To: CHIME Members
From: CHIME Public Policy Staff
Date: May 19, 2015
Re: Summary - Interoperability Section (Sec. 3001) of the 21st Century Cures Legislation

Purpose:
Below is an overview of the section of the 21st Century Cures Legislation specific to Interoperability. The main provisions of the bill would:

1. Create a "Charter Organization" to study and identify standards that vendor products must adopt to be deemed 'interoperable.'
2. Force EHR vendors to meet interoperability standards by 2018, with penalties including decertification of products, by 2019.

Background:
In March, Congressman Michael C. Burgess, M.D. (R/TX) introduced draft legislation for enhancing nationwide interoperability as part of the Energy & Commerce Committee's year-long flagship 21st Century Cures initiative, which takes a comprehensive look at what steps Congress can take to accelerate the pace of cures in America through medical innovation. Frustrated that five years after $28 billion had been sunk into electronic health records (EHRs), Burgess said "health data continues to be fragmented." Despite growing adoption rates among providers, and increased access to health data by patients, EHRs cannot communicate with one another easily or cheaply.

Stakeholders have identified a lack of standards, or adherence to standards, as a key barrier to interoperability. Others have identified legal and policy barriers, or financial barriers to moving data from one system to another. To address some of these concerns, the Office of the National Coordinator for Health IT (ONC) published a draft Interoperability Roadmap, meant to develop consensus on near-term and long-term strategies to achieve interoperability within healthcare.

The 21st Century Cures legislation is much improved over past drafts, yet still leaves many unanswered questions. Access remains the theme, rather than use. Decertification has become the tool by which ONC can hold vendors accountable, though improvements on testing or certification policies remain absent, as does standards to address patient identification challenges. While the bill no longer aims at eliminating the Health IT Policy Committee, it does sunset the Health IT Standards Committee, the draft does propose a "Charter Organization" comprised of Standards Developing Organization (SDO) representatives that will select the standards in five key categories by which products must adopt to be deemed interoperable vs. not interoperable.

The legislation was approved unanimously out of the House Energy & Commerce Health Subcommittee on May 14, 2015 and will be considered by the entirety of the Energy & Commerce Committee on May 19th and 20th. Rep. Fred Upton (R-MI), chairman of the Energy and Commerce Committee, has indicated that the 21st Century Cures package will pass through the House early this summer.

Many of the bill's provisions, including the interoperability section summarized below, are still being amended by the Committee staff.

Summary of Proposed Legislation:
Title III: Delivery; Subtitle A - Interoperability

Ensuring Interoperability of Qualified Electronic Health Records
Interoperability – In order for qualified electronic health records to be considered interoperable, they must satisfy the following criteria:

1. Secure transfer – The technology allows the secure transfer of the entirety of a patient's data from any and all health information technology for authorized use under applicable law
2. Complete Access to Health Data – The technology allows access to the entirety of a patient's available data for authorized use under applicable law without special effort, by the requestor of such data unless such data is not disclosable under applicable law
3. No Information Blocking – The technology is not configured, setup or implemented to engage in information blocking, as defined in 3010A(f).

Categories for Interoperability Standards
The legislation requires development of standards in the following five categories:

1. Vocabulary and terminology standards
2. Content and structure standards
3. Standards with respect to transport of information
4. Security Standards
5. Service Standards

Guidance
By January 1, 2017, HHS shall issue guidance relative to the implementation of interoperable health information technology, including defining and providing examples of authorized use of health information technology

Improvements to Recommendation Process
HIT Policy Committee to Incorporate Policies for Updates to Interoperability Standards

1) The HITPC is authorized to provide recommendations to the Secretary and not authorized otherwise to affect the development or modification of any standard, implementation specification, or certification criterion
2) Any recommendations made by the HIT Policy Committee on or after the date of enactment with respect to interoperability of qualified electronic health records shall be consistent with the definition set forth in this legislation

Sunset of HIT Standards Committee
Termination – The HITSC shall terminate on the date that is 90 days after enactment

Contract with Standards Development Organizations
1. The Secretary shall contract with health care standards development organizations accredited by the American National Standards Institute (ANSI) to establish a committee to be knowns as the "Charter Organization."
2. Timing – As soon as practicable after the date of enactment
3. Period of Contract – For a period determined by the Secretary in consultation with ONC, may be renewed after a subsequent bidding process
4. Appropriate Organizations – The Secretary shall ensure the most appropriate ANSI-accredited organization is selected for the contract

Duties
Initial Contract – The Standards Development Organizations shall develop recommendations for interoperability standards consistent with the interoperability criteria and with respect to the categories of standards

Subsequent Contracts – Under subsequent contracts, the organizations shall provide to the Secretary, in consultation with ONC, recommendations for any standards (including interoperability criteria), implementation specifications, and certification criteria (and modifications, including additions to such standards, specifications and criteria) which are in accordance with the policies and priorities developed by the Secretary in consultation with ONC

Modifications to Subsequent Contracts – The Secretary in consultation with ONC, shall periodically conduct hearings to evaluate and review the standards, implementation specification, and certification criteria for purposes of determining if modifications, including additions, are needed

Trigger for Contracting – based on the needs for standards, implementation specifications and certification criteria (and modifications, including additions to such standards, specifications and criteria) as determined by HHS, in coordination with ONC, shall enter into contracts as needed in addition to the initial contract.

Appropriations Authorization – $10 million for a contract with the Charter Organization, to remain until expended

Modifications to the Role of ONCHIT

Limitation – The Secretary may not adopt any standards, implementation specifications, or certification criteria that is duplicative or inconsistent

Adoption of Initial Interoperability Standards

Review of Standards – Within 90 days of receiving recommendations by the Charter Organization the Secretary in consultation with ONC and other relevant federal agencies, shall review them and determine whether or not to propose adoption of such recommendations

Determination to Adopt – If the Secretary determines

a. To propose adoption of such methods, the Secretary shall by regulation, determine whether or not to adopt such methods;
b. Not to prose adoption of such methods, the Secretary shall notify ONC and the standards development organizations in writing of such determination and the reasons for not proposing the adoption of the recommendation methods

Publication – The Secretary shall provide for publican in the Federal Register of all determinations made by the Secretary

Application – Any method adopted shall be effective 12 months after the date of publication of the determination to adopt such methods

Rules for Adoption – In the case of a standard (including interoperability standard), implementation specification, or certification criteria adopted under this section

Special Rule if no standard, specification or criterion recommended – The Secretary should rely on recommendations from the National Committee on Vital and Health Statistics (NCVHS), in consultation with state and federal agencies. The Secretary shall publish in the Federal Register any recommendation from NCVHS regarding the adoption of a standard, implementation specification or certification criterion.

<u>Reports and Notifications</u>

1. Dissemination of Information –
    a. Initial Summary Report – By July 1, 2017 HHS shall submit to congress and the Federal Register:
        1. The initial set of methods;
        2. Strategies for achieving widespread interoperability;
        3. An overview of the extent to which qualified electronic health records offered as of that date satisfy the initial set of methods;
        4. Interoperability barriers; and
        5. A Plan, with milestones and specific steps to achieve widespread interoperability.
2. Follow-up Determination and Report on Widespread Interoperability: Not later than Dec. 31, 2019 HHS shall submit to the Federal Register:
        1. A determination by the Secretary whether the goal of widespread interoperability has been achieved;
        2. A list of vendors in compliance or not in compliance with proposed certification criteria
        3. Actions that may be taken by entities identified as not being in compliance to become in compliance with criteria and requirements
        4. Penalties will then apply beginning Jan. 1, 2019 if such technology are not in compliance.

3. Ongoing Publication of Recommendations – The Secretary shall provide for publication in the Federal Register and posting on the ONC website all recommendations made

Certification and Other Enforcement Provisions –

1. Certification of Qualified Electronic Health Record Technology -
    a. Changes definition of certification by creating a line for those certified before January 1, 2018 and those on or after January 1, 2018.
    b. Those certified on or after Jan. 2018 must be in compliance with applicable standards and to be interoperable relative to new criteria, including the methods

Enforcement; Decertifications

1. Vendors must attest that:
    a. They've met interop criteria and that they have not knowingly done anything to limit or restrict exchange of information, or prevent, or disincentive widespread interoperability between providers;
    b. Pricing information on data transmission (to be displayed on a portal) and other services affiliated use of qualified electronic health records
    c. They've published APIs for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications;
    d. The entity has successfully tested the use of the record in the type of setting in which it would be marketed;
    e. The entity has in place implementation guidelines for such record that support interoperability;
    f. The entity has in place data sharing based on common data elements through application programming interfaces without requirement for specific middleware or vendor-specific interfaces
    g. Publish application programming interfaces and associated documentation, with respect to such records, for medical records data, search and indexing, sematic harmonization and vocabulary translation and user interface applications
    h. They've demonstrated to the "satisfaction of the Secretary that data is able to be exchanged through the use of APIs and used in a manner that allows for exchange and everyday use of such records by authorized users."
2. Decertification – Beginning January 1, 2019 any qualified electronic health record that does not satisfy the certification criteria, that doesn't satisfy the requirements (or is determined to be in violation of the terms of attestation or other requirements) shall no longer be certified
3. Annual Publication – For 2019 and each following year, the Secretary shall post on the HHS website a list of any vendors or other entities offering qualified electronic health records with respect to which certification has been withdrawn.
4. Periodic Review – The Secretary shall periodically review and confirm the vendors of and other entities offering qualified electronic health records have public published APIs and associated documentation as required for certification and maintaining certification

5. Pricing information – With respect to a vendor or other entity offering a qualified electronic health record
    a. Additional types of costs or fees (whether fixed, recurring, transaction based, or otherwise) imposed by the entity (or any third-party from whom the entity purchases, licenses, or obtains any technology products, or services in connection with the qualified electronic health record) to purchases, license, implement, maintain, upgrade, use or otherwise enable and support the use of capabilities to which such record is to be certified, or in connection with any data generation in the course of using any capability to which the record is certified.
    b. Limitations, whether by contract or otherwise, on the use of any capability to which the record is to be certified for any purpose within the scope of the record's certification; or in connection with any data generated in the course of using any capability to which the record is to be certified
    c. Limitations, including technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support or use of any capabilities to which the record is to be certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which the record is certified.

Sec 3010A. Enforcement Mechanisms

<u>Additional Enforcement Provisions –</u>

Inspector General Authority – Investigate claims of –

a. Vendors or other entities offering qualified electronic health records –
    i. Being in violation of attestation with respect to the use of records by a health care provider under a specified Medicare program;
    ii. Having engaged in information blocking, unless for a legitimate purpose specified by the Secretary, with respect to the use of such records by a health care provider

b. Healthcare providers, with respect to the use of such records under a specified Medicare incentive program, having, unless for a legitimate purpose specified by the Secretary, engaged in information blocking;
    iii. Health information system providers (HIEs) having engaged in information blocking, unless for a legitimate purpose, with respect to the use of such records under a specified Medicare incentive program
    iv. Vendors of, or other entities offering, health information technology (other than technology), health care providers, with respect to the use of such technology, and health information system providers, with respect to such technology, unless for legitimate purpose specified by the Secretary

c. Health Information System Providers – The Inspector General of HHS, in coordination with the FTC, ensure that health information system providers (such as operators of health information exchanges and other systems that facilitate the exchange of information between qualified electronic health records) investigate claims of information blocking, with respect to the use of records for Medicare incentive programs

Information Sharing Provisions –

a. ONC may serve as a technical consultant to OIG and the FTC for the purposes of carrying out information sharing challenges. ONC can share information related to claims or investigations under with OIG and FTC
    i. Protecting from Disclosure of Information – Any information shared by ONC shall not be subject to FOIA. Any information acquired should be held in confidence and not disclosed to anyone but those necessary
b. Penalty – Any person or entity determined to have committed an act of information blocking shall be subject to a civil monetary penalty of not more than $10,000 for each such act.
c. Specified Medicare Incentive Program – Medicare incentive programs including incentive payment types to EHs, EPs, CAHs and MAs under Meaningful Use and the Medicare Shared Savings Program (MSSP).
d. Information Blocking –
    i. The term means, with respect to use of qualified electronic health records under a specified Medicare incentive program, business, technical, and organizational practices, including practices that –
        1. Prevent or materially discourage the exchange the exchange of health information;
        2. The actor knows or should know is likely to interfere with the exchange or use of electronic health information; and,
        3. Do not serve to protect patient safety, maintain the privacy and security of individuals' health information or promote competition and consumer welfare.
    ii. Practices described –
        1. Contract terms, policies or other business or organization practices that restrict individuals access to their electronic health information or restrict the exchange or use of that information for treatment
        2. Charging prices or fees (such as data exchange, portability, and interfaces) that make exchanging and using electronic health information cost prohibitive.
        3. Developing or implementing health information technology in non-standard ways that are likely to substantially increase the costs, complexity or burden of sharing electronic health information, especially in cases in which relevant interoperability standards or methods to measure interoperability have been adopted by the Secretary.
        4. Developing or implementing health information technology in ways that are likely to lock in users or electronic health information, such as not allowing for the full export of data; lend to fraud, waste, or abuse; or impede innovations and advancements in health information exchange and health information technology-enabled care delivery.

Treatment of Vendors With Respect to Patient Safety Organizations

1. Vendors shall be treated as providers for purposes of reporting requirements, to the extent that such reports are related to attestation requirements
2. Claims of information blocking shall be treated as patient safety activity
3. Health care providers that are not members of patient safety organizations shall be treated in the same manner as health care providers that are such members relevant to information blocking claims.

ONC Actions

1. Price Portal - Not later than January 1, 2019, ONC to make available in a public manner that allows for comparison of price information among health information technology products and that aids in making informed decisions for purchasing such product.
2. Information Blocking Report - Not later than 12 months after the date of enactment, the National Coordinator shall, through rulemaking, implement the provisions relative to information blocking.
3. HIPAA Report - Not later than January 1, 2017, ONC shall publish guidance to clarify the relationship of the HIPAA privacy and security law, as such provisions relate to information blocking, including examples of how such provisions may result in information blocking.

Demonstration required for meaningful use incentives under Medicare –

A. Incentives for Professionals –
    a. Interoperability – with respect to EHR reporting periods for payment years beginning with 2018, the Secretary shall include a demonstration, through means such as attestation, that the professional have no taken any action with respect to information blocking
    b. Hardship Exemption in Case of Decertified EHRs –
        i. Significant Hardship Exemption – significant hardships
        ii. Decertification – On a case-by-case basis, exempt eligible professionals from the application of payment adjustments, if the provider is not a meaningful user due to the qualified electronic health record technology has been decertified, An exemption may be applied to an eligible professional only during the first year with respect to which such decertification applies
            1. Duration – In no case shall an exemption be less than 12 months
            2. Limitation – In no case may an eligible professional be granted an exemption for more than five years.
B. Incentives for Hospitals -
    a. Interoperability – with respect to EHR reporting periods for payment years beginning with 2018, the Secretary shall include a demonstration, through means such as attestation, that the hospital has not taken any action with respect to information blocking
    b. Hardship Exemption in Case of Decertified EHRs –
        i. Significant Hardship Exemption – significant hardships
        ii. Decertification – On a case-by-case basis, exempt eligible hospital from the application of payment adjustments, if the provider is not a meaningful user due to the qualified electronic health record technology has been decertified,

An exemption may be applied to an eligible hospital only during the first [fiscal] year with respect to which such decertification applies

1. Duration – In no case shall an exemption be less than 12 months
2. Limitation – In no case may an eligible hospital be granted an exemption for more than five years.

C. Demonstration Required for Meaningful Use Incentives Under Medicaid –

a. Interoperability – with respect to EHR reporting periods for payment years beginning with 2018, the Secretary shall include a demonstration, through means such as attestation, that the hospital has not taken any action with respect to information blocking

b. Hardship Exemption in Case of Decertified EHRs –

i. Significant Hardship Exemption – significant hardships

ii. Decertification – On a case-by-case basis, exempt eligible hospital from the application of payment adjustments, if the provider is not a meaningful user due to the qualified electronic health record technology has been decertified, An exemption may be applied to an eligible hospital only during the first [fiscal] year with respect to which such decertification applies

1. Duration – In no case shall an exemption be less than 12 months
2. Limitation – In no case may an eligible hospital be granted an exemption for more than five years.

<u>Definitions:</u>

1. Certified EHR Technology – A qualified electronic health record that is certified pursuant the criteria as meeting the criteria that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals) and, beginning January 1, 2018, with respect to which the vendor or other entity offering such technology is in compliance with requirements
2. Widespread interoperability – On a nationwide basis:
    a. Health information technology are interoperable, in accordance and measured by the methods adopted,
    b. Such records are employed by meaningful EHR users under the specified Medicare incentive programs and other clinicians and health care providers.

<u>Patient Empowerment – Sense of Congress that:</u>

1. Patients have the right to the entirety of the health information of such patient, including such information contained in an electronic health record of such patient
2. Such right extends to both structured and unstructured data
3. To further facilitate patient ownership over health information of such patient –
    a. Healthcare providers should not have the ability to deny a patient's request for access to the entirety of such health information of such patient
    b. Healthcare providers do not need the consent of their patients to share personal health information of such patients with other covered entities, in compliance with the HIPAA privacy regulations for the purpose of supporting patient care except in situations where consent is specifically required under such regulations, such as in cases related to psychiatric records of such patient