June 20th, 2023

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Dr. Tripathi,

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

Submitted electronically via www.regulations.gov

Dear Dr. Tripathi,

athenahealth, Inc. ("athenahealth" or "athena") appreciates the opportunity to respond to the proposed changes outlined in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule.

Over the past 26 years, athenahealth has built a network of approximately 385,000 healthcare providers in both the ambulatory and acute settings in all 50 states. We provide electronic health record (EHR), practice management, care coordination, patient engagement, data analytics, revenue cycle management, and related services to physician practices and hospitals. More than 140,000 providers utilize our single instance, continuously updated, cloud-based platform. We also support on-premise software solutions. In both hosting paradigms, athenahealth seeks out and establishes connections with partners across the care continuum, enabling our clinicians to improve the quality of care they deliver.

athenahealth's vision is to create a thriving healthcare ecosystem that delivers accessible, high quality, and sustainable healthcare for all. We work towards this vision partially by reducing burdensome administrative tasks for providers so that they can focus on improving patient outcomes. We applaud ONC's continued focus on the advancement of Certified Electronic Health Record Technology (CEHRT) utilization and improving interoperability. athenahealth is committed to a healthcare ecosystem where information exchange is the norm, not the exception. As we look forward, we must recognize that healthcare is undeniably better connected today than it was yesterday, and certainly than it was ten years ago. Ongoing policy and regulation should build on this progress through a balanced approach that ensures every stakeholder meets minimum standards while allowing those at the forefront of greater connectivity and interoperability to continue to push the envelope through innovative tools and functionality. Interoperability is part of the athenahealth DNA, and we believe that if implemented appropriately, this rule can achieve that balance.

We commend ONC for their commitment to improve interoperability through more modern standards and newer versions of existing standards. Raising the baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3 will contribute to the health IT industry identifying and mitigating healthcare inequities. The addition of patient demographic fields will improve healthcare quality, enhance communication, and bolster cultural competency. Second, we applaud the logical updates to certification criteria by discontinuing editions, rather than establishing a new edition of certification. Iterative changes allow the industry to adapt to new

market forces and maintain stability. Sweeping overhauls have a cooling effect on organic innovation and growth. ONC should continue to seek to maximize the impact of these certification changes and pursue all opportunities to simplify existing criteria.

While we praise ONC's desire to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information, there are several modifications that must be adopted in the final rule to ensure it effectively accomplishes these goals.

1. **ONC Must Allow Reasonable Time to Adopt Updates**

athenahealth shares ONC's vision of advancing interoperability, improving transparency, and supporting the access, exchange, and use of electronic health information. However, the complexity of modifications, upgrades, and new requirements present challenges for health IT developers to implement on the current timeline. For the rule to be successful, the entire industry must properly build and implement the updates. A too hasty timeline may jeopardize stability and quality for some participants. As proposed, HTI-1 does not allow sufficient time for health IT developers to fully scope, build, test and deploy high quality versions of certified products, or for providers to implement upgraded software. Rushed timelines create the potential for significant burden and compliance challenges. We encourage ONC to extend the adoption deadline to ensure the objectives are implemented properly across the industry. Our specific timeline proposals are noted in the comments below.

2. **ONC Must Narrow the Scope of Predictive Decision Support Intervention (DSI)**

athenahealth supports ONC's role in advancing transparent and trustworthy predictive technology in healthcare. We are concerned that the definition of predictive DSI intended for regulation is broader than the risks the ONC is trying to protect against. As proposed, the language inadvertently pulls in functionality not currently subject to certification such as simple calculators (e.g. BMI, growth charts, screeners) and any basic workflow intelligence (e.g. task prioritization). We strongly encourage a more limited definition of predictive DSI, recognizing that certain types of interventions are not conducive to ONC regulation, source attribute sharing or feedback gathering. Further challenges with DSI are noted in the respective section(s) below.

In addition to these suggestions, we provide the following specific comments:

Section III – ONC Health IT Certification Program Updates

"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: athenahealth is supportive of this proposal.

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

* * * * *

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: athenahealth agrees with ONC that discontinuing the concept of editions for certification is a logical move. However, we seek clarification on the new criteria/standards adoption and the ability of health IT developers to respond in a way that is not disruptive to business and provider practices. If this proposal is finalized, we ask ONC to provide clarification on the following items will be managed:

1) Tracking a continuous stream of deadlines and obligations for both developers and providers in terms of developing and implementing new technologies, which was somewhat simplified with neatly aligned "editions" under the current program structure.

2) In terms of the potential frequency with which the ONC may adopt new criteria, understanding the product release and development cycle is important to mitigating the burden on both developers and providers. Requiring clients to upgrade their certified product is a resource intensive task for these sites that would be further complicated under an "edition-less" program structure.

3) In the standards development industry, the desire is to align development and standards cycles. While we agree that consistent updates are important, that must be balanced with continuous standards updates as they become available. This proposal may add to an already substantial burden, introduce inconsistencies into the process, and divert resources away from what providers are requesting be developed within health IT.

§ 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

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

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).

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: athenahealth agrees with and supports the transition to USCDI v3. The addition of patient demographic fields can improve healthcare quality, enhance communication**,** and bolster cultural competency. We encourage the government to set a floor as to what should be included, while leaving room for the industry to further innovate.

While we applaud this effort, the timeframe for development and implementation between the final rule and USCDI v1 expiration is too short and requires alignment with CMS timelines. As such, we recommend adjusting the proposed timeline to the end of the second calendar year following the final rule, which we estimate to be December 31, 2025. This would also align with ONC's proposal under the new "Assurances" Maintenance of Certification requirements where "we propose, in § 170.402(b)(3)(iii)(A), that a health IT developer must update

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

and provide a Health IT Module 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 certification criterion or criteria".

§ 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 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).

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

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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: athenahealth is supportive of the proposed Implementation Guides, with the caveat that because of the newness, challenges may be encountered, and adjustments required as the industry begins implementation.

§ 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)* * *

§ 170.207 - "Minimum Standards" Code Sets Updates

(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).

§ 170.207 - "Minimum Standards" Code Sets Updates

(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)).

§ 170.207 - "Minimum Standards" Code Sets Updates

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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).

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: athenahealth supports the adoption of USCDI v3 data elements, however, we are concerned about the short timeframe for development and implementation required in the proposed rule. We recommend a timeline that is the end of the second calendar year following the final rule, which we estimate to be December 31, 2025. This would also align with ONC's general approach to timeframes.

§ 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:

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

(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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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: athenahealth appreciates the benefits of electronic case reporting in modernizing and accelerating electronic data reporting capabilities across the United States. We also recognize the need to refine the requirements in line with movement of the standards and the industry. However, because electronic case reporting has not yet substantially replaced manual reporting and business practices for public health, we believe the proposed requirements are too broad and urge a more tempered approach to permit the space to continue maturing as integrations increase. More specifically:

The proposed standards in paragraph (t) added to 170.205 for creating case reports are not possible with current capabilities of eCR Now because:

- (t)(1) requires eICR FHIR profile
- (t)(2) requires eICR 3.1 which is not yet supported by eCR Now
- Neither of these options allows support for eICR 1.1 which is currently the only eICR standard supported by eCRNow.

APHL Informatics Messaging Services (AIMS) and eCR Now officially support the 1.1 version of the eCR CDA and the eCR Now FHIR App. Regulating the 3.1 version of the eCR CDA or use of the FHIR bundle introduces a disconnect between certification and real-world use. It is also our understanding that many public health agencies are not ready to receive eICR 3.1.

Furthermore, athenahealth disagrees with the requirement for support of the eRSD FHIR specification, which is mainly in use today by the eCR Now FHIR App. The underlying standard is not robust enough or well implemented enough for broad use. Emerging FHIR capabilities for eCR are immature, evolving, and not a sufficient standard for widespread use.

§ 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:

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

(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;

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

(*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: athenahealth supports ONC's role in advancing transparent and trustworthy predictive technology in healthcare. While we applaud ONCs policy and compliance goals embedded throughout this section of the rule, there are several areas that we encourage ONC to revisit, reevaluate, and revise prior to the rule being finalized, including:

1) Scope
2) "Health IT Module Enables or Interfaces With"
3) Transparency and Source Attributes
4) User Feedback

Scope: We are concerned that the definition of predictive DSI intended for regulation is broader than the risks the ONC is trying to protect against. One point of conflict and complexity is that as proposed, DSI is extensively focused on Artificial Intelligence (AI) and Machine Learning (ML) models, but it does not make a clean separation of considerations between those and other flavors of DSI, such as simple algorithmic calculators (e.g., BMI calculators or HbA1C thresholds), which can be manually coded and verified through traditional engineering practice. While it's important that the latter are also fair, appropriate, valid, effective, and safe, they do not have the same "black box" nature that modern ML systems do. athenahealth believes that these two categories can and should be separated. We are supportive directionally of what the ONC is working towards, with the caveat that other assurances will be more appropriate for more "traditional" software systems that fill DSI roles (e.g. (g)(4) criterion which already has a robust QA process for certified features). Failure to narrow the scope of DSI will lead to a cascade of unintended consequences for health IT developers, providers, and the patients they serve. We encourage ONC to take an iterative and sustainable approach when expanding such definitions, in a way that does not bankrupt a health IT developers' ability to innovate while also complying with testing requirements. We also encourage ONC to defer regulation of technologies like artificial intelligence to the FDA and ensure that any certification criteria does not subject EHR developers to unnecessary regulation as medical device manufacturers.

"Health IT Module enables or interfaces with": athenahealth encourages the removal of "enables or interfaces with" from the proposed rule. As written, health IT developers would need to meet the transparency requirements for all third-party apps that customers utilize via (g)(10) technology. Many of these relationships are between the client and the application. There are many client- and/or third-party-created DSI for which the health IT developer will not have source attribute information. There is nothing in the proposed rule that would motivate a third party to renegotiate contracts to require the provision of source attributes. We are supportive of the ONC narrowing the applicability of the definition, and given its newness, setting requirements for a limited number of applications to test the process.

Transparency and Source Attributes: We applaud ONC's goal of enhancing trustworthiness through

transparency on how health IT developers manage potential risks and address fundamental information asymmetries in the marketplace. While greater transparency is the goal, it must be balanced with the appropriate audience and level of detail. The end-users of the DSIs should have confidence in the integrity of the tools they are using. ONC must ensure that the information required by these proposals related to source attributes does not include confidential information such as intellectual property. Many of the technologies used for decision support are proprietary, and ONC should avoid the potential that this proposal is interpreted as mandating the sharing of intellectual property.

athenahealth agrees that transparency in source attribution is important. As proposed, ONC is indicating that patients should be aware of DSI within EHRs that their providers utilize through a public facing link. Much of this information is not tangible or understandable for patients and is more likely to cause confusion and potential mistrust. Transparency does not need to be through a public facing link, but rather embedded within the product for its intended users. Certain interventions should not require source attributes which will clutter the user experience, and add to product, provider, and user burden. We also encourage ONC to develop standards and hook specifications to standardize how source attributes should be displayed. Furthermore, users should have the ability to view source attributes within the product, however, it is unreasonable to allow users to modify attributes.

User feedback: athenahealth agrees that user feedback can be a useful tool to support quality improvement within health IT. However, as proposed, we are concerned with the feedback loop requirement. Requiring an optional free text field could lead to unintentional privacy issues. If a clinician were to add PHI to their feedback, that information then becomes publicly available and exportable. There is no way for a health IT developer to control what information users submit and export. We also note that requiring a UI for user feedback will likely degrade usability.

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§ 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: athenahealth does not agree with ONCs proposal to require (a)(9) to be included in Real World Testing (RWT). DSI should only be required in RWT when a health IT developer certifies to (b)(11). The level of burden required to satisfy this requirement would not provide suitable value to rationalize the request.

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.

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

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

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

Public Comment Field: athenahealth is supportive of this proposal and appreciates the added level of flexibility.

§ 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.

§ 170.215 – Application Programming Interface Standards

(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 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: athenahealth is supportive of ongoing specification creation and consistent timelines of USCDI and US Core. However, we recommend a two-year window following publication of the final rule to ensure sufficient time for developers to do the work necessary to support the latest specifications, which we estimate to be December 31, 2025.

1) US Core v6.0.0: Due to the large number of internal and external API users, as well as the development needed for US Core v6.0.0 updates, athenahealth considers the current deadline challenging to complete development, test changes with users, and rollout US Core v6.0.0 by Jan 1, 2025. With such large-scale API update across all in-use FHIR R4 endpoints, our users expect sufficient time for adoption readiness, including code remediation to consume the new US Core version, which in turn affects their applications, business and customers. We consider the transition period to be a critical component in ensuring great user experience and overall satisfaction with our API solutions. Thus, we strongly advocate extending the expiration deadline to accommodate for operational steps to roll out US Core v6.0.0.

2) FHIR Endpoint for Service Base URLs: athenahealth recommends the finalization of the "Patient-access Brands" conceptual model along with a modification to include support for "ndjson" in lieu of or in addition to FHIR Bundles. Using a FHIR Bundle to contain thousands of Organizations would make parsing a challenge. We support the specification of the finalized "Patient-access Brands" conceptual model as a published

§ 170.215 – Application Programming Interface Standards

implementation guide to be included in a future HTI rule.

3) SMART App Launch 2.0: athenahealth recommends an extension of the expiration deadline to allow sufficient development time to fulfill compliance with SMART v2. We seek clarification from the ONC on whether a health IT developer may support SMART v1 and SMART v2 simultaneously after the expiration date. V1 scopes are used in 2015 Edition tests in Inferno, and discontinuing support of V1 will cause health IT developers to fail these tests. It is also advisable that health IT developers support both versions for the foreseeable future to allow customers to adopt v2 as they are ready.

4) Gradual Scope Constraints: athenahealth agrees with the current requirement to support the SMART v2 optional capability "3.0.2.3 Finer-grained resource constraints using search parameters" for a prescribed set of search parameters with limited cardinality and corresponding to an enumerable set of scopes. However, we caution against future expansion to search parameter-based scopes that introduce arbitrary values like dates (e.g., Observation.rs?patient.birthdate=1990) as this would allow infinite scope permutations that would need to be created and enforced at runtime and creates more complex access requests to the detriment of patient experience.

5) Authorize-post: athenahealth does not agree with the SMART v2 requirement that authorization servers support use of the HTTP POST method for the /authorize endpoint, noting that it exists only to accommodate very large authorize requests, and has generally been replaced with pushed authorization requests. Pushed authorization requests are (a) more secure and (b) industry best practice compared to POST /authorize. We ask that the ONC either remove the POST /authorize requirement or allow optionality for push authorization requests (POST /par) to reflect best practice. Post/Par source: https://datatracker.ietf.org/doc/html/rfc9126.

6) New Feature: CRUDS scope syntax: athenahealth seeks clarification on whether a health IT developer must support the scopes which map to the permission-v1 framework which are already implemented. If a health IT developer currently support Resource.read, which would be equivalent to Resource.rs in V2 syntax, do they also need to support Resource.r and Resource.s scopes?

7) athenahealth is aligned with the concept of online access, however, we propose to eliminate the requirement to support the SMART v2 "permission-online" capability. At this time, it is not sufficiently defined (for example, when is a user considered "online" and how is this verified with the authorization server?) and lacks standard implementation guidance in either the SMART v2 guide or in industry. If SMART v2 "permission-online" capability is adopted, we seek clarification and welcome continued industry collaboration on how ONC will check capability during certification testing, given the lack of definition.

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

Included in Base EHR Definition? Yes

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

(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: athenahealth firmly believes that patient demographics are an essential part of a medical record. We are supportive of the proposal; however, we encourage ONC to follow the established process when introducing USCDI data elements and classes. This standardized approach will lead to greater consistency and compliance across the industry.

§ 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: athenahealth supports this proposal, however, the timeframe for development and implementation is too short. As such, we recommend adjusting the proposed timeline to the end of the second calendar year following the final rule, which we estimate to be December 31, 2025.

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

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

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

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: Safeguarding patient privacy is critical to athenahealth's vision of a thriving ecosystem that delivers accessible, high-quality, and sustainable healthcare for all. The HIPAA Privacy Rule grants patient's broad flexibility in the restrictions they can request, some of which are use-case dependent. Giving patients the ability to request restriction is a net positive for the patient, however, we ask ONC to consider the following information.

It will not be feasible for developers to implement support for every permutation of restrictions on the use of data that a patient might request, especially because it is often impossible to programmatically map the purpose for which data will be used in the system to a patient-defined purpose for which the restriction applies.

Restricting the use of data by other clinicians in the same organization can also have significant safety risks, since those clinicians may no longer have access to a complete patient record. It is also unclear whether critical safety tools such as decision support would be able to be triggered based on data for which the patient has requested restrictions, which could result in what otherwise would have been preventable medical errors.

athenahealth believes that the ONC should mandate certain standards for security labels as opposed to leaving it up to health IT developers. We encourage the ONC to utilize defined use cases that are high level. For example, the ability to withhold data form payers, family members, non-BH providers, etc. are all groups that a health IT developer can reasonably support.

We also urge ONC to narrow the set of data that restrictions can be requested for, instead of all USCDI v3. For example, some demographics (specifically sexual orientation and gender identity info), problems, clinical notes, lab results, procedures, or social history. Finally, we urge ONC to focus on establishing, with the relevant SDOs (perhaps Argonaut as a cross-cutting accelerator) and SHIFT to address these topics that are implementable by individual organizations yet can grow and be shared through a common infrastructure that enables patients to only document their consent rules once, while having a common definition of all relevant privacy rules across US jurisdictions.

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)* * *

Real World Testing – Inherited Certified Status

(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: athenahealth is supportive of this proposal to account for the inheritance model within the certification program. We believe that it aligns well with existing sub-regulatory guidance on Real World Testing.

§ 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

§ 170.407 Insights Condition and Maintenance of Certification

(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;

§ 170.407 Insights Condition and Maintenance of Certification

(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.

§ 170.407 Insights Condition and Maintenance of Certification

(2) [Reserved]

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

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

Public Comment Field: athenahealth is a firm believer in transparency and holding vendors accountable to their interoperability. We support ONCs effort to measure interoperability capabilities and ensuring that they meet the intended success criteria. As proposed, we have several concerns that we would like to address:

1) Our first concern lies with developer burden, and whether the ONC can get answers to many of these questions elsewhere through peer agencies (e.g., CDC will have data on immunizations). Overlapping requirements coupled with unrealistic timelines further burdens health IT developers.

2) As a separate burden reduction effort, we ask ONC to specifically clarify that when there is overlap between the Insights and Real World Testing (RWT) Conditions of Certification (e.g., same certified HIT module and criteria subject) developers have the flexibility to re-use Insights Condition reporting measurements and outputs for their RWT plans and results, respectively. This is a significant burden reduction for developers with no clear downside for the needs of ONC and the purpose of the respective requirements.

3) We urge the ONC to restructure timing for annual reporting submission and delay the start of the first measurement period until at least CY 2025. Additionally, we ask that the annual reporting submission occur mid-year to avoid conflict with other significant deadlines and obligations occurring at the end of the year and April/Oct for Attestations submissions.

4) The proposed rule notes that "data on the volume of information exchanged would provide the means to assess the extent that patient information is moving between providers to facilitate high value care." athenahealth does not agree with this statement, as pure volume is not the sole indicator of quality, and there is limited means to determine duplicates.

5) We are concerned with the need to obtain data from customers. The ONC should provide embedded exceptions/flexibility for health IT developers who face challenges obtaining data due to customer resistance and/or contractual barriers (or other similar reasons). This could be structured as a requirement that developers make a good faith effort to invite all their customers to participate or to allow their data to be utilized and developers are not responsible for including data from any who resist. Establishing a minimum threshold of customers is not viable as it may vary widely across developers.

6) We urge the ONC not to underestimate the level of burden required by health IT developers to obtain the necessary data for each measure. athenahealth is concerned that the level of burden needed for data stratification does not provide suitable value to rationalize the request. For example, the immunization administration measure which requires stratification by IIS and age group presents unnecessary challenges, with little ROI. Extracting patient information from interface messages as they exist today for immunizations is resource intensive. The ONC should alleviate some of this burden by requiring only overall administration submission numbers. There are numerous opportunities to restructure the proposed "measures" into a single table format identifying the associated applicable criterion. This would avoid duplication of measurement

§ 170.407 Insights Condition and Maintenance of Certification

across different categories and would also be more honest to the fact that the multiple data sets and stratifications equate to far more than nine "measures."**.**

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: athenahealth believes that the current HL7 implementation specification (2.5) is mature enough to be utilized broadly. To achieve true interoperability, labs must adhere to standard HL7 specifications and follow standard terminologies for laboratory data exchange (e.g. LOINC and SNOMED). Standard terminologies are not consistently received by all labs at this time. The industry must focus on maximizing the utilization of existing standards by finding ways to enforce laboratory compliance

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: The FHIR Subscription resource was completely redesigned between R4 (v4.0.1) and R5 (v5.0.0). athenahealth's understanding is that R4B (v4.3.0) was originally envisioned as a non-breaking way for R5 Subscription features (including SubscriptionTopic and SubscriptionStatus) to slot in alongside existing R4

FHIR Subscriptions Request for Information

implementations. Unfortunately, the fact that this was released under a separate base url (/R4B) makes it impractical to leverage the new paradigm within a (g)(10)-compliant R4 implementation. Therefore, we believe more time is needed to test and mature these resources before adopting Subscriptions as part of any certification requirements.

We also believe it is too early to define a minimum set of required SubscriptionTopic resources at this time, but there may be value in an industry working group to begin sharing and coalescing a list of common topics across EHR implementations.

We believe the current error handling mechanisms defined for the rest-hook channel are too restrictive and not conducive to scalability of EHR systems that operate at national scale. We recommend that this channel adopt the content distribution and authentication mechanisms defined in the W3C-recommended WebSub standard: https://www.w3.org/TR/websub/#content-distribution.

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: athenahealth encourages the ONC to adopt the CDS Hooks FHIR Implementation Guide v2.0 as part of the requirements in the Program as the framework for accessing and retrieving CDS content from CDS services.

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: athenahealth believes that Argonaut scheduling improves upon the standard FHIR pattern of "search-for-schedules then search-for-slots-by-schedule-id" by reducing it to "search availability by properties of the schedule". We support the argonaut model for external scheduling APIs. This model is particularly helpful in cases where the location or provider is known, and the user is searching how to find availability. Outside of that scope, we believe that it is worth investigating the larger network-management/provider-discovery problem (e.g. when user's main ask is for the best provider regardless of how scheduling occurs). In this case, availability should be an input, but not the primary driver, when helping a patient search for a provider.

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: athenahealth supports the evolution of and the eventual use of the SMART Health Links Protocol. We would like to see this initiative mature into an Implementation Guide for future requirements and implementation.

Section IV – Information Blocking Enhancements

§ 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?

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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.

(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

§ 171.301 - Manner Exception – TEFCA Reasonable and Necessary Activities

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: athenahealth appreciates ONC's recognition of TEFCA and its potential for interoperability. As proposed, if ONC considers TEFCA to TEFCA exchange a reasonable manner for the exchange of information outside of the fee's exception, then limitations must be addressed within TEFCA.

We do not agree with ONC's proposal that actors providing data via TEFCA should not be required to provide data in any other manner. TEFCA participation alone is not enough to encourage interoperability. Data is often needed in other methods/formats than what is currently included in TEFCA. There must be optionality in the

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way that information is exchanged. Information hinderance is a newer form of information blocking where information may be made available, but no reasonable effort is provided to help identify the information in a sea of documents. The industry needs improved access to data, and should focus on record location, not just information blocking.

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.

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

Public Comment Field: As healthcare moves toward greater connectivity in response to regulatory requirements and user demand advances technology, stakeholders must decide if they will lean in and embrace this new set of practices and tools to improve data exchange. athenahealth believes that interoperability will move us towards a more connected healthcare ecosystem. It is with that context that we seek clarification on the following questions:

1) What guardrails, if any, does ONC intend to place on fees being charged for the exchange of data using "TEFCA means?" Will the ONC carve out TEFCA exchange from these requirements?

2) Does ONC intend to allow for actors using TEFCA to charge royalties that are not based on the independent value of the technology? Does the actor still need to "base fees on objective and verifiable criteria that are uniformly applied to all similarly situated classes of persons or entities " per Cures?

3) We also seek clarification on the following statement: "Even when the EHI may exceed the minimum data classes and elements required by the Common Agreement as of the date a particular request is fulfilled." Can

Possible Additional TEFCA Reasonable and Necessary Activities – Request for Information

this be interpreted as a partial fulfilment of an EHI request that exceeds the scope of CA requirements, using "TEFCA means" put that actor within the Manner Exception?

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: While there is a lot of focus on how to handle sensitive and/or confidential data when leaving a system, there is no mention of how to handle sensitive and/or confidential data when it is received. There is an industry need for the limitation in scope of applicable data, at least to start, to minimize provider documentation burden. Current HL7 tags do not offer enough flexibility to meet the needs of patients, providers, or health IT developers. Current data tagging capabilities do not allow for the degree of segmentation needed to balance interoperability expectations with patient privacy needs. And any processes established through future rulemaking must account for industry iteration and implementation.

We look forward to engaging with your office on this important proposed rule. Please do not hesitate to reach out directly by phone at 845-323-3454 or email jemichaels@athenahealth.com.

Regards,

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