

21st Century Cures Act Overview for States

SIM State Educational Session 1 An Overview of the 21st Century Cures Act for States

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Goals for These Learning Sessions

1. What does the Cures Act say?

Not seeking to interpret the Cures Act, but extracting important language associated with key topics of potential interest to states. Use this information to plan your own activities and understand how the Cures Act may have an impact on your projects.

2. Who is responsible for each action?

The Cures Act usually identifies the party responsible for completing each of the actions it identifies, often in collaboration with others. Use this information as a basis for who to monitor in order to keep abreast of progress, and how best to participate in public forums, if any.

3. When is each action due?

The Cures Act usually identifies dates by which progress is due. Use this information in planning your own activities, and for a general sense of the timeline for Cures Act activities.



Goal for Today

- An overview of What, Who, and When for each of the topic areas of Title IV of the Cures Act, which focuses on Delivery
 - » An introduction to the contents of the Cures Act of interest to states, identifying what it is to accomplish and ONC's role
 - » Future sessions will provide more detail on individual topics
- Key outcome
 - » Begin to think about how to apply outcomes of the Cures Act to your own initiatives

For details of the 21st Century Cures Act, see

Summary: https://www.congress.gov/bill/114th-congress/house-bill/34

Full Text: https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf



History of the 21st Century Cures Act

| 01/06/2015 | Introduced in House |
|------------|--|
| 01/07/2015 | Passed/agreed to in House |
| 10/06/2015 | Passed/agreed to in Senate: Passed Senate with an amendment |
| 11/30/2016 | House actions: House agreed with an amendment to the Agreed to |
| 12/07/2016 | Senate actions: Senate agreed to the House amendment to the Senate amendment |
| 12/08/2016 | Presented to President |
| 12/13/2016 | Signed by President and became Public Law |



21st Century Cures Act

Title IV – **DELIVERY**

- Sec. 4001. Assisting doctors and hospitals in improving quality of care for patients.
- Sec. 4002. Transparent reporting on usability, security, and functionality.
- Sec. 4003. Interoperability.
- Sec. 4004. Information blocking.
- Sec. 4005. Leveraging electronic health records to improve patient care.
- Sec. 4006. Empowering patients and improving patient access to their electronic health information.
- Sec. 4007. GAO study on patient matching.
- Sec. 4008. GAO study on patient access to health information.
- Sec. 4009. Improving Medicare local coverage determinations.
- Sec. 4010. Medicare pharmaceutical and technology ombudsman.
- Sec. 4011. Medicare site-of-service price transparency.
- Sec. 4012. Telehealth services in Medicare.



Assisting doctors and hospitals in improving quality of care for patients

- 4001(a) Amends the HITECH Act to require HHS to establish a goal, develop a strategy, and make recommendations to reduce regulatory or administrative burdens relating to the use of EHRs
- 4001(b) ONC must encourage, keep, or recognize the certification of health IT for use in medical specialties
 - HHS must adopt certification criteria to support health IT for pediatrics, and begin certification soon after
- 4001(c) HHS must publish attestation statistics for the Medicare and Medicaid EHR Incentive Programs to Health Information Technology Advisory Committee

Transparent reporting on usability, security, and functionality

- 4002(a) Requires HHS through notice and comment rulemaking to require, as a condition of certification and maintenance of certification, that the HIT developer or entity "does not take any action that constitutes information blocking" (as defined in Section 3022(a) of the Public Health Service Act, as amended), or "any other action that may inhibit the appropriate exchange, access, and use of electronic health information"
- 4002(b) A health care provider whose adopted health IT is decertified is exempted from the application of a payment adjustment
- 4002(c) HHS must support the convening of stakeholders to develop reporting criteria

Interoperability

4003(a) Defines Interoperability as:

The term 'interoperability', with respect to health information technology, means such health information technology that—

- A. enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
- B. allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
- C. does not constitute information blocking as defined in section 3022(a) of the PHSA as amended.

Trusted Exchange Framework and Common Agreement

21st Century Cures Act - Section 4003(b)

"Not later than 6 months after the date of enactment of the 21st Century Cures Act, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

"(I) a common method for authenticating trusted health information network participants;

"(II) a common set of rules for trusted exchange;

"(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

"(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement."

21st Century Cures Act - Section 4003(c)

"Not later than 1 year after convening stakeholders...the National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed or supported under paragraph B..."



Format of the Draft Trusted Exchange Framework

Part A—Principles for Trusted Exchange

General principles that provide guardrails to engender trust between Health Information Networks (HINs). Six (6) categories:

- » **Principle 1 Standardization:** Adhere to industry and federally recognized standards, policies, best practices, and procedures.
- » Principle 2 Transparency: Conduct all exchange openly and transparently.
- » Principle 3 Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange electronic health information, even when a stakeholder may be a business competitor.
- » Principle 4 Security and Patient Safety: Exchange electronic health information securely and in a manner that promotes patient safety and ensures data integrity.
- » Principle 5 Access: Ensure that patients and their caregivers have easy access to their electronic health information.
- » Principle 6 Data-driven Accountability: Exchange multiple records at one time to enable identification and trending of data to lower the cost of care and improve the health of the population.



Part B—Minimum Required Terms and Conditions for Trusted Exchange

A minimum set of terms and conditions for the purpose of ensuring that common practices are in place and required of all participants who participate in the Trusted Exchange Framework, including:

- » Common authentication processes of trusted health information network participants;
- » A common set of rules for trusted exchange;
- » A minimum core set of organizational and operational policies to enable the exchange of electronic health information among networks.



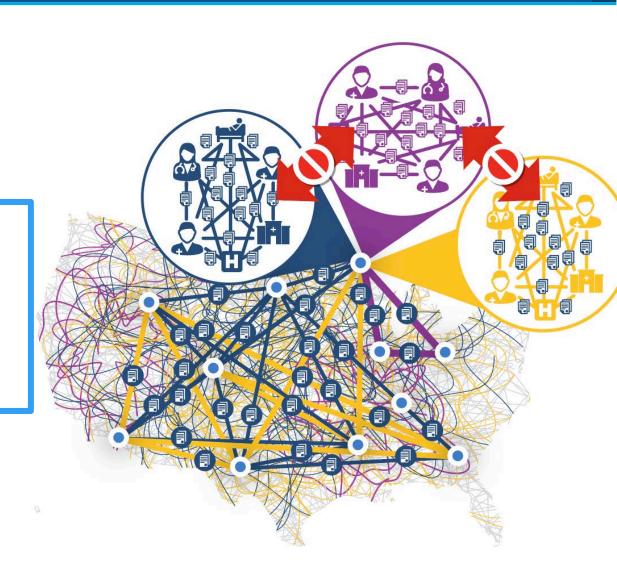
Need for the Trusted Exchange Framework – Complexity

OF AGREEMENTS

Many organizations have to join multiple Health Information Networks (HINs), and the HINs do not share data with each other.

Trusted exchange must be simplified in order to scale.

Each line color on the map represents a different network. There are well over 100 networks in the U.S.



Need for the Trusted Exchange Framework – Costs

Costs to healthcare providers due to lack of Trusted Exchange Framework

Healthcare organizations are currently burdened with creating many costly, point-to-point interfaces between organizations.

The Trusted Exchange Framework will significantly reduce the need for individual interfaces, which are costly, complex to create and maintain, and an inefficient use of provider and health IT developer resources.



Proliferation of Interoperability Methods

Based on a pilot survey of roughly 70 hospitals:

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Few hospitals used only one interoperability method.

- A majority of hospitals required three or more methods
- About three in 10 used five or more methods

Rated their own Interoperability as...

63% Not or a little bit interoperable

17% Somewhat interoperable

19% Largely or Fully interoperable

Goals of the Draft Trusted Exchange Framework



GOAL 1 Build on and extend existing work done by the industry

The Draft Trusted
Exchange Framework
recognizes and builds
upon the significant work
done by the industry over
the last few years to
broaden the exchange of
data, build trust
frameworks, and develop
participation agreements
that enable providers to
exchange data across
organizational boundaries.

GOAL 2 Provide a single "on-ramp" to interoperability for all

The Draft Trusted Exchange
Framework provides a single
"on-ramp" to allow all types
of healthcare stakeholders to
join any health information
network they choose and be
able to participate in
nationwide exchange
regardless of what health IT
developer they use, health
information exchange or
network they contract with, or
where the patients' records
are located.

GOAL 3 Be scalable to support the entire nation

The Draft Trusted
Exchange Framework aims
to scale interoperability
nationwide both
technologically and
procedurally, by defining a
floor, which will enable
stakeholders to access,
exchange, and use
relevant electronic health
information across
disparate networks and
sharing arrangements.

GOAL 4 Build a competitive market allowing all to compete on data services

Easing the flow of data will allow new and innovative technologies to enter the market and build competitive, invaluable services that make use of the data.

GOAL 5 Achieve long-term sustainability

By providing a single "onramp" to nationwide interoperability while also allowing for variation around a broader set of use cases, the Draft Trusted Exchange Framework ensures the long-term sustainability of its participants and end-users.



Stakeholders who can use the Trusted Exchange Framework

HEALTH INFORMATION NETWORKS

FEDERAL AGENCIES

Federal, state, tribal, and local governments

INDIVIDUALS

Patients, caregivers, authorized representatives, and family members serving in a non-professional role

PROVIDERS

Professional care providers who deliver care across the continuum, not limited to but including ambulatory, inpatient, long-term and post-acute care (LTPAC), emergency medical services (EMS), behavioral health, and home and community based services

PUBLIC HEALTH

Public and private organizations and agencies working collectively to prevent, promote and protect the health of communities by supporting efforts around essential public health services

PAYERS

Private payers, employers, and public payers that pay for programs like Medicare, Medicaid, and TRICARE

TECHNOLOGY DEVELOPERS

Organizations that provide health IT capabilities, including but not limited to electronic health records, health information exchange (HIE) technology, analytics products, laboratory information systems, personal health records, Qualified Clinical Data Registries (QCDRs), registries, pharmacy systems, mobile technology, and other technology that provides health IT capabilities and services



Trusted Exchange Framework Benefits for HINs

For Qualified HINs and HINs the Trusted Exchange Framework will:



Give HINs and their participants access to more data on the patients they currently serve.

This will enhance care coordination and care delivery use cases.

The Trusted Exchange Framework ensures that there is no limitation to the aggregation of data that is exchanged among Participants.



 This will allow organizations, including Health IT Developers, HINs, Qualified Clinical Data Registries (QCDRs), and other registries to use the Trusted Exchange Framework to obtain clinical data from providers and provide analytics services. (Note that appropriate BAs must be in place between the healthcare provider and analytics provider.)



Trusted Exchange Framework Benefits for Providers

For Health Systems and Ambulatory Providers the Trusted Exchange Framework will:



Enable them to join one network and have access to data on the patients they serve regardless of where the patient went for care.

• This enables safer, more effective care, and better care coordination.



Enable them to eliminate one off and point-to -point interfaces

 This will allow providers and health systems to more easily work with third parties, such as analytics products, care coordination services, HINs, Qualified Clinical Data Registries (QCDRs), and other registries. (Note that appropriate BAs must be in place between the healthcare provider and analytics provider.)



Trusted Exchange Framework Benefits for Patients

For Patients and Their Caregivers, the Trusted Exchange Framework will:



Enable them to find all of their health information from across the care continuum, even if they don't remember the name of the provider they saw.

 This enables patients and their caregivers to participate in their care and manage their health information.

Recognized Coordinating Entity (RCE)

Recognized Coordinating Entity

The RCE is the entity selected by ONC that will enter into agreements with HINs that qualify and elect to become Qualified HINs in order to impose, at a minimum, the requirements of the Common Agreement set forth herein on the Qualified HINs and administer such requirements on an ongoing basis as described herein.



The RCE will act as a governance body that will operationalize the Trusted Exchange Framework by incorporating it into a single, all-encompassing Common Agreement to which Qualified HINs will agree to abide. In its capacity as a governance body, the RCE will be expected to monitor Qualified HINs compliance with the final TEFCA and take actions to remediate non-conformity and non-compliance by Qualified HINs, up to and including the removal of a Qualified HIN from the final TEFCA and subsequent reporting of its removal to ONC.

The RCE will also be expected to work collaboratively with stakeholders from across the industry to build and implement new use cases that can use the final TEFCA as their foundation, and appropriately update the TEFCA over time to account for new technologies, policies, and use cases.

Recognized Coordinating Entity (RCE)

2018 Selection

Process for Recognizing Entity

ONC will release an open, competitive Funding Opportunity Announcement (FOA) in spring 2018 to award a single multi-year Cooperative Agreement to a private sector organization or entity. The RCE will need to have experience with building multi-stakeholder collaborations and implementing governance principles in order to be eligible to apply for the Cooperative Agreement.

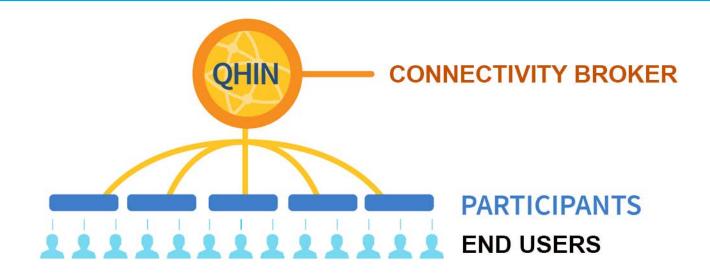


Expectations for Entity

ONC will work with the RCE to incorporate the Trusted Exchange Framework into a single Common Agreement to which Qualified HINs and their participants voluntarily agree to adhere.

The RCE will have oversight, enforcement, and governance responsibilities for each of the Qualified HINs who voluntarily adopt the final TEFCA.

Structure of a Qualified Health Information Network



A Qualified HIN (QHIN) is a network of organizations working together to share data. QHINs will connect directly to each other to ensure interoperability between the networks they represent.

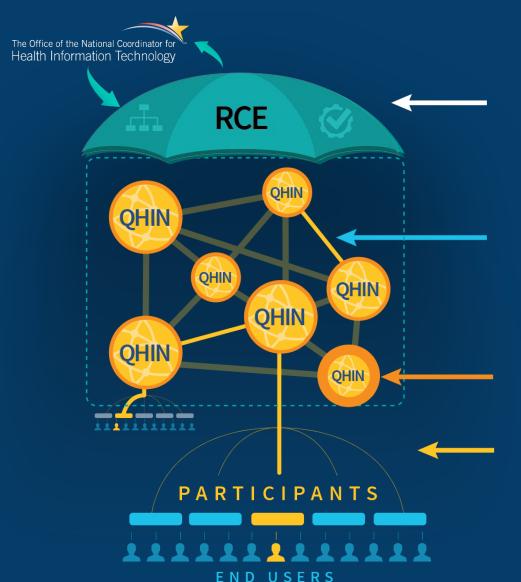
A Connectivity Broker is a service provided by a Qualified HIN that provides all of the following functions with respect to all Permitted Purposes: master patient index (federated or centralized); Record Locator Service; Broadcast and Directed Queries, and eHI return to an authorized requesting Qualified HIN.

A Participant is a person or entity that participates in the QHIN. Participants connect to each other through the QHIN, and they access organizations not included in their QHIN through QHIN-to-QHIN connectivity. Participants can be HINs, EHR vendors, and other types of organizations.

An End User is an individual or organization using the services of a Participant to send and/or receive electronic



How Will the Trusted Exchange Framework Work?



RCE provides oversight and governance for Qualified HINS.

Qualified HINs connect directly to each other to serve as the core for nationwide interoperability.

QHINs connect via connectivity brokers

Each Qualified HIN represents a variety of networks and participants that they connect together, serving a wide range of end users.

Qualified HIN Requirements Clarifications

INCLUDED

- A minimum floor in the areas where there is currently variation between HINs that causes a lack of interoperability.
- Obligation to respond to broadcast or directed queries for all the Permitted Purposes outlined in the Trusted Exchange Framework.
- Qualified HINs must exchange all of the data specified in the USCDI to the extent such data is then available and has been requested.
- Base set of expectations for how Qualified Health Information
 Networks connect with each other.

NOT INCLUDED

- A full end-to-end agreement that would be a net new agreement.
- No expectation that every HIN will serve same constituents or use cases i.e. no requirement that Qualified HINs initiate broadcast or directed queries for all of the Permitted Purposes outlined in the Trusted Exchange Framework.
- Not dictating internal technology or infrastructure requirements.
- No limitation on additional agreements to support uses cases other than Broadcast Query and Directed Query for the Trusted Exchange Framework specified permitted purposes.

TRUSTED EXCHANGE FRAMEWORK CONTENTS





Permitted Purposes





Supported Use Cases



Broadcast Query

Sending a request for a patient's Electronic Health Information (EHI) to all Qualified HINs to have data returned from all organizations who have it.

Supports situations where it is unknown who may have electronic health information about a patient.



Directed Query

Sending a targeted request for a patient's Electronic Health Information (EHI) to a specific organization(s).

Supports situations where you want specific Electronic Health Information (EHI) about a patient, for example data from a particular specialist.



Population Level Data

Querying and retrieving Electronic Health Information (EHI) about multiple patients in a single query.

Supports population health services, such as quality measurement, risk analysis, and other analytics.



US Core Data for Interoperability (USCDI) Glide Path

The USCDI
(https://www.healthit.gov/sites/d
efault/files/draft-uscdi.pdf)
establishes a minimum set of data
classes that are required to be
interoperable nationwide and is
designed to be expanded in an
iterative and predictable way over
time. Data classes listed in the
USCDI are represented in a
technically agnostic manner.

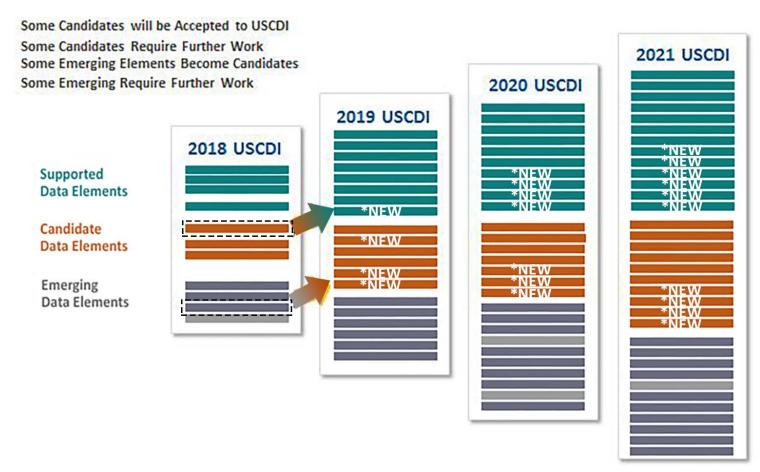
- 1. USCDI v1— Required—CCDS plus Clinical Notes and Provenance
- 2. Candidate Data Classes—Under consideration for USCDI v2
- 3. Emerging Data Classes—Begin evaluating for candidate status

U.S. CORE DATA FOR INTEROPERABILITY USCDI v1 **REQUIRED Candidate Data Classes UNDER CONSIDERATION Emerging Data Classes BFGIN FVALUATING**

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Expansion of US Core Data for Interoperability (USCDI)

As the USCDI expands, Qualified HINs and their Participants will be required to upgrade their technology to support the data specified in the USCDI.



Privacy/Security: Identity Proofing



Identity proofing is the process of verifying a person is who they claim to be. The Trusted Exchange Framework requires identity proofing (referred to as the Identity Assurance Level (IAL) in SP 800-63A).

End Users and Participants Each Qualified HIN shall require proof of identity for Participants and participating End Users at a minimum of IAL2 prior to issuance of credentials.

Individuals Each Qualified HIN shall require its End Users and Participants to proof the identity for Individuals at a minimum of IAL2 prior to issuance of credentials. Individuals must provide strong evidence of their identity.

| IAL 2 REQUIREMENT | DESCRIPTION |
|-------------------------|--|
| Evidence | One (1) piece of SUPERIOR or STRONG evidence; OR Two (2) pieces of STRONG evidence; OR One (1) piece of STRONG evidence plus two (2) pieces of ADEQUATE evidence |
| Validation | Each piece of evidence must be validated with a process able to achieve the same strength as the evidence presented. Validation against a third-party data service SHALL only be used for one piece of presented identity evidence. |
| Address Confirmation | • The Credential Service Provider (CSP) SHALL confirm address of record through validation of the address contained on any supplied, valid piece of identity evidence. |



Privacy/Security: Identity Proofing - EXCEPTIONS

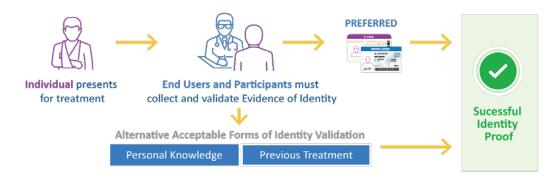


Qualified HINs, Participants, or End Users are responsible for proofing Individuals at the IAL2 level, HOWEVER:

Trusted Referee and Authoritative Source:

In instances where the individual enrolling cannot meet the identity evidence requirements specified, organization staff may act as a trusted referee, allowing them to use personal knowledge of the identity of patients when enrolling patients as subscribers to assist in identity proofing the enrollee.

Antecedent Event: Staff may also act as authoritative sources by using knowledge of the identity of the individuals (e.g., physical comparison to legal photographic identification cards such as driver's licenses or passports, or employee or school identification badges) collected during an antecedent, in-person registration event.



For example, IAL2 identity proofing for an Individual can be accomplished by two of the following:

- Physical comparison to legal photographic identification cards such as driver's licenses or passports, or employee or school identification badges,
- Comparison to information from an insurance card that has been validated with the issuer, e.g., in an eligibility check within two days of the proofing event, and
- 3. Comparison to information from an electronic health record (EHR) containing information entered from prior encounters.



Privacy/Security: Authentication



Digital authentication is the process of establishing confidence in a remote user identity communicating electronically to an information system. NIST draft SP 800-63B refers to the level of assurance in authentication as the Authenticator Assurance Level (AAL). Federal Assurance Level (FAL) refers to the strength of an assertion in a federated environment, used to communicate authentication and attribute information (if applicable) to a relying party (RP).



End Users and Participants

Individuals

AAL 2 Authentication Support for FAL2 or FAL3

Each Qualified HIN shall authenticate End Users, Participants, and Individuals at a minimum of AAL2, and provide support for at least FAL2 or, alternatively, FAL3.

Connecting to a Qualified HIN or one of its Participant will require **two-factor authentication**. A list of acceptable second factors (in addition to a username and password) can be found at https://pages.nist.gov/800-63-3/sp800-63b/sec4 aal.html.

Interoperability (continued)

- 4003(c) HHS must establish an index of digital contact information for health professionals, health facilities, and others to encourage the exchange of health information
- 4003(e) Replaces the Health IT Policy Committee and the Health IT Standards Committee with the Health IT Advisory Committee (HITAC)

The ONC must periodically convene the HITAC to report on priority uses of health IT and standards and implementation specifications that support the implementation of a health information technology infrastructure that advances the electronic access, exchange, and use of health information.



Information blocking

Recall that...

- 4002(a) Requires HHS through notice and comment rulemaking to require, as a condition of certification and maintenance of certification, that the HIT developer or entity "does not take any action that constitutes information blocking"
- 4004 "(1) The term 'information blocking' means a practice that—
 - "(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and
 - "(B) (i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or
 - (ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information."

Section 4004, continued

Information blocking

4004 "(3) RULEMAKING.—The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1)."

Any individual or entity described in subparagraphs (A) or (C) (e.g. a developer, exchange, or network) may be penalized for engaging in information blocking, up to \$1M per violation.

Providers determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.

Leveraging electronic health records to improve patient care

- 4005(a) To be certified, EHR must be capable of transmitting to and receiving from data registries certified by the ONC
- 4005(c) HHS must report on best practices and current trends provided by patient safety organizations to improve the integration of health IT into clinical practice



Empowering patients and improving patient access to their electronic health information

4006(a) HHS must

- (1) Encourage partnerships between health information exchanges and others to offer patients access to their electronic health information;
- (2) Educate providers on leveraging health information exchanges
- (3) Issue guidance to health information exchanges on best practices, and
- (4) Promote policies to facilitate patient communication with providers

ONC and OCR shall promote patient access to health information in a convenient form, without burdening the health care provider involved

OCR, in consultation with ONC, shall provide education for individuals on accessing and exchanging personal health information

The ONC may require health IT certification criteria support certain patient access components

Sections 4007 and 4008

4007 GAO study on patient matching

4008 GAO study on patient access to health information



What We Learned Today - 1

- 1. The primary activities called for in Title IV of the 21st Century Cures Act
- 2. Who is responsible for each activity and ONC's role
- 3. When states may expect to see each activity initiated or completed, and when to watch for progress reports

Plus a bit more about the Trusted Exchange Framework and Common Agreement in Section 4003(b)

What We Learned Today - 2

- This session focused on Delivery provisions in Title IV
- Other sections may also be of interest to states

For example:

TITLE XII – MEDICAID MENTAL HEALTH COVERAGE

Sec. 12006. Electronic visit verification system required for personal care services and home health care services under Medicaid



What's Next?

Future educational webinars, FAQs, white papers, and case studies may include a focus on specific topics in the Cures Act, such as:

- Trusted Exchange Framework and Common Agreement
- 2. Information Blocking
- 3. Reducing Administrative Burden
- 4. Prioritization of Interoperability Standards
- Patient Access
- 6. Patient Matching
- 7. Provider Directories



Questions?





Draft Trusted Exchange Framework Resources

- TEFCA webpage: https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement
- Blog post: https://www.healthit.gov/buzz-blog/interoperability/trusted-exchange-framework-common-agreement-common-sense-approach-achieving-health-information-interoperability
- Draft Framework: https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf
- Guidance: https://www.healthit.gov/sites/default/files/draft-guide.pdf
- USCDI: https://www.healthit.gov/sites/default/files/draft-uscdi.pdf

Webinar Recording

- A recording of the January 8, 2018 2-3 pm EST webinar is available at:
 https://attendee.gotowebinar.com/recording/6408254321306804226?assets=true
 - » GoTo Webinar will ask for an email entry to access the recording







Thank you for attending

CONTACT YOUR ONC SME FOR MORE INFORMATION, OR TO SUGGEST PRIORITIES FOR FUTURE SESSIONS

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