



December 28, 2023

Dr. Micky Tripathi
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: 21st Century Cures Act: Establishment of Disincentives for Health Care
Providers That Have Committed Information Blocking Proposed Rule,
Mary E. Switzer Building
Mail Stop: 7033A, 330
C Street SW
Washington, DC 20201

**RE: 21st Century Cures Act: Establishment of Disincentives for Health Care
Providers That Have Committed Information Blocking Proposed Rule [RIN 0955–
AA05]**

Dear National Coordinator Tripathi:

The Confidentiality Coalition appreciates the opportunity to comment on the proposed rule entitled “21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking” issued by the Department of Health and Human Services (HHS or Department) Office of the National Coordinator of Health Information Technology (ONC) in coordination with the Centers for Medicare and Medicaid Services (CMS), and published in the Federal Register on November 1, 2023 (“proposed rule”).¹

The [Confidentiality Coalition](#) is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, and others, committed to advancing effective health information privacy and security protections. Our mission is to advocate policies and practices that safeguard the privacy and security of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

¹ 88 Fed. Reg. at 74947 (November 1, 2023).

The Confidentiality Coalition strongly supports the goals of the proposed rule to deter information blocking and further the appropriate sharing of electronic health information (EHI) to improve care coordination and support safer and better care. We also agree that it is important that actors who knowingly engage in information blocking face meaningful penalties, since it is only through such measures that information blocking will be effectively deterred and the goals of the 21st Century's Cures Act (Cures Act) achieved.

We are concerned, however, that the proposed rule focuses almost exclusively on the punishment of health care providers, without any discussion of education or technical assistance. While penalties are necessary, we believe that an approach that emphasizes education and technical assistance first before resorting to punishment is likely to lead to better results in terms of fewer instances of information blocking and a greater willingness to share EHI. This is particularly the case as the information blocking regulation is still relatively new, untested, and in a state of flux, with a new final rule (HTI-1)² just released on December 13, 2023. This final rule makes several significant modifications to the regulation, and in its preamble discussion ONC states its intent to make yet more changes.³ In the preamble, ONC also notes that it received many comments asking for additional guidance on the regulation, and expressing concern about potential conflicts with the HIPAA Privacy Rule and other privacy requirements.

While we appreciate the extended guidance and examples ONC provides on the application of the regulation in the preamble to HTI-1, the comments clearly demonstrate that there is still considerable confusion and uncertainty regarding the regulation's operation, as well as concern that complying with the regulation in certain circumstances could result in a violation of other laws or patients' wishes. ONC's helpful example on "stacking" different exceptions shows how the regulation does in fact accommodate privacy laws and patient preferences, but also illustrates the complexity of the law, and the difficulty of navigating the different exceptions and sub-exceptions. Therefore, we ask that ONC and CMS consider providing guidance and technical assistance before imposing disincentives, and that the good faith concerns of health care providers that sharing EHI in some situations may not be permissible or in the best interests of their patients, be considered an extenuating circumstance to reduce the number of disincentives imposed.

We are also concerned that the proposal to list the names of actors determined to have engaged in information blocking on ONC's public website will do little to advance transparency regarding the impact of information blocking on the nationwide health information technology (HIT) infrastructure, but will result in public shaming of actors who have already been penalized for their conduct. As with the public posting on the


² See "[Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing](#)" and the [ONC Press Release](#), December 13, 2023..

³ See p.608 of unofficial version of HTI-1 ("We will issue additional guidance as needed and intend to propose additional exceptions in future rulemaking to further support health information privacy, including for information that patients may view as particularly sensitive such as reproductive health-related information.")

HHS website of entities that have suffered a major breach, this double penalty will serve only to create distrust and an adversarial relationship between actors and HHS, which will result in actors being less willing to approach HHS when they are uncertain whether to share EHI, lest their conduct be deemed information blocking. There is no indication that the public posting of major breaches on the HHS website has reduced the number of major breaches, and there is little reason to believe the public posting of actors on the ONC website will decrease the instances of information blocking if the significant financial penalties for violations fails to do so. Finally, transparency on the types and impact of information blocking on the nationwide HIT infrastructure can be achieved without identifying specific actors, as is achieved with the current ONC postings. As with the HHS breach notification web site, a public website is a crude instrument with which to punish violating actors, since it makes no distinction between major and minor offenses or degrees of culpability. We strongly urge ONC to reconsider the utility and benefit of such a public posting.

Thank you for your consideration of our comments, and please do not hesitate to contact me at tgrande@confcoa.com or 202-306-3538 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Tina O. Grande". The signature is written in a cursive, flowing style.

Tina O. Grande
Chair, Confidentiality Coalition and
Executive VP, Policy, Healthcare Leadership Council