**Association of
American Medical Colleges**
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

June 20, 2023

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator (ONC)
U.S. Department of Health and Human Services
Attention: Health Data, Technology, and Interoperability Proposed Rule
Mary Switzer Building, Mail Stop: 7033A
330 C St. SW
Washington, DC 20201

RE: *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* [RIN 0955-AA03]

Dear Dr. Tripathi:

The AAMC (Association of American Medical Colleges) appreciates the opportunity to comment on the notice of proposed rulemaking entitled "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing," 88 *Fed. Reg.* 23746 (April 18, 2023).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The AAMC shares the ONC's commitment to improving interoperability and to ensuring that patients and providers can seamlessly access, exchange, and use electronic health information (EHI) to improve clinical care and outcomes. Efforts to standardize data for interoperability should prioritize information that is critical for delivering high quality care that meets patients' needs as they move through the health care system, and that supports their broader health goals outside of the health care system. At the same time, it is critical to protect the privacy and security of patient's sensitive health information and to ensure trust in adoption of innovative algorithm-based tools, machine learning (ML), and artificial intelligence (AI) in health care.

Many of our member institutions were early adopters of electronic health records (EHRs) and remain committed to continuous improvements to interoperability and technological innovation to support the delivery of high-quality health care for all patients. Advancing interoperable data sets is also critical for research and population health, including developing evidence-based solutions to achieve health equity goals. However, the AAMC must acknowledge that steadfast commitment to interoperability and innovation is not without financial and administrative burden. Quick implementation timelines require significant investment from health care providers to implement upgrades necessary to maintain use of a certified health IT module required for other federal programs. Rapid regulatory change requiring frequent upgrades, in line with vendor offerings and ability to meet ONC's timelines, can frustrate clinicians, and require health systems to manage the pace of change to the EHR contributing to high levels of burnout.[1] ONC should balance timely technical improvements for interoperability with downstream costs and burden on the health care system. Feedback in response to specific proposals follows.

Update to the United States Core Data for Interoperability (USCDI) Version 3 No Later than January 1, 2025

The ONC proposes to update the USCDI standard in 45 CFR § 170.213 to add the newly released Version 3 and sunset the original Version 1 as of January 1, 2025. Any Health IT Modules seeking certification that reference the USCDI would need to be able to exchange the data classes and elements that comprise USCDI v3. (p. 23763). As noted in the proposal, the USCDI standard is cross-referenced to certain certification criterion, including criterion under "Care coordination," "Patient engagement," and "Design and performance" certification standards. ONC notes that adopting the USCDI v3 "would provide more comprehensive health data for providers and patients accessing and exchanging" EHI including additional demographic data elements and data elements regarding social determinants of health. (p. 23764)

The AAMC supports policies to improve the widespread adoption of updates to the USCDI. While current policy would allow certified Health IT Modules to adopt finalized updates to the USCDI without changes to certification criterion, to our knowledge, such proactive adoption is not the norm. Considering the growing consensus that we must improve data collection standards for demographic data and data regarding health-related social needs,[2, 3] **we wholeheartedly support this update to USCDI v3 as an important step to better address data gaps to support equitable care and improve patient outcomes, though ask ONC to consider developer readiness to deploy and widespread health care provider ability to implement as early as January 2025.**

The AAMC has two broad comments regarding the USCDI and efforts to improve data interoperability to improve care delivery and address health inequities. **First, we simply wish to flag that the ONC should follow efforts by the Office of Management and Budget (OMB) regarding**

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[1] J Budd, "Burnout Related to Electronic Health Record Use in Primary Care," J Prim Care Community Health (April 2023), finding in part that EHRs overall have an inferior usability score when compared to other technologies.
[2] O Biermann et al., Data, Social Determinants, and Better Decision-making for Health: the 3-D Commission, J Urban Health (August 2021).
[3] AAMC Center for Health Justice, Data for Health Equity, describing the Center's commitment to ensuring that we have the data necessary to build the evidence base to achieve health equity in the United States.

potential adoption of new race and ethnicity data standards. The AAMC's Center for Health Justice recently commented to the OMB on its initial proposals for updating OMB Race and Ethnicity Statistical Standards, noting that collection should focus on a single question of how an individual self-identifies, add "Middle Eastern or North African" as a new minimum category, and that OMB should provide additional criteria and guidance for federal agencies to use detailed race and ethnicity categories by default.[4] We urge ONC to be prepared to expeditiously use its policy levers to modernize health IT modules in line with any new data standards established by OMB.

Second, the AAMC recommends that the ONC commit resources to addressing *semantic differences* across health systems when implementing data standards under the updates to the USCDI. Data standardization is critical for interoperability, and we believe that the USCDI is a key to such standardization. However, we have heard from members that data standardization alone has not yet moved the needle for improving interoperability of health information to improve care delivery due to semantic differences by health systems when implementing data standards. The AAMC leads Project CORE: Coordinating Optimal Referral Experiences through implementation of electronic consultations through tools built into the EHR. Our experience working with member academic health systems through Project CORE has highlighted significant interoperability issues across systems, even in cases where they are operating within the same platform or using the same EHR tools developed by the same EHR vendor. For example, a call at one institution for the value of a white blood count lab may return the value but using the same vendor platform (or a FHIR API) to call at another institution might not result in a returned value due to semantic inconsistency. Currently, there are no feedback loops to address such inconsistencies in the implementation of normative standards across the nation. ONC could support broader semantic standardization through the development of national and regional user groups that provide feedback loops on semantic differences, helping to serve as a mechanism for truly normalizing national data standards into clinical practice. Additionally, ONC support for broader adoption and implementation of standard ontologies with quality assurance processes (i.e., LOINC, RxNorm, SNOMED, etc.) may help improve semantic differences between health systems.

Algorithm Transparency & the New Decision Support Intervention Criterion § 170.315(b)(11)

ONC proposes to reconceptualize the existing Clinical Decision Support (CDS) certification criterion for certified Health IT Modules at § 170.315(a)(9) with a new Decision Support Intervention (DSI) certification criterion to address "the continued evolution of decision support software, especially as it relates to AI- and ML-driven predictive DSIs." (p. 23775) Overall, these proposals center around information transparency of DSIs that certified Health IT Modules enable or interface with, intending for potential users to "have sufficient information about how a predictive DSI was designed, developed, trained, and evaluated to determine whether it is trustworthy." ONC is clear that the proposals "are not aimed at approving or guaranteeing the quality of predictive DSIs or the models they are based on." Instead, the proposals are intended to "provide users and the greater public information, available in a consistent manner, on whether predictive DSIs are fair, appropriate, valid, effective, and safe [FAVES]." Due to a current lack of consensus on measures of FAVES, ONC

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[4] AAMC Center for Health Justice, Comments to OMB RE: Initial Proposals for Updating OMB's Race and Ethnicity Statistical Standards, Docket No. OMB-2023-0001 (April 17, 2023).

believes it is premature to propose the establishment or definition of regulatory baselines, measures, or thresholds of FAVES for predictive DSIs. (p. 23780)

The AAMC supports transparency as one tool to balance innovation with potential unintended consequences and bias that could result in health inequities from its use. We also acknowledge that ONC may only regulate predictive DSIs within the authority of the Health IT certification programs, which is only a part of the broader federal regulatory authority over DSIs, with separate and distinct regulatory structures under other bodies, like the U.S. Food and Drug Administration (FDA) and the National Institute of Standards and Technology (NIST).

We urge ONC to further flesh out the role of certification relative to the application of predictive DSIs within an EHR for safe and equitable clinical use. As proposed, health care systems and clinicians will need to make decisions on whether to enable or interface with a predictive DSI, based on information provided to meet certification standards. The AAMC is concerned that few (and certainly not most) systems or clinicians will have both the expertise and resources to evaluate sophisticated information about certified predictive DSI tools to determine trustworthiness or to make equity-based assessments on potential use. A recent report found that large health systems currently are most likely to use AI tools, and typically limited to specific use case or area of the organization.[5] Putting the burden of evaluation of DSIs on end users could lead to greater inequities in widespread adoption of high quality, effective predictive DSI tools that truly improve care for those patients and populations with access to providers using such tools.

ONC should commit to greater collaboration with federal partners to best determine how to regulate the responsible, equitable use of ML and AI-based tools, like predictive DSIs, in health care. This would be in line with recommendations from the Equitable Data Working Group established pursuant to Executive Order 13985 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government."[6] That Working Group recommends capacity building for robust equity assessment for policymaking and program implementation. Specific to this certification criterion, the AAMC asks the ONC to consider whether there is value in requiring additional disclosures by developers on whether a tool is subject to FDA regulations of software as a medical device,[7] and if so, whether ONC should withhold certification until approved by the FDA. Additionally, ONC should consider instead whether to pilot test a certification environment for DSIs prior to a full-scale launch. This could help ONC to better understand the value of the information presented for certification and whether health care systems, clinicians, patients, and the public will be able to meaningfully use the information provided by developers. A pilot approach also could provide more time for the development of consensus-based definitions, baselines, measures, and thresholds of FAVES for predictive DSIs that could be incorporated to the full-scale launch of the revised criterion. Greater standards for communicating measures of FAVES

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[5] Center for Connected Medicine, Optimizing Clinical Trials at Health Systems: The Role of Artificial Intelligence and the State of the Market (Jun. 2023).

[6] White House Equitable Data Working Group, "A Vision for Equitable Data: Recommendations from the Equitable Data Working Group," (Apr. 2022)

[7] *See* FDA, Artificial Intelligence and Machine Learning in Software as a Medical Device webpage (last updated Sep. 2021), detailing a potential future FDA regulatory framework to enable the FDA and manufacturers to evaluate and monitor a software product, including postmarket performance.

for predictive DSIs will help to broaden clinical use of FAVES models through reduced burden on systems and clinicians to evaluate models, and consequently benefit more patients.

Privacy and security – New Patient Requested Restrictions Criterion § 170.315(d)(14)

ONC proposes to establish a new certified health IT criterion, effective by January 1, 2026, as part of the Privacy and Security Framework that will allow users of the health IT to implement a process to restrict data expressed in the USCDI standards from use or disclosure in response to a patient's request. This proposal creates a criterion aligned with the HIPAA Privacy Rule's "right to request a restriction" on uses and disclosures. (p. 23822) ONC notes that this proposal is in part also to recognize the dynamic and highly individualized perception of "sensitive data" privacy that must be balanced relative to policies intended to improve interoperability and increased sharing of health data. (p. 23821) ONC's proposal is standards-agnostic, though ONC requests feedback on alternative proposals that would adopt standards in full, including implementation specifications for the new criterion. (p. 23824)

The AAMC supports this critical functionality as a certification criterion for Health IT Modules. Without such functionality, it is increasingly challenging for health care providers to ensure patient trust in maintaining the privacy and security of sensitive personal health information. This is increasingly necessary, as ONC notes, in response to other policy goals of improving data sharing to support care delivery. Additionally, such required functionality should support providers implementing information sharing practices in compliance with potential future policies to protect sensitive health information regarding highly politicized lawful health care services.[8] Regarding the proposal as standards-agnostic, the AAMC urges ONC to listen to the health IT developer community regarding the alternative proposals to determine whether there is broad consensus on a single standard that could be adopted. In general, we believe it is easier to implement new capabilities for EHRs when there are national standards and specifications. ONC should consider expanding timeline for the new criterion if national standards and specifications are not ready as of this rulemaking.

Information Blocking

ONC proposes several changes and additions to the information blocking regulations first adopted in 2020. These changes include narrowing the scope of "offer health IT" in the definition of "health IT developer of certified health IT" to expressly exclude certain funding subsidy arrangements, common activities associated with purchasing health IT, and consulting and legal services as part of a package of administrative services. ONC believes these exclusions will "encourage beneficial arrangements under which providers in need can receive subsidies for the costs of obtaining, maintaining, or upgrading certified health IT" or "give health care providers…certainty that implementing certain health IT features and functionalities…will *not* be considered an offering of certified health IT." (p. 23858) Additionally, ONC proposes to amend the Manner exception to information blocking to create a narrow exception for practices that are necessary to comply with requirements under the

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[8] For example, HHS OCR proposals to modify the HIPAA Privacy Rule regarding prohibited uses and disclosures of PHI related to reproductive health care.
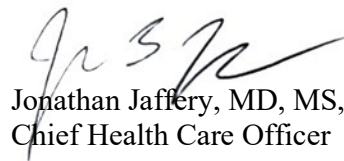
Trusted Exchange Format and Common Agreement (TEFCA). The proposal is intended to better acknowledge "the value of TEFCA in promoting access, exchange, and use of EHI in a secure and interoperable way." (p. 23872)

The AAMC supports these proposals. We appreciate clarity to the definition of "offering health IT" to ensure that academic health systems do not inadvertently become "health IT developers" for purposes of information blocking. Including academic health systems inadvertently as "health IT developers" previously could potentially frustrate their efforts to enter value-based care arrangements with other providers in their communities or otherwise implement health IT features to improve care delivery. Such value-based arrangements often include provisions to obtain or upgrade certified health IT and adopt common activities for accessing and exchanging EHI to coordinate care for patients served under the arrangement. The AAMC agrees with the ONC's policy choice to better promote TEFCA adoption by regulated actors through the proposed adoption of a narrow Manner Exception. The ONC recently published a blog post analyzing data reported from an American Hospital Association survey regarding hospital knowledge of TEFCA, finding that more than half of hospitals surveyed are aware of TEFCA and plan to participate and very few hospitals aware of TEFCA were *not* planning to participate.[9] These results help support policy actions that encourage participation in TEFCA to best promote information sharing as envisioned under the 21st Century Cures Act.

Conclusion

We thank the ONC for the opportunity to provide input on the proposed certification program changes and updates to the information blocking rules. We would be happy to work with you on any of the issues discussed above or other topics relating to interoperability that involve the academic medicine community. Please contact my colleague Phoebe Ramsey (pramsey@aamc.org) with any questions about these comments.

Sincerely,

Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO

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[9] J Everson and K Tavernia, TEFCA Awareness Among Hospitals and Variations Regarding Intent to Participate, ONC Health IT Buzz (May 31, 2023).