

Charles N. Kahn III President and CEO

June 20, 2023

Micky Tripathi, PhD
National Coordinator for Health IT
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0955–AA03, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing; Proposed Rule; 88 Fed. Reg. 23,746 (April 18, 2023)

Dear Dr. Tripathi:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying public and privately held hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's and cancer services.

The FAH appreciates the opportunity to provide the Office of the National Coordinator (ONC) for Health IT with feedback regarding the *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency* proposed rule (HTI-1 or Proposed Rule). The FAH continues to believe in the potential of health information technology (health IT) to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates ONC's commitment to improving interoperability and patient access to information through use of standards and believes many of the policies contained in the Proposed Rule would advance those goals. The FAH offers the comments and recommendations below to guide these efforts.

Certification Standards and Functionality Updates

ONC proposes to update a range of functions and standards that must be accommodated by certified health IT. The FAH shares ONC's goal to make continued progress toward interoperable health IT systems that can improve health care by supporting the efficient access, exchange, and use of relevant data.

<u>United States Core Data for Interoperability (USCDI)</u>

ONC adopted the USCDI v1 in the 21st Century Cures Act Final Rule (2020). USCDI is considered the minimum data needed for interoperability and includes a range of data elements and vocabulary standards. ONC proposes to adopt USCDI v3, which includes additional data elements and updated standards. ONC has followed a structured approach to gather public input on updates to the USCDI, which has expanded significantly to allow a more comprehensive common understanding of an individual's health.

The FAH supports the adoption of USCDI v3, which, among other things, will allow a standards-based collection of information related to social drivers of health (SDOH) – such as SDOH assessments, goals and interventions – and health insurance information. We note, however, that certain data elements in <u>USCDI v3</u> still lack standards, such as Care Team Member Role. Other data elements, such as Date of Diagnosis, could generally fail to tie in and identify a direct encounter, thus leaving room for multiple interpretations, which could lead to misunderstandings by clinicians creating and receiving the data. The FAH urges ONC to define all applicable standards prior to implementation of USCDI v3. Where standards are not already established, ONC should consider Fast Healthcare Interoperability Resources (FHIR) standards. This will help ensure that USCDI v3 will promote its intended outcome to provide more comprehensive health data while minimizing interpretation discrepancies.

With respect to timing, ONC notes that health IT developers must update their products to accommodate USDCI v3 and deliver those updates to their customers before January 1, 2025. It is critical that hospitals and clinicians have sufficient time to also implement upgrades and make any needed changes to workflows in time to meet their obligations under the Medicare Promoting Interoperability Programs, which will have 180-day reporting periods in 2025. We urge ONC to collaborate with the Centers for Medicare and Medicaid Services (CMS) to coordinate regarding these timelines.

Application Programming Interface Standards

ONC proposes to update the standards that developers of certified health IT must support to create application programming interfaces (APIs) that allow internet-based sharing of individual data elements contained within USCDI. The FAH supports advances in standards-based API exchange, including:

- Adoption of new baseline standards for USCDI v3, US Core, and the SMART App Launch Framework.
- Adoption of standards-based requirements for authentication, authorization, and token introspection, leveraging SMART v2.

Provider organizations with multiple hospitals, affiliated providers, and clinics may inadvertently cause interference with actors trying to connect to APIs when the requestors cannot easily identify the true endpoint tied to the health system at large. The proposal to require a repository of such information would help aggregate endpoint information associated with one organization, promoting interoperability.

The FAH also supports the proposed clarification that would require developers of certified health IT to ensure that when a patient chooses to revoke access to an API for a specific app developer (or other third party), access is terminated within one hour of the request being made. ONC should further clarify, however, that it is the responsibility of the health IT developer to provide an automated solution that does not require action on the part of the health care provider to revoke access. In addition, to fully honor the patient's control over data, providers should be able to request that an app developer delete any data received through the API between when the request was made and when access has been revoked, without triggering concerns over information blocking. This is particularly important given the large volume of data available through the APIs and the limited tools currently available from certified health IT developers to limit the scope of information shared.

Standards-Based Electronic Case Reporting

The 2015 Edition certification criteria only includes functional requirements for electronic case reporting (eCR). Consequently, health care providers have been burdened with creating and maintaining unique connections to a range of public health authorities (PHAs), leading to inefficiency and limiting the ability to share data vital to the public's health. ONC's proposal to require that certified health IT modules support consensus-based, industry-developed standards is a welcome step toward reducing an unnecessary burden that the FAH supports. However, the benefits of the proposal are limited because ONC proposes to allow health IT developers to choose to support either the latest balloted HL7 CDA standards for eCR or the latest balloted FHIR standards for eCR, but not both. While the health care field is moving toward FHIR, it is essential that certified health IT modules support both standards. Optionality for the health IT developer will pose a burden on providers who share information with multiple PHAs, some of which may use the HL7 CDA standards while others rely on FHIR.

The FAH also urges ONC to work with the Centers for Disease Control and other agencies to accelerate the modernization and standardization of IT capabilities across PHAs. The COVID-19 pandemic highlighted the shortcomings of the public health community to be able to leverage IT solutions to gather and share critical information during an emergency and FAH members report that onboarding to PHA eCR systems is currently slow and challenging. In some cases, the use of third-party intermediaries or state-based health information networks has made it easier to connect. However, these organizations do not all use the same approach, leading to inefficiency and burden for providers that operate in multiple jurisdictions. Moving quickly to improve the capacity of PHAs to support standards-based transactions is crucial to ensuring that improvement in the future.

Patient-Requested Restrictions

ONC proposes that for any data elements included in the USCDI, a health IT developer must enable a provider (or other user) to flag whether such data needs to be restricted from being subsequently used or disclosed. The health IT developer must also prevent any data that has been

flagged from being included in a subsequent use or disclosure (such as being available through an API or included in a CCDA). ONC proposes to allow developers flexibility to create this functionality, without requiring the use of standards.

ONC separately proposes to require health IT developers to support the ability for "patients (and their authorized representatives) [to] be able to use an internet-based method to request a restriction to be applied for any data expressed in USCDI." This method could include functionality built into a patient portal, an API, or other approaches.

ONC notes that this functionality would support providers and other HIPAA-covered entities to fulfill their obligation under the HIPAA Privacy Rule to allow individuals to request a restriction on the use or disclosure of their PHI for treatment, payment, and health care operations and to have policies in place by which to accept or deny such requests. ONC states that it believes "certified health IT should – to the extent feasible – support covered entities so they can execute these processes to protect individuals' privacy and to provide patients an opportunity to exercise this right."

The FAH fully supports the idea that certified health IT should support covered entities to meet their obligations under the HIPAA Privacy Rule. However, the proposed approach would not help automate the process of receiving and acting on individual requests for restrictions. Rather, it would require manual work by the provider to separately activate flags for each of scores of granular data elements in the USCDI. And, given the lack of a standardized approach, the flags used in one system may not correspond to the flags used in another. Further, this approach would not apply an individual's requested restrictions to additional types of data not contained in the USCDI, such as images, that could also convey the information that an individual would like to restrict. Nor would it restrict the disclosure or use of a certain piece of information, such as a lab result, by other entities if that information is held in multiple systems (such as a provider system, a lab system, and a health information network).

It is important to note that the specific rights in the HIPAA Privacy Rule are limited to considering a patient-requested restriction. This means that a covered entity can choose whether to comply with the request. If ONC moves forward with this proposal, it could create significant confusion for individuals who may reasonably, but incorrectly, assume that providers are required to withhold data based on a request, particularly one made through an internet-based method.

In many cases, health care providers are concerned that restricting the use and sharing of certain pieces of health information could lead to serious unintended consequences because clinicians will lack clinical context crucial for care decisions. For example, withholding information about specific medications could lead to prescribing errors that result in serious drug interactions, resulting in both safety issues and questions about liability for any resulting harm. Similarly, withholding information about certain diagnoses could lead emergency physicians or other clinicians without full information to come to erroneous conclusions about a patient's condition. The risk of significant gaps in clinical records is particularly concerning in an era of federally supported information sharing, where a provider may reasonably assume they have

-

¹ 45 CFR 164.522(a)(1)(i)(A).

² 88 Fed. Reg. 23,821 (April 18, 2023).

received accurate medical records through a health information network or a query-based exchange.

For these reasons, the FAH recommends that ONC work with the provider, developer, and patient communities to develop and test a standardized approach to automating the receipt, consideration, implementation, and downstream communication of patient-requested restrictions. These standardized solutions also should include procedures for alerting clinicians to the fact that data has been withheld from a shared record and providing at least some transparency into what information they may be missing. This effort should include assessment and possible refinement of the HL7 CDA and FHIR Data Segmentation for Privacy Implementation Guides, as well as the HCS Security Label Vocabulary as a starting point for standardization. ONC also should support and fund pilot tests of these functionalities that include specific metrics of outcomes for patients, usability for providers across a range of settings, and efficiency, with the results of the pilot tests made publicly available. Unless testing shows that the functionality will work as intended, it could provide a false sense of comfort to individuals.

"Update and Provide" Requirements for Certified Technology

ONC proposes to require the developers of certified health IT to update their certified health IT to all applicable certification criteria and provide such updated health IT to their customers in a timely manner. The timeliness requirements generally would be no later than December 31 of the calendar year that falls 24 months after the effective date of the final rule, unless expressly stated otherwise in regulation. Assuming the Proposed Rule is finalized in 2023, this means developers must update and provide health IT certified to a revised criterion to existing customers by no later than December 31, 2025.

The FAH is strongly supportive of the timeliness requirements that include providing updates to customers. We also urge ONC to ensure that providers can receive and implement updates with sufficient time to meet reporting and other requirements in a range of CMS programs. Most notably, as discussed above, the CMS Promoting Interoperability Program requires the use of certified EHR technology and will require 180 days of reporting beginning in 2025. If upgrades are significant, it would be very challenging for providers to have sufficient time to meet the CMS reporting requirements.

Implementation of the EHR Reporting Program (Renamed Insights Condition and Maintenance of Certification)

ONC proposes to implement the 21st Century Cures Act provision to establish an EHR Reporting Program that will provide the public and purchasers of certified technology with metrics reporting the performance of certified health IT. ONC states that the program will "address information gaps in the health IT marketplace and provide insights on the use of specific certified health IT functionalities" while providing ONC with "information about consumers' experience with certified health IT."³

The FAH supports public accountability for certified health IT developers and recommends that ONC finalize the requirement to publicly post the metrics in a central place on

³ Id at 23,750.

the ONC website that can be easily accessed by users of certified health IT and the general public.

The categories of measures that have been proposed will provide information on important functionality such as individual access to health records, the types of apps that are connecting to certified health IT, the sharing of health information to support care, immunizations, and the ability to export electronic health information. However, these categories are missing key elements important to users of health IT, including security and usability, despite the fact that these are the first two categories of measures that the 21st Century Cures Act states the reporting program "shall include." We urge ONC to focus future measure development efforts on security and usability.

The FAH strongly urges ONC to be mindful of the burdens the Insights Condition could place on health care providers in terms of time and costs and take all necessary steps to minimize such burdens. ONC should create guidelines and other supports for developers of certified health IT to calculate and report the metrics without asking their customers to contribute data.

Information Blocking

ONC proposes a set of changes to the information blocking regulations that are responsive to queries ONC has received from stakeholders and reflect advancements in interoperability, including progress toward implementing the Trusted Exchange Framework and Common Agreement (TEFCA).

Modifications to Definitions

The FAH supports ONC's proposals to narrow the definition of *health IT developer of certified health IT* by making changes to the definition of what it means to "offer health IT." Taken together, the proposals would:

- Clarify that providing subsidies, in the form of funding or cost coverage subsidy arrangements for certified health IT will **not** be considered offering health IT, as long as: (i) the subsidy is not conditioned on steps that would limit the interoperability or use of the health IT; and (ii) other applicable laws, such as the Medicare anti-kickback statute, are met.
- Clarify that certain implementation and use activities, such as providing login credentials for public health agencies or independent practitioners treating patients in a provider's setting, do not constitute offering health IT.
- Clarify that providing certain consulting and legal services will not constitute offering health IT.
- Confirm that health care providers who self-develop certified health IT would continue to be excluded from this definition if they supply their self-developed certified health IT to others under arrangements that comply with the revised definition of "offer health IT."

The FAH thanks ONC for proposing to provide additional clarity on these issues. Health care providers are already a class of actor under the information blocking rules and should not

-

⁴ 42 USC 300jj-19(a)(3)(A).

also meet the definition of a health IT developer when they self-develop technology, engage in voluntary and lawful subsidy arrangements, or engage in common implementation and use activities.

Modifications to the Information Blocking Exceptions

The FAH generally supports ONC's proposals to modify the information blocking exceptions that identify situations when it may be appropriate to not allow access or use of electronic health information, with certain qualifications outlined below. Specifically, ONC proposes to:

Establish a Third-Party Seeking Modification Use Condition under the Infeasibility Exception. This condition would allow an actor to deny a request from a third party to modify electronic health information (such as creating or deleting electronic health information held by the actor). For example, a health care provider could use this condition if it has concerns about the accuracy of patient information that a third-party wants to add to its EHR and, therefore, declines to provide access or use. In this way, the condition appropriately supports health care providers in their efforts to maintain confidentiality, integrity, and availability of their health IT systems. ONC offers a caveat, however, that a health care provider should be able to require that a business associate (such as an EHR vendor) allow such third-party access on behalf of the provider. This proposed caveat also would be important to health care providers because they work with a range of business associates and other partners to conduct functions such as quality measurement or data integrity audits and must, therefore, be able to provide direction to their EHR vendors and others on which entities are allowed to modify their systems. To facilitate the use of this condition, ONC should include in the certification criteria for health IT the functionality to alert the actor when a third party seeks modifications to electronic health information.

Manner Exception Exhausted Condition under the Infeasibility Exception. This condition would allow an actor to not fulfill a request to access, exchange, or use electronic health information if: (i) the actor and requestor could not come to acceptable terms to provide the information in the manner requested; (ii) the actor has offered to provide the information in each of the alternate, standard-based manners listed in the regulation, but the requestor has not accepted any of those alternate manners; and (iii) the actor does not currently provide the type of non-standard access or use that was originally requested to a substantial number of similarly situated individuals or entities.

This proposed condition would reinforce the transition toward standards-based exchange and prevent actors from having to devote time and resources to fulfilling requests that involve burdensome, customized solutions.

TEFCA Condition for the Manner Exception. This condition would allow entities that participate in TEFCA-based exchange to fulfill requests for EHI from another participant in TEFCA-based exchange using the capabilities of TEFCA. Under the proposed condition, the actor would not be required to offer the EHI in an alternate manner and would not have to meet the fees and licensing exceptions under information blocking.

The FAH supports nationwide interoperability and sees great clinical and efficiency benefits from TEFCA-based exchange. The FAH also supports the inclusion of TEFCA-based exchange in the information blocking rules. However, we are concerned that the proposed exception could result in less sharing of information in the early stages of TEFCA's development. While significant progress has been made to operationalize TEFCA, it is not yet available to actors, and may not support exchange of all EHI for all purposes for some time to come. Therefore, TEFCA-based exchange should be included under the information blocking rules as a preferred approach to sharing EHI, but not in a way that enables an actor to deny a request if the requestor cannot receive it via TEFCA-based exchange.

RFI on Health IT Capabilities for Data Segmentation

As part of the information blocking section of the Proposed Rule, ONC seeks comments on health IT capabilities for data segmentation. Data segmentation is important for meeting privacy obligations under federal, state, and local laws. For example, numerous state laws impose additional limitations on the use and disclosure of health information beyond those imposed by HIPAA. For instance, while HIPAA permits covered entities to disclose protected health information for treatment, payment, or health care operations activities without the explicit consent of the individual, New York law states that health care providers can be liable for professional misconduct for "Revealing of personally identifiable facts, data, or information obtained in a professional capacity without the prior consent of the patient, except as authorized or required by law." In a number of states, disclosures of various categories of sensitive health information that would be permissible under federal law are only permitted with the consent of the patient. This includes, among other things, the sharing of certain parts of adolescent health records with their parents.

Today, hospitals and health care providers invest tremendous resources to track and assess the web of privacy and health information management requirements they are expected to meet across jurisdictions. We urge ONC to work with the Office for Civil Rights and other agencies to provide resources that could support health care providers and others to identify and understand the varying, and sometimes conflicting, array of health privacy and health information management obligations they must meet. Greater clarity and certainty regarding these obligations would free up resources that can be better spent on providing care.

Data segmentation tools also could help hospitals and health systems operationalize privacy and preventing harm exceptions under the information blocking rules. For example, many physicians have expressed concerns that the sharing of life-altering test results, such as a pathology report, via a portal before the physician and patient can discuss the results could lead to significant psychological harm. Technology tools should support the ability of patients to choose to wait to see the results in the context of a clinical visit and, in those circumstances, allow the physician to hold back those results. Similarly, if a physician believes that sharing certain health information could result in physical harm to a patient (such as in conditions of intimate partner abuse), technology tools should support the physician's ability to segment those data from sharing.

While the benefits of data segmentation are clear, the health IT industry has not yet developed solutions that will clearly accomplish data segmentation with an acceptable level of burden. Therefore, as also noted above in the context of patient-requested restrictions, the FAH recommends that ONC use its convening power and devote resources to working with

stakeholders and other federal agencies to accelerate progress, including funding for real-world testing of standards-based solutions. In doing so, the FAH urges ONC to carefully balance the potential benefits for patients with the potential burden on health care providers and health IT developers.

Decision Support Interventions (DSI) and Algorithmic Transparency

ONC proposes to create a new set of certification requirements related to DSIs and algorithmic transparency. The DSI requirements would modify existing certification requirements related to clinical decision support tools and extend far beyond them through transparency and risk management measures. ONC's stated goal is to "improve the trustworthiness of predictive algorithms and support their widespread use in health care." ONC cites research and concerns that tools in use can embed bias and lead to other unintended consequences that may lead to harm and notes that transparency about the training data and algorithms used to develop DSIs, as well as the results of any studies or evaluations that have been conducted, can help clinicians and other users of these tools to make their own judgments about whether and how to use them.

Definition and Scope of Predictive DSI. ONC proposes to identify a new class of "Predictive DSI", defined broadly to mean: "technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis." 5

ONC further notes that its proposals are agnostic to the specific purposes or uses (clinical, administrative, operational) of a DSI tool, are not based on the level of risk associated with the use of a particular DSI tool, and would apply to all DSI, whether created by health IT developers, health systems, clinicians, or third-party developers. ONC specifically notes that tools commonly used in hospitals, such as alerts, order sets, and flowsheets could meet the definition of DSI.

Transparency Requirements. ONC proposes to require that health IT developers create a mechanism to collect a range of source attributes about all DSI, with a greater level of transparency for predictive DSI, including information on the intended use, training data, measures of fairness, and ongoing maintenance activities. This information would need to be provided in plain language and be available to users via direct display, drill down or link out functionality. Health IT developers would be responsible for collecting source attributes for all DSI that is connected to or enabled by their certified technology. Developers would be required to include all of the source attributes for DSI that they create. If a health care provider or third party creates DSI, the developer would be required to solicit the source attribute information. If it is not provided, ONC proposes that the health IT developer prominently display that the information is not available.

Risk Management Requirements. ONC proposes to require health IT developers to create and maintain a risk management strategy for predictive DSI that includes analyzing and mitigating risks, as well as establishing a governance mechanism and publicly reporting summary information.

⁵ 88 Fed. Reg. 23,785 (April 18, 2023).

The FAH shares ONC's concerns about the potential risks of DSI tools that may inadvertently embed bias or lead to poor patient outcomes. As with medications, procedures, or other health care interventions, transparency regarding the action, expected use, and possible cautions about a DSI tool will inform appropriate use. As health care embraces artificial intelligence and other analytic tools, it will be important for clinicians and patients to have access to reliable information about DSI. Risk management approaches would also support safe, appropriate, and equitable design.

It is important, however, to balance these transparency and risk management approaches with innovation and the risk of unnecessary burden. For example, how would these requirements work in the context of guidance from the Food & Drug Administration regarding clinical decision support? Is there a risk of duplicative effort?

The FAH encourages ONC to work with stakeholders to further develop and publish clear guidance and standards around what would constitute a "fair, appropriate, valid, effective and safe (FAVES)" DSI tool. Current information in the Proposed Rule constitutes a goal but not a standard. Once developed, these standards could be applied to individual tools and give health care providers a baseline level of assurance that a tool is trustworthy without having to individually evaluate criteria in the midst of patient treatment. The FAH also asks ONC to clarify that the certification requirements for vendors do not convey an obligation for health care providers to review all of the source attributes of a DSI each time they choose to use a tool.

In addition, the FAH is concerned about the application of these transparency requirements to tools that hospitals and health systems develop for use within their own organizations. To avoid unnecessary burden, we recommend that ONC specifically carve out tools developed by health systems that are not commercially available from its definition of predictive DSI. Many hospitals routinely develop order sets or flowsheets that are enabled by their EHRs based on reviews of the evidence and the medical expertise of their clinicians. It is unclear what benefit a health system would gain from sharing the information proposed by ONC with their EHR vendor in order for the vendor to share it back with the health system. Similarly, it is unclear what benefit would come from having an EHR developer conduct risk management on a tool self-developed by a health care system. Health care providers are already subject to a wide range of quality oversight processes and bear ultimate liability for the care they provide.

Request for Information on Pharmacy Interoperability

ONC asks for information to inform future rulemaking that would establish certification criteria for real-time prescription benefit (RTPB) tools, consistent with the requirements of the *Consolidated Appropriations Act of 2021*. The inclusion of RTPB functionality in certified health IT, if done appropriately, could allow clinicians to counsel patients on their treatment options at the point of care, informed by real-time and accurate information about pharmacy benefits, plan-specific formularies, prior authorization requirements, and out-of-pocket costs. The request for information includes questions about the use of the NCPDP RTPB standard version 12, as well as other potential requirements regarding integration into workflow, eligibility checks, electronic prior authorization, and other issues.

The FAH generally supports ONC's approach to testing a health IT module's ability to perform a set of scenarios related to RTPB. However, to be useful, the information shared with a clinician during a patient visit will need to be accurate and reflect actual benefits and out-of-

pocket costs, including consideration of primary and secondary insurance coverage. As ONC develops a possible approach to RTPB certification, the FAH agrees that certified modules should also include functions such as formulary and benefits checks and electronic prior authorization. However, in doing so, ONC must carefully consider the workflow impacts on providers. To the maximum extent possible, health IT standards should support the ability for these workflows to be automated and reduce burden for providers. In addition, the functions should be able to be performed by either the clinician during a visit or by other staff outside the visit.

ONC asks whether items other than medications, such as vaccines or medical devices, should be in scope for any future RTPB certification requirements. The FAH believes that including additional items would benefit patients and provide them, as well as their clinicians, with more complete information to inform decision-making. These potential benefits should be carefully weighed against possible challenges with standardizing the data for these additional items.

Finally, we appreciate ONC's efforts to standardize the RTPB certification process. However, we request further clarity on ONC's proposal to establish RxNorm as the single source of clinical data replacing National Drug Codes (NDC) for such purposes, and specifically related to the level of RxNorm code that is being considered as the single source. We believe that RxNorm cannot replace NDC unless it is a granular enough version that displays data elements such as dose and route. With the proposal of USCDI v3, we request more robust data to understand how those elements would play into the RTPB certification criteria.

The FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership as we strive to advance the use of health IT to improve our nation's health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

MullMaluntt