individuals' access to electronic health information measure*. (i) A health IT developer must submit responses for the individuals' access to electronic health information measure if the health IT developer has:

(A) Any Health IT Module certified to sections 170.315(e)(1), or (g)(10); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to one or more of the applicable certification criteria specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified

health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criteria specified in the applicable measure during the reporting period.

(2) *C-CDA documents obtained using certified health IT by exchange mechanism measure.* (i) A health IT developer must submit responses for the C-CDA documents obtained using certified health IT by exchange mechanism measure if the developer has:

(A) Any Health IT Module certified to section 170.315(b)(2); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion specified in the applicable measure during the reporting period.

(3) *C-CDA medications, allergies, and problems reconciliation and incorporation using certified health IT measure.* (i) A health IT developer must submit responses for the C-CDA medications, allergies, and problems reconciliation and incorporation using certified health IT measure if the health IT developer has:

(A) Any Health IT Module certified to section 170.315(b)(2); and

(B) Has at least 50 hospital users or 500 clinician users across their certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification

criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion specified in the applicable measure during the reporting period.

(4) *Applications supported through certified health IT measure*. (i) A health IT developer must submit responses for the applications support through certified health IT measure if the health IT developer has:

(A) Any Heath IT Module certified to section 170.315(g)(10); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion or criteria specified in the applicable measure during the reporting period.

(5) *Use of FHIR in apps supported by certified API technology measure*. (i) A health IT developer must submit responses for the use of FHIR in apps supported by certified API technology measure if the health IT developer has:

(A) Any Health IT Module certified to section 170.315(g)(10); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion specified in the applicable measure during the reporting period.

(6) *Use of FHIR bulk data access through certified health IT measure*. (i) A health IT developer must submit responses for the use of FHIR bulk data access through certified health IT measure if the health IT developer has:

(A) Any Health IT Module certified to section 170.315(g)(10); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion specified in the applicable measure during the reporting period.

(7) *Electronic health information export through certified health IT measure*. (i) A health IT developer must submit responses for the electronic health information export through certified health IT measure if the health IT developer has:

(A) Any Health IT Module certified to section 170.315(b)(10); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion specified in the applicable measure during the reporting period.

(8) *Immunization administrations electronically submitted to an immunization information system through certified health IT measure*. (i) A health IT developer must submit responses for immunization administrations electronically submitted to an immunization information system through certified health IT measure if the health IT developer has:

(A) Any Health IT Module certified to section 170.315(f)(1); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion specified in the applicable measure during the reporting period.

(9) *Immunization history and forecasts measure.* (i) A health IT developer must submit responses for Immunization history and forecasts measure. if the health IT developer has:

(A) Any Health IT Module certified to section 170.315(f)(1); and

(B) Has at least 50 hospital users or 500 clinician users across its certified health IT products.

(ii) A health IT developer must submit a response that it does not meet the minimum reporting qualifications for this measure if:

(A) The health IT developer does not have at least one product that is certified to the certification criterion specified in the measure requirements;

(B) The health IT developer does not have at least 50 hospital users or 500 clinician users across its certified health IT; or

(C) If the health IT developer's product does not have any users using the functionality specified by the certification criterion specified in the applicable measure during the reporting period.

(b) *Maintenance of Certification*. (1) A health IT developer must provide responses to the Insights Condition of Certification specified in paragraph (a) of this section semiannually for any Health IT Module that has or has had an active certification at any time under the ONC Health IT Certification Program during the prior six months:

(i) A health IT developer must provide responses for measures specified in paragraphs (a)(1), (4), (8), and (9) of this section beginning April 2025;

(ii) A health IT developer must provide responses for measures specified in paragraphs (a)(2), (3), and (5) through (7) of this section beginning April 2026.

(2) [Reserved]

Preamble FR Citation: 88 FR 23831 **Specific questions in preamble?** Yes

§ 170.407 Insights Condition and Maintenance of Certification

Regulatory Impact Analysis: Please see 88 FR 23898 for estimates related to this proposal.

Public Comment Field: There are two measures related to public health that are identified in the NPRM, both related to immunization data interoperability. The first measure is focused on immunization data submission to immunization information systems (IIS). ONC claims that current information on this is insufficient, especially when they ask clinical sites about it via surveys. ONC wants to know "whether and to what extent providers are using their certified health IT to electronically send and receive public health information to and from public health agencies." While the current compliance data that ONC collects on "active engagement" does not provide statistics, public health agencies certainly know the landscape of data submission for clinical sites submitting data. One has to wonder whether engaging with public health to generate some meaningful data might not be less of a burden on EHR vendors and their users and perhaps paint a more complete picture of the situation.

To achieve this measure, vendors will need to submit a numerator which is the number of immunizations submitted electronically to public health during the reporting period. Submissions that failed due to error (as reported back by the IIS in an HL7 v2 ACK message) would be subtracted. ONC wonders whether an immunization submitted to more than one IIS should count more than once. I don't see why not, if this is a measure of interoperability. They also ask whether resubmissions to correct errors should count (they think they should). I see no reason why successful resubmissions of rejected transactions should not count since they were removed when unsuccessful. The denominator is the total number of immunizations administered. Both the numerator and denominator would be provided in total, and then segmented by children and adults. ONC states that, "Reporting by these subgroups will assist in interpreting the data and in creating public awareness that could inform IISs and others in the public health community about the progress being made in immunization data exchange... The data collected for this proposed measure would enable ONC to calculate the percent of immunizations administered where the information was electronically submitted to an IIS."

Note that there are a number of important subtleties with respect to the proposed measures. Remember, an EHR may be just as likely to send a patient's immunization history as much as a patient's newly administered dose, or even both. In fact, an EHR can send the history over and over again. So in fact it is quite possible (or even likely) that the total number of doses submitted electronically exceeds the number of doses administered. It might be necessary to either ensure that the count of doses sent electronically only include those doses tagged as newly administered which is certainly possible but which complicates the data collection process. This concern could be mitigated by either making sure they are also included in the denominator or excluding them entirely. Note that historical doses may have questionable data quality and should have already been reported previously (even by a different provider).

Another issue is the potential that while only transmission of fatal errors are excluded from the count, the transmissions that had warnings of potential issues from the IIS (via HL7 v2 ACK messages) might in fact be resubmitted with some additional or corrected information. This has the potential to inflate the numerator in the calculation unless the vendor knows enough to exclude these resubmissions from the count. Keep in mind that any double counting of doses administered, especially in the numerator, makes all of the data suspect. To implement this right, an EHR must store the ACK(s) for each dose; and if the dose has at least one good ACK from an IIS, it can be counted in the numerator. Importantly, without a requirement to store the ACK, ONC would have no way to reliably audit a vendor's reported metric. If storing ACKs is a requirement (as it must be in order to ensure the integrity of the metric),

then ONC will also need to ensure that there is a standards-based way to store ACKs in FHIR resources.

To make matters worse, some providers delete a dose and then recreate it in order to edit a dose in their EHR. If a dose is deleted, logically it should be removed from the numerator and denominator going forward, but this could cause headaches for the data analysis at ONC if deleted doses have already been reported. Another potential problem is if two practices merge, or if a practice using two EHRs merges them into one, or if a practice simply migrates to a new EHR. ONC will need to provide guidance on exactly how doses should be counted in the metrics once they have migrated from one EHR to another.

The second measure is related to "Immunization History and Forecast," in other words, query of an IIS. The numerator would be the total number of query responses received. Queries that failed due to error (as reported back by the IIS in an HL7 v2 ACK message) would be subtracted. ONC asks whether both queries with and without a forecast should count. Given that it's the EHR that specifies what kind of data it wants in return, and there are use cases for both including and excluding an immunization forecast, I see no reason why both types of queries should not be included. There would be two denominators reported: first, the total number of queries; and second, the total number of encounters which might actually have a secondary use of measuring potential "missed opportunities" for immunization services. Both the numerator and denominators would be provided in total, and then segmented by children and adults. ONC states that "We propose to add this denominator to the measure proposed by the Urban Institute (the entity that developed the draft measures) to provide data on the total number of query responses that are and are not successfully received from an IIS." I'm not sure I really know what that means.

§ 170.523 - Principles of Proper Conduct for ONC-ACBs – Insights Condition	
(u) *Insights*. Confirm that developers of certified health IT submit responses for Insights Conditions and Maintenance of Certification requirements in accordance with § 170.407.	
Preamble FR Citation: 88 FR 23847	**Specific questions in preamble?** No
Regulatory Impact Analysis: N/A	
Public Comment Field: Enter comments on § 170.523 - Principles of proper conduct for ONC-ACBs – Insights Condition.	

Laboratory Data Interoperability Request for Information	
We seek public comment generally on any topics identified for the Consolidated Appropriations Act, 2023, Section 2213(b) study on the use of standards for electronic ordering and reporting of laboratory test results, such as the use of health IT standards by clinical laboratories, use of such standards by labs and their effect on the interoperability of laboratory data with public health systems, including any challenges of the types identified above. We also seek comment on whether ONC should adopt additional standards and laboratory-related certification criteria as part of the ONC Health IT Certification Program.	
Preamble FR Citation: 88 FR 23847	**Specific questions in preamble?** Yes
Public Comment Field: Enter comments on Laboratory Data Interoperability Request for Information.	

Request for Information on Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities	
We request comment from the public about specific issues related to establishing a certification criterion utilizing NCPDP RTPB standard version 12, as well as other potential actions in the Program that could support complementary and interoperable workflows. Given the statutory definition in PHSA § 3000(13) of "qualified electronic health record" as an electronic record of health-related information on an individual that includes, or is capable of including, RTBT functionality, we seek to understand whether ONC should offer or require certification of other capabilities to optimize the value of real-time prescription benefit capabilities to clinicians and patients.	
Preamble FR Citation: 88 FR 23848	**Specific questions in preamble?** Yes
Public Comment Field: Enter comments on Request for Information on Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities.	

FHIR Subscriptions Request for Information
We seek input on the maturity of the following resources that enable FHIR Subscriptions: Subscription, SubscriptionTopic and SubscriptionStatus in the FHIR Release 4 standard that is incorporated in 45 CFR 170.315(g)(10) of this proposed rule. Additionally, we seek comment on whether the FHIR Subscriptions capability aligns with the adoption of the FHIR Release 5 standard, and whether alignment with FHIR Release 5 would avoid any costly refactoring of the resources and give more time for industry to test the various features and capabilities under development. We request comment on whether there is a need to define a minimum set of Subscription Topics that can be consistently implemented by all health IT developers of certified health IT to provide a base level expectation of behavior for clients using the services; appropriate industry led activities to maintain and keep the artifacts up to date; and comment on security, channels, payloads, and any other areas that would need to be further specified to achieve our goal of providing this capability across all certified Health IT Modules in a consistent and standardized manner using an already adopted standard.
Preamble FR Citation: 88 FR 23855 **Specific questions in preamble?** Yes
Public Comment Field: Enter comments on FHIR Subscriptions Request for Information.

Clinical Decision Support Hooks Request for Information
Given the growing use of CDS and potential for CDS to improve clinical decision making, we request comment on the scope and maturity of the FHIR CDS Hooks specification v1.0, which we are considering for future inclusion as part of the Program. Recognizing that CDS Hooks does not prescribe a default or required set of hooks for implementers, we further request comment on specific hooks that we might include in future certification criteria (the CDS Hooks specification, for example, defines a small set of hooks), as well as input on use of CDS Hooks for supporting workflow improvement and reducing health care provider burden. To the extent commenters have specific CDS Hook use cases for supporting the latter, we welcome input on this including comment on the readiness and feasibility of such use cases including, as an example, for the screening and assessing of social risk and health related social needs or history.
Preamble FR Citation: 88 FR 23855 **Specific questions in preamble?** Yes
Public Comment Field: Enter comments on Clinical Decision Support Hooks Request for Information.

FHIR Standard for Scheduling Request for Information
We seek input on the maturity and scope of the SMART Scheduling Links Implementation Guide that is aligned with FHIR Release 4, to be considered for future certification as part of the Program. We request comment on the guidance specified in the SMART Scheduling Links Implementation Guide for publishers to advertise the API endpoints and whether there are other approaches that ONC could take to ensure that the APIs are easily discoverable by users of the API. We also invite comments on any other appropriate industry led activities that we should consider such as the Argonaut Scheduling Implementation Guide. Additionally, we welcome any other comments on how to ensure accuracy and timeliness of appointment information. Finally, we welcome comments on how to support the scalability of the standard for use in a variety of healthcare settings, in order to achieve our goal of providing this capability across all certified Health IT Modules in a consistent and standardized manner using an already adopted standard.
Preamble FR Citation: 88 FR 23856 **Specific questions in preamble?** Yes
Public Comment Field: Enter comments on FHIR Standard for Scheduling Request for Information.

SMART Health Links Request for Information	
We seek input on the value and feasibility of the SMART Health Links Protocol, as well as concerns regarding its implementation. Furthermore, we invite comment from the public on approaches ONC could take, within our authorities, to encourage rapid advancement of the technology. We also request information on any other promising industry-led innovative activities that we should consider that are aligned with the FHIR standard, and which would help us advance towards achieving our goal of improving interoperability using health information technology.	
Preamble FR Citation: 88 FR 23857	**Specific questions in preamble?** Yes
Public Comment Field: Enter comments on SMART Health Links Request for Information.	

Section IV – Information Blocking Enhancements

§ 171.102 Definitions - Offer Health Information or Offer Health IT

* * * * *

Offer health information technology or *offer health IT* means to hold out for sale, resale, license, or relicense; or to sell, resell, license, relicense, or otherwise provide or supply health information technology (as that term is defined in 42 U.S.C. 300jj(5)) that includes one or more Health IT Modules certified under the ONC Health IT Certification Program, for use by other individual(s) or entity(ies) under any arrangement other than the following:

(1) Donation and subsidized supply arrangements are not considered offerings when an individual or entity donates, gives, or otherwise makes available funding to subsidize or fully cover the costs of a health care provider's acquisition, augmentation, or upkeep of health IT, provided such individual or entity offers and makes such subsidy without condition(s) limiting the interoperability or use of the technology to access, exchange or use electronic health information for any lawful purpose.

(2) Implementation and use activities conducted by an individual or entity as follows:

(i) Issuing user accounts and/or login credentials for the individual's or organization's employees to use the individual's or organization's health IT to access, exchange, or use *electronic health information* (as defined in this section) in the course of their employment.

(ii) Implementing, operating, or otherwise making available production instances of application programming interface (API) technology (whether certified or not) that supports access, exchange, and *use of electronic health information* (as defined in this section) that the individual or entity has in its possession, custody, control, or ability to query or transmit from or across a *health information network* or *health information exchange* (as defined in this section).

(iii) Implementing, operating, and making available production instances of online portals for patients, clinicians, or other health care providers, or public health entities to access, exchange, and use *electronic health information* (as defined in this section) that the individual or entity has in its possession, custody, control, or ability to query or transmit from or across a *health information network* or *health information exchange* (as defined in this section).

(iv) Issuing login credentials or user accounts for the individual's or entity's production, development, or testing environments to public health authorities or such authorities' employees as a means of accomplishing or facilitating access, exchange, and *use of electronic health information* (as defined in this section) for public health purposes including but not limited to syndromic surveillance.

(v) Issuing login credentials or user accounts for independent healthcare professionals who furnish services in a healthcare facility to use the facility's electronic health record or other health IT system(s) in furnishing, documenting, and accurately billing for that care.

(3) Consulting and legal services arrangements as follows:

(i) Legal services furnished by outside counsel—when furnishing legal services to a client in any matter or matters pertaining to the client's seeking, assessing, selecting, or resolving disputes over contracts or other arrangements by which the client obtains use of certified health IT. Outside counsel also does not offer health IT if or when facilitating limited access or use of the client's health IT or EHI within it to independent expert witnesses engaged by counsel, opposing parties' counsel and experts, and special

§ 171.102 Definitions - Offer Health Information or Offer Health IT

masters and court personnel, as necessary or appropriate to legal discovery.

(ii) Health IT consultant assistance selection, implementation and use consultant —provided by an individual or firm when furnishing expert advice and consulting services to a health IT customer or user that help the customer or user, or on the customer's behalf, do any or all of the following with respect to any health IT product that the consultant does not sell or resell, license or relicense, or otherwise supply to the customer under any arrangement on a commercial basis or otherwise:

(A) define the customer or user business needs; evaluate or select health IT product(s);

(B) negotiate for the purchase, lease, license, or other arrangement under which the health IT product(s) will be used; or

(C) oversee configuration, implementation, or operation of health IT product(s).

(iii) Comprehensive and predominantly non-health IT clinician practice or other health care provider administrative or operations management services—provided by an individual or entity when furnishing a clinician practice or other health care provider administrative or operational management consultant services where the management consultant acts as the agent of the provider or otherwise stands in the shoes of the provider in dealings with the health IT developer or commercial vendor, and/or in managing the day-to-day operations and administrative duties for the health IT, as part of a comprehensive array of predominantly non-health IT administrative and operational functions that would otherwise fall on the clinician practice or other health care provider's partners, owner(s), or staff.

* * * * *

Provide is defined as it is in § 170.102.

* * * * *

Preamble FR Citation: 88 FR 23857 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23903 for estimates related to this proposal.

Public Comment Field: Enter comments on § 171.102 Definitions - Offer Health Information or Offer Health IT.

§ 171.102 Definitions - Health IT Developer of Certified Health IT: Self-developer Healthcare Providers

* * * * *

Business associate is defined as it is in 45 CFR 160.103.

* * * * *

Health IT developer of certified health IT means an individual or entity, other than a health care provider that self-develops health IT not offered to others, that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj-11(c)(5) (ONC Health IT Certification Program).

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Preamble FR Citation: 88 FR 238654 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23903 for estimates related to this proposal.

Public Comment Field: Enter comments on § 171.102 Definitions - Health IT Developer of Certified Health IT: Self-developer Healthcare Providers.

§ 171.103 - Information Blocking Definition

(a) Information blocking means a practice that except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information; and

(b) If conducted by:

(1) A health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information; or

(2) A health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

Preamble FR Citation: 88 FR 23864 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23903 for estimates related to this proposal.

Public Comment Field: Enter comments on § 171.103 - Information Blocking Definition.

§ 171.204 – Infeasibility Exception

§ 171.204 Infeasibility exception - When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking?

* * * * *

(a) *** (1) *Uncontrollable events*. The actor cannot fulfill the request for access, exchange, or use of electronic health information because of a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.

* * * * *

(3) *Third party seeking modification use*. The request is to enable use of EHI in order to modify EHI (including but not limited to creation and deletion functionality) provided the request is not from a health care provider requesting such use from an actor that is its business associate.

(4) *Manner exception exhausted*. The actor is unable to fulfill a request for access, exchange, or use of electronic health information because paragraphs (i), (ii), and (iii) are all true.

(i) The actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested;

(ii) The actor offered all alternative manners in accordance with § 171.301(b) for the electronic health information requested but could not reach agreement with the requestor; and

(iii) The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.

(5) *Infeasible under the circumstances.* (i) The actor demonstrates, prior to responding to the request pursuant to paragraph (b) of this section, through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of the following factors that led to its determination that complying with the request would be infeasible under the circumstances:

(A) The type of electronic health information and the purposes for which it may be needed;

(B) The cost to the actor of complying with the request in the manner requested;

(C) The financial and technical resources available to the actor;

(D) Whether the actor's practice is non-discriminatory and the actor provides the same access, exchange, or use of electronic health information to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship;

(E) Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged; and

(F) Why the actor was unable to provide access, exchange, or use of electronic health information consistent with the exception in § 171.301.

(ii) In determining whether the circumstances were infeasible under paragraph (a)(3)(i) of this section, it shall not be considered whether the manner requested would have:

(A) Facilitated competition with the actor.

(B) Prevented the actor from charging a fee or resulted in a reduced fee.

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§ 171.204 – Infeasibility Exception

Preamble FR Citation: 88 FR 23865 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23903 for estimates related to this proposal.

Public Comment Field: Enter comments on § 171.204 – Infeasibility Exception.

§ 171.301 - Manner Exception – TEFCA Reasonable and Necessary Activities

§ 171.301 Manner exception - When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

§ 171.301 Manner exception - When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

An actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information will not be considered information blocking when the practice follows the conditions of this section.

(a) *Manner requested*. (1) An actor must fulfill a request for electronic health information in any manner requested, unless the actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested.

(2) If an actor fulfills a request for electronic health information in any manner requested:

(i) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

(ii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

(b) *Alternative manner*. If an actor does not fulfill a request for electronic health information in any manner requested because it is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested, the actor must fulfill the request in an alternative manner, as follows:

(1) The actor must fulfill the request without unnecessary delay in the following order of priority, starting with paragraph (b)(1)(i) of this section and only proceeding to the next consecutive paragraph if the actor is technically unable to fulfill the request in the manner identified in a paragraph.

(i) Using technology certified to standard(s) adopted in part 170 that is specified by the requestor.

(ii) Using content and transport standards specified by the requestor and published by:

(A) The Federal Government; or

(B) A standards developing organization accredited by the American National Standards Institute.

(iii) Using an alternative machine-readable format, including the means to interpret the electronic health information, agreed upon with the requestor.

(2) Any fees charged by the actor in relation to fulfilling the request are required to satisfy the exception in § 171.302.

§ 171.301 - Manner Exception – TEFCA Reasonable and Necessary Activities

(3) Any license of interoperability elements granted by the actor in relation to fulfilling the request is required to satisfy the exception in § 171.303.

(c) *TEFCA manner*. If an actor who is a QHIN, Participant, or Subparticipant offers to fulfill a request for EHI access, exchange, or use for any purpose permitted under the Common Agreement and Framework Agreement(s) from any other QHIN, Participant, or Subparticipant using Connectivity Services, QHIN Services, or the specified technical services in the applicable Framework Agreement available to both parties, then:

(i) The actor is not required to offer the EHI in any alternative manner;

(ii) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

(iii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

(d) *Definitions*. The terms used in paragraph (c) of this section shall have the following meanings.

(1)(i) *Qualified Health Information Network (QHIN)* means a Health Information Network that is a U.S. Entity that has been Designated by the Recognized Coordinating Entity (RCE) and is a party to the Common Agreement countersigned by the RCE.

(ii) *Participant* means a U.S. Entity regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive information via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes.

(iii) *Subparticipant* mans a U.S. Entity regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either:

(A) a Participant-Subparticipant Agreement to use the services of a Participant to send and/or receive information; or

(B) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used of the Common Agreement to send and/or receive information.

(iv) *Connectivity Services* means the technical services provided by a QHIN.

(v) *Framework Agreement(s)* means any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.

(2) QHIN Services means any technical services provided within a QHIN.

Preamble FR Citation: 88 FR 23871 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23903 for estimates related to this proposal.

Public Comment Field: Enter comments on § 171.301 - Manner Exception – TEFCA Reasonable and Necessary Activities.

Additional Exclusions from Offer Health IT – Request for Information

We seek comment on whether we should consider proposing in future rulemaking any additional exclusions from the offer health information technology or offer health IT definition proposed in § 171.102 of this proposal.

We seek comment in particular on health IT developers and users' experience with activities or arrangements that they believe are beneficial to patients and/or health care providers and that they can demonstrate may be occurring less often specifically due to prospective participants' concerns about potential information blocking liability.

We further welcome observations, evidence, or feedback specific to how potential additional exclusions could be structured or balanced by other measures to mitigate risks of unintended consequences of such exclusions—not limited to, but specifically including potentially insulating individuals or entities with shoddy practices or nefarious intent from accountability for subjecting their customers, clients, patients, or exchange partners to information blocking conduct.

We also welcome comments on other steps that the public would recommend ONC consider taking to further encourage lawful donation or other subsidized provision of certified health IT to health care providers who may otherwise struggle to afford modern, interoperable health IT.

Preamble FR Citation: 88 FR 23873 **Specific questions in preamble?** Yes

Public Comment Field: Enter comments on Additional Exclusions from Offer Health IT – Request for Information.

Possible Additional TEFCA Reasonable and Necessary Activities – Request for Information

We seek comment on whether any other particular practices that are not otherwise required by law but are required of an individual person or entity by virtue of their status as a QHIN, Participant, or Subparticipant pursuant to the Common Agreement pose a substantial concern or uncertainty regarding whether such practices could constitute information blocking as defined in 45 CFR 171.103.

We seek comment on what, if any, particular practices required of QHINs, Participants, or Subparticipants may pose such concerns or uncertainty, and the specific source of the requirement, obligation, or commitment to engage in the practice—such as the Common Agreement, flow-down requirements in Framework Agreements, the QHIN Technical Framework, or Standard Operating Procedures published by the ONC Recognized Coordinating Entity (RCE).

We also request identification of which practices commenters believe are not covered by existing information blocking exceptions and that commenters would advocate we assess for potential identification as reasonable and necessary activities that do not constitute information blocking as defined in 45 CFR 171.103.

Recognizing that not all individuals or entities who may have a right or be allowed under applicable law to access, exchange, or use EHI may be in a position to become a QHIN, Participant, or Subparticipant, we also seek comment on whether and how any such identification of additional reasonable and necessary activities might pose concerns about unintended consequences for EHI access, exchange, or use by individuals or entities who are not QHINs, Participants, or Subparticipants.

Possible Additional TEFCA Reasonable and Necessary Activities – Request for Information	
Preamble FR Citation: 88 FR 23873	**Specific questions in preamble?** Yes
Public Comment Field: Enter comments on Possible Additional TEFCA Reasonable and Necessary Activities – Request for Information.	

Health IT Capabilities for Data Segmentation and User/Patient Access – Request for Information	
We seek comment related to the capabilities of health IT products to segment data and support health care providers (and actors) in sharing information consistent with patient preferences and all laws applicable to the creation, use, and sharing of EHI. We seek comment on experiences with the availability and utility of certified health IT products' capabilities to segment data in use cases including but not limited to the illustrative examples above. We seek comment on how greater consistency in provider documentation practices could enhance the feasibility of technical segmentation solutions. We seek comment on barriers to technical feasibility presented by local, state, and federal regulations. We also seek comment on how the Program could better support the data segmentation use cases described in this section either through functional or standards-based certification requirements.	
Preamble FR Citation: 88 FR 23874	**Specific questions in preamble?** Yes
Public Comment Field: Enter comments on Health IT Capabilities for Data Segmentation and User/Patient Access – Request for Information.	

Section V – Incorporation by Reference (IBR)

Incorporation by Reference
Preamble FR Citation: 88 FR 23875
Public Comment Field: Enter comments on Incorporation by Reference.

Section VII – Collection of Information Requirements (PRA)

Collection of Information Requirements
Preamble FR Citation: 88 FR 23878
Public Comment Field: Enter comments on Collection of Information Requirements.

Section VIII – Regulatory Impact Statement

Regulatory Impact Statement
Preamble FR Citation: 88 FR 23880
Public Comment Field: Enter comments on Regulatory Impact Statement.