Information Blocking

ACR Government Relations
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The following overview is for educational purposes only—it is not intended to be used as guidance.
Acronyms

- HHS – Department of Health and Human Services
- OIG – Office of Inspector General
- ONC – Office of the National Coordinator for Health IT
- EHI – electronic health information
- HIN/HIE – health information network/exchange
21st Century Cures Act (2016)

- **Cures Section 4004**
  - Expanded HHS OIG authority to investigate claims of information blocking by certain actors
  - Intended to deter anticompetitive behaviors not already addressed by the interoperability prerequisites of the EHR exception/safe harbor from self-referral/anti-kickback rules.
  - Intended to address various electronic health information (EHI) and systems beyond merely EHRs.
ONC’s rule

- Information blocking is one of several issues in rulemaking. For info-blocking:
  - Defines key terms, parameters, and timelines
  - Defines “exceptions” to information blocking
  - Defers on key enforcement issues for OIG and other agencies under HHS
- Proposed rule released in February 2019; published in March 2019
- Final rule released in March 2020; published on May 1, 2020.
3 actor types subject to info-blocking

- **Health IT developers of certified health IT**
  - Includes info-blocking involving the developer’s other, non-certified products (for example, a radiology IT product developed or offered by a company that also has an EHR solution certified under ONC’s program)

- **Health care providers**
  - See definition [here](#).

- **Health information networks/exchanges (HINs/HIEs)**
  - Connects 2 or more other entities for treatment, payment, or health care operations purpose
What is *information blocking*?

- A practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI; and,
  - If by a developer or HIN/HIE, they *should* know it is likely to do so
  - If by a provider, they *do* know the practice is unreasonable and likely to do so
- *Practices* can be behaviors or policies such as unreasonable restrictions, burdens, and implementations, etc.
What is electronic health information (EHI)?

- **After 6 months post-publication of final rule** until 24 months post-publication:
  - EHI is limited to the minimal dataset that is included in the U.S. Core Data for Interoperability (USCDI)
  - The USCDI is architecture agnostic, but generally EHR-oriented, and contains basic data like demographics, vitals, clinical notes (including imaging narrative), etc.

- **After 24 months post-publication of the final rule**: 
  - EHI expands to include any electronic protected health information (ePHI) included in the designated record set per HIPAA patient access requirements—other than psychotherapy notes and information gathered for a civil, criminal, administrative action or proceeding
  - Importantly, EHI is inclusive of non-EHR-managed radiology data meeting the above definition
So does enforcement start soon?

- **Not necessarily…**
  - Enforcement **will await a future OIG rulemaking** to define civil monetary penalties for developers and HIEs/HINs (which can be up to $1 million per violation)
    - Info-blocking before OIG’s future final rule will not be enforced
    - Although provider disincentives will be handled separately, ONC has indicated that enforcement for these actors will also await the OIG final rule.
    - OIG’s final rule being promulgated by the ONC-defined timeframe is achievable but very optimistic.
  - Info-blocking **providers** will be subject to disincentives under existing HHS authorities (for example, through CMS payment programs); however, **the provider disincentives have yet to be identified by HHS**
  - Therefore, the timeline in ONC’s final rule may not reflect OIG’s actual enforcement timeline (i.e., when info-blocking claims will be investigated and penalized)
8 Exceptions to Information Blocking

- ONC’s rule describes 8 reasonable and necessary practices that will not be penalized, provided the specified criteria are met.
- Failure to meet an exception does not automatically constitute info-blocking—each instance will need to be examined on a case-by-case basis.
- ONC’s information sheet about the 8 exceptions is available [here](#).

**Exceptions**
1. Preventing harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT performance
6. Procedure for fulfilling request 1: content and manner
7. Procedure for fulfilling request 2: fees
8. Procedure for fulfilling request 3: licensing
How to *report* possible info-blocking by others?

- Feds are required to **protect the anonymity** of those reporting the claim.
- ONC to establish a standard process.
- Currently, ONC has an **online form** for reporting claims; however, as previously mentioned, enforcement has not yet begun so the purpose of reporting now is unclear.
Questions?

ACR members with specific questions about information blocking can contact:

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