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June 20, 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,

On behalf of our 30 member companies, the HIMSS Electronic Health Record (EHR) Association appreciates the opportunity to provide feedback to the ONC on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

While we have long supported the nation's goals of advancing interoperability, improving transparency, and supporting further access, exchange, and use of electronic health information, we have a number of concerns about the impact this proposed rule will have on the industry. Many center on the timeframes associated with the various concepts included in HTI-1 and the burden compliance with several of its proposals would place on providers and health information technology (IT) developers (see Appendix B - EHR Association Estimates of HTI-1 Proposed Requirements). We appreciate that ONC is under pressure to implement the remaining requirements from the 21st Century Cures legislation, but health IT developers need more time than allotted to deliver safe, compliant, and high-quality versions of certified products and providers need sufficient time to implement and train on that upgraded software. We note, as well, that many of ONC's proposed requirements are at odds with key priorities raised by our healthcare provider customers to reduce administrative burden, as they continue to face immense financial and operational strains while emerging from the COVID-19 pandemic.

Additionally, we encourage ONC to work more closely with the Centers for Medicare and Medicaid Services (CMS) to align when ONC tells software developers to deploy new certified versions and when CMS requires providers to use them. In recent years, CMS has left insufficient time for implementation, testing, and training after our deadlines to make software available, and it is important that ONC assertively work to help CMS understand the latest date by which health IT developers are allowed to release their new versions. Further, we ask that ONC work with CMS to address the proposals within HTI-1 that create a dependency on collaboration with healthcare provider organizations for developers

to be successful in meeting their obligations, but for which CMS has included no corresponding incentives for them to do so.

We appreciate this opportunity to provide ONC with the following detailed comments and look forward to continued collaboration toward improved patient care.

Sincerely,

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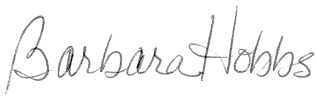

Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
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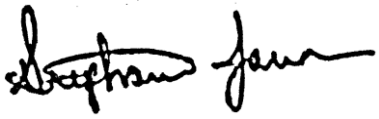

Stephanie Jamison
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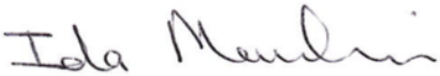

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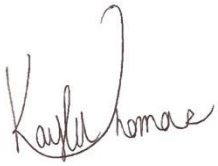

Kayla Thomas
Oracle Cerner

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

The ONC Certification Criteria for Health IT and Discontinuing Year Themed "Editions" - (p. 5)

We propose to rename all criteria within the Program simply as ''ONC Certification Criteria for Health IT.'' We believe maintaining a single set of ''ONC Certification Criteria for Health 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 certificates over time. This proposal to remove ''editions'' from the Program would also help users of certified health IT identify which certification criteria are necessary for their participation in other HHS programs, such as Medicare Promoting Interoperability Program and the Promoting Interoperability Performance category of the MIPS.

The EHR Association has identified several challenges that we urge ONC to consider when determining whether to finalize its proposal to eliminate "editions" of certification. Specifically, we request ONC think carefully about and (if finalized) address how the following would be managed under the proposed program structure:

(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 healthcare providers to upgrade their certified products is a resource-intensive task for these sites, and this process would be further complicated under an "edition-less" program structure with a more frequent cadence of regularly changing requirements necessitating new releases. There is also a risk of creating confusion for providers as they try to make the correct selections from the Certified Health IT Product List (CHPL) amongst listings that are more frequently being updated – and at a more granular level – than in the past.
(3) Aligning health IT development efforts with the standards development cycle. While we agree that consistent updates are important, they must be balanced against 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 that we as their software partners develop within health IT.

Addressing these considerations will help streamline the program while ensuring provider organizations have clear expectations about whether the software they use meets certification requirements for participation in CMS programs.

The United States Core Data for Interoperability Standard Version 3 (USCDI v3) - (p. 6)

We propose that USCDI v1 would remain in regulation and now be codified in § 170.213(a) and we propose to add USCDI v3 to § 170.213 (to be codified as § 170.213(b)).

We also propose to incorporate by reference USCDI v3 in § 170.299 as of the effective date of the final rule.

In addition, we propose that the USCDI v1 (July 2020 Errata) in the USCDI standard in § 170.213(a) will expire on January 1, 2025. Under this proposal, both versions would be referenced as applicable in the USCDI standard in § 170.213 for the time period up to and including December 31, 2024.

The EHR Association is generally supportive of the continued thoughtful expansion of USCDI. The transparency with which USCDI is developed and the incremental nature of its updates are appropriate for interoperability advancement. However, the proposed timeframe for development, testing, and implementation between when the final rule is realistically expected and the expiration of USCDI v1 is simply too short. We recommend adjusting the proposed timeline to the end of the second full calendar year following the publication of the final rule, which we estimate would thus be December 31, 2025. This would also align with ONC's default approach of requiring revised certification timelines two to three years after the publication of a Final Rule.

Further, we reiterate our previous feedback that as the scope of USCDI data classes increases, organizations and EHRs should be allowed to achieve certification by adding only those data classes and elements necessary to meet their users' needs. For example, geriatric-focused EHRs should not be required to support pediatric data, non-Laboratory Information Systems should not be required to capture certain lab data, and those systems that do not collect data via a user interface, extract it from/generate into C-CDA documents, or make accessible through FHIR US Core based APIs, or other transactions, should not be required to certify against such related USCDI data.

Adopting a dynamic approach based on the data that is actually managed by the health IT – an approach that removes the requirement that all systems support all aspects of USCDI regardless of user needs – eliminates an unnecessary burden for both health IT developers and the providers for whom the broader list of data elements is not applicable, without creating an unmanageable set of overlapping USCDI+ datasets for all the variations in health IT deployed.

C-CDA Companion Guide Updates - (p. 6)

We propose to adopt the HL7® CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes STU Companion Guide, Release 3—US Realm (C–CDA Companion Guide R3) in § 170.205(a)(6).

The EHR Association is generally supportive of the proposed Implementation Guides. Due to their newness, challenges may be encountered and adjustments to testing tools required as the industry begins implementation.

Electronic Case Reporting - (p. 6)

We propose to revise the "transmission to public health agencies—electronic case reporting" criterion in § 170.315(f)(5) to adopt consensus-based, industry-developed electronic standards and implementation guides (IGs) to replace all functional, descriptive requirements in the present criterion in § 170.315(f)(5).

These standards are proposed to support the following requirements for Health IT Modules certified to § 170.315(f)(5):

(i) create a case report for electronic transmission;

(ii) consume and process a case report response; and

(iii) consume and process electronic case reporting trigger codes and parameters.

The EHR Association recognizes the extreme growth of electronic case reporting since the publication of the initial criteria, as well as the need to refine the requirements in line with the 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.

The mix of CDA and FHIR standards in the case reporting ecosystem requires careful regulation. The format of the incoming Reportability Response should be tied to the method of the outgoing case report. In other words, if a Case Report is sent in CDA format, the EHR should expect to receive a Reportability Response in CDA format. Case Reports sent in FHIR format should result in a Reportability Response in FHIR format.

Active integrations today primarily function through the use of the Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) Platform. While the regulation indicates a hesitancy to require AIMS, we believe that continued success in case reporting relies on a reasonable expectation of a routing and decision support intermediary such as AIMS. This intermediary, if in use, can provide assurance that a given jurisdiction can accept the supported standard (CDA or FHIR) being sent by the EHR, translate it to any appropriate communication or data format for the recipient, and respond with in-kind standards-based interoperability. Additionally, an intermediary helps mitigate concerns over versions of specifications. As we migrate from older versions to more current versions of eICR and the Responsibility Response and expand the use of FHIR vs. CDA-based reporting, intermediaries can facilitate these advances enabling both providers and PHA to migrate at their pace.

We are also concerned with the lack of detail around the proposed requirement that the reporting health IT must be able to receive, consume, and process a Reportability Response. We urge ONC to recognize the significant variability between jurisdictions in terms of the usefulness and data use expectations of the Reportability Response. We, therefore, suggest the reporting health IT must be able to receive and display the Responsibility Response to the provider considering this variety of Responsibility Responses in non-computable formats across jurisdictions. As PHAs further align and deploy computable Responsibility Responses further consumption of its contents can be considered.

Decision Support Interventions and Predictive Models - (p. 6)

We propose the certification criterion, ''decision support interventions (DSI)'' in §170.315(b)(11). The DSI criterion is a revised certification criterion as it serves as both an iterative and replacement criterion for the ''clinical decision support (CDS)'' criterion in §170.315(a)(9). This criterion 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.

The EHR Association recommends against renaming Clinical Decision Support to Decision Support Interventions as the term “intervention” has other meanings within healthcare. Retaining the name “Clinical Decision Support” also aligns better with the legislative definition of a qualified electronic health record, which must have the capacity to provide clinical decision support.

Expanding the scope of certification to non-clinical decision support introduces a disparity between the expectations for non-clinical decision support included in certified EHRs and the expectations for decision support included in frequently not-certified administrative systems.

We suggest ONC make predictive clinical decision support a separate certification criterion from the existing clinical decision support criterion to better facilitate it being on a more extended timeframe and potentially impacting different products.

Decision Support Interventions and Predictive Models - (p. 7)

We propose to adopt a new definition for "predictive decision support intervention," in § 170.102, and we propose that developers of certified health IT with Health IT Module(s) certified to the criterion we propose in § 170.315(b)(11) that enable or interface with predictive DSIs would be subject to requirements to provide transparency of predictive DSIs.

The broadness of this definition presents a key challenge; it could include anything from commonly used simple algorithms, growth charts, and default selections in the system to suggested word completions when typing and/or rules-based decision support. It also fails to adequately distinguish between evidence-based DSI, which is also broadly defined and effectively infeasible to scope based on existing guidance (i.e., not limited to alerts, notification, and explicit care suggestions, nor to any particular type of deployment). As such, we recommend narrowing the overly broad definition of "predictive decision support intervention," as some types of interventions are not conducive to source attributes or feedback gathering. Greater clarity is also needed on the definition of "predictive."

Decision Support Interventions and Predictive Models - (p. 7)

We also propose that developers of certified health IT with Health IT Modules that enable or interface with predictive DSIs employ or engage in "intervention risk management" practices. We also propose that summary information regarding these intervention risk management practices be made available via a publicly accessible hyperlink.

The EHR Association reiterates our concerns that there are many DSIs created by clients and third parties about which the developer will not be able to provide source attribute information, making engagement in "intervention risk management" practices challenging. It would be much more effective and credible for regulators to directly issue requirements for transparency to the authors of alerts/interventions as opposed to EHR developers providing the delivery mechanism.

We propose that Health IT Modules certified to § 170.315(b)(11) 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.

"ONC proposes that certified HIT must be able to export such feedback data, including but not limited to the intervention, action taken, user feedback provided (if applicable), user, date, and location, so that the exported data [in a "computable format"] can be associated with other relevant data."

"We propose that such feedback data be available for export by users for analysis in a computable format, so

that it can be associated with other relevant data, such as diagnosis, other inputs into the DSI, and the outputs of the DSI for a particular patient, to evaluate and improve DSI performance."

The EHR Association recommends limiting the requirement to enable user feedback – which would likely be a text string – to interruptive alerts, as passive alerts cannot have associated user actions. However, we do not want to inadvertently encourage interruptive alerts with the related negative effect on usability.

We also seek to clarify that adding a comment is an option for users – not an obligation – and note that requiring a UI for collecting user feedback would likely degrade usability.

Finally, collecting feedback data would not necessarily be patient-identified for privacy reasons, which means it may not facilitate ONC's stated goal of association with other data, such as diagnosis. As such, and absent of standards and a target audience, we feel this recommendation will have questionable use or value, particularly considering the volume of work it would entail for software developers.

We propose that developers of certified health IT with Health IT Modules certified to § 170.315(b)(11) comply with these new requirements by December 31, 2024.

For the intervening time between finalization of this proposed rule and December 31, 2024, we propose to add § 170.315(a)(9) to the list of applicable certification criteria for the real-world testing Condition and Maintenance of Certification requirement in § 170.405(a), thus requiring developers of certified health IT with Health IT Module(s) certified to § 170.315(a)(9) or § 170.315(b)(11) to participate in real world testing plan and results submission.

The proposed December 31, 2024, timeline for compliance with the new requirements is entirely unrealistic, given the significant scope proposed. We recommend the deadline be moved to January 1, 2026, if the final rule is issued in fall 2023.

If ONC and HHS more broadly are unwilling to consider a different regulatory construct that works directly with alert/intervention authors, we urge ONC to consider splitting this proposal in two, with an earlier deadline for updates to evidence-based DSI and a separate certification criterion for predictive DSI with a later deadline.

If ONC wishes to expedite portions of the regulation, we note that the proposed updates to evidence-based DSI would be feasible 18 months from the date of the final rule. ONC's impact estimates significantly misjudge the full burden that compliance with the predictive DSI proposal would place on software developers to complete the requirements safely (see Appendix B - EHR Association Estimates of HTI-1 Proposed Requirements). Thus, in this case, we would propose a timeline for predictive DSI compliance of January 1, 2027.

Finally, we propose to update the Base EHR definition in § 170.102 to include an option of either the existing ''clinical decision support (CDS)'' version of the criterion in § 170.315(a)(9) or the revised ''decision support interventions'' criterion in § 170.315(b)(11) for the period up to and including December 31, 2024, and to include only ''decision support interventions'' in § 170.315(b)(11) on and after January 1, 2025.

We suggest ONC make predictive clinical decision support a separate certification criterion from the existing clinical decision support criterion; that distinction would better facilitate predictive DSI being on an extended timeframe and potentially impacting different products.

The EHR Association supports the proposal of permitting certification to both the old and revised version of the criterion during a transition time period. The time periods proposed need to be extended by a sizable margin to be feasible.

Request for comment on whether to continue requiring use of Infobutton standards for linked referential DSI: "we welcome comment regarding the functionalities and standards listed in § 170.315(a)(9)(iv), the HL7 Context Aware Knowledge Retrieval Application ("Infobutton") standards, including whether linked referential CDS are commonly used with, or without, the named standards in § 170.315(a)(9)(iv)(A)(1) and (2) and whether we should continue to require use of these standards."

The EHR Association supports the removal of the linked referential DSI requirements and associated "Infobutton" standards from the scope of the criterion, given their low overall utilization and the significant expansion of the criterion in the areas of evidence-based and predictive DSI.

Synchronized Clocks Standard - (p. 7)

We propose in section III.C.6 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.

The EHR Association supports this proposal, as it is valuable to have this added level of flexibility.

Standardized API for Patient and Population Services - (p. 7)

We propose to require a certified Health IT Module's authorization server to issue a refresh token according to the implementation specification adopted in § 170.215(c). The token should be valid for a period of no less than three months and will apply to all applications using the ''confidential app'' profile for both first time and subsequent connections.

The EHR Association supports this proposal.

We also propose to adopt the FHIR US Core Implementation Guide STU version 5.0.1 in § 170.215(b)(1)(ii). Based on the annual US Core release cycle, we believe US Core IG v6.0.0 will be published before ONC issues a final rule.13 Therefore, it is our intent to consider adopting the updated US Core IG v6.0.0 that supports the data elements and data classes in USCDI v3 since we propose to adopt USCDI v3 in this rule.

The EHR Association is supportive of ongoing specification creation and consistent timelines of USCDI and FHIR US Core, including the updated US Core IG v6.0.0. However, we recommend finalizing a deadline at the end of the second calendar year following at least a two-year window from the publication of the final rule to ensure sufficient time for developers to do the work necessary to support the latest specifications, which we estimate would mean a deadline of December 31, 2025.

We also again reiterate that as the scope of USCDI data classes increases, organizations and EHRs should be allowed to achieve certification by adding only those aspects necessary to meet user needs. Removing the

requirement that all systems support all aspects of USCDI and instead adopting a dynamic approach based on the data actually managed by the health IT eliminates an unnecessary burden for health IT developers and the providers for whom the broader list is not applicable, without creating an unmanageable set of overlapping USCDI+ datasets for all the variations in health IT deployed.

We propose to amend the API Condition and Maintenance of Certification requirements by adding the requirement that Certified API Developers with patient-facing apps must publish their service base URLs for all customers, regardless of whether the certified Health IT Modules are centrally managed by the Certified API Developer or locally deployed by an API Information Source, according to a specified format.

The EHR Association supports the goal of standardizing published endpoints with the caveat that the format aligns with the industry. This is imperative if the true goal is to achieve standardization for app developers facilitating patient access. However, while we support ONC's goal, we also believe that there is a better approach to defining the format for Organization and Endpoint resources, which is using the Argonaut Project's Implementation Guide for Patient Access Brands. This IG is based on the same FHIR resources ONC has cited but provides more specific requirements for developers to follow in a dedicated published guide. Citing it will also take an important step towards establishing consistency across related purposes in the industry. Along with this, we note that the Sequoia Project has also published the Recognized Coordinating Entity (RCE) Implementation Guide for endpoint publication under TEFCA. Accordingly, we ask ONC to advocate for TEFCA to also be re-aligned under the Argonaut IG we have recommended above.

We also request clarification that the proposed requirement is to publish NPIs (using the Organization FHIR resource format as specified in the above IG) for each organization with an NPI issued that is serviced by an endpoint. Publishing individual practitioner NPIs, which would be represented with a Practitioner FHIR resource, would be out of scope.

It is important that ONC recognizes that EHR developers have found providers and provider organizations unwilling to cooperate when it comes to providing their endpoints or keeping them updated. Thus, we recommend that CMS publish and update a required attestation by providers, recognizing that this would not address the occasional scenario in which a provider does not participate in CMS programs.

We also propose to revise the requirement in § 170.315(g)(10)(vi) to specify that Health IT Modules presented for certification that allow short-lived access tokens to expire, in lieu of immediate access token revocation, must have such access tokens expire within one hour of the request.

The EHR Association supports this proposal.

We propose to adopt the Substitutable Medical Applications, Reusable Technologies (SMART) Application Launch Framework Implementation Guide Release 2.0.0 (SMART v2 Guide) in § 170.215(c)(2), which would replace SMART v1 Guide.

We propose that the availability of the SMART v1 Guide to be adopted as a standard in the Program would expire on January 1, 2025. After this time, the SMART v2 Guide would be the only version of the IG available for use in the Program.

The EHR Association supports this proposal, as it continues to allow flexibility in how scopes are controlled and displayed – such as allowing for drill downs into sub-types – to the patient to enable the most patient-friendly

experience. However, we encourage ONC to allow scopes to be defined by US Core in alignment with USCDI. Not all levels of finer-grained access should be required, as they could be highly customizable, complex, and burdensome to support.

As part of this proposal, we propose to adopt several sections specified as "optional" in the SMART v2 Guide as "required" for purposes of the Program for certification criteria that reference § 170.215(c). Specifically, we propose to adopt all Capabilities as defined in "8.1.2 Capabilities," which include but are not limited to (1) backward compatibility mapping for SMART v1 scopes as defined in "3.0.2 Scopes for requesting clinical data;" (2) asymmetric client authentication as defined in "5 Client Authentication: Asymmetric (public key);" and granular scopes as defined in (3) "3.0.2.3 Finer-grained resource constraints using search parameters." Additionally, we propose to require support for the "Patient Access for Standalone Apps" and "Clinician Access for EHR Launch" Capability Sets from "8.1.1 Capability Sets." Also, we propose to adopt token introspection as defined in "7 Token Introspection." Again, we clarify that for the period before January 1, 2025, Health IT Modules certified to certification criteria that reference § 170.215(c) may use either SMART v1 or SMART v2 for certification.

The EHR Association supports requiring these previously optional sections, as those which are not named will continue to be considered optional.

Patient Demographics and Observations Certification Criterion in § 170.315(a)(5) - (p. 7-8)

In section III.C.1 of this proposed rule, we introduce proposals to change certain data elements in USCDI, namely Sex (Assigned at Birth), Sexual Orientation, and Gender Identity, that are also data elements in § 170.315(a)(5).

The EHR Association recommends removing this criterion from the program entirely, in favor of aligning with and allowing the maturity of data elements through the USCDI process. This is consistent with how ONC has progressed the program historically, having withdrawn other criteria under the 170.315(a) Clinical category for Problem List, Medication List, Medication Allergy List, and Smoking Status.

Furthermore, many of the updates named in (a)(5) are already accounted for in USCDI v2 and v3 (date of death, sexual orientation) or are planned for future USCDI updates (pronouns, sex for clinical use, name to use). Alignment would allow for greater industry consistency and avoid unnecessary rework, e.g., Sex for Clinical Use is already undergoing revisions with the Gender Harmony Project.

Therefore, to ensure consistency, in section III.C.8 of this preamble, we propose to change the name of the certification criterion in § 170.315(a)(5) from ''demographics'' to ''patient demographics and observations.''

The EHR Association similarly recommends removing this requirement based on the same logic.

We propose to replace the specific codes sets referenced in § 170.315(a)(5)(i)(D) and (E), Sexual Orientation and Gender Identity, respectively, with the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) code set, as referenced in the standard proposed in § 170.207(o)(3)

The EHR Association recommends removing this requirement in favor of aligning with and allowing maturity of data elements through the USCDI process. As noted above, many of the updates named in (a)(5) are already

accounted for in USCDI v2 and v3 or are planned for future USCDI updates. Removing this proposed requirement and aligning with the USCDI process will enhance industry consistency and prevent unnecessary rework.

We propose that the adoption of the code sets referenced in § 170.207(n)(1) would expire on January 1, 2026, and we also propose that health IT developers can continue to use the specific codes in the current terminology standard until December 31, 2025, in order to provide adequate time for health IT systems to transition to the updated terminology standards.

As noted above, we recommend removing this criterion entirely in favor of aligning with and allowing the maturity of data elements through the USCDI process. As noted above, many of the updates named in (a)(5) are already accounted for in USCDI v2 and v3 or are planned for future USCDI updates. Removing this proposed requirement and aligning with the USCDI process will enhance industry consistency and prevent unnecessary rework.

However, if the criterion is maintained and any new proposals adopted, we suggest establishing a deadline that would be a minimum of 24 months after the effective date of the final rule in line with the standards proposed for the Timeliness provisions of the Assurances Condition.

We also propose to add ''Sex For Clinical Use'' (SFCU) as a new data element in § 170.315(a)(5)(i)(F).

The EHR Association supports the addition of this data element, but we recommend ONC wait to do so until it has a matching USCDI data element (likely USCDI v5). We also recommend allowing the data element to be standardly defined in USCDI with input from the Gender Harmony Project before trying to implement it in this rule, which is inconsistent with the Gender Harmony Project as it is proposed.

Most specifically, Gender Harmony Project recommendations as reflected in the USCDI Level 2 data class are for concept-specific observations of a "Sex Parameter for Clinical Use" (not a single observation), and we also note that there is a need to monitor the use of this concept against "ask at order entry" questions. This clearly suggests that the concept is not ready for adoption as a mandatory requirement in the program.

We propose to add new data elements ''Name to Use'' in § 170.315(a)(5)(i)(G) and ''Pronouns'' in § 170.315(a)(5)(i)(H), to facilitate data capture that supports providers' ability to provide culturally competent care for their patients.

While we are supportive of adding these data elements, we recommend waiting until a matching USCDI data element has been finalized (likely USCDI v5). We also suggest waiting for the data element to be standardly defined in USCDI before trying to implement it in this rule, particularly as Name to Use and Pronouns are among Level 2 suggestions.

Updates to Transitions of Care Certification Criterion in § 170.315(b)(1) - (p. 8)

We propose in section III.C.9 to update the ''transitions of care'' certification criterion (§ 170.315(b)(1)) to align it with changes proposed in § 170.213, including the proposed adoption of USCDI v3 in § 170.213(b)). This change would ensure that Health IT Modules certified to § 170.315(b)(1) are capable of accessing, exchanging, and using USCDI data elements referenced in § 170.213.

The EHR Association supports this proposal.

Requirement for Health IT Developers to Update their Previously Certified Health IT - (p. 8)

We propose to make explicit in the introductory text in § 170.315 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 included in § 170.315.

More specifically, we propose in section III.C.11 that health IT developers with health IT certified to any of the certification criteria in § 170.315 would need to update their previously certified Health IT Modules to be compliant with any revised certification criterion adopted in § 170.315, including any new standards adopted in 45 CFR part 170 subpart B and capabilities included in the revised certification criterion.

We further propose 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.

There is an inconsistency between the proposed definition of "provide" and how it is discussed in the preamble that needs to be remedied. Specifically, while the proposed definition is straightforward and speaks only to making the certified health IT available to our customers, HTI-1's preamble states: "We propose that to 'provide' the product means the developer must do more than make the product available and there must be demonstrable progress towards implementation in real-world settings."

Not only does this suggested approach mean that software developers would have even less time to complete our development and testing than has already been unreasonably proposed, but we also assert that developers cannot be expected to force our clients to upgrade to the most recently certified versions of our products.

The role of a developer is to "provide" certified products by a specified deadline. It is up to the healthcare provider or provider organization to determine when to upgrade to or implement the new version, and we have virtually no ability to coerce clients into a timeline that is inconvenient for them or forces them to disrupt their operations at a time that is misaligned with other organizational priorities.

Thus, we strongly request that ONC clarify in the final rule that the definition and expectation for "providing" updated certified health IT to our customers is solely making it available for them to implement at their discretion. When or if a customer chooses to adopt those updates is outside the developer's scope of responsibilities.

While we support the related proposal that developers are not required to provide updates to any customers who may decline them, we note that developers can "provide" updates to customers without them having to accept and adopt them if ONC correctly repositions and redefines what it means to "provide" updates.

Assurances Condition and Maintenance of Certification Requirements - (p. 8)

We propose as a Condition of Certification that a health IT developer must provide an assurance that it will not interfere with a customer's timely access to interoperable health IT certified under the Program.

We propose that a health IT developer must update a Health IT Module, once certified to a certification criterion adopted in § 170.315, to all applicable revised certification criteria, including the most recently adopted capabilities and standards included in the revised certification criterion.

If a developer does not update a module to a revised certification criterion, the EHR Association suggests ONC should retire the certification of the module only certified to the older criterion when the revised certification takes effect. However, requiring attestations about whether or not developers plan to update their products would add unnecessary administrative burden and exceed the scope of a voluntary certification program.

Requirement for Health IT Developers to Update their Previously Certified Health IT - (p. 8)

We also propose that a health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers of such certified health IT.

If a developer does not update a module to a revised certification criterion, ONC should retire the certification of the module when the revised certification takes effect. It remains a developer's decision as to whether they choose to certify their products in ONC's voluntary certification program and whether they choose to continue to upgrade their products to again certify their products in ONC's voluntary certification program as ONC revises criteria. This proposal might confuse certification stakeholders that developers are obligated to continue to participate in the voluntary certification program, and it should be revised or removed.

The EHR Association suggests that ONC needs to make clear in the definition of "providing" that the developer's role in providing updated certified health IT to its customers ends at making it available for implementation at their discretion and supporting that process as the client chooses to move forward – that when/if a customer chooses to adopt those updates is outside the developer's scope of responsibilities. Developers do not have the capacity or legal right to force clients to upgrade to certified products; our role is to provide certified products by a specified deadline. It is up to the provider or provider organization to determine when to upgrade or implement the new version based on their various motivations (including, frequently, payment models from CMS and commercial payers).

If ONC and HHS more broadly are highly focused on providers moving from older versions of software to the newest certified versions, such motivation must be provided by CMS through payment models, attestations, or conditions of certification.

We propose separate ''timely access'' or ''timeliness'' requirements for each of the two proposed Maintenance of Certification requirements above dictating by when a Health IT Module must be updated to revised certification criteria and by when a Health IT Module certified to a revised certification criterion must be provided to the health IT developer's customers.

The EHR Association is highly supportive of the proposal for a 24+ month standard for the incorporation of new updates. However, we are highly concerned about the flexibility ONC maintains to set different deadlines at its discretion and about the implications of these update timelines for providers who need to implement them pursuant to their own requirements under CMS regulations.

EHR developers have proven their nimbleness in adding new requirements to software as the market demands and collaborating with their clients on things that are needed, as was demonstrated with the addition of new immunization and transport of that information to public health agencies throughout the COVID-19 pandemic.

We ask that ONC provide explicit guidelines on when they may propose a deadline exception to the "24 months plus X" post-final rule publication requirement, and then explain when proposing an exception to the usual cycle why the situation merits expedited treatment. We also ask ONC to be thoughtful about how to ramp up to the "24 months" requirement on the first cycle, which we believe would be helpful to developers' product life cycle.

This proposed rule itself is an excellent example of suggested deadlines that are out of sync with this general principle and that may contribute to poorly developed functionality, a situation that would be amplified for smaller developers and community provider groups with fewer resources. In many cases, there is a delay between ONC and CMS final rules, a period during which CMS is defining which certified health IT must be used for their quality and value-based care programs. This delay makes it challenging for providers and provider organizations to effectively plan for necessary upgrades. Because ONC is ultimately the arbiter of the pace at which health IT work must be completed, we recommend that ONC better coordinate rule release with CMS and that changes made by CMS to the certified health IT definition not be effective until the next reporting period/performance year.

Real World Testing – Inherited Certified Status - (p. 8)

***In order to ensure that all developers continue to test the real world use of their technology as required, we propose in section III.E to eliminate this anomaly by requiring health IT developers to include in their real world testing results report the newer version of those certified Health IT Module(s) that are updated using Inherited Certified Status after August 31 of the year in which the plan is submitted*.**

The EHR Association is supportive of this proposal to account for the inheritance model within the certification program, as we believe it aligns well with existing sub-regulatory guidance on Real World Testing.

Insights Condition and Maintenance of Certification - (p. 9)

We propose in section III.F to adopt nine reporting measures for developers of certified health IT that focus initially on the interoperability category, emphasizing four areas of interoperability: individuals' access to electronic health information, public health information exchange, clinical care information exchange, and 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.

We also propose in section III.F to implement the Insights Condition and Maintenance of Certification requirements in § 170.407 in two phases, where some of the measures will be required to be reported earlier than others.

To be feasible, the timeline must be revised significantly to move the deadline to the end of the second calendar year following the final rule (estimated to be December 31, 2025), which would also align with ONC's general 24+x approach. As reporting Insights measures is dependent on clients upgrading to new software versions containing Insights measures, the timelines for Insights reporting must also align with upgrade timelines for the use of CEHRT set by CMS.

"The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions" - (p. 14)

We propose to rename § 170.315 as the ''ONC Certification Criteria for Health IT'' and replace all references throughout 45 CFR part 170 to the ''2015 Edition'' with this new description (this would impact the wording,

though not the substance or effect, of §§ 170.102, 170.405, 170.406, 170.523, 170.524, and 170.550, as shown in proposed revised regulation text, below). We welcome public comment on this proposal.

While the EHR Association is generally neutral as to the proposal for an "edition-less" program on the surface, there are several challenges we ask that ONC address before finalizing the rule:

(1) How to support tracking a continuous stream of deadlines and obligations for both developers and providers in terms of developing and implementing new technologies.
(2) How to limit the complications an "edition-less" program structure introduces in terms of understanding the release and product development cycle and requiring our clients to upgrade their certified product when ONC adopts new criteria.
(3) How to limit the burden and inconsistencies an "edition-less" program structure adds to the development and standards cycles when updates become available and, subsequently, preventing the diversion of resources away from what providers are requesting be developed within health IT.

We propose applicability or implementation timelines for both our certification criteria and the standards adopted in 45 CFR part 170 by establishing the dates by which an existing version of a criterion is no longer applicable and by establishing a date by when a new or revised certification criterion or standard version is adopted. For example, if finalized as proposed, a user and the public would know that a Health IT Module certified to ''revised'' § 170.315(b)(1) would support USCDI v3 (§ 170.213(b)) after January 1, 2025, because we state that USCDI v1 expires on January 1, 2025, in § 170.213(a).

The EHR Association supports the proposed implementation timelines, but we are concerned about the flexibility ONC maintains to set different deadlines at its discretion and about the implications of these update timelines for providers who need to implement them pursuant to their own requirements under CMS regulations. As such, we ask that ONC provide explicit guidelines on when they may make an exception to the "24 months plus X" post-final rule publication requirement and request a thoughtful approach to ramping up to the "24 months" requirement on the first cycle, which we believe would be helpful to developers' product life cycle.

We also reiterate our stance that this proposed rule is an excellent example of proposing to enforce deadlines that are out of sync with this principle (being significantly shorter in some instances) and that will put tremendous pressure on software developers and likely contribute to poorly developed and potentially even safety-compromised product functionality. In many cases, there is a delay between ONC and CMS final rules during which CMS is defining which certified health IT must be used for their quality programs, making it challenging for providers and provider organizations to effectively plan for necessary upgrades. Thus, we recommend that changes made by CMS to the certified health IT definition take effect no sooner than the next reporting period/performance year.

Standards and Implementation Specifications - (p. 18)

We propose that as of January 1, 2025, any Health IT Modules seeking certification for criteria referencing § 170.213 would need to be capable of exchanging the data classes and data elements that comprise USCDI v3.

The EHR Association is generally supportive of ongoing USCDI growth and continued thoughtful expansion to make it more manageable to uplift. However, 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 general approach to certification deadlines.

New and Revised Standards and Certification Criteria - USCDI v3 (p. 19/20)

We clarify that under this proposal, for the time period up to and including December 31, 2024, USCDI v1 would remain applicable as the minimum version of the USCDI required for certification criteria that reference § 170.213.

USCDI v2 would remain available via SVAP for developers of certified health IT who want to voluntarily update their Health IT Modules, or for developers of certified health IT who want to certify to applicable criteria in addition to or instead of USCDI v1 up to and including December 31, 2024.

The current structure of SVAP allows only one new approved version of a standard to be available at a time, which is unnecessarily limiting and misaligned with development cycles/timelines. As such, we recommend updating the SVAP Fact Sheet to allow at least two new versions of the same standard (e.g., USCDI v2 and USCDI v3) to be available under SVAP at a time to accommodate developers' timelines and provider organizations' right to determine their upgrade schedule. Doing so is a reasonable compromise against asking to maintain the availability of all new SVAP-approved versions of a standard in perpetuity. We also recommend that some standards be conditional in that they may only be adopted when dependent standards are also adopted. For example, FHIR US Core and CCDA Companion Guide releases supporting USCDI v3 are not officially published until April, thus the updated USCDI v3 standard should not be utilized until those standards are also formally adopted via SVAP.

Adopting USCDI v3 would provide more comprehensive health data for providers and patients accessing and exchanging electronic health information. USCDI v3 includes Sexual Orientation, Gender Identity, Functional Status, Disability Status, Mental/ Cognitive Status, and Social Determinants of Health data elements including: SDOH Assessment, SDOH Goals, SDOH Interventions, and SDOH Problems/Health Concerns. Access, exchange, and use of these data elements can support more informed care for patients. These data elements are described in more detail below.

i. Social Determinants of Health (SDOH)

In the 2015 Edition, ONC adopted a certification criterion to enable users of Health IT Modules(s) that certified to that criterion with the functionality to electronically capture, modify, and access SDOH data elements—that is information that identifies common SDOH conditions in a standardized manner—in § 170.315(a)(15) social, psychological, and behavioral data (80 FR 62631)

ii. Care Team Member

In USCDI v1, the Care Team Member data class had one data element to capture all aspects about a care team member. ONC received submissions recommending the addition of more granular data elements that provide greater detail around a patient's healthcare provider and other members of the care team. USCDI v3 includes five Care Team Member data elements: Name, Identifier, Role, Location, and Telecom.

iii. Clinical Notes

For the data element Discharge Summary Note in the Clinical Notes data class, we specified additional requirements in USCDI v3 including admission and discharge dates and locations, discharge instructions, and reason(s) for hospitalization, which are also required elements in the Transitions of Care certification criterion (§ 170.315(b)(1)).

iv. Clinical Tests

USCDI v3 includes a data class for Clinical Tests, which has two data elements, Clinical Test and Clinical Test Result/Report. This is a new data class as compared to USCDI v1. These elements will enable the capture and exchange of non-imaging and non-laboratory tests. Some examples include electrocardiogram (ECG), visual acuity exam, macular (ophthalmic) exam, or graded exercise testing (GXT). These tests are routinely performed on patients and result in structured or unstructured (narrative) findings that facilitate the diagnosis and management of a patient's condition(s).

v. Diagnostics Imaging

USCDI v3 includes the Diagnostic Imaging data class and its two elements: Diagnostic Imaging Test and Diagnostic Imaging Report. This is a new data class as compared to USCDI v1. These data elements added a critical missing capability of health IT to capture and exchange structured and unstructured imaging test and report data for a patient.

vi. Encounter Information

USCDI v3 includes the Encounter Information data class, which includes five data elements: Encounter Type, Encounter Diagnosis, Encounter Time, Encounter Location, and Encounter Disposition. This is a new data class as compared to USCDI v1.

vii. Health Insurance Information

USCDI v3 includes the Health Insurance Information data class, which provides an opportunity for health IT to capture and exchange key elements of healthcare insurance coverage. This information can be useful for patient matching and record linkage, coverage determination, prior authorization, price transparency, claims and reimbursement efficiencies, and identifying disparities related to insurance coverage. This is a new data class as compared to USCDI v1. This data class includes seven data elements: Coverage Status, Coverage Type, Relationship to Subscriber, Member Identifier, Subscriber Identifier, Group Identifier, and Payer Identifier.

viii. Health Status Assessments

USCDI v3 includes a data class called Health Status Assessments, which contains four new data elements: Disability Status, Mental/Cognitive Status, Functional Status, and Pregnancy Status.

ix. Laboratory

USCDI v3 includes Specimen Type and Result Status data elements, which have been added to the USCDI Laboratory data class to address public health reporting priorities.

x. Medications

USCDI v3 includes Dose, Dose Units of Measure, Indication, and Fill Status data elements, which have been added to the USCDI Medications data class in response to public feedback and because these data elements are necessary for certain CMS reporting programs and are also critical to certain ONC certification criteria (including the electronic prescribing certification criterion at § 170.315(b)(3)).

xi. Patient Demographics/Information

Based on submissions and comments during the USCDI update processes described above, ONC changed or added data elements in the Patient Demographics/Information data class.

USCDI v3 includes data elements Sexual Orientation and Gender Identity, which have been added to the USCDI Patient Demographics/Information data class. Previously, ONC adopted standards for Sexual Orientation in the demographics criterion in § 170.315(a)(5)(i)(D) and for Gender Identity in the demographics criterion in § 170.315(a)(5)(i)(E). These criteria include requirements to code Sexual Orientation and Gender Identity according to the adopted SNOMED CT® codes and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor as referenced § 170.207(o)(1) and § 170.207(o)(2), respectively.

The EHR Association supports the adoption of these new USCDI v3 data classes. However, the short timeframe for development and implementation is untenable, and we are concerned, as we have expressed elsewhere, about the lack of alignment with CMS timelines. We recommend a timeline that imposes a deadline at the end of the second calendar year following the final rule, estimated to be December 31, 2025. This would also align with ONC's general approach to timeframes.

New and Revised Standards and Certification Criteria - USCDI v3 (p. 21) Patient Demographics

Finally, we have taken note of the substantial effort in this area to develop a clinically meaningful way for identifying a patient's sex from observable information (e.g., Clinical Observation, Radiology report, Laboratory report, genetic testing data) that may be suitable for clinical care, including the development of a new data element Sex for Clinical Use, which we may consider including in future standards adoption. We welcome public comment on this concept and approach.

The EHR Association supports adding this data element to USCDI, though we recommend doing so only once necessary standards and guidance have been promulgated to properly support it. As expressed elsewhere in this comment letter, we also recommend ONC remove this element from proposals for addition to the Patient Demographics and Observations criterion and remove that criterion altogether in favor of direct alignment with USCDI, as has been the approach for other data falling under the 170.315(a) Clinical criteria category.

Additionally, regarding race and ethnicity code sets, while we support the 1.0 to 1.2 upgrade, we are concerned about upgrading to 2022 because the new version changes existing codes, adding an unnecessary burden on the industry. As such, we recommend only adding codes and not changing existing ones. If a change is needed, additional reasoning and use case value would be beneficial (i.e., who benefits from the code change/why is it important to change). *For additional information and context, see EHR Association Comments on the CDC Race and Ethnicity Code System Update.*

We also recommend delaying the 2022 upgrade to allow for more review and industry discussion. In particular, we request additional input from ONC on why the change in codes is needed and how those codes are currently being used.

New and Revised Standards and Certification Criteria - USCDI v3 - (p. 22)

xii. Problems

As discussed in sub-section i of this section, USCDI v3 includes the SDOH Problems/Health Concerns data element added to the prior USCDI Problems data class. In addition, USCDI v3 includes Date of Diagnosis and Date of Resolution data elements added to the prior USCDI Problems data class to include timing elements for recorded and maintained problem lists within electronic health records.

xiii. Procedures

USCDI v3 includes the Reason for Referral data element added to the prior USCDI Procedures data class. This data element is already part of the Program requirements for the transitions of care certification criterion (§ 170.315(b)(1)(iii)(E)) in the ambulatory setting and is broadly implemented in health IT. As discussed in sub-section i of this section, the USCDI v3 also includes the SDOH Interventions data element added to the prior USCDI Procedures data class.

xiv. Updated Versions of Vocabulary Standard Code Sets

In the 2015 Edition Final Rule, we established a policy for minimum standards code sets that update frequently throughout a calendar year at 80 FR 62612, and we have listed several standards as minimum standards code sets in 45 CFR part 170 subpart B. As with all adopted minimum standards code sets, health IT can be certified to newer versions of the adopted baseline version minimum standards code sets for purposes of certification, unless the Secretary specifically prohibits the use of a newer version (see § 170.555 and 77 FR 54268). In USCDI v3, we included the most recent versions of the minimum standards code sets.

While we support the adoption of these new USCDI v3 data classes, we are concerned about the short timeframe for development and implementation required in the proposed rule, as well as the misalignment with CMS timelines. We request 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.

Proposed New Source Attributes for Predictive DSI - (p. 44)

While we do not prescribe how a Health IT Module must indicate that an attribute is missing, we clarify that the Health IT Module must communicate an attribute is missing unambiguously and in a conspicuous manner to a user.

Understanding the genuine benefit of increasing transparency in this area, the EHR Association is nonetheless concerned that the policy efforts being proposed by ONC attempt to use the lever of the certification program to achieve a goal that would be more efficiently achieved through regulations that directly apply to creators of clinical decision alert content. In some cases that would remain those developing EHRs, but in most instances, those creating alerts are either third-party businesses or healthcare providers themselves. Requiring health IT

software developers to expend significant resources to gather information from numerous sources is an unnecessary burden that could be accomplished more effectively by the FDA going straight to the sources.

Further, we are concerned that there are many client- and/or third party-created DSI for which the 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. While we do not want to inflict a greater volume of certification requirements on our clients, we nonetheless believe it would likely be more effective for the industry as a whole if there were separate certifications for the content of interventions vs. the presentation of interventions. Third parties and clients that author their own interventions could pursue the content certification on their own, without making CEHRT responsible for the content of interventions that the developer did not author. Such a certification might be helpful for third parties to market that they have provided the required content, although there would need to be a self-developed exception for their own DSI. This would also provide greater transparency with organizations and users regarding the entity ultimately responsible for furnishing and updating relevant information.

We also seek clarification of the intent of this proposal. Could ONC provide examples of the source attributes to clarify the intention?

Can the definition of what needs a source attribute and what attributes are required be narrowed – especially for well-accepted interventions or recommendations? For example, even content from CDC or the US Preventive Services Task Force does not seem to include all of these source attributes.

We note that it is only feasible to link to or include source attributes for certain displays of clinical decision support, such as interruptive alerts and direct recommendations. Some types of interventions (e.g., highlighting a row) do not provide an elegant place to put source attributes.

If there were an interoperable library of decision support with capability statements, would this be the responsibility of the decision support developer?

Finally, this proposal gives rise to additional concerns. For example, conspicuous labeling of unknown source attributes will clutter the UI.

Patient Right to Request a Restriction New Criterion – Primary Proposal - (p. 77)

We propose to adopt a new certification criterion specifically in support of the HIPAA Privacy Rule's "right to request a restriction" on certain uses and disclosures (See also 45 CFR 164.522(a)).

We propose to add the new certification criterion "patient requested restrictions" in § 170.315(d)(14) to enable a user to implement a process to restrict uses or disclosures of data in response to a patient request when such restriction is agreed to by the covered entity.

We do not support ONC's adoption of this new certification criterion as written. The HIPAA Privacy Rule grants patients broad flexibility in the restrictions they can request, some of which are use-case dependent. 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. The industry will

not be able to support this goal without significant additional guidance and infrastructure that the current proposed standards and implementation guidance documents simply do not yet offer.

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 impacted in their triggering logic based on missing data for which the patient has requested restrictions, which could result in what otherwise would have been preventable medical errors.

Implementing restrictions on disclosures in the context of exchange for treatment, payment, and/or operations undermines the benefits of interoperability and will result in an increased burden on stakeholders that have come to rely on seamless electronic exchange in recent years.

ONC should instead consider adopting a certification criterion for specific, privacy-enhancing features that are designed to support a targeted use case. For example, ONC could create a certification criterion that allows a patient to restrict the visibility of certain clinical notes, lab results, medications, and problems for proxies in the patient portal.

Such a certification criterion would advance privacy for patients by providing additional granular controls over access to their sensitive health information and could be applicable across a variety of use cases (e.g., adolescent and older adult privacy, restricting visibility of reproductive health information, etc.).

Such a revised approach would also mitigate the risks to patient safety and be more feasible to implement, as such a feature would not interfere with the ability of clinicians and other users within a healthcare organization to use the information for treatment, payment, and operations.

We propose that this new criterion in § 170.315(d)(14) would be standards-agnostic, allowing health IT developers seeking to certify a Health IT Module to the criterion flexibility in how they design these capabilities so long as they meet the functional requirements described for certification. We specifically intend the proposed § 170.315(d)(14) to advance the technological means to support clinicians and other covered entities when honoring patient requests for the restriction of uses or disclosure of PHI through certified health IT.

If ONC proceeds with adopting this certification criterion as written, we agree that ONC should provide developers with flexibility in how they implement a patient-requested restrictions feature in their systems. While standards are essential in aligning privacy and patient consent policies to be uniformly shared where data is exchanged, it will be challenging – if not impossible – to standardize the implementation of restrictions on "use" in a given system, given the breadth of activities, workflows, and features in which a patient's information might be used.

We also note that existing standards for segmentation, such as DS4P, have seen low adoption in the industry due to concerns about the feasibility of implementation. Adopting a standards-agnostic approach will allow health IT developers to determine appropriate implementation in their own systems and could lead to the future development of new, consensus-based standards informed by robust real-world implementation experience across a broad set of developers and healthcare provider organizations.

We propose to add the following in § 170.315(d)(14) for this new criterion "patient requested restrictions":

- ***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***
- ***Prevent any data flagged pursuant to paragraph (d)(14)(i) of this section from being included in a subsequent use or disclosure for the restricted purpose.***

We urge ONC to remove this certification criterion, as written, from consideration. The proposed approach provides flexibility to use a variety of techniques to identify data that cannot be shared based on privacy and patient consent rules. ONC also provides considerations of specific standards that could be used to implement the interoperability aspects of this in whole or in part using data segmentation with either C-CDA focused DS4P, FHIR Security Labels, and/or HCS, which runs a high risk of allowing for a wide variety of misaligned implementations.

Meanwhile, the considerations on data segmentation standards create a mindset of dedicated flags on data that leads to a privacy and patient consent management infrastructure that is hard to manage and scale, given that the rules are not static. They change over time, and having to adjust flags that need to be changed according to the updated rules across all the data sources where the patient's data is available (and could be re-shared) is virtually impossible to manage. It invites challenges in ensuring an orderly and aligned progression in advancing the ability to manage the definition, maintenance, application, and scaling of privacy and patient consent rules properly and comprehensively.

If ONC does choose to pursue segmentation, it should be done holistically as part of a broader privacy and patient consent policy management infrastructure in conjunction with other relevant agencies. Such an approach would need to address both the appropriate identification of sensitive data and how to apply policies that define permissible uses and disclosures to that data based on patient-defined preferences. A patient's data holder can then assert whether they can share certain data with others using the most current policies and using any exchange and access method/standard. That is a daunting but essential ability to be developed and matured that cannot be achieved by requiring CDA DS4P and FHIR Security Labeling alone. Instead, it must cover HL7 v2 and other exchange and access methods, as well. Further, it should identify a specific data class or element and functional capability as an initial targeted implementation and specify one or more restrictions that health IT is able to support. For example, restricting data from being available to be viewed by proxies in the patient portal or from being shared via patient access FHIR APIs. Another option is the ability to opt out of the exchange of the entirety of the patient's record in health information networks from the patient portal.

Such an undertaking would also require collaboration with policy and technical stakeholders from across the healthcare industry. ONC would need to work with OCR and SAMHSA, as well as its Congressional partners and stakeholders from the health IT and provider communities to redesign HIPAA rules and the right to request a restriction in a manner that is congruent with patient-specified consents.

In the interim, we also urge ONC to narrow the set of data for which restrictions can be requested, 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.

We propose that the new "patient requested restrictions" certification criterion in § 170.315(d)(14) would be required for the Privacy and Security Framework by January 1, 2026.

If ONC narrows the scope to a limited set of USCDI v3 data elements for which restrictions can be requested and clearly and narrowly defines the set of restrictions that certified health IT must support (e.g., restricting the specified data from being accessed by proxy users of the patient portal), two years from the publication of a final rule would be feasible. If ONC instead adopts an approach that does not narrow the scope or pursues a holistic effort to also address updates to consent policies, a significantly longer implementation period will be required (i.e., four years or longer). Time will be needed to work with the standards development community to build consensus on how sensitivity classifications should be applied to data elements and value sets, the set of restrictions that can be implemented, and the method for standardizing the collection of consent before development can begin. A development project to take on that scope would likely require two to three years to code and test and another one to two years for healthcare organizations to implement.

We do not propose any changes to the current certification criteria for "security tags - summary of care - send " and "security tags - summary of care – receive" in § 170.315(b)(7) and § 170.315(b)(8) respectively; however, we note that the inclusion of the proposed new certification criterion in § 170.315(d)(14) into the Privacy and Security Framework in § 170.550(h) would mean that the proposed new certification criterion would be applicable for Health IT Modules certified to the security tags—send and security tags—receive certification criteria as well. We seek comment on whether those certification criteria should also be directly modified in alignment with the proposals described in this section.

We agree, for now, with keeping the other tagging criteria focused on the existing DS4P standards. However, as the industry pursues the long-term vision we described previously, ONC should revise the DS4P and segmentation certification criteria to ensure they align with current consensus and standards.

We seek comment on the capabilities we have proposed for the new criterion in relation to the HIPAA Privacy Rule right to request a restriction. We specifically seek comment on whether the proposed new criterion should include additional functions to better support compliance with the HIPAA Privacy Rule right to request a restriction.

These are examples of the complexity and safety risks associated with supporting segmentation or restrictions on the use or disclosure of patient records. We recommend focusing on the narrow patient-facing privacy controls suggested above to avoid running into these risky, burdensome, and complex scenarios.

Finally, we seek public comment on each part of this proposal—the new criterion in § 170.315(d)(14), the inclusion of the request capability for patients in § 170.315(e)(1), and the requirements with the Privacy and Security Framework in § 170.550(h)—both separately and as a whole. We specifically seek comment on the feasibility of each part in terms of technical implementation and usefulness for patients and covered entities using these capabilities.

We also seek comment on the health IT development burden associated with implementation of the capabilities including for the individual certification criterion referenced in the Privacy and Security Framework in § 170.550(h).

The EHR Association notes that restricting access to data within and across a patient's data addresses patients' privacy concerns but may lead to incomplete records in critical care decision-making that could impact the patient's care and safety.

The HIPAA Privacy Rule grants patients broad flexibility in the restrictions they can request, some of which are use case dependent. It is simply infeasible for developers to implement support for every permutation of restrictions on the use of data that a patient might request; it is often impossible to programmatically map the purpose for which data will be used to a patient-defined purpose for which the restriction applies.

We recognize that striking this balance is challenging, but such a balance must be found that addresses both patients' privacy concerns and the need for complete medical records while creating the least amount of documentation burden to the provider. Patients and policymakers must be able to establish reasonable and easily computable rules to honor the policies and restrictions once defined, without endangering patient safety.

We therefore strongly recommend that ONC initially focus on the narrow patient-facing privacy controls suggested above to avoid the creation of risky, burdensome, and complex scenarios, based on data already being documented.

In addition, we seek comment on any unintended consequences that the new criterion in § 170.315(d)(14) or the addition to the Privacy and Security Framework in § 170.550(h) might place on patients, clinicians, or other covered entities using certified health IT. We seek comment on whether, and by how much, the use of this criterion as part of broader privacy workflows might represent a reduction in manual effort for covered entities, a positive impact on uptake by patients, or other benefits such as supporting documentation of restrictions as required under the HIPAA Privacy Rule in § 164.522(a)(3).

We have identified several unintended consequences related to the proposed new criterion, including the added burden on providers to tag sensitive data at an individual element/item level and the added patient safety risk associated with providers not having the full record. Additionally, reduced availability of data for exchange and for use in operational needs for activities like quality reporting could reduce the reliability of metrics and the value of interoperability, while extracting data for TPO may add to the administrative burden.

Additionally, regulatory complexity could lead to missed expectations for patients about how their data is used and privacy preferences are respected, which could lead to a loss of trust if patients do not believe their preferences are being honored. Also, if patients are presented with complex data-element sharing options, they may get confused and, in an attempt to simplify, wind up deciding against sharing any data. This would limit the benefits of health information networks that have grown over the last several years.

Insights Condition and Maintenance of Certification – General

(1) Insights Condition is structured as 9 individual "measures" under various categorizations, each of which contains several "sub-measures" formatted in a numerator/denominator set which are repeated across different measures in some instances.

(2) Timeline proposed as 6-month continuous reporting periods with a 6-month "buffer" between close of reporting period and submission deadline. Measures 1,4,8,9 first submission = April 2025 (measure Apr-Sept 2024); measures 2,3,5,7 first submission = April 2026 (measure Apr-Sept 2025)

(3) Obtaining data from customers: "We also note that there may be other factors that could impact a developer of certified health IT's ability to easily collect data to comply with the Insights Condition's requirements. For example, a developer of certified health IT may have contracts or business agreements that inhibit the health IT developer's ability to collect data from its customers. We note that in such scenarios, developers of certified health IT would need to renegotiate their contracts if we finalize our proposals."

The EHR Association has, over the past few years, provided detailed feedback on several rounds of draft measures for the EHR Reporting Program. While we appreciate that some of that feedback has been incorporated into HTI-1, the proposed measures still lack the basic structure and clarity that are necessary for effective and consistent reporting. Our comments on individual measures outline some of those main concerns and associated recommendations.

First, we recommend re-structuring the measure for the Condition into a single set of measures (metrics) in a single table format identifying the associated applicable criterion. This would avoid duplication of measurement across different categories and would also avoid the impression that there are only nine measures when there are actually many more. Each numerator and denominator "metric" should be denoted with a unique row in the table and could still be categorized as they are currently for alignment and identification of the associated criterion that determines whether a developer is subject to reporting on the particular measure. We have provided a sample of what this would look like for the existing "sub-measures" which also includes specific feedback: Table of Insights Measures. *Please note that for all comments on individual measures, any recommendations or concerns specific to only one numerator or denominator are encompassed in this table. Comments applying to the measure as a whole or multiple numerators/denominators are maintained in this primary comment letter.*

Next, we urge ONC to restructure the timing for annual reporting submission and delay the start of the first measurement period until at least CY 2025, assuming a final rule is published in late 2023. 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.

The EHR Association recommends ONC require a full 12-month reporting period aligned to each CY with submission by June 30 of the following CY (five months for data organization with an overlap of the next measurement period). If ONC chooses not to follow this path, we offer the following alternatives for consideration.

a) Report on a fixed six-month reporting period aligned to July-December of each CY with submission by June 30 of the following CY (five months for data organization, and submission complete before the new measurement period commences).
b) Report on a fixed six-month reporting period aligned to July-December of each CY with submission by July 31 of the following CY (six months for data organization, and submission completely overlaps with the first month of the next measurement period).
c) Report on a full 12-month reporting period aligned to each CY with submission by July 31 of the following CY (six months for data organization with an overlap of next measurement period).

Regarding obtaining data from customers, ONC should provide embedded exceptions/flexibility for developers who face challenges acquiring data due to customer resistance and/or contractual barriers (or other similar reasons). This should 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 along with clarification that developers are not responsible for including data from any who resist. If a health IT developer were to email, send a letter, and attempt to hold individual conversations with their clients to secure their participation and still find that they had a small number of clients willing to participate, that should be considered sufficient effort and satisfactory in meeting their obligation. Further, establishing a minimum threshold of customers is not viable as the number available to work with or who agree to participate varies widely across developers. It is also not reasonable for ONC to expect longstanding contracts to be renegotiated to facilitate Insights reporting when clients have zero motivation to agree, as such reporting offers no direct benefit to the customer.

Instead, ONC should consider collaborating with CMS to adopt attestation statements as part of the Medicare PI program and MIPS PI performance category under which participants would need to attest to agreeing to allow data from their systems to be utilized for Insights Condition reporting. Existing attestations exist for agreeing to cooperate with ONC-ACB surveillance activities, so such an addition would not be unprecedented.

As a separate burden reduction effort, we ask ONC to specifically clarify that where there is overlap between the Insights and Real World Testing Conditions of Certification (e.g., same certified health IT 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 reduces burden for developers while presenting no clear downside for the needs of ONC and the purpose of the respective requirements.

Insights Condition and Maintenance of Certification - Cross-cutting Requirements - (p. 86)

"...there are certain requirements that we propose to apply across multiple measures, including but not limited to: (1) data submitted by health IT developers would be provided and aggregated at the product level (across versions); (2) health IT developers would provide documentation related to the data sources and methodology used to generate these measures; and (3) health IT developers may also submit descriptive or qualitative information to provide context as applicable."

The EHR Association has several concerns with this proposal, including the requirement for product-level reporting exclusively, as it is problematic for many of our member developers. Developers with integrated products or platforms are not able to differentiate certain Insights measures per product as drafted, making product-level reporting impossible.

Further, while we are generally supportive of accompanying documentation for measurement approach, ONC needs to be explicit about the expectations for such documentation. We also support the flexibility to provide additional information beyond the standard required documentation outlined above, as/if needed. However, developers should have the option of keeping this confidential.

We recommend that ONC adopt a flexible approach wherein developers can choose the level at which they report – product or developer – and require an attestation to understand what that level is. We also object to forcing or allowing any reporting at a level lower than a certified health IT module (product). This is similar to the level of flexibility currently afforded under Real World Testing, where plans can cover multiple or individual modules.

We also recommend that ONC adopt the requirement for specific documentation related to measurement but establish clear and consistent topics and categories on which to provide information for consistency purposes.

Further, we recommend allowing developers to provide additional information beyond the required minimum details when deemed necessary or appropriate and allow the option to keep this information confidential where requested.

"For measures where patient encounters are relevant, we propose the definition of an encounter should be based on the National Committee for Quality Assurance (NCQA) outpatient value set and SNOMED CT inpatient encounter codes. For outpatient codes, developers should use NCQA's Outpatient Value Set.[324 325] For inpatient codes, developers should use SNOMED CT codes 4525004, 183452005, 32485007, 8715000, and 448951000124107.[326] Listed below is a description of each SNOMED CT code:"

The EHR Association supports the approach of aligning with the definition of encounters used for eCQM reporting. However, the proposed methodology for identifying encounters is confusing as to the intended scope and how the specific codes identified are to be interpreted (e.g., as definitional components that can be mapped or as literal components?). The methodology also does not align well with other standards, such as FHIR for the Encounter.type field.

As such, we suggest ONC develop a simpler definition of encounters that developers can apply to their own systems and encounter classification structures or establish a clear set of encounter type categories with fully defined mapping such as OMB/CDC Race categories/details. If ONC wants to continue using a subset of all allowable encounter types under 308335008, we suggest that it coordinate with CMS to ensure that the value set referenced in FHIR US Core Encounter.type either includes all SNOMED and CPT codes in the proposal or identifies alternatives that are within the value set without needing to depend on extensibility, as that may lead to inconsistent use of applicable type codes.

"...a developer of certified health IT would be expected to report as required by each measure under the following circumstances:

- ***If the developer has at least 50 hospital users or 500 clinician users across their certified health IT products;***
- ***Applicable criterion/criteria associated with the measure; and***
- ***If the developer has any users of the applicable criterion/criteria associated with the measure.***

Otherwise, the health IT developer would report that it does not meet the minimum reporting qualifications."

We support the proposal to allow exceptions from measurement for developers with a customer base under a certain threshold ("minimum reporting qualifications"). However, we strongly suggest there should be product-level exceptions instead of developer-level. This would be more appropriate to account for scenarios where a developer may have a larger customer base but an individual product with a minimal scope of users that could be subject to one or more measures. Applying exception thresholds at the product level would account for this scenario while still accommodating developers who meet the thresholds across all products in total. As such, we recommend ONC maintain the proposed thresholds and policy for "minimum reporting qualifications" but apply these thresholds to individual products.

Insights Condition and Maintenance of Certification - Individuals' Access to EHI Measure

Proposed measure specifications: https://www.healthit.gov/sites/default/files/2023-04/1.Measure_Spec_Individual_Access_1.3.pdf

The EHR Association supports the general intent and focal points of the proposed measure, but several issues require remedy prior to finalizing the specifications.

First, given that ONC proposes to apply reporting at the product level, the structure of this measure does not align. Many products implicated by one criterion or the other ((e)(1) or (g)(10)) will not be certified to both. Even if our recommendation is followed to allow flexibility for reporting at the developer level, it is more sensible to separate these out as distinct measures focused on each "category" of individual access (VDT via patient portal vs. FHIR via apps) and combine results as necessary for ONC's metric purposes. Crossing measurements across different products will inherently create issues and inconsistencies.

Second, the access method of "App offered by the health IT developer or health care provider…" is problematic as this is not readily available information for developers. Per the API Condition and Maintenance of Certification requirements, we are held to treating all (similarly situated) app developers the same, which means that making distinctions based on whether the app is owned by a certified health IT developer or by a healthcare provider is not something we do – they are all "API Users" as defined by ONC.

Finally, as defined, the measure appears to focus solely on instances of a patient accessing their own record (exclusive of access events by authorized representatives). This is based on the consistent use of "access their EHI" language throughout the measure specifications and requires further clarification.

Based on these concerns, we recommend that the measure be split into two separate measures applicable to products (certified Health IT Modules) certified for the 170.315(g)(10) criterion and 170.315(e)(1) criterion, respectively. These measures would maintain the proposed numerators and denominators as structured, but only for the types of access methods applicable to the relevant criterion. They would also remove the proposed "App offered by the health IT developer or health care provider…" method of access type that applies to products certified for the 170.315(g)(10) criterion.

The types of access methods should also be reduced to just two categories:

1) Patient portal using technology certified to the "view, download, and transmit to 3rd party" certification criterion under § 170.315(e)(1) only OR
2) App using technology certified to "standardized API for patient population services" certification criterion under § 170.315(g)(10).

These access categories would then be separated out by their individual metrics associated with the appropriate criteria.

Finally, we request that ONC clearly state that the scope of the measure is for patients accessing their own records, exclusive of authorized representative access events.

Please see additional recommendations on specific numerators/denominators for the measure in Appendix A - Table of Insights Measures.

Insights Condition and Maintenance of Certification - C-CDA Mechanism Measure.

Proposed measure specifications: https://www.healthit.gov/sites/default/files/2023-04/2.Measure_Spec_CCDA_Mechanism_1.3.pdf.

While the EHR Association supports the general intent and focal points of the measure, several issues require remedy prior to finalizing the specifications. First, the definition of "duplicate C-CDAs" is problematic as it specifies both documents with the same identifier and documents with "substantially identical data." The former is appropriate as it is a clear line that can be drawn by technology. The latter, however, is infeasible. Where would ONC suggest software developers draw the line? If there is just one data element that is different, is that a unique document, or is there a threshold? It is also extremely challenging technically to compare the full set of content of every document received against each other to detect uniqueness. ONC needs to limit this definition to documents with duplicate identifiers, particularly for smaller developers.

Second, ONC notes that "obtaining a C-CDA without any data would not count as receipt." This needs further specificity. Does this mean that if there is at least one piece of data, even if there are only demographics in the header, it is valid? This is also asking us to break open the C-CDA document to determine this, which is overly burdensome and not the correct stage of measurement to be doing so (that would be relevant at the reconciliation layer). We recommend defining an applicable document as a valid file format with a header indicating it is a C-CDA R2.1 document template.

Finally, further clarity is needed on how to define "obtained" for the metrics within this measure beyond the "push" and "pull" clarification provided in the specification sheet.

We recommend re-defining "duplicate C-CDAs" as strictly those without an identical document identifier. Further, we recommend defining an applicable document as a valid file format with a header indicating it is a C-CDA R2.1 document template for the CD, Discharge Summary, and Referral Note document templates. Finally, we recommend that the definition for "obtained" be clarified as documents that were actually "associated" to a patient in the system, i.e., if something is sent inbound and sits in an inbox where it's never viewed/used or is otherwise not fully tied to a patient, then it would be excluded from the count.

Please see additional recommendations on specific numerators/denominators for the measure in Appendix A - Table of Insights Measures.

Insights Condition and Maintenance of Certification - C-CDA Reconciliation

Proposed measure specifications: https://www.healthit.gov/sites/default/files/2023-04/3.Measure_Spec_CCDA_Reconcile_1.3.pdf

We are supportive of the general intent and focal points of the measure, however, several issues require remedy prior to finalizing the specifications.

We recommend re-defining "duplicate C-CDAs" to strictly those without an identical document identifier.

Additionally, ONC notes that they believe this to be a low burden to implement because many developers already support similar measurements for g2 certification of PI/MIPS measures. However, this is comparing apples to oranges, as this measurement is across our entire customer base as opposed to providing reporting used by individual customers separately for their own population. As such, this measurement imposes a noteworthy burden even for developers certified for applicable g2 measure calculation today.

Please see additional recommendations on specific numerators/denominators for the measure in Appendix A - Table of Insights Measures.

Insights Condition and Maintenance of Certification - Supported Apps Measure

Proposed measure specifications: ***https://www.healthit.gov/sites/default/files/2023-04/4.Measure_Spec_Supported_Apps_1.3.pdf***

The EHR Association is generally supportive of this measure, but requests clarification on whether any FHIR resources supported by a CEHRT need to be counted. We recommend that FHIR resources be isolated within the scope of criterion 170.315(g)(10) for consistency across developers, which would be USCDI v1 resources. This is also appropriate given the alignment with the scope of the criterion to which the measurement applies.

Further, while we appreciate the standardized list of purposes and uses provided, we request that ONC directly acknowledge that incorporating these questions into our registration process as hard requirements would not violate the API Condition of Certification. We also note that, for those apps that are already registered, it may be difficult obtaining this information reliably until such a point where they may need to re-register their app after changes or similar reasoning. Accordingly, we would like to make the ONC aware that there will likely be a disproportionate number of "unknown" entries during the early years of reporting.

Insights Condition and Maintenance of Certification - Use of FHIR Measure

Proposed measure specifications: ***https://www.healthit.gov/sites/default/files/2023-04/5.Measure_Spec_Use_FHIR_1.3.pdf***

The EHR Association requests clarification on whether any FHIR resources supported by CEHRT need to be counted. We recommend isolating FHIR resources within the scope of criterion 170.315(g)(10) for consistency across developers, which would be USCDI v1 resources. This is also appropriate given the alignment with the scope of the criterion to which the measurement applies.

Please see additional recommendations on specific numerators/denominators for the measure in Appendix A - Table of Insights Measures.

Insights Condition and Maintenance of Certification - Use of FHIR Bulk Data Measure

Proposed measure specifications: ***https://www.healthit.gov/sites/default/files/2023-04/6.Measure_Spec_Use_FHIR_Bulk_1.3.pdf***

The EHR Association requests clarification on whether any FHIR resources supported by CEHRT need to be counted. We recommend isolating FHIR resources within the scope of criterion 170.315(g)(10) for consistency across developers, which would be USCDI v1 resources. This is also appropriate given the alignment with the scope of the criterion to which the measurement applies.

We also request clarification on whether the specification of "operationalized as [FHIR ServerBase]/Grou/[group id]/$export" is used for both numerators in this measure. We are unsure whether the count should be on the completion of the group export request, regardless of whether that group export was subsequently accessed/downloaded by the requestor, or whether the latter is the count needed. We recommend this be the number of completed requests, regardless of whether they are subsequently accessed by the requestor.

Please see additional recommendations on specific numerators/denominators for the measure in Appendix A - Table of Insights Measures.

Insights Condition and Maintenance of Certification - EHI Export Measure

Proposed measure specifications: https://www.healthit.gov/sites/default/files/2023-04/7.Measure_Spec_EHI_Export_1.3.pdf

This measure is feasibly written.

Insights Condition and Maintenance of Certification - Immunization Administration Measure

Proposed measure specifications: https://www.healthit.gov/sites/default/files/2023-04/8.Measure_Spec_Immune_Admin_1.3.pdf

We recommend that this measure be initially implemented without stratifications (by IIS and by age group) and instead require only overall administration submission numbers. The level of burden to stratify these measures is not fully appreciated by ONC in the proposed rule, nor would it provide suitable value to rationalize the request.

Please see additional recommendations on specific numerators/denominators for the measure in Appendix A - Table of Insights Measures.

Insights Condition and Maintenance of Certification - Immunization Query Measure

Proposed measure specifications: https://www.healthit.gov/sites/default/files/2023-04/9.Measure_Spec_Immune_Query_1.3.pdf

Please see additional recommendations on specific numerators/denominators for the measure in Appendix A - Table of Insights Measures.

Requests for Information

Laboratory Data Interoperability RFI - (p. 103)

1. Which implementation guides or other standards should ONC adopt in certification criteria for health IT supporting transmittal and receipt of laboratory orders, laboratory results, and directory of services?

We do not believe it is necessary to adopt additional certification requirements for lab transactions. Rather, we recommend ONC instead focus primarily on LOINC, SNOMED, and UCUM improvements and mapping. Further, directory of services improvements could be handled in either the HL7v2 or FHIR spaces, in which case it would make sense to focus additional investment on FHIR (HL7v2 eDOS, FHIR Catalog, and FHIR LIVD).

We note that enabling access to this data does not require all EHRs to receive/ingest such data, whereas general catalog services and mapping (as envisioned by SHIELD) can enable access to the relevant data to those configuring their LIS and ordering health IT systems.

2. The utility and maturity of existing HL7 v2 and C–CDA standards supporting laboratory interoperability and the impact of moving to FHIR-based laboratory data exchange.

The EHR Association feels it would be extremely disruptive to change standard requirements that are already well-established in this space, given that HL7 v2 is already widely used for orders and results exchange between EHRs and lab systems and other pre-defined partnerships. HL7 v2 has demonstrated its value in managing both the lab structure of data and the lab workflow needs (e.g., status/task management, error handling, handling abnormal test result escalations, etc.). Further, CDA allows the broad exchange of lab results as part of documents that do not require the detailed data necessary to support operational workflows enabling laboratory test orders and results reporting conformant to CLIA.

Further, while FHIR is helpful in a query model, such as patient access to their lab results, FHIR-event-based models are immature and would require a significant investment of time to make advancements that support the laboratory orders and results workflows for little return.

3. What barriers would additional health IT certification criteria for laboratory interoperability create for developers and other interested parties, and how might this affect adoption and use of such technology?

Certification increases costs and, with the absence of incentives for providers or laboratories to upgrade their interfaces to the latest HL7 v2 standards and implementation guides, offers little added benefit – particularly because of the broad adoption of current criteria. Focusing on select profiles addressing additional data that can be added to existing HL7 v2 laboratory messages and enhancing the use of key vocabularies (including LOINC, SNOMED, LOINC, and select other value sets identified in the latest implementation guides) would yield substantial benefits without the high and unnecessary cost that would come from requiring wholesale replacement of all existing laboratory orders and results interfaces.

4. Would developers of laboratory information systems or in vitro diagnostics systems that have not traditionally submitted products for certification under the Program seek out and benefit from certification to criteria relevant to such developers' products?

As it relates to Laboratory Data Interoperability, we would expect that demand and benefits would be limited, given the substantial cost to upgrade all interfaces to be certified, particularly given that laboratories and providers are not incited to perform upgrades that would largely be replacements without useful new functions.

Only where incentives are aligned across all participants in the workflow and build on existing implementations (e.g., by focusing on new data requirements, e.g., AOEs, pandemic data, and genomic data, for which profiles have been defined that can work with existing interfaces) is there a potential opportunity for certification to yield sufficient additional benefits without the cost of like-for-like upgrades.

5. Are there any other steps that ONC and HHS should consider taking to advance laboratory interoperability?

There are several steps that should be taken into consideration. Appropriate, consistent use of LOINC and SNOMED codes in particular is a substantial challenge in standardized exchange. While frequently sufficient to support the immediate completion of the order and result report, the use of consistent decision support tools and data analytics at a population level requires more consistent and complete use of industry-standard vocabulary.

As such, significant time and accuracy are required to map these concepts. To enable industry success in this effort, we urge you to go directly to the source by collaborating with CLIA and the FDA on standardizing how lab codes are set in the LIS, which will in turn provide a consistent expectation for downstream systems such as EHRs.

Similarly, enabling the use of relevant device information from the source should start with the source being able to include the relevant device identifiers; those can then be passed along for subsequent analysis before requiring downstream health IT (such as EHRs) to be able to capture and include such data within their reporting.

Formulary and Benefit Management - (p. 108)

We seek comment on whether we should further explore capabilities for Health IT Modules to support access to formulary and benefits information, specifically:

- ***Should ONC propose a new certification criterion that would enable a user to use a Health IT Module to obtain formulary and benefits information using a more recent NCPDP Formulary and Benefit standard?***

- ***What current challenges do health care providers face in obtaining formulary and benefit information and would a standards-based criterion help to address these challenges?***

- ***Should ONC consider incorporating functionality using the NCPDP Formulary and Benefit standard within the potential real-time prescription benefit criterion discussed above, rather than creating an independent criterion for formulary and benefits functionality?***

- ***What are the key benefits health care providers would likely experience from availability of functionality within certified health IT utilizing the most recent NCPDP Formulary and Benefit standard? If formulary check capabilities have already been widely adopted, how would certification of these capabilities benefit providers?***

This information can be very useful to a patient when presented within the patient portal, more so than as part of the provider workflow. This is based on feedback we have received from providers indicating that the formulary and benefit information can be overwhelming and too much to consume when presented as part of their workflow.

We also have several other concerns: one being the impact on overall system performance if RTPB criteria were required for every prescription that is written. Another is based on our skepticism about overall industry readiness for this type of criteria.

RTPB is a good criterion to consider as certification requirements and to make visible for providers when they are prescribing medications for their patients. However, while we would be comfortable with ONC moving forward with this RTPB criteria, we do not feel that formulary and benefit criteria need to be considered within this criterion. Nor do we feel there is a need to create a new (separate) formulary and benefit criteria.

Electronic Prior Authorization - (p. 109)

We invite comments on the potential incorporation of these transactions into the ''Electronic prescribing'' certification criterion and whether we should consider requiring certification to these transactions in a future rulemaking.

The EHR Association is supportive of ePA functionality, which is something the industry as a whole is moving towards. It could clearly greatly help with the prior authorization process that causes so much frustration today, including reducing the time it takes to complete.

However, we strongly encourage ONC to allow sufficient implementation time for providers and provider organizations if this functionality is required in the future. This would be a hugely significant work effort for all stakeholders involved.

Certification Approaches - (p. 110)

If ONC were to propose and finalize additional pharmacy interoperability certification criteria similar to those discussed in this RFI, what would be the challenges of testing each criterion individually? // Could a bundled approach to testing more than one pharmacy interoperability criterion in a single testing event address these challenges? What other principles or parameters should be applied to such an approach?

The EHR Association is not concerned with whether certification criteria are bundled or tested separately, as we do not believe either will create meaningfully different challenges.

If ONC were to propose an alternate approach to bundled testing for related certification criteria, should such an approach be required for any product a health IT developer seeks to certify to multiple criteria within the bundle, or should it be optional?

We suggest that ONC consider an optional approach to allow for greater flexibility.

FHIR Subscriptions Request for Information - (p. 110)

We seek input on the maturity of these resources in the FHIR Release 4 standard that is incorporated in 45 CFR 170.315(g)(10)

FHIR R4 Subscriptions is not sufficiently defined, and there are no known real-world cases currently live. Additionally, the approach was substantially changed in FHIR R4B and then even further in FHIR R5. As such, we do not believe it is ready for use in production, but the FHIR R5 could instead provide a more appropriate target for consideration.

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.

R5 Subscription is more mature and better defined, although it too has not yet seen any real world. Additional industry guidance is needed. Therefore, we recommend encouraging HL7 and other industry groups to outline how R5 subscriptions could be used with R4 content such that the community could leverage the investment in R4/USCDI content.

Use cases should be defined to weigh opportunity, how it will improve outcomes, and likely burden to the system. For example, starting with event-based subscriptions like event notifications and allowing well-defined workflows to be trigger points. More complex subscriptions (e.g., whenever a field changes) could put more burden on the system and cut down on performance and other benefits.

Furthermore, 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 for clients using the services.

We suggest starting small, defined around use cases, with a subset of topics that will provide the most benefit. While the standards have matured, there are still few if any real-world implementations of subscriptions, so starting with a small scope can make sure the model has time to be tested out in production.

It is also important that implementation guidance is established to enable consistent and scalable capabilities across a large set of health IT solutions managing the same data. Thus, certification to the base standard would not achieve the necessary benefits given the variety of incompatible implementations that would yield.

We also invite comments on appropriate industry-led activities to maintain and keep the artifacts up to date.

We recommend continuing to rely on the standards bodies to maintain and upkeep specifications. Also, consider working with Argonaut to launch a project to define the starting subscription topics/events for industry testing, holding a connectathon, and creating a specification that can be referenced in the future.

Additionally, we welcome comments on security, channels, payloads, and any other areas that would need to be further specified to achieve our goal of providing subscription capabilities across certified Health IT Modules in a consistent and standardized manner using an already adopted standard.

The specification allows for many options and configurations. We recommend focusing the industry on specific FHIR subscription channels and payloads that leverage the work the community has already done in the space. We also recommend starting with the rest-hook channel and supporting payloads that are either empty/event-only or id-only so that the client can continue communicating with FHIR servers (EHRs) as they do currently. This would give the community a good starting place for leveraging existing support and building on it in the future.

Clinical Decision Support Hooks Request for Information - (p. 111)

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.

CDS Hooks has naturally been gaining industry use without the need to regulate the general framework. While we are supportive of this infrastructure, we do not see a benefit in broad requirements, given our concern that such an approach could be overly burdensome and ultimately miss out on defining clear outcomes CDS Hooks

could deliver. Instead, we suggest naming specific Implementation Guides for specific workflows (e.g., the prior authorization IG utilizing CDS Hooks) that would benefit from certification, thus ensuring the use of CDS Hooks is consistent in the context of that workflow.

FHIR Standard for Scheduling Request for Information - (p. 111)

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.

This IG is a great fit for specific use cases and contexts but does not need to be regulated or required, as not every system would have to support this particular method to enable access to available scheduling slots. As this specification is already experiencing natural adoption when needed, we do not see any added benefit to requiring its broader use.

Furthermore, 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.

While the EHR Association generally supports increasing the discoverability of FHIR endpoints, we recommend leveraging TEFCA or another broader initiative for endpoint directory and availability. This is not the right place to invest in endpoint publishing.

We also invite comments on any other appropriate industry led activities that we should consider for potential models and approaches, such as the Argonaut Scheduling Implementation Guide.393

Argonaut Scheduling IG is based on FHIR STU3 and would need further changes to make it a good choice, for example by uplifting to R4. We do not see any added benefit to requiring specifications for broader use.

Additionally, we welcome any other comments on how to ensure accuracy and timeliness of appointment information.

We do not see a benefit in broad requirements, which could be overly burdensome and miss defining clear outcomes. Instead, look to name specific implementation guides for a specific need, which we believe would be a better method of scoping a requirement if one is needed.

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.

The EHR Association does not see a benefit in broad requirements, believing such an approach to be overly burdensome. It could also miss defining clear outcomes. Instead, we suggest naming specific implementation guides for a specific need would be a better method of scoping a requirement if one is needed.

SMART Health Links Request for Information - (p. 112)

We seek input on the value and feasibility of the SMART Health Links Protocol, as well as concerns regarding its implementation.

This specification should not be a requirement, as it is a very new generic framework. A better first step would be to focus on use cases that demonstrate benefits with associated implementation guides that support consistent scaling across all relevant health IT.

Furthermore, we invite comment from the public on approaches ONC could take, within our authorities, to encourage rapid advancement of the technology.

We recommend continuing to rely on industry groups like HL7 and accelerators like Argonaut that can rapidly create, test, and implement specifications for specific use cases. We also recommend allowing these to mature before naming in a requirement.

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.

While the Association is clearly supportive of FHIR generally, there is currently enough to focus on in the space. We, therefore, do not recommend additional initiatives be added at this time. Additionally, we recommend that future direction continue to leverage standards' natural maturity/adoption, align with other initiatives like TEFCA, and encourage global consistency with concepts like IPA and IPS.

Information Blocking

Health IT Developer of Certified Health IT: Self-developer Health Care Providers - (p. 119)

To ensure it is immediately clear from the face of the regulations' text that we had put all health care providers that engage in other activities consistent with exclusions (1) through (3) from the offer health information technology or offer health IT definition on the same footing regardless of who develops the health IT involved in these activities, we would revise the health IT developer of certified health IT definition in § 171.102. Specifically, we propose to replace ''other than a health care provider that self-develops health IT for its own use'' with ''other than a health care provider that self-develops health IT not offered to others.'' We have proposed this updated definition in the draft regulation text section of this rule to reflect this proposed change.

It seems appropriate to update this definition in alignment with other definitional updates. We also agree that healthcare providers who are offering self-developed software to others should meet all the same regulatory expectations to which health IT developers are held.

Information Blocking Definition - (p. 119)

Because October 6, 2022, has passed, we propose to revise § 171.103 (information blocking definition) to remove § 171.103(b), which designates the period of time for which the information blocking definition is limited to EHI that consists of the data elements represented in the USCDI. Similarly, because we included the same date in two paragraphs of the Content and Manner exception (§ 171.301(a)(1) and (2)), we propose to revise § 171.301 to remove the existing § 171.301(a)(1) and (2) as no longer necessary. The proposed revised version of § 171.301 refers simply to EHI as defined in § 171.102.

We agree that simplifying the definition as proposed would be appropriate given the references to past time periods.

Infeasibility Exception – Uncontrollable Events Condition - (p. 120)

The fact that an uncontrollable event specified in § 171.204(a)(1) occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception.

While this condition has always required causal connection between the actor's inability to fulfill the request and the natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority, we propose to revise the condition by replacing the words ''due to'' with ''because of.'' This revision may provide additional clarity, but we welcome comments on this proposal, including whether alternative or additional refinements to the wording of the condition may make the causal connection requirement more immediately obvious from the face of the text in § 171.204(a)(1).

We have no objections to the language changing to "because of." However, we request clarification as to how ONC believes those two terms to be different in terms of implications for or obligations now expected of covered actors.

Third Party Seeking Modification Use - (p. 120)

Specifically, we propose that the third party seeking modification use condition of the infeasibility exception would be limited to situations when ''[t]he request is to enable use of EHI in order to modify EHI (including but not limited to creation and deletion functionality), provided the request is not from a health care provider requesting such use from an actor that is its business associate'' (proposed new § 171.204(a)(3), emphasis added).

We appreciate that ONC recognizes the risks posed by additions, modifications, or deletions to EHI in a designated record set. We also appreciate that ONC acknowledges the effort involved in using some of the existing exceptions. This exception would help to simplify the handling of certain requests.

As to whether this condition should be eliminated in the future when additional technical capabilities are available, it is premature to say. As such, we suggest reconsidering at some point several years in the future, as the industry further advances. We do anticipate that the flexibility to implement appropriate data integrity protections without undue regulatory overhead will remain important even as more technical capabilities are adopted.

Manner Exception Exhausted - (p. 122)

It is not our intent that the information blocking regulations drive actors to prioritize various requestors' non-standardized, non-scalable preferences for manners of achieving access, exchange, or use of EHI over directing the actors' development resources to developing and implementing scalable, interoperable solutions to meet patients' and health care providers' needs. Consistent with policy goals for advancing secure, interoperable access, exchange, and use of EHI, we would rather encourage use of standards-based and other generally available mechanisms whenever available to serve the access, exchange, or use need so that as many

development resources as possible remain available to actors to focus on continuously improving generally available products' capabilities.

We agree and greatly appreciate ONC's acknowledgment of this current dynamic.

The proposed § 171.204(a)(4) manner exception exhausted condition provides actors the option of satisfying the Infeasibility Exception without needing to assess whether they could theoretically or technically meet the requestor's particularized demands regarding the manner and/or terms in which they want to achieve access, exchange, or use of requested EHI. In other words, the manner exception exhausted condition covers an actor's reasonable and necessary practice of prioritizing resources in favor of interoperable technology. To satisfy § 171.204(a)(4) manner exception exhausted, an actor would be considered ''unable'' to fulfill a request for access, exchange, or use of electronic health information when three factors are true: (i) The actor could not reach agreement with a requestor in accordance with § 171.301(a) manner requested condition (as we have proposed it in this proposed rule) or was technically unable to fulfill a request for electronic health information in the manner requested; (ii) The actor offered all alternative manners in accordance with § 171.301(b) alternative manner condition (as we have proposed it in this proposed rule) for the electronic health information requested but could not reach agreement with the requestor; and (iii) The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.

Part (b) of the Infeasibility Exception requires the actor to respond to the requestor within 10 business days as to why the request is infeasible. However, going back and forth with the requestor about the requested manner and applicable alternative manners realistically can be expected to take longer in many cases, which seems to preclude the use of this exception in cases where it would frequently be relevant.

In general, we strongly suggest ONC reconsider the 10-business-day response timeframe to permit flexibility for responding in a timely and iterative fashion. If a 10-business-day timeframe for responding to the requestor is retained, it should begin after the process of assessing alternative manners has been exhausted. We also note that it is difficult to meaningfully determine if a request is feasible without sufficient detail (a common scenario when requests come in), requiring responses from the requester to follow-up questions in a timely manner, which we do not control. A more reasonable timeframe to perform an infeasibility analysis would be 10 days from the point where sufficient information about a request has been received.

Another challenging scenario we have identified is repeated requests from the same requester for data via the same manner. We ask that ONC clarify that a response is not necessary each time if a response has previously been provided indicating the infeasibility of the manner and nothing has changed since the previous response.

We are considering, and propose in the alternative to the factor as detailed above (and in proposed § 171.204(a)(4)(i)), that the second of three factors that must be true to satisfy § 171.204(a)(4) manner exception exhausted condition would instead be that the actor offered at least two (or at least three) alternative manners in accordance with § 171.301(b), at least one of which was consistent with § 171.301(b)(1)(i) or (ii), for the EHI requested but could not reach agreement with the requestor. This alternative factor would offer actors with certified health IT the option of offering as few as two alternative manners that each make use of content and transport standards published by the Federal Government or a standards-developing organization accredited by the American National Standards Institute, or one such manner plus an alternative machine-readable format consistent with § 171.301(b)(1)(iii). This alternative

version of the factor would also provide a clear option for an actor without certified health IT to satisfy the § 171.204(a)(4) manner exception exhausted condition either:

- ***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***

- ***by offering fulfilment in at least one such manner and an alternative machine-readable format consistent with § 171.301(b)(1)(iii).***

This condition should still be available in circumstances where the machine-readable format is the only applicable option for the data requested.

In seeking comment on the proposed new § 171.204(a)(4) manner exception exhausted condition, we seek comment specifically on whether commenters expect the needs of patients, health care providers, and the advancement of interoperability, EHI exchange, and/or health IT innovation would be better served by the factor proposed in § 171.204(a)(4)(ii), requiring the actor have offered all alternative manners consistent with § 171.301(b)(1), or by simply requiring that the actors offer only two or three alternative manners so long as at least one of those manners used either certified technology consistent with § 171.301(b)(1)(i) or used content and transport standards consistent with § 171.301(b)(1)(ii) in order for the request to meet this condition.

Re-emphasizing the points made above, the EHR Association asks that ONC reconsider adjusting the 10-day timeframe to something more reasonable within which to perform an infeasibility analysis, which we suggest would be 10 days from the point where sufficient information about a request has been received. It is difficult to meaningfully determine if a request is feasible without sufficient detail and responses to follow-up questions (and timely responses from the requestor).

We also encourage ONC to address the challenge created by a scenario in which repeated requests are received from the same requestor for the same manner. If a response has already been provided indicating the infeasibility of the manner and nothing has changed since the previous response, is the actor obligated to respond each time the request is made?

Finally, as stated previously, we would like to see the manner exception exhausted condition be available in circumstances where the machine-readable format is the only option applicable for the data requested.

TEFCA Condition for the "Manner" Exception - (p. 127)

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

(i) The actor is not required to offer the EHI in any alternative manner;
(ii) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

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

We appreciate ONC's recognition of TEFCA and its potential for interoperability.

Health IT Capabilities for Data Segmentation and User/Patient Access – Request for Information - (p. 129)

In addition to the specific right to request a restriction on disclosure consistent with 45 CFR 164.522, there are other use cases related to patient preferences—and specific nuances within use cases—which present challenges from a technical point of view. Through public forums and correspondence with ONC, interested parties in the healthcare community have conveyed that their certified health IT lacks capabilities to differentiate the timing of release of certain EHI based on patients' individual preferences. Some interested parties have also indicated that their certified health IT may have little or no ability to restrict a patient's personal representative's access to only some of the patient's EHI using electronic means such as a portal or API or to easily hold back only some pieces of the patient's EHI, in response to or at the patient's request, while honoring the patient's simultaneous preference for the rest of their EHI to be shared with another of their health care providers.

We seek comment to inform steps we might consider taking to improve the availability and accessibility of solutions supporting health care providers' and other information blocking actors' efforts to honor patients' expressed preferences regarding their EHI.

Each health IT product involved – EHRs and LISs – might have different capabilities with respect to the scenarios ONC outlines. The EHR Association has gathered information from our members related to ONC's example scenario about lab results from an EHR perspective: "A health care provider (or other actor) chooses to grant a patient's request to delay the release of certain EHI – such as new diagnoses or particular laboratory or imaging result(s) – to the patient or the patient's personal representative either for a particular period of time or until a particular event, such as communication between the patient and a clinician or patient educator, has occurred."

EHR Association members reported in a survey:

1. A majority of responders indicated their EHR had the ability to withhold or embargo sensitive information from a patient through the portal, even if the information originated in an external lab system.
2. A majority of responders again indicated their EHR had the ability to withhold or embargo sensitive information from a patient through FHIR APIs.
3. Responders indicated a variety of approaches to indicating what is withheld or embargoed, including approaches such as:
    a. Withholding all results or releasing all
    b. Withholding all results for a particular visit
    c. Withholding all results based on patient service type
    d. Setting time periods per result type for provider review of results prior to release to the patient
    e. Providers manually selecting what is shared in the patient portal
    f. Setting time periods for embargo for individual tests for a particular patient
4. A majority of responders indicated there was no ability in their EHR to request a lab system to withhold/embargo on directly sharing the test result with the patient.

5. Given other regulatory requirements in flight, a majority of responders indicated greater than two years was an appropriate regulatory timeframe for adding the capability to withhold/embargo sensitive information from a patient in a portal and through APIs with a configurable time window and requesting a withhold/embargo on direct sharing the test result from the patient from the lab system.

Where this involves an external lab, standards to request such a delay have only recently been defined, and primarily for HL7 v2 using specific profiles in the HL7 LOI and LRI implementation guides to enable inclusion in any HL7 v2 version for consistent inclusion on the order. That has mostly focused on a provider request and may require further updates to accommodate a patient's preference as the source. This approach has not yet been adopted, as the necessary standards to help manage this embargo when data is shared through C-CDA documents and FHIR-based APIs have not been addressed yet. Based on feedback from our members, we note that having the ability for the patient and provider to address this external request would at least require two years to further define and begin the implementation.

We also note that various states have started to enact legislation requiring support (for example, Kentucky and Texas). We have shared with them the same considerations of current abilities and time necessary to progress the standards and development to make this widely available.

Given this time window, we suggest this is not ready for certification, and that ONC should instead engage the industry in further research and initial deployments to mature the standards and approach while determining how to address awareness of an embargo through C-CDA-based documents and FHIR-based APIs as well.

While the EHR Association has not conducted surveys of its members on the other scenarios mentioned in ONC's proposed rule and was not able to do so during the public comment window, we would welcome further conversations with ONC on some of the other questions posed.

Appendix A - Table of Insights Measures

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
1	Interop_Individual Access_1_v1	Denominator 1	Number of unique individuals who had an encounter (see Definitions) during the reporting period	See comments regarding concerns with the definition of an encounter.	Low
2	Interop_Individual Access_1_v1	Denominator 2	Number of unique individuals who used at least one of three types of methods (see Definitions) to access their EHI who had an encounter during the reporting period.	Use of "during the reporting period" is unclear. The EHR Association recommends clarifying that this measure includes the patients who both had an encounter during the reporting period and accessed their EHI in the same reporting period.	Medium
3	Interop_Individual Access_1_v1	Denominator 3	Number of unique individuals who used at least one of the three types of methods (see Definitions) to access their EHI during the reporting period regardless of whether the individual had an encounter or not.		Medium
4	Interop_Individual Access_1_v1	Numerator 1	Number of unique individuals who had an encounter and accessed their EHI at least once during the reporting period via at least one of the three types of methods (see Definitions).	How would ONC stratify patients who used multiple methods in the reporting period? We suggest that this request represents 4 separate metrics: • Number of unique individuals who had an encounter and accessed their EHI at least once during the reporting period via Method	High

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			Stratification: Type of Method to Access EHI	1. ● Number of unique individuals who had an encounter and accessed their EHI at least once during the reporting period via Method 2. ● Number of unique individuals who had an encounter and accessed their EHI at least once during the reporting period via Method 3. ● Number of unique individuals who had an encounter and accessed their EHI at least once during the reporting period via at least one of the three types of methods.	
5	Interop_Individual Access_1_v1	Numerator 2	Number of unique individuals who access their EHI regardless of an encounter during the reporting period using at least one of the three types of me (see Definitions). Stratification: Type of Method to Access EHI		High
6	Interop_Clini	Denominator 1	Number of encounters (see	See comments regarding concerns with the	Low

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
	cal Care_1_v1		Definitions) during the reporting period.	definition of an encounter.	
7	Interop_Clinical Care_1_v1	Denominator 2	Number of unique patients with an encounter during the reporting period.	See comments regarding concerns with the definition of an encounter.	Low
8	Interop_Clinical Care_1_v1	Denominator 3	Number of unique patients with an associated C-CDA document during the reporting period.	Further clarity is needed on the distinction between Interop_Clinical Care_1_v1 Denominator 4 and Interop_Clinical Care_1_v1 Denominator 3. Our assumption is that Denominator 3 is intended to be the number of patients with at least one "associated" C-CDA during the reporting period, whereas Denominator 4 is the total number of such documents across all patients for the same time period. We note that in this case, a clear definition for "associated" is also needed. The EHR Association recommends ONC provide this further clarification in the final rule and associated specification sheets.	High
9	Interop_Clinical Care_1_v1	Denominator 4	Number of unique C-CDA document obtained (see Definitions) using certified health IT during the reporting period.	Further clarity is needed on the distinction between Interop_Clinical Care_1_v1 Denominator 4 and Interop_Clinical Care_1_v1 Denominator 3. Our assumption is that Denominator 3 is intended to be the number of patients with at least one "associated" C-CDA during the reporting period, whereas Denominator 4 is the total number of such documents across all patients for the same time	Medium

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
				period. We note that in this case, a clear definition for “associated” is also needed. The EHR Association recommends ONC provide this further clarification in the final rule and associated specification sheets.	
10	Interop_Clinical Care_1_v1	Numerator 1	Number of unique C-CDA documents obtained using certified health IT and Direct Messaging during the reporting period.	We note that this appears to simply be a stratification of Interop_Clinical Care_1_v1 Denominator 4. Accordingly, we suggest that Denominator 4 could seemingly be eliminated in favor of the more specific permutations which could simply be added together by ONC for total counts.	Medium
11	Interop_Clinical Care_1_v1	Numerator 2	Number of unique C-CDA documents obtained using certified health IT and a local/regional health information exchange (HIE) or national health information network during the reporting period.		Medium
12	Interop_Clinical Care_1_v1	Numerator 3	Number of unique C-CDA documents obtained using certified health IT and a developer-specific health information network (i.e., a network that facilitates exchange between entities using the same health IT		Medium

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			developer's products) during the reporting period.		
13	Interop_Clinical Care_1_v1	Numerator 4	Number of unique C-CDA documents obtained using certified health IT and a method not listed above and not including electronic fax during the reporting period.	The EHR Association suggests ONC remove this metric as it is unclear. This metric would seem to include behavior such as system conversions, where large volumes of C-CDAs might be imported. That data will be difficult to interpret in this context and would not appear to align with the intended scope of exchange for measurement. Thus, we would discourage including that for the initial measure set.	Medium
14	Interop_Clinical Care_2_v1	Denominator 1	Number of encounters (see Definitions) during the reporting period.	See comments regarding concerns with the definition of an encounter.	Low
15	Interop_Clinical Care_2_v1	Denominator 2	Number of unique patients with an encounter during the reporting period.	See comments regarding concerns with the definition of an encounter.	Low
16	Interop_Clinical Care_2_v1	Denominator 3	Number of unique patients with an associated C-CDA document during the reporting period.	Further clarity is needed on the distinction between Interop_Clinical Care_2_v1 Denominator 4 and Interop_Clinical Care_2_v1 Denominator 3. Our assumption is that Denominator 3 is intended to be the number of patients with at least one "associated" C-CDA during the reporting period, whereas Denominator 4 is the total number of such documents across all patients for the same time period. We note that in this case, a clear definition	High

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
				for “associated” is also needed. The EHR Association recommends ONC provide this further clarification in the final rule and associated specification sheets.	
17	Interop_Clinical Care_2_v1	Denominator 4	Number of unique C-CDA document obtained (see Definitions) using certified health IT during the reporting period.	Further clarity is needed on the distinction between Interop_Clinical Care_2_v1 Denominator 4 and Interop_Clinical Care_2_v1 Denominator 3. Our assumption is that Denominator 3 is intended to be the number of patients with at least one “associated” C-CDA during the reporting period, whereas Denominator 4 is the total number of such documents across all patients for the same time period. We note that in this case, a clear definition for “associated” is also needed. The EHR Association recommends ONC provide this further clarification in the final rule and associated specification sheets.	Medium
18	Interop_Clinical Care_2_v1	Numerator 1	Number of C-CDA documents of the Continuity of Care Document (CCD), Referral Note, Discharge Summary document types that are obtained and incorporated across all exchange mechanisms (see Definitions) supported by certified health	We are concerned that the numerator is too centered around reconciliation actions occurring at the C-CDA document level, whereas many developers aggregate data across documents for consolidated or “bundled” clinical reconciliation. We recommend providing guidance that developers who take a “bundled” approach to clinical reconciliation can qualify all documents in the	High

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			IT during the reporting period.	numerator received for an encounter where PAM reconciliation is completed for that encounter. Additionally, we are concerned about the numerator definition specifying reconciliation needing to be performed by a human end-user. This ignores automation that some developers incorporate to aid end-users (e.g., automated deduplication with existing record entries or writing of new entries where appropriate). The EHR Association recommends changing the definition to include counting auto-reconciliation in addition to allowing reconciliation by human intervention.	
19	Interop_Standards_1_v1	NA	Data Collection • Application name • Developer (company/organization or individual) responsible for the app • Intended Purpose of App Using the Following Categories: ◦ Administrative Tasks (e.g., scheduling & check-in, billing & payment) ◦ Clinical Tools (e.g., clinical decision support, risk calculators, remote patient		High

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			monitoring) ◦ Individuals' Access to their EHI (e.g., enables patients to access their health information, medications, test results, vaccine records) ◦ Research (e.g., used to perform clinical research) ◦ Population Data (e.g., bulk transfer of data, population analytics & reporting) ◦ Public Health (e.g., electronic case reporting) ◦ Patient-Provider Communication (e.g., secure messaging, telehealth) ◦ Educational Resources (e.g., patient and provider educational resources) ◦ Other Intended Purpose ◦ Unknown (e.g., missing) • Intended User of App Using the Following Categories: ◦ Individual/Caregiver ◦ Clinician ◦ Health Care Organization ◦ Payer ◦ Researcher ◦ Other Intended User ◦ Unknown (e.g., missing) • Status of App Using the Following Categories: ◦ Actively Used (see Definitions) ◦ Not Actively Used (see		

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			Definitions)		
20	Interop_Standards_2_v1	Denominator 1	Number of distinct certified API technology deployments (across clients). Stratification: ● Type of endpoint (see Definitions) ○ Patient-facing ○ Non-patient-facing ● FHIR version ● U.S. Core Implementation Guide version	The EHR Association seeks clarification on whether the denominator is the total number of endpoints active at any time during the reporting period or whether it should be the total active endpoints as of the end of the reporting period. We recommend the total number active at any point in the reporting period to appropriately account for onboarding and offboarding activity.	Low
21	Interop_Standards_2_v1	Numerator 1	Number of FHIR resources returned/transferred in response to a call to a certified API technology by resource type. Stratification: ● Type of endpoint (see Definitions) ○ Patient-facing ○ Non-patient-facing ● FHIR version ● U.S. Core	The EHR Association requests clarity on whether developers should report the number of total resources returned or the number of requests that returned at least 1 resource (e.g., when a request returns 100 different observations, is that 1 or 100?). We recommend it be the number of total resources (i.e., 100 in our example). Regarding stratifications: ● The EHR Association approves of stratifying by patient-facing vs non-patient facing. ● Since FHIR R4 is the only relevant version,	Medium

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			Implementation Guide version	the EHR Association finds it unnecessary to stratify at that level. ● In most cases, a developer is only conformant to 1 version of the US Core IG, so the EHR Association does not feel there would be a high value in reporting on a single version.	
22	Interop_Standards_2_v1	Numerator 2	Number of distinct certified API technology deployments (across clients) associated with at least one FHIR resource returned/transferred in response to a call. Stratification: ● Type of endpoint (see Definitions) ○ Patient-facing ○ Non-patient-facing ● FHIR version ● U.S. Core Implementation Guide version		Low
23	Interop_Standards_3_v1	Denominator 1	Number of distinct certified health IT deployments or	The EHR Association seeks clarification on whether the denominator is the total number of endpoints	Low

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			installations (across clients).	active at any time during the reporting period or whether it should be the total active endpoints as of the end of the reporting period. We recommend the total number active at any point in the reporting period to appropriately account for onboarding and offboarding activity.	
24	Interop_Standards_3_v1	Numerator 1	Number of data/download requests completed during the reporting period using certified health IT certified to the "standardized API for patient and population services" (§ 170.315(g)(10)) (across clients) criterion in response to a bulk data download request to export all data for patients within a specified group.		Medium
25	Interop_Standards_3_v1	Numerator 2	Number of distinct certified health IT deployments or installations certified to the "standardized API for patient and population services" (§ 170.315(g)(10)) (across clients) that successfully completed at least one bulk data download request during the reporting period.		Low

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
26	Interop_Standards_4_v1	Count	The number of full data EHI exports requests processed during the reporting period. Stratification: ◦ Single patient EHI export ◦ Patient population EHI Export		Low
27	Interop_Standards_4_v1	Attestation	"We enable direct-to-individual EHI exports"		Low
28	Interop_Public Health_1_v1	Denominator	The number of immunizations administered during the reported period. Stratifications: ◦ IIS ◦ Age Group ◦ Adults = 18 years and over ◦ Adolescents/infants = 17 years and under		High
29	Interop_Public Health_1_v1	Numerator	The number of immunization administrations from which the information was electronically submitted to an IIS successfully (see Definitions) during the reporting period.	The EHR Association strongly recommends that ACK with a severity level of W is not a failure because it could be something as insignificant as an address mismatch, whereas level E would be something that actually prevents the data from being processed. The Association also recommends that replays should count as there are scenarios where the	High

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			Stratifications: ◦ IIS ◦ Age Group ◦ Adults = 18 years and over ◦ Adolescents/infants = 17 years and under	registry could be down or perhaps are experiencing networking issues through no fault of the developer, that compel a replay. Disqualifying these would inappropriately skew the numbers.	
30	Interop_Public Health_2_v1	Denominator 1	The number of immunization queries sent during the reported period. Stratifications: ◦ IIS ◦ Age Group ◦ Adults = 18 years and over ◦ Adolescents/infants = 17 years and under		High
31	Interop_Public Health_2_v1	Denominator 2	The number of encounters (see Definitions) during the reporting period.	See comments regarding concerns with the definition of an encounter.	Low
32	Interop_Public Health_2_v1	Numerator	The number of query responses received successfully (see Definitions) from an IIS during the reporting period. Stratifications:	The EHR Association requests clarity from ONC on how “refines” are handled for measurement. For example, if you try 4 times and finally get a success, is that 1/1 or ¼? We recommend it should be ¼ to accurately reflect the total queries performed. As with the administration measure, we support	High

Row #	Measure ID	Metric ID	Description	EHR Association Comments	Burden Rating
			◦ IIS ◦ Age Group ◦ Adults = 18 years and over ◦ Adolescents/infants = 17 years and under	using only ACK with severity level E as a failure. Additionally, both Z42 (history + forecast) and Z32 (history only) should be included in the measurement as both are objectively relevant to patient care.	

Appendix B - EHR Association Estimates of HTI-1 Proposed Requirements

These estimates were generated by collecting data from developer members of the EHR Association in a survey. The responses represent >65 certified products.

Notes:

1. The estimates underrepresent the total scale of development because of a flaw in our data capture method. The scale for collecting estimates capped out at ">3,000 hours" which was insufficient to convey the scale of some of the larger projects. Some projects are estimated as "greater than" the amounts shown given this data collection issue. Next time we collect estimates we will use a scale that continues to larger increments to mitigate this issue.

2. The Association did not gather data on ONC's estimated benefits of the proposed requirements, which may be inflated.

Project	**ONC Estimates**	**EHRA Estimates (Range)**
USCDI v3	3,000 to 7,200	4,000 to >100,000
Electronic Case Reporting	0 to 4,660	850 to >70,000
Decision Support Interventions and Predictive Models	2,630 to 11,570	6,500 to >100,000
Standardized API for Patient and Population Services	1,300 to 3,100	3,500 to >70,000
Patient Demographics and Observations Certification Criterion in § 170.315(a)(5)	720 to 1,820	40 to >40,000
Patient Requested Restrictions Certification Criterion	Input requested	>100,000*
Insights Condition and Maintenance of Certification (Infrastructure, general)	Analyst 3,496 to 9080 Developer 17,640 to 35,920	4,300 to >130,000

*>3,000 hours was the largest choice in the EHR Association survey, which was universally selected for this item, giving no meaningful lower bound to the range. Write-in comments on this item indicated that estimates exceeded 100,000 hours.