June 20, 2023

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Attention: Health Data, Technology, and Interoperability: Certification Program Updates,
Algorithm Transparency, and Information Sharing Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW,
Washington DC 20201

RE: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule (RIN Number 0955–AA03)

Dear Dr.Tripathi:

The Confidentiality Coalition appreciates the opportunity to comment on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule published by the Department of Health and Human Services (HHS) Office of the National Coordinator of Health Information Technology (ONC) in the Federal Register on April 18, 2023 (proposed rule or HTI-1).[1]

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, and others, committed to advancing effective health information privacy and security protections. Our mission is to advocate policies and practices that safeguard the privacy and security of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

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[1] 88 Fed. Reg. at 23746 (April 18, 2023).

We strongly support the goals of HTI-1 to advance interoperability and support the access, exchange, and use of electronic health information (EHI). We particularly appreciate the efforts of ONC to support health equity, improve information sharing through enhancements to the information blocking rules, incentivize the development and wider use of fair, effective and safe predictive decision support interventions (DSI) to aid decision-making, and improve API standards to help patients and their authorized health care providers to securely access their health information.

Below we provide specific comments on some of these issues and the requests for information included in HTI-1.

1. The U.S. Core Data for Interoperability Standard Version 3 (USCDI v3)

ONC proposes to adopt the United States Core Data for Interoperability Standard Version 3 (USCDI v3). If finalized, the adoption of USCDI v3 would update the USCDI standard to include data elements such as sexual orientation and social determinants of health, as well as capturing and promoting the sharing of key data elements related to public health. ONC states that this could potentially help data users address disparities in health outcomes for all patients, including those who may be marginalized and underrepresented, help identify and address gaps in care, and facilitate the gathering, sharing, and publication of data for use in public health and emergency response.

We support the adoption of selected data classes from USCDI v3 for all the reasons stated by ONC. We do have some concerns about standardization of data in the USCDI, such as inconsistencies in the use of data element like payer ID, as well as questions about the appropriate handling and display of data elements when contradictory data is received for that data element. We recommend that ONC revise the Health Insurance Information data class to focus on sharing information that can be feasibly collected based on national standards and can facilitate patient care, help consumers and health care providers assess quality and understand the impacts of social determinants of health. ONC should work with stakeholders to standardize and define data elements and address different data collection scenarios.

Recommendations:
- ➢ *We support the adoption of selected data classes from USCDI v3, since it will allow a richer data set and help health organizations support health equity and public health.*
- ➢ *ONC should work with stakeholders to standardize and define certain data elements and develop a protocol for data collection from different sources.*

2. Predictive Decision Support Interventions

ONC proposes a definition for ''predictive decision support intervention'' to mean ''technology intended to support decision-making based on algorithms or models … used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis.'' ONC states that predictive models represent one widely used form of artificial intelligence (AI), but do not include all AI, and that its proposed definition would not include the computer readable

implementation of clinical guidelines or similar types of knowledge except when those guidelines—and the interventions implemented based on them—incorporate a predicted value, such as a predicted risk, in guiding clinical decision-making.

We support limiting the definition of predictive decision support intervention (DSI) to DSI that is for purposes of prediction i.e., to predict a future event or occurrence. As written, the proposed definition is broader, and would encompass use of technology and training and example data for purposes of classification, evaluation, and analysis as well. Such a broad definition would encompass much of what health care organizations do routinely, and that does not involve the risks or concerns associated with predictive AI. We therefore ask that ONC consider tailoring the definition accordingly to focus on clinical predictive DSI.

ONC also proposed to enable a user to review a plain language description of source attribute information of predictive DSIs that are certified, and to require that developers engage in intervention risk management practices and make summary information about these practices available publicly. While we support providing a plain English description of the source attribute information at a high level that is sufficient for the effective evaluation of the product, it is important that developers not be required to reveal proprietary information. Such information is likely to be far more meaningful and helpful to competitors than to users. In light of the potential to undermine competition without demonstrable value to users, we ask that ONC clarify in the requirement that developers will not be required to reveal proprietary information as part of this requirement.

Recommendations:
> ➢ ***ONC should narrow the definition of "predictive DSI" to focus on algorithmic-based decision support technology for the purpose of prediction only.***
> ➢ ***ONC should not require developers of predictive DSI to disclose source attribute information that includes proprietary information, as this would undermine competition and innovation.***

3. Patient Right to Request a Restriction New Criterion—Primary Proposal
ONC proposes new and revised certification criteria to support additional tools for implementing patient requested information privacy restrictions. We appreciate the goal of the proposal to make compliance with the existing HIPAA right to restrict more technically feasible. The proposal acknowledges the complexities in implementation but without specifying a solution, stating that the requirement would be "standards-agnostic" so long as they meet the functional capabilities specified in the criterion. While we appreciate the intended flexibility this would provide, there are significant challenges to implementing the proposal. For example, restriction requests are frequently not just housed in one system, and so may require multiple places to denote the restriction. In addition, the lack of standards may provide flexibility to an EHR developer specific to their product but presents difficulties for organizations that use different systems or have a larger network. Moreover, if criteria for limiting data takes on more granularity, this

would require systems that are able to isolate certain services, which will be burdensome and costly.

We strongly recommend that ONC encourage HHS to provide educational materials to patients about this functionality once finalized, and that certification criteria allows patients to request restrictions that correspond to standard diagnosis codes that allow patients to understand what categories of data they are seeking to restrict. We also believe that patient education should include explaining to patients the importance of providing a complete medical record to their health care providers and health plans, and that limiting or restricting the disclosure of their records could have a negative impact on their health care.

Recommendations:

> ➢ ***ONC should collaborate with stakeholders to develop appropriate standards for implementing restrictions, taking into account the implementation challenges facing most health care organizations.***
> ➢ ***HHS should develop educational materials to help patients understand not only how they may restrict access to their records, but also the potential negative consequences to their health care because of such restrictions.***

4. Information Blocking Enhancements

ONC proposes to adopt a definition for "offer health IT" so as to narrow the applicability of the definition of "health IT developer of certified health IT." The proposed definition would do so by excluding from the term certain beneficial arrangements designed to benefit recipients of subsidized certified health IT, as well as health care provider activities implementing features and functionalities in their EHR systems, such as APIs for patients and clinicians to use third-party apps of their choosing. We support this new definition, and agree that it will help small, safety net and other lower resource providers' ability to afford certified health IT. We also support providing definitive assurance to health care providers, such as hospitals, that activities such as issuing login credentials to physicians in independent practice who use the hospital's EHR system to furnish care to patients in the hospital will not be considered to be offering health IT, and to fall within the definition "offer health IT," when they undertake these activities. We ask that ONC consider providing additional examples of beneficial and necessary activities that would fall outside the definition.

ONC also proposes two new conditions for the infeasibility exceptions, namely, third-party seeking modification use and manner exception exhausted. We support both these new conditions, which would increase certainty and reduce the burden for actors. The third-party seeking modification use will be especially useful for health care providers who are concerned about the accuracy or reliability of data that a third party would like to add to an individual's designated record set maintained by the health care provider or to delete data from that record set. It will save time and resources that would otherwise be needed to determine whether another exception applies and, if so, to

document it appropriately. The manner exhausted exception will provide assurance to actors that they do not need prioritize non-standardized, non-scalable preferences of requestors for exchanging EHI, and can instead focus on developing and implementing scalable, interoperable solutions to meet patients' and health care providers' needs. We agree that ONC should seek to encourage use of standards-based and other available mechanisms to exchange EHI. The information blocking regulations should not become a vehicle to force actors to inefficiently allocate resources on nonstandard, non-scalable manners of exchanging EHI because they are uncertain whether refusal to do so would potentially be viewed as a form of information blocking.

Finally, ONC proposes a new Trusted Exchange and Common Agreement (TEFCA) condition for the newly renamed manner exception, which will allow entities that participate in TEFCA at any level to use "TEFCA means" for the exchange of EHI. We agree that this will prioritize exchange amongst TEFCA participants using TEFCA means and support it for this reason. ONC states that it hopes, through this new condition, to incentivize and accelerate use of the available, interoperable, and secure TEFCA technical services by TEFCA entities to support the access, exchange, and use of as much EHI as possible for as many purposes as are permitted under the TEFCA governing agreements. We encourage ONC to consider expanding the condition to provide that if the requestor is not a TEFCA participant, but the actor to whom the request is made is, that the requestor should have the burden of showing it is impracticable for it to join TEFCA if it is unwilling to exchange EHI using TEFCA means. Broadening the condition in this manner will provide greater encouragement to qualifying organizations to join TEFCA, and appropriately allow entities that do so to benefit from their participation. This should be the case whether the requestor is a TEFCA participant or not.

Recommendations: We support the proposed modifications to the information blocking regulation and recommend that ONC consider expanding the TEFCA condition to apply even when only the actor to whom the request is made is a participant in TEFCA.

5. **Health IT Capabilities for Data Segmentation and User/Patient Access—Request for Information**

ONC seeks comments on ways health IT can support EHI segmentation for access, exchange, and use of EHI. ONC states that this is to assist health care providers with sharing EHI consistent with patient preferences and laws applicable to the creation, use, and sharing of EHI. ONC gives the example of a patient requesting that some of their information be withheld from some of their health care providers because the patient expects certain information could be associated with conditions or care that may be stigmatized by health care providers other than the one to whom the individual disclosed the information or who provided the specific care.

We understand these and other use cases provided by ONC, such as those based on state laws requiring different legal treatment for certain types of health information. However, we are concerned that data segmentation is a consequence of other issues

that need to be addressed, not a solution. Data segmentation has the potential for significant negative effects on patient care and health outcomes, and will serve only to entrench, rather than counter, the stigmatization of certain health conditions or types of care. HHS, together with Congress, has been working assiduously to align the rules governing the confidentiality of substance use disorder (SUD) records at 42 CFR Part 2 (Part rules) with HIPAA precisely to avoid having to segment or separate out these records because of the detrimental effect of such segmentation on patient care. As HHS states (quoting U.S. Representative Earl Blumenauer) in the preamble to that proposed rule:
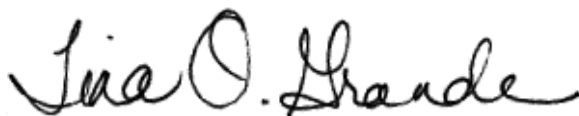
If substance use disorder treatment is not included in your entire medical records, then they are not complete. It makes care coordination more difficult and can lead to devastating outcomes. This bill works to remove the stigma that comes with substance use disorders and ensures necessary information is available for safe, efficient, and transparent treatment for all patients.[2]

Rather than invest resources in facilitating data segmentation, ONC should work with other agencies and Congress to ensure that all health data, including health data collected and held by health apps and other entities outside of HIPAA, is protected. HIPAA covered entities and their business associates should not be mandated to share EHI held in an electronic health record (EHR) with third parties not under an obligation to protect the data unless the request is accompanied by a HIPAA authorization from the patient. By facilitating access to EHI for health purposes, such as the treatment, payment and health care operations of HIPAA covered entities, and requiring additional safeguards in the case of access for other purposes, HHS would achieve a better equilibrium between appropriate and inappropriate data sharing. We believe this would be more beneficial for patients than by facilitating data segmentation with its inevitable consequence of data fragmentation and adverse health outcomes.

Recommendation: ONC should not require or support data segmentation as part of the certification criteria program out of concern for serious adverse impact on patient care and health outcomes.

Thank you for your consideration of our comments. Please do not hesitate to contact me at tgrande@hlc.org or 202-449-3433 if you have any questions.

Sincerely,

Tina O. Grande
Chair, Confidentiality Coalition and
Executive VP, Policy, Healthcare Leadership Council

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[2] 87 Fed. Reg. at 24221, Footnote 36.