



CIO Legislative Brief

Comparison of Health IT Provisions in the Committee Print of the 21st Century Cures Act (dated November 25, 2016), H.R. 6 (21st Century Cures Act) and S. 2511 (Improving Health Information Technology Act)

Policy Proposal	Senate – Innovations Initiative	House – H.R. 6 Passed House July 10, 2015	Committee Print of the 21st Century Cures Act November 25, 2016
Administrative Burdens Imposed by HHS Regulations	Requires ONC to reduce the regulatory and administrative burdens of using EHR technology and relieve physicians of EHR documentation requirements specified in HHS regulations.	N/A	Requires ONC to reduce the regulatory and administrative burdens of using EHR technology and relieve physicians of EHR documentation requirements specified in HHS regulations and publish a strategy to reduce the burden within one year.
Specialty Certification of EHRs	ONC also would be required to encourage the certification of HIT for use in medical specialties and sites of service, and to adopt certification criteria for HIT used by pediatricians.	N/A	ONC also would be required to encourage the certification of HIT for use in medical specialties and sites of service, and to adopt certification criteria for HIT used by pediatricians.
ONC CERT Transparency	To help healthcare providers choose HIT products, the proposal establishes a program and methodology for calculating and awarding a star rating to each certified HIT product—based on criteria such as: <ul style="list-style-type: none"> the product’s security, user-centered design, interoperability, and conformance to certification testing. 	As a condition of certification, an EHR vendor would be required to attest that it has: <ul style="list-style-type: none"> engaged in efforts to promote interoperability, including publishing its application program interface (“API”) making available implementation guidelines that support interoperability. 	To help healthcare providers choose HIT products, the proposal establishes conditions of certification and an attestation to the secretary concerning certified HIT products—based on criteria such as: <ul style="list-style-type: none"> the product’s security, user-centered design, interoperability, and real-world testing has been conducted. <p>The EHR Reporting Program is created and will consist of reporting criteria on:</p>

	<p>HIT developers would be required to report on these criteria for each of their certified products.</p> <p>The rating program's methodology and criteria would be posted online, as would each HIT product's star rating (the rating system must use at least three stars).</p> <p>Each developer of an HIT product that received a one-star rating would have to develop and implement a plan to improve the rating, or risk having the product decertified.</p> <p>Hospitals and physicians would be exempted from the Medicare EHR payment adjustment if their EHR technology was decertified</p>	<ul style="list-style-type: none"> • not taken any action that disincentivizes interoperability, and • publically made available any additional costs or fees needed to purchase certified capabilities. <p>ONC would be required to create a portal by January 1, 2019 that would allow the public to compare the price information (including any additional costs for certified capabilities) among health information technology products. EHR vendors obtaining certification would need to publish their pricing information on the portal.</p> <p>Beginning January 1, 2019, any EHR that did not meet these interoperability certification criteria or does not satisfy the related interoperability requirements would be decertified by the Secretary, and the Secretary must publish a public list of the vendors that have been decertified each year.</p>	<ul style="list-style-type: none"> • the product's security, • user-centered design, • interoperability, and • conformance to certification testing; among other categories. <p>\$15,000,000 has been authorized to be appropriate to carry out the grants, contracts and agreements to generate reporting criteria in suggested categories.</p>
<p>Interoperable HIT</p>	<p>'Interoperability' with respect to health information technology means such health information technology that has the ability to securely exchange electronic health information with and use electronic health information from other health information technology without special effort on the part of the user.</p>	<p>Health Information Technology (HIT) Must Satisfy Three Criteria: With respect to all <i>electronically accessible</i> health information, HIT must:</p> <ul style="list-style-type: none"> A. allow for secure transfer of such information to and from other HIT; B. allow for complete access to, exchange, and use of such information; and C. not information block. 	<p>Interoperability is defined as: "(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)."</p>

<p>Information Blocking</p>	<p>Information blocking' means— With respect to a <i>health information technology developer, exchange, or network</i>, business, technical, or organizational practices that:</p> <ul style="list-style-type: none"> • except as required by law or specified by the Secretary, interferes with, prevents, or materially discourages access, exchange, or use of electronic health information; and • the developer, exchange, or network knows, or should know, are likely to interfere with or prevent or materially discourage the access, exchange, or use of electronic health information. <p>With respect to a <i>healthcare provider</i>, the person or entity knowingly and unreasonably restricts electronic health information exchange for patient care or other priorities as determined appropriate by the Secretary</p> <p>Gives the HHS Office of Inspector General (OIG) the authority to investigate and penalize information-blocking practices by:</p> <ul style="list-style-type: none"> • HIT developers, * • health information exchanges and networks, * and • health care providers.** 	<p>Information Blocking is defined to include any technical, business, or organizational practices that an actor <i>knows, or should know</i>, prevents or materially discourages access to, exchange, or use of health information.</p> <p>Give the HHS Office of Inspector General (OIG) new enforcement authority to investigate claims of HIT developers engaged in information blocking.</p> <p>Require ONC to publish guidance on the HIPAA privacy rule and its relationship to information blocking.</p> <p>Starting with the 2018 EHR reporting period, EPs and EHs under the Medicare and Medicaid EHR Incentive Programs would be required to demonstrate in a method established by the Secretary (such as an attestation), that they have not engaged in “information blocking”.</p>	<p>Information blocking' means— With respect to a <i>health information technology developer, exchange, or network</i>, business, technical, or organizational practices that:</p> <ul style="list-style-type: none"> • except as required by law or specified by the Secretary, interferes with, prevents, or materially discourages access, exchange, or use of electronic health information; and • the developer, exchange, or network knows, or should know, are likely to interfere with or prevent or materially discourage the access, exchange, or use of electronic health information. <p>With respect to a <i>healthcare provider</i>, 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.</p> <p>The Secretary through rulemaking shall identify reasonable and necessary activities that do not constitute information blocking.</p> <p>Gives the HHS Office of Inspector General (OIG) the authority to investigate and penalize information-blocking practices by:</p> <ul style="list-style-type: none"> • HIT developers,* • health information exchanges and networks,* and • health care providers.** <p>*Developers, exchanges, and networks found to have engaged in information blocking and submitted a false attestation would be subject to civil monetary penalties not to exceed \$1,000,000 per violation.</p> <p>**Health care providers found to have engaged in information blocking would be subject to incentives and disincentives to change their behavior.</p>
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	<p>*Developers, exchanges, and networks found to have engaged in information blocking would be subject to civil monetary penalties.</p> <p>**Health care providers found to have engaged in information blocking would be subject to incentives and disincentives to change their behavior.</p> <p>ONC would be authorized to refer instances of information blocking to the Office for Civil Rights (OCR) if a HIPAA privacy consultation would resolve the matter.</p>		<p>ONC would be authorized to refer instances of information blocking to the Office for Civil Rights (OCR) if a HIPAA privacy consultation would resolve the matter.</p> <p>ONC must implement a standardized process for the public to submit claims of HIT products or developers not being interoperable or resulting in information blocking.</p>
Trusted Exchange Framework	Requires ONC to convene stakeholders to develop a trusted exchange framework and a common agreement among existing networks to exchange electronic health information (i.e., a “network of networks”).	N/A	Requires ONC to convene stakeholders to develop a trusted exchange framework and a common agreement among existing networks to exchange electronic health information (i.e., a “network of networks”).
Provider Directory	The Secretary would be required to establish a digital contact directory for health care professionals, practices, and facilities.	N/A	The Secretary would be required to establish a digital contact directory for health care professionals, practices, and facilities.
Transmissions to Clinical Registries	require certified HIT to be capable of transmitting data to, and receiving data from, clinician-led (and other) registries.	N/A	Requires certified HIT to be capable of transmitting data to, and receiving data from certified, clinician-led (and other) registries.
HIT Developers as Patient Safety Organization	Extends federal privilege and confidentiality protections to HIT developers who report and analyze patient safety information related to HIT use	Extend federal privilege and confidentiality protections to HIT developers who report and analyze patient safety information related to HIT use.	Extends federal privilege and confidentiality protections to HIT developers who report and analyze patient safety information related to HIT use.
Patient Access	Facilitates patients’ access to their electronic health information by requiring ONC to:	Includes a sense of Congress on individual rights associated with health information, which includes, but is not limited to, the following:	GAO study on patient access to their own protected health information, including barriers to such patient access and complications or difficulties providers

	<ol style="list-style-type: none"> 1. Encourage partnerships between health information networks, health care providers, and other stakeholders to offer access through secure, user-friendly software; 2. Educate providers on using exchanges to provide patient access; and 3. Issue guidance to exchanges on providing patient access. <p>ONC and OCR would be required to develop policies that support dynamic technology solutions for promoting patient access, and would have to help educate individuals and providers on patients' rights under HIPAA.</p> <p>ONC would have to ensure that HIT standards and certification support patients' access to their electronic health information.</p>	<ul style="list-style-type: none"> • Right of Access: HIPAA currently grants individuals a right to access their health information; however, it does not specify what form that access should take. HIT should contain mechanisms that allow patients electronic access to their health information, and HIT should not deny patient requests for health information or impose costs on individuals for access to such information. 	<p>experience in providing access to patients. GAO has 18 months to submit a report to Congress.</p>
<p>Patient Matching</p>	<p>Require GAO to conduct a review of the methods used for secure patient matching and report its findings to Congress within two years.</p>	<p>Establishes as sense of Congress that:</p> <ul style="list-style-type: none"> • Individuals have the right to feel confident that health information in their record is actually their information, which is critical to patient safety and care coordination. 	<p>Requires a GAO report to review policies and activities at ONC and other relevant stakeholders to ensure appropriate patient matching to protect patient privacy and security and ongoing efforts related to those policies and activities within 2 years of enactment.</p> <p>Areas of concentration: Evaluate current methods used in CERT for patient matching:</p> <ol style="list-style-type: none"> a. Privacy of patient information b. Security of patient information c. Improving matching rates d. Reducing matching errors e. Reducing duplicate records <p>Determine whether the ONC could improve patient matching by taking steps including</p>

			<ol style="list-style-type: none"> a. Defining additional data elements to assist in patient data matching b. Agreeing on a required minimum set of elements that need to be collected and exchanged c. Requiring EHRs to have the ability to make certain fields required and use of specific standards d. Other options recommendation by relevant stakeholders
<p>Development of Interoperability Standards</p>		<p>While the process leaves significant discretion to the entity or entities ultimately contracted to recommend standards appropriate for adoption on a national scale, this provision sets forth six categories of standards that are required for interoperability, which include the following:</p> <ol style="list-style-type: none"> 1. vocabulary and terminology; 2. content and structure; 3. transport of information; 4. security; 5. service; and 6. querying and requesting health information for access, exchange, and use. <p>There is a preference for recommending standards, rather than developing them, so that standards are not adopted on a national basis before the healthcare systems is able to use them on a national scale.</p> <p>Compliance with interoperability criteria and standards is required for:</p> <ul style="list-style-type: none"> • vendors of health information technology offered for use by a provider participating in Medicare or Medicaid; • health information systems; • hospitals; and • healthcare providers. 	<p>The HIT Advisory Committee assumes a significant focus on standards and implementation specifications in three primary areas with others suggested:</p> <ol style="list-style-type: none"> 1. Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records. 2. The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment and healthcare operations. 3. The facilitation of secure access by an individual to such individual's health information and access to such information by a family member, caregiver or guardian.

		Non-compliance will be punishable by decertification and civil monetary penalties.	
Elimination of the HITSC	N/A	The HIT Standards Committee will sunset and be replaced by contracting authority granted to the Secretary, thus placing primary responsibility for HIT standards with the private sector.	HIT Standards and Policy Committees are combined into one HIT Advisory Committee, for purposes of standards, implementation specifications, and certification criteria relating to the implementation of a health information technology infrastructure. It remains a FACA of at least 25 members.
Hardship Exemptions for Decertified EHRs	Decertification of an adopted health information technology product under subsection shall be considered a significant hardship resulting in a blanket exemption from the payment adjustments for eligible professionals, eligible hospitals and critical access hospitals.	Providers with electronic health records (EHRs) that have been decertified will receive an automatic one-year hardship exemption from meaningful use penalties, regardless of whether they have already used the current five-year maximum; extensions may also be granted by the Secretary on a case-by-case basis.	Providers with electronic health records (EHRs) that have been decertified will receive an automatic one-year hardship exemption from meaningful use penalties, regardless of whether they have already used the current five-year maximum; extensions may also be granted by the Secretary on a case-by-case basis.
Health Software Regulation	<p><i>Medical Electronic Data Technology Enhancement for Consumers' Health Act (S. 1101)</i></p> <p>Exclude certain types of health software from the FFDCRA definition of medical device, including:</p> <ul style="list-style-type: none"> • products that provide a variety of administrative and health management functions; • electronic health record technology that creates, stores, transfers, and displays patient information; and • software that interprets and analyzes patient data to help make clinical diagnosis or treatment decisions (including CDS tools). 	<p><i>SOFTWARE Act (H.R. 6 Sections 2241-2243)</i></p> <p>Exclude various types of software applications from FDA's regulatory oversight, including:</p> <ul style="list-style-type: none"> • include: products that provide administrative and health management functions; • software that creates, stores, transfers, and displays patient information; and • analytic tools that provide both general health information and patient-specific information (i.e., CDS). <p>Establishes a risk-based exception allowing FDA to exert regulatory authority.</p> <p>However, the House proposal creates a narrower exception for CDS software that the agency determines "poses a significant</p>	<p>Excludes software functions that are intended for:</p> <ul style="list-style-type: none"> • Administrative support of a healthcare facility, including processing and maintaining financial records, claims or billing, scheduling, business analytics, practice or inventory management, admissions, analysis of historical claims data, determination of benefit eligibility, population health management and lab workflow • Maintains or encourages a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention or treatment of a disease or condition • Serves as 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 patient medical chart <ul style="list-style-type: none"> ○ As long as the chart was created, stored, transferred or reviewed by healthcare professions or individuals under their supervision ○ Such records are certified under the ONC CERT program

	<p>In general, this would preclude FDA from regulating these products as medical devices.</p> <p>Also creates an exception allowing FDA to exercise regulatory authority if the agency determines that the use of the software “would be reasonably likely to have serious adverse health consequences” based on four specified criteria:</p> <ol style="list-style-type: none"> 1. Likelihood and severity of patient harm if the software were not to perform as intended. ** The exception would apply to EHR systems (and other software that simply creates, stores, transfers, and displays data), as well as CDS and other analytic tools. 2. The extent to which the software function is intended to support the clinical judgment of a health care professional. 3. Whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function. 4. The intended user and user environment, such as whether a health care professional will use a software function <p>This risk-based approach broadly reflects the agency’s current guidance on</p>	<p>risk to patient safety” based on the same four criteria specified in S. 1101:</p> <ol style="list-style-type: none"> 1. Likelihood and severity of patient harm if the software were not to perform as intended. 2. The extent to which the software function is intended to support the clinical judgment of a health care professional. 3. Whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function. 4. The intended user and user environment, such as whether a health care professional will use a software function 	<ul style="list-style-type: none"> ○ Such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of diagnosis, cure, mitigation, prevention or treatment ● Transfers, stores, converts formats, or displays clinical lab test or other device data and results, finds by a healthcare professional with respect to such data and results, general information about such findings, general background information about such lab test or device data, unless such function is intended to interpret or analyze clinical lab test or other device data, results, and findings ● Unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or a signal from a signal acquisition system for the purpose of <ul style="list-style-type: none"> ○ Displays, analyzes or prints medical information about a patient or other medical information ○ Supports or provides recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition ○ Enables such healthcare professional to independently review the basis for such recommendations that such software presents for that it is not the intent that such healthcare professional rely primarily on any such recommendations to make clinical diagnosis or treatment decisions regard and individual patient <p>The Secretary shall not regulate the software function as a device in the case of a product with multiple functions that contain:</p>
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	<p>regulating mobile medical apps.</p>		<ul style="list-style-type: none"> a. At least one of the software functions above or that otherwise does not meet the definition of a device; and b. At least one function that does not meet the criteria above and that otherwise meets the definition of a device <p>Also creates an exception allowing FDA to exercise regulatory authority if the agency determines that the use of the software “would be reasonably likely to have serious adverse health consequences” based on four specified criteria:</p> <ul style="list-style-type: none"> 1. Likelihood and severity of patient harm if the software were not to perform as intended. ** The exception would apply to EHR systems (and other software that simply creates, stores, transfers, and displays data), as well as CDS and other analytic tools. 2. The extent to which the software function is intended to support the clinical judgment of a healthcare professional. 3. Whether there is a reasonable opportunity for a healthcare professional to review the basis of the information or treatment recommendation provided by the software function. 4. The intended user and user environment, such as whether a healthcare professional will use a software function
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