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Information Blocking Exceptions and Agreeable Terms

1. Background

Following the publication of the [21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule \(Final Rule\)](#) entered into the Federal Register by the Office of the National Coordinator for Health Information Technology (ONC), Healthcare Organizations (HCOs) across the United States are required by law to cease any Practices deemed “Information Blocking,” defined as:

“...a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information (EHI).” -

<https://www.healthit.gov/topic/information-blocking>

To allow for real-world application of the provisions, the Final Rule provides for a number of exceptions that acknowledge legal requirements and define conditions which may prohibit an Actor from providing Patient data upon Request and will not be found to be Information Blocking if all requirements and conditions of the exception can be met.

This policy is a component of the compliance policy framework, for additional information refer to CPL-001 - Information Blocking Policy.

2. Purpose

This policy is intended to identify the applicability of exceptions in the Final Rule as they may pertain to VITL’s operations, functionalities, capabilities, or abilities under current laws or agreements in place, and to provide guidance in finding agreeable terms with a Requestor.

3. Scope

This policy lists the exceptions in the Final Rule applicable to the VHIE. These exceptions identify in which cases a determination not to fulfill a Request for Patient data or to fulfill a Request in an alternate manner from what was requested would not be considered Information Blocking. This policy also guides VITL in reaching agreeable terms with a Requestor, consistent with an exception, if VITL cannot fulfill a Request or will not do so in the requested manner.

4. Policy

All Requests to access, exchange or use EHI outside of the standard operations of the VHIE shall be tracked and responded to without unnecessary delay. The VITL Support team with oversight by the Director of Technology is responsible for managing EHI Requests. VITL may invoke the exceptions in the Final Rule as set forth in this policy. The invoking of any exceptions can only be approved by the Director of Operations or the CEO.

Exceptions

Preventing Harm Exception

So long as the conditions of the Preventing Harm exception are met, it will not be information blocking if the Practice substantially reduces a regulatory cognizable risk of harm to a natural person.

For the most part, this exception is intended for clinicians to make a clinical decision about potential harm. However, in a situation where VHIE data might be corrupted or otherwise compromised, it is possible VITL could use this exception. VITL maintains procedures to avoid the access, exchange, and use of EHI that would result in mismatched, corrupt, or erroneous EHI being released to a Requestor. In the event of such risk, VITL will follow its procedures to avoid the release of EHI that could cause harm due to its lack of integrity or to delay the release of EHI for the time necessary to correct errors that would otherwise pose a risk of harm. Beyond this, VITL is generally not able to determine or otherwise assess when EHI, as a result of the professional judgment of an involved healthcare professional, could cause a risk of harm to a person and will not utilize this exception at this time.

Privacy Exception

It will not be information blocking if an organization engages in privacy-related Practices, so long as one or more of the conditions of the Privacy exception are met.

The Privacy Exception, as described in the Final Rule and in the Healthit.gov Information Blocking Exceptions Guide, lists three sub-exceptions relevant to VITL – one of which must be met to qualify as a privacy exception.

1.) Precondition not satisfied: If an Actor is required by a state or federal law to satisfy a precondition (such as a Patient consent or authorization) prior to providing access, exchange, or use of EHI, the Actor may choose not to provide access, exchange, or use of such EHI if the precondition has not been satisfied under certain circumstances.

2.) Denial of an Individual's Request for their EHI consistent with 45 CFR 164.524(a) (1) and (2): An Actor that is a Covered Entity or business associate may deny an Individual's

Request for access to their EHI in the circumstances provided under 45 CFR 164.524(a)(1) and (2) of the HIPAA Privacy Rule, including, without limitation, the withholding of psychotherapy notes or EHI created in the course of research.

3.) Respecting an Individual's Request not to share information: An Actor may choose not to provide access, exchange, or use of an Individual's EHI if doing so fulfills the wishes of the Individual, provided certain conditions are met.

VITL must comply with federal and state law pertaining to its role as a Business Associate of healthcare organizations and the operator of the VHIE.

VITL will facilitate an Individual's Request for access to their EHI, and will appropriately review other Requests for the access, exchange, or use of EHI, pursuant to VITL's Policy CPL-002 Disclosure of Protected Health Information. VITL's Practices will be applied consistently and in a non-discriminatory manner where denial of a Request for the access, exchange or use of EHI is required by federal or state law. If an Individual has opted out of having their information available on the VHIE, no EHI from that Individual will be made available to a third-party Requester outside of an emergency treatment situation.

If a Privacy Exception is claimed in response to a Request, VITL will document facts related to the Request and how the exception applied in a response to the Request.

Security Exception

It will not be information blocking if an organization engages in Practices that protect the security of EHI, so long as the conditions of the Security exception are met.

VITL's Practices that safeguard the confidentiality, integrity, and availability of EHI are and will be tailored to specific documented security risks and implemented consistently, without discrimination across similar circumstances related to Requests.

VITL will follow its HIPAA Security Policies¹, procedures, risk assessment processes, and other security Practices to evaluate Requests for access, exchange, or use of EHI outside of normal VHIE operations. These collective security Practices, which evolve over time, may conflict with fulfilling Requests for EHI, prompting the application of the Security Exception. If this occurs, VITL will document why the security Practice was necessary to mitigate the identified risk, what alternative mitigations were assessed, and why the alternatives were unable to sufficiently mitigate the risk. Under exigent circumstances a mitigation may be implemented prior to assessing alternatives; however, once circumstances return to normal the initial Practice must undergo the review described above.

¹ InfoSec1 – Management Process Policy
InfoSec2 – Information System User Policy
InfoSec3 – Information System Access Control Policy
InfoSec4 – Information Security Incident Response Policy.

Negotiation of Terms if Security Exception is Invoked:

If VITL declines to provide EHI specified in an information Request because of a security risk to a VITL system, the risks and concerns will be presented to the Requestor within the Request response letter. VITL's leadership representative responding to the information Request will open a discussion about the risks and concerns that have been raised. VITL will work with the Requestor to determine if there are any alternate resolutions available where a response can be made to the Request without risk to the confidentiality, integrity, or availability of the EHI or System.

- If a resolution or partial resolution is found, then VITL will provide the EHI according to the modified Request.
- If no resolution can be reached, the Request will not be fulfilled under the Security Exception.

VITL will document the security risks and concerns related to the EHI and its response.

Infeasibility Exception

It will not be information blocking if an organization faces legitimate practical challenges that may limit the organization's ability to comply with a Request for Access, Exchange or Use of EHI, so long as the conditions of the Infeasibility exception are met.

There are three reasons that VITL might invoke the infeasibility exception when responding to a Request for EHI outside of the operations of the VHIE.

- **Uncontrollable Events:** VITL may not be able to fulfill an EHI Request due to a natural or humanmade disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.
- **Data Segmentation:** VITL may not be able to fulfill an EHI Request because it is not possible to unambiguously segment the requested EHI from EHI that cannot be disclosed due to legal requirements relevant to the privacy exception or otherwise relevant to another exception.
- **Infeasible under the circumstances:** VITL may determine based on a number of factors that it would be infeasible to respond to a Request given the significant extra resources that it would require. If this sub-exception is invoked, a written record (or other similar documentation) demonstrating consistent and non-discriminatory consideration of any factors that led to VITL's determination that complying with the Request would be infeasible.

When making an infeasibility determination, VITL will not consider either of the following two factors:

- Whether complying with the EHI Request in the manner requested would facilitate competition with VITL.
- Whether complying with the EHI Request would prevent VITL from charging a fee or will result in a reduced fee.

Whenever VITL invokes the Infeasibility exception, a notification of the determination, including the reasons for the decision, will be sent to the Requester **within 10 business days** of receiving the EHI Request.

Negotiation of Terms when an Infeasibility Exception is invoked:

If VITL determines it cannot provide EHI specified in an information Request due to the Infeasibility Exception, the specific reason the Request was deemed infeasible will be presented to the Requestor **within 10 business days**. Following the notification that the Request was infeasible VITL's representative responding to the information Request will open a discussion with the Requestor to explain why the Request was infeasible, when circumstances may change, or if there are any alternative solutions that may be available to share EHI under a different mechanism.

If a Request is not fulfilled due to infeasibility, but the post-decision discussion identifies a reasonable alternative solution then an updated information Request should be submitted.

VITL will document the circumstances related to any infeasibility determination.

Health IT Performance

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.

If VITL must make its health IT temporarily unavailable or degrade its performance, the following conditions must be met:

- The action causing downtime or degraded performance will last no longer than necessary to achieve the goal of the action.
- The action will be implemented consistently and in a non-discriminator manner; and
- If the action is:
 - **Planned** - then the maintenance or upgrade must be consistent with existing service level agreements.
 - **Unplanned** - then the health IT Platform must be restored as soon as feasible.

If VITL is required to take action to deny a Third-Party's access, exchange, or use of EHI through an application that is negatively impacting the health IT's performance, any actions will:

- Last for a period of time no longer than necessary to resolve the negative impact.
- Be implemented consistently and in a non-discriminatory manner; and
- Be consistent with existing services level agreements (where applicable).

VITL will document situations where access, exchange, or use of EHI is interrupted as a result of unplanned unavailability, including the scope of impact.

Content and Manner Exception

It will not be information blocking if an organization fulfills an EHI Request in an alternative manner, so long as the conditions of the Content and Manner exception are met.

VITL's response to a Request for the access, exchange, or use of EHI may be limited to data elements set forth in the USCDI through October 6, 2022. Thereafter, VITL will provide EHI consistent with an Individual's Designated Record Set, subject to the application of the exceptions discussed in this policy.

It is VITL's intention to fulfill Requests for access, exchange, or use of EHI outside of VHIE operations in the manner requested; however, VITL may respond in an alternative manner if there are technical limitations with VITL's ability to provide EHI in the requested format, or if VITL is otherwise unable to agree to terms with the Requestor. If this exception is invoked, VITL will notify the Requestor within 10 business days of receiving the EHI Request.

If the Request can be responded to in an alternate manner, the following prioritized list of methods will be utilized to determine the next best option:

- Using certified technology specified by the Requestor (e.g., via application programming interface (API), Direct protocol).
- Using content and transport standards specified by Requestor and published by the federal government or standards development organization accredited by the American National Standards Institute (ANSI); or
- Using an alternative machine-readable format agreed upon with the Requestor (e.g., Extensible Markup Language (XML), comma-separated value (CSV) files).

VITL will document its arrangements related to fulfilling the specified Request in an alternate manner.

If fees will be applied, VITL will comply with the Fee Exception provisions.

Fees Exception

If an organization will respond to the EHI Request in an alternative manner, that organization will not violate the Information Blocking Final Rule by charging a reasonable fee, so long as conditions of the Fees exception are met.

This Exception does not permit or support the sale of EHI.

VITL will not charge any fees that are prohibited under the HIPAA Privacy Rule or 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.

For third-party Requestors, other than an Individual's Personal Representative or any Participating Health Care Organization and outside of VHIE operations, VITL may impose a fee on the access, exchange, or use of EHI, so long as the fee is based on the following:

- An objective and verifiable criterion that is uniformly applied for all similarly situated classes of Requestor and Requests.
- The fee is reasonably related to VITL's costs of providing the type of access, exchange, or use of EHI to, or at the Request of, the person or entity to whom the fee is charged.
- The fee is reasonably allocated among all similarly situated Requestor to whom the technology or service is supplied, or for whom the technology is supported; and
- The costs are not otherwise recovered for the same instance of service to another party.

Any fees that are charged will not be based on any of the following:

- Whether the Requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with VITL.
- 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.
- Costs that VITL 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 EHI.
- Costs associated with intangible assets other than the actual development or acquisition costs of such assets.
- Opportunity costs unrelated to the access, exchange, or use of EHI.
- Any costs that led to the creation of intellectual property, if VITL charged a royalty for that intellectual property under the Licensing Safe Harbor and that royalty included the development costs for the creation of the intellectual property.
- Fees to perform an export of EHI via certified health IT for the purposes of switching health IT or to provide Patients their EHI; or
- Fees to export or convert data from another technology that was not agreed to in writing at the time the technology was acquired.

Terms for Fees Under Fees Exception:

VITL will charge reasonable fees based on the cost of fulfilling Requests as defined in the “Pricing Policy for Access to PHI”. If an EHI Request falls within the scope of one of the identified scenarios where VITL intends to charge a fee, then a representative of VITL will contact the Requestor to discuss the fee structure and obtain payment information as appropriate; fees for third party Requests that include building a new interface will be reviewed and discussed based on the scope of the Request.

If a Requester declines to pay the fee associated with fulfilling a Request, then the Request will not be fulfilled.

Licensing Exception

If an organization will respond to the EHI Request in an alternative manner, that organization will not violate the Information Blocking Final Rule by imposing terms and conditions (e.g., a license or non-disclosure agreement) on the Requestor’s use of Interoperability Elements to Access, Exchange or Use EHI, if the requirements of the Licensing Exception are met.

In the event VITL chooses to license the use of Interoperability Elements to access, exchange, or use EHI in an alternative manner, then VITL will:

- Begin license negotiations with a Requestor **within 10 business days** of the Request: and
- Negotiate in good faith a license **within 30 business days** of the Request.

The license will meet all the following requirements (as applicable):

- **Scope of License.** The license will provide all rights necessary to enable the Requestor to achieve the intended access, exchange, or use of EHI via the Interoperability Elements.

- **Royalty.** If a royalty is charged, the royalty will be reasonable, non-discriminatory and based solely on the independent value of VITL's technology to the licensee's products. The royalty will not be based on any strategic value stemming from VITL's control over essential means of accessing, exchanging, or using EHI. VITL will not charge a royalty for intellectual property if it recovered any development costs that led to the creation of the intellectual property.
- **Non-Discriminatory.** The licensing terms will be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons and Requests. The terms will not be based on (1) whether the Requestor or other person is a competitor, potential competitor, or will be using EHI obtained in a way that facilitates competition with VITL, or (2) on the revenue, or any other value the Requestor may derive from the access, exchange, or use of EHI obtained via the Interoperability Elements.
- **Collateral Terms.** VITL will not require the Requestor to do any of the following:
 - Execute a non-compete in any product, service, or market.
 - Deal exclusively with VITL in any product, service, or market.
 - Obtain additional licenses, products, or services that are not related to or can be unbundled from the requested Interoperability Elements.
 - License, grant, assign, or transfer to VITL any intellectual property of the licensee; or
 - Pay a fee of any kind unless the Fees Exception is met.

If VITL will require the use of a non-disclosure agreement (NDA) in connection with the use of Interoperability Elements to access, exchange or use EHI, the NDA must meet the following requirements:

- It must be reasonable; and
- No broader than necessary to prevent the unauthorized Disclosure of VITL's trade secrets. The information VITL claims as trade secrets must be stated with particularity in the NDA and such information must meet the definition of a trade secret under applicable law.

Finally, when provisioning a Requestor with use of Interoperability Elements, VITL will not engage in any Practice that has any of the following purposes or effects:

- Impedes the efficient use of the Interoperability Elements to access, exchange or use EHI for permissible purposes.
- Impedes the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand; and/or
- Degrades the performance or interoperability of the licensee's products or services, unless necessary to improve VITL's technology and after affording the licensee a reasonable opportunity to update its technology to maintain interoperability.

Negotiating Terms when Licensing Exception is Invoked:

VITL may require a licensing or similar agreement be reached prior to fulfilling certain Requests as defined in the section above. If, upon a legal review, the EHI Request is determined to be a scenario where a license is required, then a representative of VITL will contact the Requester to discuss the

license terms, conditions, and royalties **within 10 business days** of the Request and will negotiate in good faith to provide a license **within 30 business days** of the Request.

If a Requester declines to agree to the license terms for an Interoperability Element associated with fulfilling a Request, then the Request will not be fulfilled.

5. References



This policy is a component of the compliance policy framework, for additional information refer to CPL-001 - Information Blocking Policy.

6. Definitions

Refer to VITL's CPL-006 - Glossary of Information Blocking Terms document for definitions relating to this policy.

7. Policy Review & Approval

VITL management performs periodic reviews of this policy as referenced by the next review date field above; based on this review, VITL management reserves the right to update this policy.

	04/05/2021
_____ Policy Sponsor	_____ Date
	04/05/2021
_____ Approving Official	_____ Date