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What is Information Blocking?

Health information blocking refers to processes that hinder the access, sharing, or use of electronic health information (EHI). The 21st Century Cures Act (Cures Act) seeks to prevent information blocking and encourage the smooth and secure access, exchange, and use of EHI. The law specifies certain exceptions where blocking is allowed, such as for privacy protection or to prevent harm. Healthcare providers, health IT developers and health information exchanges or networks may cite these exceptions to engage in information blocking.

Information Blocking Enforcement for Health IT Entities

The Cures Act also aims to enhance interoperability and patient access to EHI. A significant aspect of the Cures Act is the prohibition of information blocking, <u>defined</u> in Section 4004 as a practice that "is likely to interfere with, prevent, or materially discourage access, exchange or use of EHI." The Cures Act directed the Office of the National Coordinator for Health Information Technology (ONC) to implement a standardized process to report claims of potential information blocking. In June 2023, the HHS OIG published its <u>final rule</u> implementing information blocking penalties. The rule establishes financial penalties for information blocking up to \$1 million in fines per violation.

HHS OIG began enforcing information blocking penalties in September 2023. Only certain entities are subject to OIG information blocking penalties, including health IT developers of certified health IT, entities offering certified health IT, health information exchanges and health information networks. The OIG set criteria to prioritize its investigations, including the potential or actual patient harm caused, significant impact on a provider's ability to care for patients, the duration of the blocking, financial losses incurred and the actor's knowledge of the blocking practices. Investigations involve fact-gathering, interviews, and consultations with other agencies like ONC and the Federal Trade Commission (FTC).

In December 2023, the ONC issued its Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, outlining what constitutes information blocking and establishing permissible exceptions. The final rule <u>outlines</u> new conditions for the Infeasibility Exception related to information blocking, including an uncontrollable events condition, third party seeking modification use condition and manner exception exhausted condition.

Regulatory Compliance and Impacts on Patient Care

When providers cannot access important medical records, it negatively impacts treatment. In recognition of this, the information blocking regulations under the Cures Act prohibit healthcare providers and certified health IT developers from engaging in activities likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. While there are exceptions that allow for limiting the exchange of electronic health information under certain circumstances, those exceptions are narrowly defined.

The bi-directional exchange of information between providers is meant to ensure that *all* providers have access to *all* the health information necessary to effectively treat patients. However, there are organizations blocking the flow of data to provider customers and not providing any justification for doing so, as well as potentially blocking others from querying information about millions of patients. Information blocking can have significant impacts on patient care in your state, and the enforcement of information blocking penalties is critical. The sudden disconnection jeopardizes clinical operations and erodes the trust and confidence essential to a Trusted Exchange Framework.