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Federal Health Information Technology Rules and Legislation

An Update for the e-Health Advisory Committee

July 17, 2020

Revised 07/22/2020

Presentation Overview 1

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- Overview of Recent Federal Final Rules regarding health information technology (Health IT)
- Federal Final Rules from the Department of Health and Human Services (US-DHHS)
  - The Centers for Medicare and Medicaid Services' (CMS) Interoperability and Patient Access Final Rule (CMS Final Rule)
  - The Office of the National Coordinator for Health Information Technology's (ONC's) Interoperability, Information Blocking, and the ONC Health Information Technology Certification Program Final Rule (ONC Final Rule)
  - US-DHHS Office of Inspector General's Draft Final Rule on Financial Penalties (OIG Draft Final Rule)

Presentation Overview 2

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- Trusted Exchange Framework and Common Agreement (TEFCA)
- Federal Health IT Strategic Plan, 2020-2025
- Report on Federal Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and Electronic Health Records (EHRs)

Overview of the Recent Federal Final Rules

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- Recent Final Rules:
  - Continue to advance EHR utilization & interoperability;
  - Impact providers, certified health electronic record technology (CEHRT) developers, payers and others and
  - Continue to improve patients' access to data.
- The United States Core Data for Interoperability (USCDI) is a new data standard to be used going forward.
- There is a consistent focus on Application Programming Interfaces (APIs) as a method for accessing data.
- "Electronic Health Information" (EHI) is a term for the electronic version of a patient's health information.
- Different rule requirements may have different effective, compliance and enforcement dates.

Entities and individuals should consult materials from the US-DHHS at www.cms.gov and www.HealthIT.gov for specific rule requirements and timelines.

CMS Final Rule

There are four (4) main policy areas addressed in the CMS Final Rule:

- Patient data access through APIs,
- Access through APIs to published provider directory data,
- Payer-to-payer data exchange and
- Increased frequency of state/federal data exchanges for dual-eligible enrollees.

The CMS Final Rule's web page is https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index#:~:text=CMS%20Interoperability%20and%20Patient%20Access%20final%20rule%201,Information%20Blocking%20%28applicable%20late%202020%29%20More%20items...%20.

CMS' Payer Data Access Policies

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Access through APIs to Published Provider Directory Data

- CMS-regulated payers must make provider directory information publicly available via a standards-based API.
- The compliance date is January 1, 2021. It will not be enforced until July 1, 2021.

Patient Data Access Through APIs

- CMS-regulated payers must use secure, standardized, open APIs to make claims and encounter data available to patients.
- The compliance date is January 1, 2021. It will not be enforced until July 1, 2021.

Additional CMS Payer Data Exchange Policies

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Payer-to-Payer Exchange

- Data exchange is driven by a patient's request.
- Data must be exchanged with all payers.
- Exchange is limited to USCDI.
- There is no requirement to change data format.
- Data received must be included in a patient's record.
- The requirement applies to data from service dates on or after January 1, 2016.
- Compliance date: January 1, 2022.

Increased Frequency of State/Federal Data Exchanges for Dual-Eligible Enrollees

- The change requires a shift to daily data exchange.
- Compliance date: April 1, 2022.

Applicability of CMS' Health Care Provider Policies

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- **Hospitals**
  Eligible hospitals (EH), short-term acute care hospitals, long-term care hospitals, rehabilitation hospitals, psychiatric hospitals, children's hospitals, cancer hospitals and critical access hospitals (CAHs).

- **Clinicians**
  Physicians and eligible clinicians (EC).

CMS' Health Care Provider Policies

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Admission, Discharge, and Transfer (ADT) Events Notifications

- Hospitals, including psychiatric hospitals and CAHs, must electronically send notifications to other healthcare facilities, another community provider or practitioner.

Public Reporting of Information Blocking

- CMS will publish reports on ECs, hospitals and CAHs that may be involved in information blocking.
- Data sources include attestations for Promoting Interoperability programs or Merit-based Incentive Payment System (MIPS).
- Compliance dates: Initial report will be based on 2019 attestations. Public reporting becomes applicable in late 2020.

CMS' Health Care Provider Policy on Public Reporting of Digital Contact Information

- In late 2020, CMS will begin publicly reporting providers who do not list or update their digital contact information in the National Plan and Provider Enumeration System (NPPES).
- Individual health care providers and facilities should update their NPPES record to ensure it includes digital contact information.

Topics Addressed in the ONC Final Rule

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- Health IT Certification Standards.
  - Regulations apply to Health IT developers developing CEHRT.
- Information Blocking.
  - When is information blocking allowable?
  - Regulations apply to:
    - Health care providers (Public Health Act definition),
    - CEHRT developers,
    - Health information networks and
    - Health information exchanges.
- Health IT for the Care Continuum.
  - The focus is on pediatrics and voluntary certification.
  - Regulations apply to:
    - Health IT developers developing CEHRT and
    - Health care providers.

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ONC Final Rule Background

- Authority for the rule is provided in Section 4004 of the 21st Century Cures Act (Act).
- The Act authorizes the US-DHHS to identify activities that **do not** constitute information blocking.
- The ONC Final Rule was released on March 9, 2020 and was published in the Federal Register on May 1, 2020.
- The ONC Final Rule impacts barriers to access and interfaces to health data by:
  - Requiring standardized APIs,
  - Establishing constraints on fees for accessing data,
  - Requiring open access to data and no evaluation of competitor status and
  - Requiring that patients have electronic access to all of their data.

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Information Blocking Defined

Information blocking is a practice that, except as required by law or allowed by an exception, is likely to interfere with the access to, exchange of or use of EHI.

Health IT developers, health information networks and health information exchanges may be considered to be information blockers when they know, or should know, a practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.

Health care providers may be considered to be information blockers when the provider knows that a practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

Reference:
https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingFinalRuleWebinar.pdf

Elements of Information Blocking

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The elements of information blocking include:

- The entity/individual regulated by the information blocking provision;
- EHI is involved;
- The practice is likely to interfere with the access, exchange, or use of EHI;
- The entity/individual has requisite knowledge;
- Limiting access to EHI is not required by law and
- The action is not covered by an exception included in applicable rules.

Exceptions to Information Blocking in ONC Final Rule

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Exceptions that involve procedures for **fulfilling** requests to access, exchange, or use EHI include:

- Content and Manner,
- Fees and
- Licensing.

Exceptions for **not fulfilling** requests to access, exchange or use EHI include:

- Preventing Harm,
- Privacy,
- Security,
- Infeasibility and
- Health IT Performance.

ONC Final Rule Initial Compliance Dates 1

Compliance with the provisions below is required by November 2, 2020.

- 45 CFR 170.401. Information blocking: Condition of Certification requirement.
- 402(a)(1). Assurances/Condition of Certification requirement. A health IT developer must provide assurances to US-DHHS that the health IT developer will not take any action that constitutes information blocking on and after November 2, 2020, unless the blocking is for a purpose specified by the US-DHHS. The developer may not take other action that may inhibit the appropriate exchange, access and use of EHI.

Reference: https://www.emids.com/cms-and-onc-final-rules-what-it-means-for-providers-and-payers

ONC Final Rule
Initial Compliance Dates 2

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Compliance with the provision below is required by November 2, 2020.

- 45 CFR part 171. Information Blocking/General Provisions. Exceptions that involve not fulfilling requests to access, exchange or use electronic health information; and exceptions that involve procedures for fulfilling requests to access, exchange or use electronic health information.

Reference: https://www.emids.com/cms-and-onc-final-rules-what-it-means-for-providers-and-payers

See https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf.

Select Changes in Certification Requirements 1

- **Adoption of the USCDI.** Requires CEHRT to support the USCDI as data classes to be available for health information exchange. Vendor compliance is required 24 months plus three months after the publication of the ONC Final Rule on May 1, 2020.
- **Clinical Quality Measures Report.** Requires transition to Health IT modules that support the CMS Quality Reporting Document Architecture (QRDA) Implementation Guide. Requirements that CEHRT support the Health Level 7 Quality Reporting Document Architecture standard have been removed. The effective date is 60 days after the publication of the ONC Final Rule on May 1, 2020.

Reference: https://www.emids.com/cms-and-onc-final-rules-what-it-means-for-providers-and-payers

Select Changes in Certification Requirements 2

- **EHI Export.** New functionality required to support patients' requests for a exported copy of their EHI. Vendor compliance is required 36 months plus three months after the publication of the ONC Final Rule on May 1, 2020.

Reference: https://www.emids.com/cms-and-onc-final-rules-what-it-means-for-providers-and-payers

Additional Changes in Certification Requirements

- **API.** Regulations have been updated to allow the request of one or more patients' data in a single transaction. APIs must support the Fast Healthcare Interoperability Resources (FHIR®) Release 4.

- **Security Tags and Consent Management**. Functionality to allow tagging of sections of a continuity of care document (CCD) that contain sensitive data is required. Transmitting a CCD, even if portions are restricted, must also be supported. Vendor compliance is required in 2022.

Reference: https://www.emids.com/cms-and-onc-final-rules-what-it-means-for-providers-and-payers

EHR Certification Criteria for Pediatric Care/Pediatric Settings

- ONC identified EHR certification criteria to support **voluntary** certification of health IT for pediatric care and pediatric settings.
- There is no current, published compliance date. Compliance dates will be established in future rulemaking.
- Providers may proactively implement the recommended functionality.

OIG Draft Final Rule

- The OIG Draft Final Rule was released on April 21, 2020.
- Comments were due on June 23, 2020.
- The OIG Draft Final Rule includes new Civil Money Penalty (CMP) authorities for information blocking activities by health IT developers or other entities providing CEHRT, health information exchanges and health information networks.
- Health care providers are NOT included in the OIG Draft Final Rule.
- Proposed penalty limit is $1,000,000 per violation. Each violation would be subject to a separate penalty.

TEFCA

TEFCA:

- Is a provision of the 21st Century Cures Act,
- Establishes a new framework for information exchange,
- Leverages existing infrastructure and organizations,
- Uses connections established between Qualified Health Information Networks (QHINs) and
- Has the Sequoia Project serving as the Responsible Coordinating Entity (RCE), selected by ONC.

The Sequoia Project established a workgroup consisting of representatives from QHINs in April 2020 to work on the Common Agreement, focusing on QHIN-QHIN interactions.

Updates are available at http://www.sequoiaproject.org.

Federal Health IT Strategic Plan, 2020-2025

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- The plan was produced by ONC in coordination with over 25 other federal organizations.
- This plan is intended to guide federal health information technology activities.
- The plan explains how federal government organizations intend to use health IT to:
  - Promote health and wellness;
  - Enhance the delivery and experience of care;
  - Build a secure, data-driven ecosystem to accelerate research and innovation and
  - Connect healthcare and health data through an interoperable health IT infrastructure.
- See https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan for additional information.

Federal Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

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The final report was released February 2020 at www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.

- The report outlines three primary goals and provides recommendations to:
  - Reduce the effort and time required to record information in EHRs for health care providers during care delivery;
  - Reduce the effort and time required to meet regulatory reporting requirements and
  - Improve the functionality and intuitiveness of EHRs.

Focus Areas for Reducing Regulatory and Administrative Burdens

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Four areas have been identified as critical in reducing burdens:

- Clinical documentation,
- Health IT usability/ease of use of health IT tools and systems,
- Federal health IT and EHR reporting requirements and
- Public health reporting and prescription drug monitoring programs.

Questions/ Thank You

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Presentation Contact:

Steve Eichner
Health Information Technology Lead
Center for Health Policy and Performance
Texas Department of State Health Services
Steve.Eichner@dshs.texas.gov
Ph: 512.221.5632