



**Comparison of Health IT Provisions in H.R. 6 (21<sup>st</sup> Century Cures Act) and S. 2511 (Improving Health Information Technology Act)**

<b>Policy Proposal</b>	<b>Senate – Innovations Initiative</b>	<b>House – H.R. 6</b> Passed House July 10, 2015
<b>Health Software Regulation</b>	<p><i>Medical Electronic Data Technology Enhancement for Consumers’ Health Act (S. 1101)</i></p> <p>Exclude certain types of health software from the FFDCa definition of medical device, including:</p> <ul style="list-style-type: none"> <li>• products that provide a variety of administrative and health management functions;</li> <li>• electronic health record technology that creates, stores, transfers, and displays patient information; and</li> <li>• software that interprets and analyzes patient data to help make clinical diagnosis or treatment decisions (including CDS tools).</li> </ul> <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"> <li>1. Likelihood and severity of patient harm if the software were not to perform as intended.</li> </ol> <p>** The exception would apply to EHR systems (and other software that simply creates, stores,</p>	<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"> <li>• include: products that provide administrative and health management functions;</li> <li>• software that creates, stores, transfers, and displays patient information; and</li> <li>• analytic tools that provide both general health information and patient-specific information (i.e., CDS).</li> </ul> <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 risk to patient safety” based on the same four criteria specified in S. 1101:</p> <ol style="list-style-type: none"> <li>1. Likelihood and severity of patient harm if the software were not to perform as intended.</li> <li>2. The extent to which the software function is intended to support the clinical judgment of a health care professional.</li> <li>3. Whether there is a reasonable opportunity for a health care professional to review the basis of the</li> </ol>

	<p>transfers, and displays data), as well as CDS and other analytic tools.</p> <ol style="list-style-type: none"> <li>2. The extent to which the software function is intended to support the clinical judgment of a health care professional.</li> <li>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.</li> <li>4. The intended user and user environment, such as whether a health care professional will use a software function</li> </ol> <p>This risk-based approach broadly reflects the agency's current guidance on regulating mobile medical apps.</p>	<p>information or treatment recommendation provided by the software function.</p> <ol style="list-style-type: none"> <li>4. The intended user and user environment, such as whether a health care professional will use a software function</li> </ol>
<b>Policy Proposal</b>	<b>Improving Health Information Technology Act S. 2511</b>	<b>21<sup>st</sup> Century Cures Act H.R. 6</b> Passed House July 10, 2015
<b>Administrative Burdens Imposed by HHS Regulations</b>	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
<b>Specialty Certification of EHRs</b>	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
<b>ONC CERT Transparency</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• the product's security,</li> <li>• user-centered design,</li> <li>• interoperability, and</li> <li>• conformance to certification testing.</li> </ul> <p>HIT developers would be required to report on these criteria for each of their certified products.</p>	<p>As a condition of certification, an EHR vendor would be required to attest that it has:</p> <ul style="list-style-type: none"> <li>• engaged in efforts to promote interoperability, including publishing its application program interface ("API")</li> <li>• making available implementation guidelines that support interoperability.</li> <li>• not taken any action that disincentivizes interoperability, and</li> <li>• publically made available any additional costs or fees needed to purchase certified capabilities.</li> </ul>

	<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>	<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>
<b>Interoperable HIT</b>	<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"> <li>A. allow for secure transfer of such information to and from other HIT;</li> <li>B. allow for complete access to, exchange, and use of such information; and</li> <li>C. not information block.</li> </ul>
<b>Information Blocking</b>	<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"> <li>• 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</li> <li>• the developer, exchange, or network knows, or should know, are likely to interfere with or prevent or materially discourage the access,</li> </ul>	<p>Information Blocking is defined to include any technical, business, or organizational practices that an actor <i>knows</i>, or <i>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>exchange, or use of electronic health information.</p> <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"> <li>• HIT developers,*</li> <li>• health information exchanges and networks,* and</li> <li>• health care providers.**</li> </ul> <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>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>
<b>Trusted Exchange Framework</b>	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
<b>Provider Directory</b>	The Secretary would be required to establish a digital contact directory for health care professionals, practices, and facilities.	N/A
<b>Transmissions to Clinical Registries</b>	require certified HIT to be capable of transmitting data to, and receiving data from, clinician-led (and other) registries.	N/A
<b>HIT Developers as Patient Safety Organization</b>	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.

<b>Patient Access</b>	<p>Facilitates patients' access to their electronic health information by requiring ONC to:</p> <ol style="list-style-type: none"> <li>1. Encourage partnerships between health information networks, health care providers, and other stakeholders to offer access through secure, user-friendly software;</li> <li>2. Educate providers on using exchanges to provide patient access; and</li> <li>3. Issue guidance to exchanges on providing patient access.</li> </ol> <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>	<p>Includes a sense of Congress on individual rights associated with health information, which includes, but is not limited to, the following:</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Patient Matching</b>	<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"> <li>• 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.</li> </ul>
<b>Development of Interoperability Standards</b>		<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"> <li>1. vocabulary and terminology;</li> <li>2. content and structure;</li> <li>3. transport of information;</li> <li>4. security;</li> <li>5. service; and</li> <li>6. querying and requesting health information for access, exchange, and use.</li> </ol> <p>There is a preference for recommending standards, rather than developing them, so that standards are not adopted</p>

		<p>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"> <li>• vendors of health information technology offered for use by a provider participating in Medicare or Medicaid;</li> <li>• health information systems;</li> <li>• hospitals; and</li> <li>• healthcare providers.</li> </ul> <p>Non-compliance will be punishable by decertification and civil monetary penalties.</p>
<b>Elimination of the HITSC</b>	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.
<b>Hardship Exemptions for Decertified EHRs</b>	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.