AMERICAN ACADEMY OF FAMILY PHYSICIANS

June 19, 2023

National Coordinator Micky Tripathi
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C. St SW, 7th Floor
Washington, DC 20024

Re: RIN 0955–AA03; Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Dear National Coordinator Tripathi:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 129,600 family physicians and medical students across the country, I write to provide comments on the recent proposed rule from the Office of the National Coordinator (ONC) for Health Information Technology (IT) on the Certification Program, Algorithm Transparency, and Information Sharing (HTI-1).

The AAFP has long supported ONC's efforts to advance interoperability of health IT. Interoperability is essential for ensuring family physicians have access to meaningful, actionable data at the point of care, which in turn enables them to provide high-quality, patient centered care across the lifespan. Truly interoperable health records will also reduce administrative tasks for physicians and facilitate patients' access to their health data. We appreciate ONC proposing several changes through the electronic health record certification program (CEHRT) and information blocking to help ensure physicians and other end users have ready access to affordable, current health IT. Among several other recommendations detailed in our comments, **the AAFP recommends ONC:**

- **Adopt electronic prior authorization standards into CEHRT as soon as possible, including standards that automate prior authorization requests for prescription medications;**
- **Continue to advance real-world testing through various authorities, including ensuring new standards perform successfully in real-world testing before mandating their adoption;**
- **Work with industry to advance effective, user-friendly data segmentation functionality that protects patient safety and security without adding to clinicians' administrative burden, and**
- **Finalize proposals to advance transparency for predictive decision support interventions without unnecessarily restricting access to these technologies.**

1133 CONNECTICUT AVE., N.W., STE. 1100 | WASHINGTON, DC 20036-4305 | (800) 794-7481 | (202) 232-9033

Certification Changes

ONC proposes to rename all criteria within the Program to "ONC Certification Criteria for Health IT" to create more stability for the Program, make it easier for developers to maintain their product certificates, and help users of certified health IT identify which certification criteria are necessary for their participation in other HHS programs.

The AAFP agrees with this proposal to rename all criteria within the ONC Health IT Certification Program to "ONC Certification Criteria for Health IT." This would create more stability for the Program and make it easier for developers of certified health IT to maintain their product certificates over time.

ONC is proposing to update the ONC Health IT Certification Program to include version 3 of the United States Core Data for Interoperability (USCDI v3) to expand the amount of data available to be used and exchanged for patient care. Under this proposal, both versions (version 1 and 3) would be referenced as applicable in the USCDI standard in § 170.213 for the time period up to and including December 31, 2024. USCDI v1 (July 2020 Errata) in the USCDI standard in § 170.213(a) would expire on January 1, 2025.

The AAFP agrees with the proposal to advance to USCDI v3 and agrees with ONC's reasoning that USCDI v3 expands the data elements and data classes included in USCDI and will increase the amount of data available to be used and exchanged for patient care. The USCDI is a standard for data that must be accessible through certified health IT (EHRs and other health IT products) for numerous certification criteria. The AAFP believes that ONC should continue to advance USCDI to expand the breadth and depth of highly structured clinical data to support deep integration across EHR systems. This will allow for more efficient and effective care coordination, which will ultimately improve patient outcomes. We urge ONC to move forward with the proposal to advance to USCDI v3. This is an important step in improving the quality, safety, and efficiency of healthcare in the United States.

ONC also proposes to adopt Consolidated-Clinical Document Architecture (C-CDA) Templates for Clinical Notes STU Companion Guide, Release 3 – US Realm (C-CDA Companion Guide R3) in § 170.205(a)(6). If the updated C-CDA Companion Guide Release 4 (R4) is published before the date of publication of the final rule, ONC intends to consider adopting the updated Companion Guide that provides guidance and clarifications for specifying data in USCDI v3. The C-CDA templates provide implementation guidance on how to structure clinical documents so they are interoperable between EHRs and across health care organizations.

The AAFP supports the advancement of Consolidated – Clinical Document Architecture (C-CDA), which is foundational to today's EHRs. Incorporating newer versions of C-CDA standards into the certification program will help improve interoperability of clinical data and therefore has the potential to improve the quality and efficiency of healthcare. However, we also believe that it is important to conduct real-world testing before any standard use is mandated. This will help to ensure that C-CDA meets the needs of physicians and their patients.

ONC is proposing to establish new requirements for health IT developers to ensure that they continue to provide timely access to interoperable health IT to their customers and meet the needs of patients and providers as new standards and capabilities are developed. ONC proposes two accompanying Maintenance of Certification requirements:

- 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.
- A health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers of such certified health IT.

The AAFP appreciates ONC proposing regulations to ensure vendors are making new capabilities and standards available to their customers, including physician practices. Making updates available to customers in a timely manner is important for advancing interoperability, patients' access to their data, and potentially reducing administrative burden. However, updating EHR systems can be both costly and disruptive to physician practices as they have to pay for new modules, interrupt functionality to install updates, and train staff on how to use new modules. We are concerned that vendors may force practices to update their solutions more quickly than practices would like, resulting in unaffordable costs and disruption to patient care and physician workflow. The AAFP is also concerned that the "timely" requirements may be too stringent, which could make it difficult for vendors to meet them. This could lead to vendors abandoning the health IT market, which would make it harder for practices to find and implement interoperable health IT.

The AAFP urges ONC to carefully consider the potential unintended consequences of this mandate before it is finalized. It is important to strike a balance between ensuring health IT continues to meet the needs of patients and physicians as new standards and capabilities are developed and avoiding unintended consequences that could harm practices and the health IT market. **ONC should consider including language in these new requirements that directs Health IT developers to update modules in consultation with their customers, including end users. Additionally, HHS should provide a safe harbor for those customers that wish to delay implementation of the updated modules, such that the customer continues to have a certified EHR technology which is required for other HHS programs.**

Real World Testing

ONC proposes to clarify real world testing reporting requirements by requiring health IT developers to report on all newer versions for certified Health IT Modules.

Real-world testing is critical to ensuring that health IT is effective and interoperable for the physicians, clinical staff, and other end users that rely on EHRs every day. The AAFP recently joined with our partners in the Health IT End Users Alliance to publish a consensus statement on real-world testing, which notes that policy proposals should build from the results of real-world testing and consider the implementation pathway for a variety of end user settings. By clearly requiring health IT developers to test all applicable certified Health IT Module(s) as

part of their real-world testing requirements, ONC is taking an important step to ensure that health IT is meeting the needs of patients and clinicians. **We urge ONC to finalize this proposal and to make real-world testing a mandatory requirement for all health IT developers.**

Decision Support Interventions

ONC proposes to introduce transparency requirements to address uncertainty regarding the quality of predictive decision support interventions (DSIs) that certified health IT modules enable or interface with. Predictive DSI includes those using artificial intelligence and machine learning. This transparency is intended to provide potential users with information about how a predictive DSI was designed, developed, trained, and evaluated to determine whether it is trustworthy.

The proposed transparency requirements are meant to establish a framework for the types of information about DSI technology that should be made readily available to the users. ONC proposes requirements that focus on two areas:

- Technical and performance aspects of predictive DSIs, such as underlying details of the predictive model, how the model was trained, and how its outputs were validated.
- Organizational competencies employed to manage risks for predictive DSIs, including bias

The proposed transparency requirements are not intended to certify predictive DSIs, but to provide users with information to make their own judgments about their quality and guide decisions at the time and place of care. ONC ultimately hopes this will reduce uncertainty and advance the trustworthiness of emerging fair, appropriate, valid, effective, and safe technologies.

We are supportive of the use of predictive and evidence-based decision support interventions (DSI) and agree there needs to be transparency to customers and users of DSI so that end-users are able to determine their level of trust and reliance on the recommendations from DSI. For example, physicians need enough information to determine if the data used to develop and pilot a DSI solution are relevant for their patient population, specialty, or other focus. Additionally, it is critical that EHRs have the functionality to integrate data, both read and write, with third party modules that provide DSI. We urge ONC to provide certification criteria for both of these critical functions.

In reviewing the proposal for “source attributes” it is somewhat ambiguous as to what certified modules would need to implement. We request that ONC provide more clarity on the expectation of how they must be implemented in a health IT module. As for the specific meta-data for DSI (i.e., source attributes), we believe a broader conversation and national consensus is needed beyond that of certification. We urge ONC and HHS to convene stakeholders to develop a consensus set of meta-data that should and must be transparently provided by DSI developers. We would strongly support a standard representing a Structure Product Label for Predictive Decision Support. At the same time, we are concerned that mandatory, large meta-

data requirements could limit some DSI access. This either due to a lack of such meta-data or DSI that was built by hospitals, health systems, or practices for their own use. We urge ONC to pursue a balanced approach that advances transparency without being overly prescriptive or restricting access.

When the proposed rule references USCDI data classes, it is unclear how they would be incorporated in certification criteria for DSI. We urge ONC to clarify whether a health IT Module must support these data elements so external DSI solutions can be integrated. The AAFP believes the ability to integrate third party DSI solutions into CEHRT is a critical functionality. We ask ONC to clarify what is intended by referencing data classes in the DSI criteria.

The proposed rule in § 170.315(b)(11)(ii)(C) introduces a new functionality to enable users to provide electronic feedback data based on the information displayed through the DSI. This feedback data will include information such as the intervention, action taken, user feedback provided (if applicable), user, date, and location. There is only functionality requiring these data to be exportable. ONC sees this feedback as valuable for evaluating the effectiveness of DSIs.

We agree that user feedback on DSI is critical as is the ability to record/document when DSI is used and the action taken by the end-user. We do have some concern though that truly using end-user feedback for safety and improvement requires much more than capturing end-user feedback. We believe it is too early to mandate this type of functionality and recommend ONC finalize this proposal in future rulemaking.

Revised Demographic Certification Criteria

ONC is proposing to rename the “Demographics” criterion as “Patient Demographics and Observations” and add the data elements “Sex for Clinical Use”, “Name to Use”, and “Pronouns.” These additions reflect concepts developed by the HL7 Gender Harmony Project and would take effect on January 1, 2026.

The AAFP strongly supports increasing inclusiveness of language used in health IT. We agree that the standards and terms used to represent specific USCDI data elements should be updated to be more appropriate and clinically useful. However, the AAFP is concerned that, as proposed, these data elements may lack usability. We encourage ONC to work with the HL7 Gender Harmonization group and others to develop greater granularity for the data elements to better leverage these important concepts.

Specifically, the AAFP encourages ONC to include discussions of the semantics of ‘clinical use’ and provide defined semantics for data elements to improve physician workflow. Additionally while we agree with the potential negative connotations of “refused to answer,” we have concerns about using the term “specified” to denote “unspecified” (or other null flavor).

Patient Requested Restrictions

The proposed rule adds a new certification criterion called “patient requested restrictions.” This criterion intends to allow patients to request that their health information be restricted from being

used or disclosed. This will be done by enabling users of health IT Modules to flag such data. The flagged data will then be prevented from being included in any subsequent use or disclosure. The proposed rule also provides flexibility to health IT developers in how they implement the "enable a user to flag" functionality. Developers can use security labels, data standards, or other specifications as they see fit. The developer will also have flexibility in how they implement the restriction on the inclusion of flagged data in subsequent uses or disclosures. The proposed rule is intended to give patients more control over their health information and to protect their privacy in line with Health Insurance and Portability and Accountability Act (HIPAA).

The AAFP strongly supports patients' right to privacy and the need to provide differential confidentiality to support patients' privacy. As discussed further below, we have long called for effective data segmentation standards that enable physicians to prevent the sharing of select patient data to protect patient privacy and security. The need for these functionalities has become even more pressing as certain types of evidence-based medical care are being criminalized in some states. The AAFP has urged ONC to use its authority to provide physicians and patients with more tools to protect patients' data and we appreciate ONC's efforts to do so. **However, existing technology does not meet current data segmentation needs, could lead to unintended consequences, and will instead add to physicians' administrative burdens.** For example, we are concerned that existing technology will not properly identify all of the related data elements, clinical notes, and other types of data that are associated with a patient's flag. This will result in data leakage and could negatively impact the patient-physician relationship. We are further concerned that some technologies will instead segment out significant portions of a patient's data in an attempt to comply with the flag, making the record useless to other members of the care team.

We therefore urge ONC not to finalize this proposal. ONC should instead include this criterion for trial use once the market is mature enough. We again note that any standard must be real-world tested before mandated for adoption.

In future rulemaking, the AAFP recommends ONC strengthen this proposal by establishing a consensus process to define an ontology that defines both the types of restrictions as well as the semantics to inform implementation of restrictions.

In the meantime, **the AAFP recommends ONC include a certification criterion for the "tracking of patient privacy and disclosure requests." This is a key missing functionality of CEHRT and one that is long overdue. We are strongly supportive of adding this functionality to certification.**

Information Blocking Exceptions

ONC proposed two additional exceptions under the Information Blocking rules, namely "Third Party Seeking Modification Use" and "Manner Exception Exhausted." The Third Party Seeking Modification Use is an exception for the case where a non-health care provider requests for information to be modified. Under the current exceptions, if the modification should not be made, the health care provider would need to leverage the patient harm, security risk, or other

exception all of which would require significant effort by the provider to execute (i.e., data collection, data analysis, and documentation). This new exception is to reduce those administrative burdens. It is noted that only health care providers or organizations can use this exception. It does not apply to business associates. The Manner Exception Exhausted is an except for information is needed because the entity has tried all reasonable manners to fulfill the information use request but is unable.

The AAFP strongly agrees with the inclusion of a new "Third Party Seeking Modification Use" exception and agree it should not apply to non-health care entities. We do look forward to further guidance by ONC on how this exception should be documented if enacted and strongly recommend that such documentation requirements be minimal. We are also supportive of the inclusion of a new Manner Exception Exhausted exception. However, we note that physicians and practices will be constrained by the manners (i.e., formats and standards) supported by their certified EHR technology. **We urge ONC to clarify that, if the physician or practice provided the information in the manners supported by their CEHRT and any other manner that requires minimal effort; they should then be able to leverage the Manner Exhausted Exception.**

Requests for Information

Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities

ONC indicates that it plans to propose in future rulemaking the establishment of a real-time prescription benefit health IT certification criterion. ONC requested public comment on the potential of adopting the National Council for Prescription Drug Programs Real-Time Prescription Benefit (NCPDP RTPB) standard. ONC seeks comment on these potential future proposals, as well as comments regarding other standards and certification criteria that are needed to fully support other electronic prescribing workflows, like prior authorization.

The AAFP has supported other policy proposals to advance the adoption and widespread use of NCPDP standards. This is consistent with AAFP policy which notes that physicians must have real-time information made available to them about drug formularies at the point of care. Such information facilitates shared decision making between physicians and their patients about the best treatments available to them, the cost of those treatments, and associated insurer utilization management requirements or other restrictions that may require patients to try an alternative. Enabling these conversations at the point of care can help reduce care delays and patient frustration. **The AAFP therefore would support ONC proposing to adopt NCPDP RTPB standards into certification criteria provided they performed successfully in real-world testing.** The AAFP further urges ONC to work with CMS to ensure public payers are required to use these standards.

Family physicians are overwhelmed by prior authorization requests, appeals, and related administrative tasks. Prior authorizations cost practices significant resources and time, as well as drive physician burnout. **The AAFP strongly urges HHS to take steps to dramatically decrease the overall volume of prior authorization requirements. However, health IT**

solutions are also needed to support real-time automation between prescribers and payers.

Family physicians consistently report that prior authorization requirements for prescription medications make up a significant portion of the prior authorization requirements they deal with on a daily basis. **The AAFP therefore urges ONC to include electronic prior authorization functionalities in CEHRT as soon as possible, including for prescription medications and all other services for which prior authorization is required by payers.**

We support the modular approach to certification, but we are concerned that certifying each drug financial transaction independently will not ensure that the functionality integrates seamlessly into a workflow. This is because multiple transactions are needed in a single patient encounter/prescription. To ensure that the functionality integrates seamlessly, the certification criteria should include the ability for the payload of one transaction to flow into the request of the next transaction in logical succession.

Data Segmentation

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

The AAFP appreciates ONC raising the importance of data segmentation to protect patient privacy. We along with several other stakeholders have raised concerns regarding patient privacy and confidentiality, as well as personal safety and security, as health information becomes increasingly interoperable and amid a growing trend of criminalizing medical care. We appreciate ONC hearing these concerns and examining its authorities to address them within CEHRT and other programs. The AAFP has raised concerns regarding the lack of meaningful, effective data segmentation capabilities for years. We continue to believe these concerns will prevent data segmentation from being a timely solution for protecting patient privacy and confidentiality.

EHI is electronic protected health information (ePHI) that would be included in a patient's medical records, billing records, payment, enrollment, or other records. The breadth of information that currently qualifies as EHI and is thus subject to segmentation and confidentiality regulations makes the feasibility of these regulations challenging for many physician practices. Modernization of current widely available technology is needed to ensure physicians and their practices can segment appropriate data elements, ensure timely and effective deidentification of data when needed, and uphold patient consent and privacy requirements.

Today, physicians generally lack the ability to segment out certain parts of a patient's record while maintaining the ability to meaningfully share treatment data across the patient's care team for the purposes of care coordination and management. This lack of granular data segmentation

functionality increases administrative burden and creates challenges for clinicians who are complying with requests not to disclose EHI while still complying with HIPAA and information blocking requirements. **As such, the AAFP strongly urges HHS to work with health IT developers and health data management platforms to advance meaningful data segmentation capabilities. Given the lack of industry progress in this area, the AAFP urges ONC to examine how it can spur action to respond to growing threats to patient privacy, the patient-physician relationship, and patient and clinician safety.**

Thank you for the opportunity to provide comments on the proposed rule. Should you have any questions please contact Meredith Yinger, Senior Manager of Federal Policy at myinger@aafp.org or (202) 235-5126.

Sincerely,

Sterling Ransone, Jr., MD, FAAFP
Board Chair
American Academy of Family Physicians