

Are You Information Blocking? Understanding Compliance in the New Era

Montana Primary Care Association

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MPCA

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A practice that, *except as required by law or covered by an exception set forth in the Information Blocking Rule*, is likely to interfere with access, exchange, or use of EHI and

- (1) if conducted by a developer of certified health IT or HIE/HIN, such developer or HIE/HIN *knows, or should know*, that such practice is likely to interfere with access, exchange, or use of EHI; or
- (2) If conducted by a health care provider, such provider knows that such practice is *unreasonable and is likely* to interfere with access, exchange, or use of EHI.



Unreasonable Practices



Delays in Patient Information & Care



Incompatible Technology & Data



Price Gauging



Ensure patients always have access to and control of their own health information and that care teams have the benefit of this information to guide their decisions



Implement seamless, more efficient interoperability to streamline data sharing between providers and within health IT companies



Promote sharing within HIPAA and privacy laws to support the privacy of health data

Term	Definition
Actor	A health care provider, health IT developer of certified health IT, health information network or health information exchange
Access	The ability to make electronic health information (EHI) available for use or exchange
Disincentive	Means a condition specified in § 171.1001 (a) that is imposed by an appropriate agency on a health care provider that OIG determines has committed information blocking for the purpose of deterring information blocking practices
EHI*	The electronic protected health information (ePHI) in a designated record set (as defined in the Health Insurance Portability and Accountability Act (HIPAA) regulations) regardless of whether the records are used or maintained by or for a covered entity
Exchange	Means the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks
Use	Ability for EHI to be understood and acted upon once accessed or exchanged. “Acted upon” includes the ability to read and write and is also bidirectional

If the information

1

Is individually identifiable health information, that is:

Maintained in electronic media

or

Transmitted by electronic media

and

2

Would be included in one of the following groups of records:

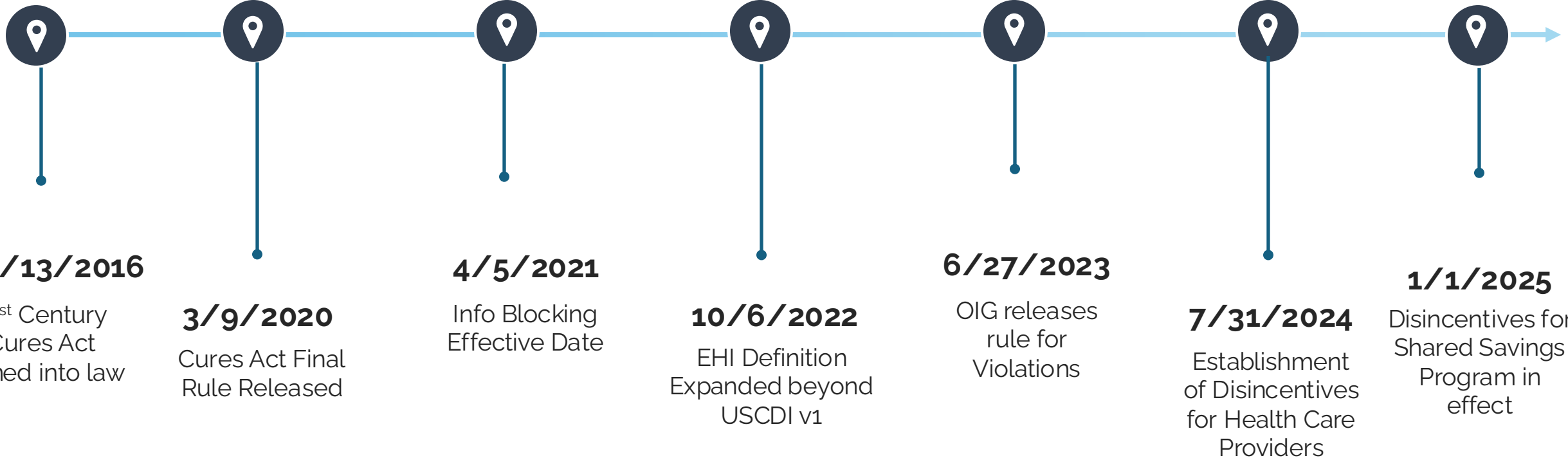
- medical records and billing records of a provider about individuals;
- enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan;
- records used in whole or in part, to make decisions about individuals

and

3

Is not excluded from the EHI definition (see exclusions listed below)

Then it is EHI



For a practice to be considered Info Blocking, it needs to meet ALL elements of Info Blocking:

- Not required by law
- Not covered by Exception
- Likely to “**interfere with**” access, exchange, or use of ePHI
- Undertaken by an actor
- Requisite Knowledge of actor
 - In other words, the actor knows it is unreasonable

Clinicians may be implicated the Info Blocking rule **if they knowingly** take actions that interfere with exchange, access, and use of EHI, even if no harm materializes

- Policies that restrict access to patient lab results for a certain amount of time would “likely” interfere with the access, use, or exchange of EHI could be considered info blocking
- Policies that require staff to obtain a patient’s written consent before sharing any EHI with unaffiliated providers for treatment purposes
- Practice disables the use of an EHR capability that would enable staff to share EHI with users at other systems
- A clinician has the capability to provide same-day EHI access in a format requested by an unaffiliated provider—or by their patient—but takes several days to respond

- An important tool for providers to use in defense of Info Blocking Claims
- Need to consider documentation
- Failing to meet the conditions of an exception does not automatically mean a practice is info blocking



9 EXCEPTIONS TO THE INFORMATION BLOCKING PROVISION

- PREVENTING HARM**
- PRIVACY**
- SECURITY**
- EXCEPTIONS THAT INVOLVE** not fulfilling requests to access, exchange, or use EHI
- INFEASIBILITY**
- HEALTH IT PERFORMANCE**
- 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



Preventing Harm

- Reasonable belief that would reduce risk harm to patient
- Practice is no broader than necessary
- Based on organizational policy and consistently applied
- Must satisfy at least one condition: type of risk, type of harm, and implementation basis
- Must satisfy patient's request to review
- Examples:
 - *Not sharing erroneous data*
 - *Not sharing data resulting from a mismatch of data or records*
 - *Refraining from disclosure that may endanger a patient or another person*



Privacy Exception

- Action aligns with state or federal privacy laws
- Four sub-exceptions
 - Preconditions (e.g. consent to share)
 - Certified health IT developer not covered by HIPAA (e.g. app)
 - Denial aligns with HIPAA Privacy Rule for “unreviewable grounds”
 - Individual preference not to share



Security Exception

- Directly related to safeguarding the confidentiality, integrity, and availability of EHI
- Tailored to the specific security risk being addressed
- Implemented in a consistent and non-discriminatory manner and align with organizational policy
- The practice is necessary to mitigate the security risk to EHI and there are no reasonable alternatives



Infeasibility Exception

- Legitimate practice challenges (e.g. technical capabilities, legal rights, or means)
- Meet one of the two conditions:
 - Uncontrollable Event
 - Segmentation
 - Third-Party seeking modification
 - Infeasible Under the Circumstance
- You may need to implement workarounds – such as printing and redacting
- Must provide written response to requestor within 10 business days as to why request is infeasible



Health IT Performance Exception

- Planned and Unplanned Downtime
 - Measures to improve overall performance
- Performance impact due to third-party applications
- Must be consistent with SLAs and contractual agreements



Content and Manner Exception

- Scope of request
- Content Condition
 - An Actor may respond to a request to access, exchange, or use EHI by providing the data elements in the USCDI for 24 months following the final rule's publication date
- Manner Condition
 - Must respond in the manner requested unless technically unable to respond or agreeable license terms cannot be reached, in which case it must respond in an alternative manner
- This is an important exception for physicians who are limited by their EHR vendor's ability to access, use, or exchange patient information



Fees Exception

- “Reasonable profit” based on objective and verifiable criteria
- Basic Fees vs. Excluded Fees
- Leverage Health IT that complies with the Conditions of Certification condition”
- More likely applicable to EHR vendors



Licensing Exception

- 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
- Reasonable royalties and terms
- Meant to balance legitimate interest in protecting its intellectual property and earning a return on the investment



TEFCA Manner Exception

- Actor and Requestor both part of TEFCA
- Request can be supported via TEFCA for both Actor and Requestor
- Request not made via API standards
 - Allows an actor to fulfill a request in an alternative manner if they are unable to fulfill the request in the requested manner or cannot reach agreeable terms with the requestor

Prior to July 31, 2024

- Financial penalties of up to \$1 million per violation for a subset of actors, including health information technology (IT) developers of certified health IT or other entities offering certified health IT, health information exchanges, and health information networks
- Publication on the ONC Public Site

As of July 31, 2024

- **Healthcare Provider Disincentives**
- Financial penalties of up to \$1 million per violation for a subset of actors, including health information technology (IT) developers of certified health IT or other entities offering certified health IT, health information exchanges, and health information networks
- Publication on the ONC Public Site

21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (the “Final Rule”)

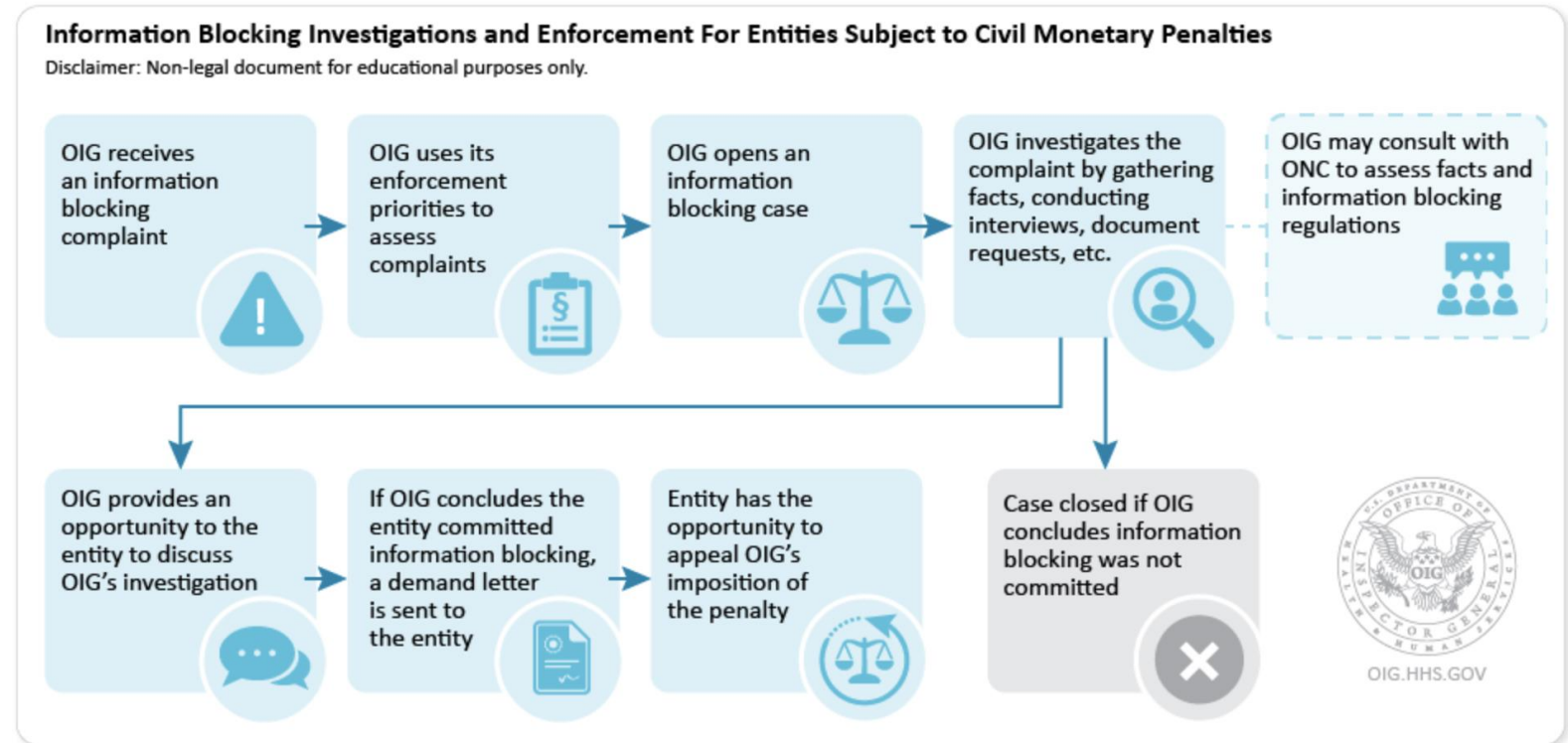
- Establishes disincentives for health care providers that commit information blocking as determined through an investigation by OIG
- Describes the process by which OIG investigates a claim of information blocking by a health care provider, determines the health care provider has committed information blocking, and refers that health care provider to an appropriate agency to be subject to disincentives.
- Establishes sharing of information with the public about actors (including health care providers, health IT developers of certified health IT, and health information exchanges and health information networks) that commit information blocking

Program	Potential Disincentive
Medicare Promoting Interoperability Program	<ul style="list-style-type: none"> • Not be a meaningful electronic health record (EHR) user in an applicable EHR reporting period • EH - reduction of three quarters of the annual market basket update • CAH - payment will be reduced to 100 percent of reasonable costs instead of 101 percent • If not already a Meaningful User, financial disincentive does not apply but would be posted by name
Quality Payment Program	<ul style="list-style-type: none"> • MIPS eligible clinician who commits information blocking will not be a meaningful user in a performance period and will therefore receive a zero score in the Promoting Interoperability performance category of MIPS (~ a quarter of the score) <ul style="list-style-type: none"> • Category is up to 75 points for 2024, so clinician would get a zero • So best case scenario, clinician would receive a neutral payment Medicare Part B • MIPS eligible clinician participating in group reporting is found to have committed information blocking, only the individual will be subject to a disincentive <ul style="list-style-type: none"> • Recommend that group not include individual in submission and individual separately submit data
Medicare Shared Savings Program	<ul style="list-style-type: none"> • Accountable Care Organization (ACO), ACO participant, or ACO provider or supplier may be deemed ineligible to participate in the program for a period of at least one year <ul style="list-style-type: none"> • This would result in these health care providers potentially not receiving revenue that they might otherwise have earned if they had participated in the Shared Savings Program • Removed from an ACO or prevented from joining an ACO • Prevent the ACO's participation in the Shared Savings Program

- Providers could be subject to multiple disincentives if applicable to the provider – but agencies will exercise “discretion”
- OIG investigations are not retroactive, and will apply for actions taken 30 days post effective date (7/31/24)

Investigation Priorities

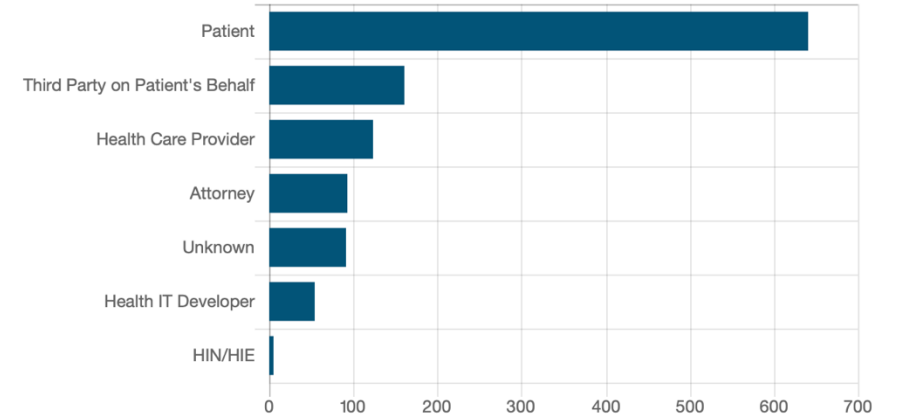
- resulted in, is causing, or had the potential to cause patient harm;
- significantly impacted a provider's ability to care for patients;
- was of long duration;
- caused financial loss to Federal health care programs, or other government or private entities; or
- was performed with actual knowledge



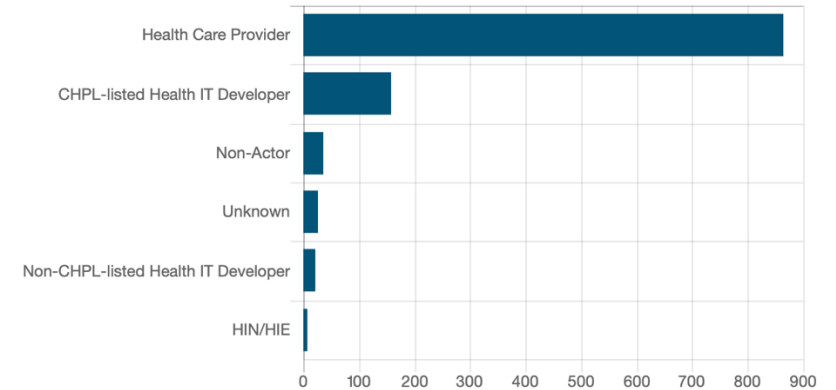
Information on submissions received through the Report Information Blocking Portal²

Total number of information blocking portal submissions received	1,134
Total number of possible claims of information blocking	1,059
Total number of submissions received that did not appear to be claims of potential information blocking ³	75

Claims Counts by Types of Claimant



Claims Counts by Potential Actor



- **Review existing compliance program**
 - Align with state law
 - Clearly define your DRS – not just the EHR
 - Define “reasonableness” standard, including workflows, and processes for handling cases
 - Develop written policies to address the information blocking exceptions, **including exceptions**
 - Lab results, redaction of data from notes
 - Ensure policies and procedures provide for consistent application of access requests
 - You have a clear and documented process for processing requests
 - Identify any policies or procedures that may result in unreasonably delay or prohibit data sharing or access
 - Conduct staff training on procedures
- **Understand vendor practices and limitations**
 - Review business associate agreements to ensure you will be able to comply and can't be used to limit disclosures

On the Radar

- Aligning 42 CFR Part 2 (Effective Date:4/16/24)
 - Allows single consent to share and CEs and Bas to redisclose data for TPO purposes
 - Permits disclosure of records without patient consent to public health authorities, provided that the records disclosed are de-identified according to the standards established in the HIPAA Privacy Rule
 - Segregating or segmenting Part 2 records is not required
- HIPAA Privacy - Patient Access Revisions (NPRM)
 - Allowing patients to inspect their PHI in person and take notes or photographs of their PHI.
 - Changing the maximum time to provide access to PHI from 30 days to 15 days.
 - Requests by individuals to transfer ePHI to a third party will be limited to the ePHI maintained in an EHR.
 - Individuals will be permitted to request their PHI be transferred to a personal health application
 - States when individuals should be provided with ePHI at no cost and require providers to post fee schedules on their websites for PHI access and disclosure

- CMS Interoperability and Patient Access Final Rule (CMS-9115-F)
 - Payer-focused
 - Support patient access through APIs
- HIPAA Privacy Rule Final Rule to Support Reproductive Health Care Privacy (Effective Date: 6/25/24)
 - Strengthens privacy protections by prohibiting the use or disclosure of protected health information (PHI) for either of the following activities:
 - To conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, where such health care is lawful under the circumstances in which it is provided.
 - The identification of any person for the purpose of conducting such investigation or imposing such liability
 - Requires an attestation

- American Medical Association. "What is Information Blocking?" <https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf>
- Assistant Secretary for Technology Policy. "[What Healthcare Providers Need to Know: Info Sharing.](#)" February 10, 2022.
- HHS. 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking." June 2024. <https://www.healthit.gov/sites/default/files/2024-06/Disincentives%20Final%20Rule%20Overview%20Fact%20Sheet.pdf>
- Office of the National Coordinator. "Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking." June 28, 2024. <https://www.youtube.com/watch?v=DaGjOIkQT1U>
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- Office of the National Coordinator. "Information Blocking Claims: By the Numbers." <https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>
- Office of the National Coordinator. "Information Blocking Exceptions." April 2024. https://www.healthit.gov/sites/default/files/2024-04/IB_Exceptions_Fact_Sheet_508_0.pdf
- Lewis, Jack. "Information Blocking and HIPAA's Right to Access: Compliance Burdens for Healthcare Providers." July 22, 2021. <https://www.jacksonlewis.com/insights/information-blocking-and-hipaas-right-access-compliance-burdens-healthcare-providers>