URF1

Regulatory Requirement
21st Century Cures Act

New Federal Regulations on Patients Accessing their Health Information

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CMS Interoperability and Patient Access Final Rule (CMS-9115-F)

Draft Release: 3/6/2020

Final Publication: 5/1/2020

Regulatory Components

- Attestation of Interoperability for MIPS and the Promoting Interoperability programs
- NPPES digital contact information requirement
- Interoperability requirements for payers
- ADT electronic notification requirement in the CMS Condition of Participation

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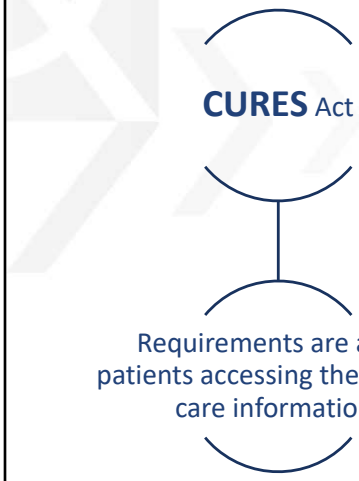
All the Rules…

- **Interoperability and Patient Access Final Rule**
  - Released March 2020
  - Part of MyHealthEData initiative
  - **Agency:** Centers for Medicare and Medicaid Services
- **Interoperability, Information Blocking, and the ONC Health IT Certification Program**
  - Released May 2020
  - Part of the 21st Century Cures Act
  - **Agency:** Office of the National Coordinator for HIT

NOTE

The CURES Act is different from the CARES Act



Requirements are about patients accessing their health care information.

COVID-related: reporting COVID test results to the appropriate health department

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CURES Act

Why?

- Patients have easier access & more control to their own health information
- **Rapid** full access to test results, medication lists, referral information, and clinical notes in **electronic formats**
- Government continues to seek to make health data accessible and available to patients through different formats, including smartphones & web portals
  - App of their choice in fully automated, low-cost manner

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CURES Act: Empowering Patients

Putting the patient first in health technology enables the health care system to deliver:

- Transparency into the cost and outcomes of their care
- Competitive options in getting medical care
- Modern smartphone apps to provide them convenient access to their records
- An app economy that provides patients, physicians, hospitals, payers, and employers with innovation and choice

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https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule

CURES Act: Clinicians & Hospitals

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Interoperability and Patient Access Final Rule

- Highlights:
  - Identifies HL7 FHIR 4.0.1 as standard for data exchange
  - Patient Access API
  - Provider Directory API
  - Payer-to-Payer Data Exchange
  - Public Reporting and Information Blocking
  - Digital Contact Information
  - ADT Event Notifications

Exchange Standards

- Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) Release 4.0.1
  - Identified as the foundational standard to support data exchange for secure application programming interfaces (APIs)
  - Finalized in 21st Century Cures Act
  - Supports privacy and security of patient information

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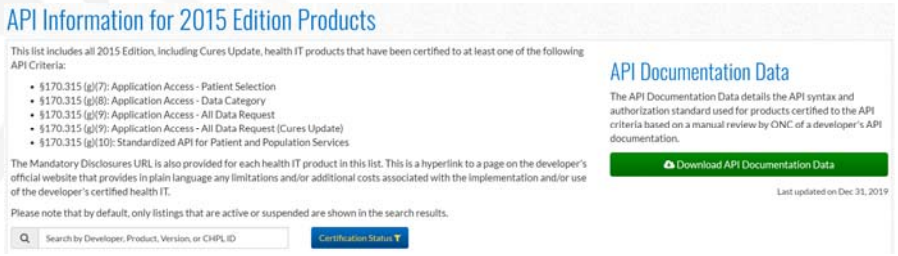
API – enable information systems to send or retrieve data that can update an individual's record or provide collective data used to make reports
APIs can also send information from one system to another

Patient Access
Application Program Interface (API)

- CMS regulated payers (i.e. Medicare Advantage, Medicaid FFS, CHIP, etc.) are required to implement and maintain an API that allows patients to easily access their claims and encounter information through a 3rd party app of the patient's choice
  - Includes a cost and clinical sub-set
  - Update: Rules will be enforced July 1, 2021

Application Program Interface (API)

- https://chpl.healthit.gov/#/collections/api-documentation



Additional Payer Regulations

Provider Directory API

- For CMS regulated payers, required to make a provider directory publicly available – for 3rd party developers to create apps to connect patients to providers

Payer-to-Payer Data Exchange

- CMS regulated payers are required to exchange the US Core Data for Interoperability (USCDI) at the patients request
- Allows them to take info with them when moving from payer to payer – create a cumulative health record

US Core Data for Interoperability (USCDI)

- Standardized set of data classes and constituent data elements for nationwide, interoperable health information exchange
  - **Data Class**: aggregation of various data elements by a common theme or use case
    - i.e. Clinical notes, demographics, vital signs
  - **Data Element**: most granular level at which data is represented for exchange
    - i.e. H&P, DOB, Temperature

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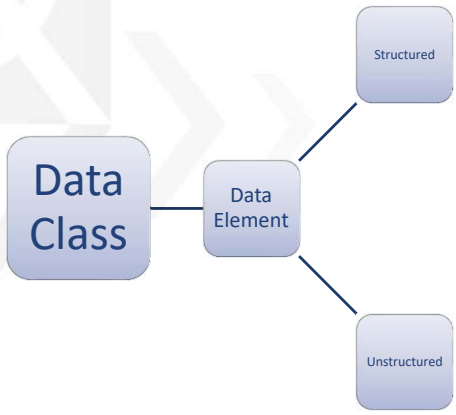
USCDI



- **Data Class:**
  - *Clinical note: composed of both structured and unstructured (free text) data*
- **Data Element:** *Discharge Summary Note*

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8 Mandatory Categories of Clinical Notes

1. Consultation notes
2. Discharge summary notes
3. History and physicals
4. Imaging narratives
5. Lab report narratives
6. Pathology report narratives
7. Procedure notes
8. Progress notes

Exempt:

- Notes compiled in reasonable anticipation of, or use in a civil, criminal or administrative action or proceeding
- Psychotherapy session notes. However, other components of psychiatric care (e.g., diagnoses, medications, appointment times, etc.) may not be blocked.

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Provider to Patient Exchange

- Provide Patients Electronic Access to Their Health Information (*"Patient Portal"*)
  - **Measure**: Provide patients *timely access* to view online, download, and transmit their health info
    - Ensure health info is available for the patient to access using any application of their choice configured to meet the tech specs of the Application Programming Interface (API) within CEHRT

API – set of standards that enable communication between multiple sources, most typically software applications

Health Information Exchange

- 2 options for HIE reporting in 2021
  - **Option 1**: Report num/denom data on Support Electronic Referrals Send & Receive measures
  - **Option 2**: HIE Bi-Directional exchange
- Heavily weighted to emphasize importance of interoperability & care coordination

Sending Health Information

- Support Electronic Referral Loops by Sending Health Information
  - **Measure:** For at least one transition of care (TOC) or referral –
    1. Create a summary of care using CEHRT
    2. Electronically exchange the summary of care

Receiving and Incorporating Health Information

- Support Electronic Referral Loops by Receiving and Incorporating Health Information
  - **Measure:**
    - Only counts summary of care documents you have received electronically
    - Clinician must conduct clinical information reconciliation for medications, medication allergies, and current problem list

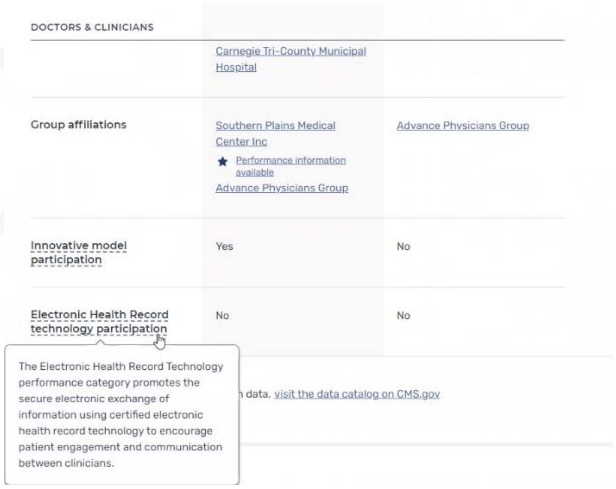
Information Blocking

Public Reporting and Info Blocking

- CMS will report individuals/organizations that have been info blocking and how they attested to certain PI requirements – applicable to clinicians, hospitals, and CAHs
  - **Information Blocking**: *practice by an HIT developer, HIN, HIE, or health care provider that is likely to interfere with access, exchange, or use of electronic health info*

Hospital/Physician Compare

https://www.medicare.gov/care-compare/



Examples of Information Blocking

Practices that restrict authorized access, exchange, or use of health information 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 Electronic Health Information (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.

Info Blocking Exceptions

It's your burden to prove your innocence!

24 https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf

Digital Contact Information

- CMS will publicly report providers that do not update their digital contact info in NPPES
  - Direct address and FHIR API endpoint

NPPES
National Plan & Provider Enumeration System

  - https://nppes.cms.hhs.gov/webhelp/nppeshelp/HEALTH%20INFORMATION%20EXCHANGE.html#

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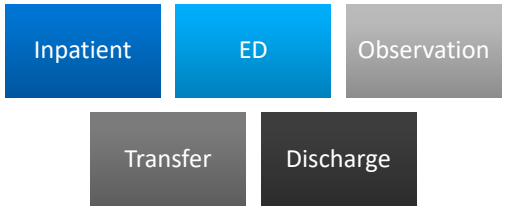
ADT Event Notifications

Hospitals must make a *reasonable effort* to notify each patient's *primary care physician(s), post-acute care provider(s), and any providers identified by the patient at registration*, when a patient is *admitted, transferred and/or discharged from the hospital*.

- Eligible hospitals, psychiatric hospitals, and CAHs must send electronic patient event notifications – admission, discharge, or transfer



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Transfer – from outpatient to inpatient; unit transfers not required

Electronic Notifications

- Improve care coordination while imposing minimal burden on providers
- Hospitals must convey, at a minimum, the following info:
  - Patient demographics
  - Name of the sending institution
  - Patient diagnosis (if not prohibited by applicable law)
- Sends notifications directly, or through an intermediary that facilitates exchange of health information, and at the time of the patient's admission to the hospital and either immediately prior to or at the time of the patient's discharge and/or transfer from the hospital

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You can send a full USCDI, but this is the *minimum*

Recipients of ADT Event Notification

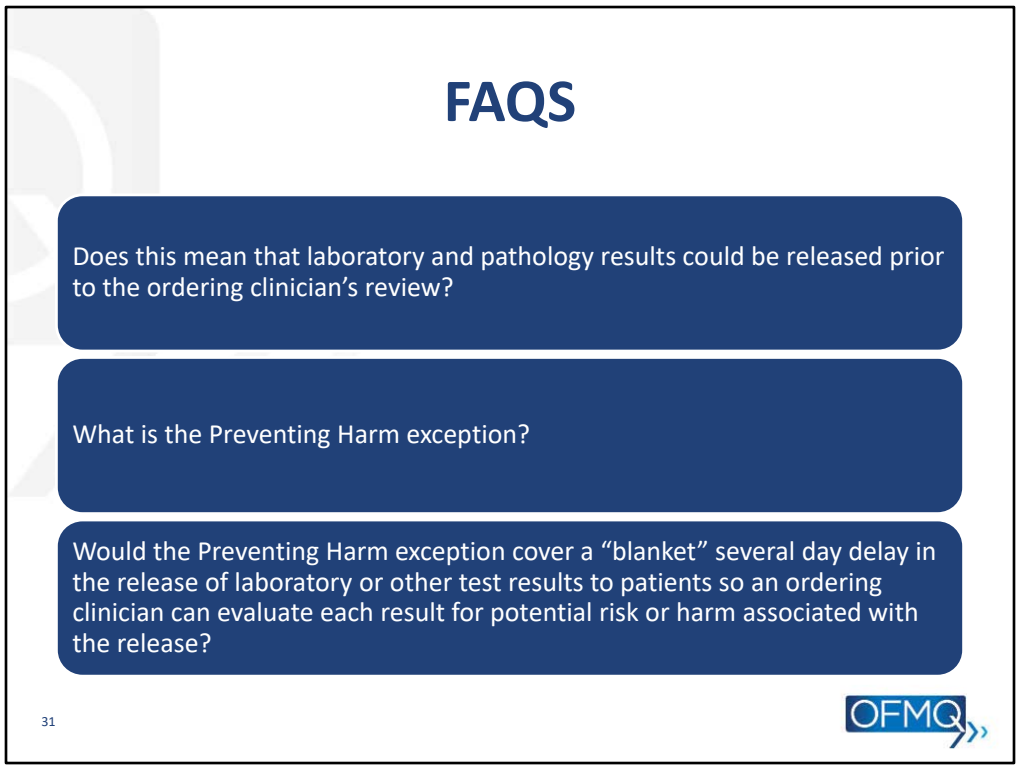
- Receive notifications for attributed patients
- Reach out to patient to plan transition from hospital
- Coordinate care with sending provider
- Work with hospital to tailor notification delivery to your preference
  - Receive only specific alert types
  - Receive alerts in a daily digest

ADT Compliance

- Hospitals must demonstrate compliance to surveyor or accrediting organization
  - Review of hospital processes and policy
  - Review of a sample of active and closed medical records for completeness and accuracy, including any patient event notifications
  - Interview and observation of medical records and other hospital staff for compliance

Enforcement

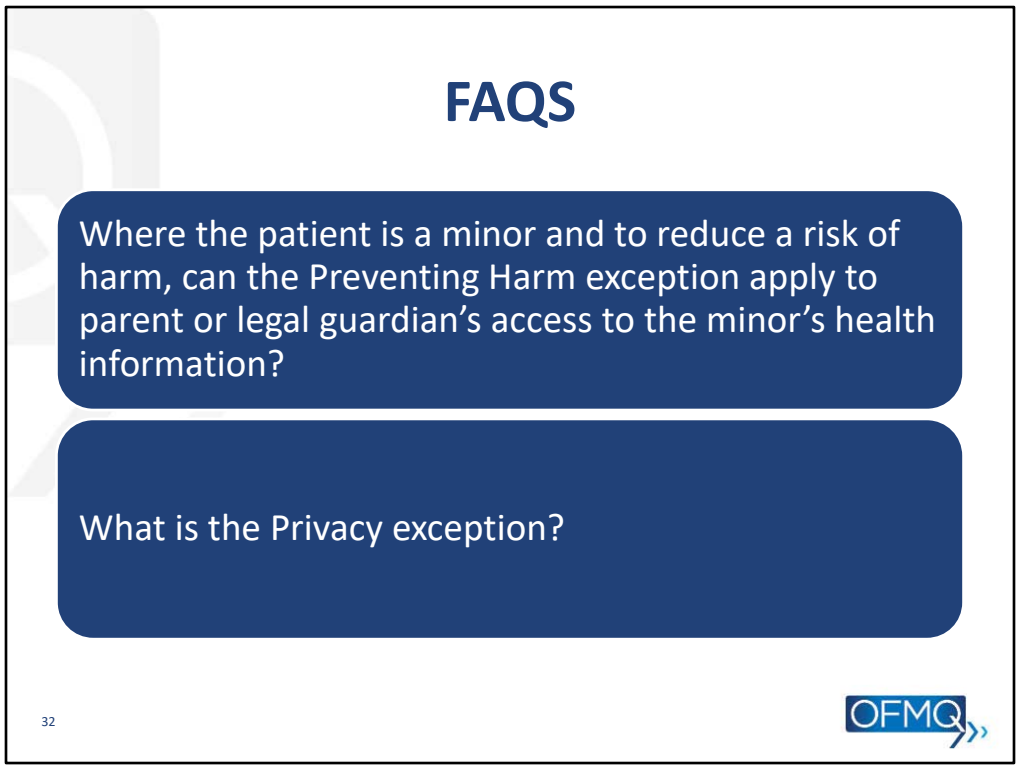
- Enforcement will be done by the Office of Inspector General (OIG) (not OCR like other HIPAA issues)
- Enforcement for HIT, HIE, and HINs is not until at least 60 days after civil monetary penalty is finalized. It is possible compliance could be done retrospectively, to prove compliance from day 1.
- Enforcement for providers:
  - Unclear when it starts
  - Will be done through disincentives (nothing drafted or published yet)
  - Example of disincentives could be penalizing all Medicare and Medicaid payments for previous year year
- Since the penalties aren't defined, you'll want to be careful not to violate without knowing how severe the consequences could be



Organizations should not block patient access until a physician has a chance to review results. Organizations may be able to create a policy that enables physicians to consider the release of lab tests on a case-by-case basis. This becomes the responsibility of the ordering clinician, and the rules of the organization.

Information blocking necessary to prevent harm to a patient or another person, provided certain conditions are met. Key conditions for this exception include: a reasonable belief that the practice will substantially reduce a risk of harm; the practice must be no broader than necessary; it must be an individualized assessment of the risk of harm.

No. Blanket delays that affect a broad array of routine results do not qualify for the Preventing Harm Exception. The Preventing Harm Exception is designed to cover only those practices that are no broader than necessary to reduce a risk of harm to the patient or another person. The exception is made in context of a clinician-patient relationship. In the context of that relationship, the clinician ordering a particular test would know the range of results that could be returned and could prospectively formulate, in the exercise of their professional judgment, an individualized harm determination for the specific patient.



Yes. Where the risk of harm has been determined on an individualized basis and is no broader than necessary—this is also usually at the discretion of the ordering clinician.

Information blocking necessary to protect an individual's privacy. Clinicians are not required to disclose health information in a way that is prohibited under state or federal privacy laws. Key conditions include (but are not limited to) respecting an individual's request not to share information.

CHECK List- Policies

- All rules and regulations should be implemented, and processes well documented in policy
- Not only HIPAA Security and Privacy Policy but
  - Patient Access
  - Information Blocking
  - Etc
- Document all exceptions

Are You Ready?

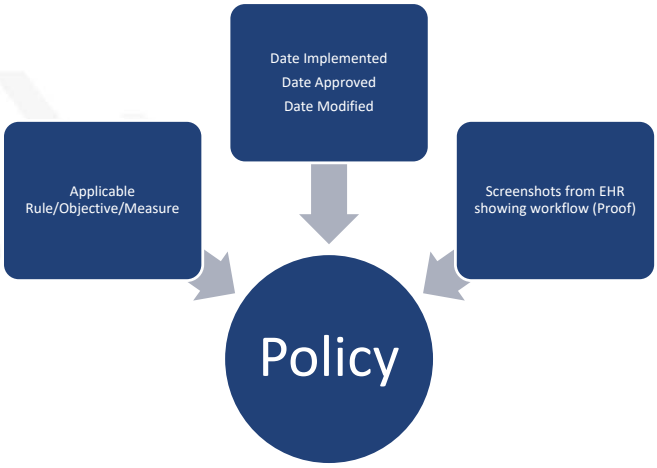
Review your practice privacy and security policy to ensure operations are outlined for patient information access requests.

Develop a process of communicating the steps of how patients will request access to EHI

Consider developing a policy for incoming reports from other health care providers. Consider workflows for lab and test results needing physician review prior to access.

Establish timeliness for the data being made available for access, exchange and use.

What's Included



Ask Yourself…

Patient Electronic Access

- How do patients access information?
  - ❑ Through the portal
  - ❑ Requests for PHI
  - ❑ Is information provided in a timely manner?

Health Information Exchange

- What's your process? Is it documented?
  - ❑ Do you send, receive, and incorporate health information?
  - ❑ ADT alerts (how do you know your patients are in ER or hospital? What's your follow up? How do you coordinate follow-up care?)
  - ❑ Information blocking
- Build out the process whether it is direct messaging, secure email, HIE/HIN, etc through screenshots

ADT Notifications

- ❑ When, how, and to whom do you send info when a patient is admitted, transferred, or discharged?
- ❑ Is PCP always documented? If not to whom do you send the info?
- ❑ Real-life closing referral/transfer loops electronically

Exceptions

- ❑ Define any exceptions for withholding patient information (No blanket exceptions but rather case by case)

Digital Contact Info

- ❑ Update provider info in NPPES to include Direct Address and FHIR API Endpoint

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Resources/References

- https://documents.cap.org/documents/sharing-test-results-cures-act-fact-sheet.pdf
- https://www.healthit.gov/curesrule/

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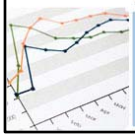


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