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

HIPAA Summit 2017

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21st Century Cures Act: A Large Piece of Legislation

25 Sections, 996 pages

- 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
- Includes significant health IT provisions

Goals of this talk

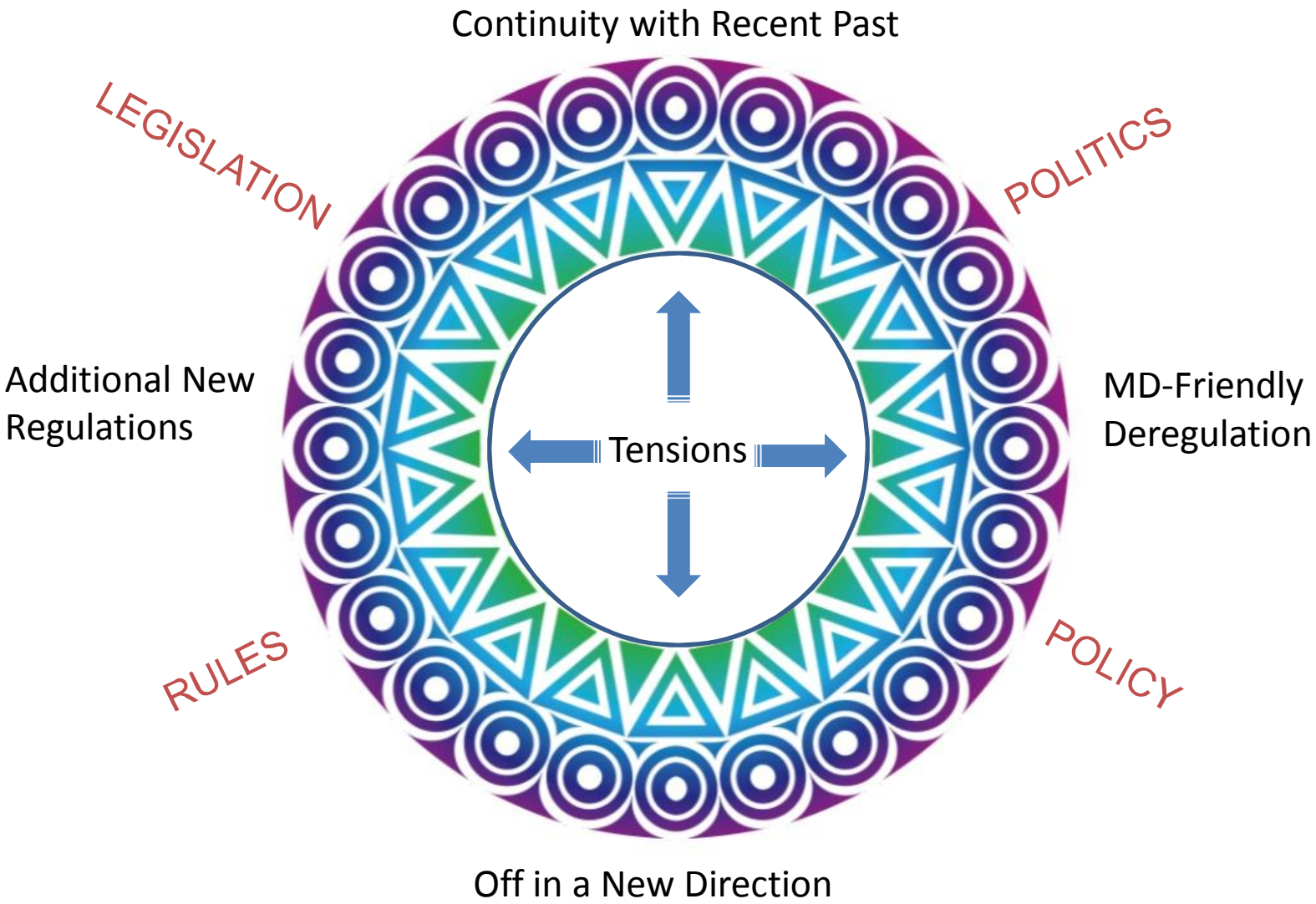
- Answer the following questions:
  - What are the key HIT provisions of the Cures legislation, and when do they take effect?
  - How will the far-reaching components, and inherent tensions, in the legislation play out in terms of new rules and regulations?
  - What can my industry segment or professional 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 – A Response to Providers Complaints on MU

- Key HIT provisions of the Cures legislation:
  1. Require the Secretary 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.
  2. Seek to advance interoperability and curb information blocking.
     - By promoting new reporting measures on usability, security, and functionality for EHRs and other HIT and require adherence for certification.
     - By establishing a new HIT Advisory Committee with broad duties and responsibilities.
     - By supporting a development of a new trust framework and agreement for networks.
     - By seeking to improve patient care and access to health information in EHRs.
     - By requiring the establishment of a new digital contact index, e.g. a directory, for health care professionals, practices, and facilities.
     - By ensuring adequate patient matching to protect privacy and security.

Timeline for Major Cures HIT Provisions

The Mandala of Cures
HIT Provisions



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 and their enforement
  - 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:


THE MILBANK QUARTERLY
A MULTIDISCIPLINARY JOURNAL OF POPULATION HEALTH AND HEALTH POLICY
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Original Investigation

Information Blocking: Is It Occurring and What Policy Strategies Can Address It?

JULIA ADLER-MILSTEIN ✉, ERIC PFEIFER

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Specific Forms of Information Blocking Found in Milbank Quarterly Study

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

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

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