Hello and welcome!

- The meeting will begin momentarily

- This meeting is being recorded

- Links to meeting materials are in the chat and on the OHIT website :
  - Slides: https://www.oregon.gov/oha/HPA/OHIT-HITOC/Federal%20Rules%20Meeting%20Documents/HITOC_FinalRulesWebinarSlides.pdf
  - Handout: https://www.oregon.gov/oha/HPA/OHIT-HITOC/Federal%20Rules%20Meeting%20Documents/HITOC_FinalRulesWebinarHandout.pdf

- Have questions or comments during the webinar?
  - Use the 'Chat' feature
  - Send to host, Marta Makarushka

Oregon Health Authority

Health Information Technology Oversight Council (HITOC) Ad-hoc Webinar: Federal Interoperability Final Rules

October 1, 2020

This webinar is being recorded

Office of Health Information Technology (OHIT)

Agenda

- Webinar Introduction

- Final Rules Overview

- ONC 21st Century Cures Act Final Rule

- CMS Interoperability and Patient Access Final Rule

HITOC Webinar Introduction

- Health IT Oversight Council is a committee of the Oregon Health Policy Board

- Oregon Legislature created HITOC to ensure health system transformation efforts are supported by HIT

- HITOC's responsibilities under the law/charter include monitoring federal health IT law and policy

HITOC Webinar Purpose

- Inform and educate about federal policies
  - ONC 21st Century Cures Act Final Rule
  - CMS Interoperability and Patient Access Final Rule

- Webinar presentation by national health IT subject matter expert and OHA consultant Rim Cothren

- For further information go to Office of Health IT website: https://www.oregon.gov/oha/HPA/OHIT-HITOC/Pages/Federal-Rules.aspx

Webinar Logistics

- Links to meeting materials in the chat and on OHIT website (click on the event to see the details/materials): https://www.oregon.gov/oha/HPA/OHIT-HITOC/Pages/Federal-Rules.aspx

- Meeting is being recorded
  - Recording will be posted on website

- Questions during webinar: pauses throughout
  - Send to Marta via Chat at any time
  - We may not get to answer all questions during this webinar
  - FAQs will be posted on OHIT website (see link above)

- CCO/Payer webinar will be hosted 11/5
  - Will include time to answer more specific questions
  - More details to follow

Federal Interoperability Final Rules

Rim Cothren, Consultant

Two Separate Rules

Issued on the same day, coupled, but independent

1. ONC 21st Century Cures Act
   1) Updates to EHR Certification Criteria
   2) Exceptions to Information Blocking

2. CMS Interoperability and Patient Access
   1) Patient Access Application Programming Interface (API)
   2) Provider Directory API
   3) Payer-to-Payer Data Exchange
   4) Increased Reporting on Dual Eligibles
   5) Public Reporting and Information Blocking
   6) Digital Contact Information
   7) ADT Event Notifications

Goals of Final Rules

1. ONC

   – Give patients and their healthcare providers secure access to health information

   – Increase innovation and competition by fostering an ecosystem of new applications

   – Empower patients by putting them in charge of their health records

2. CMS

   – Put patients first, giving them access to their health information when they need it most and in a way they can best use it

   – Liberate health information and move the healthcare system toward greater interoperability

Links to Final Rules

1. ONC 21st Century Cures Act

   – Information and updates at https://www.healthit.gov/curesrule/

   – Fact sheets at
     https://www.healthit.gov/curesrule/resources/fact-sheets

   – Rule at https://www.federalregister.gov/d/2020-07419

2. CMS Interoperability and Patient Access

   – Information and updates at https://www.cms.gov/Regulations-
     and-Guidance/Guidance/Interoperability/index

   – Fact sheet at https://www.cms.gov/newsroom/fact-
     sheets/interoperability-and-patient-access-fact-sheet

   – Rule at https://www.federalregister.gov/d/2020-05050

ONC 21st Century Cures Act Final Rule

Scope of the ONC Cures Act Final Rule

1. Updates to EHR Certification Criteria

2. Exceptions to Information Blocking

Scope of the ONC Cures Act Final Rule

1. Updates to EHR Certification Criteria

2. Exceptions to Information Blocking

Updates to EHR Certification Criteria (highlights)

Revised

1. USCDI as the minimum data set for exchange

2. Updated C-CDA to most recent companion guide

3. Alignment with CMS CQM reporting criteria

New

1. Electronic health information (EHI) export requirements

2. Standardized application programming interface (API) for patient access

USCDI: United States Core Data for Interoperability
C-CDA: Consolidated-Clinical Document Architecture
CQM: clinical quality measures

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Updates to EHR Certification Criteria, Revised: Minimum Data Set for Exchange

- Adoption of the USCDI v1 https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
  - Includes new data elements
    - additional patient demographics
    - clinical notes (based on C-CDA)
    - data provenance
    - pediatric vitals
  - Will be updated periodically, probably annually

- Specifies both terminologies and data elements
  - Terminologies required for certification by in 2022
  - Data elements required by information blocking provisions by November 1, 2020

Updates to EHR Certification Criteria, New: EHI Export Requirements

- CEHRT modules must include export capabilities for:
  - A single patient export to support patient access
  - Patient population EHI export to support transitions between EHRs

- Export files
  - Must be electronic and in a computable format
  - May use any format designated by the health IT developer
  - Health IT developers must publish the export file's format

Updates to EHR Certification Criteria, New: Standardized API for Patient Access

- Transition to use of Fast Healthcare Interoperability Resources (FHIR) Release 4.01 as a standard
  - Patient access API was previously required, but without specifying a standard

- Requires use of OAuth2 and OpenID Connect for security

Conditions and Maintenance of Certified EHR Technology (CEHRT) Certification

Health IT developer:

1. May not take actions that constitutes information blocking

2. Must assure DHHS that it will not take part in any action that constitutes information blocking

3. May not prohibit or restrict communications on usability, interoperability, security, user experience, exchange practices, manner of use

4. APIs (covered above)

Conditions and Maintenance of CEHRT Certification (con't)

Health IT developer:

5. Must successfully test real-world use

6. Must attest to compliance with conditions of certification

7. Must attest to compliance with maintenance of certification

Failure can result in the certification being revoked

Linkage between ONC and CMS Rules

ONC Final Rule

1. Defines technical standards for patient access (API and security)

2. Defines clinical data to be exchanged

CMS Final Rule

1. Uses same technical standards for patient access

2. Uses same definition for payer-to-payer exchange

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Considerations and Barriers

- USCDI will change over time, perhaps annually

- Providers must exchange USCDI data elements before they are part of certification to avoid information blocking

- EHI export formats are not standardized

- Patient access API mandates an emerging standard

- Patient access API requires providers to share data with app developers that are not covered by HIPAA and have no data sharing agreement with the provider

- Health IT developers may lose product certification if 7 conditions are not met

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Questions?

ONC Cures Act Final Rule:
Updates to EHR Certification Criteria,
Conditions and Maintenance of Certification

Scope of the Final Rule

1. Updates to EHR Certification Criteria

2. Exceptions to Information Blocking

Scope of the ONC Cures Act Final Rule

Regarding Information Blocking

- 21st Century Cures Act (i.e., Congress)
  - Defined information blocking
  - Expanded applicability to healthcare providers, health information exchanges, health information networks
  - Defined monetary penalties

- ONC Cures Act final rule
  - Defined healthcare providers, HIE, HIN
  - Defined exceptions to information blocking that allow Cures Act provisions to go into effect

Information Blocking

Defined by Cures Act as:

"A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information."

ONC Definition of EHI

- Focused to mean
  - electronic protected health information (ePHI)
  - to the extent that the ePHI is included in a designated record set as defined under HIPAA

- Applicable whether the actor is a covered entity or not

- USCDI is an example of a "designated record set"

  - Information blocking provisions require the USCDI data elements (but not the code sets) to be exchanged

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ONC Definition of HIE and HIN

- ONC combined the definitions of HIE and HIN to create one definition that applies to both statutory terms

- HIN or HIE means an individual or entity that determines, controls or has the discretion to administer any requirement, policy or agreement that permits, enables or requires the use of any technology or services for access, exchange or use of EHI:
  - Among more than two unaffiliated individuals or entities that are enabled to exchange with each other
  - For a treatment, payment, or healthcare operations purpose

- Applies only to information blocking

Exceptions to Information Blocking

- "It will not be information blocking for an actor to engage in practices that are reasonable and necessary…

  …provided certain conditions are met."

- All instances of information blocking are subject to investigation by OIG

  - OIG is the only recourse for information blocking

https://www.healthit.gov/curesrule/final-rule-policy/information-blocking

Exceptions to Information Blocking

Not Fulfilling Requests

1. <u>Preventing Harm Exception</u>: Practices to prevent harm to a patient or another person

2. <u>Privacy Exception</u>: Not fulfilling a request in order to protect individual privacy

3. <u>Security Exception</u>: Interfering with a request in order to protect the security of EHI

4. <u>Infeasibility Exception</u>: Not fulfilling a request due to its infeasibility

5. <u>Health IT Performance Exception</u>: Measures for the benefit of overall performance

Procedures in Fulfilling Requests

6. <u>Content and Manner Exception</u>: Limiting the content or manner in which a request if fulfilled

7. <u>Fees Exception</u>: Charging fees, including fees that result in a reasonable profit margin

8. <u>Licensing Exception</u>: Licensing interoperability elements

OIG Proposed Rule on Enforcement

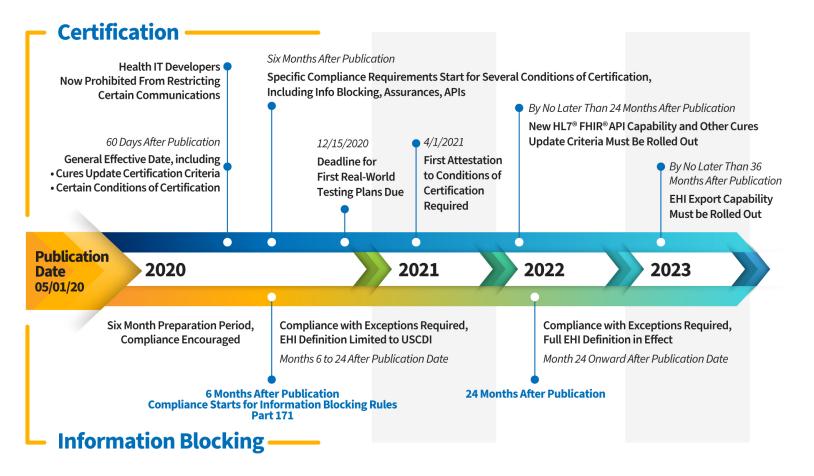https://oig.hhs.gov/newsroom/news-releases/2020/infoblocking.asp

- OIG has discretion on which complaints to investigate
  - Will focus on cases that cause patient harm, impact provider ability to provide care, persist over long durations, cause financial loss to federal health care programs, are known to actor
  - Will not enforce "innocent mistakes"
  - Will be evaluated per facts and circumstances of each case

- Violations would be defined as each practice that is information blocking, using ONC rules for practices
  - Will determine penalties based on nature and extent, harm, number of patients affected, number of providers affected, duration it persists

Timeline for Information Blocking

- Compliance by November 1, 2020
  - Includes exchange of USCDI data elements

- Enforcement discretion until February 1, 2020

- OIG proposed additional enforcement discretion for civil monetary penalties until 60 after publication of final rule
  - Healthcare providers are not subject to civil monetary penalties

- Enforcement for healthcare providers dependent upon additional rulemaking by DHHS
  - Rulemaking to define appropriate disincentives for healthcare providers

Timeline for the Entire ONC Final Rule

Certification

Health IT Developers Now Prohibited From Restricting Certain Communications

Six Months After Publication
Specific Compliance Requirements Start for Several Conditions of Certification, Including Info Blocking, Assurances, APIs

By No Later Than 24 Months After Publication
New HL7® FHIR® API Capability and Other Cures Update Criteria Must Be Rolled Out

60 Days After Publication
General Effective Date, including
• Cures Update Certification Criteria
• Certain Conditions of Certification

12/15/2020
Deadline for First Real-World Testing Plans Due

4/1/2021
First Attestation to Conditions of Certification Required

By No Later Than 36 Months After Publication
EHI Export Capability Must be Rolled Out

Publication Date 05/01/20

2020   **2021**   **2022**   **2023**

Six Month Preparation Period, Compliance Encouraged

Compliance with Exceptions Required, EHI Definition Limited to USCDI
Months 6 to 24 After Publication Date

Compliance with Exceptions Required, Full EHI Definition in Effect
Month 24 Onward After Publication Date

6 Months After Publication
Compliance Starts for Information Blocking Rules Part 171

24 Months After Publication

Information Blocking

ONC will exercise enforcement discretion until 3 months after each initial compliance date

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Linkage between ONC and CMS Rules

ONC Final Rule

1. Defines technical standards for patient access (API and security)

2. Defines clinical data to be exchanged

3. Defines health information networks for purposes of information blocking

CMS Final Rule

1. Uses same technical standards for patient access

2. Uses same definition for payer-to-payer exchange

3. Definition of health information network might apply to payers

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Considerations and Barriers

- Every organization must determine whether the definition of health information network applies to them
  - HIN/HIE is a functional definition that depends upon how an entity functions, not upon facts about the entity
  - Any specific business line might be considered a HIN
  - Generally, for the organization to be considered a HIN
    - More than two participants must exchange data
    - Participants must exchange information among themselves
    - Participants must exchange for treatment, payment, or healthcare operations purposes
  - Information blocking will be enforced on a case-by-case basis following OIG investigation

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Questions?

ONC Cures Act Final Rule:
Information Blocking

CMS Interoperability and Patient Access

Scope of the CMS Patient Access Final Rule

1. Patient Access API

2. Provider Directory API

3. Payer-to-Payer Data Exchange

4. Increased Reporting on Dual Eligibles

5. Public Reporting and Information Blocking

6. Digital Contact Information

7. ADT Event Notifications

Scope of the CMS Patient Access Final Rule

1. Patient Access API

2. Provider Directory API

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7. ADT Event Notifications

Patient Access API

- Must implement patient access API
  - Must allow access to claims and encounter information
  - Must include cost and clinical information
  - Must allow use of 3rd-party app of patient's choosing

- Must use standards identified by ONC Final Rule
  1. Exchange via FHIR Release 4
  2. Clinical data must include USCDI data elements
  3. Authentication/authorization via OAuth2, OpenID Connect

- Potential CMS guidance documents can be found here:
  https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

Patient Access API Applicability

- CMS-regulated entities:
  - Medicare Advantage
  - Medicaid fee-for-service programs
  - Medicaid managed care plans
  - CHIP fee-for-service programs
  - CHIP managed care entities
  - Qualified health plan issuers on federally-facilitated exchanges

  Note: Excludes issuers offering only stand-alone dental plans or federally-facilitated small business health options

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Patient Access API Considerations/Barriers

- Payers will need to budget for system changes

- Uses emerging standards unfamiliar to current vendors with immature implementation guides

- Must aggregate and map clinical data from administrative transactions

- Must manage beneficiary logins and passwords

- Must share EHI with app developers not covered by HIPAA, without a data sharing agreement

- Consider the user experience of the patient

- Provide patient education (see CMS resource)

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Provider Directory API

- Must implement provider directory API
  - Must allow access to complete provider list
  - Must include names of providers, addresses, phone numbers and specialty

- Must use standards identified by ONC Final Rule
  - Exchange via FHIR Release 4

- Potential CMS guidance documents can be found here: https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

Provider Directory API Applicability

- CMS-regulated entities :
  - Medicare Advantage
  - Medicaid fee-for-service programs
  - Medicaid managed care plans
  - CHIP fee-for-service programs
  - CHIP managed care entities

  Note: excludes health plans on exchanges

Provider Directory API Considerations/Barriers

- Payers will need to budget for system changes

- Uses emerging standards unfamiliar to current vendors with immature implementation guides

- Must collect any missing provider data

- Must map provider data from administrative transactions

- Must share information with app developers without a data sharing agreement

Patient Access and ONC Final Rule

- Borrows API technical standards from ONC

- Borrows authentication/authorization standard from ONC

- Borrows clinical data requirements from ONC
  - USCDI requirements will change over time, perhaps annually

- Mirrors API standards required for patient access of clinical data in CEHRT

API Timeline

- Patient access and provider directory APIs to be implemented by January 1, 2021

- CMS will exercise enforcement discretion until July 1, 2021

Questions?

CMS Interoperability and Patient Access Final Rule:
Patient and Provider Directory APIs

Scope of the Final Rule

1. Patient Access API

2. Provider Directory API

3. Payer-to-Payer Data Exchange

4. Increased Reporting on Dual Eligibles

5. Public Reporting and Information Blocking

6. Digital Contact Information

7. Event Notification

Payer-to-Payer Data Exchange

- Must exchange clinical data at beneficiary request
    - Intended to allow patient to take their information with them as they move from payer to payer over time
    - Must respond to queries if individual was a beneficiary within the last 5 years
    - Must respond with all clinical data from 2016 onward
    - Patient must identify entities from which to request data

- Must include USCDI data elements
    - No interface standard is specified for API
    - Use of FHIR may be suggested by CMS, but not required

Applicability and Timeline

- Exchange among CMS-regulated entities excluding fee-for-service entities:
  - Medicare Advantage
  - Medicaid managed care plans
  - CHIP managed care entities
  - Qualified health plan issuers on federally-facilitated exchanges

    Excluding issuers offering only stand-alone dental plans or federally-facilitated small business health options

- Must be implemented by January 1, 2022

Payer to Payer Exchange Considerations/Barriers

- Requires funding that may not yet be available

- Requires robust beneficiary identity and patient matching capabilities

- Uses data standards unfamiliar to current vendors, with changing requirements over time

- No technical standard is identified, must be coordinated

- Requires long-term data retention with on-line access

- Requires new processes for beneficiaries and plans to request information and fulfill those requests

- Coordinate with other payers

Information Blocking and Payers

- Every organization must determine whether the definition of health information network applies to them
  - Information blocking may attach to patient access or payer-to-payer exchange
  - Information blocking may attach to other activities if meeting the requirements of HIN

Questions?

CMS Interoperability and Patient Access Final Rule: Payer-to-Payer Exchange

Scope of the Final Rule

1. Patient Access API

2. Provider Directory API

3. Payer-to-Payer Data Exchange

4. Increased Reporting on Dual Eligibles

5. Public Reporting and Information Blocking

6. Digital Contact Information

7. ADT Event Notifications

Increased Reporting on Dual Eligibles

- States must support daily exchange of certain enrollee data of dual eligibles for Medicare and Medicaid
  - Must include state buy-in files and "MMA files"

- Applicable to all states

- Must be implemented by April 1, 2022
  - May not be an issue for many states already planning for more frequent updates

- May require states or coordinate deletions and additions to avoid gaps in dual-eligible coverage

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Scope of the Final Rule

1. Patient Access API

2. Provider Directory API

3. Payer-to-Payer Data Exchange

4. Increased Reporting on Dual Eligibles

5. Public Reporting and Information Blocking

6. Digital Contact Information

7. ADT Event Notifications

Public Reporting Related to Information Blocking and Digital Contact Information

- CMS will publicly report providers that may be involved in information blocking

  - Applies to eligible clinicians, hospitals, and critical access hospitals

  - Based on how providers attest to CMS Promoting Interoperability Program or Merit-based Incentive Payment System

- CMS will publicly report providers who do not list or update their digital contact information in the National Plan and Provider Enumeration System (NPPES)

- Public reporting begins late 2020

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Public Reporting Considerations

- Providers must review and update attestations

- Providers must be aware of their current digital contact information
  - May not be limited to Direct secure messaging addresses

- Provider must update their digital contact information
  - Most providers do not maintain information in NPPES
  - Not clear now updates to NPPES will be monitored

- Providers may be concerned about abuse of publicly-available Direct secure messaging addresses

Questions?

CMS Interoperability and Patient Access Final Rule:
Public Reporting

Scope of the Final Rule

1. Patient Access API

2. Provider Directory API

3. Payer-to-Payer Data Exchange

4. Increased Reporting on Dual Eligibles

5. Public Reporting and Information Blocking

6. Digital Contact Information

7. ADT Event Notifications

ADT Event Notifications

- Hospitals required to send electronic patient event notifications

  – Requirement extends to psychiatric and critical access hospitals

  – Includes admission, discharge, and/or transfer events

  – Requires use of HL7 v2.5.1 ADT messages

- Must be implemented by May 1, 2021

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ADT Notification Considerations/Barriers

- Hospitals must identify appropriate recipients of notifications
  - May include primary care providers or provider groups
  - May include others identified by the patient
  - May require modification of patient registration processes

- Hospitals must create interfaces to recipients or use a 3rd-party service (e.g., HIE)
  - May require hospital to identify recipient to 3rd-party services

- Does not include any specific requirement for the recipient of notifications
  - Ambulatory EHRs may not accept ADTs
  - Hospitals must exercise due effort

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ADT Notification Considerations/Barriers (cont.)

- Requirement puts hospital participation in Medicare at risk
  - Implemented as part of Conditions of Participation
- CoP process may be ill-equipped to assess fulfillment of this requirement

Questions?

CMS Interoperability and Patient Access Final Rule: Event Notification

Other Questions?

Wrap-up

Please visit the OHIT's federal final rules website https://www.oregon.gov/oha/HPA/OHIT-HITOC/Pages/Federal-Rules.aspx for additional resources, including FAQs

CCO/Payer Interoperability Final Rules Webinar
- 11/5 2-3:30 pm
- Details will be posted on the website and sent to listserv (click here if you'd like to sign-up)

If you have questions, please contact Marta Makarushka at Marta.M.Makarushka@dhsoha.state.or.us