Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Information, Resources & Quick Links – April 2023

The Office of the National Coordinator for Health IT (ONC) released a notice of proposed rulemaking (NPRM) on April 18 – Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing – referred to as "HTI-1" or the "HTI-1 proposed rule." You can find the proposed rule here. It implements provisions of the 21st Century Cures Act and makes updates to the ONC Health IT Certification Program (Certification Program) with new and updated standards, implementation specifications, and certification criteria. According to ONC, implementation of these provisions will advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information (EHI).

Key provisions of the proposed rule include:

- **Implementing the Electronic Health Record (EHR) Reporting Program as new Condition and Maintenance of Certification requirements (Insights Condition) for developers of certified health information technology (health IT) under the Certification Program;**
- Modifying and expanding exceptions in the information blocking regulations to support information sharing and certainty for regulated actors;
- Revising several Certification Program certification criteria, including existing criteria for clinical decision support (CDS), patient demographics and observations, electronic case reporting, and application programming interfaces (APIs) for patient and population services;
- Raising the baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3; and
- Updating standards adopted under the Certification Program to advance interoperability, support enhanced health IT functionality, and reduce burden and costs.

Additionally, in collaboration with federal partners – including the Food & Drug Administration (FDA) – ONC is proposing new policies that, if finalized, would, "promote greater trust in the predictive decision support interventions (DSIs) used in healthcare." They would help enable users to determine whether the predictive DSI is fair, appropriate, valid, effective, and safe, and enable market competition and align with the FDA's recent guidance on clinical decision support (CDS).

Standards and Certification Criteria & Certification Program Proposals

ONC is proposing several revisions to certification criteria and standards previously adopted.[1] The proposals across this section would: 1) improve interoperability through more modern standards and newer versions of existing standards; 2) assist partner agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Prevention and Control (CDC) in fulfilling their missions through certified health IT; 3) improve care delivery for clinicians and care experience for individuals by improving access to more interoperable data – consistently and reliably – for patient care and individual access; and 4) require transparency on how a predictive algorithm used for clinical decision-making is designed, developed, trained, evaluated, and should be used.

[1] 45 CFR Part 170

ONC Health IT Certification Program Updates

ONC has authority[2] to establish a certification program or programs for the voluntary certification of health IT – and first introduced the concept of an "edition" of ONC health IT certification criteria in 2012. ONC no longer believes that it is helpful or necessary to maintain an "edition" naming convention or to adopt entirely new editions of certification criteria to encapsulate updates over time. Rather, ONC is proposing that there should be a single set of certification criteria, which will be updated in an incremental fashion in closer alignment to standards development cycles and regular health IT development timelines. This proposal would rename all criteria within the Program simply as "ONC Certification Criteria for Health IT." By maintaining a single set of certification criteria, ONC believes that it would create more stability for the Program and for federal partners who reference the Program, as well as make it easier for developers of certified health IT to maintain their product certifications over time. The proposal to remove "editions" from the Program would help users of certified health IT identify which certification criteria are necessary for their participation in other Department of Health and Human Services (HHS) programs – including the Medicare Promoting Interoperability (PI) Program and the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS).

USCDI v3 Updates

ONC is proposing to adopt the USCDI Version 3 (v3) as a new baseline, which would coexist with existing requirements for USCDI Version 1 (v1) until it expires on Jan. 1, 2025 (i.e., USCDI v3 would be the new data set baseline across applicable certification criteria, replacing v1 by Jan. 1, 2025). ONC is also proposing to adopt the Consolidated Clinical Document Architecture (C-CDA) Companion Guide Release 3[3] and Fast Health Interoperability Resources (FHIR) US Core IG 5.0.1,[4] which would coexist with existing standards until Jan. 1, 2025.

Decision Support Interventions and Predictive Models

ONC is proposing to make significant proposals that would: 1) establish a definition for algorithm-based, "predictive" Decision Support Interventions (DSIs); 2) require certified Health IT Modules certified to the criterion that enable or interface with predictive DSIs to enable users to review information about additional source attributes relevant to health equity, among other purposes; 3) require developers of certified Health IT Modules certified to the criterion to employ or engage in intervention risk management practices for all predictive DSIs that the developers' certified Health IT Modules enable or interface; and 4) make summary information regarding these practices available publicly.

ONC is proposing to revise the existing clinical decision support (CDS) certification criterion by proposing a new "Decision Support Interventions" (DSIs) certification criterion to keep pace with advances in software that developers of certified health IT enable or interface with to aid decision-making in healthcare. In other words, the current criterion for CDS would be renamed as the "Decision Support Interventions" certification criterion and includes several new requirements for Health IT Modules that enable or interface with technology intended to support decision-making based on predictive algorithms or models.

Given the proposed changes to this criterion, ONC is proposing to revise the name of the CDS criterion to "decision support interventions" (DSIs) to reflect the various and expanding forms of decision support that certified Health IT Modules enable or interface with. Increasingly, DSIs include use cases or are intended to support decision-making across all areas of healthcare, including early detection of disease, automating billing procedures, facilitating scheduling, supporting public health disease surveillance, and other uses beyond traditional CDS. ONC intends for the DSI criterion to be inclusive of the wide variety of use cases that Health IT Modules may support moving forward.

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[2] Section 3001(c)(5) of the PHSA

[3] It is ONC's 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 ONC's intention to adopt the updated Companion Guide R4 that provides guidance and clarifications for specifying data in USCDI v3.

[4] Based on the annual US Core release cycle, ONC believes US Core IG v6.0.0 will be published before ONC issues a final rule. Therefore, it is the National Coordinator's intention to adopt the updated US Core IG v6.0.0 that provides guidance for specifying data in USCDI v3.

The DSI criterion is a revised certification criterion as it serves as both an iterative and replacement criterion for the CDS criterion. It would reflect an array of contemporary functionalities, data elements, and software applications, including the use of predictive models or algorithms, that certified Health IT Module(s) enable or interface with to aid decision-making in healthcare. As part of the DSI criterion, ONC is proposing to add **"predictive decision support interventions" (predictive DSIs)** – and the corresponding proposed definition would include predictive DSIs and the list of current intervention types, including evidence-based decision support in and **linked referential DSI**. ONC believes together, these intervention types are reflective of the variety of DSIs increasingly enabled by or interfaced with certified Health IT Modules. ONC is proposing a definition of "predictive decision support intervention" to mean "technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis." This proposed definition is not dependent on who developed the algorithm or model (i.e., can be someone other than a health IT developer).

ONC's use of the term "predictive DSI" is not tied to a specific use case, such as those that fall under treatment (clinical or medical purpose), payment (financial) or health care operations (administrative), nor those that support clinical research or public health. The proposed definition would **not** include the computer readable implementation of clinical guidelines or similar types of knowledge except when those guidelines – and interventions implemented based on them – incorporate a predicted value, such as a predicted risk, in guiding clinical decision-making. The proposal notes that the term "intervention" in predictive DSI is not intended to mean an intervention (medicine, medical procedure, or medical treatment) as the term is used in the practice of medicine, but rather, an intervention occurring within a workstream. Instead, it encompasses the broad forms that DSIs can take, including but not limited to alerts, order sets, flowsheets, dashboards, patient lists, documentation forms, relevant data presentations, protocol or pathway support, reference information or guidance, and reminder messages. The definition would not be limited based on the specific nature of the data to be processed; for instance, models that analyze text or images are included.

ONC states that the phrase "intended to support decision-making" is intended to be interpreted broadly and to encompass technologies that require users' interpretation and action as well as those that initiate management and require action to contest. The proposed use of predictive DSI is not tied to the level of risk or degree to which the predictive DSI informs or drives treatment, is relied upon by the user, relates to time sensitive action, or whether it is augmentative or autonomous. ONC's proposed definition of predictive DSIs would also include more complex models leveraging machine learning (ML) – and would include predictive DSIs that use adaptive, online or unlocked models. In other words, it would include models that continue to adapt when exposed to new data, as well as those that are locked to the relationships learned in training data. It would also include predictive DSIs that use natural language processing (NLP) and large language models (LLMs) – sometimes referred to as generative Artificial Intelligence (AI) – such as GPT-3 and LaMDA that power chatbots ChatGPT and Bard, respectively.

The National Coordinator is requesting comment on whether there are prominent models (e.g., simulation models, unsupervised learning models) used to support decision-making in healthcare that are not effectively captured under the proposed definition of a predictive DSI, and, if so, whether it is feasible and appropriate to include such models in the scope of this proposed rule.

With ONC's proposal to add a new definition for predictive DSIs, they are also proposing that developers of certified health IT with Health IT Module(s) certified to the criterion that enable or interface with predictive DSIs would be subject to requirements to provide transparency of predictive DSIs. ONC is specifically proposing that Health IT Modules that enable or interface with predictive DSIs enable a user to review predictive DSI "source attribute" information through the Health IT Module. The National Coordinator is also proposing that developers of certified health IT with Health IT Modules that enable or interface with predictive DSIs employ or engage in "intervention risk management" (IRM) practices.

Summary information regarding these IRM practices would be made available via a publicly accessible hyperlink. Together, ONC's proposals for predictive, DSI-specific source attributes and intervention risk management practices are intended to provide appropriate information to help guide medical decisions at the time and place of care, consistent with existing statute.[5]

The National Coordinator acknowledges that the continued evolution of decision support software, especially as it relates to AI and ML-driven predictive models, necessitates new requirements and a new name for the Program's CDS criterion. They feel the revised DSI certification criterion would improve transparency, enhance trustworthiness, and support consistency around the use of predictive algorithms or models in healthcare. They also believe it would also advance health equity by design by making it known to users of certified Health IT Modules certified to this criterion whether demographic and social determinants of health (SDOH) assessment data are used in DSIs.

In addition to proposing to adopt the above source attributes – ONC is proposing to include new source attributes for evidence-based DSIs. ONC is proposing that Health IT Modules enable users to review what, if any, of the following data elements were used in the DSI, specifically: 1) Patient Demographics and Observations data, including data on race, ethnicity, language, sexual orientation, and gender identity; 2) SDOH data elements; and 3) the data elements of the Health Status Assessments data class as expressed in the standards. The Health Status Assessments data class includes several data elements, including: 1) Health Concerns; 2) Functional Status; 3) Disability Status; 4) Mental or Cognitive Status 5) Pregnancy Status; and 6) Smoking Status, which are part of the USCDI v3 (proposed for adoption in this rule). The SDOH data elements include: 1) SDOH Assessment; 2) SDOH Goals; 3) SDOH Problems/Health Concerns; and 4) SDOH Interventions (also part of the USCDI v3), and ONC is not proposing any changes to the source attributes for linked referential DSIs.

ONC is proposing that the new evidence-based DSI source attributes would also pertain to predictive DSIs that are enabled by or interface with certified Health IT Modules, by means of a cross-reference in statute. They are also proposing several additional source attributes for Health IT Modules that enable or interface with predictive DSIs. Specifically, those that pertain to predictive DSIs, and would include: 1) intervention details, such as a description of the output and intended use of the intervention; 2) intervention development details, such as input features, training and test data details, and process(es) used to ensure fairness in development of the intervention, as well as external validation process(es), if available; 3) quantitative measures of intervention performance, such as validity and fairness of prediction in test data and references to any evaluations of the intervention on outcomes; and 4) ongoing maintenance of intervention implementation and use, including an update schedule and to the extent practicable, how well the intervention works (i.e., its validity and fairness) in the specific setting for which it is designed or deployed in. ONC asserts that these additional source attributes would better support the transparency of predictive DSIs and that such information is necessary for users to decide whether and how to use the predictive DSI, including whether to apply the predictive DSI to individual patients.

Given the potential for a growing market of third-party developed predictive DSIs and development of predictive DSI by customers of developers of certified health IT, ONC expects that Health IT Modules certified to these newly proposed requirements would provide users with source attribute information from these other parties. In circumstances where the developer of certified health IT does not receive source attribute information, ONC is proposing that Health IT Modules clearly indicate when source attributes related to DSIs developed by others are not available for the user to review. ONC is proposing, as part of source attribute requirements for Health IT Modules that enable or interface with one or more predictive DSIs, that users have transparency into how and whether a predictive DSI's recommendation or output was measured for fairness in test data, external data (if available), and local data (if available) respectively. ONC believes it is important that users be made aware when source attribute information is missing or unknown – and is thus proposing that Health IT Modules enable users to author attributes and revise attributes beyond what is proposed in the new certification criterion to support the ongoing

[5] 42 U.S.C. § 300jj–11(b)(4)

evolution of what source attributes are important to users to make informed decisions regarding the DSI's recommendation(s).

ONC is proposing to require developers of certified health IT with Health IT Modules certified to newly proposed criterion that enable or interface with predictive DSIs (i.e., developers that attest "Yes" for one or more modules) to employ or engage in and document information regarding their intervention risk management (IRM) practices.[6] ONC is further proposing three categories of IRM practices, including "risk analysis," "risk mitigation," in and "governance," for each predictive DSI[7] they enable or interface with. The National Coordinator is also proposing that developers of certified health IT compile detailed documentation regarding the results of these proposed IRM practices. As an additional requirement of this provision, they are proposing that developers of certified health IT must make detailed documentation available to ONC upon their request for any predictive DSI that the Health IT Module enables or interfaces with.

Further, ONC is proposing that Health IT Modules certified to the new proposed and revised certification criteria enable users to provide feedback regarding DSI information displayed through the Health IT Module, and that such Health IT Modules make available such feedback data for export in a computable format. Developers of certified health IT with Health IT Modules certified to the newly revised criteria would have to comply with these new requirements by Dec. 31, 2024. For the intervening time between finalization of this proposed rule and Dec. 31, 2024, ONC is proposing to add "Clinical – Clinical decision support (CDS) (to be recategorized as "Care Coordination)" to the list of applicable certification criteria for the real-world testing Condition and Maintenance of Certification requirements – thus requiring developers of certified health IT with Health IT Module(s) certified to either in order to participate in real world testing plan and results submission.

ONC is further proposing that developers of certified health IT submit summary information related to their IRM practices described to ONC-Authorized Certification Bodies (ACBs) via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps. They are proposing that health IT developers subject to these requirements review annually and, as necessary, update their documentation as described in this proposal. The proposed requirement to make summary information regarding IRM practices publicly accessible is similar to requirements related to API documentation requirements.[8] ONC believes that disclosure of summary information regarding IRM practices is necessary for users to evaluate the organizational competencies of those parties that develop predictive DSIs, further improving users' understanding of the steps that have been taken to mitigate negative impacts or prevent future harm and better support the transparency of predictive DSIs.

ONC is also proposing a new Principle of Proper Conduct for the ONC-ACBs such that they are required to report the proposed summary information that they received from health IT developers of certified health IT, on the Certified Health IT Product List (CHPL) for the applicable certified Health IT Modules. ONC states that this new Principle of Proper Conduct is consistent with existing public disclosure requirements under the Program – and will help ensure accountability for the public availability of information.

Additionally, ONC is proposing to update the Base EHR definition[9] to include an option of either the existing "clinical decision support (CDS)" version of the criterion or the revised "decision support interventions" criterion for the period up to and including Dec. 31, 2024, and to include only "decision support interventions" on and after Jan.1, 2025. In other words, ONC is proposing that the adoption of the CDS criterion, for purposes of the Program, expires on Jan. 1, 2025. This timeline would support the proposal that developers of certified health IT must certify their Health IT Modules to new proposed requirements by Dec. 31, 2024, if they wish such Health IT Modules to meet the newly proposed "Base

[6] These practices are listed in proposed § 170.315(b)(11)(vii)(A)(1) through (3)

[7] Defined in § 170.102

[8] § 170.315(g)(9)(ii)

[9] § 170.102

EHR" definition[10] and ensure continuity for customers using Health IT Modules currently certified to statute. Finally, ONC is proposing to require health IT developers of certified health IT with a Health IT Module certified to submit real world testing plans and results consistent with current statute[11] for the period until the CDS criterion is no longer part of the Program.

The National Coordinator is aware of existing and emerging efforts to establish guidelines, frameworks, and principles to encourage optimization of predictive models in healthcare, including recent industry recognition for evaluation, monitoring, and guardrails. **ONC refers to DSIs that are fair, appropriate, valid, effective, and safe as "FAVES."** Fair DSIs do not exhibit biased performance, prejudice, or favoritism toward an individual or group based on their inherent or acquired characteristics. Appropriate DSIs are well-matched to the specific contexts and populations to which they are applied. Valid DSIs have been demonstrated to estimate targeted values accurately and as expected in both internal and external data. Effective DSIs have demonstrated meaningful benefit in real-world conditions. And, finally, safe DSIs are free from any unacceptable risks, including risks to privacy and security, and are DSIs for which the probable benefits outweigh any probable risks. When the National Coordinator refers to predictive DSIs and models that are FAVES, it means they are high-quality. While ONC believes it is premature to propose requirements for specific measures or thresholds for FAVES, they nevertheless believe these proposals would enable consistent and routine access to source attribute information about technical and performance dimensions specifically relevant to FAVES, which would support users to make informed decisions about whether and how to use predictive DSIs.

The proposal states that ONC is being intentional with the level of prescriptiveness in these proposals because these are nascent technologies with enormous potential benefit – and they are seeking to establish appropriate guardrails for information transparency about predictive DSIs that do not undercut the value that could be offered to patients and clinicians from such promising technologies. ONC asserts that, together, these proposed requirements should improve transparency, promote trustworthiness, and incentivize the development and wider use of fair, appropriate, valid, effective, and safe predictive DSIs to aid decision-making. They believe the resulting information transparency would enable users, including healthcare providers, to scrutinize these technologies and would increase public trust and confidence in them. It could expand the use of these technologies in safer, more appropriate, and more equitable ways. This transparency would also inform wider discussions across industry and academia regarding how to evaluate and communicate performance related to predictive DSIs. Ultimately, transparency regarding both the technical and performance details of a predictive DSI, as well as the organizational competencies of the developer of certified health IT to manage risks for a predictive DSI are intended to contribute to the trustworthiness of these emerging and important technologies.

Standardized API for Patient and Population Services

ONC is proposing to adopt the Smart App Launch Implementation Guide Version 2 (v2), which would replace the Smart App Launch Implementation Guide v1 as the standard by Jan. 1, 2025. Additionally, ONC is proposing to amend the API Condition and Maintenance of Certification requirements for Service Base URLs which support patient-facing apps by identifying and requiring the use of standardized formats for FHIR endpoints. Finally, ONC is proposing to revise the current requirement[12] to specify that Health IT Modules presented for certification must be able to revoke an authorized application's access at a patient's direction within one hour of the request.

Patient Requested Restrictions

ONC proposes to adopt new requirements for certified health IT specifically in support of the HIPAA Privacy Rule's "right to request a restriction" on uses and disclosures.[13] These requirements would include a new certification criterion, an addition to ONC's Privacy and Security Framework under the

[10] § 170.102

[11] § 170.405

[12] § 170.315(g)(10)(vi)2

[13] 45 CFR 164.522(a)

Program, and a revision to an existing criterion to support additional tools for implementing patient requested restrictions.

Requirement for Health IT Developers to Update their Previously Certified Health IT

ONC is proposing to make explicit[14] in statute that health IT developers voluntarily participating in the Program must update their certified Health IT Modules and provide that updated certified health IT to customers in accordance with the timelines defined for a specific criterion or standard. More specifically, ONC is proposing that health IT developers with health IT certified to any of the certification criteria would need to update their previously certified Health IT Modules to be compliant with any revised certification criterion adopted, including any new standards adopted[15] and capabilities included in the revised certification criterion. Finally, ONC is further proposing that health IT developers would also need to provide the updated heath IT to customers of the previously certified health IT according to the timelines established for that criterion and any applicable standards.

Assurances Condition and Maintenance of Certification

ONC is proposing to require a health IT developer, as a Condition of Certification requirement under the Program, to provide an assurance that it will not interfere with a customer's timely access to interoperable health IT certified under the Program, and includes two accompanying Maintenance of Certification requirements that require a health IT developer to update a certified Health IT Module to all applicable revised certification criteria and provide all Health IT Modules certified to a revised certification criterion to its customers of such certified health IT within certain proposed timelines.

Insights Condition and Maintenance of Certification

The 21st Century Cures Act called for establishing an EHR Reporting Program to provide transparent reporting to measure the performance of certified health IT and specified that health IT developers be required, as a Condition and Maintenance of Certification requirement, to submit responses to reporting criteria in accordance with the EHR Reporting Program established. ONC refers to the Condition and Maintenance of Certification associated with the "EHR Reporting Program" as the "Insights" Condition and Maintenance of Certification (also referred to as the "Insights Condition") throughout this proposed rule. ONC believes this descriptive name captures a primary policy outcome of this requirement.

According to ONC, implementation of the Insights Condition would provide transparent reporting that aims to address information gaps in the health IT marketplace and provide insights on the use of specific certified health IT functionalities. This new Condition and Maintenance of Certification requirement would allow ONC to gain understanding of the use of health IT and provide the National Coordinator with information about consumers' experience with certified health IT.

ONC is proposing to adopt nine reporting measures for developers of certified health IT that focus initially on the interoperability category, emphasizing four areas of interoperability: 1) individuals' access to electronic health information (EHI); 2) public health information exchange; 3) clinical care information exchange, and 4) standards adoption and conformance. Through this first set of proposed measures, ONC intends to provide insights on the interoperability category specified in the Cures Act. The National Coordinator intends to explore the other Cures Act categories – security, usability and user-centered design, conformance to certification testing, and other categories to measure the performance of EHR technology – in future years.

ONC intends for this first set of proposed measures to provide insights on the interoperability category specified in the Cures Act. Developers of certified health IT with at least 50 hospital users or 500 clinician users would be expected to report on each applicable measure, according to the implicated certification criterion. Developers of certified health IT would report data related to the Insights Condition twice a year

[14] In the introductory text in § 170.315

[15] In 45 CFR part 170 subpart B

aligned with their “Attestations” Condition and Maintenance of Certification requirement (April, October submission dates), beginning April 2025.

Proposed Insights Condition Measures
Individual Access to Electronic Health Information (EHI) • Individual’s Access to EHI Supported by Certified API Technology
Public Health Information Exchange • Immunization Administrations Electronically Submitted to an Immunization Information System through Certified Health IT • Immunization History and Forecasts
Clinical Care Information Exchange • C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism • C-CDA Medications, Allergies, and Problems Reconciliation and Incorporation Using Certified Health IT
Standards Adoption and Conformance • Applications Supported Through Certified Health IT • Use of FHIR in Apps Supported by Certified API Technology • Use of FHIR Bulk Data Access through Certified Health IT • Electronic Health Information Export through Certified Health IT

ONC has explored various pathways on how to make it easier for the public to view and comment on the detailed technical specifications supporting the proposed measures. Thus, they determined that measure specification sheets would be a logical and accessible method for the public to also review and provide comment. This is consistent with the approach used by other HHS programs to solicit public feedback related to measure technical specifications (e.g., CMS Electronic Clinical Quality Measures (CMS eCQMs)). These methods allow for more effective review of the technical detail including supporting public comment on those specifications in a transparent manner. For more details and to provide comment on the technical specifications for measure calculation for the proposed measures, the measure specification sheets are available here; links to each are also included below under “Resources & Quick Links.”

Other Proposals Include:

- Revising electronic case reporting certification criterion to be based on consensus-based, industry developed standards by HL7;
    - Developers of certified health IT would have until the end of 2024 to adopt HL7 Clinical Document Architecture (CDA) or HL7 FHIR implementation guides (IGs) to provide functionality;
- Adding new data elements, and renaminh the demographics certification criterion;
- Updating the transitions of care certification criterion to USCDI v3;
- Requiring developers of certified health IT to update their certified Health IT Modules to the most recently adopted certification criterion and providing that updated certified Health IT Module to its customers in accordance with the dates identified for each revised certification criterion and each applicable standard; and
- Revising and standardizing the service base URL publication APIs Maintenance of Certification requirement.

Information Blocking Regulations Proposals

The proposed rule would provide enhancements to support information sharing under the information blocking regulations and promote innovation and competition, as well as address market consolidation.

ONC believes that addressing information blocking is critical for promoting innovation and competition in health IT and for the delivery of healthcare services to individuals.

ONC reiterates that the information blocking provision of the Public Health Service Act (PHSA) itself expressly addresses practices that impede innovation and advancements in EHI access, exchange, and use, including care delivery enabled by health IT.[16] Actors subject to the information blocking provisions may, among other practices, attempt to exploit their control over interoperability elements to create barriers to entry for competing technologies and services that offer greater value for health IT customers and users, provide new or improved capabilities, and enable more robust access, exchange, and use of EHI.[17]

Information blocking may also harm competition not just in health IT markets, but also in markets for healthcare services.[18] In the ONC Cures Act Final Rule, ONC described practices that dominant market providers may leverage and use to control access and use of their technology, resulting in technical dependence and possibly leading to barriers to entry by would-be competitors, as well as making some market providers vulnerable to acquisition or inducement into arrangements that enhance the market power of incumbent providers to the detriment of consumers and purchasers of healthcare services. The implementation of the new information blocking provisions in this proposed rule would promote innovation, encourage market competition, and address consolidation in the interest of the patient to advance interoperability, improve transparency, and support the access, exchange, and use of EHI.

Defining "Offer Health IT"

ONC is proposing to modify the definition of a "health IT developer of certified health IT" so that it remains clear that healthcare providers who self-develop certified health IT for their own use would continue to be excluded from this definition if they do not offer any certified health IT to others.

Additionally, ONC is proposing to revise the definition for "information blocking" to remove the time period for which EHI is limited to the data elements represented in the USCDI v1 because, as of Oct. 6, 2022, EHI is no longer limited to the data elements represented in the USCDI v1. Because ONC included the same date in the Content and Manner Exception, ONC proposes to also revise the exception to remove the existing date as no longer necessary.

ONC is proposing what it means to "offer health information technology" or "offer health IT" for purposes of the information blocking regulations.[19] This definition of what it means to offer health IT would, as proposed, narrow the applicability of the health IT developer of certified health IT definition. While the definition of "offer health IT" would generally continue to include holding out for sale, selling, or otherwise supplying certified health IT to others on commercial or other terms, it would carve out by explicit exclusion the provision of funding for obtaining or maintaining certified health IT.

According to ONC, stakeholders posed questions and expressed concerns that healthcare providers and entities not otherwise considered other forms of information blocking actors (health information exchanges, health information networks, and vendors) might stop funding subsidies to providers who cannot otherwise afford certified health IT. A key source of concern identified was a lack of certainty as to whether such subsidies could be considered to be offering health IT, resulting in the donor/benefactor entities making available funding subsidies becoming subject to the definition of health IT developer of certified health IT across all of their technology, business lines, and activities.

This is of significance to current and potential donors who are either not otherwise information blocking actors of any type or otherwise would be considered healthcare providers for purposes of the information blocking regulations. For (potential) donors who are not otherwise information blocking actors, such as

[16] Section 3022(a)(2)(C)(ii) of the PHSA

[17] 85 FR 25820

[18] 85 FR 25820

[19] 45 CFR part 171

philanthropic organizations or health plans, a key concern reportedly affecting their willingness to subsidize certified health IT to providers in need under current policy is presumably that their choice to offer certified health IT is also a choice to subject all of their technology and business practices potentially affecting access, exchange, or use of EHI across their entire business to the information blocking regulations[19], as well as up to $1 million per violation civil monetary penalties authorized in the Cures Act's information blocking provision.[20]

Although healthcare providers are already information blocking actors, those who might be in a position to offer cost subsidies to other providers may be hesitant to do so because of the differences in the information blocking definition and consequences for a health IT developer of certified health IT compared with those for a healthcare provider. First, it is significant that information blocking, when conducted by a healthcare provider, is defined in part by whether the healthcare provider "knows that such practice is unreasonable and is likely to interfere," which is for the actor, a less exacting knowledge standard than that applied to conduct of a health IT developer of certified health IT: whether the developer "knew or should have known that such practice is likely to interfere."[21]

To give clarity about the definitional implications under information blocking regulations of making available funding subsidies and certain features or uses of certified health IT, ONC is proposing to codify a definition of what it means to offer certified health IT. The definition ONC is proposing generally includes providing, supplying, or otherwise making available certified health IT under any arrangement or terms, but explicitly excludes certain activities for one of two purposes:

1) to encourage beneficial arrangements under which providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT; or
2) to give healthcare providers (and others) who use certified health IT concrete certainty that implementing certain health IT features and functionalities, as well as engaging in certain practices that are common and beneficial in an EHR-enabled healthcare environment, will not be considered an offering of certified health IT (regardless of who developed that health IT).

ONC is seeking comments on other steps that the National Coordinator should consider to further encourage lawful donation or other subsidized provision of certified health IT to health care providers who may otherwise struggle to afford modern, interoperable health IT without reducing the assurances and other benefits ONC's information blocking and Health IT Certification Program regulations provide to these recipient health care providers in comparison to providers who obtain certified health IT directly from its developer or under other non-subsidized arrangements.

Infeasibility Exception

ONC is proposing to revise one condition and create two new conditions for the Infeasibility Exception:

- Proposing to revise the "uncontrollable events" condition[22] to further clarify when an actor's practice meets the "uncontrollable events" condition such that it would not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI.
- Proposing to add a new "third party seeking modification capability" condition (option).
    - Would apply in certain situations where the actor is asked to provide the ability for a third party (or its technology, such as an app) to modify EHI; and
    - Would apply to an actor's practice of denying a third party's request to enable use of EHI in order to modify EHI, including but not limited to creation and deletion functionality, provided the request is not from a healthcare provider requesting such use from an actor that is its business associate (BA).
- Proposing to add a new "manner exception exhausted" condition:

[20] 42 U.S.C. 300jj–52(b)(2)(A))

[21] § 171.103, see also 42 U.S.C. 300jj–52(a)(1))

[22] https://www.ecfr.gov/current/title-45/part-171

- Would apply where an actor does not fulfill a request for access, exchange, or use of EHI after offering alternative, interoperable manners; and
- The condition would not apply under certain circumstances, including when the actor currently provides to a substantial number of individuals or entities, similarly situated to the requestor, the same requested access, exchange, or use of the requested EHI.

To satisfy the proposed manner exception exhausted, an actor would be considered "unable" to fulfill a request for access, exchange, or use of EHI when three factors are true:

1) The actor could not reach agreement with a requestor in accordance with manner requested condition (as proposed in this proposed rule) or was technically unable to fulfill a request for EHI in the manner requested;
2) The actor offered all alternative manners in accordance with an alternative manner condition (as proposed in this proposed rule) for the EHI requested but could not reach agreement with the requestor; and
3) The actor does not provide the same access, exchange, or use of the requested EHI to a substantial number of individuals or entities that are similarly situated to the requester.

ONC is proposing an alternative version of the factor would also provide a clear option for an actor without certified health IT to satisfy the newly proposed manner exception exhausted condition either: 1) by offering to fulfill the request in two manners that use content and transport standards published by the Federal Government or a standards-developing organization accredited by the American National Standards Institute; or 2) by offering fulfilment in at least one such manner and an alternative machine readable format.[23]

Manner Exception – TEFCA Manner

ONC is proposing to rename the Content and Manner Exception and add a Trusted Exchange Framework and Common Agreement (TEFCA) manner condition:

- Would acknowledge that certain agreements have been reached by parties who join TEFCA;
- Proposal aligns with a foundational policy construct underpinning the Manner Exception in that it facilitates an actor reaching agreeable terms with a requestor to fulfill an EHI request and acknowledges that certain agreements have been reached between these parties for the access, exchange, and use of EHI; and
- The proposed TEFCA manner condition would be available for any and all EHI and any TEFCA permitted purpose.

The proposed TEFCA manner exception would identify as reasonable and necessary an information blocking actor's practice of prioritizing using, in lieu of other feasible manners, the appropriate TEFCA means:

1) for any and all EHI for which access, exchange, or use can be supported by TEFCA means for both the actor and requestor;
2) so long as the requestor is a QHIN, Participant, or Subparticipant and the purpose of the access, exchange, or use is permitted under the TEFCA governing agreements;
3) regardless of whether the request is initially made through TEFCA means or otherwise; and regardless of whether all of the particular data class(es) or exchange purpose(s) requested are yet required by TEFCA's governing agreements to be returned in response to a TEFCA request.

In order to satisfy this condition, ONC is considering requiring that an actor would need to check an available directory of all QHINs, Participants, and Subparticipants under the TEFCA governing agreements in order see if the requestor is listed. While the listing or non-listing of a requestor in such a directory would not be dispositive as to the truth of the matter, an actor checking the directory would likely improve the efficiency of such interactions (i.e., EHI requests and responses) and would help

[23] Consistent with § 171.301(b)(1)(iii); only the least-interoperable "alternative machine-readable format" that would be codified in proposed § 171.301(b)(1)(iii) (presently codified in § 171.301(b)(2)(i)(C)).

inform the assessment of the actor's intent under the circumstances. ONC is seeking comments on this potential requirement for satisfaction of the new proposed TEFCA condition.

In summary, the first new proposed infeasibility condition would apply to an actor's practice of denying a third party's request to enable use of EHI in order to modify EHI, including but not limited to creation and deletion functionality, provided the request is not from a health care provider requesting such use from an actor that is its BA. The second new proposed infeasibility condition would apply where an actor has exhausted the manner exception[24], including offering all alternative manners in current statute[25], and the actor does not currently provide a substantial number of individuals or entities similarly situated to the requestor with the same requested access, exchange, or use of the requested EHI.

Other Proposals Include:
ONC is also seeking comment on ways health IT can support EHI segmentation for access, exchange, and use of EHI; and particularly how the Program, through the certification of health IT to certain functionalities and/or standards, can support EHI segmentation for access, exchange, and use, including to assist healthcare providers with sharing EHI consistent with patient preferences and all laws applicable to the creation, use, and sharing of EHI.

Additionally, ONC outlines a range of questions for public comment and request information to specifically consider the policy implications related to supporting health IT users' ability to segment and selectively display, delay, or withhold EHI consistent with patient preferences for information sharing, applicable law, and other considerations such as when a delay or other interference with particular EHI access, exchange, or use may be reasonable and necessary under the conditions of an information blocking exception.

Information Blocking Requests for Information (RFI) – contained in Section IV.C.3 of the proposed rule (beginning on page 416) – contain discussion and questions related to an illustrative sampling of use cases for data segmentation and user/patient access management functionalities. ONC is also seeking public comment on this proposal to support patients' right to request a restriction of disclosure in the context of information sharing requirements under the ONC Cures Act Final Rule.

Resources & Quick Links

- ONC Resources on Proposed Rule
- Review the Proposed Rule
- Press Release
- ONC Blog Post on the Proposed Rule
- ONC Blog Post on DSI Proposals
- ONC General Overview Fact Sheet
- ONC At-a-Glance Fact Sheet
- Measurement Spec Sheets on the Proposed Rule
  - Individual Access Spec Sheet
  - C-CDA Mechanism Spec Sheet
  - C-CDA Reconcile Spec Sheet
  - Supported Apps Spec Sheet
  - Use of FHIR Spec Sheet
  - Use of FHIR Bulk Data Spec Sheet
  - EHI Export Spec Sheet
  - Immunization Administrations Spec Sheet
  - Immunization Query Spec Sheet

[24] § 171.301
[25] In accordance with § 171.301(b)