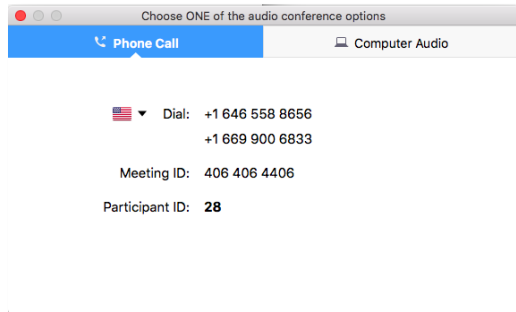# CURES Act Compliance: Prevent Information Blocking

Presented by Susan Clarke

Health Care Information Security and Privacy Practitioner

Thursday, February 18 | 10:00 - 11:00 a.m.
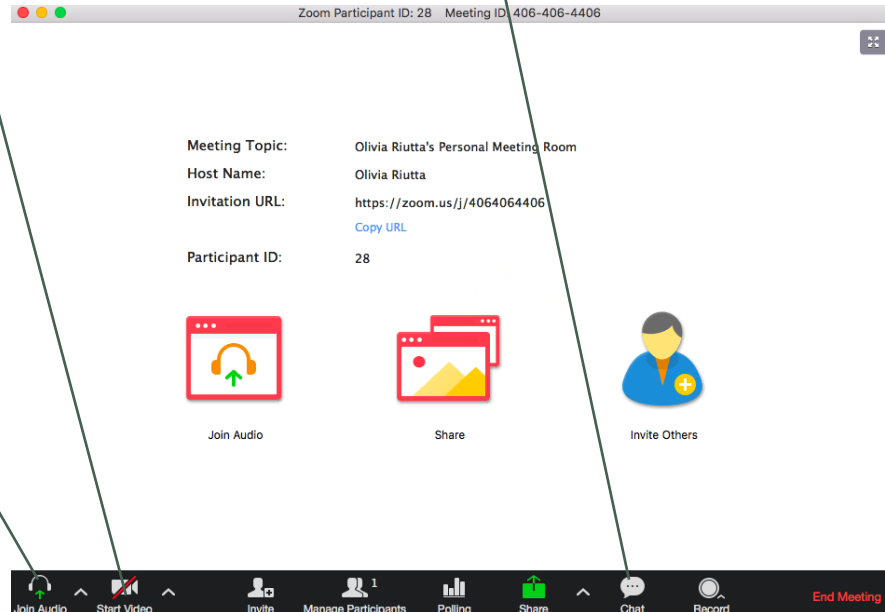
Zoom tips and tricks!

CHAT: Please jump in if you have something to share, but we also have this nifty chat function.

ATTENDANCE: If there are multiple attendees together on the call, please list the names and your location in the chat box

VIDEO: We want to see you!
If your camera isn't on, start your video by clicking here.

Choose ONE of the audio conference options

Phone Call   Computer Audio

Dial: +1 646 558 8656
         +1 669 900 6833

Meeting ID: 406 406 4406

Participant ID: **28**

AUDIO: You can use your computer speakers or your phone for audio. The phone is generally better quality. If you click "Join Audio," this "Choose one…" box will pop up. If you dial in, just make sure you include your audio code.

MUTE/UNMUTE: *6 or click the mic on the bottom left of your screen.

Zoom Participant ID: 28   Meeting ID: 406-406-4406

Meeting Topic: Olivia Riutta's Personal Meeting Room
Host Name: Olivia Riutta
Invitation URL: https://zoom.us/j/4064064406
                    Copy URL

Participant ID: 28

Join Audio   Share   Invite Others

Mute   Stop Video

Join Audio   Start Video   Invite   Manage Participants   Polling   Share   Chat   Record   End Meeting

Upcoming HCCN Sessions

TELEHEALTH TUESDAY SESSIONS

3rd Tuesday of each month at 11:00 a.m.

March 16: Telehealth Workflows and Staffing Optimization

April 20: Remote Patient Monitoring for Patient Care

May 18: Privacy and Security Considerations with Telehealth

CURES ACT COMPLIANCE: MANAGING RISK

MARCH 10TH AT 11:00 AM

HIPAA Webinar Series with Susan Clarke
Thursday, March 25 at 11:00 a.m.
Thursday, June 17 at 11:00 a.m.
Thursday, September 16 at 11:00 a.m.
Thursday, December 16 at 11:00 a.m.

Big Sky Care Connect Webinar
March 4 at 1:00 PM
Join Meeting Here
Meeting ID: 820 8846 6487
Passcode: 4221078

MPCA Events

Susan Clarke, HCISPP

(ISC)^2 Healthcare Information Security and Privacy Practitioner and Computer Scientist at Mountain-Pacific Quality Health.

Conducts privacy and security risk analysis in addition to HIPAA and 42 CRF, Part 2 training.

20 years' experience in health care operations.

10 years' design and coding EHR software including HL7 Healthcare application development.

Served on IT security, disaster recovery and joint commission steering committee at Mayo Clinic-affiliated health care system.

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Learning Objectives

1. What is 21st Century Cures Act?

2. What is information blocking and its impact on interoperability and privacy?

3. How will it affect your health center?

4. What your health center needs to be prepared

5. Resources available

6. Q&A

Acronyms with Definitions

HHS: Department of Health and Human Services

ONC: Office of the National Coordinator

OIG: Office of Inspector General

EHI: Electronic Health Information

USCDI: United States Core Data for Interoperability Standard

CDA: Clinical Document Architecture

Direct: Secure messaging system used in health care

API: Application Programing Interface

FHIR: Fast Healthcare Interoperability Resource

ACCESS: To make EHI available for exchange, use, or both

EXCHANGE: EHI can be transmitted between and among different technologies, systems, platforms, or networks

USE: EHI to be understood and acted upon once accessed or exchanged

Information Blocking

21st Century Cures Act

ONC Final Rule

Interoperability, Information Blocking and ONC Health IT Certification Program

CMS Final Rule

CMS Interoperability and Patient Access

Effective Dates

60 days after publication the Federal Registe Final Rule) and ms after pr for inform cking and s; January 1, (provisions of the CMS Final Rule)

Now April 5, 2021

The Bigger Picture

The new rules are described by HHS as:

"The **most extensive health care data sharing policies** the federal government has implemented, **requiring both public and private entities to share health information** between patients and other parties **while keeping that information private and secure**."

https://www.healthit.gov/curesrule/

Who is covered?

Health care providers
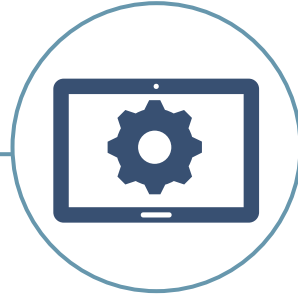
Health IT developers of certified health IT

Health Information Networks (HINs)/ Health Information Exchanges (HIEs)
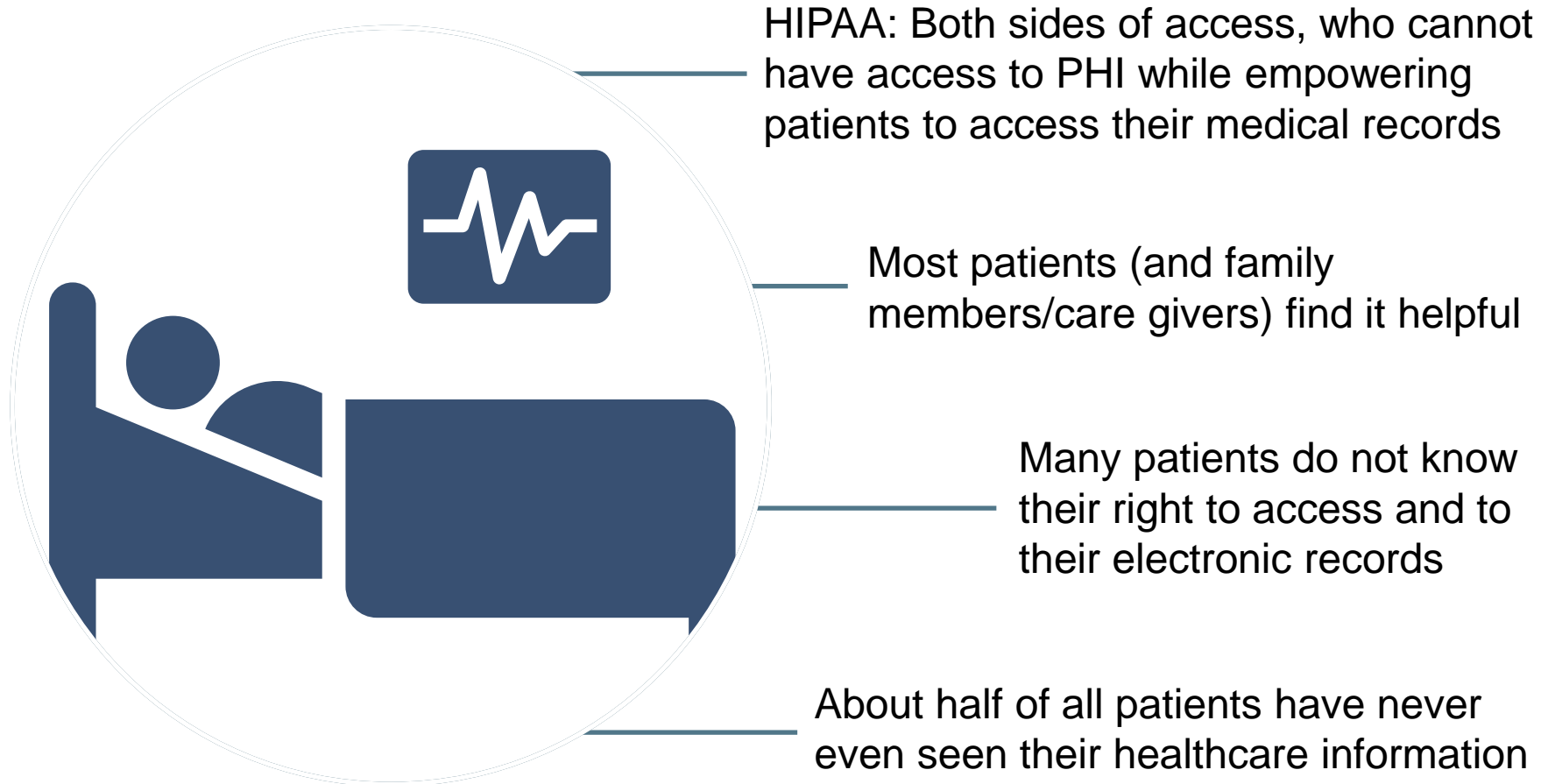
PASS

Who is impacted?
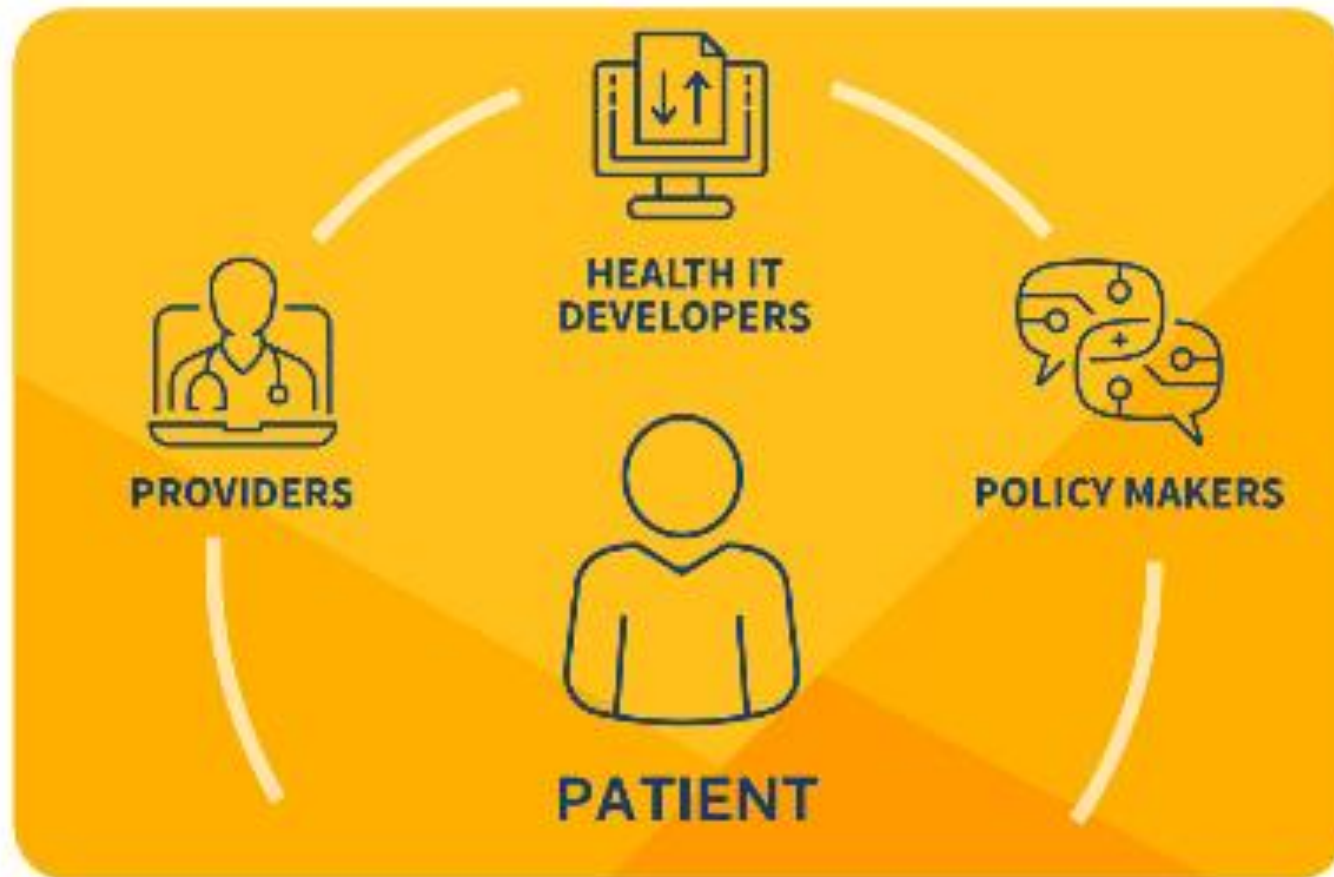
What is information blocking?

45 CFR, Part 171.103

- ✓ Information blocking – Practice likely to interfere with access, exchange and use of EHI

- ✓ If provider knows such a practice is unreasonable and likely to interfere

- ✓ Before Oct 6, 2022, limited to EHI identified by United States Core Data for Interoperability (USCDI)

Patient Facts

HIPAA: Both sides of access, who cannot have access to PHI while empowering patients to access their medical records

Most patients (and family members/care givers) find it helpful

Many patients do not know their right to access and to their electronic records

About half of all patients have never even seen their healthcare information

Become familiar with new patient education…

Health Care Provider Facts

Federal regulation – applies to all

Penalties are not yet finalized

How does your EHR protect information?

Electronic method of sharing

May share → must share

PASS

Electronic Health Information (EHI)

Applies to any electronically stored PHI/EHI

Must be shared electronically if requested by patient

Consider your EHR's sensitive data

Unable to hold back entire problem list for one diagnosis

Consequences of Being an Information Blocker

Cures Act prescribes penalties for information blocking

Certified health IT developers, HINs and HIEs: Civil monetary penalties (CMPs) up to $1 million per violation

Health care providers: Appropriate disincentives

Certification ban for health IT developers in violation of Conditions of Certification

Information blocking Condition of Certification

Public listing of certification bans and terminations

Information Blocking Exceptions

Not fulfilling requests to access, exchange or use EHI

1. Preventing Harm Exception

2. Privacy Exception

3. Security Exception

4. Infeasibility Exception

5. Health IT Performance Exception

Procedures for fulfilling requests to access, exchange or use EHI

6. Content and Manner Exception (USCDI)

7. Fees Exception (cost of providing access, exchange,use)

8. Licensing Exception (license interoperability)

Preventing Harm Exception

Information Blocking ≠ Engaging in practices reasonable and necessary to prevent harm to patient or another person, provided certain conditions are met

Practice must satisfy at least one condition from each category:

1 Type of Risk

2 Type of Harm

3 Implementation Basis

Information Blocking FAQs

Preventing Harm Exception ⬍

Filter   Reset

Preventing Harm Exception

Q: Where the patient is a minor and to avoid breaching the patient's confidentiality and trust with the provider, will the Preventing Harm Exception cover an actor's practices that interfere with a parent or legal representative's access, exchange, or use of the minor's EHI? *1/15/2021*   **+**

Q: Do the Preventing Harm Exception requirements for the type of harm align with the HIPAA Rules? *1/15/2021*   **+**

Q: Would the Preventing Harm Exception cover a "blanket" several day delay on the release of laboratory or other test results to patients so an ordering clinician can evaluate each result for potential risk of harm associated with the release? *1/15/2021*   **+**

Q: Will the Preventing Harm Exception cover practices interfering with a patient's access, exchange, or use of their EHI only for the purposes of reducing an imminent or immediate risk of harm? *1/15/2021*   **+**

Q: Where the patient is a minor and to reduce a risk of harm other than physical abuse, will the Preventing Harm Exception cover an actor's practices that interfere with a parent or legal guardian's access, exchange, or use of the minor's EHI? *1/15/2021*   **+**

PASS

Privacy Exception

If you can provide access, exchange or use EHI under privacy law, **you should**…

BUT

Not in a way prohibited under state or federal privacy laws

Security Exception

Intended to cover all legitimate security practices

but does not prescribe a maximum level of security or dictate a one-size-fits-all approach
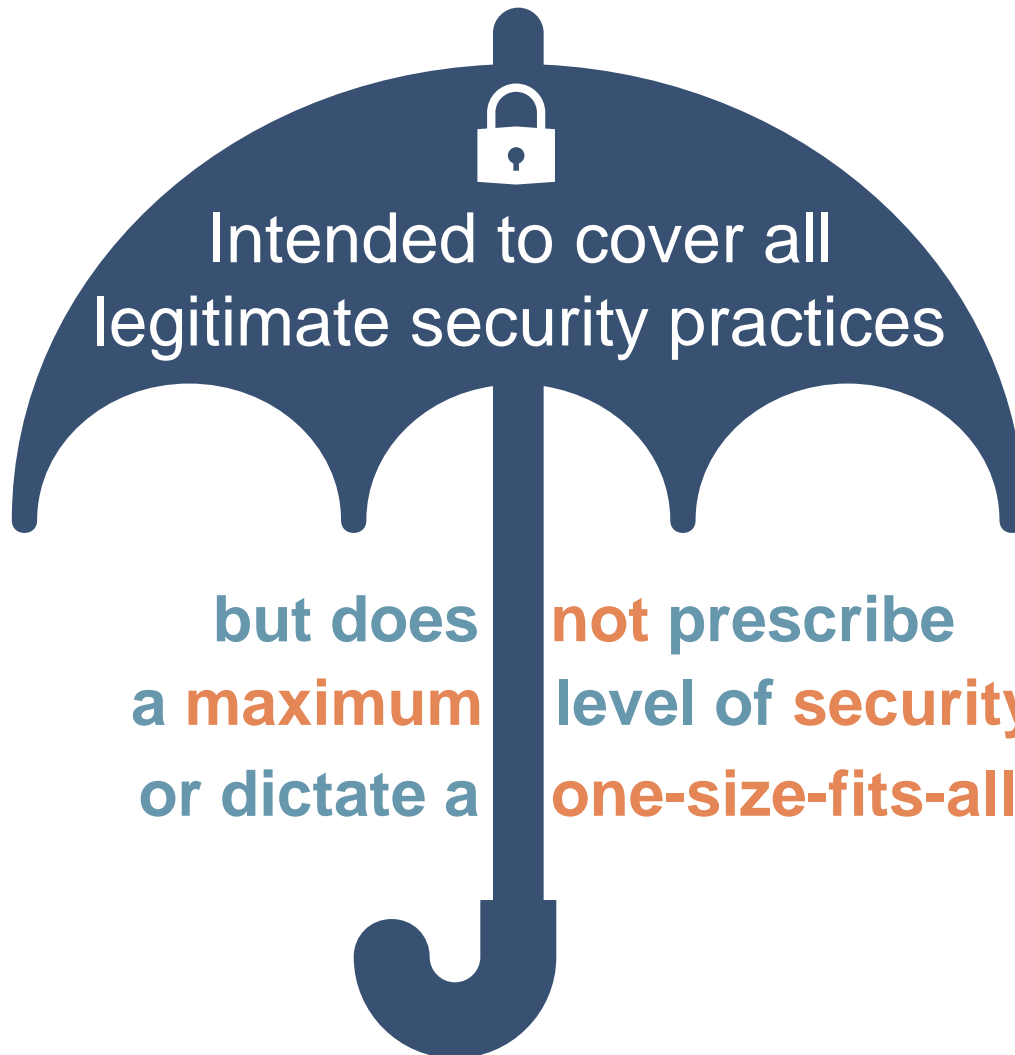
Infeasibility Exception

Legitimate practical challenges may limit the ability to comply with requests for access, exchange or use of EHI.

For example:
May not have and may not be able to get required technological capabilities, legal rights or other means necessary to enable access, exchange or use

Health IT Performance Exception

For health IT to perform properly and efficiently…

Must be maintained and sometimes improved

May have to go offline to benefit performance
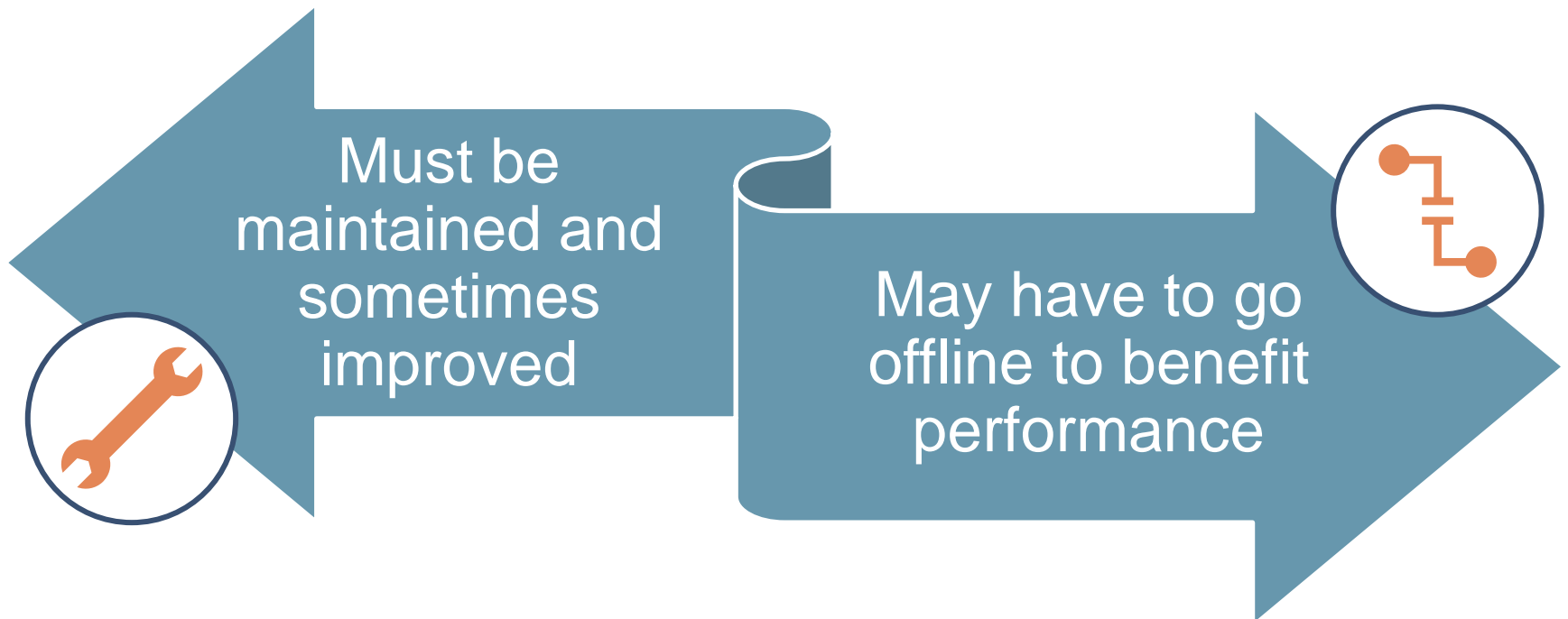
Health IT Developers

Changes to these standards for functionality of health IT (EHRs) include…

Adoption of U.S. Core Data (USCD) for Interoperability standard…

To replace Common Clinical Data Set (CCDS)…

As default data classes and data elements…

Health IT users should expect to be able to change between systems

USCDI ver 1

Please reference the **USCDI version 1 document** to the left for applicable standards versions associated with USCDI v1.

Allergies and Intolerances

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

Substance (Drug Class)
Substance (Medication)
Reaction

Assessment and Plan of Treatment

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

Assessment and Plan of Treatment

Care Team Member(s)

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

Care Team Member(s)

Clinical Notes

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

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

Goals

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

Patient's Goals

Health Concerns

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

Health Concerns

Immunizations

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

Immunizations

Laboratory

Tests
Values/Results

Medications

Medications

Patient Demographics

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

Problems

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

Problems

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

Procedures

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

Author Time Stamp
Author Organization

Smoking Status   Classification of a patient's smoking behavior.

Smoking Status

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

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

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

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

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

https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

USCDI ver 1

Clinical Notes

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https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

Information Blocking FAQs

Filter by Tags:

Interference ⬍

Filter   Reset

Interference

Q: Do the information blocking regulations (45 CFR Part 171) require actors to proactively make electronic health information (EHI) available through "patient portals," application programming interfaces (API), or other health information technology? *1/15/2021* ＋

Q: Are actors (for example, health care providers) expected to release test results to patients through a patient portal or application programming interface (API) as soon as the results are available to the ordering clinician? *1/15/2021* ＋

Q: Is it information blocking when state law requires a specific delay in communication of EHI, or that certain information be communicated to the patient in a particular way, before the information is made available to the patient electronically? *1/15/2021* ＋

Q: When a state or federal law or regulation, such as the HIPAA Privacy Rule, requires EHI 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? *1/15/2021* ＋

Q: Will educating patients about the privacy and security risks posed by third-party apps that the patient chooses be considered interference? ＋

Q: Do the information blocking regulations require actors to violate existing business associate agreements in order to not be considered information blockers? ＋

Alignment with HIPAA

The 21st Century Cures Act final rule is designed to operate in a manner consistent with the framework of the HIPAA Privacy Rule and other laws providing privacy rights for patients. Foremost, they do not require the disclosure of EHI in any way that would not already be permitted under the HIPAA Privacy Rule (or other Federal or State law).

Source=25812 Federal Register / Vol. 85, No. 85 / Friday, May 1, 2020 / Rules and Regulations

Alignment with HIPAA

Information Blocking FAQs – Preventing Harm Exception

Q: Do the Preventing Harm Exception requirements for the type of harm align with the HIPAA Rules?

Yes. The Preventing Harm Exception's *type of harm* condition relies on the same types of harm that serve as grounds for reviewable denial of an individual's right of access under the Privacy Rule (45 CFR 164.524). (*See* ONC Cures Act Final Rule preamble Table 3—Mapping of Circumstances Under § 171.201(d) to Applicable Harm Standards.) In most instances, including where a practice interferes with a patient's own or the patient's other health care providers' legally permissible access, exchange, or use of the patient's electronic health information (EHI), coverage under the Preventing Harm Exception requires that the risk be of

https://www.healthit.gov/curesrule/resources/information-blocking-faqs?options=23ec10bf-a1b0-4115-aa32-e01e63c7098e

Compliance Tips

Like HIPAA, do annual privacy and security risk analysis

Both require policies and procedures; identify gaps and develop plan to address them

Plan is not a once and done

Part of new work: information blocking compliance officer

Use most restrictive law

Getting Prepared

Identify Team Lead

- Become educated and stay informed

- Ensure team alignment

- Do mock drill to practice

- Empower patients

- Continuous improvement
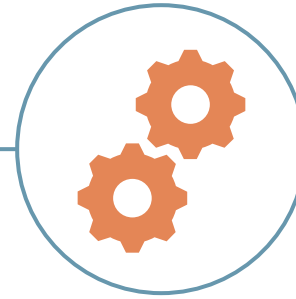
Policies and Procedures

- Patient access/record requests

- Amendment of patient records

- Notice of privacy practices

- Staff training on responding to patient requests for EHI

- Review BAAs

Getting Prepared

EHR

- In-depth review of sensitive EHI

- IMPORTANT--patient portal

- HIE and HIN relationship
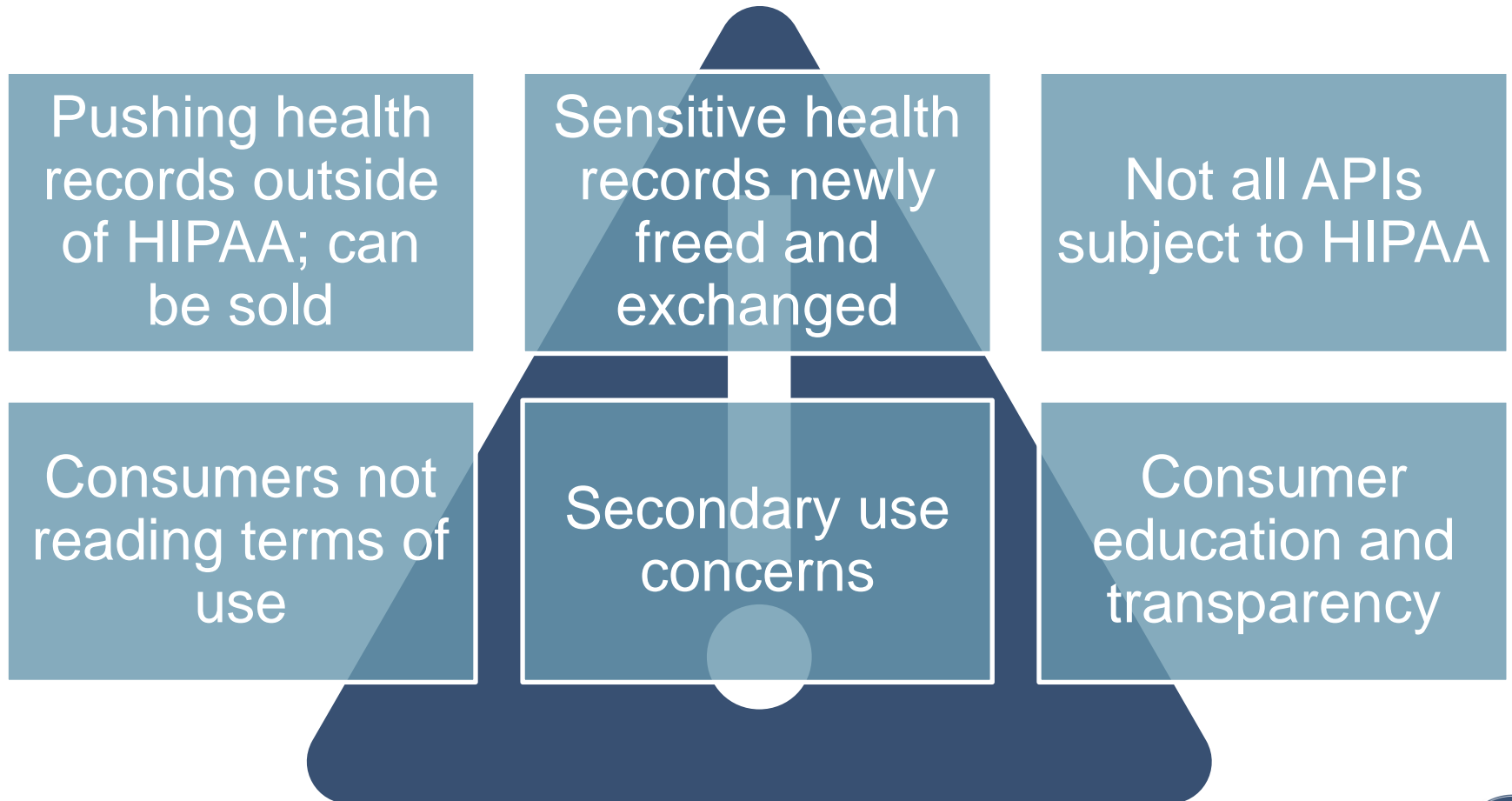
- Identify receiving EHI blocking

New Functions Needed

- Understand USCDI, is it captured in EHR?

- Understand EHR privacy features

- Identify gaps in how to provide EHI electronically

Information Blocking Policy

- ✓ Policy should outline how you share information with patients/ caregivers both self-serve, i.e., patient portal and by request.

- ✓ Policy should delineate what (if any) information you protect, how, and why, including jurisdictional mandates, i.e., minors.

- ✓ Policy should list any identified gaps in your ability to meet 21st Century Cures Act requirements and your plans to close them, including assigning ownership and deliverables with dates.

- ✓ Policy should outline your health centers policy for monitoring your compliance with the 21st Century Cures Act.

- ✓ Policy should delineate your health center's policy and procedures for handling any complaints about information blocking.

- ✓ Policy should be reviewed and updated to maintain compliance.

Privacy Concerns

Pushing health records outside of HIPAA; can be sold

Sensitive health records newly freed and exchanged

Not all APIs subject to HIPAA

Consumers not reading terms of use

Secondary use concerns

Consumer education and transparency

Resources

- ONC Information Blocking FAQs: https://www.healthit.gov/curesrule/resources/information-blocking-faqs

- ONC Cures Act Final Rule: www.healthit.gov/curesrule

- AMA Information Blocking Overview: https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf

- USCDIv1 details/updates: https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020- Errata-Final_0.pdf

- Information Blocking Exceptions Cheat Sheet from CHIME (College for Information Management Executives): https://chimecentral.org/wp-content/uploads/2020/06/061420_CHIME-Informatio n-Blocking-Cheat-Sheet-FINAL-RULE1-1.pdf

Please let me know how I can help.

For assistance please contact:
Susan Clarke

sclarke@mpqhf.org | (307) 248-8179

THANKS FOR YOUR VALUABLE TIME TODAY!

Questions