



Navigating Compliance Challenges with the Information Blocking Rule: A Collection of Case Studies

HITEQ Center and Feldesman Tucker Leifer Fidell LLP, September 2023

Introduction

The Office of the National Coordinator for Health Information Technology's (ONC) [21st Century Cures Act Information Blocking Rule](#) (Info Blocking Rule) prohibits covered actors – including health care providers, health IT developers of certified health IT, and health information exchanges/health information networks– from engaging in practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI). The Info Blocking Rule includes [eight exceptions](#) that provide actors with certainty that, when their practice interferes with the access, exchange, or use of EHI and meets the conditions of one or more exception, such practice will not be considered information blocking.¹ An actor's practice that does not meet all the conditions of an exception will be evaluated on a case-by-case basis to determine whether information blocking has occurred.²

¹ 45 CFR 171.200; 45 CFR 171.300.

² "Frequently Asked Questions," HealthIT.gov, The Office of the National Coordinator for Health Information Technology (ONC), www.healthit.gov/faq/would-it-be-information-blocking-if-actor-does-not-fulfill-request-access-exchange-or-use-ehi.



Since the Info Blocking Rule went into effect in 2021, EHI has become more available than ever as it is posted to portals, sent through health information exchanges, and available via health-related apps upon request by patients.³ As the availability of EHI has increased, so too have concerns about the privacy of EHI. Like other actors, health centers are faced with new compliance challenges, including how to best protect sensitive EHI, how to respond to patient requests to restrict access to their EHI, and how to respond when patients request changes to their EHI. Health centers must navigate complex and, at times, conflicting federal and state laws and regulations.

The case studies in this Issue Brief demonstrate recent compliance challenges faced by health centers. Each includes a review of the applicable federal, legal, and regulatory requirements and recommendations for navigating conflicting requirements. The table below provides an overview of and the citations for three exceptions that are particularly relevant to the case studies.

³ In this Issue Brief the term “patient” includes both the individual “who is the subject of the protected health information” as defined by HIPAA (per 45 CFR § 160.103) and the individual’s personal representative (as designated under 45 CFR § 165.502(g)).

Three Key Information Blocking Exceptions⁴

Exception	Overview
Preventing Harm Exception: 45 CFR § 171.201	<p>This exception is designed to apply when an actor determines that, in order to prevent harm to a patient or another person, it cannot fulfill a request to access, exchange or use EHI. Key requirements to fitting within the exception include that:</p> <ol style="list-style-type: none"> 1. The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm; 2. The actor’s practice must be no broader than necessary; 3. The actor’s practice must meet at least one condition from the type of risk, type of harm, and implementation basis categories; and 4. A patient must be provided with the opportunity to request review of an individualized determination of risk of harm.
Privacy Exception: 45 CFR § 171.202	<p>This exception is designed to apply when an actor determines that, to protect a patient’s privacy under state or federal privacy laws, it cannot fulfill a request to access, exchange or use EHI. There are four sub-exceptions. The two addressed in the case studies in this Issue Brief are:</p> <ol style="list-style-type: none"> 1. Precondition Not Satisfied: An actor may choose not to provide access, exchange or use of EHI protected by a state or federal law that requires certain conditions, such as completion of a consent or authorization form. 2. Respecting a patient’s request not to share information: An actor may choose not to provide access, exchange or use of EHI if the patient requests that the actor not access, exchange, or use their EHI.
Infeasibility Exception: 45 CFR § 171.204	<p>This exception is designed to apply when an actor does not fulfill a request to access, exchange or use EHI because it is infeasible for the actor to respond to the request. There are three conditions under this exception. The condition addressed in the case studies in this Issue Brief is:</p> <ol style="list-style-type: none"> 1. Segmentation: The actor cannot fulfill the request for access, exchange or use because the actor cannot unambiguously segment the requested EHI from EHI that cannot be made available due to a patient’s preference, because the EHI cannot be made available by law, or because the EHI may be withheld under the Preventing Harm Exception.

⁴ “Cures Act Final Rule Information Blocking Exceptions,” HealthIT.gov, The Office of the National Coordinator for Health Information Technology (ONC), 2023, <https://www.healthit.gov/sites/default/files/2022-07/InformationBlockingExceptions.pdf>



Case Study #1

If state law allows patients who are minors to consent to sexually transmitted infection (STI) testing and treatment without their parent or guardian's permission, how do we keep those visits confidential if the parent or guardian has access to the patient's portal (e.g., proxy portal access)? Can we block the parent or guardian's access to the minor's records related to confidential services or to all the minor's records?

To determine how best to protect minors' records, the health center should take the following steps:

- 1 Understand the state law:** An understanding of the applicable state law is critical to determining whether a parent or guardian can access information in a minor's record. Many states have laws that grant minors decision-making authority for certain health care services, referred to as "confidential services." Confidential services may include sexual and reproductive health care, mental health services, and substance use disorder treatment.⁵ State laws vary in the services and ages for consent. For example:
 - a. All 50 states and the District of Columbia explicitly allow minors to consent to STI services; however, the age of consent varies (generally from 12 to 14) by state, as does whether HIV testing and treatment are included in STI services;
 - a. In 18 states physicians are permitted (but not required) to inform a minor's parent that they are seeking or receiving STI services; and,
 - a. In 1 state (Iowa) physicians are required to inform a minor's parent in the case of a positive HIV test.⁶

In general, if a minor can consent to the confidential services and the consent of the parent is not required under state or other applicable law, then the parent may not access the minor's records unless the minor authorizes the disclosure. Information about the confidential services received by the minor must not be available to the parent or guardian via the portal or any other format (paper, verbal disclosure, etc.), unless the required preconditions under the state law are met, such as the minor signing an authorization form permitting the parent to access the information. Under the Privacy Exception's "Precondition Not Satisfied" sub-exception, it would not be considered information blocking if the health center refused to provide access, exchange, or use of EHI related to the confidential services if the health center has not received the required authorization from the minor.

⁵ "Opinion 2.2.2 - Confidential Health Care for Minors," Code of Medical Ethics, American Medical Association, Accessed July 10, 2023, <https://code-medical-ethics.ama-assn.org/ethics-opinions/confidential-health-care-minors>.

⁶ "Minors' Access to STI Services, Guttmacher Institute, Last Modified July 1, 2023, <https://www.guttmacher.org/state-policy/explore/minors-access-sti-services>.

Because the “Precondition Not Satisfied” sub-exception must be no broader than necessary, the health center should not block access to all the minor’s records, unless segmentation of the record is infeasible (see *below section on understanding the electronic health record (EHR)/portal*).

- 2 Understand the EHR/portal:** When an individual receives shared access to another patient’s portal, such as a parent receiving access to their child’s patient portal, the person with the shared access is often referred to as the “proxy.” If the EHR allows for data segmentation, it would likely be information blocking if the provider failed to enable data segmentation and failed to grant the proxy access to the minor’s other EHI (that EHI unrelated to the confidential services). If the EHR does not allow for data segmentation, then the provider could deny a parent’s request to access the minor’s records because it would be infeasible to keep records of the confidential services confidential. If an actor denies a request to access, exchange or use EHI due to infeasibility, within 10 business days of receipt of the request the actor must provide the requester with the reason(s) why the request is infeasible.



Compliance Checklist

- ✓ Identify applicable state laws that permit minors to consent to confidential services.
- ✓ Understand functionality of the EHR to segment data. For example, ask the EHR vendor:
 - ✓ Can the EHR automatically implement proxy access for parents when a minor reaches the age of consent under applicable state laws?
 - ✓ Can the EHR automatically implement proxy access for minors already at the age of consent under applicable state laws?
 - ✓ Can patient records be segmented to protect specific data, fields or parts of the records?
 - ✓ What steps must staff members take to identify the parts of the records to be protected?
- ✓ Develop guidance for providers on documenting sensitive health care services, including where and how to document provision of confidential services.
- ✓ Develop guidance for parents, guardians and minors on how proxy accounts work and what EHI is available through the portal.
- ✓ Develop guidance for all health center staff on confidential services, including a procedure for minors to authorize any disclosure of records of confidential services to a parent or guardian through the parent or guardian’s access to the minor’s portal account.



Case Study #2

A patient came to our health center for a consult on knee pain. During the visit, the patient stated that they did not want a prescription for opioids because their son struggled with opioid use disorder and died by suicide. The provider noted this information in the patient's record. The patient was referred to an orthopedist who mentioned the son's suicide when reviewing the patient's record. The patient called our health center stating that he does not want information about his son shared. How should we respond to the patient's request?

The health center may treat this as a “Request Not to Share Information” under the Privacy Exception. This sub-exception permits an actor, in certain circumstances, to not fulfill a request to provide access, exchange or use of EHI if a patient has specifically requested the actor not to do so. To meet the requirements of the sub-exception, the request must be initiated by the patient without any improper encouragement or inducement by the actor; the actor must document the request within a reasonable time period; and the actor's practice must be implemented in a consistent and non-discriminatory manner. If the actor agrees to the request and documents it, the request remains in effect until terminated as described in the Info Blocking Rule.⁷ This sub-exception aligns with a patient's right to request restrictions on the use and disclosure of their protected health information under the HIPAA Privacy Rule.⁸

The health center should carefully review patient requests not to share EHI. If the health center determines that information about a family member's opioid use disorder is essential to the patient's treatment, it may deny the patient's request and share the EHI. In the case study above, the health center may determine that a family history of opioid use disorder is relevant for certain referrals (for example, to another provider who can prescribe opioids or for a behavioral health provider) but that it is not relevant for other referrals (for example, to physical therapy). When denying a patient's request, the health center may explain to the patient the reason for sharing the EHI (treatment purposes) and the obligations of the recipient (also a HIPAA covered entity) to protect the privacy of the EHI. If the health center grants the patient's request not to share EHI, it must next determine whether it can segment the EHI at issue.

⁷ 45 CFR 171.202(e)(4).
⁸ 45 CFR § 164.522(a).



Compliance Checklist

- ✓ Review policies and procedures on responding to requests for restrictions to:
 - ✓ Incorporate the Info Blocking Rule's sub-exception on responding to a patient's request not to share EHI into the health center's HIPAA Privacy Rule policy and procedure on a patient's right to request restrictions on uses and disclosures; or
 - ✓ Develop a separate policy and procedure on the Info Blocking Rule's sub-exception on responding to a patient's request not to share EHI and include reference to that separate policy in the health center's HIPAA Privacy Rule policy and procedure on a patient's right to request restrictions on uses and disclosures.
- ✓ Develop guidance for providers on documenting patient requests to restrict access, exchange, or use of their EHI.



Case Study #3

Prior to prescribing pre-exposure prophylaxis (PrEP), patients complete a sexual health assessment that includes questions about their gender identity, number of sexual partners, and gender identity of their sexual partners. The responses are documented in our EHR and the information is available in the patient portal. One of our patients became very upset when they saw this information in their portal account. The patient contacted the health center asking for an explanation. Can we block the patient's information from appearing in the portal?

The health center may treat this as a “Request Not to Share Information” under the Privacy Exception. As discussed above, except in very limited circumstances, neither the Info Blocking Rule nor the HIPAA Privacy Rule require a provider to agree to the requested restrictions. For example, if an actor determines the information is essential to the patient’s treatment, the actor may deny the patient’s request and share the EHI. In this case study, the Preventing Harm Exception may also apply if the health center determines that, in order to prevent harm to the life or physical safety of the patient, EHI related to the patient’s sexual health assessment should not be posted to the portal. To fit within the Preventing Harm Exception, an actor must (1) have a reasonable belief that by denying the request to access, exchange or use EHI, the risk of harm to the patient or another person will be substantially reduced; (2) ensure the denial is limited to only those data points, elements, or classes of data necessary to prevent harm to the patient or another person; (3) it satisfies at least one condition from each of the following categories: type of risk,⁹ type of harm,¹⁰ and implementation basis;¹¹ and (4) the practice satisfies the condition concerning a patient’s right to request review of an individualized determination of risk of harm. The ONC has clarified that, “the reasonable belief condition does not include a requirement that the harm be expected to occur within a particular time period or that the likelihood of harm be high enough to be considered ‘imminent.’”¹²

9 45 CFR § 171.201(c).

10 45 CFR § 171.201(d).

11 45 CFR § 171.202(f).

12 “Frequently Asked Questions,” HealthIT.gov, The Office of the National Coordinator for Health Information Technology (ONC), January 2021, <https://www.healthit.gov/faq/will-preventing-harm-exception-cover-practices-interfering-patients-access-exchange-or-use>.



Case Study #4

Our state law requires certain health care providers to collect patient immigration status on admission or registration forms and to send quarterly reports to the state on the number of undocumented patients receiving care.

We're concerned this will discourage patients who are undocumented from receiving necessary health care. How can care be appropriately documented in the EHR?

At the federal level, health care providers do not have an affirmative legal obligation to inquire into or report to immigration authorities about patient immigration status; however, some states have passed laws requiring certain health care providers to collect and report information on patient immigration status. A careful read of these state laws is critical to understanding whether health centers are required to comply with the law and, if so, the information that must be collected and documented. For example, this case study describes a state law that requires patient immigration status be collected using an admission or registration form; however, there does not appear to be a requirement to document patient immigration status in the patient's record, to scan the form into the patient's record or to retain the forms. A health care provider may be able to develop a registration process that meets the collection requirements under the state law without documenting immigration status in the patient's record and without retaining the forms reflecting immigration status.

If a state law requires disclosure of EHI for public health or other purposes, the Info Blocking Rule's Privacy Exception would not apply. An actor would not be in a position to grant a patient's request for confidentiality under the Info Blocking Rule if a state law required disclosure.¹³

Similar questions arise when conducting social determinants of health screening. Health centers should take care when developing questions and documenting responses in patient records. Instead of direct questions about a patient's current immigration status, questions focused on whether a patient is concerned about their family's health and stability for immigration-related reasons with responses limited to "yes" or "no" may help to limit immigration status information from being documented in a patient's record.¹⁴

¹³ Department Of Health And Human Services, Office of the Secretary, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" Federal Register 85, no. 85 (May 1, 2020): 25642, <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf>.

¹⁴ Elena Byhoff et al. "Screening for Immigration-Related Health Concerns in a Federally Qualified Health Center Serving a Diverse Latinx Community: A Mixed Methods Study," *Journal of Immigrant and Minority Health* 22, no.5 (2020): 988–995. doi: 10.1007/s10903-020-01005-6



Compliance Checklist

- ✓ Determine if the state law requires health centers to collect and report information on patient immigration status. If so, determine what information must be collected, where/how it must be documented, and how it must be disclosed.
- ✓ Provide training for all staff members on documentation best practices to ensure patient records contain required information without containing additional details that create risk for patients.



Case Study #5

Our state law permits minors to receive gender affirming care. In a bordering state, minors are not permitted to receive gender affirming care. Our providers are concerned about the privacy and safety of minors with one parent living in our state and another parent living in the bordering state. Of special concern is the safety of minors who are exploring or starting to receive gender affirming care at our health center. Parents in the bordering state may not (yet) know the minor is receiving gender affirming care. The parents may find out if a health care provider in the bordering state accesses our provider notes through the health information exchange (HIE) and copies or refers to our provider's notes in the patient portal. Such access may put both the minor and our providers at risk of harm. Can we block all EHI related to gender affirming care of minors from the HIE under the Preventing Harm Exception?

No, the Preventing Harm Exception would not apply to a practice that blocks all EHI related to gender affirming care received by minors from the HIE. For the Preventing Harm Exception to apply, the type of risk applicable to this case study must be determined on an individualized basis in the exercise of professional judgment by a licensed healthcare professional who has a current or prior clinician-patient relationship with the patient whose EHI is affected by the determination. The health center's proposal to block all EHI related to gender affirming care of minors from the health information exchange is too broad. The Info Blocking Rule does not permit an actor to have a blanket rule that applies the Preventing Harm Exception to all records of gender affirming care for minors. Instead, the Preventing Harm Exception could apply, if the risk of harm is determined on an individual basis and the other conditions of the exception are met. The health center would need to determine whether it can segment the EHI. If not, the Infeasibility Exception may apply.

The HITEQ Center is a HRSA-funded National Training and Technical Assistance Partner operated by JSI Research & Training, Inc. and Westat.

This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of awards totaling \$693,000 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.

These materials have been prepared by the attorneys of Feldesman Tucker Leifer Fidell LLP. The opinions expressed in these materials are the views of Feldesman Tucker Leifer Fidell LLP and not necessarily the views of the federal government, any state government, or of any other organization or person.

The materials are being issued with the understanding that the authors are not engaged in rendering legal or other professional services. If legal assistance or other expert assistance is required, the services of a competent professional with knowledge of your specific circumstances should be sought.

