



January 2, 2024

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Department of Health and Human Services
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National Coordinator
Office of the National Coordinator for Health
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Submitted electronically via www.regulations.gov

RE: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (RIN 0955-AA05)

Dear Mr. Blum and Dr. Tripathi,

Thank you for the opportunity to comment on the proposed disincentives for information blocking. As the professional home of the leading experts in safe health exchange and interoperability, the American Medical Informatics Association (AMIA) appreciates the opportunity to serve as a resource to the Department.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across care settings and patient populations.

With commodification of patients' health data, the Quadruple Aim (enhancing patient experience, improving population health, reducing cost, and improving work life of health care workers) is at risk. Information blocking may threaten patient safety, outcomes, cost, exacerbate administrative burden and cause duplication in care.

AMIA currently stands by our Health IT Data Standards & Interoperability Policy [Principle](#), which clearly describe AMIA's support for information sharing through our belief that clinical, research, and health information technology systems must be able to exchange data consistently and, ideally, uniformly.¹ Additionally, information exchange should be closed-loop, automated, electronic, legible, relevant, timely enough to ensure continuity of care, safe care transitions, incorporated into workflow, and not cost-prohibitive.

¹ AMIA Public Policy Principles. 2020. Available here: <https://www.amia.org/m/2e7af7b35c4b5154>.



Currently, AMIA members providing patient care report waiting up-to 30 days to receive requested records, which can often only be shared via fax. This is ineffective at routine point-of-care, as well as in urgent and emergent scenarios, as it disrupts continuity of care and can result in preventable errors. Some practices are using ONC-certified electronic health records (EHR) but are facing technical or administrative barriers to setting up electronic health information exchange and are at risk for information blocking and would benefit from training and support. Additionally, some practices are unable to afford the integration fees EHR vendors and others charge, creating additional risk for information blocking. These fees may be necessary for effective system integration, making them unavoidable. As such, some practices may avoid using an EHR altogether to avoid these fees. This further exacerbates existing equity issues. For example, if patient-care providers are providing services to patients who cannot access larger healthcare systems that can afford to overcome such barriers and pay integration fees. ONC may consider addressing the fact that the cost of integration work may be a barrier for some and encourage transparency to these costs to avoid one party using excessive fees to attempt to stifle competition or interoperability with a potential competitor. FHIR may address some of these integration issues, but FHIR does not magically make this process free as there are still costs to develop, maintain, support, and update these technical interoperability methods, no one should attempt to be way out of the norm for what they charge as a surreptitious attempt to stifle interoperability. In addition to the recommendation to encourage transparency of such costs, ONC may consider a bonus for practices who need EHR but cannot afford the associated fees. ONC must support practices robustly by removing practical barriers to information exchange and using stronger metrics beyond the current attestation to ensure practices are able to access and use electronic exchange of information, increasing access to information and reducing burden for all stakeholders.

In addition to the meaningful use of electronic health record attestation, AMIA proposes ONC use these metrics to measure information exchange:

- interfaces with practice's EHR for exchanging information with state prescription drug monitoring program (PDMP), state departments of health disease reports, state immunization registries, individual pharmacies and pharmacy benefit managers;
- the presence and amount of system integration fees;
- communication methods such as fax, e-fax, closed-loop referral systems, and continuity of care documents;
- redundant documents; and
- time between information request to information receipt.

AMIA also recommends ONC to encourage the phasing out of archaic communication methods such as standard fax machines only used for limited, specified purposes as they create redundancy, burden, and are inefficient, all of which contribute to information blocking and documentation burden. Unless an institution lacks alternative means to transfer records, fax machines are not needed. Data in PDFs do not lend to information exchange. When this information is incorporated in PDF format, it is less integrated, usable, or searchable at point-of-care. The HL7 FHIR resource for ImagingStudy is an example that could be considered for adoption by imaging centers and EHR companies.

AMIA encourages ONC to offer training for practice managers on methods of information exchange, including working with state HIEs, continuity of care documents, and electronic referrals.



It would be prudent for key stakeholders to be engaged in a forum to iteratively optimize any proposed plan for information exchange. As gatekeepers of information, electronic medical record companies, Health Information Exchange (HIE) organizations, QHINs, Informatics and Interoperability experts, primary care offices, hospitals, subspecialists, laboratories, imaging centers, pharmacies, skilled nursing facilities, rehabilitation centers, should all be consulted by ONC to make medical communication a top priority.

AMIA's recommendations to discourage information blocking and improve information exchange consider equitable access to care and documentation burden reduction for all health care stakeholders. AMIA cautions ONC that these proposed disincentives must not exacerbate the overzealous documentation burdens clinicians already face. Due to the confusing and redundant nature of administrative burdens providers currently face, providers will always be encouraged to over document to ensure they are reimbursed for their work. AMIA is concerned that the disincentives for information blocking may unintentionally result in providers adding more paperwork to demonstrate their intentions to promote interoperability. Burden from information blocking is also likely to be disproportionately heavy on under-resourced institutions that are already feeling the strain in many ways, including the need to have duplicate policies that meet the needs of the regulations, potential costs of maintaining EHR systems and functionalities that meet changing rules and regulations, and in terms of ensuring their patients have access to those records.

Finally, the proposed rule addresses providers as both individuals and entities (as per 42 USC 300jj). AMIA strongly encourages clear language confirming that individual clinical informaticians will not be held liable for building systems in good faith that may unintentionally result in information blocking.

AMIA would be pleased to serve as a resource as the Department continues to advance safe health information exchange. If you have questions or require additional information, please contact AMIA's Vice President of Public Policy, Reva Singh, at rsingh@amia.org.

Sincerely,

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