Ensuring Interoperability of Health Information Technology Under the 21st Century Cures Act

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21st Century Cures Act: A Large Piece of Legislation

• After almost two years of negotiations the final bill passed the House 392 to 26, and the Senate 94 to 5.
• On December 13, 2016 President Obama signed the 21st Century Cures Act into law.
• The law authorizes a $6.3 billion package of medical innovation bills including:
  – $4.8 billion to the National Institutes of Health (NIH) which includes $1.4 billion for Precision Medicine Initiative;
  – $1.8 billion for Beau Biden Cancer Moonshot initiative; and
  – $1.6 billion for the BRAIN initiative
• Also provides $1 billion in state grants over two years to address opioid abuse and addiction
• Provides $500 million through 2026 to the FDA
Goals of this Talk

• Answer the following questions:
  – What are the key HIT provisions of the Cures legislation, and when do they take effect?
  – How will the inherent tensions in the legislation play out in terms of new rules and regulations?
  – What can my industry segment or professional group expect from Cures that might change what we do or how we do it?
  – Are there clear winners or losers?
HIT Provisions of the Cures Legislation

• Key HIT provisions of the Cures legislation:
  – Require the Secretary within one year to establish a strategy to reduce administrative and regulatory burdens associated with providers’ use of electronic health records (EHRs). Must include MU, MIPS, APMs, certification, standards.
  – Seek to advance interoperability and curb information blocking.
  – Promote new reporting measures on usability, security, and functionality for EHRs and other HIT and require adherence for certification.
  – Seek to improve patient care and access to health information in EHRs.
  – Require the establishment of a new digital contact index, e.g. a directory, for health care professionals, practices, and facilities.
  – Ensure adequate patient matching to protect privacy and security.
Timeline for Major Cures HIT Provisions

**Milestone 1**
ONC convenes HIT Advisory Committee.

**Milestone 2**
Sec. submits MU report to HITAC.

**Milestone 3**
ONC convenes stakeholders to support trusted exchange framework.

**Milestone 4**
Sec. develops strategy and recommendations to reduce regulatory burdens.

**Milestone 5**
Sec. makes as a condition of certification that technology vendors do not block information, have APIs for access, and have tested the real world use of products for interoperability.

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**Milestone 7**
Sec. must convene stakeholders for the purpose of developing the reporting criteria for EHR Reporting Program, and award grants to implement a process for reporting.

**Milestone 8**
Comptroller Gen. conducts study to ensure appropriate patient matching to electronic health information.

**Milestone 9**
ONC publishes on its website trusted exchange framework and common agreement.

**Milestone 10**
CMS must report on suitability and barriers to telehealth services.

**Milestone 11**
Sec. recommends on voluntary certification of health IT used by pediatricians.

**Milestone 12**
Comptroller Gen. reports to Congress on patient access to PHI, incl. barriers and difficulties experienced.

**Milestone 13**
ONC publishes on its website health info networks that have adopted common trust agreement.

**Milestone 14**
Comptroller reports to Congress on patient matching.

Within 3 years the Sec. shall directly or through partnership with a private entity establish a provider digital contact index for providers and health facilities.
The Mandala of Cures HIT Provisions

Continuity with Recent Past

Additional New Regulations

Tensions

Off in a New Direction

MD-Friendly Deregulation

POLICY

RULES

LEGISLATION

POLITICS
Where to Focus Attention

• For EHR vendors and their customers, process merits close scrutiny:
  – Stakeholder group meetings, information gathering
  – Notices of proposed rule making
  – Comments to NPRMs
  – New rules, requirements, and certifications

• Areas where tensions are greatest include:
  – ONC certification extensions, dealing with:
    • the product’s security,
    • user-centered design,
    • interoperability, and
    • real-world testing.
  – EHRs or mobile apps, telehealth, wearables
  – Penalties for information blocking
  – Inclusion of patients’ access to complete medical records
Restructure of Federal Advisory Committees

• Abolishes the HIT Standards Committee and the HIT Policy Committee that advise ONC
• Establishes new HIT Advisory Committee to consist of at least 25 members
  – Eight members to be appointed by Congress
  – Three appointed by the HHS secretary and
  – All remainder appointed by the comptroller general of GAO
• Committee must have representation from specific health sectors
Interoperability

• Creates a statutory definition for interoperability as Health IT (HIT) that:
  • Enables the secure exchange of electronic health information with, and use of electronic health information from, other HIT without special effort on the part of the user
  • Allows for complete access, exchange and use of all electronically accessible health information for authorized use under applicable state or federal law
  • Does not constitute information blocking as defined in the Cures legislation
Information Blocking

• Defines information blocking as:
• A practice, except as required by law or allowed by the HHS secretary pursuant to rulemaking, that:
  – Is likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information
  – If conducted by an HIT developer, exchange or network, such entity knows or should know that such practice is likely to interfere with, prevent or materially discourage the access, exchange or use of electronic health information
  – If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information
New National Study on Information Blocking Finds Widespread Problem

“Half of [60 HIE leader] respondents reported that EHR vendors routinely engage in information blocking, and 25% of respondents reported that hospitals and health systems routinely do so. Among EHR vendors, the most common form of information blocking was deploying products with limited interoperability. Among hospitals and health systems, the most common form was coercing providers to adopt particular EHR or HIE technology. Increasing transparency of EHR vendor business practices and product performance, stronger financial incentives for providers to share information, and making information blocking illegal were perceived as the most effective policy remedies.”

Source:
Specific Forms of Information Blocking Found in Milbank Quarterly Study

<table>
<thead>
<tr>
<th>EHR Vendors</th>
<th>Often/Routinely</th>
<th>Sometimes</th>
<th>Rarely/Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deployment of products with limited interoperability</td>
<td>49%</td>
<td>31%</td>
<td>20%</td>
</tr>
<tr>
<td>High fees for HIE unrelated to cost</td>
<td>47%</td>
<td>40%</td>
<td>13%</td>
</tr>
<tr>
<td>Making third-party access to standardized data difficult</td>
<td>42%</td>
<td>41%</td>
<td>17%</td>
</tr>
<tr>
<td>Refusing to support HIE with specific vendors or HIEs</td>
<td>31%</td>
<td>37%</td>
<td>32%</td>
</tr>
<tr>
<td>Making data export difficult</td>
<td>28%</td>
<td>40%</td>
<td>32%</td>
</tr>
<tr>
<td>Changing HIE contract terms postimplementation</td>
<td>19%</td>
<td>21%</td>
<td>60%</td>
</tr>
<tr>
<td>Unfavorable contract terms for HIE</td>
<td>17%</td>
<td>35%</td>
<td>48%</td>
</tr>
<tr>
<td>Gag clauses on providers speaking out about information-blocking practices</td>
<td>12%</td>
<td>18%</td>
<td>70%</td>
</tr>
</tbody>
</table>

| Hospitals and Health Systems                                               |                |           |              |
| Coercing providers to adopt particular EHR or HIE technology               | 28%             | 24%       | 48%          |
| Controlling patient flow by selectively sharing patient health information | 22%             | 24%       | 54%          |
| Using HIPAA as a barrier to patient health information sharing when it is not | 15%             | 35%       | 50%          |
Information Blocking

• Establishes that information blocking practices may include:
• Practices that restrict authorized access, exchange or use of such information for treatment and other permitted purposes under such applicable law, including transitions between certified HIT systems
• Implementing HIT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging or using electronic health information
• Implementing HIT in ways that are likely to Restrict access, exchange or use of electronic health information with respect to exporting complete information sets or in transitioning between HIT systems
• Lead to fraud, waste or abuse, or impede innovations and advancements in health information access, exchange and use, including care delivery enabled by HIT
Information Blocking

- Establishes new civil monetary penalties of up to $1 million per information blocking violation, including false attestations, that would be applicable to HIT developers, health information exchanges and networks.

- In contrast, provider penalties will be determined through notice and comment rulemaking.

- For enforcement purposes, information blocking does not include any practice or conduct occurring prior to the date that is 30 days after enactment.
Trusted Exchange Framework

• Requires ONC, NIST and other relevant agencies to convene public-private partnerships to build consensus around developing or supporting a trusted exchange framework
• Including common agreement among health information networks* nationally such as
  – method for authenticating participants
  – rules for trusted exchange
  – enabling organizational and operational policies and
  – a process for adjudicating disagreements
• Within two years of convening event, and annually thereafter, ONC must publish a list of HIE networks that have adopted the common agreement

* HHS Secretary must consider existing exchange networks to minimize disruption
Trusted Exchange Framework
Healthcare Directory

- Requires that within three years of enactment, the Secretary must establish a provider digital contact information index for health professionals and health facilities to encourage the exchange of electronic health information.

- The Secretary must include “all health professionals and health facilities” to create the most useful, reliable, and comprehensive index of providers possible.
GAO Studies

- Patient Matching
- Requires that GAO conduct a study of the current HIT policy landscape and activities of the National Coordinator for HIT and make recommendations to Congress, within two years of enactment, on ways to improve patient matching across the healthcare system such as
  - Creating common minimum data sets for exchange of data
  - Reduce duplication of data while
  - Continuing to protect patient privacy and security
GAO Studies

Patient Access to Their Health Information

• Requires that GAO conduct a study and report to Congress within 18 months of enactment to review patients’ access to their own PHI, including describing
• Practices of charging patients, third parties, and health care providers, for EHR data
• Examples of the amounts and types of fees charged to individuals for record requests,
• Instances in which third parties may request PHI through patients’ individual right of access to circumvent appropriate fees, and
• policies that enable providers to charge appropriate fees to third parties while providing patients access at low or no cost.
Questions
Contact Information

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