

Information Blocking Updates in the A.I. Era

Chad P. Brouillard, JD, MA
Partner



FOSTER & ELDRIDGE LLP

Release of Information

- Traditional “Medical Records” Department
- State Laws
- HIPAA Privacy Regulations
 - Use and Disclosures
- HIPAA Security Regulations
- HIPAA Updates
- Information Blocking Rules

Designated Record Set

([45 CFR 164.501](#))

- Medical records and billing records about individuals
- Enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan
- Other records that are used, in whole or in part, to make decisions about individuals

Towards Patient Centric ROI

- Open Notes Study
- Tension with HIPAA interpretation
- Information Blocking Rules

OpenNotes

Annals of Internal Medicine®

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LATEST ISSUES IN THE CLINIC JOURNAL CLUB MULTIMEDIA CME/MOC AUTHORS/SUBMIT

Original Research | October 2, 2012

Inviting Patients to Read Their Doctors' Notes: A Quasi-experimental Study and a Look Ahead

Tom Delbanco, MD*, Jan Walker, RN, MBA* ✉, Sigall K. Bell, MD, Jonathan D. Darer, MD, MPH, ... [See More +](#)

[Author, Article and Disclosure Information](#)

<https://doi.org/10.7326/0003-4819-157-7-201210020-00002>

OpenNotes

In 2010, the OpenNotes program began as a collaboration between Beth Israel Deaconess Medical Center in Boston, Geisinger Health System in Pennsylvania, and Harborview Medical Center in Seattle. With funding from the Robert Wood Johnson Foundation, they launched an exploratory study of 105 primary care doctors who invited 20,000 of their patients to read their notes via a secure online portal.

- Did not add to workload
- Increase in patient satisfaction
- Patients not confused about medical jargon
- Generally felt enhanced live visit

OpenNotes is NOT the Cures Act

- The study influenced law makers.
- However, Cures Act has its own rules.
- Open Notes articulates only one intent of rules.

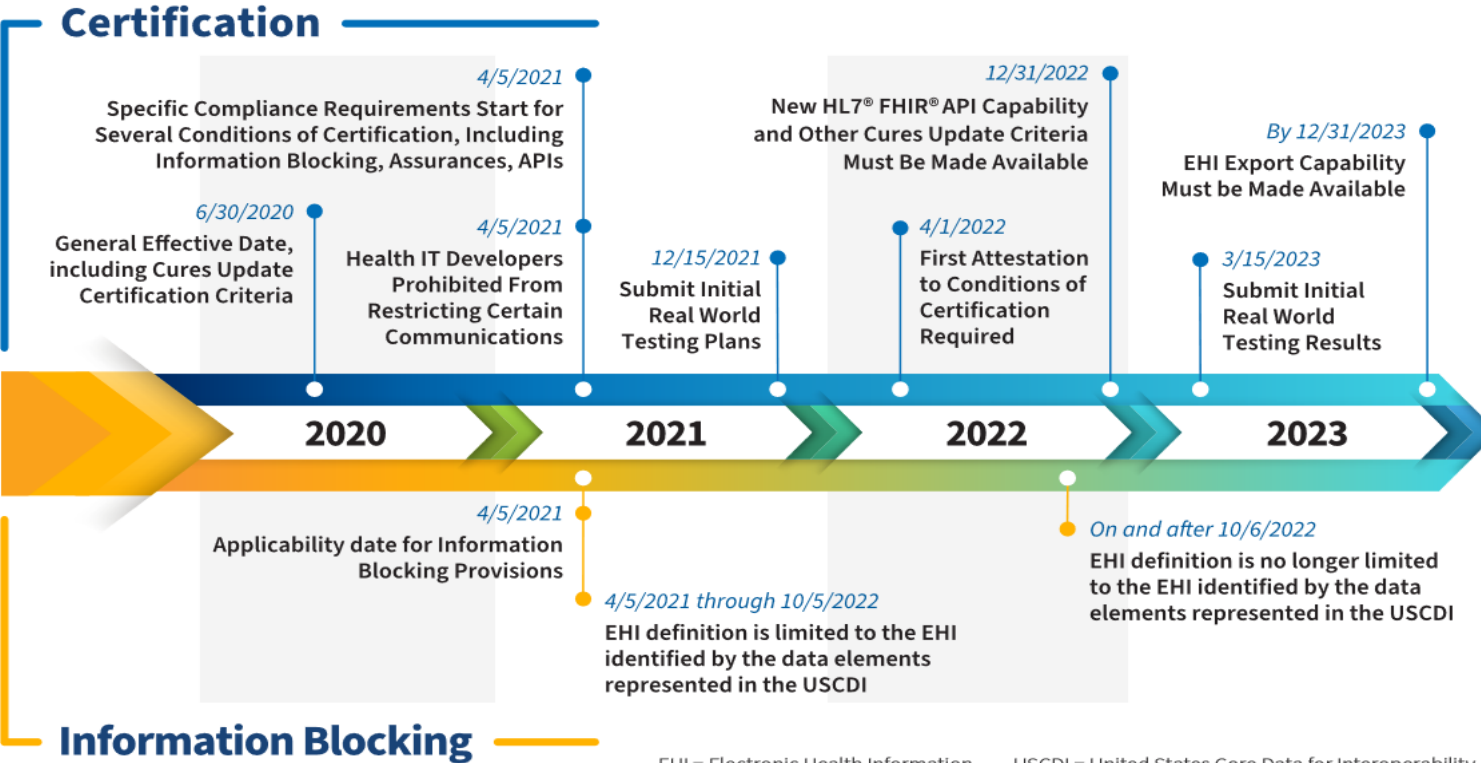
HIPAA- Timeline

- HIPAA (1996)
- Privacy Standards (1999)
- Security Rule (2005)
- HITECH ACT (2009)
- Omnibus Rule (2013)
- Final Rule Effective Date: September 23, 2013
- Right to Access Guidance (2016)
- Ciox Health, LLC v. Azar, No. 18-cv-0040 (D.D.C. January 23, 2020)
- 21st Century Cures Act (June 2020)
- 2023 Updates to both 21st Century Cures and HIPAA (Privacy Rules)

21st Century Cures Act (2020)

- Return to issue of patient access of electronic records
- Prohibition to Information Blocking
- Updates for HIT Certification Process (exporting, audit trails, etc.)
- Building architecture for access to third party apps
- EHI and USCDI

Information Blocking and the ONC Health IT Certification Program:
Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency Interim Final Rule



Bad Behavior

- Software Vendors for Year Blocking Export of Data
- Interoperability problem
- Some business value to keeping health data stuck in one product
- Overcharging patients for copying records
- Moving to a Patient Centric Information Model

Connecting the Dots: OpenNotes & Information Blocking

Under this new rule, certain elements of clinical notes must be shared by health systems by **April 5, 2021**, and the full electronic **Designated Record Set** by **October 6, 2022**.

As of today providers must be prepared to share full EHI and Designated Records set!

Breaking Down the Alphabet Soup

- PHI= Protected Health Information
- ePHI = Electronic Protected Health Information (45 CFR 160.103)
- DRS = Designated Record Set (45 CFR 164.501)
- EHI =electronic protected health information (ePHI) as defined in HIPAA, to the extent that ePHI would be included in a designated record set. (45 CFR 171.102)

Breaking Down the Alphabet Soup

Protected Health Information (PHI)

Electronic PHI (ePHI)

EHI = all ePHI in the DRS

On and after October 6, 2022

The information blocking definition includes the entire scope of the Electronic Health Information (EHI) definition (i.e., ePHI that is or would be in a Designated Record Set (DRS))*

EHI = USCDI v1

Prior to October 6, 2022

The information blocking definition is limited to the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI) v1*



**Paper
portion
of DRS**

— Designated Record Set (DRS) Scope

Breaking Down the Alphabet Soup

- EHI does not include:
- Psychotherapy notes (45 CFR 164.501)
- Information compiled in reasonable anticipation of litigation

United States Core Data for Interoperability (USCDI)

- Consultation notes
- Discharge summary notes
- History & physical
- Imaging narratives
- Laboratory report narratives
- Pathology report narratives
- Procedure notes
- Progress notes
- EXCEPTIONS: Psychotherapy, Litigation materials, Peer Review

What is a Progress Note?

A progress note “represents a patient’s interval status during a hospitalization, outpatient visit, treatment with a LTPAC provider, or other healthcare encounter.” (45 CFR 171)

- Can include any type of interval status information (MD, PT, RN, etc.)
- Progress notes just do not correspond to a “progress note” document template (C-CDA)

United States Core Data for Interoperability (USCDI) What About Unfinished Notes?

- Draft clinical notes and lab results may not be appropriate to exchange
- UNLESS they have been used in clinical decision making
- Because once they are used, they become part of the DRS

Information Blocking: Healthcare Actors

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinical pharmacy
- a laboratory
- renal dialysis facility
- blood center
- emergency medical services provider
- federally qualified health center
- group practice
- a pharmacist
- a physician (as defined 42 U.S.C 1395x(r))
- a practitioner (as described in 42 U.S.C 1395u(b)(18)(C))
- community mental health center (as defined in 42 U.S.C. 300x-2(b)(1))
- ambulatory surgical center described in 42 U.S.C. 1395l(i)
- a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]), tribal organization, or urban Indian organization (as defined in 25 U.S.C. 1603)
- a rural health clinic
- a covered entity under section 42 U.S.C 256b
- an ambulatory surgical center described in 42 U.S.C. 1395l(i)
- a therapist (as defined in 42 U.S.C. 1395w-4(k)(3)(B)(iii)), and
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

- 1 45 CFR §§ 171.101, 171.102. 2 45 CFR § 171.102; 42 U.S.C. § 300jj (3)

Information Blocking

Prohibits:

- 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 information technologies (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

Section 4004

Information Blocking – Practices

- Technological
- Operational
- Contractual

Information Blocking – Examples

Technological Blocking:

A mid-sized primary care office utilizes an electronic medical record which comes with the capability for a patient to access their records through a downloadable patient app for their smartphone or computer. The practice made a decision on implementation that they did not want to enable direct patient access as they were concerned it would generate too many questions and phone calls. As a result, they had the software company disable connectivity via the patient portal.

Information Blocking – Examples

Operational Blocking:

A mid-sized primary care office is in competition with a large primary care office group backed by a large hospital system. A patient decides to transfer care and authorizes all EHI to be sent to the competitor. The practice has a policy, however, that records will only be printed and sent directly to the patient. The practice has the capability to send this information to the new provider electronically.

Information Blocking – Examples

Operational Blocking 2:

A mid-sized primary care office collects many external reports on a patient from a regional medical center including discharge summaries, imaging reports, lab reports. This material is not generated by the practice, but kept electronically for better continuity of care. The patient authorizes release of all EHI in the system. The release of information manager does not include the external hospital records as the practice has a policy not to produce outside records that “we did not generate or are responsible for.”

Information Blocking – Examples

Operational Blocking 3:

A mid-sized primary care office has an EMR with enable patient portal. Due to concerns about constant patient access, patients are limited to accessing the patient portals for a 48-hour time period before access is disabled. The EMR supports constant access if enabled, which is the default.

Information Blocking – Examples

Contractual Blocking:


A mid-sized primary care office uses a cloud based electronic medical record. The cloud based EMR vendor entered a contract whereby patients have to pay \$100 directly in order to subscribe to annual access to their records. If a patient refuses to pay \$100, they do not have electronic access to their PHI.

Information Blocking:


What is it really about?

- Transparency -- Patient Access to EHI (Electronic Health Information)
- Interoperability – EHR Vendors cannot prevent export of EHI into another system
- Choice – Actors cannot prevent use of API (Application Programming Interface, which is a software intermediary that allows two applications to share information; i.e. Phone app and EHR)
- Continuity of Care – Replaces MU CCD standard, now USCDI
- Forcing information exchange – May share for treatment purposes now a MUST


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AccessOne

Information Blocking:

What is it really about?

- A framework for digital (A.I.) access to all patient records.
- FDA regulates devices, but not EHRs.
- ONC has no meaningful guidelines around A.I. as we/they don't understand it fully.



PREVENTING HARM



PRIVACY



SECURITY

EXCEPTIONS THAT INVOLVE
not fulfilling requests to access,
exchange, or use EHI



INFEASIBILITY



**HEALTH IT
PERFORMANCE**

9

**EXCEPTIONS TO THE
INFORMATION
BLOCKING
PROVISION**



LICENSING



FEES



CONTENT

EXCEPTIONS THAT INVOLVE
procedures for fulfilling requests
to access, exchange, or use EHI



TEFCA MANNER EXCEPTION

EXCEPTIONS THAT INVOLVE
practices related to actors'
participation in the Trusted Exchange
Framework and Common Agreement

Important Clarifications about Exceptions

- If an exception existed under HIPAA exists now
- State laws can apply
- No blanket exceptions, fact based. Need to document
- No requirement to buy a new product (feasibility)
- No requirement to use a patient portal if not part of your system
- No requirement to share info in an insecure way or in violation of patient privacy rules
- Creates tension between privacy and blocking rules

Information Blocking

How Does this Change ROI?



- Capability to Produce Data Electronically a Must. Even under Content and Manner Exception.
- The Goal is to have Machine Readable Data available
- PDF export may not be enough in some circumstances if not machine-readable format
- Fees Exception must align with HIPAA Privacy (45 CFR 164.524(c)(4) and not excluded by 45 CFR 171.302(b)
- Reasonableness Standard

What can contribute to Information Blocking

- Old systems
- Network Management Design (Not Standard)
- Contracting
- Charging Fees that Exceed Actual Cost to Produce
- Individual Actors

Rule examples:

A provider might impermissibly block information where it has capabilities to release information on the same day a request is made, but yet delays release of information for several days (for instance relying on Privacy Rule deadlines.)

A provider might impermissibly block information if it refuses to release information to an unaffiliated provider for treatment purposes without the individual's written consent.

Enforcement

- HHS Portal to send complaints about Information Blocking
- Knowledge and Intent to Block key in Rule.
- The HHS Office of the Inspector General (OIG) has both investigatory and enforcement authority over information blocking and may issue civil money penalties (\$1,000,000 per incident) for information blocking conducted by certified health IT developers and HIN/HIEs.

Updates on Enforcement

- Enforcement of the information blocking penalties began on September 1, 2023.
- OIG will not impose a penalty on information blocking conduct occurring before September 1, 2023.
- Who does enforcement apply to:
 - [health IT developers of certified health IT](#),
 - [entities offering certified health IT](#),
 - [health information exchanges](#), and
 - [health information networks](#).
- Providers/entities not included in this rule but....

Updates on Enforcement

- Enforcement of the information blocking penalties for healthcare providers began on July 31, 2024.
- Wall of Shame
- Pull “Meaningful Use” status for hospitals, MIPS eligible clinicians, effects CMS reimbursement.
- Prevent providers from being added to ACOs or Shared Savings Programs.
- Allows CMS to consider mitigating factors...

Updates on Enforcement

- Mitigating factors:
- The nature of the health care provider's information blocking,
- The health care provider's diligence in identifying and correcting the problem,
- The time since the information blocking occurred,
- Whether the provider was previously subject to a disincentive in another program
- Other factors

Updates on Enforcement

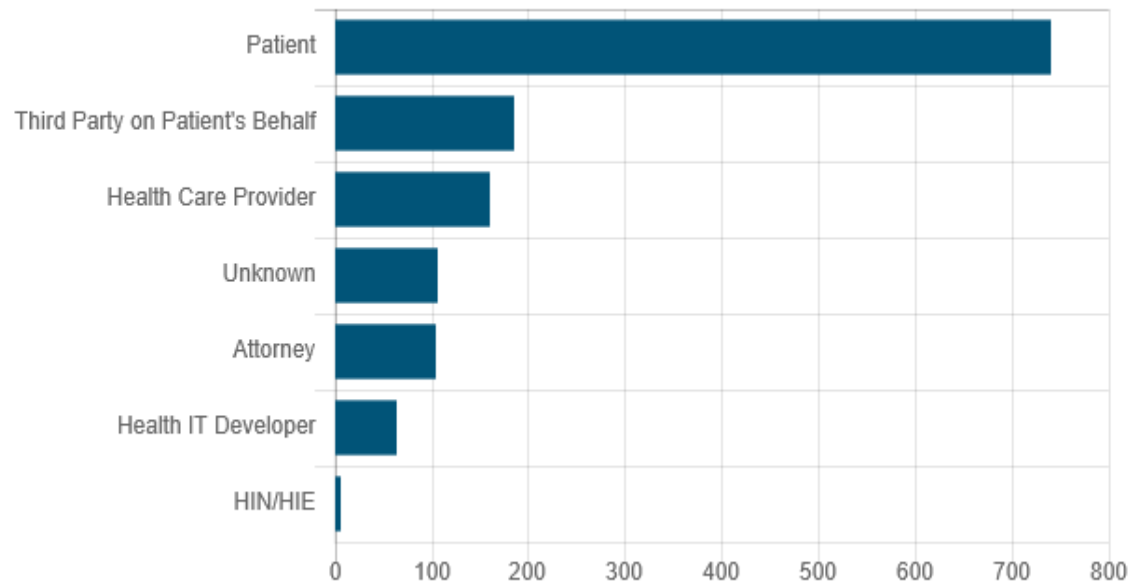
Enforcement Priorities

- Resulted in Patient Harm
- Caused Financial Loss
- Impact on Care
- Duration of Conduct
- Intent

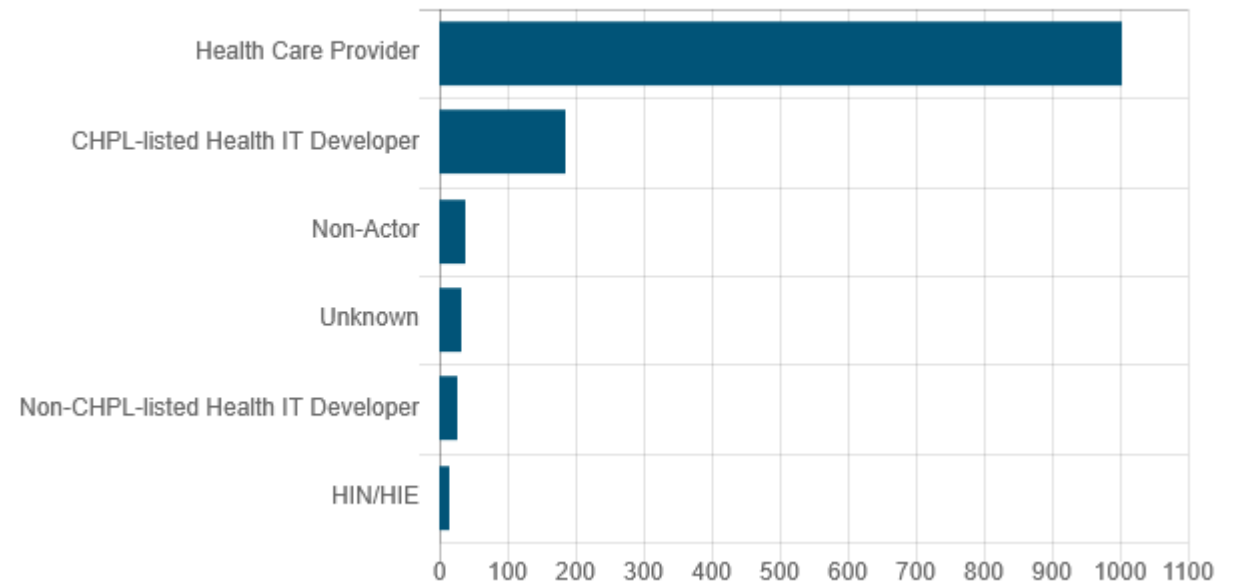
Updates on Enforcement

- 1,241 claims as of May 2025.

Claims Counts by Types of Claimant



Claims Counts by Potential Actor



Information Blocking

- Applies to all health care “actors”
- Mostly targeting HIT Vendors
- Can impact health care institutions and practices

BUT WHAT ARE THE UNINTENDED CONSEQUENCES???

Guidance on Exceptions

- Preventing Harm includes Harm to Others
- HIPAA Exceptions still operant
- No blanket exceptions
- Fact-based determination
- Documentation

Guidance on Exceptions

Reasonable Harm

- The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm;
- The actor's practice must be no broader than necessary;
- The actor's practice must satisfy at least one condition from each of the following categories: type of risk, type of harm, and implementation basis; and
- The practice must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm

Access, exchange, or use of patient's EHI	EHI for which access, exchange, or use is affected by the interfering practice is	Applicable type of harm ¹
Patient exercising own right of access	Patient's EHI	Danger to life or physical safety of the patient or another person
	Patient's EHI that references another person	Substantial harm ³ to such other person
Patient's personal representative as defined in HIPAA Privacy Rule (45 CFR 164.502) exercising right of access to patient's EHI (for example, parent of a minor child) ²	Patient's EHI	Substantial harm ³ to the patient or to another person
	Patient's EHI that references another person	Substantial harm ³ to such other person

Guidance on Exceptions

Reasonable Harm

- Emotional harm?
- Desire to keep patient confidentiality in general not enough.
- Multiuser access vs. proxy access
- Minors?

Minors

- Confidentiality of adolescent health information protected by state and federal laws.
- Screening & treatment of STI (all states)
- Substance Abuse and mental health (some states)
- Emancipated minors decide about all health care (some states)
- Joint custody complications.

2023 Updates to HIPAA Privacy RHI



- RHI -- Reproductive Health Information. Establishes a shield.
- Scenario where RH treatment: is provided outside of the state where an investigation or proceeding is authorized and where such healthcare is lawfully provided
- RHI is protected, required or authorized by federal law, regardless of the state in which such healthcare is provided, or
- RH treatment is provided in the state in which the investigation or proceeding is authorized and that is permitted by the law of that state.

2023 Updates on Exceptions



- an actor does not disclose an individual's EHI based on the individual's request that the actor's EHI not be disclosed (FAQ47.1.2023APR)
- an actor does not fulfill a request to access, exchange or use EHI in order to comply with federal privacy laws that require certain conditions to have been met prior to disclosure (FAQ48.1.2023APR)
- an actor, such as a healthcare provider, that operates in more than one state implements practices to uniformly follow the state law that is the most privacy protective across all the other states in which the actor operates (FAQ49.1.2023APR)

Guidance on Exceptions

Privacy

- No authorization or other necessary precondition for release;
- HIT Developer not covered by HIPAA;
- Psychotherapy notes, legal, inmates, research in progress, reveal source of confidential information.
- Patient request not to share.
- Cannot improperly induce a patient to request to block.

Guidance on Exceptions

Security

- Must be directly related to maintaining security and applied globally.

Guidance on Exceptions

Infeasibility

- Disaster, war, terrorism, etc.
- Inability to segment; (i.e. embedded psychotherapy notes)
- Third party seeking access to modify
- Catch all: the actor demonstrates through a 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.

Guidance on Exceptions

Manner

- Unable to fulfill a request in manner request.
- May need to provide alternate manner.
- Alternate manner subject to fees and licensing exception.

Guidance on Exceptions

Fees

- Must be reasonable based on objective and verifiable criteria, and actor's cost of providing access.
- Applied globally (no higher rates for attorneys and competitors.)
- Not be specifically excluded in other laws.

Guidance on Exceptions

Licensing

- If you have developed your own HIT IP, you must negotiate terms of a license to access this proprietary information starting within 10 days, concluding no later than 30 days.

Guidance on Exceptions

TEFCA (Trusted Exchange Framework and Common Agreement)

- Actors and requestors that are both part of TEFCA not considered blockers.

Best Practices



- Consider your new real time audience.
- Reasonableness.
- Policies may be key in showing non-discriminatory use of an exception.
- Contemporaneous documentation of factors when an exception is invoked.
- Providing individualized determination of applicability of exception on request.
- Read your vendor contracts, BAAs on terms that may contribute to blocking.

Best Practices



DON'T FORGET YOUR FRONT LINE STAFF

- Policies only stand up if they are taught and uniformly applied.
- It is your front line staff who often are the first dealing with patient EHI request.
- Educate early and often and establish a process to bump EHI access questions to the next level of review.

References

- Open Notes -- <https://www.opennotes.org/>
- HHS Information Blocking Overview--
<https://www.healthit.gov/topic/information-blocking>
- The 21st Century Cures Act & Adolescent Confidentiality NASPAG/SAHM Statement
- The Cures Act: What Nursing Professionals Need to Know – National Alliance of Wound Care and Ostomy
- American Medical Association Resources
- <https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf>
- <https://www.ama-assn.org/system/files/2020-11/info-blocking-compliance.pdf>
- <https://www.ama-assn.org/system/files/2020-10/onc-final-rule-ama-summary.pdf>

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- For more information and resources, please feel free to follow me on:
- LinkedIn: www.linkedin.com/in/chadbrouillard



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