



Preparing for Cures Act Regulatory Compliance, Part 2

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Disclaimers

- This presentation is for informational purposes only
- It does NOT, and is not intended to, constitute legal advice
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This is intended to teach and provide you with the information to have an informed discussion regarding your organization's readiness to comply with the requirements of the information blocking provision and exceptions.

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Consult with your organization's attorney regarding the application of this information to your particular circumstances.

About the Empowering Patients Educational Series

- Designed to support CHCANYS members as they work toward compliance with information blocking regulations stemming from the 21st Century Cures Act
- November 2021-March 2022
- Includes:
 - **Webinar presentations** providing foundational knowledge for all member roles (provider, compliance, HIM)
 - **Ask the Experts** interactive Q&A sessions focusing on information needs of specific member roles
 - **Supporting resources** to help members operationalize the regulations within their organizations



Note that we've included a calendar slide at the end.
Will be providing the recording and slides after the presentation.

Agenda



Learning Objectives



Technical Readiness



Patient Engagement



Communication with External Stakeholders



Compliance Readiness Checklist



Q&A



Today's Learning Objectives

- Know what to ask your health IT vendors / service providers about your systems' technical capabilities, and required configuration for interoperability and to fulfill requests for EHI access, exchange, or use
- Know the actions your organization needs to take to engage its patients
- Determine key external stakeholders and communication needed
- Understand activities and owners for compliance readiness with the Cures Act Final using a self-assessment checklist



Also know what to ask your Health Information Network organization about the resources they have to help your organization comply with the information blocking requirements.

Technical Readiness

- Health IT System Capabilities and Configuration for Interoperability
 - EHR, PM, RCM, and other systems holding EHI and patient portal
 - Cures updates to 2015 Edition health IT?
 - Data segmentation
 - Publishing clinical notes to patient portal
 - Partitioned / restricted access to patient portal for adolescent accounts
 - Interoperability elements / electronic methods for sharing EHI, including patient and population health APIs for fulfilling EHI requests
 - Technical capabilities and process to fulfill EHI requests using an “alternative manner”
 - FHIR server, 3rd-party app registration, digital endpoints (i.e., FHIR URL, provider/FQHC Direct secure messaging address)
 - Vendor educational resources



In the previous webinar on internal compliance readiness, we discussed completing an inventory of the EHI in your designated record set and identifying which systems hold the data. This would include your front-office systems for registration, scheduling, and practice management; your clinical systems, including the EHR, and radiology, lab and pharmacy systems, if applicable; and your back-office systems for Health Information Management and Revenue Cycle Management. Completing that inventory and system mapping will inform you on who you need to consult with externally to discuss system capabilities and the optimal configuration for these systems and your patient portal. Understanding the capabilities and how your systems can and should be configured will enable you to fulfill requests for EHI electronically to the greatest extent possible. Ask your EHR vendor what their plan is for distinguishing between data elements included in the USCDI and other EHI included in the EHR for purposes of responding to requests for EHI. When consulting with your health IT vendor(s), you will want to cover the topics listed on this slide.

Are the Cures updates already applied to the version of the 2015 Edition of the EHR you are using? If not, ask the vendor when they will be available and when your system will be upgraded. If your IT department hosts and operates the systems, you will need to plan and schedule the upgrade and may need the assistance of your vendor. If you require vendor resources that could affect your schedule, depending on their availability.

Does the technology support data segmentation and to what extent, especially with regards to pushing data to or segmenting data on the patient portal? If the technology does not provide the capability to electronically segment the data when required, then the Preventing Harm, Privacy, or Infeasibility exceptions may come into play when fulfilling EHI requests.

What capability does the patient portal have for partitioning or restricting access for adolescent accounts? If this capability is not available, then the Privacy exception may come into play when fulfilling EHI requests from parents or guardians of adolescents and the EHI they are authorized to access will have to be provided in another manner.

Your vendors should familiarize you with all the interoperability elements available in their systems including the APIs, how to properly configure them, and how to use them to electronically fulfill requests for EHI. They should also address fulfilling EHI requests using the alternative manners in the Content and Manner exception, if applicable to their technology.

Talk with your EHR vendor about the FHIR server and 3rd-party app registration. What will they provide and do for your organization? Will your IT department host the server and manage the registration process or will the vendor?

Your health center providers should register their digital endpoints in NPPES if this has not been done already. The CMS final interoperability and patient access rule required providers to register their digital contact information in NPPES and encourages registration of their digital endpoints. The following text is from the rule:

“We are finalizing our proposal to publicly report the names and NPIs of those providers who do not have digital contact information included in the National Plan and Provider Enumeration System (NPPES) system beginning in the second half of 2020 as proposed. Additionally, we will continue to ensure providers are aware of the benefits of including digital contact information in NPPES, and when and where their names and NPIs will be posted if they do not include this information. We do strongly encourage providers to include FHIR endpoint information in NPPES if and when they have the information, as well.”

Digital endpoints you can include in NPPES

(<https://nppes.cms.hhs.gov/webhelp/nppeshelp/HEALTH%20INFORMATION%20EXCHANGE.html>):

Direct Messaging Address

SOAP URL

CONNECT URL

FHIR URL

RESTful URL

Other URL

Finally, what educational resources does your vendor have that you can leverage?

Technical Readiness (continued)

- Connectivity to local, regional, and / or state health information exchanges (HIE) / health information networks (HIN) in New York
- Arrange consultation meetings with your health IT vendors and HIE / HIN organizations to discuss technical readiness, available resources, and any additional costs
 - Consider conducting these meetings with other health centers using the same systems and/or using or having access to the same HIE / HIN



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According to CHCANYS, all the Centers are connected to one of the qualified regional health information network entities in New York. You will want to understand how that connectivity works when it comes to fulfilling legally permissible requests for access, exchange, or use of EHI. Arrange a technical consultation meeting with your regional HIN representative and include your EHR vendor, if needed, to discuss your technical readiness to leverage the HIN services to fulfill EHI requests from patients and providers. Are you presently sending only a minimum set of data to the HIN? If so, what might you do to expand the data set you are sending to the HIN? If there are costs involved, does the health center's cost-based reimbursement cover these costs?

HIEs

athena Practice Solution (formerly Centricity) / athenaOne connectivity to CommonWell Health Alliance HIE? CommonWell members can connect to the Carequality Framework via CommonWell.

Six New York regional health information networks connected to SHIN-NY.

Referred to as "Qualified Entities" as they meet all the governance, policy and procedural requirements of NYeC and SHIN-NY.

1. Bronx RHIO
2. Healthe Connections
3. HEALTHeLINK
4. Healthix

5. Hixny
6. Rochester RHIO

Information on NYeC and SHIN-NY:

New York eHealth Collaborative (NYeC) governs and leads the Statewide Health Information Network for New York (SHIN-NY).

Review the Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State under 10 N.Y.C.R.R. § 300.3(b)(1), dated July 2021. This document provides Privacy and Security Guidance for Qualified Entities and their Participants provides information related to privacy and security for qualified entities participating in New York's Statewide Health Information Network, consistent with 10 N.Y.C.R.R. § 300.3(b)(1). This guidance ensures secure health information exchange through the Statewide Health Information Network for New York (SHIN-NY) that will improve health care delivery and health outcomes for all New Yorkers. The New York State Department of Health (NYSDOH), along with key stakeholders, participated in the development of this guidance, which is compliant with all applicable state and federal laws. A Qualified Health IT Entity (QE) means a not-for-profit entity that has been certified as a QE under 10 N.Y.C.R.R. Section 300.4 and has executed a contract to which it has agreed to be bound by SHIN-NY Policy Standards.

SHIN-NY is an opt-in network. It is footnoted in the policy document above that New York law currently requires patient consent for the disclosure of information by health care providers for non-emergency treatment purposes. For general medical information, this consent may be explicit or implicit, written or oral, depending on the circumstances. The disclosure of certain types of sensitive health information may require a specific written consent. Under federal law (HIPAA), if the consent is not a HIPAA-compliant authorization, disclosures for health care operations are limited to the minimum necessary information to accomplish the intended purpose of the disclosure. Also, disclosures of information to another Participant for health care operations of the Participant that receives the information are only permitted if each entity either has or had a relationship with the patient, and the information pertains to such relationship.

The SHIN-NY Privacy and Security policies require QE's to not disclose a patient's Protected Health Information via the SHIN-NY to a Participant unless the patient has provided an Affirmative Consent authorizing the Participant to Access or receive such Protected Health Information. There are some exceptions described in Section 1.2 of the document. An Affirmative Consent may be executed by an electronic signature as permitted by Section 1.9.5 of the policy document.

Technical Readiness (continued)

- Business Associate Agreements (BAAs) and Contracts
 - Health information access, exchange or use
 - Restrictions on communications by provider about the health IT / vendor
 - SLAs
 - Planned and unplanned downtime



In addition to meeting with your health IT vendor(s) to discuss technical readiness, cover any needed BAA and contract amendments as well with the vendor(s).

This would include any changes to language about access, exchange or use of health information that need to be made to comply with the ONC Cures Act rule.

Note the Cures Act requires as a Condition and Maintenance of Certification requirement under the ONC Certification Program that health IT developers do not prohibit or restrict communications about certain aspects of the performance of health IT and the developers' related business practices. The ONC finalized (in § 170.403(b)) provisions that permit developers to impose certain types of limited prohibitions and restrictions that strike a balance between the need to promote open communication about health IT, and related developer business practices, with the need to protect the legitimate business interests of health IT developers and others. The provisions identify certain narrowly defined types of communications, such as communications required by law, made to a government agency, or made to a defined category of safety organization, which will receive "unqualified protection" under our ONC's Program. Under this policy, developers are prohibited from imposing any prohibitions or restrictions on such protected communications in their contracts with health care providers. ONC did include provisions that allow health IT developers certified under the Program to place limitations on certain types of communications, including screenshots and video. Therefore, a health IT developer must not impose or enforce any contractual

requirements that contravene the requirements of this Condition of Certification around communications by a health care provider about the developer's health IT. If a health IT developer has contracts/agreements in existence that contravene the requirements of this Condition of Certification, the developer was required to notify all affected customers, other persons, or entities that they will not enforce the prohibition or restriction within the contract/agreement. Health IT developers were not required to amend their contracts/agreements to remove or make void such provisions within a specified time, only when existing contracts/agreements are next modified for other purposes or renewed/replaced.

If you do not presently have SLAs and planned and unplanned downtime procedures in place in your contracts with your health IT vendors and managed services providers, address this with them to ensure the contracts will enable you to meet the conditions of the the Health IT Performance exception when your systems are down for planned maintenance or upgrades, and any unplanned outages.

Patient Engagement

- Communicate changes to health information sharing practices
 - Notice of Privacy Practices
 - Patient portal access
 - Third-party consumer app access
- Create and distribute patient educational materials
 - Address how patients and their authorized caregivers / Personal Representatives can electronically request and receive their EHI
 - Specific requirements for patient education, engagement and access to Statewide Health Information Network – New York (SHIN-NY) data
 - What to consider when choosing a third-party consumer health app (i.e., privacy and security practices of app developer)
 - How will you disseminate patient education?



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As a result of completing your internal compliance readiness assessment and work effort to close gaps, you may have made changes related to your health information sharing practices. Communicate these changes to your patients, such as any changes to your Notice of Privacy Practices related to sharing their PHI. Also, communicate any changes to how they access the patient portal or what information will now be available to them via the patient portal. If you are now technically able to support 3rd-party consumer app access, inform patients this capability is available, either from you directly or through the qualified regional health information network entity.

Educational materials should address how patients and their authorized caregivers / Personal Representative can electronically request and receive their EHI, including via the:

- Patient portal, including proxy access provisions
- Secure messaging
- Secure and unsecure email
- 3rd-party consumer apps
- Or the qualified regional HIN entity--Section 5 of the SHIN-NY privacy and security policies addresses patient access to his/her data in the NY SHIN and what your health center, as a Participant in a NY regional HIN, may be required to do regarding patient education.

ONC encourages providers to provide educational information to their patients on

what to consider when choosing a 3rd-party consumer app and authorizing access to their health data when it comes to the privacy and security practices of the app developer. Possibly the Centers could collaborate on materials to provide to your Centers' patients. Also, check out the CARIN Alliance's resources. The CARIN Alliance's vision is to rapidly advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals. Specifically, they are promoting the ability for consumers and their authorized caregivers to gain digital access to their health information via open APIs. The Alliance developed a code of conduct for app developers to voluntarily sign and have their app listed on their "My Health Application" website. The Code of Conduct is a set of industry-leading best practices these application developers have voluntarily adopted to protect and secure your health information. Here are links to the CARIN Alliance and their My Health Application website:

<https://www.carinalliance.com/>

<https://myhealthapplication.com/>

Think about and discuss how you will disseminate your patient education and materials. In addition to distributing educational materials to patients during an office visit or posting them on your website or patient portal (if able to), consider holding patient-focused educational webinars and recording the webinars and making them available on your website.

Communication with External Stakeholders and HIEs /HINs

- Include external stakeholders in your communication plan
 - Referring and partner providers
 - Inform providers on how they can electronically request and receive a patient's EHI from your health center or send a patient's EHI to your health center
 - Hospitals
 - Receiving event notifications
 - Payers / Health Plans
- Communicate and meet with your regional HIN representative
 - Understand resources available to you from the HIN to comply with the information blocking regulation
 - Be familiar with the latest updates to the SHIN-NY privacy and security policies and procedures



There are several external stakeholder groups besides your patients with whom you will want to engage and communicate.

First, plan to communicate with the providers you typically refer your patients to for specialty care or other care. Let them know about your capabilities to electronically send and receive your patients' EHI.

It appears all the hospitals in the State of New York are connected to the SHIN-NY through one of the qualified regional HIN entities and are likely participating in event notification services for patient admission, discharge and transfer events to comply with the CMS Interoperability and Patient Access final rule. Communicate with your HIN entity or your local hospitals to ensure you are receiving these notifications if you are not already. There is other EHI that you will want to receive electronically from the hospitals, such as when one of your patients is discharged, so understand how that is or will be handled by the hospitals where your providers have admitting privileges.

For Payers and Health Plans you usually work with, please note the advice from the AMA when fulfilling payer or health plans requests for EHI access, exchange, or use, especially if they are requesting direct access to your EHR:

The AMA stated the following in one of its publications on complying with the information blocking requirements: "You can expect the information blocking regulation to be "weaponized" by those seeking data access. We expect entities

such as payers and health plans to leverage the info blocking rules to gain increased access to your EHR and patient records. While this may be communicated to you or your organization as a way to reduce administrative burden, (e.g., reduce the burden around prior authorizations), there is increasing concern that payers could threaten physician practices with ‘info blocking action’ if their requests for direct access into your EHR is denied. Payers having unfettered access to all your patients’ records may impact patient coverage, access to care, narrowing of networks, or your autonomy to practice medicine. We strongly urge all physicians to seek counsel from an attorney prior to responding to any payer or health plan requests for direct access into their EHR.”

Remember that under the Manner condition of the Content and Manner exception, you and the requester must come to terms on the technical manner and costs for requests to provide access to EHI in “any manner” and can decline. Instead, suggest one of the alternative manner to the requestor as provided in the exception, assuming you are technically capable of fulfilling requests in one or more of the three alternative manners. Be crystal clear in your communications with payers about how your organization will fulfill payer/health plan requests for EHI access, exchange, or use in accordance with the Content and Manner exception and other exceptions as they may apply, such as the Privacy exception.

As noted earlier, we understand from CHCANYS, all the health centers are connected to and participating in one of the qualified HIEs in NY. Meet with your regional QE representative. Ask your HIN representative what resources they have available for your health center that can assist with your compliance with the Information Blocking regulation. Learn how you can use the HIN to fulfill requests for EHI and what your response should be when a provider outside your organization requests a patient’s EHI be provided to them electronically via an HIE’s TPO Services or one of your patient requests his/her EHI be provided via an HIE’s Individual Access Services.

If your health center is only sharing a minimum dataset with the HIN, then discuss with the HIN representative about what is involved in sharing additional information to enable you to have the HIN fulfill your patients’ requests for their EHI, especially if your EHR technology does not presently have an automated way to post clinical notes to the patient portal. Most patients do not want only the EHI you hold in your systems but instead would prefer a complete longitudinal record with data integrated from all the providers they see. This is the value of the HIN providing patients individual access services to their EHI.

Be familiar with the latest version of the SHIN-NY privacy and security policies and procedures. Their policy and procedure document was last revised in July 2021 and Section 5 addresses the requirements for how the qualified regional HIN entities must facilitate patients’ and their Personal Representatives’ access to the patient’s PHI maintained by the HIN.

Information Blocking Compliance Readiness Checklist Overview

- Compliance Program / Team
- Policies / Procedures / Agreements
- EHI Inventory / Mapping
- EHR and Patient Portal (and other systems holding EHI)
 - Consult with your health IT vendor if you are unsure or don't know the answers
- Information Blocking Exceptions
 - General questions
 - Assessment questions specific to each exception
- Training and Education
- Communications



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The checklist provides a framework for conducting a self-assessment of your health center's readiness to comply with the information blocking provision and requirements in the Office of the National Coordinator for Health IT (ONC) Final Cures Act Rule and ONC Interim Final Rule published in 2020. Completing this checklist will enable your organization to determine the gaps it needs to address in its policies, processes, procedures, technology, and training and education related to fulfilling requests for access, exchange, or use of Electronic Health Information (EHI) as defined in the ONC rules. This checklist should not be assigned to a single individual to complete. Instead, identify a project lead and a team of subject matter experts and assign portions of the checklist to the appropriate SME(s) to complete. Then compile the results and discuss as a team. Your team will then be able to develop a workplan and make assignments to close the gaps identified in the assessment. The project lead would start with the first section of the checklist, "Compliance Program / Team," before making assessment assignments. There is a section for each of the other topic areas listed on the slide. We will finalize and provide your organizations the checklist along with some supplemental information for the checklist sometime after the Ask the Expert sessions next week.

Key Takeaways / Actions

- Everyone is involved in Cures Act Final Rule compliance
- Results of your internal readiness effort will inform the external actions to take to prepare for your technical readiness, engage your patients and communicate with external stakeholders
- Work directly and continually with your health IT vendors and HIE / HIN to understand interoperability / health information sharing capabilities
- After the March Ask the Expert sessions, you will receive the self-assessment compliance readiness checklist and supplemental supporting information covering the February and March topics to assist in your health center's preparedness



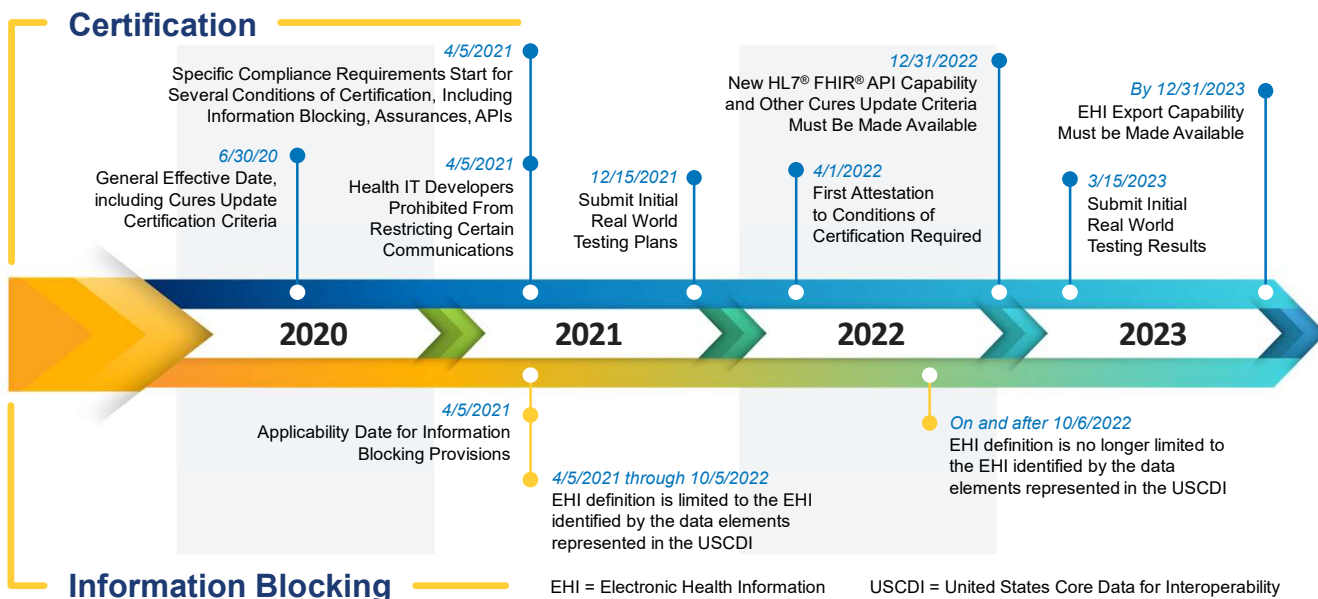
Everyone in the organization has a role to play in compliance.

The time you invest in your internal readiness effort will guide you on the actions you need to take with your health IT vendors, your regional Health Information Network, your patients, and other stakeholders.

Your organization should start conversations with your health IT vendors and Health Information Network organization now if you have not already to understand what they provide and how they can help.

Think about any questions you still have and join one of the last two Ask-the Expert sessions next week. Submit your questions in advance if possible.

Cures Act Final Rule Applicability, Compliance and Comply-By Dates



Remind participants about the key dates:

4/5/21: Information Blocking provisions applicability date (complaints and enforcement can go back to this date)

10/6/22: Expanded definition of EHI to all ePHI in designated record set (beyond data elements represented in USCDI)

12/31/22: Your health IT vendor must make the EHR Cures updates available to you for USCDI (replaces CCDS in the interoperability certification criteria) and the FHIR R4 Patient and Population API

12/31/23: EHI export capability must be made available to healthcare organizations

Educational Series Schedule

Additional Ask the Experts sessions will be scheduled based on member interest. We welcome your suggestions!
HCCN@chcanys.org

Month	Topic	Webinar Date	Ask the Experts (ATE) Date(s)	
November 2021	Cures Act Overview	Wed, Nov 10 Noon-1 ET	All roles Wed, Nov 17 Noon-1 ET	
December	OpenNotes Overview	Wed, Dec 1 Noon-1 ET	Providers Wed, Dec 15 Noon-1 ET	
January 2022	Information Blocking Exceptions	Wed, Jan 12 Noon-1 ET	Compliance, HIM Tue, Jan 18 Noon-1 ET	
February	Preparing for Cures Act Regulatory Compliance, Part 1 (organizational readiness)	Wed, Feb 16 Noon-1 ET	Compliance, HIM, IT Wed, Feb 23 Noon-1 ET	
March	Preparing for Cures Act Regulatory Compliance, Part 2 (communication of records)	Wed, Mar 16 Noon-1 ET	Providers Wed, Mar 23 Noon-1 ET	Compliance, HIM, IT Wed, Mar 23 2-3 ET



Before we move to Q&A...

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Appendix



Information Blocking Glossary of Terms

- **Actors**

- Individuals and entities covered by the information blocking provision, i.e., health care providers, health IT developers of certified health IT, health information networks, and health information exchanges

- **Certified Health IT**

- A health IT product that meets the certification requirements under the ONC Health IT Certification Program. Requirements for certification are established by standards, implementation specifications and certification criteria adopted by the Secretary at the Department of Health and Human Services (HHS)

- **Consumer Third-Party Application**

- Applications developed by third parties authorized and used by patients to access, exchange and use their electronic health information



Information Blocking Glossary of Terms

- **Designated Record Set**

- The set of information that a patient is required to have access to, such as medical and billing records, case management and health plan enrollment. Includes records that are used “to make decisions about individuals” also are included; this definition is not fully defined by the ONC but is addressed in an [ONC FAQ](#)

- **Electronic Access**

- An internet-based method that makes EHI available at the time the electronic health information is requested and where no manual effort is required to fulfill the request

- **Electronic Health Information (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



Information Blocking Glossary of Terms

- **Health Information Network (HIN)/ Health Information Exchange (HIE)**

- Individual or entity that determines, controls, or has discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology for access, exchange, or use of EHI: (1) Among more than two unaffiliated individuals or entities (other than individual or entity to which this definition might apply) that are enabled to exchange with each other; and (2) Is for a treatment, payment, or health care operations (TPO) purpose regardless of whether individuals or entities are subject to 45 CFR 160 and 164

- **Health IT developer of certified health IT**

- An individual or entity that develops or offers health information technology and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health IT (one or more) certified under the ONC Health IT Certification Program



Information Blocking Glossary of Terms

- **Information Blocking**

- If conducted by a health provider, a practice likely to interfere with access, exchange or use of electronic health information (EHI) when the provider knows that such practice is unreasonable and is likely to interfere with access, exchange or use of EHI

- **Interoperability**

- Health information technology that (a) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (b) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (c) does not constitute information blocking

