



*Submitted electronically via [www.regulations.gov](http://www.regulations.gov)*

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

October 4, 2024

Micky Tripathi, PhD, MPP  
National Coordinator  
Assistant Secretary for Technology Policy (ASTP)  
Office of the National Coordinator (ONC) for Health Information Technology  
U.S. Department of Health and Human Services  
330 C St. SW, 7<sup>th</sup> Floor  
Washington, DC 20024

***RE: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability [RIN 0955-AA06]***

Dear Assistant Secretary and National Coordinator Tripathi:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the notice of proposed rulemaking entitled “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability,” 89 *Fed. Reg.* 63498 (August 5, 2024), also referred to as the HTI-2 rule.

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 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, 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, academic health systems 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 participation in the AAMC by U.S. and international academic health centers.

The AAMC shares the ASTP/ONC’s commitment to improving interoperability and to ensuring that patients and providers can seamlessly access, exchange, and use electronic health information 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 the access, exchange, and use of clinical information.

Academic health systems 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 critical for research and population health, including developing evidence-based solutions to achieve health equity goals. However, it is important to acknowledge that such steadfast commitment to interoperability and innovation is not without financial and administrative burden. Implementing upgrades necessary to maintain use of a certified health information technology (IT) module required for other federal programs requires significant investment from health care providers. Rapid regulatory change requiring frequent upgrades, in line with vendor offerings and ability to meet ONC's timelines, can frustrate clinicians, and be challenging for health systems to manage the pace of change to the EHR, contributing to high levels of burnout.<sup>1</sup> Health systems must balance disruptions to operations during health IT system upgrades, including temporary reductions in efficiencies, data access and integrity issues, and reliance on manual processes or backup systems as downtime procedures. Our members go to great lengths to limit disruptions, often through additional investment in health IT implementation and maintenance. ONC should balance HTI rulemaking cycles implementing technical improvements for interoperability with downstream costs and burden on health care systems and clinicians. Feedback in response to specific proposals follows.

## **ONC HEALTH IT CERTIFICATION PROGRAM UPDATES**

### ***Update Systems to Implement the United States Core Data for Interoperability (USCDI) Version 4 No Later than 2028***

ASTP/ONC proposes to update the USCDI standard in 45 CFR § 170.213 to add Version 4 and sunset the Version 3 as of January 1, 2028. (p. 63515) 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 v4. (p. 63516). 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,<sup>2, 3</sup> **we wholeheartedly support this update to USCDI as an important step to better address data gaps to support equitable care and improve patient outcomes.**

**Additionally, the AAMC recommends that the ONC commit resources to addressing semantic differences across health systems when implementing data standards under the**

---

<sup>1</sup> 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.

<sup>2</sup> R Chunara, et al., "[Social determinants of health: the need for data science methods and capacity](#)," The Lancet: Digital Health, Vol. 6, Iss. 4 (Apr. 2024), noting that the first challenge to address the social determinants of health is having the data available.

<sup>3</sup> 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.

**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. As an example, 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 Fast Healthcare Interoperability Resource [FHIR®] application programming interface) 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.

***Leverage Application Programming Interface (API) Technology to Improve Prior Authorization Processing and Benefit Transparency***

ASTP/ONC proposes to update certification criteria for APIs required by the Centers for Medicare & Medicaid Services (CMS) to improve information exchange between patients, providers, and certain regulated payers. (p. 63580) Specifically, CMS will require the following APIs: Patient Access API, Provider Access API, Payer-to-Payer API, Prior Authorization API, and the Provider Directory API.<sup>4</sup> **The AAMC strongly supports updated certification criteria that require vendors to support standardized electronic capabilities and functionalities, particularly for improving prior authorization to improve patient care.** Additionally, adopting certification criterion for electronic prior authorization APIs will ensure providers are able to meet regulatory requirements set by CMS to complete prior authorization transactions utilizing an API to be meaningful users of certified EHR technology (CEHRT).<sup>5</sup> Having vendors support the same implementation guides cited in the CMS rule will help providers comply with this requirement.

---

<sup>4</sup> CMS, Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, etc. on the Federally-Facilitated Exchanges, etc., 89 FR 8758 (Feb. 8, 2024).

<sup>5</sup> *Id.*, at. 8909, establishing measures included in the Promoting Interoperability Program for hospitals, impacting 75% of the annual payment update, and the Promoting Interoperability Performance Category for the Merit-based Incentive Payment System for eligible clinicians, impacting payment incentives of up to ± 9% payment adjustment.

The AAMC supports adding two new payer and provider API requirements into the base EHR definition. For providers to realize the benefits of electronic prior authorization, their EHR developers must provide and support this technology as part of the base CEHRT product offering. However, for each end of the electronic PA exchange to function successfully (e.g., payer APIs connecting to EHR developer APIs), payers must be required to use certified electronic PA technology. Providers cannot be guaranteed their EHRs will communicate with payers in a standardized and effective way absent this requirement. **The AAMC encourages ASTP/ONC to collaborate with CMS and require that impacted payers, such as Medicare Advantage Organizations, adopt and use certified payer APIs as a condition of their participation in CMS programs.** Adding this requirement will further incentivize payers to implement the Health Level Seven International (HL7®) implementation guides as they are currently only recommended by the CMS rule, not required.

### ***Protect Providers from Unreasonable Fees to Use Certified APIs to Exchange Information with Payers***

The AAMC strongly supports proposals to leverage certification of APIs that facilitate the exchange of clinical information between patients, providers, and payers. However, we are concerned that providers will shoulder the brunt of health IT costs to support these APIs. It is reasonable to anticipate that health IT developers seeking voluntary certification will impose additional fees to support API certification standards, as they do for each update, upgrade, and enhancement required to meet CEHRT. While providers budget for reasonable expenses to maintain up-to-date health IT standards and functionality, unexpected fees have become excessive. On top of system upgrades, health systems must train staff on new features and ensure optimal use of EHR technology while maintaining patient care standards.

Without CMS requirements that regulated payers adopt certified API technology, the AAMC anticipates that providers will be forced to upgrade, purchase, and use new EHR features without guarantees that payers will support standardized APIs, likely leading to additional EHR costs. Also, payers might charge providers to connect to the payer's API system. As most providers contract with multiple payers, the resulting EHR developer fees will likely compound and become excessive. **ASTP/ONC should work with CMS to identify policy solutions to prevent unreasonable fees for providers.** This could include requirements that payers use certified payer APIs as well as leveraging policies that mitigate certified health IT developer fees (particularly through the information blocking fee limitations). **ASTP/ONC should utilize all available disincentives to protect providers from unreasonable fees associated with APIs that are necessary to exchange information to improve patient care.**

### ***Finalize New Interoperable Imaging Requirements for Health IT Modules with Specified Standards***

ASTP/ONC proposes new certification requirements to support images and "imaging links" within certified health IT products to promote access and exchange of images to include

capabilities to support a link to diagnostic imaging. (p. 63520) Specifically, this would be required for capabilities that support “transitions of care,” “application access – all data requests,” and the “standardized application programming interface (API) for patient and population services,” as well as requiring function support for viewing and downloading diagnostic quality and lower quality images under the “view, download, and transmit to a 3<sup>rd</sup> party” criterion. ASTP/ONC does not propose a specific standard for either images or imaging links though the agency anticipates that DICOM and the DICOMweb standard are likely to be among the standards widely used by providers to support images and imaging links, respectively. (p. 63521)

**The AAMC supports technological updates to support seamless sharing of imaging data to promote optimal patient outcomes and reduce the need to rely on physical media.** However, we are concerned that the lack of a specific standard could pose challenges. Without clearly defined standards, there is a risk that health IT vendors and/or providers adopt varying approaches to managing and sharing imaging data, leading to inconsistencies and inefficiencies in data exchange. This variability could frustrate efforts to transition away from physical media, like CDs, and hinder real-time sharing of critical imaging information, particularly in care transitions or when multiple healthcare providers are involved in a patient’s treatment. While DICOM and DICOMweb could very well become an established standard and foundation for imaging data sharing, failure to require a specified standard at the outset could delay progress and compromise the quality of care that patients receive. **We urge ASTP/ONC to modify the proposal to require specific standards as a necessary step toward achieving improved interoperability, better data-sharing practices, and ultimately better health outcomes for patients.**

### *Leverage Standards for Health IT Modules to Better Support Public Health Data Exchange*

ASTP/ONC proposes significant updates to the Program’s certification criteria related to public health for the first time since 2015. Specifically, proposals seek to add new functional requirements and adopt newer versions of standards within existing criteria at § 170.315(f), add two new criteria (one for birth reporting and another for bi-directional exchange with a prescription drug monitoring program) in current (f) criteria, adopt new certification criteria for health IT for public health in (f)(21) through (29), adopt enhancements to standardized API for patient and population services at § 170.315(g)(10), and adopt a new certification criterion for a standardized FHIR®-based API for public health data exchange at § 170.315(g)(20), which is also proposed for adopting in the Base EHR definition. (p. 63540)

**The AAMC strongly supports efforts to modernize public health through advancing data science capabilities.** Improving public health interoperability is key not only for the health of individual patients but also for the wellbeing of entire communities. The ability to exchange public health data efficiently between hospitals, health systems, and state/local public health entities is vital for addressing large-scale health challenges, such as pandemics, vaccination programs, and tracking public health trends. The proposed updates including transitioning to

FHIR-based exchange, bi-directional exchange with programs like the PDMP, and birth reporting, could greatly improve the quality and portability of public health data. These changes would also facilitate the integration of external data sources, such as those from foundations and registries, ensuring a more unified and efficient approach to public health interoperability. Improved public health data and data sharing directly influences the collective health and safety of communities and the nation. We urge ASTP/ONC to continue to collaborate with the Centers for Disease Prevention and Control on efforts to improve public health interoperability, including efforts to understand limitations with underfunded state and local public health departments and their underlying public health technology infrastructure to ensure that our public health agencies have the capabilities needed to work with providers to improve public health interoperability through updated health IT module certification requirements.

## **INFORMATION BLOCKING ENHANCEMENTS**

### ***Adopt the Protecting Care Access Exception With as Much Flexibility as Possible to Ensure Trust in the Safeguarding of Sensitive Health Information***

ASTP/ONC proposes a new Protecting Care Access Exception that would except practices from the information blocking definition that are implemented based on the actor's belief that sharing EHI indicating that any person(s) sought, received, provided, or facilitated the provision or receipt of lawful reproductive health care could result in risk of potential exposure to legal action for those persons and that the risk could be reduced by practices likely to interfere with particular access, exchange or use of specific EHI. (p. 63627) This new exception would be a new § 171.206 "Protecting Care Access – When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information (EHI) in order to reduce potential exposure to legal action not be considered information blocking?" (p. 63804)

### **The AAMC strongly supports the adoption of a new exception to information blocking specifically intended to ensure trust between patients and their health care providers.**

Physicians are committed to protecting their patients from all forms of harm, and improper access, exchange, or use of highly sensitive reproductive health care information is likely to cause significant emotional and physical harm to patients. Without this exception, health care providers will be put in the tenuous position of either switching to non-electronic recordkeeping (which is not subject to information blocking rules) or alarming patients with their concern that under the information blocking rules they cannot be fully confident in fully safeguarding the privacy of care information without significant financial penalty from the federal government. Either solution would be likely to erode trust and frustrate the use of interoperable health information to promote patient safety and improve outcomes. The proposal also enables health IT developers and HIE/HINs to take necessary actions based on their own or their customers' concerns that sharing specific EHI could expose physicians or individuals seeking, obtaining, providing, or facilitating reproductive care to risk, ensuring that providers have greater confidence in the safeguarding of sensitive EHI by other regulated actors.

**We encourage the ASTP/ONC to finalize this exception in a manner that provides actors with as much flexibility as possible to protect patients and providers.** This includes finalizing the exception to be based on an actor’s “belief” rather than “good faith belief” that the person(s) seeking, obtaining, providing, or facilitating reproductive health care are at risk of being potentially exposed to legal action and that the practice to interfere with the access, exchange, or use of that specific EHI could reduce that risk. Reducing the standard to “belief” would reduce potential misunderstandings and better encourage appropriate use of this exception and broadly support the policy objective of fostering trust between patients and their care providers.

***Revise the Privacy Sub-exception for Individuals to Request an Actor Not Share EHI***

ASTP/ONC proposes to revise the sub-exception for privacy at § 171.202(e) specifically relating to an individual’s request not to share EHI to remove existing limitations that apply the exception only to individual requested restrictions on sharing EHI that are permitted by another applicable law. (p. 63622) Removing this limitation on the sub-exception would allow an actor to implement restrictions a patient has requested on the access, exchange, or use of the patient’s EHI even where the actor may be concerned that another law or instrument could attempt to compel them to share EHI contrary to the patient’s expressed wishes.

**The AAMC supports this proposed revision to the sub-exception to ensure that the information blocking rules best protect an individual’s requests for not sharing their information.** Health care providers are concerned about the information blocking implications of honoring individual requests not to share EHI when facing demands for disclosure that might ultimately be enforced through the legal system. Currently, confusion about withholding EHI due to an unsettled court order are leading providers to grapple with disclosing EHI out of fear of information blocking accusations or penalties. As proposed, the revised sub-exception will give providers confidence that they may delay the disclosure of EHI when they are aware that a court order is being contested and ensure that they only share EHI contrary to an individual’s request for restrictions when truly compelled to do so.

***Link the Privacy Exception with the Infeasibility Exception Regarding Data Segmentation***

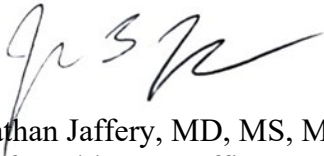
ASTP/ONC proposes to extend coverage under the *segmentation* condition at § 171.204(a)(2) to situations where the actor is unable to unambiguously segment EHI that could be made available from specific EHI that the actor may choose to withhold from the individual or their representative, consistent with the Privacy sub-exception “denial of individual access based on unreviewable grounds” at § 171.202(d). (p. 63623) This proposal would ensure that the *segmentation* condition would continue to apply in such scenarios, allowing the actor to honor the individual’s request not to share the EHI and to ensure the Privacy Exception Sub-exception — Precondition not Satisfied can be utilized by all actors without fear of being an information blocker.

**The AAMC strongly supports this proposal to ensure the safeguarding of sensitive health information within the limits of health IT's capabilities to segment data for privacy.** This proposal will protect providers from information blocking penalties when they are unable to segment specific EHI from the medical records that an individual has requested not to share. Physicians and other actors have been concerned about facing information blocking accusations if they withhold most of a patient's medical record to protect a subset of information that cannot be redacted or segmented. In the case of information regarding lawful reproductive health care, such information is often interspersed through the record and not easily isolated for segmentation purposes. The Office for Civil Rights (OCR) has recently modified its Privacy Rule to require providers receive an attestation that reproductive EHI will not be used for prohibited purposes.<sup>6</sup> The OCR rule creates a precondition – the need for a valid attestation – before a provider can disclose specific EHI. Under this proposal, if a provider does not receive a valid attestation, they or their EHR developer may withhold most of the medical record if prohibited from sharing specific EHI based on OCR, state, or other privacy regulations.

## 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](mailto: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

---

<sup>6</sup> OCR, HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 89 FR 32976 (Apr. 26, 2024).