Summary of Key Health IT Provisions in the 21st Century Cures Act

As signed into law 12/13/2016

HIMSS North America

Background

On Tuesday, December 13, 2016, President Obama signed into law a House-Senate compromise version of the 21st Century Cures Act. The legislation, which passed both chambers with strong bipartisan support, combines policies from the House 21st Century Cures Act passed last summer and a number of individual health IT and innovation bills passed by the Senate HELP Committee this year.

The core of the legislation is focused on "expediting discovery, delivery and development of new cures and treatments" and "maintaining America's global status as the leader in biomedical innovation." This extensive legislative package, which provides for additional funding for NIH, FDA and the states, and addressing issues ranging from precision medicine to opioid abuse, includes a significant focus on health IT as the foundation of medical research and care delivery. The summary below covers a number of key health IT policies, although health IT is woven throughout the legislation.

Key Health IT Sections

TITLE III—DEVELOPMENT

Sec. 3060. Clarifying Medical Software Regulation (pg. 257-264)

- The term 'device' shall be excluded from regulation by the FDA if the software function of the device is intended for:
  - Such purposes as administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, population health management, and laboratory workflow, among others;
  - Maintaining or encouraging a healthy lifestyle, unrelated to diagnosis, cure, mitigation, prevention, or treatment of a disease or condition**.**
  - Electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, as long as:
    - The records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals
    - Such records are certified under section 3001(c)(5) of the Public Health Service Act

        - It doesn't include software intended to interpret or analyze patient records, including medical image data
    - Transferring, storing, converting formats, or displaying clinical laboratory tests or other device data results; findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings;
    - (Unless) the Software function is intended to acquire, process, or analyze medical images or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system for the purpose of:
        - Displaying, analyzing, or printing medical information about a patient or other medical information
        - Supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition.
        - Enabling health care professionals to independently review the basis for such recommendations that software presents so that it is not the intent that health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.
- For devices with multiple functions, when at least one function is excluded from the definition of 'device' and at least one function meets the definition of a 'device', the Secretary shall not regulate the function excluded from the definition.
- However, when assessing the safety and effectiveness of the function that meets the definition of a 'device', the Secretary may assess the impact that the excluded (or unregulated) function has on the device function.
    - For devices with multiple functions that include both regulated and excluded functions, the Secretary may assess the impact that the excluded (or unregulated) function has on the safety and effectiveness of the regulated function.
- A software function <u>shall not be excluded</u> from the definition of a 'device', even if a software function meets the criteria for being excluded from the definition of a 'device', if:
    - <u>The Secretary finds that such function is reasonably likely to have serious adverse health consequences</u>; and,
    - The software function has been identified in a final order that has gone through the public comment process and includes the rationale and evidence behind the Secretary's findings.
- When considering whether a function may have adverse health consequences, the Secretary shall consider issues such as the likelihood and severity of the software not performing as intended, whether it is intended to support the judgment of a health care professional, and if there is opportunity to review the basis or recommendation of the software.
- The Secretary shall publish a report every 2 years that:
    - Includes input from outside experts;
    - Examines information on risks and benefits to health associated with software functions that are excluded from the definition of a 'device'
    - Summarizes findings regarding impact of such functions on patient safety, including best practices to promote safety and education.
- The Secretary must classify an accessory based on its intended use, not on the classification of the medical device with which it is used.

<u>TITLE IV—DELIVERY</u>

Sec. 4001. Assisting doctors and hospitals in improving quality of care for patients (pg. 328-334)

- Directs HHS Secretary (Secretary) to work with a host of stakeholders, including health care providers, payers, health IT developers, public health entities, and States, to develop a strategy and recommendations, within 1 year after enactment, to reduce regulatory and administrative burdens (including documentation requirements) on the use of EHRs. The Federal Advisory Committee Act shall not apply to the activities described in this section.
- The strategy should prioritize, among other things:
    - Value-based payment programs (Meaningful Use program, MIPS, APMs, etc.);
    - Health IT certification;
    - Standards and implementation specifications;
    - Privacy and security of, and access to, electronic health information;
    - Facilitating health and clinical research, and public health;
    - Aligning and simplifying quality measures in Federal programs;
- The recommendations should address ways to improve clinical documentation experiences and patient care, as well as actions taken by the HHS Secretary.
    - A physician may delegate EMR documentation requirements to a person who is not a physician (removed reference to "members of the care team") so long as they have signed and verified the documentation
- Directs the National Coordinator for Health IT to encourage, keep, or recognize the voluntary certification of health IT for use in medical specialties and sites of service where such technology isn't available or where more advancement is needed.
- The Secretary, in consultation with stakeholders, will make recommendations for the voluntary certification of health IT for use by pediatric health providers within 18 months after enactment of this bill,
    - Within 2 years, the Secretary shall adopt certification criteria for voluntary certification for pediatric health providers.
- 6 months after enactment, the Secretary shall submit to the HIT Advisory Committee a report on Meaningful Use attestation statistics to assist in informing standards and other practices.

Sec. 4002. Transparent Reporting on Usability, Security, and Functionality (pg. 335-350)

- One year after date of enactment, the Secretary will require, as a condition of certification or maintenance of certification, that the health IT developer or entity:
    - Does not take any action that constitutes information blocking or inhibits the appropriate exchange, access, and use of EHI;
    - Does not prohibit or restrict communication regarding the usability, interoperability, or security of EHI, users' experiences using health IT, and business practices of health IT developers related to exchanging EHI;
    - Has published programming interfaces and allows health information to be exchanged, accessed and used through the use of application program interfaces (APIs) or successor technology or standards;
    - Has successfully tested real world use of technology for interoperability;
    - Provides to the HHS Secretary an attestation to comply with the activities listed above, and submits proper reporting criteria.
- The Secretary may encourage compliance and take action to discourage noncompliance, as appropriate.
- The Secretary may exempt an eligible professional or eligible hospital from application of payment adjustment, subject to annual renewal, for compliance with meaningful use requirements if they used EHR technology that has been decertified.
- Not later than 1 year after enactment, the Secretary will convene stakeholders (providers, hospitals, patient and consumer advocates, health IT experts, data sharing networks,

certification bodies, security experts, etc.) to develop EHR reporting criteria through a public, transparent process

- The reporting criteria shall include measures on security, usability and user-centered design, interoperability, conformance to certification testing, and other categories to measure performance of EHR technology.
- The reporting criteria *may* also include, among other:
    - Enabling users to order and view lab, imaging, and diagnostic test results;
    - Submitting, editing, and retrieving data from registries
    - Accessing and exchanging information from health information exchanges and medical devices;
    - Accessing and exchanging patient generated data and information from other health care providers
- The reporting criteria shall be designed to ensure small and startup health IT developers are not unduly disadvantaged by reporting criteria
- The Secretary may convene stakeholders and conduct a public comment process to modify the reporting criteria.
- Not later than 1 year after enactment, the Secretary shall award grants, contracts, or agreements to independent entities (with expertise in health IT usability, interoperability and security) to support the convening of stakeholders, collect necessary information required for the reporting criteria, and develop and implement a process to collect and verify confidential feedback from health care providers, patients, and developers and users of certified EHR technology
- No later than 4 years after enactment, and every 2 years after, the Secretary shall assess performance of the independent entities based on quality and usability of reports, and re-determine grants, contracts, and agreements as necessary.
- Proprietors and developers of certified health IT, as well as state or local government agencies, are prohibited from seeking a grant, contract or agreement.
- Each recipient of a grant, contract, or agreement shall report to the Secretary on information collected for public distribution.
- Participating EHR technology developers may review and recommend changes to the reports created prior to the publication each report.

Sec. 4003. Interoperability (pg. 350-382)

- Defines Interoperability as “health IT that enables the secure exchange of electronic health information with, and use electronic health information from, other health IT without special effort on the part of the user, and allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.”
- To support full interoperable network-to-network exchange, not later than 6 months after enactment the National Coordinator shall work with NIST and other relevant HHS agencies to convene public-private and public-public partnerships to build consensus and develop a trusted exchange framework, including trust policies and practices, and a common agreement among health information exchange networks nationally.
- The common agreement may include (1) a common method for authenticating trusted health information network participants; (2) a common set of rules for trusted exchange; (3) organizational and operational policies to enable the exchange of health information, including minimum conditions for such exchange to occur; and, (4) a process for filing and adjudicating non-compliance with the common agreement.
- ONC, in consultation with NIST, will provide pilot testing of the trusted exchange framework and common agreement. Pilot testing activities may be delegated to independent entities.

- The trusted exchange framework and common agreement will be published within one year on the ONC website.
- Within two years, the ONC will publish a directory (updated annually) of health information exchange networks that have adopted the common agreement and are capable of trusted exchange. A process shall be established for health information networks to voluntarily attest to the adoption of the framework and agreement.
- Federal agencies contracting agreements with health information exchange networks may require that such networks may adopt, where available, the trusted exchange framework and common agreement.
- Nothing in this Act shall be construed to require a health information exchange network to adopt the framework or agreement.
- Directs the HHS Secretary, within 3 years after enactment, to establish a provider digital contact information index.
    - The index shall include all health professionals, health facilities, and other applicable individuals or organizations.
- Directs the HHS Secretary to give deference to standards published by Standards Development Organizations.
- Combines the HIT Policy and Standards Committees into the HIT Advisory Committee to make recommendations to ONC on policies, standards, implementation specifications, and certification criteria relating to the implementation of national and local health IT infrastructure.
- The HIT Advisory Committee shall recommend a policy framework which shall seek to prioritize achieving advancements in:
    - Achieving a health IT infrastructure that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, and exchanging information without duplication;
    - Promotion and protection of privacy and security of health information in health IT, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information for the purpose of treatment, payment, and operations;
    - The facilitation of secure access by an individual to their protected health information and access to such information by a family member, caregiver, or guardian;
    - The use of health IT to improve quality of health care, such as by promoting the coordination of health care and improving continuity of care among providers, reducing medical errors, improving population health, reducing chronic disease, and advancing research and education;
    - The use of technologies that address the needs of children and vulnerable populations;
    - The use of electronic systems to ensure the comprehensive collection of patient demographic data;
    - The use of self-service, telemedicine, home health care, and remote monitoring technologies;
    - The use of technologies that meet the needs of diverse populations and support data for use in quality reporting programs, public health, and drug safety;
    - The use of technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals;
    - The use of certified health IT for each individual in the United States
- In the development, harmonization, or recognition of standards implementation specifications, and certification criteria the HIT Advisory Committee shall, as appropriate, provide for testing of standards and specifications by NIST.

- Not later than 30 days after the first meeting, the HIT Advisory Committee shall develop a schedule for the assessment of policy recommendations to be updated annually, and shall conduct public meetings to allow for public comment on the schedule and recommendations.
- ONC shall establish and update objectives and benchmarks for advancing and measuring priority target areas, and the HIT Advisory Committee shall submit annually a report to Congress and the Secretary on, among other things, the progress made during the preceding fiscal year to advance interoperability.
- The ONC shall take the lead in the establishment and operations of the HIT Advisory Committee. Membership of the committee shall be at least 25, serving for 3 year terms, and includes advocates for patients or consumers of health information technology, and members appointed by the Secretary, Senate Majority and Minority Leaders, Speaker of the House, House Minority Leader, and the Comptroller General.
- Members shall reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use of standards for such activity.
- No later than 6 months after the first HIT Advisory Committee meeting, the National Coordinator shall periodically convene the Committee to identify priority uses (including standards and implementation specifications) of health IT including focusing on implementation of Meaningful Use incentive programs, MIPS, APMs, Hospital Value-Based Purchasing program, other value-based payment programs, healthcare quality, public health, privacy and security, innovation, patient access to their information, usability, among others.
- The HIT Advisory Committee shall identify existing standards and implementation specifications that support the use and exchange of electronic health information. In identifying standards and implementation specifications, the Committee shall prioritize those developed by consensus-based standards development organizations.
- 5 years after enactment, and every 3 years after, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations on maintaining or phasing our standards.

Sec. 4004. Information Blocking (pg. 382-393)

- Defines "information blocking" as a practice that (accept as required by law) "is likely to interfere with, prevent, or materially discourage access, exchange, or use of health information", and:
    - For a technology developer, exchange, or network, "knows, or should know, that such practice is likely to interfere with, prevent, or materially discourages access exchange or use of electronic health information."
    - For a health care 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".
- Information blocking practices may include:
    - Practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health IT;
    - Implementing health IT in nonstandard ways that are likely to substantially increase the complexity or burden of access, exchanging, or using electronic health information;
    - Implementing health IT in ways that could (1) restrict access, exchange, or use of electronic health information with respect to exporting complete information sets or transitions between health IT systems, or (2) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use.

- Through rulemaking the Secretary shall identify reasonable and necessary activities that DO NOT constitute information blocking.
- Information blocking will not include any practice occurring prior to 30 days after enactment.
- A health care provider shall not be penalized for the failure of developers of health IT or other entities to ensure that such technology meets requirements
- The HHS Inspector General (OIG) can investigate claims that a health IT developer or other entity offering certified health IT submitted a false attestation or engaged in information blocking, a healthcare provider engaged in information blocking, and a health information exchange or network engaged in information blocking.
- A person or entity (developer, network, and exchange) determined by the OIG to have committed information blocking shall be subject to civil monetary penalties determined by the Secretary, which may not exceed $1,000,000 per violation.
- A health care provider determined by the OIG 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.
- For recovered penalty funds, some will go to the OIG fir costs to carry out investigations, and the rest shall be transferred to the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, in such proportion as the Secretary determines appropriate.
- If the OIG determines a consultation regarding privacy and security rules under HIPAA will resolve an information blocking claim, it may be referred to the HHS OCR for resolution.
- Defines “trusted exchange” as when certified EHR technology has the technical capability to enable secure health information exchange between users and multiple certified health IT systems.
- Directs the ONC, in consultation with the OCR, to issue guidance on common legal, governance, and security barriers that prevent trusted exchange.
- Allows ONC and OCR to refer to the OIG instances or patterns of refusal to exchange health information.
- ONC shall implement a standardized process for the public to submit reports on claims of health IT products, or developers and entities offering such products, not being interoperable or resulting in information blocking, and actions that result in information blocking.

Sec. 4005. Leveraging Electronic Health Records to Improve Patient Care. (pg. 393-396)

- To be certified, EHRs shall be capable of transmitting to, and where applicable receiving and accepting data from, registries (such as clinician-led clinical registries) that are also certified to be technically capable of receiving and accepting from, and where applicable transmitting, data to other certified EHR technology, in accordance with standards recognized by the ONC.
- Defines a clinician-led clinical registry as a “clinical data repository” that:
    - Is established by a clinician-led, tax exempt, professional society or organization, devoted to care of a population defined by a specific disease, condition, exposure, or therapy;
    - Is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services or therapies for particular diseases, conditions or exposures;
    - Meets standards for data quality, including systematically collecting clinical and other head data using standardized data elements, and subject to regular data checks or audits;
- Treats health IT developers as a “provider” for purposes of reporting and conducting patient safety activities concerning clinical care, when health IT can be used to improve patient safety, and health care quality and outcomes.

- Directs the Secretary to submit a report to Congress within 4 years after enactment on best practices and trends by Patient Safety Organizations to improve integration of health IT into clinical practice.

Sec. 4006. Empowering Patients and Improving Patient Access to their Electronic Health Information. (pg. 396-402)

- The Secretary shall use existing authorities to encourage partnerships between health information exchange organizations and networks, health care providers, health plans, and other entities to offer patients access to their electronic health information in a single, longitudinal format that is secure and easy to understand;
- The Secretary, in coordination with HHS OCR, shall educate providers on how to best provide patients with access to their electronic health information through HIEs, and clarify misunderstanding about using HIEs for patient access.
- The Secretary, in coordination with HHS OCR, shall issue guidance to HIEs on best practices to ensure that electronic health information is private and secure, accurate, verifiable, and, where a patient's authorization is required by law, easily exchanged;
- The Secretary, in consultation with ONC, shall promote policies that ensure access to electronic health information for a patient or designee, by facilitating communication across health providers and researchers, consistent with patient's consent.
- OCR, in consultation with ONC, shall help individuals and providers to understand a patient's right to access and protect their personal health information under HIPAA, including through best practices for requesting personal health information in a computable format.
- In carrying out certification programs, ONC may require that certification criteria support:
    - Patient access to electronic health information in a single longitudinal format that is easy to understand, secure, and may be updated automatically;
    - A patient's ability to electronically communicate patient-reported information
    - Patient access to their electronic health information for research, and the option of the patient
- The HIT Advisory Committee shall develop and prioritize standards, implementation specifications, and certification criteria required to help support patient access to electronic health information, patient usability, and support for technologies that offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

Sec. 4007. GAO Study on Patient Matching. (pg. 402-404)

- Within one year of enactment, GAO shall conduct a study to review the policies and activities of ONC and other relevant stakeholders, such as health IT experts and developers, to ensure appropriate patient matching to protect privacy and security of electronic health records and exchange of health information. The study shall also review ongoing efforts occurring in the private sector.
- Areas of consideration include (1) evaluating current methods used in certified EHRs for patient matching based on performance related to privacy, security, improving matching rates, reducing matching errors, reducing duplicative records, etc. and, (2) determining whether ONC could improve patient matching by taking steps including defining additional data elements to assist with patient matching, agreeing on a required minimum set of elements to be collected, and requiring EHRs to have the ability to make certain fields required and use specific standards.
- GAO is required to submit the findings of the study to Congress within 2 years of enactment.

Sec. 4008. GAO Study on Patient Access to Health Information. (pg. 404-406)

- GAO shall build on prior studies to review patient access to their own protected health information, including barriers to access and complications providers experience in providing patients access.
- Areas of consideration include (1) instances when covered entities charge individuals for record requests, (2) examples of the amounts and types of fees charged for record requests, (3) the extent to which covered entities are unable to provide access to the individual in the form or format requested, (4) opportunities that permit covered entities to charge appropriate fees to third parties for patient records while providing with access at low or no cost, and, (5) circumstances that may inhibit the ability of providers to provide patients with access to their records.
- GAO is required to submit the findings of the study to Congress within 18 months of enactment.

Sec. 4011. Medicare Pharmaceutical and Technology Ombudsman. (pg.409-410)

- Within 12 months after enactment, the Secretary shall appoint new Pharmaceutical and Technology ombudsman within CMS to review and respond to complaints, grievances, and requests on new and life-saving technologies.

Sec. 4013. Telehealth Services in Medicare (pg. 412-415)

- Within 1 year after enactment, CMS shall provide to Congress the following information:
    - The populations of Medicare beneficiaries, including dual eligible and those with chronic conditions, who may see the most improvement in quality and efficiency through the expansion of telehealth services under section 1834(m)(4);
    - Activities by CMMI that examine the use of telehealth services;
    - Types of high-volume services which might be suitable to be furnished via telehealth;
    - Barriers to expansion of telehealth services under section 1834(m)(4)
- Not later than March 15, 2018, MedPAC shall provide information to Congress that identifies:
    - Telehealth services for which payment can be made under the fee-for-service program
    - Telehealth services for which payment can be made under private health insurance plans;
    - Ways in which payment for such services (in private health insurance plans but not fee-for-services program) might be incorporated into such fee-for-service program (including any recommendations for ways to accomplish this incorporation).
- Provides a Sense of Congress that:
    - Originating sites should be expanded beyond those currently described in section 1834(m)(4)(C)
    - Any expansion of telehealth in the Medicare Program must recognize that telemedicine is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery; and must meet or exceed the conditions of coverage and payment with respect to the Medicare program if the service was furnished in person, including standards of care.