

CHIME and AHIMA: The Intersection of HIM and Info Blocking

March 23, 2021



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Agenda

1. Overview of Information Blocking Requirements
2. What's New Since Nov. 2
3. Recently Released FAQs from ONC
4. Burning Questions
5. Best Practices for the Intersection of HIM and CIOs
6. Questions and Answer

Information Blocking Overview



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The Birth of Information Blocking

- Signed into law in December of 2016, the 21st Century Cures Act contained multiple provisions impacting health IT.
- Of those provisions, one of them was for “Information Blocking” which encompasses a series of provisions aimed at providing patients with more access to and control of their health information.
- Two agencies contained within the U.S. Department of Health and Human Services (HHS) have taken on the primary responsibilities for developing the regulations and implementing enforcement actions:
 - Office of the National Coordinator for Health IT (ONC)
 - Centers for Medicare & Medicaid Services (CMS)

What is Information Blocking?

Information blocking is a practice that is:

- (1)** likely to interfere with the access, exchange, and use of electronic health information (EHI) [defined below] except as required by law or covered by an exception; and
- (2)** conducted by a health IT developer, health information network or health information exchange that knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI; or
- (3)** conducted by a health care provider that knows that such practice is unreasonable and likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.

Who is Subjected to Info. Blocking Restrictions?

Throughout the regulations, “**Actors**” are the ones detailed as being the subjects of information blocking requirements.

The **Actors** are defined as:

- Providers
- Payers
- Vendors
- Health Information Exchanges (HIEs)/Health Information Networks (HINs)

But Really, What Does it Mean?

- On April 5, 2021 you as an actor need to be able to respond to requests for information and fulfill those requests in a digital format containing a patient's information that aligns with the United States Core Dataset for Interoperability (USCDI) – the current electronic health information (EHI) requirements.
- Unless you can fulfill – ***and document*** – one of the eight exceptions:
 - Preventing Harm
 - Privacy
 - Infeasibility
 - Health IT Performance
 - Content and Manner
 - Fees
 - Licensing

... But.... What If I Don't Do That?

- It's unclear, but you should still comply ←
- As it stands today, there is no final rule for enforcement of information blocking for any actor and CMS has not outlined any penalties
- The HHS Office of the Inspector General (OIG) released a proposed rule in 2020, but it has not yet been finalized
- You could still be subject to penalties, as a result see **above!**



U.S. Department of Health and Human Services
Office of Inspector General



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Wait, What Does CMS Have to Do With This?

The OIG final rule states that any investigations that confirm the practice of information blocking by an actor would be referred to the **appropriate regulatory authority for disincentives.**

For provider actors, that means CMS would hold jurisdiction for implementing disincentives. CMS has not declared how exactly they would do that or what the penalties would look like.

CMS.gov

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Where Do These Requirements Reside in Health Data?

The data that is being transmitted to a patient when they make a request for their data is defined as electronic health information (EHI).

Currently, **until Oct. 6 2022**, EHI is defined as all the contents of the United States Core Dataset for Interoperability (USCDI) as defined by ONC.

After **Oct. 6, 2022**, EHI is defined as all electronic personal health information (ePHI) to the extent it is included in the designated record set (as defined by HIPAA).

When Can an Actor Utilize an Exception?

There are **eight exceptions** to the information blocking provisions available to actors. The exceptions must:

- Be reasonable and necessary
- Address a significant risk
- Adhere to strict conditions.

The eight available exceptions include:

- Preventing harm
- Privacy
- Security
- Infeasibility
- Health IT Performance
- Content and Manner
- Fees
- Licensing



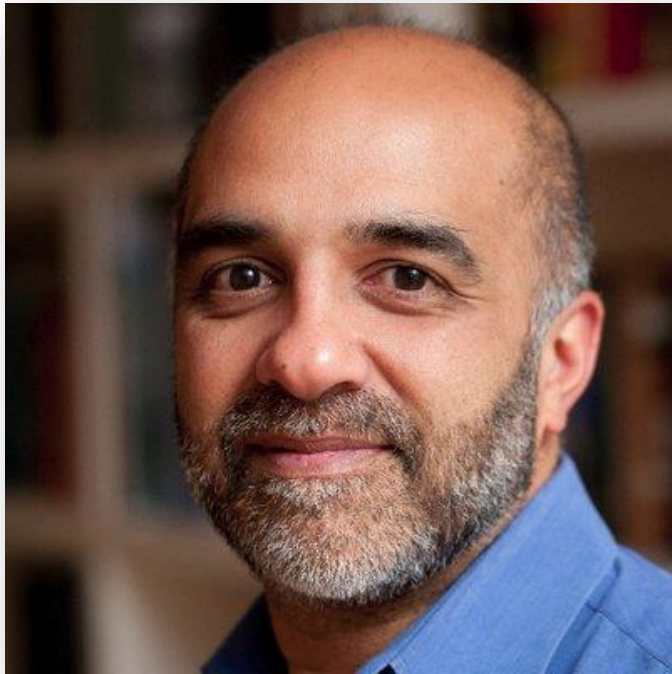
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What's New Since November



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Office of the National Coordinator for Health Information Technology New Leadership



Micki Tripathi, National Coordinator

Formerly:

- Arcadia Health

Former Board Member:

- HL7 FHIR
- CommonWell, and
- Sequoia Project

Centers for Medicare & Medicaid Services New Leadership (Pending)



Chiquita Brooks-LaSure, Nominated Administrator

Formerly:

- Manatt, Phelps & Phillips
- Breakaway Policy Strategies
- CMS – CCIIO
- Office of Health Report, HHS

April 5, 2021 Info Blocking Applicability Date

New Applicability and Compliance Dates/Timeframes & Corresponding Provisions		
April 5, 2021	December 31, 2022	One Calendar Year Extension
<ul style="list-style-type: none"> Information blocking provisions (45 CFR Part 171) Information Blocking CoC/MoC requirements (§ 170.401) Assurances CoC/MoC requirements (§ 170.402, except for § 170.402(b)(2) as it relates to § 170.315(b)(10)) API CoC/MoC requirement (§ 170.404(b)(4)) - compliance for current API criteria Communications CoC/MoC requirements (§ 170.403) (except for § 170.403(b)(1) – where we removed the notice requirement for 2020) 	<ul style="list-style-type: none"> 2015 Edition health IT certification criteria updates (except for § 170.315(b)(10) – EHI export, which is extended until December 31, 2023) New standardized API functionality (§ 170.315(g)(10)) 	<ul style="list-style-type: none"> Submission of initial attestations (§ 170.406) Submission of initial plans and results of real world testing (§ 170.405(b)(1) and (2))

What Does ONC Say About the Delay?

Who are the actors covered by information blocking?



Health Care Providers



Health Information Networks (HIN)/Health Information Exchanges (HIE)



Health IT Developer of Certified Health IT

Why does this interim final rule matter to you?



Applicability Date Extension

This interim final rule moves the applicability date from **November 2, 2020 to April 5, 2021**. This means that actors now will be subject to the information blocking provisions beginning on April 5, 2021.



Comments

The provisions in this rule, including the date extensions, are **effective immediately**. A 60-day comment period is available for stakeholders to respond to the interim final rule.



Investigations and Penalties/Disincentives

Actors that are subject to the information blocking regulations may be investigated by the HHS Office of Inspector General if they are the subject of a claim of information blocking.

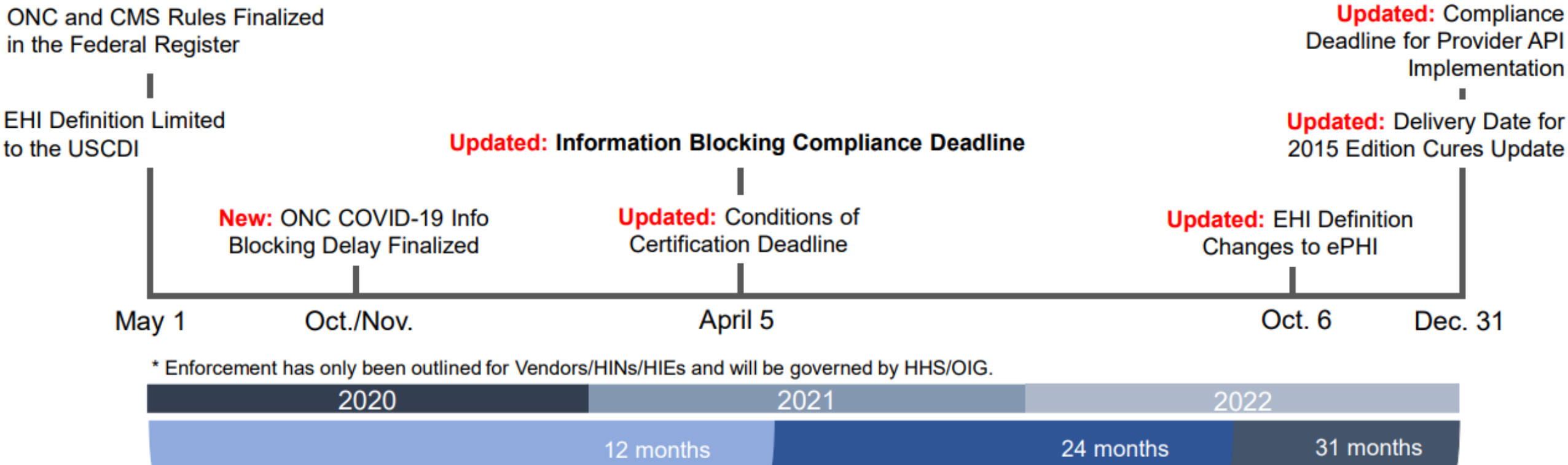
Further, actors found to have committed information blocking are subject to penalties:

- Health IT developers of certified health IT, health information networks, and health information exchanges → Civil monetary penalties (CMPs) up to \$1 million per violation
- Health care providers → Appropriate disincentives to be established by the Secretary

ONC Info Blocking Timeline As it Stands Today

10/29/20

Updated: Key ONC Interoperability and Information Blocking Timelines



Note: Provider compliance with ONC Information Blocking provisions is contingent on vendor readiness and additional CMS rulemaking outlining disincentive actions. The timeline for CMS information blocking disincentive enforcement is currently unknown.

New ONC FAQs



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Do the information blocking regulations require actors to have or use certified health IT, or upgrade the certified health IT they already have to fulfill a request to access, exchange or use EHI?

- **No.** The information blocking regulations **do not** require actors to have or use health IT certified under the ONC Health IT Certification Program. Actors subject to the information blocking regulations are not required to immediately upgrade their certified health IT (as of the applicability date (i.e., April 5, 2021)) if they also happen to participate in a separate regulatory program that requires the use of certified health IT, such as CMS' Promoting Interoperability Programs.

Are nursing, pharmacy or other professions' clinical notes included in the definition of EHI?

- **Yes.** EHI does not exclude notes or other clinical observations based on the type of specialty of the professional that offers them.
 - Keep in mind EHI's scope for purposes of information blocking is limited to USCDI until October 6, 2022. Until then, only the notes described in USCDI v1 will be required to be included in response to a request. However, none of the eight notes currently described in USCDI are limited to the type or specialty of the professional who authors them

Is non-final clinical information, such as draft clinical notes or incomplete test results that are pending confirmation, included in the definition of EHI for purposes of information blocking?

- **It depends.** Draft clinical notes and laboratory results pending confirmation are examples of data points that may not be appropriate to disclose or exchange until they are finalized. However, if such data are used to make health care decisions about an individual then that data would fall within the definition of “designated record set” and therefore within the definition of EHI.
 - Again, remember that EHI’s scope for purposes of information blocking is limited to USCDI until October 6, 2022. Therefore, during this period, interference with a request for legally permissible access, exchange, or use of non-final data points could implicate the information blocking regulations to the extent that the data are part of the definition of EHI and the data classes and elements are represented in USCDI.

Do the information blocking regulations require actors to proactively make EHI available through patient portal, APIs or other health information technology?

- **No.** There is no requirement to proactively make available any EHI to patients or others who have **not** requested the EHI.
 - However, a delay in the release or availability of EHI in response to a request of EHI may be an interference under information blocking regulations If the delay constitutes an interference under information blocking an actor's practice or actions **may** still satisfy the conditions of an exception under the information blocking regulations.

Are actors expected to release test results to patients through a patient portal or API as soon as the result are available to the ordering clinician?

- While actors are not required to proactively make EHI available, once a request to access, exchange or use EHI is made, actors must timely respond to the request. Delays or other unnecessary impediments could implicate the information blocking provisions.
 - In practice, this could mean a patient would be able to access EHI such as test results in parallel to the availability of the test results to the ordering clinician.

When state or federal law or regulation, such as the HIPAA Privacy Rule, requires EHI to be released by no later than a certain date after a request is made, is it safe to assume that any practices that result in the requested EHI's release within that other required timeframe will never be considered information blocking?

- **No.** The fact that an actor covered by the information blocking regulations meets its obligations under another law applicable to them will not automatically demonstrate that the actor's practice does not implicate the information blocking definition.
 - If an actor who could more promptly fulfill requests for legally permissible access, exchange, or use of EHI chooses instead to engage in a practice that delays fulfilling those requests, that practice could constitute an interference under information blocking, even if requests affected by the practice are fulfilled within a time period specified by a different applicable law.

On April 5, 2021, can prior agreements, arrangements, or contracts still in effect implicate the information blocking definition?

- **Yes.** On and after April 5, 2021, any actor's agreements, arrangements, or contracts are subject to and may implicate the information blocking regulations in 45 CFR part 171.

When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the information blocking regulation?

A determination as to whether a delay would be an interference that implicates the information blocking regulation would require a fact-based, case-by-case assessment of the circumstances. That assessment would also determine whether the interference is with the legally permissible access, exchange, or use of EHI; whether the actor engaged in the practice with the requisite intent; and whether the practice satisfied the conditions of an exception. Please see 45 CFR 171.103 regarding the elements of information blocking.

When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the information blocking regulation? (cont.)

Unlikely to be an Interference

- If the delay is necessary to enable the access, exchange, or use of EHI, it is unlikely to be considered an interference under the definition of information blocking (85 FR 25813).
- For example, if the release of EHI is delayed in order to ensure that the release complies with state law, it is unlikely to be considered an interference so long as the delay is no longer than necessary (see also 85 FR 25813). Longer delays might also be possible, and not be considered an interference if no longer than necessary, in scenarios where EHI must be manually retrieved and moved from one system to another system (see, for example, 85 FR 25866-25887 regarding the manual retrieval of EHI in response to a patient request for EHI).

When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the information blocking regulation? (cont.)

- **Likely** to be an Interference
 - It would likely be considered an interference for purposes of information blocking if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results (see also 85 FR 25842 specifying that such a practice does not qualify for the “Preventing Harm” Exception).
 - It also would likely be considered an interference:
 - Where a delay in providing access, exchange, or use occurs after a patient logs in to a patient portal to access EHI that a health care provider has (including, for example, lab results) and such EHI is not available—for any period of time—through the portal.
 - Where a delay occurs in providing a patient’s EHI via an API to an app that the patient has authorized to receive their EHI.

Burning Questions



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What is the best way to explain the ‘content and manner’ exception vs. ‘infeasibility’ exception?

- **Content and Manner:** Provides flexibility concerning the content (i.e.— scope of EHI) of an actor’s response to a request to access, exchange or use EHI and the manner in which an actor may fulfill the request
 - **Content:** USCDI until October 6, 2022. After October 6, 2022, ePHI to the extent it is included in the designated record set
 - **Manner:** Permits an actor to fulfill a request in an alternative manner when the actor is technically unable to fulfill the request in the manner requested *or* cannot reach agreeable terms with the requestor to fulfill the request.
- **Infeasibility:** Recognizes the practical challenges that may limit an actor’s ability to comply with requests for access, exchange, or use of EHI. One of three conditions must be met: (1) uncontrollable event, (2) segmentation, (3) infeasible under the circumstances

Are organizations required to provide notice to patients prior to blocking EHI from going to a portal (e.g. behavioral health note that a provider believes will cause harm) or only notify if the EHI is requested?

- Since actors are not required to proactively make EHI available, organizations are not required to provide notice to patients prior to information going into the portal.
- However, once the EHI is requested by the patient, the actor would be obligated to notify the patient of why the EHI has been blocked

This assumes this actor has met the conditions of the Preventing Harm Exception

Must you provide access to a requestor (e.g. health plan) in the manner they request even if the requested means is too resource intensive?

- Generally, yes
- Content and manner exception—
 - If an actor does not fulfill a request in any manner requested because it is technically unable to fulfill the request or cannot reach agreeable terms with the requestor, the actor must fulfill the request in an alternative manner to satisfy the exception. Any fees charge by the actor must also satisfy the Fees exception.
 - “technically unable:” actor cannot fulfill a request for EHI due to a technical limitation.
 - Standard would not be met if the actor is technically able to fulfill the request in the manner requested but chose not to due to cost or burden.

How do HIPAA and Information Blocking align, and where are they inconsistent or where is one more/less stringent than the other?

There are multiple places that HIPAA and the information blocking rule intersect, align and diverge.

- More anything it is important to remember if an actor who could fulfill a request chooses to delay in fulfillment of the request, then it constitutes information blocking. This is regardless of whether you are still within the HIPAA right of access timelines.

Areas of alignment:

- The harm requirements under the “type of harm” align with the HIPAA definitions, but remember it takes substantial harm to deny legal representation or parents access.

If a provider has an EHR with a CEHRT year of 2015 and does not have all of the USCDI data elements, is there an expectation that the patient will be notified of that? And when are they notified?

Information Blocking applies to those with or without certified health IT and the ability to export all EHI elements.

The content and manner exception allows the actor to engage in a “negotiation” with the requestor for the best way to fulfill the information request if they aren’t able to provide all the data in the requested format.

- The goal of the exception is for the actor to document a process of working with the requestor to fulfill the request by engaging in a process of working to identify a format and set of corresponding content that meets the requestors needs. This process may resemble a “if not this then, how about that” style of process. An example would be, if not through an API how about through an encrypted portal.

What do I need to consider with respect to my MPI/EMPI as I work to implement this rule?

- Take the time to evaluate your MPI integrity to determine whether you are confident in your policies, procedures, and technology.
- The integrity of the MPI/EMPI is critical to ensure that the right patient receives the access to their information. If the wrong patient information is released electronically this could be considered a breach and would negatively impact the organization and the patient.

Best Practices



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Best Practices

- Read the Rule
 - Determine whether your organization is an “actor”
 - Become familiar with Part 171 of the Cures Act Final Rule and related exceptions
- Establish a Governance Structure
 - Identify organizational stakeholders
 - Develop a multi-disciplinary compliance team
 - Conduct an assessment and/or risk analysis to determine readiness

Best Practices

- **Assess Systems for Compliance and Operational Efficiencies**
 - Assess patient identification and matching accuracy to ensure appropriate access to EHI
 - Conduct a system inventory to determine whether designated record sets are included
 - Define your designated record set if you have not done so already
 - Develop policies and procedures for unsigned or incomplete documents and lab/test results that require review before availability
- **Evaluate Compliance and System Infrastructure**
 - Review BAAs to determine any revisions necessary to contract, agreements, and licenses related to information blocking
 - Identify staff and processes for monitoring/auditing the organization's incoming and outgoing EHI requests
 - Review and revise consents and authorizations for compliance with information blocking and patient access

Best Practices

- Update Policies and Procedures
 - Assess and implement policies and procedures to ensure compliance and business actions related to information blocking
 - Develop an information blocking and patient access incident management policy and procedures that includes data collection, reporting and forms
 - Update and/or develop HR policies, procedures, documentation, and systems to provide for discipline for information blocking violations by workforce members
 - Develop education and training materials as well as competency tests on information blocking
 - Develops patient education plans regarding information blocking and the risks associated with using third-party applications

INFORMATION BLOCKING

RESOURCE CENTER

- InfoBlockingCenter.org is a new resource center partnership with provider focused organizations including CHIME and AHIMA
- Focused on educating provider focused organizations on how best to prepare for the April 5, 2021 information blocking applicability date



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InfoBlockingCenter.org Content

Content includes resources applicable to:

- Federal resources surrounding information blocking from ONC and CMS
- Information Blocking Actors
- Information Blocking and COVID-19
- Information Blocking and Mental Health/Substance Abuse
- Information Blocking Compliance
- Information Blocking Education
- Information Blocking Exceptions
- Information Blocking Overview
- Patient Resources



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Questions?

Reach out to us at advocacy@ahima.org and
policy@chimecentral.org



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