



## **21st Century Cures Act: Sample Pediatric Policies and Exceptions**

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# Disclaimer

- I am not a lawyer
- The information being presented does not constitute legal advice
- The information presented is my interpretation of what has been presented and discussed by leading Pediatric HIT experts as of the date of the recording
- It is the responsibility of the practice to work with their systems and advisors (medical, legal and HIT) to gain full understanding of how this will be implemented in their practice to be compliant with jurisdictional requirements

# Learning Objectives

- Review a sample Practice Policy on Information Blocking
- Discuss the acceptable Exceptions as outlined by the ONC for withholding information
- Explore common pediatric scenarios where it may be appropriate to withhold sensitive information
- Inspire confidence as to what is needed for the April 5th applicability date



# Combating Fear

April 2021				
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- There are no “Information Blocking” police that will be knocking at your door on April 5th
- There are currently no penalties or disincentives for clinicians found to be “information blocking” (*They haven’t even been proposed yet!*)
- What could ***theoretically*** happen as of April 5th?
  - *Someone* could accuse your practice of information blocking (a patient, patient representative or an organization)
  - They could do so by filing a complaint with the Office of the Inspector General
  - The Inspector General could investigate and ask for your Information Sharing Policy and information related to the specific complaint

# Sharing EHI

- EHI is PHI that is stored electronically
- Not everything that is in your EHR can be shared in an “electronic format” defined by 21st Century Cures
- The usable electronic format as currently described by the 21st Century Cures Act includes a **CDA** (with sections in the USCDI framework) and an **API**
- Pictures, text blobs and scanned documents cannot currently be provided in an electronic format as defined by above
- It doesn't mean that you should not share information that is in the forms of pictures, text blobs and scanned documents, it just means you can't share it in the above electronic format
- If the requestor wants it in a non-electronic format, that's fine!

# Preparing for Success: Focus on Information SHARING

- Create a Practice Policy on Information **Sharing**
  - Passive sharing (information available “self-serve”)
  - Active sharing (response to requests for information)
- Identify gaps in information that you would like to share, but can’t
- Identify situations in which you will be unable to share requested information based on:
  - Your duty to follow HIPAA
  - Your duty to follow state/jurisdictional laws
  - **Exceptions** as outlined by the 21st Century Cures Act
- Include language about non-discriminatory practices



# Active Sharing of Information

- Identify the ways in which patients/patient representatives can request information/medical records from you:
  - Phone
  - Fax
  - In-person
  - Email
  - Portal message
  - Portal records request
- Outline:
  - The process
  - Who is responsible
  - Expected timeframe (this *may* be considered Information Blocking if unreasonable)

# Identify the Forms/Formats You Provide Information

- Paper (for mail or pick-up)
- Fax
- External hard drive
- Email (encrypted for improved security)
- Via CDA (Direct Messaging to healthcare provider, provide to patient in some fashion)



# Address the Specific Request for Content

- What exactly is the requestor asking for?
- Don't assume, **ask/clarify**
- The requested content may influence how you honor the request

*“I'd like a copy of my medical records including those that were sent to you from my prior pediatrician in an electronic format please.”*

- You can tell them that they can download their EHR chart on the portal in the CDA themselves, **but** some content is not available in that format and ask “How would you like those old records from your prior PCP which you only have as scanned documents?”

# Cooperation and Collaboration

*If the practice is unable to provide the requested information in the **manner** and **format** requested, alternative arrangements will be sought to satisfy the requestor. Documentation will be made in the medical record related to communication to offer alternatives and document resolutions. Any information that cannot be shared will be documented as to the content, the reason it could not be shared as requested, and will reference the appropriate exceptions according to the 21st Century Cures Act.*

# Passive Sharing of Information

- **Many** large health systems are focused on this aspect of information sharing
- Some of this is driven from their challenges to efficiently process the large number of requests from patients/patient representatives
- Portal access also by defacto solves the “authentication of the right to access the information”
- Some of this is driven by legal interpretations of the 21st Century Cures Act
- Goal of the 21st Century Cures Act was to empower patients with the ability to **access**, **exchange** and **use** their EHI



# What is Special About this Electronic Format?

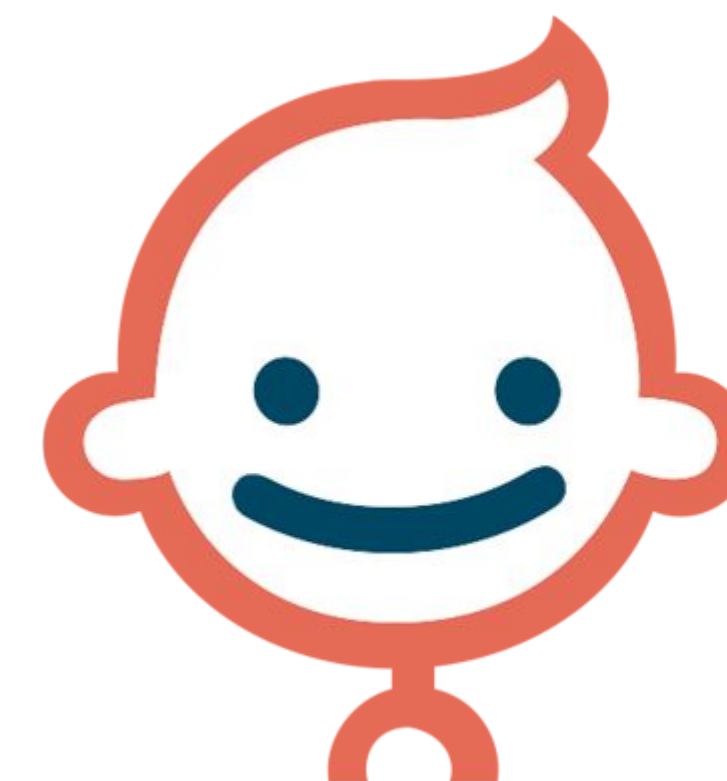
- It allows for another computer (including a different EHR) to ‘consume it’ without human transcription (instead electronic reconciliation)
- It allows it to be sent easily to another healthcare provider
- It allows for it to be used by an API to drive patient-centered apps
  - This is not very well-developed for pediatrics
  - There are significant concerns about privacy with apps as it relates to minors
- It will also facilitate patients the ability to contribute to their EHI in a format which can be consumed and shared

# Passive Sharing in Your Practice Policy

- Outline what you can and can't currently share with patients passively
- Be specific about your current state and your ***future plans with timelines***
- Delineate any specific content that you do not routinely/automatically share based on concerns about HIPAA and state/jurisdictional laws and why
- Also include how you can ***receive*** EHI in your practice

# Information Blocking “Exceptions”

**Exceptions are an important tool for physicians to use in defense of a claim that their practice is information blocking**



**Pediatric  
Success  
SERIES**



# 8 Exceptions Divided Into 2 Categories

## Category 1:

Exceptions that involve **not** fulfilling requests to access, exchange, or use EHI

## Category 2:

Exceptions that involve **procedures** for fulfilling requests to access, exchange, or use EHI

# Not Fulfilling Requests

- Preventing Harm Exception
- Privacy Exception
- Security Exception
- Infeasibility Exception
- Health IT Performance Exception

# Preventing Harm Exception

*It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.*

- Must hold a reasonable belief that the practice will substantially reduce a risk of harm
- Practice must be no broader than necessary
- Must satisfy at least one condition from each of the following categories: type of risk, type of harm, and implementation basis
- Must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm



# Preventing Harm Examples

- Declining to share data that is corrupt, inaccurate, or erroneous
- Declining to share data arising from misidentifying a patient or is matching a patient's EHI
- Refraining from a disclosure that would endanger life or *physical safety* of a patient or another person
- The licensed provider who made the determination must have done so in the context of a current or prior clinician-patient relationship
- Exceptions must be consistent with a written organizational policy that is
  1. Based on relevant clinical, technical, other appropriate expertise
  2. Implemented in a consistent and non-discriminatory manner

# Pediatric Case Example: Preventing Harm Exception

- A teen discloses to you that he is gay and asks you not to share with his parents because he believes his father will kick him out of the house.
- His father asks for a copy of the visit notes
- If you cannot technically separate the potentially harmful part of the note, you can document that you believe disclosing the note has the potential of causing serious harm to the teen.
- You cannot refuse to provide the other aspects of the chart which are not concerning
- If you can separate the specific concerning language or redact it from the note prior to sharing, then you are obligated to do so.

# Privacy Exception

*It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.*

Required to meet one of the following subsections:

- Unsatisfied legal precondition to the release of EHI
- Certified health IT developer not covered by HIPAA
- Denial of individual's request for ePHI consistent with the HIPAA Privacy Rule
- Respecting an individual's request not to share information



# Pediatric Case Example: Privacy Exception

- Your minor patient is a child of split parental household. Father requests a complete copy of the medical records to have when child spends the summer with him out of state.
- The newborn history and first few office visits contain sensitive information regarding the maternal prenatal history.
- According to HIPAA, unless the mother agrees to the release of her sensitive information, this should not be shared as part of the child's record in keeping with the mother's right to privacy.

# Pediatric Case Example: Privacy Exception

- Your adolescent patient requests treatment for an STI which is protected by state law where you practice.
- You are obligated by privacy laws to protect this information to be made available to the adolescent's parents/guardians/legal representatives without the adolescent's express consent.
- **You cannot withhold “all teen visit notes” because “some may contain information related to sexual activity”.**

# Security Exception

*It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.*

A practice is not info blocking if it is directly related to safeguarding the confidentiality, integrity, and availability of EHI

- Tailored to the specific security risk being addressed and
- Implemented in a consistent and non-discriminatory manner

# Infeasibility Exception

*It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.*

- To receive protection, the practice must meet one of the following conditions:
  1. Uncontrollable events (such as a disaster)
  2. Segmentation
  3. Infeasibility under the circumstances
- Must provide a written response to the requestor within 10 business days of receipt of the request with the reason(s) why the request is infeasible



# Pediatric Case Example: Infeasibility Exception

- Your adolescent patient has labs performed for secondary amenorrhea. Those labs include FSH/LH, prolactin, TSH and a serum HCG. The HCG is positive and protected according to your state law.
- It is infeasible for your technician to separate sharing the pregnancy test from the other labs and therefore you cannot share any of those labs in an electronic manner without violating state law.
- You may need to provide access to information that is not otherwise protected by federal or state privacy law (e.g., HIPAA Patient Right of Access). For example, you may still be required to print out the other labs individually and share or hand redact the protected information even if you claim the Infeasibility Exception.

# Health IT Performance Exception

*It will not be information blocking for an actor to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.*

An Actor's practice to maintain or improve health IT performance is not info blocking when the practice meets one of four following conditions:

1. Maintenance and improvement to health IT (e.g., an EHR upgrade)
2. Consistent with existing service level agreements, where applicable
3. Practices that prevent harm and comply with Preventing Harm Exception
4. Security-related practices that comply with Security Exception

# Exceptions that Involve Procedures

- Content and Manner Exception
- Fees Exception
- Licensing Exception

# Content and Manner Exception

*It will not be information blocking for an actor to limit the **content** of its response to a request to access, exchange, or use EHI or the **manner** in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met.*

- Content:
  - For 24 months after final rule publication must respond with the subset of EHI identified by the USCDI data elements
  - After that date (10/6/22), must respond with all EHI in a designated record set/ePHI
- Manner of Response:
  - In the manner requested or
  - In an alternative manner



# Fees Exception

*It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.*

- *Reasonable profit margin* primarily applies to EHR/technology vendors
- This specifically **excludes**: a fee based in any part on the electronic access by an individual, their personal representative, or another person or entity designated by the individual to access the individual's EHI
- Practices **cannot** charge patients/families fees to access their own EHI via a portal. Charging patients for *electronic access* is specifically what may be considered information blocking.

# Licensing Exception

*It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.*

- The Licensing Exception seeks to balance an Actor's legitimate interest in protecting its intellectual property and earning a return on the investment with Cures' goal of interoperability and access, exchange and use of EHI.
- This primarily applies to EHR/technology vendors rather than physicians or other providers.



<https://infoblockingcenter.org/>

# INFORMATION BLOCKING

## RESOURCE CENTER

[HOME](#) [ABOUT](#) [CONTACT](#)

**Next Information Blocking Deadline: April 5, 2021 – Information Blocking Applicability**



The Information Blocking Resource Center serves as a reference tool to educate and assist provider organizations subject to the Information Blocking rules implemented by the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), U.S. Centers for Medicare & Medicaid Services (CMS), Office for Civil Rights (OCR) and Office of the Inspector General (OIG).

The resource links below are provided by contributors to the resource center or collected from credible, online websites and should serve as one of many options available to actors – as defined in the ONC and CMS rules – to help them interpret and implement requirements.

Filter by: [ACP](#) | [AHIMA](#) | [AMA](#) | [AMIA](#) | [APA](#) | [CHIME](#) | [CMS](#) | [MGMA](#) | [ONC](#) | [Premier Inc.](#)

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# Resources

- ONC Information Blocking FAQs:  
<https://www.healthit.gov/curesrule/resources/information-blocking-faqs>
- AMA Information Blocking Overview:  
<https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf>
- USCDIv1 details/updates:  
[https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final\\_0.pdf](https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf)
- Information Blocking Exceptions Cheat Sheet from CHIME (College for Information Management Executives):  
[https://chimecentral.org/wp-content/uploads/2020/06/061420\\_CHIME-Information-Blocking-Cheat-Sheet-FINAL-RULE1-1.pdf](https://chimecentral.org/wp-content/uploads/2020/06/061420_CHIME-Information-Blocking-Cheat-Sheet-FINAL-RULE1-1.pdf)
- Suzanne Berman, MD, FAAP's Information Blocking Guide (Dropbox link):  
<http://bit.ly/infoblocking>





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# Am I Required to Have a Patient Portal or API?

**Q: Do the information blocking regulations (45 CFR Part 171) require actors to proactively make electronic health information (EHI) available through “patient portals,” application programming interfaces (API), or other health information technology? \*1/15/2021\***

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](#)).

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



# What If I Don't Have an Accessible API or Portal Yet?

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.

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



# Do We Need to Share Draft Notes/Partial Lab Results?

**Q: Is non-final clinical information, such as draft clinical notes or incomplete test results that are pending confirmation, included in the definition of electronic health information (EHI) for purposes of the information blocking regulations? \*1/15/2021\*** —

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.



# Can I Wait to Review Labs Results Before Sharing?

**Q: Are actors (for example, health care providers) expected to release test results to patients through a patient portal or application programming interface (API) as soon as the results are available to the ordering clinician? \*1/15/2021\*** —

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.

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



# Does the ONC Have Guidance About Minors and Harm?

**Q: Where the patient is a minor and to reduce a risk of harm other than physical abuse, will the Preventing Harm Exception cover an actor's practices that interfere with a parent or legal guardian's access, exchange, or use of the minor's EHI? \*1/15/2021\***

Yes, where the *risk of harm* has been determined on an individualized basis and all other conditions of the Preventing Harm Exception are met. For example, the practice must be no broader than necessary and the actor must reasonably believe the practice will substantially reduce the risk of harm. (For all the conditions of the Preventing Harm Exception, please see [45 CFR 171.201](#).)

For purposes of the Preventing Harm Exception, a parent or legal guardian would be considered a patient's legal representative. The Preventing Harm Exception's *type of harm* condition applies a "substantial harm" standard for practices interfering with a patient's **representative's** requested access, exchange, or use of the patient's EHI. (See 45 CFR 171.201(d)(1)).

The *type of harm* conditions for Preventing Harm Exception coverage of practices interfering with patients' and their representatives' access to EHI on the basis of an individualized determination of risk are specifically aligned with the HIPAA Privacy Rule's grounds for reviewable denial of an individual's right of access under the Privacy Rule. (See *also* ONC Cures Act Final Rule preamble [discussion](#) and [Table 3—Mapping of Circumstances Under § 171.201\(d\) to Applicable Harm Standards](#)).

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



# Will Information Blocking Be Enforced on April 5th?

## Q: What are the applicability dates and enforcement dates for the information blocking regulations?

The applicability date for the information blocking regulations in 45 CFR part 171 was established in the [ONC Cures Act Final Rule](#), and was subsequently adjusted in the [ONC Interim Final Rule](#). The Interim Final Rule moved the [applicability date from November 2, 2020 to April 5, 2021](#).

The Interim Final Rule also revised the information blocking definition in 45 CFR 171.103 to adjust the timeframe for the “USCDI limitation.” Before October 6, 2022, electronic health information (EHI) for the purposes of the information blocking definition is limited to the EHI **identified by the data elements represented** in the United States Core Data for Interoperability (USCDI) standard.

Enforcement of the information blocking regulations depends upon the individual or entity (“[actor](#)”) that is subject of an enforcement action. For health IT developers and health information networks/HIEs, the HHS Office of the Inspector General is currently engaged in rulemaking to establish enforcement dates. For health care providers, HHS must engage in future rulemaking to establish appropriate disincentives as directed by the 21<sup>st</sup> Century Cures Act.



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