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# Health Information Technology Oversight Council (HITOC) Education Session: Federal Interoperability Final Rules

March 17, 2022

This webinar is being recorded



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Office of Health Information Technology (OHIT)

# Agenda

- Final Rules Overview
- ONC 21st Century Cures Act Final Rule
- CMS Interoperability and Patient Access Final Rule

Reference handout at:

[CMS and ONC Interoperability Final Rules:  
Oregon Health Authority's Overview for HITOC](#)

# Federal Interoperability Final Rules

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# 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) US Drug Formulary
- 4) Payer-to-Payer Data Exchange
- 5) Increased Reporting on Dual Eligibles
- 6) Public Reporting and Information Blocking
- 7) Digital Contact Information
- 8) 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

# 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
  - Updated periodically (USCDA v3 out in draft now)
- Specifies both terminologies and data elements
  - Terminologies required for certification by May 1, 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, OpenID Connect, SMART Application Launch Framework 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



# US Core Data for Interoperability V1

- Patient demographics
- Health concerns
- Patient goals
- Plan of treatment
- Care team members
- Medications
- Medical allergies
- Immunizations
- Problems
- Clinical notes
- Laboratory results
- Procedures
- Implantable devices
- Smoking Status
- Vital signs
- Provenance

# Updates to USCDI (not yet required)

## USCDI v2

- Care team contact info
- Clinical tests and imaging
- Encounters
- Patient demographics (added SOGI data)
- SDOH assessment
- SDOH goals
- SDOH problems
- SDOH interventions

## USCDI v3 (draft)

- Patient demographics (tribal affiliation, related persons, occupation)
- Health insurance
- Health status

## 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

# 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



# 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. Preventing Harm Exception: Practices to prevent harm to a patient or another person
2. Privacy Exception: Not fulfilling a request in order to protect individual privacy
3. Security Exception: Interfering with a request in order to protect the security of EHI
4. Infeasibility Exception: Not fulfilling a request due to its infeasibility
5. Health IT Performance Exception: Measures for the benefit of overall performance

## Procedures in Fulfilling Requests

6. Content and Manner Exception: Limiting the content or manner in which a request if fulfilled
7. Fees Exception: Charging fees, including fees that result in a reasonable profit margin
8. Licensing Exception: Licensing interoperability elements

# OIG Proposed Rule on Enforcement

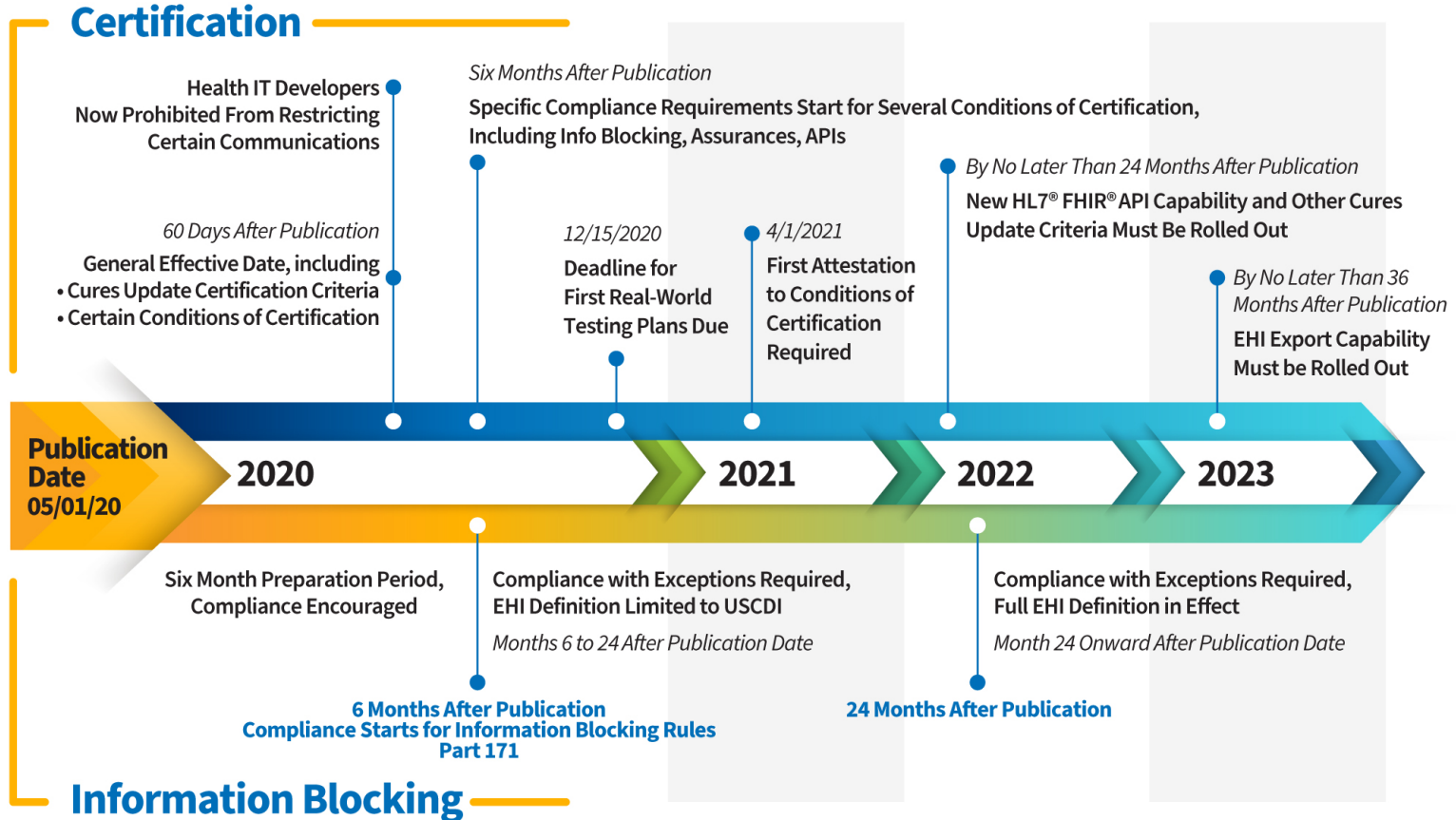
<https://oig.hhs.gov/newsroom/news-releases/2020/infoblocking.asp>

- 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 April 5, 2021
- OIG proposed additional enforcement discretion for civil monetary penalties until 60 days after final rule publication
  - 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



ONC exercised enforcement discretion for at least 3 months after each initial compliance date

# 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

# 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



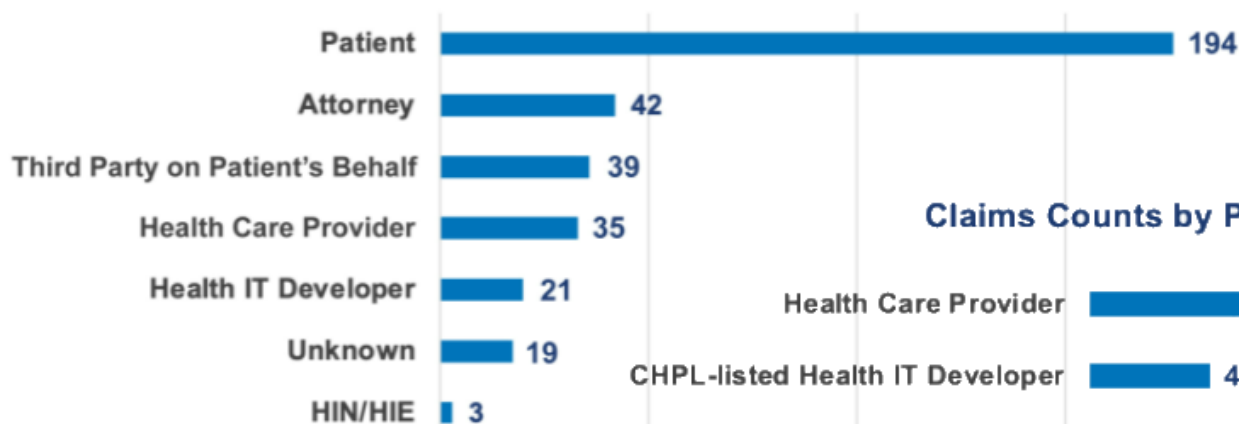
# Enforcement of Information Blocking

- OIG has not published a final rule on enforcement of information blocking for HIT vendors or HIEs/HINs
  - HIT vendors, HIEs/HINs subject to civil monetary penalties
  - A final rule may be forthcoming shortly
- DHHS has not published rules or guidance on enforcement for providers
  - Providers not subject to civil monetary penalties

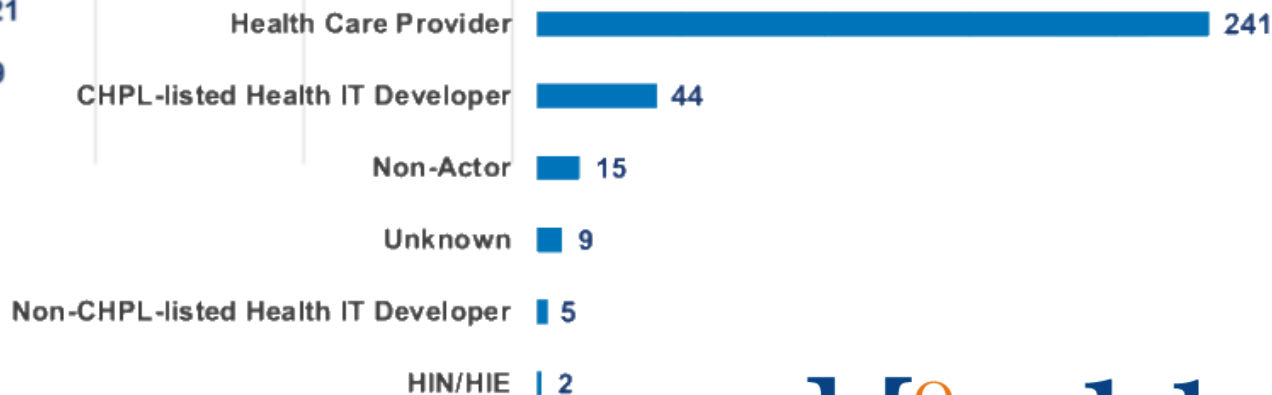
# Reports of Information Blocking

- ONC recently published reports of information blocking <https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>

Claims Counts by Type of Claimant



Claims Counts by Potential Actor



306 possible cases  
through February 2022

# 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. US Drug Formulary API
4. Payer-to-Payer Data Exchange
5. Increased Reporting on Dual Eligibles
6. Public Reporting and Information Blocking
7. Digital Contact Information
8. ADT Event Notifications

# Scope of the CMS Patient Access Final Rule

1. Patient Access API
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## 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



# Patient Access API Considerations/Barriers

- Payers needed 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](#))

# 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

# 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 needed 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 or authentication

# US Drug Formulary 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

# US Drug Formulary API Considerations/Barriers

- Payers needed to budget for system changes
- Uses emerging standards unfamiliar to current vendors with immature implementation guides
- Must share information with app developers without a data sharing agreement or authentication

# 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. US Drug Formulary API
- 4. Payer-to-Payer Data Exchange**
5. Increased Reporting on Dual Eligibles
6. Public Reporting and Information Blocking
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8. 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
  - Enforcement delayed until further rulemaking

# Payer to Payer Exchange Considerations/Barriers

- 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

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## 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

# Scope of the Final Rule

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# **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 was expected late 2020

# 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

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# 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

## 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



# 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?**