



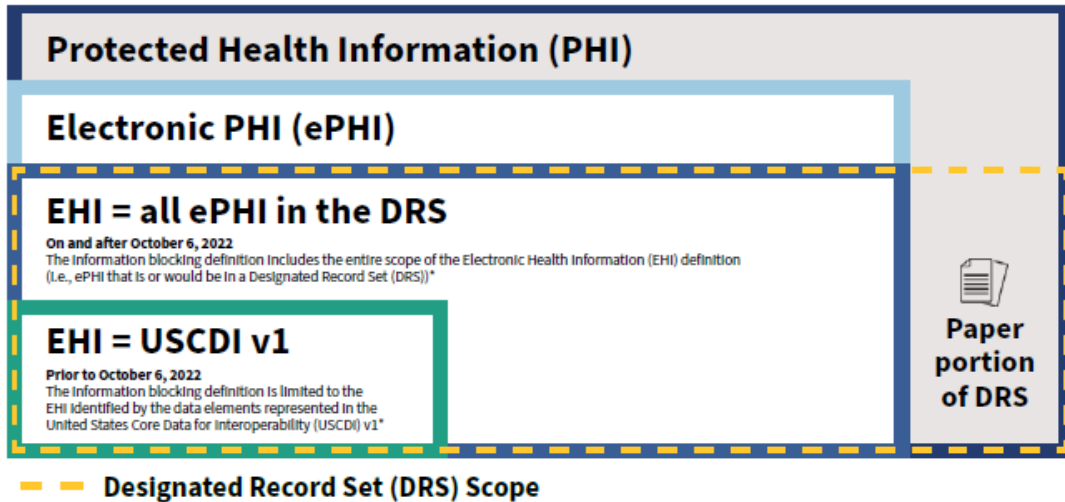
Frequently Asked Questions: Information Blocking^{1*}

Updated September 2022

Background: The Office of the National Coordinator for Health Information Technology (ONC) published the 21st Century Cures Act regulation, which aims to put patients in charge of their health records. Patients will ultimately have access, through the smartphone application of their choice, to their medical records, costs and outcomes of care, and comparative data with other providers.

Initially, the electronic health information (EHI) definition was limited to specific data elements such as demographics, clinical notes, and labs. Effective October 6, 2022, the EHI definition expands to the Designated Record Set (DRS). In addition to defining EHI, the regulation prohibits providers, health information technology (IT) developers, and Health Information Networks (HINs)/Health Information Exchanges (HIEs) from engaging in “information blocking.” Information blocking means a practice that is likely to interfere with, prevent or materially discourage access, exchange, or use of EHI, except as required by law or covered by an exception.

This infographic from ONC shows the relationship between the EHI definition expansion and other relevant healthcare terminology:



¹ *Defined in ONC 21st Century Cures Act

1. What is information blocking?

Information blocking is the practice of interfering with access, exchange or use of electronic health information (EHI) by a health IT developer or certified health IT, HIN, HIE or health care provider – also referred to as actors.

2. Are there exceptions to information blocking?

Yes. ONC has defined practices that are deemed reasonable and necessary and will not be considered information blocking. These exceptions are listed later in this document.

3. How do I know which actor type I qualify for?

Trinity Health qualifies as a Health Care Provider. The list below describes each type of actor:

- **Health Care Provider:** A hospital, skilled nursing facility, home health entity, long-term care facility, health care clinic, community mental health center, renal dialysis facility, blood center, ambulatory surgical center, federally qualified health center (FQHC), group practice, pharmacist, pharmacy, laboratory, physician, practitioner, rural health clinic, therapist, and any other category of health care facility, entity, practitioner or clinician determined appropriate by the Secretary of the Department of Health and Human Services (DHHS).
- **Health IT Developer:** An individual or entity that develops or offers health information technology and has health information technology under the ONC Health IT Certification Program.
- **Health Information Network (HIN) or Health Information Exchange (HIE):** 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 service for access, exchange or use of electronic health information:
 - Among two or more unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; **and**
 - That is for a treatment, payment or health care operation purpose.

4. What information is required to be shared electronically with patients through the patient portal? **NEW**

When this regulation took effect in 2021, the requirement was to share data elements listed in the [United States Core Data for Interoperability \(USCDIv1\)](#), which is a limited data set including demographic information, labs, provider clinical notes, medications, problems, procedures, and vitals. Effective October 6, 2022, the definition of EHI that must be shared expands to the

Designated Record Set (DRS). This includes medical records and billing records. There is limited information that will **not** be shared under the regulations, such as psychotherapy notes and information that is compiled in anticipation of civil or criminal action or proceeding.

5. What steps has Trinity Health taken to address information blocking?

Trinity Health has taken the following steps:

- Established a process for patients to request access to EHI via app of choice
- Implemented an Information Blocking Information Services Technology Operations Procedure
 - [Trinity Health Procedure](#)
- Attested annually (since 2018) to Promoting Interoperability Program Information Blocking questions
- Established a steering team and work group to evaluate current practices at Trinity Health.

6. What process does a patient follow to use a smart phone app?

If a patient has an active patient portal ID, they can download one of the apps listed on the hospital's external web site and set up the connection. If they would like to use an app that is not listed on the site, the user can request to do so through a form on the site. The forms are directed to the Digital Health team at System Office. That team facilitates data exchange with the app of choice developer and the EHR vendor. If a request cannot be fulfilled, the Digital Health team works with the ministry to respond to the requestor and provide the information through an alternate manner. It is important to note that not all EHR patient portals (and health apps) display all data elements required by the regulation.

7. Are we required to release/provide all the data included in the Designated Record Set immediately to patients and providers or only upon request? **UPDATED**

Information blocking is related to **requests** for information. Since our patients access their electronic health information through the patient portals, logging into the portal can be considered a patient request. Trinity Health has had delays in place with certain sensitive test results and documents/reports. After further review of ONC guidance, delays will be removed (where systems allow) to ensure compliance with the regulation. The only exception will be HIV test results, as some states in which Trinity Health operates require that counseling be offered at the time a positive HIV result is communicated. HIV

test results will continue to have a 7-day delay to meet these state requirements.

8. How long do we have to respond to requests for data? UPDATED

This regulation require that we respond in a timely manner without unnecessary delay, but they do not specify a length of time.

9. We are currently time delaying the release of certain categories of results to the patient portal. Are we still allowed to do so? UPDATED

Where our electronic health record (EHR) systems allow providers to block notes or results for specific reasons to protect privacy and prevent substantial harm, we have implemented that capability. Additionally (and where systems allow), we will implement a delay only when required by state law, such as with HIV results. Other delays will be removed to ensure compliance with the regulation. ONC guidance indicates that it would likely be considered an interference for purposes of information blocking if a health care provider delayed results to allow an ordering clinician to review the results or to personally inform the patient of the results before a patient can electronically access the results.

10. Should providers be allowed to set a result to a manual release at their discretion at the point of the order being placed? UPDATED

No, providers should not be allowed to set results/EHI for manual release. Manual releases would be considered the cause of unreasonable delays and not in compliance with information blocking regulation. There are certain circumstances that would support a delay, such as those required by law, but the delay should not be longer than necessary.

11. Should clinical notes be released to the portal upon signing? UPDATED

Yes. Clinical notes are required to be released. The System Office workgroup has reviewed current functionality for release of clinical notes. Trinity Health's interpretation of the regulation is that clinical notes should be available electronically to the patient portal in a timely manner.

12. Are there note types that should be limited or not shared? UPDATED

Effective April 2021, eight types of provider notes were required to be shared: consultation, discharge summary, History & Physical (H&P), imaging narrative, lab report narrative, pathology report narrative, procedure note and progress note. Effective October 6, 2022, all notes that are part of the Designated Record Set must be shared. This includes notes by all clinical

note writers including nurses, physical/occupational/speech therapists, case managers, dieticians, etc. There are limited notes that will be excluded from release, such as psychotherapy notes and notes compiled in anticipation of civil or criminal action or proceeding.

13. Does documentation of patient phone calls need to be shared?

If the telephone call is necessary to provide treatment (a scheduled call) or telephone call information is relied upon in providing care, then it is part of the information that must be shared per the regulation. Telemedicine calls are considered patient appointments, and that documentation is required to be shared. Telephone calls to physician offices that are informational and are not part of diagnosis/treatment are not required to be shared. Where our systems allow us to map to this level of specificity, we will do so in order to only share the required documents and not overload patient portals or provide unnecessary information to patients.

14. Should we allow clinical note writers to determine when not to share individual notes? UPDATED

The regulation has exceptions to information sharing when there is risk of physical harm or when the patient has requested that their information not be sent to the patient portal. The Epic system allows a note author to stop a note from being sent to the patient portal in very limited cases, including:

- Sharing the note will likely lead to the harm of the patient or another person
- The patient or proxy has requested the note does not appear in the patient portal
- The note contains information that would violate privacy rights of an individual other than the patient
- The note is part of a research record and not part of the Designated Record Set

15. Is there a specific workflow for when a patient requests that information not be shared to their portal? Is there a form required? UPDATED

No, there is no form to complete. If available, a clinical note writer can document a patient request for this by using one of the four options available when requesting information not be shared to the portal. The four options are: Sharing the note will likely lead to the harm of the patient or another person; The patient or proxy has requested that the note does not appear in the patient portal; The note contains information that would violate privacy rights of an individual other than the patient; The note is part of a research record and not part of the Designated Record Set.

16. Our nurses raised a concern regarding the nurse's name (first and last) being visible to the patient as additional data elements are released to

the portal. We currently just have first names on their badges and those most concerned were associated with Behavioral Health and ED. Do you know if and how the nurse's name will appear? **UPDATED**

First and last names of note authors are included on notes, and those documents will be sent to the patient portal, as required by the regulation. The documents are part of the DRS and are currently available to patients when record requests are made through the Health Information Management (HIM) department.

17. How should we handle historical notes (written prior to 10/6/2022)?

UPDATED

All notes that are EHI, including historical notes, are required to be released. EHI includes notes that are in the designated record set and that may be relied upon for treatment. More information is [available here](#).

If a patient requests information for a visit that occurred before the implementation date, we must provide this information. If a patient requests a push of the historical information and we are unable to do so due to capability of the EHR system, the patient should go through an HIM records request and receive the information in an alternate means.

18. How will minor access to information be addressed?

Currently minors can obtain copies of records of the medical care for which they are able to consent without notice or consent from parents/guardians. These records must be identified via a manual process and released via a records request that is fulfilled by the HIM department after filtering the record. Parents and guardians are not able to access these minors' records without consent from the minors.

It is not possible to filter the records via technology at this time to remove the records of care protected by the privacy rights of the minors. Therefore, to protect the privacy rights of minors parents and guardians are unable to access minors' records via mobile applications or patient portals in certain circumstances. For example, most of our portals do not allow access to records of minors aged 12 and older. These restrictions vary by vendor/EHR based on their ability to filter the appropriate information according to the HIPAA regulation on what parents and adolescents should have access to.

Information blocking exceptions include a Privacy Exception because federal and state laws protect the minor's record and technology inhibits the provider from separating the private part of the record (care that the minor has properly consented to receive). Access to minors' records for minors and

parents/guardians is provided in the form of filtered records, and the release process will continue to follow our current release process in HIM.

19. Who are the local contacts that the regional security officers (RSOs) can reach out to with questions?

Please contact your local [Promoting Interoperability \(PI\) lead](#) at your individual Health Ministry.

20. What needs to be done at the Health Ministries? **UPDATED**

More information will be forthcoming as we continue to identify any gaps. Please reach out to your local [Promoting Interoperability \(PI\) lead](#) at your individual Health Ministry for specific questions.

21. Do we need to update our Health Information Management (HIM) record release or release of information (ROI) procedures? **UPDATED**

Release of EHI is a separate process from the HIPAA patient right of access. The local record release and ROI procedure should align with the Trinity Health HIM procedures that ensure HIPAA compliance. Links to these can be found [here](#). Related procedures include the Health Record Definitions - Legal Health Record and Designated Record Set (RE.HIM.4) and Cost Fee Schedule for Patient Medical Record Copies (RE.HIM.8). As part of Trinity Health's response to this regulation, the work group reviewed all relevant Trinity Health policies and procedures.

22. What are the exceptions to information blocking?

Eight categories of reasonable and necessary activities have been identified as exceptions. Practices that meet the **conditions of an exception** will not be considered information blocking.

The eight exception categories are divided into two classes:

- Exceptions that involve not fulfilling requests to access, exchange or use EHI
 - **Preventing Harm Exception:** It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person.
 - Declining to share corrupt or erroneous data
 - Declining to share data arising from misidentifying a patient or mismatching a patient's EHI
 - Refraining from a disclosure that would endanger life or physical safety of a patient or another person

- Licensed provider who made determination must have done so in the context of a current or prior clinician-patient relationship with the patient.
- **Privacy Exception:** It will not be information blocking if an actor does not fulfill a request to access, exchange or use EHI in order to protect an individual's privacy.
 - Release relies on patient consent and consent is not adequate, the provider must use reasonable efforts to provide the individual with an adequate consent form and not improperly encourage or induce the individual to not provide the consent
 - Respecting an individual's request not to share information
 - Denial of an individual's request for EHI consistent with HIPAA's right of access provisions such as:
 - Psychotherapy notes
 - Information compiled in anticipation of or for use in civil, criminal or administrative proceedings
 - Information obtained by a provider in the course of research that includes treatment (subject to limitations)
 - Health IT developer not covered by HIPAA
 - Health IT developer who provides services directly to patients can refuse to disclose data based on their organizational privacy policies if those policies were disclosed in advance to the users of the vendor's products, those policies comply with the law, and are implemented in a consistent and nondiscriminatory manner.
- **Security Exception:** It will not be information blocking for an actor to interfere with the access, exchange or use of EHI in order to protect the security of EHI.
 - Must be directly related to safeguarding the confidentiality, integrity and availability of EHI
 - Be tailored to the security risk being assessed
 - Be implemented in a consistent and nondiscriminatory manner.
 - If an organizational security policy is implemented, the policy must:
 - Be in writing
 - Be directly responsive to the security risk identified
 - Be aligned with best-practice/consensus-based guidelines

- Provide other objective parameters and time frames for identifying, responding to, and addressing security incidents
 - A case-by-case determination must be made if no organization security policy is implemented
 - **Infeasibility Exception:** It will not be information blocking if an actor does not fulfill a request due to events beyond the provider's control.
 - Natural or man-made disaster, public health emergency, telecommunication or internet service disruption, etc.
 - The request is infeasible due to:
 - Type of EHI and purpose for which it is needed
 - Cost of complying
 - Financial and technical resources available
 - The provider must respond to the request in writing within 10 business days, why it was infeasible.
 - **Health IT Performance Exception:** It will not be information blocking for an actor to take reasonable and necessary measures to make health IT temporarily unavailable such as to perform maintenance or system upgrade activities.
 - Implemented for no longer than necessary
 - Compliant with service level agreements.
 - If unplanned, agreed to by the provider.
- Exceptions that involve procedures for fulfilling requests to access, exchange or use EHI
 - **Content and Manner Exception:** It will not be information blocking for an actor to limit the content of its response to a request to access, exchange or use EHI or the manner in which it fulfills a request to access, exchange or use EHI.
 - If a provider is technically unable to do so or cannot reach agreeable terms, the provider must fulfill the request in an alternative manner without unnecessary delay and within a specific order
 - If a provider fulfills a request in the **manner requested**, any fees charged do not need to satisfy the Fees Exception and any license does not need to satisfy the Licensing Exception.
 - If a provider fulfills a request in an **alternative manner**, any fees charged needs to satisfy the Fees Exception and any license needs to satisfy the Licensing Exception.

- **Fees Exception:** It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing exchanging or using EHI.
 - **Basis for Fees Condition:**
 - Must be based on objective and verifiable criteria
 - Reasonably related to the provider's cost of providing the EHI
 - Reasonably allocated among similarly situated persons
 - Based on cost otherwise not recovered for the same instance of service to a provider and third party
 - **Excluded Fee Condition:**
 - Fees prohibited by HIPAA
 - Fees based in any part on an individual's (or the individual's representative or designee) electronic access to the individual's EHI
 - Fees to perform an export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.
- **Licensing Exception:** It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged or used.
 - **Negotiation Conditions:**
 - Commence negotiations within 10 business days of request
 - Finalize negotiations within 30 business days of request
 - **Licensing Conditions:**
 - Provide all rights necessary to enable access, exchange or use of EHI and achieve the intended access, exchange or use.
 - Charge a royalty that is reasonable and based solely on the independent value of the actor's technology
 - Not charge a royalty if costs were already covered
 - **Nondiscriminatory Terms:**
 - License terms must be non-discriminatory based on objective and verifiable criteria uniformly applied for similarly situation persons, and not be based on whether the requestor is a competitor or what value the requestor may derive.
 - **Collateral Terms:**

- Do not include collateral terms such as terms prohibiting competition or requiring exclusivity. Reasonable non-disclosure agreements are permitted.
- **Not to Impede the Interoperability Elements**