

## Information Blocking and the 21st Century Cures Act

### Question

What do I need to know about compliance with the information blocking rule (also known as open notes) of the federal 21st Century Cures Act (“Cures Act”) and any potential risk in documentation?

### Answer

In 2021, the information-blocking provisions of the Cures Act went into effect. These provisions are meant to promote seamless and secure access, exchange, and use of electronic health information (EHI). Compliance with the Cures Act requires healthcare providers, health information networks, health information exchanges, and health IT developers to allow patients access to their EHI in a timely manner using the applications of their choice.

The legislation in the Cures Act makes access to electronic health records (EHRs) easier and less restricted. In an effort to increase interoperability across EHR platforms, vendors and users are required to enable the development of computer and smartphone applications to give patients full and portable access to their healthcare information.

The Cures Act Final Rule specifically requires that healthcare organizations provide patients access to their personal EHR notes without delay and without charge.<sup>1</sup> This means that healthcare organizations cannot block or prolong their patients’ access to any eligible information contained in their EHR, including test and study results.

Initially, the definition of EHI in the information-blocking regulations was limited to data elements represented in the United States Core Data for Interoperability Version 1. These data elements included eight categories of clinical notes: (1) consultation notes, (2) discharge summary notes, (3) history and physicals, (4) imaging narratives, (5) lab report narratives, (6) pathology report narratives, (7) procedure notes, and (8) progress notes.<sup>2</sup>

Exemptions to the eight categories listed above include (1) notes compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding, and (2) psychotherapy session notes.<sup>3</sup> Additionally, the Office of the National Coordinator for Health Information Technology (ONC) has identified eight information blocking exceptions, as described in this [Information Blocking Exceptions](#) fact sheet.<sup>4</sup>

In October 2022, the definition of EHI expanded to include all electronic protected health information as defined by HIPAA.<sup>5</sup> Under this definition, EHI includes medical and billing records as well as information that healthcare providers use to make decisions about patients.<sup>6</sup>

Other clarifications and modifications to information blocking have taken place in the past few years:

- In May 2023, ONC put forth information on how to interpret the information blocking in specific situations, including (1) when another federal privacy law requires that certain conditions be satisfied before disclosing information, (2) when an individual requests that their EHI not be disclosed, and (3) when one operates in several states with contrasting privacy laws.<sup>7</sup> More information can be found in HealthIT.gov's [frequently asked questions](#).
- In June 2023, the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) posted its final rule implementing information block penalties. This final rule specifies that any individual or entity that has committed information blocking may face up to a \$1 million penalty per violation as of September 1, 2023.<sup>8</sup> More information can be found at the HHS-OIG [information blocking webpage](#).
- In February 2024, HHS through the Substance Abuse and Mental Health Services Administration and the Office for Civil Rights announced final rules changes to 42 CFR Part 2, the federal law that protects the confidentiality of substance use disorder treatment records.<sup>9</sup> More information can be found at the Federal Register's [website](#).
- In June 2024, HHS issued a final rule that creates disincentives for healthcare providers that have been responsible for information blocking.<sup>10</sup> More information can be found in HHS' [21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking](#) fact sheet.

Healthcare professionals and organizations should stay up to date with any new rules associated with information blocking. They should discuss these rules with their EHR vendors to ensure compliance

with the regulations. It would behoove them to review all of their policies related to how they respond to information requests and update their policies and procedures as needed to maintain compliance.

Additionally, it's crucial for healthcare professionals to be cognizant not only of the importance of documenting care, but also their patients' possible perceptions about the words used in documentation. A recent study indicates that the language that physicians use when documenting in patients' health records can affect healthcare delivery and may contribute to disparities in care.<sup>11</sup> Further, an article in *STAT* notes that common medical terminology and abbreviations can confuse patients and may cause negative feelings.<sup>12</sup>

To avoid potential risks resulting from the choice of words in documenting care, consider the strategies discussed in MedPro's article [The Power of Words: Using Language to Support Collaborative Provider–Patient Relationships](#). Additional guidance also is available from [CRICO](#) and the [OpenNotes website](#).

## Resources

To learn more about information blocking and the Cures Act, see the following resources:

- [American College of Physicians: Interoperability and Information Blocking Regulations](#)
- [American Medical Association: How Do I Comply With Info Blocking and Where Do I Start?](#)
- [CRICO: Cures Act Overview](#)
- [HealthIT.gov: ONC's Cures Act Final Rule](#)
- [The Center of Excellence for Protected Health Information: 21st Century Cures Act Final Rule on Information Blocking](#)

## Endnotes

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<sup>1</sup> The Office of the National Coordinator for Health Information Technology. (n.d.). *ONC's Cures Act Final Rule*. Retrieved from [www.healthit.gov/topic/oncs-cures-act-final-rule](http://www.healthit.gov/topic/oncs-cures-act-final-rule)

<sup>2</sup> CRICO Strategies. (2021, April 2). *Cures Act overview*. Retrieved from [www.rmhf.harvard.edu/Clinician-Resources/Article/2021/Cures-Act-Overview](http://www.rmhf.harvard.edu/Clinician-Resources/Article/2021/Cures-Act-Overview)

<sup>3</sup> Ibid.

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<sup>4</sup> HealthIT.gov. (n.d.). *Cures Act Final Rule: Information blocking exceptions*. Retrieved from [www.healthit.gov/sites/default/files/2022-07/InformationBlockingExceptions.pdf](http://www.healthit.gov/sites/default/files/2022-07/InformationBlockingExceptions.pdf)

<sup>5</sup> OpenNotes. (2022). *Information Blocking Rule includes ePHI starting October 2022*. Retrieved from [www.opennotes.org/news/information-blocking-rule-includes-ephi-starting-october-2022/](http://www.opennotes.org/news/information-blocking-rule-includes-ephi-starting-october-2022/)

<sup>6</sup> Ibid.; Healthcare Compliance Pros. (n.d.). *The Information Blocking Rule 2022: What healthcare providers must know from the 21ST Century Cures Act*. Retrieved from [www.healthcarecompliancepros.com/blog/the-information-blocking-rule-2022-what-healthcare-providers-must-know](http://www.healthcarecompliancepros.com/blog/the-information-blocking-rule-2022-what-healthcare-providers-must-know)

<sup>7</sup> The Center of Excellence for Protected Health Information. (2023). *21<sup>st</sup> Century Cures Act final rule on information blocking*. Retrieved from <https://coephi.org/app/uploads/2023/07/21st-century-cures-act-final-rule-2023.pdf>

<sup>8</sup> U.S. Department of Health and Human Services Office of Inspector General. (2023, September 14 [Last updated]). *Information blocking*. Retrieved from <https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/>

<sup>9</sup> The Center of Excellence for Protected Health Information. (n.d.). *HHS fact sheet – 42 CFR part 2 final rule*. Retrieved from <https://coephi.org/resource/hhs-fact-sheet-42-cfr-part-2-final-rule/>

<sup>10</sup> U.S. Department of Health and Human Services. (2024, June 24). *HHS finalizes rule establishing disincentives for health care providers that have committed information blocking*. Retrieved from <https://www.hhs.gov/about/news/2024/06/24/hhs-finalizes-rule-establishing-disincentives-health-care-providers-that-have-committed-information-blocking.html>

<sup>11</sup> Park, J., Saha, S., Chee, B., Taylor, J., & Beach, M. C. (2021, July 14). Physician use of stigmatizing language in patient medical records. *JAMA Network Open*, 4(7): e2117052. doi:10.1001/jamanetworkopen.2021.17052. Retrieved from <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781937>

<sup>12</sup> Preston, E. (2021, June 18). Clinicians open their notes to patients in a grand experiment in medical care. *STAT*. Retrieved from [www.statnews.com/2021/06/18/clinicians-open-their-notes-to-patients-in-a-grand-experiment-in-medical-care/](http://www.statnews.com/2021/06/18/clinicians-open-their-notes-to-patients-in-a-grand-experiment-in-medical-care/)

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