Epoch or Evolution:

The Impact of 21st Century Cures on Health Information Exchange

Joint Advocacy/ HIE Committee Webinar Series

Webinar 1 of 2

June 30, 2020

HIMSS NEW ENGLAND CHAPTER

Next Step or Major Leap:

Analysis of the Impact 21st Century Cures will have on Health Information Exchange and Industry Stakeholders

Chris Emper, JD, MBA. President of Emper Healthcare Advisors
John D'Amore, MS. President & Founder Diameter Health

June 30, 2020

Agenda

Analysis of the Impact 21st Century Cures will have on Health Information Exchange and Industry Stakeholders

- **Overview of the new 21st Century Cures legislation:**

  the related ONC/ CMS new regulations, and the implications to information exchange

- **Changing landscape:**

  how will new regulations and industry initiatives that are intended to promote improved data access and data exchange impact HIEs and other key stakeholders

Welcome

Introductions

Chris Emper, JD, MBA.
President Emper Healthcare Advisors

John D'Amore, MS.
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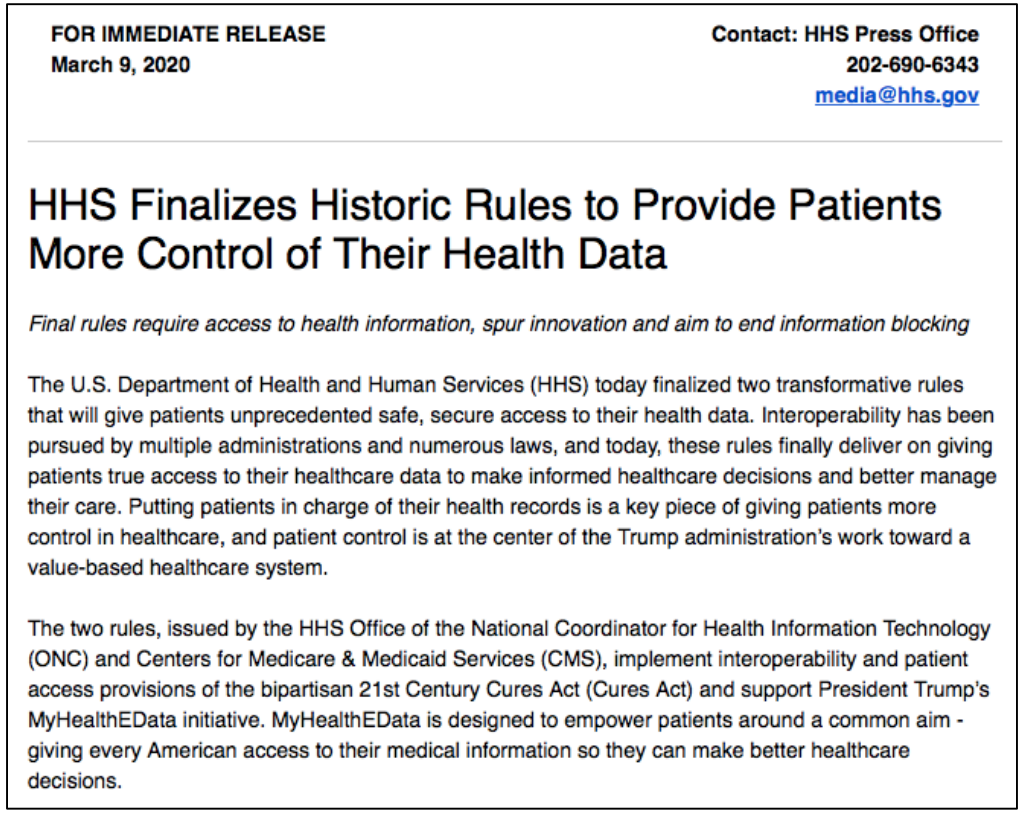
Chris Emper, JD, MBA.
President
Emper Healthcare Advisors

Chris Emper, JD, MBA, is President of Emper Healthcare Advisors, a health IT industry advisory and consulting services firm in Washington, D.C. that specializes in helping healthcare providers and technology companies successfully navigate and comply with complex regulations and value-based reimbursement models. Chris has served as a consultant and executive advisor to industry leading technology and service companies, startups, investors, and provider organizations of all shapes and sizes. Prior to forming Emper Healthcare Advisors in 2016, Chris was Vice President of Government Affairs at NextGen Healthcare (NASDAQ: NXGN) and Chair of the Electronic Health Record Association (EHRA) Public Policy committee.

An expert in The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); The Patient Protection and Affordable Care Act (ACA); The 21st Century Cures Act; and The Coronavirus Aid, Relief, and Economic Security (CARES) Act, Chris is a frequent keynote speaker at industry conferences and has written or appeared in articles in publications such as Politico, Health Data Management, Accountable Care News, and Medical Economics. From 2016-2019, Chris served as Chair of the HIMSS Government Relations Roundtable, a leading coalition of health IT government affairs professionals.

Prior to joining NextGen Healthcare in 2013, Chris served as a Domestic Policy Advisor for former Massachusetts Governor Mitt Romney's 2012 Presidential Campaign, where he advised the campaign on policy issues including healthcare, technology, and innovation. He holds a law degree and an MBA from Villanova University and a BA from Boston College.

Final interoperability rules released in March



FOR IMMEDIATE RELEASE
March 9, 2020

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Finalizes Historic Rules to Provide Patients More Control of Their Health Data

Final rules require access to health information, spur innovation and aim to end information blocking

The U.S. Department of Health and Human Services (HHS) today finalized two transformative rules that will give patients unprecedented safe, secure access to their health data. Interoperability has been pursued by multiple administrations and numerous laws, and today, these rules finally deliver on giving patients true access to their healthcare data to make informed healthcare decisions and better manage their care. Putting patients in charge of their health records is a key piece of giving patients more control in healthcare, and patient control is at the center of the Trump administration's work toward a value-based healthcare system.

The two rules, issued by the HHS Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare & Medicaid Services (CMS), implement interoperability and patient access provisions of the bipartisan 21st Century Cures Act (Cures Act) and support President Trump's MyHealthEData initiative. MyHealthEData is designed to empower patients around a common aim - giving every American access to their medical information so they can make better healthcare decisions.

- 474-page rule from the Centers for Medicare & Medicaid Services (CMS) released on March 9
- 1,244-page rule from the Office of the National Coordinator for Health Information Technology (ONC) released on March 9
- Follows controversial February 2019 proposed rules & extended public comment period
- Certain policies included in the rules were required by the 2016 *21st Century Cures Act* law
- Rules scheduled for release at HIMSS annual conference in early March with a speech from President Trump (both cancelled due to COVID-19)
- Rules were officially published in the Federal Register on May 1 (impacts compliance dates)

Legislative & Political Background on the "Cures" Act

The 21st Century Cures Act (Cures)

- ✓392–26 House vote
- ✓94–5 Senate vote
- ✓Dec. 13, 2016 signed into law by President Obama
- ✓~100 pages of health IT policies focused mostly on interoperability

- Law focused on FDA reform, genomic research, and cancer research policies and funding
- Health IT policies were included in the law to address the perceived failures of the meaningful use EHR incentive program & 2009 HITECH Act
- Support for interoperability remains a bipartisan political issue

Pre COVID-19: Administration's Health Policy Agenda

HHS Secretary Alex Azar pivoted from ACA repeal to four new priorities in 2018:

1. **Combating the opioid crisis**
2. **Bringing down the high price of prescription drugs**
3. **Addressing the cost and availability of insurance**
4. **Value-based transformation of America's healthcare system**

Pre COVID-19: HHS plan for value-based transformation

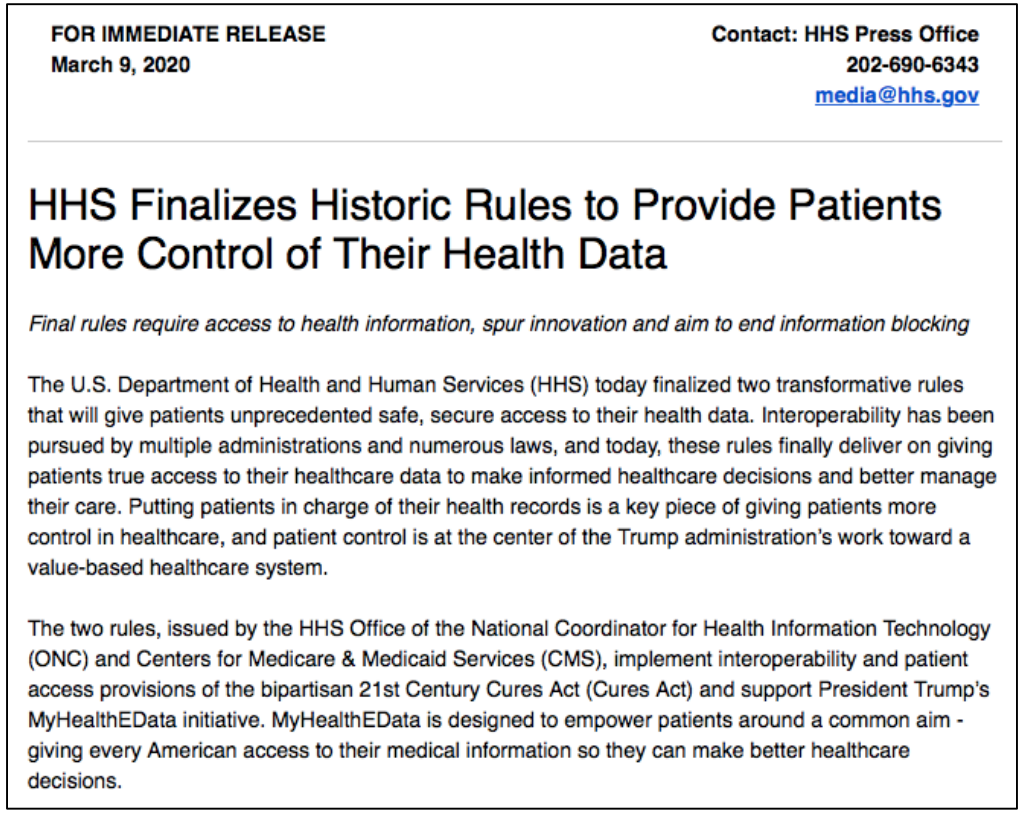
"I want to lay out four particular areas of emphasis that will be vital to laying down new rules of the road, accelerating value-based transformation, and creating a true market for healthcare…

1) ***Giving consumers greater control over health information…;***
2) ***Encouraging transparency from payers and providers;***
3) ***Using experimental models in Medicare and Medicaid to drive value and quality…;***
4) ***Removing government burdens that impede this transformation."***

-HHS Secretary Alex Azar, March 2018

1) **Data Interoperability**
2) **Price transparency**
3) **Value-based payments**
4) **Burden reduction**

Final interoperability rules released in March



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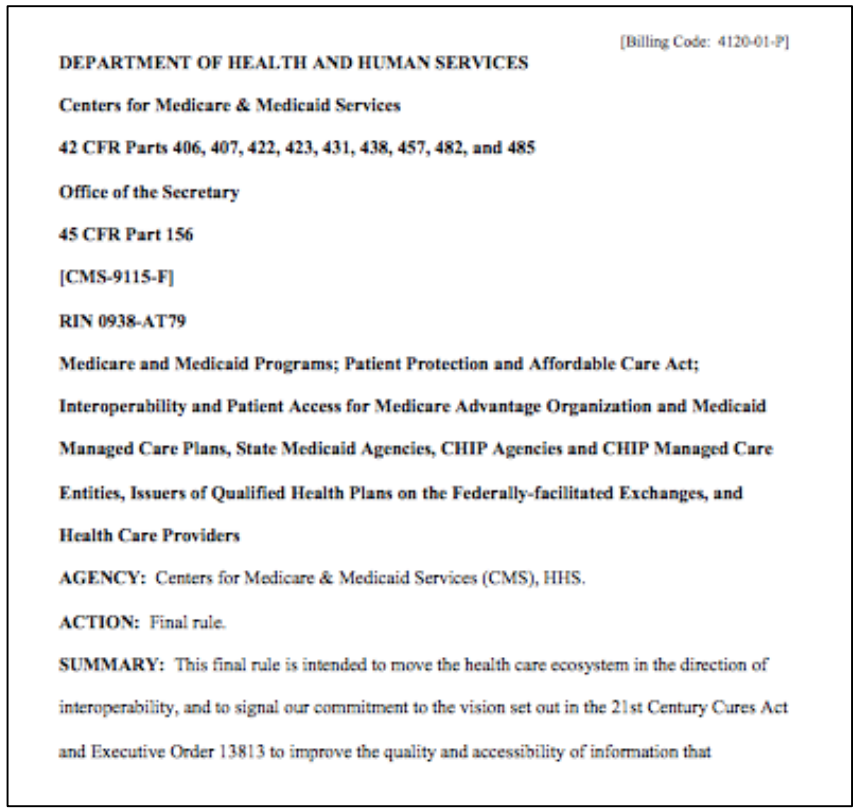
CMS Interoperability & Patient Access final rule



[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 422, 423, 431, 438, 457, 482, and 485

Office of the Secretary

45 CFR Part 156

[CMS-9115-F]

RIN 0938-AT79

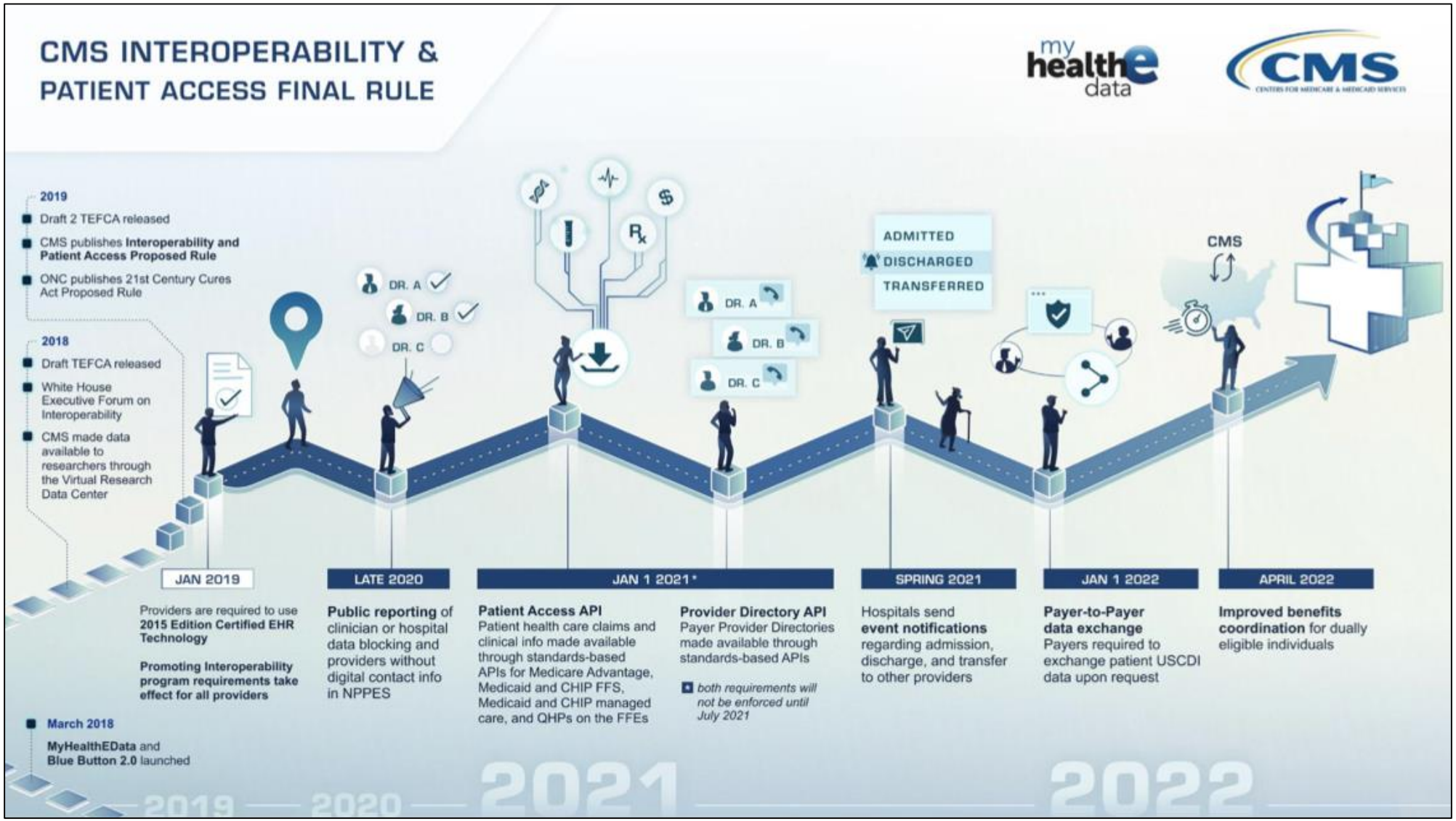
Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

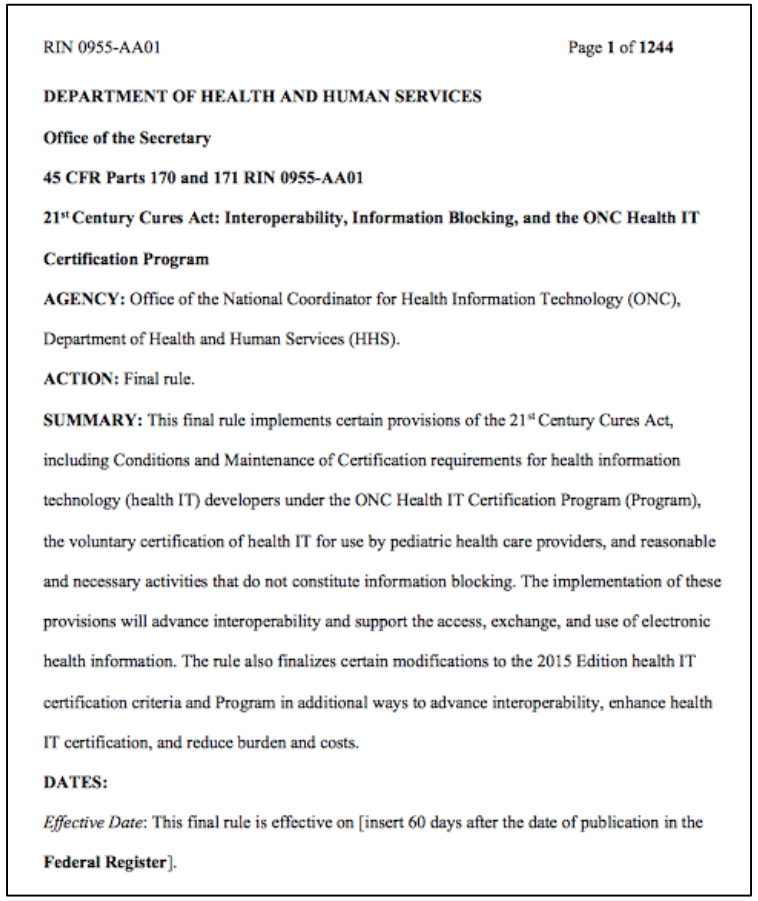
ACTION: Final rule.

SUMMARY: This final rule is intended to move the health care ecosystem in the direction of interoperability, and to signal our commitment to the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve the quality and accessibility of information that

- **Patient Access API (payers): r**equires CMS-regulated payers *(Medicare Advantage, Medicaid, CHIP, ACA exchanges)* to provide patient access to claims and clinical data via an application programming interface (API)
  - Compliance begins July 1, 2021
  - Requires HL7 Fast Healthcare Interoperability Resources (FHIR) 4.0.1) standard
- **ADT Event Notifications (hospitals):** requires hospitals to send electronic patient event notifications of an admission, discharge, and/or transfer (ADT) to another healthcare facility, PCP, or provider
  - Compliance begins May 1, 2021
  - Loosely defines recipient care team members and does not specify a standard for the content, format, or delivery


CMS INTEROPERABILITY &
PATIENT ACCESS FINAL RULE
my healthe data
CMS
2019
Draft 2 TEFCA released
CMS publishes Interoperability and Patient Access Proposed Rule
ONC publishes 21st Century Cures Act Proposed Rule
2018
Draft TEFCA released
White House Executive Forum on Interoperability
CMS made data available to researchers through the Virtual Research Data Center
March 2018
MyHealthEData and Blue Button 2.0 launched
DR. A
DR. B
DR. C
ADMITTED
DISCHARGED
TRANSFERRED
CMS
JAN 2019
Providers are required to use 2015 Edition Certified EHR Technology
Promoting Interoperability program requirements take effect for all providers
LATE 2020
Public reporting of clinician or hospital data blocking and providers without digital contact info in NPPES
JAN 1 2021*
Patient Access API
Patient health care claims and clinical info made available through standards-based APIs for Medicare Advantage, Medicaid and CHIP FFS, Medicaid and CHIP managed care, and QHPs on the FFEs
Provider Directory API
Payer Provider Directories made available through standards-based APIs
* both requirements will not be enforced until July 2021
SPRING 2021
Hospitals send event notifications regarding admission, discharge, and transfer to other providers
JAN 1 2022
Payer-to-Payer data exchange
Payers required to exchange patient USCDI data upon request
APRIL 2022
Improved benefits coordination for dually eligible individuals
2019
2020
2021
2022

ONC Cures Act final rule



RIN 0955-AA01 Page 1 of 1244

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171 RIN 0955-AA01

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule implements certain provisions of the 21st Century Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information. The rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

DATES:

Effective Date: This final rule is effective on [insert 60 days after the date of publication in the **Federal Register**].

- Bipartisan *21st Century Cures Act* was passed and signed into law in December 2016
- Law included ~100 pages of health IT policies intended to "cure" the perceived interoperability failures of the meaningful use (MU) program
- Final rule includes two main categories of health IT policies:
  1) EHR certification program changes
  2) Implementation of information blocking statute

> "***Delivering interoperability actually gives patients the ability to manage their healthcare the same way they manage their finances, travel and every other component of their lives.***
>
> ***This requires using modern computing standards and APIs that give patients access to their health information and give them the ability to use the tools they want to shop for and coordinate their own care on their smartphones."***
>
> -Don Rucker, M.D., national coordinator for health information technology

EHR certification program changes

1) New certification criteria (*required product functions*)

- Rule finalizes new and revised EHR certification criteria that EHR companies will have to develop, test, and bring their clients live on within 24 months of official publication of the rule to maintain federal certification (required for providers in MIPS, ACOs, CPC+, other APMs)
- Application Programming Interface (API) Criterion must meet the HL7 Fast Healthcare Interoperability Resources (FHIR) Release 4 standard and implementation specifications
- 36-month deadline for Electronic Health Information Export Criterion

2) New certification program requirements (*required business practices & actions*)

- "*Conditions and Maintenance of Certification Requirements*" are a list of six new business practices or actions that EHR companies must meet to maintain certification

Conditions of Certification & Maintenance of Certification Requirements
• Information Blocking
• Assurances
• Communications (i.e. gag clauses, screenshots)
• Application Programming Interfaces (APIs)
• Real World Testing
• Attestations
• EHR Reporting Criteria Submission (TBD)

Information Blocking: Overview

§ 171.103 Information blocking:

"Information blocking means 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, prevent, or materially discourage access, exchange, or use of electronic health information****."*

What are the exceptions?

- ✓ Cures Act authorized HHS to identify reasonable and necessary activities that do not constitute information blocking
- ✓ This rule finalizes eight exceptions for practices that are reasonable and necessary, provided certain conditions are met

Regulated "actors":

- ✓ Health IT Developers of Certified Health IT
- ✓ Health Information Exchanges
- ✓ Health Information Networks
- ✓ Health Care Providers*

*Health Care Providers**

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical center
- emergency medical services provider
- federally qualified health center
- group practice
- pharmacist
- pharmacy
- laboratory
- physician
- practitioner
- provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- rural health clinic
- "covered entity" under 42 U.S.C. 256b
- therapist

Information Blocking: 8 Exceptions

Exceptions that involve not fulfilling requests to access, exchange, or use EHI	Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI
• Preventing Harm • Privacy • Security • Infeasibility • Health IT performance	• Content and manner • Fees • Licensing

*"**An actor's practice that does not meet the conditions of an exception will not automatically constitute information blocking. Instead such practices will be evaluated on a case-by-case basis to determine whether information blocking has occurred.**" -ONC*

Information Blocking: covered info, penalties, & compliance timeline

Definition of "Electronic Health Information"

- Electronic protected health information (ePHI) is defined to the extent that the ePHI is included in a designated record set as these terms are **defined for HIPAA**.
- ePHI for purposes of the information blocking definition is limited to the EHI identified by the data elements represented in the **USCDI** standard until **24 months** after the publication date of the final rule.

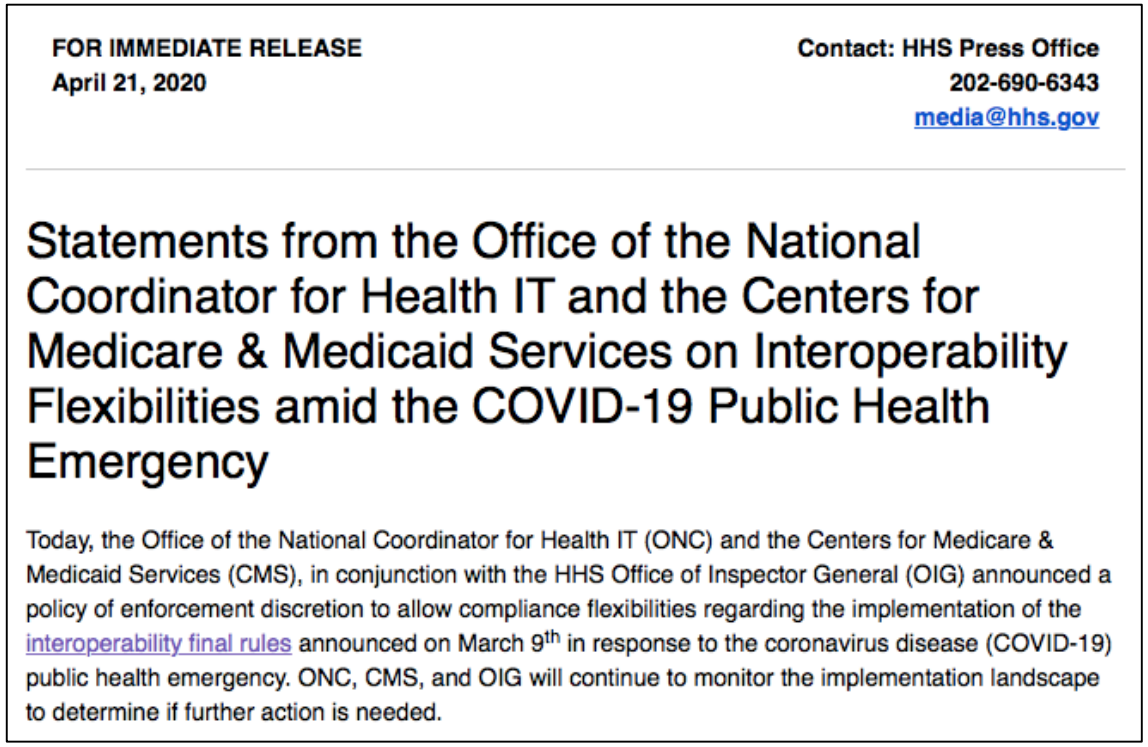
Information Blocking Penalties

- Health IT developers of certified health IT, health information networks, and health information exchanges will be subject to civil monetary penalties of **up to $1 million per violation.**
- Healthcare providers will be subject to "***appropriate disincentives***". The rule discusses the comments received regarding the potential nature of disincentives, but said they will be established by future rulemaking.

Compliance Timeline

- Actors do not have to comply with the information blocking provision until **six months** after publication of the final rule: **November 1.**
- Enforcement of information blocking civil monetary penalties will not begin until established by future rulemaking by the HHS Office of the Inspector General (OIG). As a result, actors will not be subject to penalties **until that rule is final**.
- Enforcement of "*appropriate disincentives*" for providers will **not begin until** that rulemaking is finalized.

Final interoperability rules officially published, compliance deadlines delayed



FOR IMMEDIATE RELEASE
April 21, 2020

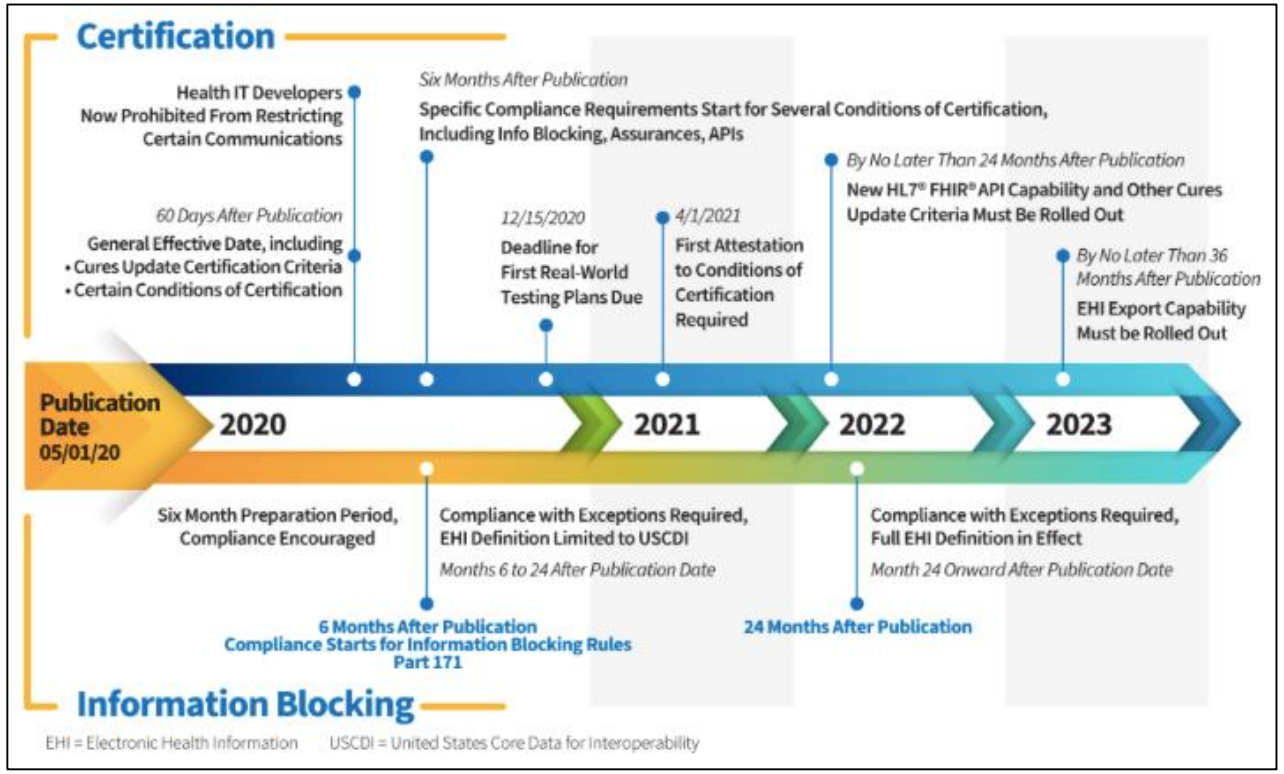
Contact: HHS Press Office
202-690-6343
media@hhs.gov

Statements from the Office of the National Coordinator for Health IT and the Centers for Medicare & Medicaid Services on Interoperability Flexibilities amid the COVID-19 Public Health Emergency

Today, the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare & Medicaid Services (CMS), in conjunction with the HHS Office of Inspector General (OIG) announced a policy of enforcement discretion to allow compliance flexibilities regarding the implementation of the interoperability final rules announced on March 9th in response to the coronavirus disease (COVID-19) public health emergency. ONC, CMS, and OIG will continue to monitor the implementation landscape to determine if further action is needed.

- Rules officially published in Federal Register on May 1, setting compliance deadlines 2, 6, 24, 36 months from May 1
- CMS announced it will exercise enforcement discretion for 6 months after insurer and hospital compliance dates
- ONC announced it will exercise enforcement discretion for 3 months after certain certification program compliance dates
- HHS Office of the Inspector General (OIG) also released its proposed rule on enforcement for information blocking and said it wont enforce information blocking penalties until 60 days after that final rule is published

Interoperability Final Rules: Compliance Impact



The Office of the National Coordinator for Health Information Technology

CERTIFICATION

CURES ACT FINAL RULE

Enforcement Discretion Dates and Timeframes

Provision	Compliance Date/Timeframe	Enforcement Discretion Date/Timeframe
Condition of Certification (CoC) – Information Blocking	6 months after final rule publication	3 months after the compliance timeframe
CoC – Assurances – Will not take any action that constitutes information blocking or actions that inhibit access, exchange, and use of electronic health information (EHI)	6 months after final rule publication	3 months after the compliance timeframe
CoC – Assurances – EHI Export Rollout	36 months after final rule publication	3 months after the compliance timeframe
CoC – Assurances – Other	Effective date of final rule	3 months after the compliance date
CoC – Communications – Notice to all customers with which developer has contracts or agreements containing provisions that contravene Communications CoC	Annually beginning in calendar year 2020	Notice can be made until March 31, 2021 for the 2020 calendar year
CoC – Communications – Other	Effective date of final rule	3 months after the compliance date
CoC – Application Programming Interface (API) – Compliance by Certified API Developers with health IT certified to ***current*** API criteria	6 months after final rule publication	3 months after the compliance timeframe
CoC – API – Rollout of new standardized API functionality	24 months after final rule publication	3 months after the compliance timeframe
CoC – Real World Testing (RWT) – Submit ***initial*** plan and ***initial*** results submission	Plan: December 15, 2020 Results: March 15, 2022	Generally remains the same, except for initial cycle for the annual submissions **Initial Plan**:Initial RWT plans (i.e., 2021 RWT plans) may be submitted through March 15, 2021 **Initial Results**: Initial RWT results from the 2021 performance year may be submitted up through June 2022
CoC – RWT – Updates to United States Core Data for Interoperability (USCDI)	24 months after final rule publication	3 months after the compliance timeframe
CoC – *Initial* Attestations	April 1-30, 2021 attestation window for attestation period running from the effective date of final rule through March 31, 2021	Generally remains the same except for the initial attestation, which will now be accepted through July 30, 2021

Agenda

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- **Changing landscape:**

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John D'Amore, MS.
President, Head of Informatics and co-Founder, Diameter Health

John D'Amore, MS has over fifteen years of experience providing informatics and strategic insight to healthcare organizations. He is co-Founder of Diameter Health and is dedicated to improving healthcare quality and efficiency through the intelligent use of data.
Previously, John was Vice President at Eclipsys (now Allscripts) overseeing enterprise performance management solutions. Before then, John worked at the largest health system in Texas overseeing clinical informatics, decision support and business intelligence.

John has published on best practices in population health and presented at national forums on how information technology can improve medical outcomes. He is a technical advisor to the National Committee for Quality Assurance and an editor of HL7's standard for care summaries, the Consolidated Clinical Document Architecture. He holds a biochemistry degree from Harvard University and a graduate degree in clinical informatics from the University of Texas, School of Biomedical Informatics. John has also taught as adjunct faculty in Health Informatics at Boston University's Metropolitan College.

Biggest Take-Away

Health Plans (2021/2022)

HL7® FHIR®

Providers (2022/2023)

Release 4

FHIR R4 & US CORE Specifications
https://www.hl7.org/fhir/us/core/

HL7® FHIR® **Release 4**

HL7® FHIR® **US CORE (STU 3.1)**

Main profiles

- US Core AllergyIntolerance Profile
- US Core CarePlan Profile
- US Core CareTeam Profile
- US Core Condition Profile
- US Core DiagnosticReport Profile
- US Core DocumentReference Profile
- US Core Encounter Profile
- US Core Goal Profile
- US Core Immunization Profile
- US Core Implantable Device Profile
- US Core Observation Profile
- US Core MedicationRequest Profile
- US Core Patient Profile
- US Core Procedure Profile

Overall Support

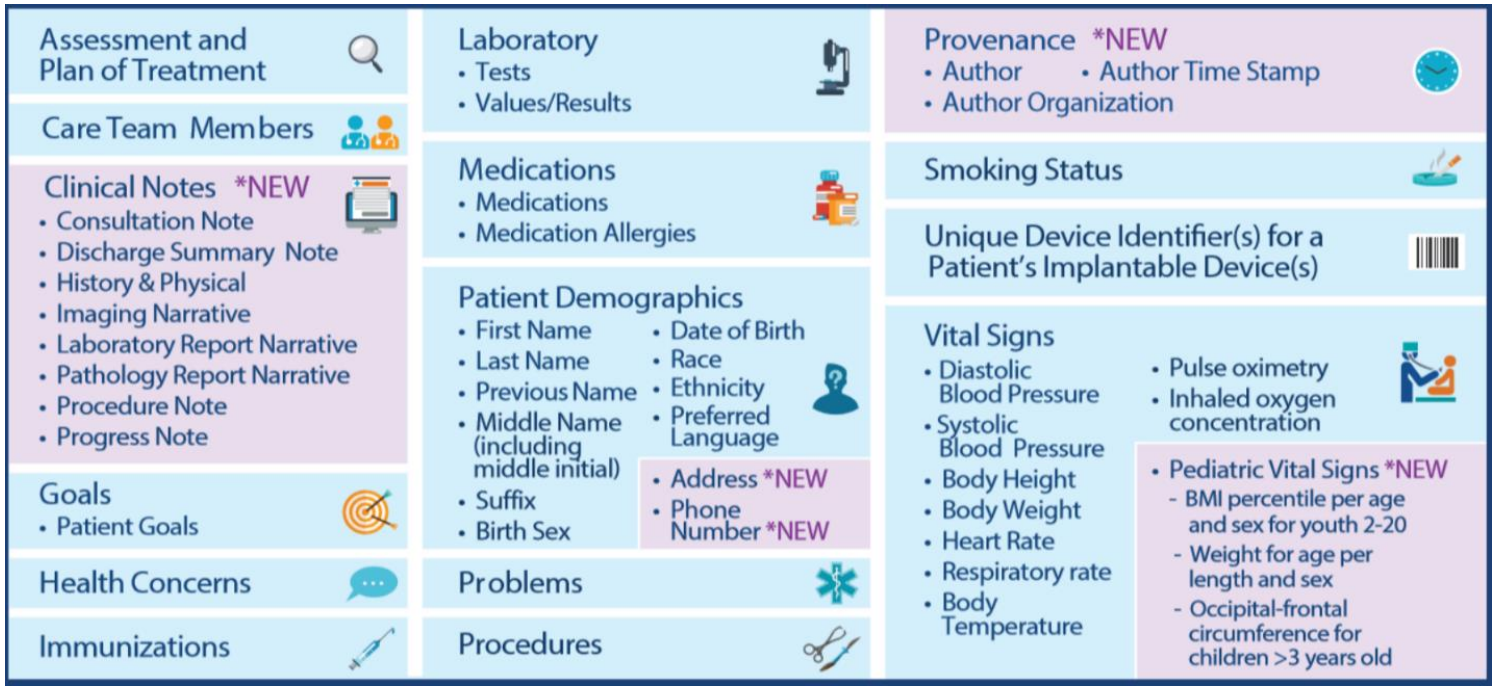
- US Core Location Profile
- US Core Organization Profile
- US Core Practitioner Profile
- US Core PractitionerRole Profile

Observation Support

- US Core Pediatric BMI for Age Observation Profile
- US Core Pediatric Weight for Height Observation Profile
- US Core Provenance Profile
- US Core Pulse Oximetry Profile
- US Core Smoking Status Observation Profile

Other

- US Core Medication Profile
- US Core Diagnostic Report, Lab Result & Notes



US Core Data for Interoperability (USCDI)

Interoperability Standards Advisory (ISA)

Representing Patient Vital Signs

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A
Standard	ISO/IEEE 11073 Health informatics - Medical / health device communication standards	Final	Production	●●●○○	No	$	Yes Yes

FHIR R4 & CARIN Alliance Profiles http://build.fhir.org/ig/HL7/carin-bb/

- CPCDS (Common Payer Consumer Data Set)
- FHIR ExplanationOfBenefit
  - ExplanationOfBenefit
  - ExplanationOfBenefitInpatientFacility
  - ExplanationOfBenefitOutpatientFacility
  - ExplanationOfBenefitPharmacy
  - ExplanationOfBenefitProfessionalNonClinician

ICD-10 Diagnoses

ICD-10 Procedures

Encounters

Provider Info

Co-pay / deductible

Total Payment / Cost

What are the FHIR Combustibles?

Consumers & Phone Apps (2021)

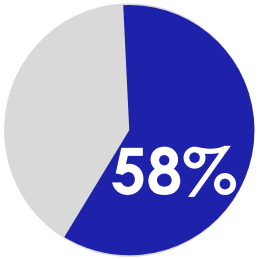
Health Plans (2022)

EHR Apps (2023+)

Thinking about HIE for Health Plans

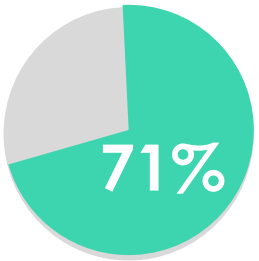
- **Welcome to the show!**
- **Every health plan I've spoken with is under-prepared for the current and future deluge of standards-based exchange. How under-prepared are you?**

How would you assess your organization's readiness to meet the new CMS Patient Access regulations?



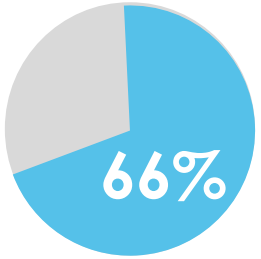
Behind or Don't Know

How would you assess the quality of clinical data that your organization receives?



Needs Work / All Over the Board

How is COVID-19 affecting your organization's use of digital clinical data?



Accelerating Need

Source: AHIP May 19 2020 Webinar. Using Clinical Data to Succeed in Uncertain Times - AHIP

Find the HIE in this picture…

Thinking about HIE (Verb) for HIEs (Noun)

- **The value of "just" exchanging data is rapidly diminishing**
- **FHIR is still read-only. EHRs will permit write, but only if they want to**
- **API directories will get really, really confusing**
- **Data quality & a comprehensive perspective will differentiate**
- **Security, privacy and trust still matter**

Information Blocking

TLDR;

- **It's bad, don't do it! (unless you have a good reason)**
- **Data is free for patients**
- **Data charges must be proportionate to costs and not disadvantage competitors**

Questions?

Christopher Emper, JD, MBA
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John D'Amore, MS
jdamore@diameterhealth.com

Thank you

… be on the look out for our survey

Up Next: Epoch or Evolution (Webinar 2 of 2)

July 14, 2020

Leading Through Change:

How the Nation's Leading HIEs are Delivering Value in a Rapidly Changing HIT Landscape

Visit our events page for more details on this and all our events

http://ne.himsschapter.org/Events/index.aspx