

Information Blocking

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3 Categories of Actors

“Health Care Providers”

*“Health Information Networks” and
“Health Information Exchanges”*

“Health IT Developers of *Certified* Health IT”



Health Care Provider

Public Health Service Act (42 U.S.C. 300jj)

- **Hospitals**
- *Skilled Nursing Facilities*
- *Nursing Facilities*
- Home Health Entities
- Other Long Term Care Facilities
- Health Care Clinics
- Community Mental Health Centers
- Renal Dialysis Facilities
- Blood Centers
- Pharmacies
- Laboratories
- Ambulatory Surgical Centers
- *FQHCs*
- Rural health clinic
- Covered Entities under 42 U.S.C. 256b
- EMS Providers
- *Group Practices*
- Pharmacists
- Physicians
- Practitioners
- Therapists
- Providers operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- ***Any other category*** of health care facility, entity, practitioner, or clinician *determined appropriate by the HHS*



Health Information Networks and Health Information Exchanges

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

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

and

- For **treatment, payment, or health care operations**

Health IT Developer of Certified Health IT

An individual or entity

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

➤ That ***develops*** or ***offers*** health information technology

and

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



“Information Blocking”

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

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

(unless the practice is required by law or an exception applies)



“Info Blocking” May Include:

- ✘ Practices that **restrict** authorized access, exchange, or use under applicable state or federal law of such information **for Treatment** and **other Permitted Purposes** under such applicable law, including transitions between certified Health IT
- ✘ Implementing Health IT in **nonstandard ways** that are likely to substantially **increase the complexity or burden** of accessing, exchanging, or using EHI
- ✘ Implementing Health IT in ways that are likely to:
 - ✘ **Restrict** the access, exchange, or use of EHI with respect to **exporting** complete information sets or in transitioning between Health IT systems;
 - OR -
 - ✘ Lead to fraud, waste, or abuse, or **impede innovations** and **advancements** in health information access, exchange, and use, including care delivery enabled by Health IT.



Example #1

A health system implements locally-hosted EHR technology certified to proposed § 170.315(g)(10) (the health system acts as an API Data Provider as defined by § 170.102). As required by proposed §170.404(b)(2), the technology developer provides the health system with the **capability** to automatically publish its **production endpoints** (i.e., the internet servers that an app must “call” and interact with in order to request and exchange patient data). The health system chooses not to enable this capability, however, and **provides the production endpoint information only to apps it specifically approves**. This *prevents other applications*—and patients that use them— from accessing data that should be made readily accessible via standardized APIs.



Example #2

A hospital ***directs its EHR developer to configure*** its technology so that ***users cannot easily send*** electronic patient referrals and associated EHI to ***unaffiliated providers***, even when the user knows the Direct address and/or identity (i.e., National Provider Identifier) of the unaffiliated provider.



Example #3

Although an EHR developer's *patient portal* offers the capability for patients to directly *transmit or request for direct transmission of their EHI to a third party*, the developer's customers (e.g., health care providers) *choose not to enable this capability*.



Example #4

A health care provider has the capability to provide ***same-day access to EHI*** in a form and format requested by a patient or a patient's health care provider, but ***takes several days to respond.***



Final Rule clarifies “*to Interfere With*”

Actors **NOT** required to violate BAAs or SLA

- **BUT**, agreements *could constitute an interference* if used in a ***discriminatory manner*** to limit or prohibit the access, exchange, or use of EHI in manner that otherwise would be permitted by HIPAA.

Educating patients or plan members about the **privacy** and **security risks posed by the Apps** they choose to receive their EHI would **NOT** be considered an “interference with.”



EIGHT EXCEPTIONS

Subpart B: *Exceptions that Involve NOT Fulfilling requests:*

- 1. Preventing Harm**
- 2. Privacy**
- 3. Security**
- 4. Infeasibility**
- 5. Health IT Performance**

Subpart C: *Exceptions that Involve Procedures for Fulfilling request:*

- 6. Content & Matter**
- 7. Fees**
- 8. Licensing**

**“Preventing Harm”
Exception
§171.201**

Elements of the Exception

- a. Reasonable Belief
- b. Scope
- c. Type of **Risk**
- d. Type of **Harm**
- e. Patient's Right to a Review (*when applicable*)
- f. Implemented by Organizational Policy or Episodic Determination

Delaying Lab Results

“*[W]e are not persuaded that **routinely time-delaying** the availability of broad classes of EHI should be recognized as excepted from the information blocking definition under this exception . . .”*

➤ ***No evidence*** that ***routinely*** delaying EHI availability to patients in the interest of fostering clinician-patient relationships ***substantially reduces danger to life or physical safety of patients or other persons*** that would otherwise routinely arise from patients’ choosing to access the information as soon as it is finalized.

➤ **Unless applicable law prohibits** making particular information available to a patient electronically before it has been conveyed in another way, **deference should generally be afforded to *patients’ right to choose*** whether to access their data as soon as it is available or wait for the provider to contact them to discuss their results.

Top Take-Aways from Preamble

- Incomplete Data
- Segmentation of Data
- Data Quality Issues & Taking Data “Off Line”
 - Data Received from Third Parties
 - Mapping
 - Duty to Correct Data
 - Disclosures to Wrong Patient – Mismatched Data Issues
- No Extraneous Factors (i.e., *competition or animus*)

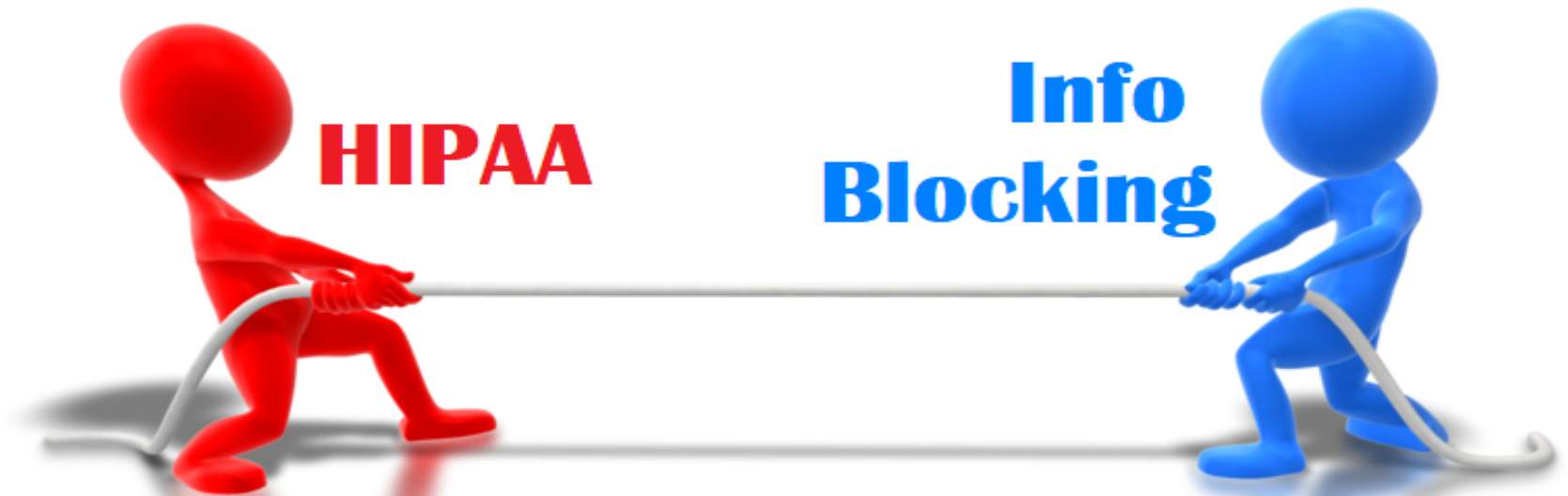
“Privacy” Exception

§171.202

Must Meet All Elements of at Least One Sub-exception

1. Precondition Not Satisfied
2. Health IT Developer of Certified Health IT Not Covered by HIPAA
3. Denial Of Individual Right Access Consistent with Privacy Rule 164.524(a)(1) & (2)
4. Respect Individual Request to Not Share Info

ONC Comment on Denial of Access



actor's denial of access to an individual consistent with the limited
condit The professional ls that are described in th "professional judgment by a
at 45 (judgement of (2), and (3) is reasonable licensed health care
circun "a licensed health re this resolves any pot or prior clinician-patient
betwe care professional an individual's right of relationship with the patient"
HIPAA Privacy Rule and the information blocking provision.

“Security” Exception

§ 171.203

Elements of the Exception

The practice **must** be:

- a) **Directly related to safeguarding** the confidentiality, integrity, and availability of EHI;
- b) **Tailored** to specific security risks; and
- c) Implemented in a **consistent** and ***non-discriminatory*** manner.

Condition

-EITHER-

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

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

-OR-



Condition (*con't*)

Implement the practice through an **Organizational Security Policy** (“OSP”) that:

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



**“Infeasibility”
Exception
§ 171.204**

“Infeasibility” Must Meet *at Least One* of the Following Conditions:

- ❑ ***Uncontrollable events***: Actor cannot fulfill the request for access, exchange, or use of EHI due to a natural or human-made 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.

-OR-

- ❑ ***Segmentation***: Actor cannot fulfill the request for access, exchange, or use of EHI because Actor cannot unambiguously segment the requested EHI that cannot be made available due to: (i) patient’s preference (refuses to sign consent), (ii) due to federal or state law preventing it, or (iii) falls within Preventing Harm Exception.

-OR-

- ❑ ***Infeasibility under the circumstances***: Actor demonstrates through contemporaneous written record or other documentation its consistent and non-discriminatory ***consideration of certain factors*** that led to its determination that complying with the request would be infeasible under the circumstances.



Documentation Requirement:

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



**“Health IT Performance”
Exception
§ 171.204**

Must Meet *at Least One* of the Following Conditions:

- a) Maintenance & Improvements
- b) Assured level of performance
- c) Practices that Prevent Harm
- d) Security-related Practices

**“Content & Manner”
Exception
§171.301**

Content

§171.301(a)

- Up until **May 2, 2022** – Actor must **only** respond to a request to access, exchange, or use EHI identified by the data elements represented in the **USCDI standard**
- **After** May 2, 2020, Actor **must** respond to a request to access, exchange, or use of **FULL EHI** (defined in §171.102)

USCDI v1 Summary of Data Classes and Data Elements



Allergies and Intolerances

Represents harmful or undesirable physiological response associated with exposure to a substance.

Substance (Drug Class)
Substance (Medication)
Reaction



Assessment and Plan of Treatment

Represents a health professional's conclusions and working assumptions that will guide treatment of the patient.

Assessment and Plan of Treatment



Care Team Member(s)

The specific person(s) who participate or are expected to participate in the care team.

Care Team Member(s)



Clinical Notes

Composed of both structured (i.e. obtained via pick-list and/or check the box) and unstructured (free text) data. A clinical note may include the history, Review of Systems (ROS), physical data, assessment, diagnosis, plan of care and evaluation of plan, patient teaching and other relevant data points.

Consultation Note
Discharge Summary Note
History & Physical
Imaging Narrative
Laboratory Report Narrative
Pathology Report Narrative
Procedure Note
Progress Note



Goals

An expressed desired health state to be achieved by a subject of care (or family/group) over a period of time or at a specific point of time

Patient's Goals



Health Concerns

Health related matter that is of interest, importance, or worry to someone who may be the patient, patient's family or patient's health care provider.

Health Concerns



Immunizations

Record of an administration of a vaccination or a record of a vaccination as reported by a patient, a clinician, or another party.

Immunizations



Laboratory

Tests
Values/Results



Medications

Medications



Patient Demographics

First Name
Last Name
Previous Name
Middle Name (including middle initial)
Suffix
Birth Sex
Date of Birth
Race
Ethnicity
Preferred Language
Current Address
Previous Address
Phone Number
Phone Number Type
Email Address



Problems

Information about a condition, diagnosis, or other event, situation, issue, or clinical concept that is documented.

Problems



Procedures

An activity that is performed with or on a patient as part of the provision of care.

Procedures



Provenance

The metadata, or extra information about data, that can help answer questions such as when and who created the data.

Author Time Stamp
Author Organization



Smoking Status

Classification of a patient's smoking behavior.

Smoking Status



Unique Device Identifier(s) for a Patient's Implantable Device(s)

A unique numeric or alphanumeric code that consists of a device identifier (DI) and a production identifier (PI).

Unique Device Identifier(s) for a patient's implantable device(s)



Vital Signs

Physiologic measurements of a patient that indicate the status of the body's life sustaining functions.

Diastolic blood pressure
Systolic blood pressure
Body height
Body weight
Heart Rate
Respiratory rate
Body temperature
Pulse oximetry
Inhaled oxygen concentration
BMI Percentile (2 - 20 years)
Weight-for-length Percentile (Birth - 36 Months)
Head Occipital-frontal Circumference (Birth - 36 Months)



Manner Condition

§171.301(b)(1)

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

(A) Any fees charged by Actor in relation to fulfilling the response are not required to satisfy the exception in § 171.302 (Fees Exception);

and

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

Alternative Manner

§171.301(b)(2)

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

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

- Any **license** of interoperability elements granted by Actor in relation to fulfilling the request is required to satisfy the exception in § 171.303 (Licensing Exception).



**“Fees”
Exception
§ 171.302**

Elements of the Exception

Fees a Actor charges **must** be —

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

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

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

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



Elements of the Exception

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

- (i) Whether the requestor or other person is a ***competitor, potential competitor***, or will be using the EHI in a way that ***facilitates competition*** with the Actor;
- (ii) ***Sales, profit, revenue, or other value*** that the requestor or other persons derive or may derive from the access, exchange, or use of the EHI;
- (iii) ***Costs*** the Actor incurred due to the health IT being designed or implemented in a ***non-standard way***, unless the requestor agreed to the fee associated with the non-standard design or implementation to access, exchange, or use the electronic health information;
- (iv) ***Costs*** associated with ***intangible assets*** other than the actual development or acquisition costs of such assets;
- (v) ***Opportunity costs*** unrelated to the access, exchange, or use of EHI; or
- (vi) Any costs that led to the creation of ***intellectual property***, if the Actor charged a royalty for that intellectual property pursuant to § 171.303 and that royalty included the development costs for the creation of the intellectual property.

Excluded Fees

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.

This exception does **not** apply to—

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

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

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

(4) A ***fee to export or convert data*** from an EHR technology that was not agreed to in writing at the time the technology was acquired.



**“Licensing”
Exception
§ 171.303**

Must Meet ALL of the Following Conditions:

- a) Negotiating a License Condition
- b) Licensing Conditions
- c) Conditions relating to Interoperability Elements

Negotiating a License

Actor must begin license negotiations with the requestor ***within 10 business days*** from receipt of the request and ***negotiate a license within 30 business days*** from receipt of the request.



Questions?



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