CHCANYs NYS-HCCN is partnering with Attorneys at Oscislawski LLC to present

Information Blocking Rule
Learning Session 2
Technology Focus

October 28, 2021 – 1:00 pm
Zoom Guidelines

• You have been muted upon entry. Please share your comments or questions in the chat window
• The webinar is being recorded.
Helen Oscislawski, Esq., Founder & Managing Partner, Attorneys at Oscislawski LLC.
Information Blocking
Part 2 – Technical Implementation

October 28, 2021

prepared for
CHCANYS

presented by
Helen Oscislawski, Esq.
About Helen O.

Helen was just selected Best Lawyers® 2022 “Lawyer of the Year” for Health Care Law in Princeton, New Jersey, a distinction awarded to one lawyer with the highest overall peer-feedback for a specific practice area and geographic region. She is also selected to the 2020 & 2021 Super Lawyers® list for Health Care Law in New Jersey, which is issued by Thomson Reuters. Every year since 2018, her law firm has also been included on the “Best Law Firms” in Health Care Law, Princeton, New Jersey list issued by Best Lawyers. Links to a description of the selection methodologies used by the organizations issuing these lists can be found here.

Helen is a corporate and regulatory attorney whose practice for over the last 20 years has focused almost exclusively on advising and representing clients in the health care industry. She is the founding member of Attorneys at Osclawski LLC, a progressive and forward-thinking law boutique providing high-quality and cost-effective legal representation to its clients. Helen cemented her reputation as a prominent privacy and health information technology attorney through decades of developed experience and working hand-in-hand with C-suite executives and in-house general counsels on how to structure and manage complex data-sharing arrangements in compliance with applicable federal and state laws. She is known to many as a “go to” attorney for legal guidance and advice on HIPAA; 42 CFR Part 2; Breach Notification laws, as well as state laws regulating the access, use and sharing of medical, health and genetic information. Helen also has substantial experience with helping her clients navigate legal issues when responding to ransomware attacks, data breaches, OCR audit and complaint letters, and return/sanitization of patient data taken by former employees. On the front end, Helen has completed numerous comprehensive HIPAA legal-gap assessments for health care organizations and business associates, including some of the largest health information exchanges (HIEs) in the tri-state area. In 2008, New Jersey Governor Jon Corzine appointed Helen to the New Jersey Health Information Technology Commission (NJ-HITC) to fill the seat designated by statute for “an attorney practicing in this State with demonstrated expertise in health privacy.” NJ.S.A. 26:1A-137(a)2). [statutorily defined]. In 2010, she was reappointed to NJ-HITC by Governor Christie and tapped to serve as Chair of the Privacy and Security Committee for the New Jersey HIT Coordinator. As a trusted advisor, Helen currently represents and advises some of the most cutting edge and sophisticated organizations in the nation, including several large multi-stakeholder collaboratives in the NJ/NY/PA region, as well as a number of burgeoning “big data” innovation projects and initiatives.

Before founding Attorneys at Osclawski LLC, Helen was a health care attorney with a national law firm for almost a decade where she counseled all types of health care clients on a wide range of legal matters. Helen received her law degree from Rutgers School of Law, with honours, in 1999, and is admitted in New Jersey (since 1999) and Arizona (since 2020). She completed her undergraduate degree at Rutgers University, Douglass College in 1994, with highest honours in her major and high honours overall. She was inducted into Phi Beta Kappa upon graduation.

Helen can be reached at helen@oscilaw.com or 609-385-0833 ext.1.
Disclaimers

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- It does **NOT**, and is not intended to, constitute legal advice.

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- The statements, views, and opinions expressed in this presentation and on the following slides are solely those of the presenter, and not those of CHCANYs.
Q&As from Learning Session 1

- Who decides if an App is secure or not? What is it based on?
- Our psychiatrists and psychologists have concerns about patients having access to entire notes. What can you do?
- Can you state that it is infeasible if your EHR vendor has the system set such that a provider has to sign off on results before they can go to the portal and the EHR vendor has yet to resolve this issue despite months of requests?
- If a patient has not signed up for the patient portal, we would continue to follow straight HIPAA law unless they ask for their records in some electronic format, correct?
- In the event an EHR system offers record sharing accounts (i.e., parents with minors) and the system is setup such that all records or no records are shared, what considerations do the health centers need to be thinking about and to include in writing their policies should they choose to turn off this feature when it comes to sharing lab results, clinical notes, etc. Is this putting health centers at risk for blocking information?
- Is a ransomware lockdown considered an 'uncontrollable event'?
- How about drug and alcohol use as described in Social History? it looks like yes (that should be shared) based on this document.
New Questions

- **MINORS RECORDS!**
  - Access to Minor Records and Custodial issues with children and adults
  - Would like to learn more about minors
  - Ways to share medical info with adolescents, what is the minimum requirement if info sharing required for patients to meet rule

- Would like to discuss any **applicability of Cures Act** to patients **not accessing records digitally**.

- **Email encryption** - both Health Information and business information
“Actors”
3 Categories of Actors

“Health Care Providers”

“Health Information Networks” and “Health Information Exchanges”

“Developers of Certified Health IT”
Health Information Networks and Health Information Exchanges

An individual or entity that *determines, controls*, or has the *discretion to administer* any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for *access, exchange, or use of EHI*:

- Among *more than two* “*unaffiliated*” individuals or entities that are enabled to exchange EHI with each other;

  and

- For treatment, payment, or health care operations

*Are you operating as a HIE/HIN?*
Health IT Developer of Certified Health IT

An individual or entity

-- other than a health care provider that self-develops health IT for its own use --

▪ That develops or offers health information technology
  ▪ and

▪ Has one or more Health IT Modules certified under a program for the voluntary certification by ONC’s Health HIT Certification Program

Are you offering certified Health IT?
☐ Determine if your organization engages in any activities that might fit the definition of "Health Information Network (HIN) or Health Information Exchange (HIE)"

☐ Determine if your organization engages in any activities that might fit the definition of offering "Certified Health IT"
“Information Blocking”
"Information Blocking" Definition

45 C.F.R. 171.103(a)(1)

"Information blocking means a practice that —
... is likely to interfere with access, exchange, or use of electronic health information..."

(unless the practice is required by law or an exception applies)
Example #1: “Interferes With”

An EHR developer of certified health IT requires third-party applications to be "vetted" for security before use but does not promptly conduct the vetting or conducts the vetting in a discriminatory or exclusionary manner.
Example #2: “Interferes With”

An HIE/HIN or Health IT Vendor charges additional fees, requires more stringent testing or certification requirements, or imposes additional terms for participants that are competitors, are potential competitors, or may use EHI obtained via the HIN in a way that facilitates competition with the HIN.
Example #3: **Disabling Patient Portals**

Although an EHR developer’s *patient portal* offers the capability for patients to directly transmit or request for direct transmission of their EHI to a third party, the *functionality is purposefully not enabled.*
Example #4: *Delaying Access*

An EMR is capable of providing *same-day access to EHI* (e.g., *lab results*) in a form and format requested by a patient or a patient’s health care provider, but *takes several days to respond.*
**Question:** Are Actors 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?*  

**Answer:** 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.*

www.healthit.gov/curesrule/faq/are-actors-for-example-health-care-providers-expected-release-test-results-patients-through
ONC FAQ: Necessary Delays

Unlikely to be an Interference

- If the delay is necessary to enable the access, exchange, or use of EHI, it is unlikely to be considered an interference under the definition of information blocking (85 FR 25813).
- For example, if the release of EHI is delayed in order to ensure that the release complies with state law, it is unlikely to be considered an interference so long as the delay is no longer than necessary (see also 85 FR 25813).

- Longer delays might also be possible, and not be considered an interference if no longer than necessary, in scenarios where EHI must be manually retrieved and moved from one system to another system (see, for example, 85 FR 25866-25887 regarding the manual retrieval of EHI in response to a patient request for EHI).
ONC FAQ:  
**Blanket Delays likely Interference**

**Likely to be an Interference**

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.

[Link to ONC FAQ](https://www.healthit.gov/curesrule/faq/when-would-delay-fulfilling-request-for-access-exchange-or-use-ehi-be-considered-interference)
ONC FAQ:  
Proactive Push Not Required

**Question:** 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? (IB.FAQ23.1.2021JAN)

**Answer:** 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).

TO DO

Identify technical practices that "interfere with" (e.g., delay; block; discourage) access, exchange and use of EHI. Review the following:

- Patient Portal
- Provider Portal
- EMR – requests for:
  - Access
  - Exchange
  - Use
8 Safe Harbors

1. Preventing Harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT Performance
6. Fees
7. Licensing
8. Content & Matter
Preventing Harm
Required Elements Must be Met

- Reasonable belief

- The practice will **substantially reduce**

- A **“Risk”** of **“Harm”** to a patient or another natural person that would otherwise arise if the access, exchange, or use of EHI were to be granted

- The practice must be **no broader than necessary** to substantially reduce the risk of harm that the practice is implemented to reduce.
The risk of harm must either:

(1) Be determined on an *individualized basis* in the exercise of *professional judgment* by a *licensed health care professional* who has a current or prior *clinician-patient relationship* with the patient whose EHI is affected by the determination;

*OR*

(2) *Arise from data* that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.
Implementation

- **Organizational policy:**
  - Be in writing
  - Be based on relevant clinical, technical, and other appropriate expertise;
  - Be implemented in a consistent and non-discriminatory manner; and
  - Conforms each practice to the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section that are applicable to the practice and its use.

- **Individualized Determination:**
  - Based on facts and circumstances known or reasonably believed by the Actor at the time the determination was made and while the practice remains in use;
  - Be based on expertise relevant to implementing the practice consistent with the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section that are applicable to the practice and its use in particular circumstances.
Technical Implementation

- Capturing the health care professional’s determination
  - EMR field
  - Clinical Notes
  - Look to HIPAA
    - How is it done when access rights are denied per HIPAA?
    - How is the determination communicated for IT implementation?

- How can the EHI be “blocked”?
  - Granularity (e.g., per episode; per type of data)
  - All-or-nothing
Privacy Exception
Four (4) Sub-exceptions

1. Precondition Not Satisfied

2. Health IT Developer of Certified Health IT Not Covered by HIPAA

3. Denial Of Individual Right Access Consistent with Privacy Rule 164.524(a)(1) & (2)

4. Respect Individual Request to Not Share their EHI
1. Precondition Not Satisfied (PNS)

State or Federal law requires **one or more preconditions** for providing access, exchange, or use of EHI that have not been satisfied. For example, certain federal and state laws require **prior written consent**:

- 42 CFR Part 2 records
- Substance abuse treatment records
- Mental Health records
- HIV/AIDS information
- STD information
- Genetic Information
- Minor’s emancipated care
PNS: Documentation Requirement

- Conforms to Actor’s organizational policies & procedures that:
  - Are in writing;
  - Specify the criteria to be used by the actor to determine when the precondition would be satisfied and, as applicable, the steps that Actor will take to satisfy the precondition;
  - and
  - Are implemented by Actor, including by providing training on the P&P;

OR

- Documented by Actor, on a case-by-case basis, identifying the criteria used by Actor to determine when the precondition would be satisfied, any criteria that were not met, and the reason why the criteria were not met.
Technical Implementation

- Identify applicable privacy laws
- How does the EHI restricted?
  - General consent
  - Specific consent
  - Notice
  - Other condition

- How can the EHI be “blocked”?
  - Granularity
    - Provider type – e.g., mental health unit)
    - Patient type – e.g., emancipated minor
    - Data type – e.g., HIV/AIDS
  - All-or-nothing
3. Denial of Right of Access (HIPAA)

If an individual requests EHI under the **right of access** provision under 45 CFR 164.524(a)(1), the Actor’s practice must be consistent with 45 CFR 164.524(a)(2):

- Access rights limited to PHI maintained in a **Designated Record Set**
- Can deny **Psychotherapy Notes**
- Can deny Info compiled in anticipation of **legal action** (e.g., civil; criminal; administrative)
- Hospitals under contract/direction of **correctional institution** can deny inmate request if would jeopardize health, safety, security, custody, or rehabilitation of inmate or other inmates, or safety;
- **Research** restrictions
- **Privacy Act** restrictions
- **Promise of Confidentiality** to third-party source
Technical Implementation

- Capture the Reason for Denial of Access
  - Field in EMR
  - Notes
  - Look to HIPAA
    - How is it done when access rights are denied per HIPAA?
    - How is a patient/PR permitted to request restrictions?
    - How is the determination communicated for IT implementation?

- How can the EHI be “blocked”?
  - Granularity (e.g., per date? per data type (e.g., research)
  - All-or-nothing
4. Respecting Individual’s Request for Restrictions

- **Individual requests** that Provider not grant such access, exchange, or use of Individual’s EHI. Cannot be any improper encouragement or inducement of the request by the Provider;

- Must *document* the Individual’s request for restriction within a reasonable time period;

  and

- Practice must be implemented in a *consistent* and *nondiscriminatory* manner.
Technical Implementation

- Capture the requested restriction
  - EMR field
  - Notes
  - Look to HIPAA
    - How is a patient/PR permitted to request restrictions?
    - How is the determination communicated for IT implementation?

- Can the EHI be “blocked” as requested?
  - Granularity
  - All-or-nothing
Security Exception
Elements of the Exception

The practice **must** be:

- **Directly related to** safeguarding the confidentiality, integrity, and availability of EHI;

- **Tailored** to specific security risks; and

- Implemented in a **consistent** and **non-discriminatory** manner.
Conditions

Make a **Determination** in each case, based on the particularized facts and circumstances that:

1. Practice is **necessary** to **mitigate** the **security risk** to EHI; and

2. **No reasonable & appropriate alternatives** to the practice that address the security risk that are less likely to interfere with, prevent, or materially discourage access, exchange or use of EHI.

**-EITHER-**

**-OR-**
Implement the practice through an **Organizational Security Policy** ("OSP") that:

1. Is in writing
2. Is prepared on the basis of, and be **directly responsive to**, the **security risks** identified and assessed by or on behalf of Actor;
3. Align with one or more applicable **consensus-based standards** or **best practice guidance**; and
4. Provide **objective timeframes** and other parameters for identifying, responding to, and addressing security incidents.
OSP: Identify Security Risks

- HIPAA Security Risk Analysis

- Other Risk Assessments:

  A good risk assessment uses an approach consistent with industry standards, and incorporates elements such as:

  - threat and vulnerability analysis
  - data collection
  - assessment of current security measures
  - likelihood of occurrence
  - impact
  - level of risk
  - final reporting
OSP: Implementing Security Practices

1. Tailored to the specific Security Risk

2. Consistent and Non-Discriminatory

3. Consensus-Based or Best Practice Guidance
   - NIST-800-53 Rev.5;
   - NIST Cybersecurity Framework; and
   - NIST SP 800-100, SP 800-37 Rev.2, SP 800-39, as updated and as interpreted through formal guidance.
   - Examples of best practice guidance on security policies developed by consensus standards include: ISO, IETF, or IEC.
OSP: Implementing Security Practices

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   • Examples of best practice guidance on security policies developed by consensus standards include: **ISO, IETF, or IEC**.
OSP: **Implementing Security Practices**

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2. Consistent and Non-Discriminatory
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   - NIST 800-53 Rev. 5
   - NIST Cybersecurity Framework
   - NIST SP 800-100, SP 800-37 Rev. 2, and SP 800-39, as updated and as interpreted through formal guidance.

Examples of best practice guidance on security policies developed by consensus standards include:
- ISO
- IETF
- IEC
OSP: *Timeframes for Identifying, Responding to, and Addressing Security Risks*

1. OSP must include a Security Response Plan that provides **objective timeframes** and **common terminology** used for identifying, responding to, and addressing security incidents.

2. Acceptable sources for development of a Security Response Plan include:
   - NIST Incident Response Procedure *SP 800-61, Rev. 2*;
   - US–CERT for interactions with government systems (https://www.uscert.gov/government-users/reportingrequirements); and
OSP: *Timeframes for Identifying, Responding to, and Addressing Security Risks*

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2. Acceptable sources for development of a Security Response Plan include:
   - NIST Incident Response Procedure SP 800-61, Rev. 2;
   - US-CERT for interactions with government systems (https://www.uscert.gov/government-users/reporting-requirements);
What About Risks Not addressed by OSP?

- That’s **OK**. Make “determination” based on particularized facts and circumstances that Security Practice is **necessary** to **mitigate security risk** and **no reasonable** and **appropriate alternatives** to the Security Practice that address the security risk and are less likely to interfere with, prevent, or materially discourage access, exchange or use of EHI.

- **Exigent/Emergency Circumstance?**
  - Delay for assessment not expected. May implement emergency Security Practice in **good faith**
  - Intended only for **shorttime**. **Expeditiously** make any necessary changes – replace with “reasonable & appropriate” alternative measures that are less likely to interfere with access, exchange, or use of EHI as expeditiously as possible.
“Many of these conditions are related to other existing regulatory requirements that have similar documentation standards. For example, an actor’s practice may meet the Security Exception at § 171.203 if it is consistent with an organizational security policy and that policy meets several requirements. We expect that many actors have existing organizational security policies based on the “Policy and procedures and documentation requirements” in the HIPAA Security Rule at 45 CFR 164.316. Consequently, the burden associated with meeting the documentation requirement in the Security Exception should be less if actors are already complying with the HIPAA Security Rule.”
Framework Security Policy

POLICY Security Exception

CATEGORY: Information Blocking

COURSE TOPIC: Security Exception

EFFECTIVE DATE: April 5, 2021

I. POLICY

Provider will not intentionally engage in any act or omission (“Practice”) that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (“EH1”) unless Provider is required by law to do so, or Provider must block EHI in order to prevent the security of electronic health information (“EHI”), if Provider decides to block EHI in order to protect the security of EHI, it shall do so only if such Practice is (A) directly related to safeguarding the confidentiality, integrity, and availability of EHI; (B) tailored to the specific security risks being addressed; and (C) implemented in a consistent and non-discriminatory manner.

A Practice that is aimed at protecting the security of EHI but is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI will be implemented in accordance with Provider’s “Organizational Security Policy,” or otherwise determined in each case in accordance with this Policy.

II. PROCEDURE

A. Organizational Security Policy

(1) Provider shall maintain an Organizational Security Policy that is prepared on the basis of, and be directly responsive to, security risks identified and analyzed by Provider, or which have been identified and assessed by a vendor on behalf of Provider.

(2) In exigent circumstances, where Provider must implement a Practice to respond to a security risk that has not been identified in Provider’s Organizational Security Policy, Provider may proceed in accordance with “Section E” below.

B. Identifying Security Risks

(1) In accordance with 45 CFR 164.306(a)(1)(ii)(A) of the HIPAA Security Rule and Provider’s applicable HIPAA Security policies, Provider shall conduct an accurate and thorough assessment (a “HIPAA Risk Analysis”) of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI held by Provider.

Potential security risks and vulnerabilities identified in such HIPAA Risk Analysis shall be documented, and must be used as a basis upon which Provider will determine which security practices to implement in order to safeguard the confidentiality, integrity, and availability of EHI.

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☑ TO DO

☑ Develop a Security Exception policy (see sample)

☐ Review/develop a written Organizational Security Policy (OSP) that:
   - Identifies specific security risks (HIPAA risk assessment; industry standards)
   - Reflects practices tailored to the identified risks that are consensus-based or industry best practices
   - Includes a security response plan for incidents & new risks

☐ Implement security practices in a consistent and non-discriminatory manner

☐ Evaluate & address new security risks as they come up or in response to new requests for EHI
Infeasibility Exception
“Infeasibility Under the Circumstances”

- Contemporaneous Written Record or Other Documentation demonstrates consideration of the Following Factors supporting the determination:
  1. The type of EHI and the purposes for which it may be needed;
  2. The cost to Actor of complying with the request in the manner requested;
  3. The financial and technical resources available to the Actor;
  4. Whether the Actor’s practice is non-discriminatory and the Actor provides the same access, exchange, or use of EHI to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship;
  5. Whether the Actor owns or has control over a predominant technology, platform, HIE, or HIN through which EHI is accessed or exchanged; and
  6. Why the Actor was unable to provide access, exchange, or use of EHI consistent with the [Content & Manner Exception].

- Shall NOT consider whether the manner requested:
  1. Would have facilitated competition with Actor; and/or
  2. Prevented Actor from charging a fee or resulted in a reduced fee.
Manner Exception

➢ **Manner Requested:** Actor must fulfill a request described in paragraph (a) of this section in any manner requested, unless Actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request.

➢ **Alternative Manner:** Actor must fulfill the request without unnecessary delay in the following order of priority, starting with first and only proceeding to the next consecutive alternative if Actor is technically unable to fulfill the request in the manner identified in a paragraph:

- Using technology certified to standard(s) adopted in part 170 that is specified by the requestor.
- Using content and transport standards specified by the requestor and published by: (1) The Federal Government; or (2) A standards developing organization accredited by the American National Standards Institute.
- Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.
“One-Off” Interface Requests

Comments. A few commenters encouraged ONC to add a provision to the exception that would enable entities who have joined TEFCA to claim the Infeasibility Exception if a requestor or third party refused to join the TEFCA and instead demanded a one-off interface.

Response. We appreciate these comments, but have decided not to adopt this suggested addition at this time. The TEFCA is still new, the Common Agreement is not yet finalized, and it would be premature to establish special treatment for entities that join the TEFCA. We may reconsider this suggestion at a later date. We note that this does not necessarily mean that actors in these situations will not be covered by the exception, as they could still show that a request for a one-off interface is infeasible under the circumstances (see § 171.204(a)(3)). However, not joining TEFCA is not de facto proof of infeasibility. We note that in addition to seeking coverage for infeasibility under the circumstances, the actor could also seek coverage from: (1) The Content and Manner Exception if the actor could not fulfill request to access, exchange, or use EHI in the manner requested (via a one-off interface), but could fulfill the request through an acceptable alternative manner (see § 171.301(b)); or (2) the Fees Exception or Licensing Exception if the actor chooses to provide the one-off interface as requested, but charges fees/royalties related to developing or licensing the one-off interface, which could include fees or royalties that result in a reasonable profit margin (see § 171.302 and 303).
Documentation Requirement:

If Actor does not fulfill a request for access, exchange, or use of EHI for any of the qualifying reasons, Actor **must**, within **ten (10) business days** of receipt of the request, provide to the requestor in writing the reason(s) **why the request is infeasible**.
Notice of Infeasibility

**NOTICE OF INFEASIBILITY**

Date Request Received: ______/____/____

Name of Requester: ____________________________

Name of Individual: ____________________________

Type of EHI Requested: ________________________

Purpose(s) for which EHI is requested: ____________________________

Date of this Notice of Infeasibility: ______/____/____

YOUR REQUEST FOR ACCESS, EXCHANGE, OR USE OF THE MAINTAINED ANONYMOUSLY CONTROLLED BY (ACTOR NAME) IS DENIED DUE TO THE INFEASIBILITY OF FULFILLING THE REQUEST FOR THE FOLLOWING REASONS (see “boxed” items):

☐ There is an “Unreasonable Effort” that makes it impossible to fulfill the request.

☐ It is technologically infeasible to unambiguously separate the EHI requested from other EHI that cannot be released because:

☐ This individual has applied to sign a consent to release when it is legally required for disclosure, or has requested that information not be shared in this manner and we have honored this request.

☐ Federal or state law prohibits it from being disclosed to any person.

☐ There would be “Serious Harm” to the individual or another person if request is fulfilled in manner requested.

☐ It is infeasible to fulfill the request in reasonable manner because:

☐ Reasonable security practices cannot be met to address identified security risks.

☐ There are limitations, improvements or performance issues with the health IT.

☐ The provider's code is not functionally or non-functional.

☐ Access is being denied based on HIPAA 110.20 to keep access under HIPAA.

☐ Requestor seeking the more than 100 EHI data (before May 1, 2003), and Actor is unable to provide access to all EHI requested, or aggregate EHI to just provide UCSC data.

☐ It is infeasible to fulfill the request in an alternative manner because:

☐ Actor is unable to provide the requested EHI using technology certified to standards specified by requestor, at all.

☐ Actor is unable to use current and transport standards specified by requestor, at all.

☐ Actor is unable to use any alternative machine-readable format to furnish the UCSC EHI data requested.

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Infeasibility Exception Decision Tree

**A. Determine the Feasibility Factor (REQUIRING):**
1. Type of EHI Requested:
   - [ ] Yes
   - [ ] No

2. Purpose for which EHI is required needed:
   - [ ] Yes
   - [ ] No

3. Cost to the Act of complying with the request in the manner required:
   - [ ] Yes
   - [ ] No

4. The financial and technical resources available to the Act:
   - [ ] Yes
   - [ ] No

5. Does Act provide the same access, exchange, or use of EHI to its own employees, to customers, patients, partners, and all persons with whom it has a business relationship?
   - [ ] Yes
   - [ ] No

6. Does Act use or control the predominant technology, platform, health information exchange, or health information network through which EHI is accessed or exchanged?
   - [ ] Yes
   - [ ] No

**B. Is it feasible to fulfill the request for EHI in a manner specified?**
1. Can necessary security protections be put in place to identify security risks?
   - [ ] Yes
   - [ ] No

2. Are there maintenance, improvement, or performance issues with the IS?
   - [ ] Yes
   - [ ] No

3. Have all other required preconditions under law been satisfied?
   - [ ] Yes
   - [ ] No

4. Could the request be denied based on Act’s right to deny access under HIPAA?
   - [ ] Yes
   - [ ] No

5. Requestor asking for more than 100K EHI data (before May 2, 2003), can Act:
   - [ ] Provide requestor with all EHI requested?
   - [ ] YES
   - [ ] NO

   [ ] Request data from other EHI and only release EHI data?
   - [ ] YES
   - [ ] NO

   [ ] Provide requestor with UCXH data?
   - [ ] YES
   - [ ] NO

**C. Infeasibility Exception Decision Tree**

Actor must provide Requestor with written response within 10 business days describing the reasons why it is infeasible for Actor to fulfill the request.
☐ Develop a Infeasibility Exception policy.

☐ Use a decision tree tool to evaluate new EHI requests under the Infeasibility Exception.

☐ Use a “Notice of Infeasibility” to inform requestor when a decision is made to deny access, exchange or use of EHI due to infeasibility. Ensure that decisions are consistent and do not discriminate.
Health IT Performance
Must Meet at Least One of the Following Conditions:

- Maintenance & Improvements
- Assured level of performance
- Practices that Prevent Harm
- Security-related Practices
Actor’s practice must be—

(1) Implemented for a period of time no longer than necessary to complete the maintenance or improvements for which the health IT was made unavailable or the health IT’s performance degraded; and

(2) Implemented in a consistent and non-discriminatory manner.
IF the unavailability or degradation is initiated by a health IT developer of certified Health IT or HIE/HIN:

- **Planned:** Must be consistent with existing service level agreements between the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT;

or

- **Unplanned:** Must be consistent with existing service level agreements between the individual or entity; or agreed to by the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT.
Assured Level of Performance

Actor may take action against a third-party application that is negatively impacting the health IT’s performance, provided that the practice is—

- For a period of time no longer than necessary to resolve any negative impacts;
- Implemented in a consistent and non-discriminatory manner; and
- Consistent with existing service level agreements, where applicable
Harm & Security Practices

**Practices that prevent harm.** If the unavailability of health IT for maintenance or improvements is initiated by Actor in response to a risk of harm to a patient or another person, Actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception.

**Security-related practices.** If the unavailability of health IT for maintenance or improvements is initiated by Actor in response to a security risk to EHI, Actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception.
TO DO

☐ Develop a Health IT Exception policy.

☐ Evaluate new EHI requests under the Health IT Exception as appropriate.

☐ Ensure that decisions to delay or deny access, exchange and use of EHI are:
  ☐ For no longer than necessary
  ☐ Consistent and do not discriminate
Fees Exception
Elements of the Fees Exception

Fees a Actor charges must be —

(i) Based on **objective** and **verifiable criteria** that are uniformly applied for all similarly-situated classes of persons or entities and requests;

(ii) Reasonably related to the **Actor’s costs** of providing the type of access, exchange, or use of electronic health information to, or at the request of, the person or entity to whom the fee is charged;

(iii) **Reasonably allocated** among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and

(iv) Based on costs **not otherwise recovered** for the same instance of service to a provider and third party.
Elements of the Exception

The fees Actor charges must **NOT** be based on—

(i) Whether the requestor or other person is a *competitor, potential competitor*, or will be using the EHI in a way that *facilitates competition* with the Actor;

(ii) *Sales, profit, revenue*, or *other value* that the requestor or other persons derive or may derive from the access, exchange, or use of the EHI;

(iii) *Costs* the Actor incurred due to the health IT being designed or implemented in a *non-standard way*, unless the requestor agreed to the fee associated with the non-standard design or implementation to access, exchange, or use the electronic health information;

(iv) *Costs* associated with *intangible assets* other than the actual development or acquisition costs of such assets;

(v) *Opportunity costs* unrelated to the access, exchange, or use of EHI; or

(vi) Any costs that led to the creation of *intellectual property*, if the Actor charged a royalty for that intellectual property pursuant to § 171.303 and that royalty included the development costs for the creation of the intellectual property.
Excluded Fees

This exception does not apply to—

(1) A fee prohibited by 45 CFR 164.524(c)(4);

(2) A fee based in any part on the electronic access of an individual’s EHI by the individual, their personal representative, or another person or entity designated by the individual;

(3) A fee to perform an export of EHI via the capability of health IT certified to § 170.315(b)(10) of this subchapter for the purposes of switching health IT or to provide patients their EHI; and

(4) A fee to export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.
Content & Manner
➢ Up until **October 5, 2022** – Actor may elect to **only** respond to a request to access, exchange, or use EHI identified by the data elements represented in the **USCDI standard**

➢ **On & after** October 6, 2022, Actor **must** respond to a request to access, exchange, or use of **FULL EHI** (defined in §171.102)
<table>
<thead>
<tr>
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<th>Soap</th>
<th>Problems</th>
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<tr>
<td>Asthma &amp; Heart Failure</td>
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<td>Hives</td>
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<tr>
<th>Assessment and Care Plan</th>
<th>Other Health Conditions</th>
<th>Procedures</th>
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</thead>
<tbody>
<tr>
<td>Headache, Migraine, Meningitis</td>
<td>Diabetes</td>
<td>Treatment and Medications</td>
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<tr>
<td>Gastroesophageal Reflux Disease</td>
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<tr>
<th>Current Issues (Health)</th>
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<tr>
<td>Weight Gain</td>
<td>Medications</td>
<td>Legal Protections</td>
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<td>Blood Pressure</td>
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<tr>
<th>Global Notes</th>
<th>Imaging</th>
<th>Smoking Status</th>
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<tbody>
<tr>
<td>Developmental Delay</td>
<td>Chest X-ray</td>
<td>Quit Smoking</td>
</tr>
<tr>
<td>Newborn Care</td>
<td>Ultrasound</td>
<td></td>
</tr>
</tbody>
</table>
Technical Implementation

- Identify EMR Fields that are USCDI.

- Can USCDI be **segmented** from all other EHI?
  - **Yes.** May (for purposes of IBR) block non-USCDI data, but must provide USCDI through October 5, 2022.

  - **No.** Can assert Infeasibility Exception. No EHI must be provided for purpose of IBR compliance.
Manner Condition

- Actor must fulfill a request in any manner requested, unless Actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request.

- If Actor fulfills a request in any manner requested:
  - Any fees charged by Actor in relation to fulfilling the response are not required to satisfy the exception in § 171.302 (Fees Exception);

  and

  - Any license of interoperability elements granted Actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303 (Licensing Exception).
Alternative Manner

- Actor must fulfill the request **without unnecessary delay** in the following order of priority, starting with first and only proceeding to the next consecutive alternative if Actor is technically unable to fulfill the request in the manner identified in a paragraph:
  - Using technology certified to standard(s) adopted in part 170 that is specified by the requestor
  - Using content and transport standards specified by the requestor and published by: (1) The Federal Government; or (2) A standards developing organization accredited by the American National Standards Institute.
  - Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.

- Any **fees** charged by Actor in relation to fulfilling the request are required to **satisfy the exception** in § 171.302 (Fees Exception).

- Any **license** of interoperability elements granted by Actor in relation to fulfilling the request is required to satisfy the exception in § 171.303 (Licensing Exception).
Can you make EHI available to Requestor in the Manner being requested?

- Access credentials to EMR/HIE
- API/FHIR (Data Pull)
- Data Push
- Other

- Yes. Must provide USCDI in manner requested
- Yes. May provide all requested EHI in manner requested
- No. Must provide in Alternate Manner if possible. If cannot provide in any Alternate Manner acceptable to Requestor, can assert Infeasibility Exception (Infeasibility Under the Circumstances).
Minor’s Records & Patient Portals

HIPAA Privacy Rule

Federal Law

As a general rule, the HIPAA Privacy Rule prohibits that if under applicable law a parent or guardian acting in loco parentis (the “Parent”) has authority to act on behalf of an unemancipated minor to make decisions related to health care, a covered entity health care provider may treat such parent as the representative of the minor’s “Personal Representative” with respect to PHI relevant to such personal representation. However, there are exceptions to this general rule: (i) if any party may not be treated as a Personal Representative of the minor, and the minor has the authority to “stand in his/her own shoes” for the purpose of the HIPAA Privacy Rule; or

1. State or other law permits the minor to consent to the health care service and
   - The minor consents to the health care service (regardless of whether the consent of the Parent might also have been obtained);
   - and
   - The minor has not requested that the Parent be treated as his/her Personal Representative.

2. The minor may legally (under such health care service) without the consent of the Parent or the Minor;
   - the minor consents;
   - or
   - a court or another person authorized by law consents to such health care service.

3. The Parent agrees to the payment of confidentiality between a covered health care provider and the minor with respect to such health care service.

4. In addition to (1), (2) and (3) above, a covered entity may elect not to treat a Parent as the minor’s Personal Representative if the covered entity provider, or in the exercise of professional judgment, determines that it is not in the best interest of the child to treat the Parent as the minor’s Personal Representative because of reasonable belief that (a) the minor has been or may be subjected to domestic violence, abuse or neglect by each Parent or (b) treating the Parent as the Personal Representative would otherwise endanger the minor's safety.

HIPAA Privacy Rule

Federal Law

The HIPAA Privacy Rule also provides three additional scenarios with which contact when a Parent may acquire or receive a copy of a minor’s PHI:

- If, and to the extent, permitted by a provision of state or other law, including applicable law, a covered entity health care provider may disclose, or provide “access rights” in accordance with §164.524 of the Privacy Rule, to PHI about an unemancipated minor to the Parent (in accordance with such law); and
- If, and to the extent, prohibited by an applicable provision of state or other law, including applicable law, a covered entity health care provider may not disclose, or provide access, to PHI about a minor to the Parent (in accordance with such law); and
- Where the Parent is not being treated as the Personal Representative of the Minor (reason of reason (1), (2) or (3) above); and where there is no applicable “access rights” provision under state or other law including state law, a covered entity health care provider may provide or deny access under $164.524 to the Parent if such extension is consistent with state or other applicable law, provided that such decision must be made by a licensed health care professional in the exercise of professional judgment.

The foregoing HIPAA analysis framework must be applied to determine whether a Parent is permitted access to the minor’s PHI based on state or other federal law.

42 C.F.R. Part 2 (“Part 2”)

A Parent’s Part 2 information may not be disclosed to a Parent without the consent of the Minor. HIPAA provides that “[I]f the to the extent prohibited by an applicable provision of state or other law, a covered entity may not disclose, or provide access in accordance with $164.524 of the Privacy Rule, about PHI to an unemancipated minor to a parent and/or legal guardian.”

The Part 2 regulations expressly prohibit the Parent’s Part 2 information from being disclosed to the Parent when the Minor has exerted his/her rights and authority under Part 2 to consent to disclosure. Therefore, any individual or entity that meets the definition of a Part 2 Program and is “legally authorized” must follow this restriction. However, any individual or entity that receives (a “recipient”) a Minor’s Part 2 Information from a Part 2 Program in a secure manner and is not authorized to access such information (as is required by 42 C.F.R. §164.522) must also treat those records in accordance with Part 2’s requirements.

For purposes of Part 2, a “Minor” is defined as: an individual who has not attained the age of majority as specified in the applicable state law, or the age of majority as specified in the applicable state law at the age of 18 years; 42 C.F.R. §164.501

42 C.F.R. §164.501


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Technical Implementation

- Which categories of care can a minor assert rights independent of the parent under New York law? (e.g., pregnancy? STD testing? HIV/AIDS? mental health? substance abuse?)

- Can the EMR technology support managing **separate portals** for the parent/minor (with consent of the parent)?

- Can the EMR technology support **segmenting & preventing** certain **episodes of care** or **data** from being pushed to the patient portal?

- If the EMR technology cannot be configured to support protecting a minor’s privacy rights under state law, then the patient portal may be disabled for minors at a “cut-off” age (e.g., 14) based on state law. If technologically feasible, can still push selected data to the portal (e.g., vaccinations).
  
  *Assert: Privacy Exception & Infeasibility Exception.*
Questions?

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Announcements

• 6 HIE Compliance Library accounts still available!
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    - Webinar presentation – Wednesday, November 10th, from 12:00-1:00pm
    - Follow-up Ask the Experts Q&A session – Wednesday, Nov 17th, 12:00-1:00pm
      - **REGISTER HERE**
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    - Webinar presentation – Wednesday, December 1st, 12:00-1:00pm
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Contact us: hccn@chcanys.org