Cutting Edge Health Technology Compliance Issues: The Double-Edged Sword

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Agenda

• 21st Century Cures Act
• Telehealth & Cloud Computing
• Devices
• BigData, Data Mining and Artificial Intelligence
• Questions & Answers
Learning Objectives

• Discuss recent laws and regulations (such as the 21st Century Cures Act)
• Identify the complexities of technology and the unique compliance challenges
• Describe compliance constraints with telehealth and emerging technologies
• Discuss the world of data analytics (BigData, artificial intelligence, and data mining).
21st Century Cures Act

• Bipartisan legislation signed into law in December 2016.
  – House 392 to 26.
  – Senate 94 to 5.

• One of the main goals of this law is to fund biomedical research and speed the approval of new drugs and medical devices.

• Legislative action to reposition the US pharmaceutical and biomedical industry.

• Law contains many other provisions as well and is divided into 4 parts: (A) Cures (B) Helping families in mental crisis (C) Increasing Choice, Access, and Quality in Healthcare for Americans, and (D) Child and Family Services Support.
21st Century Cures Act
Division A - 21st Century Cures
Title I – Innovation Projects and State Responses to Opioid Use
Title II - Discovery (includes the Precision Medicine Initiative)
Title III - Development (Medical Device Innovations)
Title IV - Delivery (Interoperability, Information blocking and telehealth)
Title V - Savings
Title III - Development

(A) Patient-Focused Drug Development,
(B) Advancing New Drug Therapies,
(C) Modern Trial Design and Evidence Development,
(D) Patient Access to Therapies and Information,
(E) Antimicrobial Innovation and Stewardship,
(F) Medical Device Innovations,
(G) Improving Scientific Expertise and Outreach at FDA,  
(H) Medical Countermeasures Innovation,  
(I) Vaccine Access, Certainty and Innovation, and  
(J) Technical Corrections.
Medical Device Innovations

• The section on Medical Device Innovations in Section 3051 contains an expedited process for the approval of medical devices that are designated as breakthrough technologies. The purpose of the section is to provide the Secretary of Health & Human Services with flexible approaches to expedite FDA approval of devices that represent breakthrough technologies. The statute mandates that one year after the enactment of the Cures Act that the Secretary of Health & Human Services will provide guidance as to the process for designation as a breakthrough technology.

• Section 3060 – Clarifying Medical Software Regulation
Clarifying Medical Software Regulation

• The Act amends the FDA “device” definition by creating exclusions from the definition of a device. Device definition:

Section 201(h) of the FD&C Act (21 USC 321(h)) provides that the term "device" means: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-

1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
Act excludes certain software functions from the FDA “device” definition

Devices for:

• Administrative support
• Encouraging a healthy lifestyle
• Electronic patient records
• Clinical laboratory test or device data and results

unless the function is intended to acquire, process, or analyze a medical image or signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system
Finding of the Secretary that the software function could have Serious Adverse Health Consequences

- A software function shall not be excluded from the definition of a device if:
  - The Secretary makes a finding that use of such software function would be reasonably likely to have **serious adverse health consequences**, and
  - The software function has been identified in a **final order** by the Secretary.

- In making a finding with respect to software function the Secretary shall consider –
  - The **likelihood and severity of patient harm** if the software function were to not perform as intended;
  - The extent to which the software function is **intended to support the clinical judgment of a health care professional**;
  - 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; and
  - The **intended user and user environment**, such as whether a health care professional will use a software function intended to acquire, process or analyze a medical image from an invitro diagnostic device or a pattern or signal from a signal acquisition system.
Authority of the Secretary to exercise enforcement discretion or regulate software

• Nothing in this subsection shall be construed as limiting the authority of the Secretary to –
  
  – exercise enforcement discretion as to any device subject to regulation under this Act
  
  – regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or
  
  – regulate software as a device under this Act if such software meets the criteria (under section 513 (a)(1)(C)) of a Class III device requiring premarket approval.
Title IV - Delivery

(1) assisting doctors and hospitals in improving quality of care for patients,
(2) transparent reporting on usability, security and functionality,
(3) interoperability,
(4) information blocking,
(5) leveraging electronic health records to improve patient care,
(6) empowering patients and improving patient access to their electronic health information,
(7) mandating that within one year of the enactment of the Cures Act that the Comptroller General shall submit to Congress a Government Accountability Office (“GAO”) study on patient matching,
Title IV Delivery continued

- (8) requiring the Comptroller General to build on prior GAO studies and conduct a study on patient access to health information,
- (9) streamlining transfers used for educational purposes,
- (10) improving Medicare local coverage determinations,
- (11) the Secretary of Health & Human Services shall provide for a pharmaceutical and technology ombudsman within CMS,
- (12) Medicare site-of-service price transparency,
- (13) telehealth services in Medicare.
Interoperability

• The term ‘interoperability’, with respect to health information technology, means such health information technology that—

• (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).
Trusted Exchange Framework

• Released on January 5, 2018
• Outlines a common set of principles for trusted exchange and minimum terms and conditions for trusted exchange.
• Designed to bridge the gap between providers’ and patients’ information systems
• Enable interoperability across disparate health information networks (HINs).
TEF - Principles

• Principle 1 - Standardization: Adhere to industry and federally recognized standards, policies, best practices, and procedures.

• Principle 2 - Transparency: Conduct all exchange openly and transparently.

• Principle 3 - Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange Electronic Health Information, even when a stakeholder may be a business competitor.

• Principle 4 – Privacy, Security, and Patient Safety: Exchange Electronic Health Information securely and in a manner that promotes patient safety and ensures data integrity.
TEF - Principles

• Principle 5 - **Access**: Ensure that Individuals and their authorized caregivers have easy access to their Electronic Health Information.

• Principle 6 - **Data-driven Accountability**: Exchange multiple records for a cohort of patients at one time in accordance with Applicable Law to enable identification and trending of data to lower the cost of care and improve the health of the population.
TEF - Challenges

- **Permitted Purposes** – Treatment, Payment, Healthcare Operations; plus Public Health, Benefits Determinations, Individual Access (to healthcare)

- **Identity Proofing** - Verifying a person is who they claim to be (Identity Assurance Level (IAL) in NIST SP 800-63A)

- **Digital Authentication** - Establishing confidence in a remote user identity communicating electronically to an information system (Authenticator Assurance Level (AAL) in NIST SP 800-63B)
  - Federal Assurance Level (FAL): strength of an assertion in a federated environment, used to communicate authentication and attribute information (if applicable) to a relying party (RP).
**TEF - Challenges**

- **Breach Notification** - Qualified HIN shall comply with all applicable Breach notification requirements pursuant to HIPAA Data Breach Rule
  - The Qualified HIN must notify the Recognized Coordinating Entity within fifteen (15) calendar days following discovery of a Data Breach
  - The Recognized Coordinating Entity must notify other Qualified HINs affected by the Data Breach within seven (7) calendar days
Information Blocking

The term ‘information blocking’ means a practice that—

• (A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

• (B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network 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; or (ii) 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.
Information Blocking Practices

• The information blocking practices described in paragraph (1) may include—
  “(A) 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 information technologies;

• (B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

• (C) implementing health information technology in ways that are likely to—
  “(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or “(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.
Anticipated Regulations by HHS

• The Secretary of Health & Human Services, pursuant to statutory authority under the Cures Act, shall promulgate regulations that:
  – Identify **reasonable** and **necessary** activities that do not constitute information blocking

• Secretary may consult with the FTC in this regard.
Telehealth Services

• Provision of Information by CMS - Within 1 year of enactment, CMS must provide information to Congress re:
  – The population of Medicare beneficiaries whose care may be improved most in terms of quality and efficiency by the expansion of telehealth services
  – Activities by CMS which examine the use of telehealth services in models, projects or initiatives funded by the Act
  – Type of high volume services that might be available through telehealth
  – Barriers that might prevent expansion of telehealth services
Telehealth & Cloud Computing

• Regulatory Issues
  – Federal
  – State laws and regulations
    • Licensure
    • Fee Splitting
    • Corporate Practice of Medicine
  – Privacy & Security
BigData, Data Mining and AI

• Legal Issues
  – Privacy Laws
    • Health Privacy Laws: HIPAA and other federal privacy laws like GINA,
    • Beyond Health: GLB, FTC regulations etc.
    • GDPR and other international laws
    • State Laws
  – Data Breach Laws
  – Ownership/Contractual Rights to the Data
Privacy & Security Laws

- HIPAA
- Non-HIPAA
- Other Federal & State Privacy Laws
- GDPR
- Other International Laws
Artificial Intelligence

• FDA Definition of Artificial Intelligence
  – A device or product that can imitate intelligent behavior or mimics human learning and reasoning. Artificial intelligence includes machine learning, neural networks, and natural language processing. Some terms used to describe artificial intelligence include: computer-aided detection/diagnosis, statistical learning, deep learning or smart algorithms.

• The Fourth Industrial Revolution.
Questions

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