Mini Summit 42: Legal Risks Around Digital Health Technology

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ROPES & GRAY

Questions for Discussion

- What are “digital health tools”?
- What are some of the key concerns of digital health tools?
- Are there particular tools that have higher risk than others?
- What is the enforcement landscape of digital health tools?
- What are the legal frameworks that apply to digital health tools?
- What are some compliance best practices to consider when evaluating digital health tools?

Digital Health Tools – Broad Category

- Digital therapeutics
- Artificial intelligence diagnostic tools
- Clinical decision support software
- Health / wellness – related apps and wearables
- Drug discovery platforms
- Electronic health records
- Health information exchange
- Clinical-trial management software
- Telehealth / telemedicine
- E-payment/online scheduling
- Population health management
- Internet of Things

Common Legal and Compliance Questions

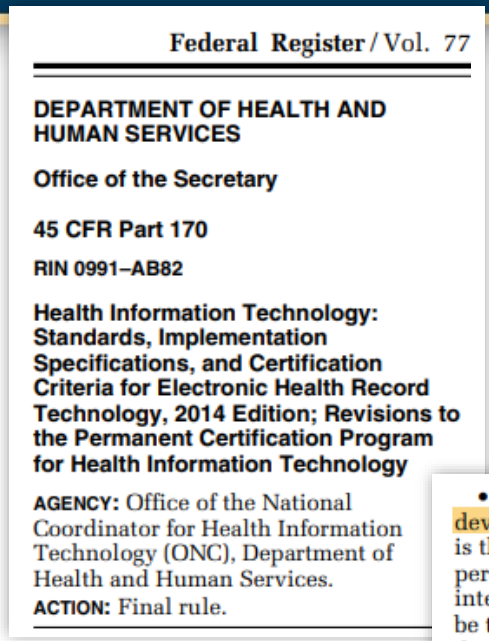
- Does the initiative involve a regulated drug or device?
- Does the initiative involve the provision of value to a patient or healthcare provider?
  - Commercially reasonable transaction?
  - Independent value?
  - *De minimis* value?
  - Nexus to product?
  - Subsidizing routine operations of healthcare providers?
  - Promotes access to care with low risk of harm?
- Does the initiative create a conflict of interest?
- If individual data is being shared, has any necessary patient consent been obtained and are any other appropriate privacy and security safeguards in place?
- What type of promotional review is warranted?
- Is the company's involvement transparent?
- Is the technology or content being presented as objective and, if so, is that accurate?
- Does the tool allow reporting of adverse events? Does it allow communication back to the Company?

Higher Risk Area: Sponsored "Clinical Decision Support"

- **Clinical decision support ("CDS") software** are digital health technologies developed to provide clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.
- Examples of CDS software include:
  - Computerized alerts and reminders to care providers and patients
  - Clinical guidelines
  - Condition-specific order sets
  - Focused patient data reports and summaries
  - Documentation templates
  - Diagnostic support
  - Treatment recommendations
  - Contextually relevant reference information

Sponsored CDS Arrangements

- Sponsored CDS arrangements generally involve sponsors funding the development or deployment of a CDS tool.
- Government guidance specifically acknowledged that the funding source, or sponsor, of the CDS may be a *"biomedical product developer"* (*i.e.*, a pharmaceutical company)
- **Pharmaceutical and medical device companies are increasingly seeking to "sponsor" CDS tools, including software intended to provide diagnostic support or treatment information related to the drugs or medical devices manufactured by the companies.**



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

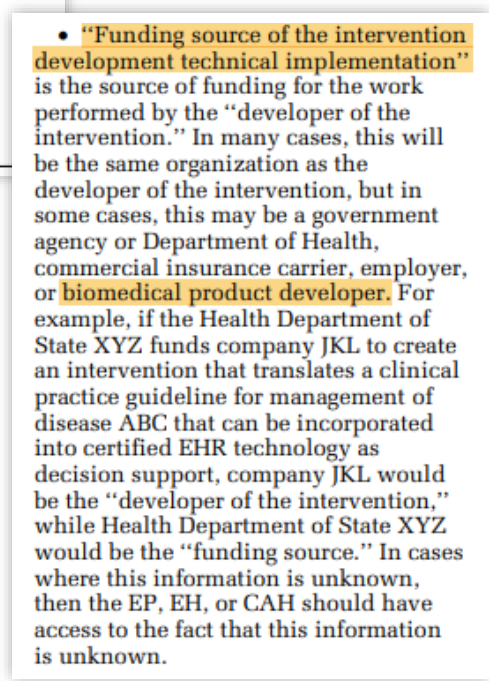
45 CFR Part 170

RIN 0991–AB82

Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Final rule.



• "Funding source of the intervention development technical implementation" is the source of funding for the work performed by the "developer of the intervention." In many cases, this will be the same organization as the developer of the intervention, but in some cases, this may be a government agency or Department of Health, commercial insurance carrier, employer, or biomedical product developer. For example, if the Health Department of State XYZ funds company JKL to create an intervention that translates a clinical practice guideline for management of disease ABC that can be incorporated into certified EHR technology as decision support, company JKL would be the "developer of the intervention," while Health Department of State XYZ would be the "funding source." In cases where this information is unknown, then the EP, EH, or CAH should have access to the fact that this information is unknown.

Practice Fusion Global Settlement – Sponsored CDS

- In January 2020, Practice Fusion settled civil and criminal investigations for $145M, including:

Criminal case ($26.4M)

- **Practice Fusion admitted to soliciting and receiving over $1M in kickback payments from major opioid manufacturer ("Pharma Co. X") to develop a clinical decision support ("CDS") alert that encouraged providers to prescribe opioid pain medications**
- Two count felony information:
  - Criminal AKS violation
  - Conspiracy to violate AKS
- First ever criminal case against EHR software company
- Deferred Prosecution Agreement (three-year term)

Civil case ($118.6M)

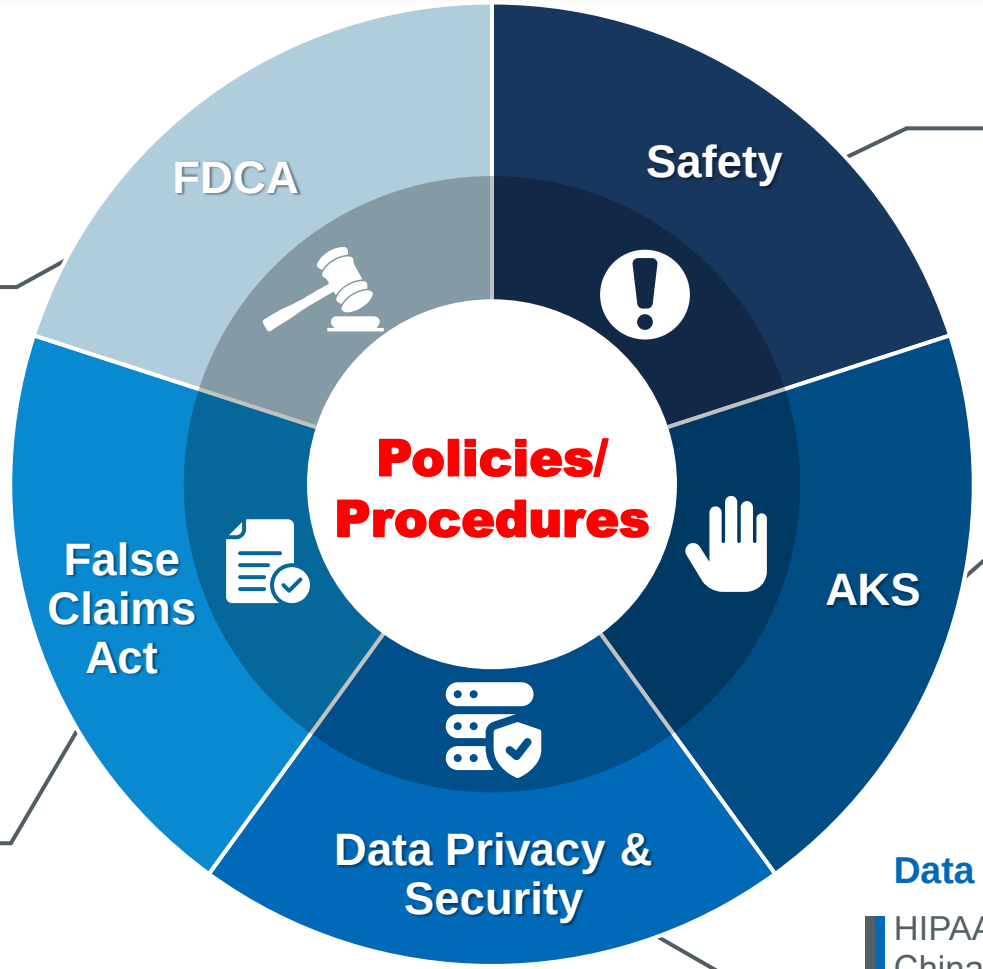
- Civil FCA liability for allegedly causing users to submit false claims for federal incentive payments by misrepresenting its EHR software capabilities
- **Civil AKS liability concerning:**
  - **Opioid-based CDS alert with Pharma Co. X**
  - **CDS arrangements with 13 other pharmaceutical companies allegedly aimed at increasing their drug sales**
- EHR certification criteria "test cheating" theory allegedly involving medical vocabulary and data portability requirements

Other Recent Enforcement Activity

- **Modernizing Medicine** (ModMed), an EHR company, allegedly violated the FCA and AKS by receiving kickbacks from Miraca Life Sciences Inc. (Miraca) in exchange for:
  - recommending and arranging for ModMed's users to utilize Miraca's lab services;
  - improperly donating ModMed's EHR services to HCPs to increase lab orders to Miraca; and
  - paying kickbacks to HCP customers and others to recommend ModMed's EHR.
- In **November 2022**, Modernizing Medicine agreed to a $45 million settlement to resolve the lawsuit.

- **NextGen Healthcare** Allegedly violated the FCA by falsely obtaining certification for its software by concealing from the certifying entity that NextGen's EHR system lacked critical functionality to comply with HHS certification criteria, and receiving government incentive payments based on the misrepresentations.
  - DOJ also alleged that NextGen violated the AKS by giving credits valued up to $10,000 to customers to recommend NextGen's EHR software.
- In **July 2023,** agreed to pay **$31 million** to settle allegations related to its EHR system.

Overview of Legal Framework



FDA Regulation

Tools must be evaluated to determine if they are subject to FDA regulation as a medical device.

Premarket review by FDA may also be required.

Safety

Where needed, having a strong safety assessment in place helps ensure careful consideration of identified risks.

AKS Compliance / Fair Market Value

Digital tools have value and providing them to users at no cost or below FMV poses an AKS risk.

Consider structural arrangements and how to document key decisions and information in support of a FMV determination.

False Claims Act

Failure to properly validate digital health tools creates heightened risk.

Certification requirements for certified EHR technology.

AKS violations can lead to FCA liability.

Data Privacy & Security

HIPAA and state privacy laws, GDPR, China's Cybersecurity Law and international privacy laws, as well as issues related to data collection, ownership and usage.

Compliance Policy Considerations

- General Assessment
  - Is the digital health initiative *similar* to activities previously conducted without using digital technology?
    - Only a change in medium?
  - If so, should existing policy for such non-digital health activities be applied to the digital health initiative (with or without modifications)?
  - If not, what are the relevant regulations and specific concerns?
- Consider requiring implementation of policies and controls around:
  - *Clinical Oversight/Involvement*
  - *Clinical Validation*
  - *Transparency / Disclosures*
  - *Risk analysis*
  - *Risk Mitigation*
  - *Governance*

Questions