What Role Does Compliance Play with Innovation and Healthcare?
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Overview
- Identify current trends in healthcare innovation
- Focus: Big Data, Big Problems?
  - Data Warehouses & Population Health
  - Integrated “Whole Person” Care
- Discuss compliance risks and mitigation strategies
- Questions & Answers

What is healthcare innovation?

In most industries, disrupted comes from startups. Yet almost all health care innovation funded since 2000 has been sustaining to the industry's business model rather than disruptive... $200 billion in venture capital to biotech, pharma, and devices where advances typically make health care more sophisticated -- and expensive. Less than 1% of those investments have focused on helping consumers to play a more active role in managing their own health, an area ripe for disruptive approaches. 

~Clayton M. Christensen, Andrew Waldeck and Rebecca Fogg


"Disruptive" Healthcare Innovations:

- Shift from volume-based to value-based reimbursement
- Personalized medicine based on a patient's molecular and genetic profiles
- Technology-enabled care delivery – telemedicine, telehealth, digital health, consumer-facing mobile apps, wearables
- Use of "Big Data" to manage high-cost patients and population health
- "Whole Person Care" models that integrate medical, behavioral health and social services

2018 Healthcare Executive Group's (HCEG) Top 10 List

1. Clinical and Data Analytics: Leveraging big data with clinical evidence to segment populations, manage health and drive decisions

2. Population Health Service Organizations: Operationalizing population health strategy, chronic care management, driving clinical integration, and integrating social determinants of health

Comorbid medical and behavioral health issues are a significant burden, driving poor outcomes and high costs…

- 30 percent of diabetics,
- 38 percent of patients with chronic lung disease, and
- 40 percent of patients with heart failure

had a co-occurring behavioral condition. These comorbidities increased the annual cost of caring for these patients considerably — by 124 percent, 186 percent, and 76 percent respectively.¹¹

Definitions

- **Big data** is high-volume, high-velocity and/or high-variety information assets that demand cost-effective, innovative forms of information processing that enable enhanced insight, decision making, and process automation.

- **Population health** is defined as the health outcomes of a group of individuals, including the distribution of such outcomes within the group. These groups are often geographic populations such as nations or communities, but can also be other groups such as employees, ethnic groups, disabled persons, prisoners, or any other defined group.

Healthcare Data Analytics

- **Database** is a data structure that stores organized information. Most databases contain multiple tables, which may each include several different fields. Relational databases allow users to access, update, and search information based on the relationship of data stored in different tables.

- **Data warehouse** exists as a layer on top of another database or databases. It takes the data from all these databases and creates a layer optimized for and dedicated to analytics.
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Compliance Risk: Secondary Use of Data

- **Privacy and data security** rules and regulations vary by data source:
  - Medical
  - Mental Health
  - Research
  - Financial
  - Employment
  - Biometrics
  - Social Services
  - Consumer Behavior
  - More…

- What standards govern **combined data sets**?

- How should privacy **breaches** and security incidents be investigated? Which breach notification requirements apply?

Tips & Strategies

- Find your big data / data warehouses
- Assess your organizational culture towards internal data sharing and secondary use of data
- Join your Data Governance committees
- Know your IT champions and data stewards
- Update HIPAA Security Risk Assessment as needed
- **Beware of “de-identified” data sets**

More Definitions

- **Integrated care** is care that results from a practice team of **primary care** and **behavioral health** clinicians, working together with patients and families, using a systematic and cost-effective approach to provide patient-centered care for a defined population.


- **Whole Person Care** is the coordination of health, behavioral health, and social services in a patient-centered manner with the goals of improved health outcomes and more efficient and effective use of resources.

Regulatory Trends & Predictions

- Expansion of Behavioral Health Benefits
  - Mental Health Parity Act of 1996 (MHPA)
  - Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)
  - Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)
  - Patient Protection and Affordable Care Act of 2010 (ACA)

- Medicaid’s Role in California
  - Dept. of Healthcare Services (DHCS) contracts with County Mental Health Departments
  - Medi-Cal Specialty Mental Health
  - Drug Medi-Cal Substance Use Disorder
  - 2014: Medi-Cal Managed Care Plans “carved-in” certain services
  - Whole Person Care Pilots
  - California’s Medi-Cal 2020 Waiver

Compliance Risk: Data Sharing

- Health Insurance Portability & Accountability Act (HIPAA)
  - Covered Entity (CE) may disclose to another CE – or that CE’s business associate – for certain health care operations activities of the recipient CE without patient authorization, including:
    - Conducting population-based activities relating to improving health or reducing health care cost
    - Conducting quality assessment and improvement activities
    - Conducting case management and care coordination (including care planning)
    - Developing clinical guidelines
  - In general, the following requirements must be met:
    - Both CEs must have – or have had – a relationship with the patient
    - Protected health information (PHI) disclosed must pertain to the relationship
    - Only “minimum necessary” information may be disclosed
  - 45 CFR 164.506(c)(4), 164.501, 164.502(b)

Compliance Risk: Data Sharing (cont.)

- CE that participates in an Organized Health Care Arrangement may disclose PHI to other OHCA participants for any health care operations activities of the OHCA. OHCA means:
  - Clinically integrated care setting in which individuals typically receive health care from more than one health care provider:
  - Organized system of healthcare in which multiple CEs participate, present themselves to the public as part of a joint arrangement, and participate in joint activities that include at least one of the following:
    - Utilization review;
    - Quality assessment and improvement activities; or
    - Payment activities, if shared financial risk
  - Certain group health plan arrangements

- Medicare Shared Savings Plan
Compliance Risk: Behavioral Health Privacy

- HIPAA "psychotherapy notes": patient authorization required to release for treatment (45 CFR 164.501, 164.508(a)(2))
- Federally-assisted drug or alcohol abuse programs: patient consent required for most disclosures to outside the program (42 CFR Part 2)
- Mental Health treatment records of certain California facilities, including public and private psychiatric hospitals: patient consent generally required for sharing other than between "qualified professionals" with "medical or psychological responsibility" for the patient’s care. (Lanterman-Petris-Short Act (LPS), Cal. Welfare & Institutions Code §§ 5328 et seq.)

Tips & Strategies

- Identify your integrated delivery models:
  - CIN, ACO, OHCA, Behavioral Health
- Assess your organizational culture towards:
  - Behavioral health records management
  - External data sharing and partnerships
- Review Health Information Management (HIM) policies, including Release of Information (ROI) procedures
- Identify non-workforce EHR users and interoperability settings
- Remember: You may always seek patient permission!

Questions & Answers