

Alert | Health Care & FDA Practice / Data Privacy & Cybersecurity



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HHS Issues Final Rule on Artificial Intelligence, Enhanced Information Blocking Requirements

On Dec. 13, 2023, the U.S. Department of Health and Human Services (HHS), through the Office of the National Coordinator for Health Information Technology (ONC), published its [Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule](#), which, among other things, establishes new and revised health IT certification requirements related to artificial intelligence and machine learning (AI/ML) algorithms in health care, and identifies additional practices that are not considered information blocking. This agency action finalized HHS's April 18, 2023, [Proposed Rule](#).

Complementary Rules

On July 3, 2023, HHS published its final rule on [Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules](#), which indicated HHS's intent to focus on violations related to information blocking rules through the imposition of civil monetary penalties starting in September 2023. In addition, on Nov. 1, 2023, HHS published its proposed rule on the [21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking](#), which established greater disincentives for regulated entities that commit information blocking violations.

Noteworthy Requirements

The Final Rule comes as the next step in HHS’s greater enforcement of information blocking rules on regulated entities, with ONC officials promising additional rules related to health data, technology, and interoperability in the coming years.

The rule is generally broken into two substantive sections: (1) updates to the ONC Health IT Certification Program, and (2) enhancements to information blocking requirements and exceptions. Modifications and additions to the ONC Health IT Certification Program span numerous topics, including changes and additions to the data classes and elements that must be capable of exchange and transparency requirements related to risk associated with use of AI/ML algorithms.

The information blocking provisions address additions and changes to definitions, including the development of the definition of “offer” in the context of persons or entities considered “health IT developer of certified health IT.” HHS also provided additional commentary regarding exceptions to information blocking.

Compliance Dates

HHS and ONC’s [HTI-1 Key Dates](#) document provides a timetable for regulated entities to undertake compliance efforts. The first deadline for compliance is Dec. 31, 2024. HHS and ONC will be hosting [five informational sessions](#) on the Final Rule.

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