

TITLE: INFORMATION BLOCKING POLICY	
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VERSION: 3	PAGE: 1 OF 13

I. PURPOSE

It is the policy of ClinicalConnect HIE (CCHIE) to not engage in the practice of information blocking of electronic health information (EHI) and to comply with 45 CFR Part 171 when applying any exception. Furthermore, CCHIE will respond to requests for EHI in a uniform, consistent, and non-discriminatory manner.

II. OVERVIEW

Participants send EHI and other electronic data to CCHIE to be exchanged with other Participants via the ConnectChart service and utilized for other services, as approved by CCHIE's Board of Directors. However, each Participant owns the EHI which it sends to CCHIE. CCHIE is only authorized to disclose such information when the disclosure is a part of a service which CCHIE provides and the recipient of the EHI has signed an agreement with CCHIE. In limited circumstances, CCHIE may disclose EHI as permitted by its Business Associate Agreement.

III. SCOPE

This policy applies to CCHIE employees and Participants.

IV. DEFINITIONS

"CFR" is the Code of Federal Regulations.

"Electronic Health Information (EHI)" means electronic protected health information as defined in 45 CFR 164.501, regardless of whether the group of records are used by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include:

- (1) Psychotherapy notes as defined in 45 CFR 164.501; or
- (2) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

"Individual" means one or more of the following:

- (1) An individual as defined by 45 CFR 160.103.

- (2) Any other natural person who is the subject of the electronic health information being accessed, exchanged, or used.
- (3) A person who legally acts on behalf of a person described in 45 CFR parts 160 and 164 or within this definition in making decisions related to health care as a personal representative, in accordance with 45 CFR 164.502(g).
- (4) A person who is a legal representative of and can make health care decisions on behalf of any person described in 45 CFR parts 160 and 164 or within this definition.
- (5) An executor, administrator, or other person having authority to act on behalf of a deceased person, described in 45 CFR parts 160 and 164 or within this definition, or the individual's estate under State or other law.

“Information Blocking” as defined in 45 CFR 171.103, means a practice that –

- (1) Except as required by law or covered by an exception in subpart B or C of this part, is likely to interfere with access, exchange, or use of electronic health information; and
- (2) If conducted by a health information technology developer, health information network, or health information exchange, such developer, network, or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; or
- (3) If conducted by a health care provider, such provider knows of such practice knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

“Participant” is an organization (including physician practice) that has signed a Data Exchange Agreement with ClinicalConnect HIE.

V. EHI REQUESTS

- A. Participants, including eHealth Exchange and P3N Participants, and other entities or individuals which have signed an agreement with CCHIE shall direct all EHI requests to the CCHIE Compliance Team for review.
- B. If the requester is legally permitted to receive the EHI and no exception applies, CCHIE shall make a good-faith effort to furnish the EHI in the manner requested and within a reasonable time. In some circumstances, CCHIE may need to coordinate with multiple Participants in which additional time may be required.

- C. If an exception within the scope of 45 CFR Part 171 and addressed within this policy applies, CCHIE shall promptly provide the requester a notice of the denial. The denial notification will explain the basis for the denial and a description of any additional rights to appeal to the denial and how to request an appeal.
- D. Individuals and entities which have not signed an agreement with CCHIE must direct all EHI requests to the specific Participant(s) which own the EHI and comply with each Participant's EHI request procedures. Participants will then engage CCHIE to assist with processing the request, only if necessary.

VI. PREVENTING HARM EXCEPTION

- A. CCHIE's practice that is likely to interfere with the access, exchange, or use of EHI will not be considered information blocking when acting for or on behalf of a Participant that is a covered entity and has met the preventing harm requirements under 45 CFR 171.201.

VII. PRIVACY EXCEPTION

- A. CCHIE's practice of not fulfilling a request to access, exchange, or use of EHI to protect an individual's privacy will not be considered information blocking when the practice meets all requirements under B of this section, in compliance with 45 CFR 171.202.
- B. *Sub-exception – precondition not satisfied.* To qualify for the exception on the basis that State or Federal law requires one or more preconditions for providing access, exchange, or use of EHI that have been satisfied, the following requirements must be met:
 - 1. The information blocking practice is tailored to CCHIE and the practice is implemented in a consistent, non-discriminatory manner and is one of the following:
 - i. Conforms to CCHIE Policies in Procedures - which meet all the following:
 - are in writing;
 - specifies how the precondition will be met and what steps CCHIE will take to meet the precondition when applicable; and
 - are implemented.
 - ii. Documented on a Case-by-Case Basis - in which documentation must address the following:
 - criteria used to determine when the precondition can be satisfied;

- any criteria that was not met; and
 - reason why the criteria was not met.
2. If the precondition relies on the provision of a consent or authorization from an individual and CCHIE has received a version of such a consent or authorization that does not satisfy all elements of the precondition required under applicable law, then CCHIE must:
 - i. Use reasonable efforts to provide the individual with a consent or authorization form that satisfies the requirements of law or provide reasonable assistance to the individual; and
 - ii. Not improperly encourage/induce the individual to withhold the authorization/consent.
 3. For purposes of determining whether CCHIE's policies and procedures and actions satisfy the requirements stated in B(1)(i) and B(2) of this section when complying with multiple laws with inconsistent preconditions, they shall be deemed compliant if CCHIE has adopted uniform privacy policies and procedures that address the more stringent preconditions.

VIII. SECURITY EXCEPTION

- A. CCHIE's practice that is likely to interfere with the access, exchange, or use of EHI to protect EHI will not be considered information blocking when the practice meets the following conditions and either meets the condition in B or C of this section, as addressed under 45 CFR 171.203:
 1. The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI.
 2. The practice must be tailored to the specific security risk being addressed.
 3. The practice must be implemented in a consistent and non-discriminatory manner.
- B. If the practice implements an organization security policy, the policy must meet the following requirements:
 1. Be in writing;
 2. Have been prepared on the basis, and be directly responsive to, security risks identified and assessed by or on behalf of CCHIE;
 3. Align with one more consensus-based standards or best practice guidance; and

4. Provide objective timeframes and other parameters for identifying, responding to, and addressing security incidents.
- C. If the practice does not implement an organizational security policy, CCHIE must have made a determination in each case, based on the particularized facts and circumstances, that:
1. The practice is necessary to mitigate the security risk to EHI; and
 2. There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with access, exchange, or use of EHI.

IX. INFEASIBILITY EXCEPTION

A. CCHIE's practice of not fulfilling a request to access, exchange, or use EHI due to the infeasibility of the request will not be considered information blocking when the practice meets one of the conditions in B and meets all requirements of C of this section, in accordance with 45 CFR 171.204.

B. *Conditions.*

1. *Uncontrollable events.* CCHIE cannot fulfill the request for access, exchange, or use of EHI due to natural or human-made disasters, 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.
2. *Segmentation.* CCHIE cannot fulfill the request for access, exchange or use of EHI because CCHIE cannot unambiguously segment the requested EHI from the EHI that:
 - i. Cannot be made available due to an individual's preference or because the EHI cannot be made available by law; or
 - ii. May be withheld in accordance with 45 CFR 171.201 (*Preventing Harm Exception*).
3. Infeasible under the circumstances.
 - i. CCHIE demonstrates, prior to responding to the request pursuant to paragraph C of this section, through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of the following factors that led to its determination that complying with the request would be infeasible under the circumstances:

(1) The type of EHI and the purposes for which it may be needed;

- (2) The cost to CCHIE of complying with the request in the manner requested;
- (3) The financial and technical resources available to CCHIE;
- (4) Whether CCHIE's practice is non-discriminatory and CCHIE 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 CCHIE owns or has control over a predominant technology, platform, health information exchange, or health information network through which EHI is accessed or exchanged; and
- (6) Why CCHIE was unable to provide access, exchange, or use of EHI consistent with the exception in 45 CFR 171.301.

ii. In determining whether the circumstances were infeasible under paragraph B3(i), it shall not be considered whether the manner requested would have:

- (1) Facilitated competition with CCHIE.
- (2) Prevented CCHIE from charging a fee or resulted in a reduced fee.

C. *Responding to requests.* If CCHIE does not fulfill a request for access, exchange, or use of EHI for any of the reasons provided in B of this section, CCHIE must within 10 business days of receipt of the request, provide to the requester in writing the reason(s) why the request is infeasible.

X. HEALTH IT PERFORMANCE EXCEPTION

A. In accordance with 45 CFR 171.205, CCHIE's practice that is implemented to maintain or improve health IT performance and that is likely to interfere with the access, exchange, or use of EHI will not be considered information blocking when the practice meets a condition in paragraph B, C, D, or E of this section, as applicable to the particular practice and the reason for its implementation.

B. *Maintenance and improvements to health IT.* When CCHIE implements a practice that makes health IT under CCHIE's control temporarily unavailable, or temporarily degrades the performance of health IT, in order to perform maintenance or improvements to the health IT, CCHIE'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;
2. Implemented in a consistent and non-discriminatory manner; and

3. If the unavailability or degradation is initiated by a health IT developer of certified health IT, health information exchange, or health information network:
 - i. *Planned*. Consistent with existing service level agreements between the individual or entity to whom the health IT developer of certified health IT, health information exchange, or health information network supplied the health IT; or
 - ii. *Unplanned*. 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, health information exchange, or health information network supplied the health IT.

C. *Assured level of performance*. CCHIE may take action against a third-party application that is negatively impacting the health IT's performance, provided that the practice is:

1. For a period no longer than necessary to resolve any negative impacts;
2. Implemented in a consistent and non-discriminatory manner; and
3. Consistent with existing service level agreements, where applicable.

D. *Practices that prevent harm*. If the unavailability of health IT for maintenance or improvements is initiated by CCHIE in response to a risk of harm to a patient or another person, CCHIE does not need to satisfy the requirements of this section, but CCHIE and its Participants must comply with all requirements of 45 CFR 171.201 at all relevant times to qualify for an exception.

E. *Security-related practices*. If the unavailability of health IT for maintenance or improvements is initiated by CCHIE in response to a security risk to EHI, CCHIE does not need to meet the requirements of this exception but must comply with all requirements of 45 CFR 171.203 at all relevant times to qualify for an exception.

XI. CONTENT AND MANNER EXCEPTION

A. CCHIE's practice of limiting the content of its response to or the manner in which it fulfils a request to access, exchange, or use EHI will not be considered information blocking when the practice meets all of the following conditions, in accordance with 45 CFR 171.301.

B. *Content condition – electronic health information*. CCHIE must respond to a request to access, exchange, or use EHI with –

1. *USCDI*. For the period before October 6, 2022, at a minimum, the EHI identified by the data elements represented in the USCDI standard adopted in 45 CFR 171.213.
2. *All electronic health information*. On and after October 6, 2022, electronic health information as defined in 45 CFR 171.102.

C. *Manner condition* –

1. *Manner requested*.
 - i. CCHIE must fulfil a request described in paragraph B of this section in any manner requested, unless CCHIE is technically unable to fulfill the request or cannot reach agreeable terms with the requester to fulfill the request.
 - ii. If CCHIE fulfills a request described in paragraph B of this section in any manner requested:
 - (1) Any fees charged by CCHIE in relation to fulfilling the request are not required to satisfy the exception in 45 CFR 171.302 (Fees Exception); and
 - (2) Any license of interoperability elements granted by CCHIE in relation to fulfilling the request is not required to satisfy the exception in 45 CFR 171.303 (License Exception).
2. *Alternative manner*. If CCHIE does not fulfill a request described in paragraph B of this section in any manner requested because it is technically unable to fulfill the request or cannot reach agreeable terms with the requester to fulfill the request, CCHIE must fulfill the request in an alternative manner as follows:
 - i. CCHIE must fulfill the request without unnecessary delay in the following order of priority, starting with paragraph C(2)(i)(1) of this section and only proceeding to the next consecutive paragraph if CCHIE is technically unable to fulfill the request in the manner identified in a paragraph:
 - (1) Using technology certified to standard(s) adopted in 45 CFR part 170 that is specified by the requester.
 - (2) Using content and transport standards specified by the requester and published by:
 - a. The Federal Government; or
 - b. A standards developing organization accredited by the American National Standards Institute.

- (3) Using an alternative machine-readable format, including a means to interpret the EHI, agreed upon with the requester.
- ii. Any fees charged by CCHIE in relation to fulfilling the request are required to satisfy the Fees Exception in 45 CFR 171.302.
- iii. Any license of interoperability elements granted by CCHIE in relation to fulfilling the request is required to satisfy the License Exception in 45 CFR 171.303.

XII. FEES EXCEPTION

- A. CCHIE's practice of charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI will not be considered information blocking when, in accordance with 45 CFR 171.302, the practice meets the conditions in paragraph B of this section, does not include any of the excluded fees in paragraph C of this section, and as applicable, meets the conditions in paragraph D of this section.
- B. Basis for the fees condition.
 1. The fees that CCHIE charges must be -
 - i. Based upon objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests;
 - ii. Reasonably related to CCHIE'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;
 - 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.
 2. The fees CCHIE charges must not be based on –
 - i. Whether the requester or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with CCHIE;
 - ii. Sales, profits, revenue, or other value that the requester or other persons derive or may derive from the access, exchange, or use of the EHI;

- iii. Costs CCHIE incurred due to the health IT being designed or implemented in a non-standard way, unless the requester agreed to the fee associated with the non-standard access, exchange, or use of EHI;
 - iv. Costs associated with intangible assets other than the actual development or acquisition of 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 organization charged a royalty for that intellectual property pursuant to 45 CFR 171.303 (Licensing Exception) and that royalty included the development costs for the creation of the intellectual property.
- C. *Excluded fees condition.* This exception does not apply to –
- 1. A fee prohibited by 45 CFR 164.524(c)(4);
 - 2. A fee based on any part on the electronic access of an individual’s EHI by the individual, their person 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 45 CFR 170.315(b)(10) 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.
- D. *Compliance with the Conditions of Certification condition.* Notwithstanding any other provision of this exception, if CCHIE is a health IT developer subject to the Conditions of Certification in 45 CFR 170.315(a)(4), 45 CFR 170.404, or both, CCHIE must comply with all requirements of such conditions for all practices and at all relevant times.
- E. *Definition of Electronic access.* The following definition applies to this section:

Electronic access – means an internet-based method that makes EHI available at the time the EHI is requested and where no manual effort is required to fulfill the request.

XIII. LICENSING EXCEPTION

- A. CCHIE’s practice to license interoperability elements for EHI to be accessed, exchanged, or used will not be considered information blocking when the practice meets all the following conditions in compliance with 45 CFR 171.303.

- B. *Negotiating a license conditions.* Upon receiving a request to license an interoperability element for the access, exchange, or use of EHI, CCHIE must –
1. Begin license negotiations with the requester within 10 business days from receipt of the request; and
 2. Negotiate a license with the requester, subject to the licensing conditions in paragraph C of this section, within 30 business days from receipt of the request.
- C. *Licensing conditions.* The license provided for the interoperability element(s) needed to access, exchange, or use EHI must meet the following conditions:
1. *Scope of rights.* The license must provide all rights necessary to:
 - i. Enable the access, exchange, or use of EHI; and
 - ii. Achieve the intended access, exchange, or use of EHI via interoperability element(s).
 2. *Reasonable royalty.* If CCHIE charges a royalty for the use of the interoperability elements described in paragraph B of this section, the royalty must be reasonable and comply with the following requirements:
 - i. The royalty must be non-discriminatory, consistent with paragraph C(3) of this section.
 - ii. The royalty must be solely based upon the independent value of CCHIE's technology to the licensee's products, not on any strategic value stemming from CCHIE's control over essential means of accessing, exchanging, or using EHI.
 - iii. If CCHIE has licensed the interoperability element through a standards developing organization in accordance with such organization's policies regarding the licensing of standards-essential technologies on terms consistent with those in this exception, CCHIE may charge a royalty that is consistent with such policies.
 - iv. CCHIE may not charge a royalty for intellectual property if CCHIE recovered any development costs pursuant to 45 CFR 171.302 (Fees Exception) that led to the creation of the intellectual property.
 3. *Non-discriminatory terms.* The terms (including royalty terms) on which CCHIE licenses and otherwise provides the interoperability elements must be non-discriminatory and comply with the following requirements:
 - i. The terms must be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons and requests.

- ii. The terms must not be based in any part on:
 - (1) Whether the requester or other person is a competitor, potential competitor, or will be using EHI obtained via interoperability elements in a way that facilitates competition with CCHIE; or
 - (2) The revenue or other value the requester may derive from access, exchange, or use of EHI obtained via the interoperability elements.
4. *Collateral terms.* CCHIE must not require the licensee or its agents or contractors to do, or to agree to do, any of the following:
 - i. Not compete with CCHIE in any product, service, or market.
 - ii. Deal exclusively with CCHIE in any product, service, or market.
 - iii. Obtain additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability elements.
 - iv. License, grant, assign, or transfer to CCHIE any intellectual property of the licensee.
 - v. Pay a fee of any kind whatsoever, except as described in paragraph C(2) of this section, unless the practice meets the requirements of the exception in 45 CFR 171.302 (Fees Exception).
5. *Non-disclosure agreement.* CCHIE may require a reasonable non-disclosure agreement that is no broader than necessary to prevent unauthorized disclosure of CCHIE trade secrets, provided:
 - i. The agreement states with particularity all information CCHIE claims as trade secrets; and
 - ii. Such information meets the definition of a trade secret under applicable law.
- D. *Additional conditions relating to the provision of interoperability elements.* CCHIE must not engage in any practice that has any of the following purposes or effects:
 1. Impeding the efficient use of the interoperability elements to access, exchange, or use EHI for any permissible purpose.
 2. Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand.
 3. Degrading the performance or interoperability of the licensee's products or services, unless necessary to improve CCHIE's technology and after affording

the licensee a reasonable opportunity to update its technology to maintain interoperability.

XIV. INFORMATION BLOCKING REPORTING & AUDITING

- A. CCHIE employees must immediately report any information blocking activities to the CCHIE Compliance Team and ensure they are logged.
- B. The CCHIE Compliance Team will review and assess all new information blocking activities and verify if an exception under 45 CFR Part 171 applies.
- C. CCHIE must regularly audit and assess all information blocking activities to ensure that EHI is blocked no longer than necessary or determine when an exception no longer applies.

XV. ANNUAL TRAINING

- A. All CCHIE employees shall complete or attend an annual information blocking training on this policy and all relevant processes and procedures.
- B. All annual information blocking training shall be documented.

XVI. SANCTIONS

- A. CCHIE employees' failure to abide by this policy may result in disciplinary action up to termination of employment.

XVII. Revision History

DATE	AUTHOR	COMMENTS
2/24/2021	Keith Dukes	Drafted Policy
3/18/2021	Keith Dukes	Updated Draft
3/25/2021	Keith Dukes	Applied Final Revisions and Included Annual Training