Complying With the New ONC Final Rule

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Larry Vernaglia
Partner, Foley & Lardner, LLP

Chanley Howell
Partner, Foley & Lardner, LLP
• Current Deadline – November 2, 2020
• 3 month enforcement discretion period until February 2, 2021
• OMB currently reviewing further extension
• OIG still working on civil monetary penalties (CMPs) and “appropriate disincentives”
• OIG is proposing that enforcement of information blocking will not begin until 60 days after its regulation becomes final or date in final rule
• OIG refers health care providers to appropriate agency for appropriate disincentives
• Health IT / EHRs – CMPs up to $1 million for HIT providers and data networks
• The ONC has stated that there is a 3-month enforcement discretion period after the November 2, 2020 deadline, to allow health care providers to focus on other priorities during the COVID-19 pandemic
• Further, enforcement of information blocking civil monetary penalties will not begin until the OIG has had the opportunity for notice and comment rulemaking on what may constitute appropriate disincentives
• Applies to all providers – not just federal program participants
• Future rulemaking. Medicare / federal reimbursement deductions; public “shaming”, False Claim Act liability.
Information blocking is a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI).

Actors

- Health Care Providers
- Health IT Developers
- HINs / HIEs
• Entity (or has control or discretion over an entity) that
• Facilitates the exchange of EHI among two or more unaffiliated providers for
• Treatment, payment or health care operations purpose
What Data - EHI?

• First 2 Years – Only USDCI Data
• Universe of EHI ...
• Medical records, billing records, payment and claims records
• Health plan enrollment records
• Case management records
• Other records used, in whole or in part, by for a covered entity to make decisions about individuals
EHI Does Not Include:

- Psychotherapy notes as defined in 45 CFR 164.501
- Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding
- De-identified health information
• First two years - EHI access, exchange, and use requirements restricted to the **US Core Data for Interoperability** (USCDI)

• USCDI - Standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange

• A USCDI “Data Class” is an aggregation of various Data Elements by a common theme or use case
A USCDI “Data Element” is the most granular level at which a piece of data is exchanged.

For example, Date of Birth is a Data Element rather than its component Day, Month, or Year, because Date of Birth is the unit of exchange.

USCDI data classes and elements. Source: HIMSS Report
https://www.healthit.gov/topic/information-blocking
Practical and Implementation Considerations

• **Turns HIPAA on its head** by requiring health-care providers and their business associates to share data in most instances where HIPAA permits, but does not require, the disclosure.

• HIPAA **historically** required business associate agreements to establish permissible uses and disclosures of PHI and to prohibit uses and disclosures not permitted or required by law.

• **Now**, when the law **permits** the access to or exchange of EHI, disclosure often will be **required**.
Practical and Implementation Considerations

• Rule requires in several places that the policies be implemented in a **consistent and non-discriminatory manner**

• If delay or denial of information may be considered interference, **compliance with an exception** may be necessary to avoid information blocking claims

• The information blocking rule will place **pressure on all actors to streamline their technology and data contracting protocols** for technology tools and data sharing projects involving EHI
Practical and Implementation Considerations

• Data-sharing projects will be particularly reliant on the content and manner exception to fulfill data requests

• Particularly relevant regarding requests from patients and third parties acting on their behalf, as well as the actor’s competitors

• To the extent the negotiation strategy instead requires reliance on the licensing or fee exceptions, consider reasonable licensing terms and allowable fees in advance to streamline your time frames for negotiating license conditions on non-discriminatory terms
• Covered entities and their business associates should **update their privacy and security policies** and modify their release of information and data-sharing practices that prohibit or delay that data sharing.

• In several places, the rule requires that organizational **policies be in writing** (for example, in the Preventing Harm, Privacy and Security Exceptions).
Practical and Implementation Considerations

- Although the ONC notes that the information blocking rule does not itself require actors to violate their business associate agreements and associated service level agreements, actors **cannot use these agreements to limit EHI disclosures in an arbitrary manner**.
- Will take time for changes to **work their way through BAAs**.
- Consider applicability of BAA language regarding modifications to laws.
Chanley Howell
Foley & Lardner LLP
E. chowell@foley.com
P. 904.359.8745

Lawrence Vernaglia
Foley & Lardner LLP
E. lvernaglia@foley.com
P. 617.342.4079