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A Brief Introduction to

The Cures Act

Agenda

- A little history
- What it means to us ‘today’
- What to look for in the future

Disclaimer
As always, iMed recommends that you do research on your own to ensure you understand all impacts of The Cures Act on your business. We’ve done our best to identify key information we think you should know, but The Cures Act is very complicated and you should not solely rely on information from iMed to make your business decisions

History

21st Century Cures Act

- Law that passed in December, 2016
- $6.3 billion funding for:
  - Modifications to FDA drug approval
  - Research for rare diseases
  - Mental health
  - Opioid drug abuse treatment
  - Sale of petroleum reserves to pay for some of it, etc.)

Healthcare Delivery & Health IT related:

- Prohibits 'Actors' from 'Information Blocking'
- Vehicle for Health & Human Services Department to:
  - Define exceptions to Information Blocking
  - Modify/enhance Certification programs for Health IT (i.e. EHR developers)
  - Impose penalties on 'Actors' that 'Block Information'

INFORMATION BLOCKING

'A practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information'

Current

- **ONC Cures Act Final Rule**
  - Released on March 9, 2020 with an update on October 29, 2020 to address COVID
  - 8 Information Blocking Exceptions
  - Modifications & Future Requirements for Health IT Certification
- **CMS Interoperability & Patient Access Final Rule**
  - Also Released on March 9, 2020
  - Primarily focused on Payer requirements for information sharing
- **CMS Prior Authorization Proposed Rule**
  - Released on December 10, 2020
  - Series of rules geared towards electronic workflows for Prior Authorizations

Information Blocking

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- **Information Blocking 'Actors'**
  - Health Care Providers - hospitals, clinics, etc.
  - Health IT Developers - EHR vendors and others
  - Health Information Networks or Exchanges - not really sure about who these guys are these days, but organizations such as LA HIE (Louisiana Health Information Exchange) which is a non-profit funded by gov't grants

April 5, 2021 'Deadline'

- **What is Information Blocking**
  - Practices (i.e. operational workflows, procedures, protocols, etc.) that would restrict or discourage information sharing
  - Implementing Health IT in a non-standard way
  - Implementing Health IT in a way that would restrict or discourage access and exchange
  - Something that leads to fraud or abuse or impedes innovation and advancements in access, exchange, and use of health information including care delivery enabled by HIT

Information Blocking Exceptions

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- **Not fulfilling Requests for Information Sharing**
  - Preventing Harm Exception
  - Privacy Exception
  - Security Exception
  - Infeasibility Exception
  - Health IT Performance Exception
- **Procedures for fulfilling Requests for Information Sharing**
  - Content & Manner Exception
  - Fees Exception
  - Licensing Exception

Info Blocking Exceptions Fact Sheet

https://www.healthit.gov/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf

Info Blocking Exception FAQs

https://www.healthit.gov/curesrule/resources/information-blocking-faqs

Information Blocking FAQs

QUESTION: When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the Information Blocking regulation?

It would *likely* be considered an interference for purposes of information blocking if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results (*see also* 85 FR 25842 specifying that such a practice does not qualify for the "Preventing Harm" Exception).

To further illustrate, it also would *likely* be considered an interference:

- where a delay in providing access, exchange, or use occurs after a patient logs in to a patient portal to access EHI that a health care provider has (including, for example, lab results) and such EHI is not available–for any period of time–through the portal.
- where a delay occurs in providing a patient's EHI via an API to an app that the patient has authorized to receive their EHI.

Information Blocking FAQs

QUESTION: Are Actors (for example, healthcare providers) expected to release test results patients through patient portals/APIs as soon as the results are available to the ordering clinician?

While the information blocking regulations do not require actors to proactively make electronic health information (EHI) available, once a request to access, exchange or use EHI is made actors must timely respond to the request (for example, from a patient for their test results). Delays or other unnecessary impediments could implicate the information blocking provisions.

In practice, this could mean a patient would be able to access EHI such as test results in parallel to the availability of the test results to the ordering clinician.

Please review the other questions under this heading for more information.

Information Blocking FAQs

QUESTION: Do the information blocking regulations require actors to proactively make EHR available through 'patient portal', APIs, or other health information technology?

No. There is no requirement under the information blocking regulations to proactively make available any EHI to patients or others who have not requested the EHI. We note, however, that a delay in the release or availability of EHI in response to a request for legally permissible access, exchange, or use of EHI may be an interference under the information blocking regulations (85 FR 25813, 25878). If the delay were to constitute an interference under the information blocking regulations, an actor's practice or actions may still satisfy the conditions of an exception under the information blocking regulations (45 CFR 171.200-303).

Please review the other questions under this heading for more information.

Information Blocking FAQs

QUESTION: Would the 'Preventing Harm Exception' cover a 'blanket' several day delay on the release of laboratory or other test results to patients so an ordering clinician can evaluate each result for potential risk of harm associated with the release?

No. Blanket delays that affect a broad array of routine results do not qualify for the Preventing Harm Exception. The Preventing Harm Exception is designed to cover only those practices that are no broader than necessary to reduce a risk of harm to the patient or another person.

As we discussed in the Cures Act Final Rule, a clinician generally orders tests in the context of a clinician-patient relationship. In the context of that relationship, the clinician ordering a particular test would know the range of results that could be returned and could prospectively formulate, in the exercise of their professional judgment, an individualized determination for the specific patient that:

- witholding the results of the particular test(s) from the patient would substantially reduce a risk to the patient's or another person's life or physical safety - *or* -
- that witholding the results of the particular test(s) from a representative of the patient would substantially reduce a risk of substantial harm to the patient or another person.

Such individualized determinations made in good faith by an ordering clinician, in the exercise of their professional judgment and in the context of the treatment relationship within which they order the test, would satisfy the *type of risk* and *type of harm* conditions of the Preventing Harm Exception. Actors, including but not limited to the ordering clinician, could implement practices in reliance on such determinations and the Preventing Harm Exception would cover such practices so long as the practices also satisfy the other four conditions of the exception.

Information Blocking FAQs

QUESTION: Is non-final clinical information, such as draft clinical notes, or incomplete test results that are pending confirmation, included in the definition of EHI for purposes of Information Blocking regulations?

It depends. Draft clinical notes and laboratory results pending confirmation are, as we discussed in the ONC 21st Century Cures Act Final Rule, examples of data points that may not be appropriate to disclose or exchange until they are finalized. However, if such data are used to make health care decisions about an individual then that data would fall within the definition of "designated record set" (*see* 45 CFR § 164.501), and therefore within the definition of EHI. To the extent a data point falls within the definition of EHI, practices likely to interfere with legally permissible access, exchange or use of that EHI could implicate the information blocking definition.

Information Blocking FAQs

QUESTION: Are nursing, pharmacy, or other professional's clinical notes included in EHI?

Yes. *Electronic health information* (EHI), as defined in 45 CFR 171.102, does not specifically include or exclude notes or other clinical observations based on the type or specialty of the professional who authors them.

Information Blocking FAQs

QUESTION: How is an Actor expected to fulfill a request for the USCDI if they do not yet have certified health IT in place an API with the USCDI standard?

An actor is not automatically required to fulfill a request using the specific content and vocabulary standards identified in the United States Core Data for Interoperability (USCDI) standard for the representation of data classes and data elements, nor are they required to use certified technology or any specific functionality. The information blocking definition (45 CFR 171.103) provides that before October 6, 2022, electronic health information (EHI) is limited to the subset of EHI represented by the data elements identified by the USCDI standard. This limitation of EHI for purposes of the information blocking definition is not contingent on whether those data elements are recorded or represented using specific content and vocabulary standards in the USCDI standard in 45 CFR 171.213. On and after October 6, 2022, the information blocking regulation in 45 CFR part 171 pertain to all EHI as defined in 45 CFR 171.102.

Again, the information blocking regulations do not require the use of any specific standard or functionality. Instead, the "Content and Manner" exception (45 CFR 171.301) outlines a process by which an actor may prioritize the use of standards in fulfilling a request for EHI in a manner that supports and prioritizes the interoperability of the data. This means that, for the purposes of information blocking, before October 6, 2022, an actor may fulfill a request with the EHI identified by the data elements represented in the USCDI standard, first in the manner requested and, if not, in an alternate manner agreed upon with the requestor, following the order of priority specified in the exception.

Health IT Certification

- We can't Information Block
- We have to publish API Information - www.imedsoftwarecorp.com/certification
- Our contracts can't restrict customers from complaining publicly about our software
- We have to meet some new compliance requirements by December 21, 2022
  - New API Format
  - USCDA data format (basically an upgrade to the CCD)

CMS Interop & Patient Access Rule

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- Patient Access API by July 1, 2021 (any gov't related plan)
  - Claims & 'encounter' data (without cost)
- Provider Directory API - July 1, 2021
  - In network providers by plan
- Payer to Payer Data Exchange - January 1, 2022
  - Pass claims, encounter, (and prior auth) data about a patient to new payer when they switch plans
- ADT Electronic Notification (Hospitals) - July 1, 2021
  - Admit, Discharge, Transfer notification to 'related' providers of care

CMS Interop & Patient Access Fact Sheet

Applies to all gov't related plans:
- MA, MCO, CHIP, Marketplace

CMS Prior Authorization Proposed Rule

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- Prior Auth API (real-time, bi-directional, embedded in EHR)
  - What data is needed
  - Streamline documentation process
  - Send requests and receive responses electronically
  - Responses within 72 hours
  - Provide specific reasons for denials
  - Metrics about authorizations approved and denied
- Pass pending prior auths to 'next payer' when a patient changes to new payer

Prior Auth Fact Sheet

Only applied to Medicaid, CHIP, and Marketplace Plans (not MAs)

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Questions?

Please Note: Several 'key' FAQs are included after this slide for quick and easy reference