Regulatory and Health Policy Issues: Consumer Genomics

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AMP Position Statements

- 2007-
  - Only healthcare provider, only CLIA
- 2015
  - OK DTC with conditions
    - Intent
      - Healthcare related
      - Business driven
      - Ancestry
      - Recreational

https://www.amp.org/AMP/assets/File/position-statements/2019/AMP_Position_Statement_Consumer_Genomics_FINAL.pdf?pass=63

AMP Position Statements

- 2019-
  - Expansion and depth
    - Clinical
      - Transparency
        - » Analytical/clinical validity
      - CLIA
      - Consumer focused
        - » Education, impact on consumer (+/-family), negative not negative, comprehension, referral to genetic counselors healthcare providers
    - Privacy

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Future of Privacy Forum
Best Practices

FUTURE OF PRIVACY FORUM

PRIVACY BEST PRACTICES FOR CONSUMER GENETIC TESTING SERVICES

PROMOTES TRANSPARENCY

Consumers are provided:

- A high level overview of key privacy practices and detailed explaination of how Genetic Data is collected, used, and shared
- Educational resources about the basics, benefits, and risks of genetic testing
- Annual transparency reports describing law enforcement requests

PROVIDES CHOICES

Consumers can:

- Give express consent for the collection and use of Genetic Data
- Give informed consent for research
- Access, correct, and delete their Genetic Data
- Request destruction of biological samples

ENHANCES PROTECTIONS

Companies will:

- NOT share Genetic Data with employers, insurance companies, and educational institutions without consent
- Require valid legal process for disclosing Genetic Data to law enforcement
- Employ strong data security practices and privacy by design

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https://fpf.org/2018/07/31/privacy-best-practices-for-consumer-genetic-testing-services/

Legal/Regulatory Protections of Consumers

- Federal:
  - HIPAA
    - Business associate of a covered entity→ data becomes PHI
  - GINA
    - Genetic discrimination by health insurers and employers
  - ADA
    - Discrimination in employment, public services, accommodations, and communications
      - 1995- prevents employment discrimination based upon genetic information related to illness, disease or other disorders

https://fpf.org/2018/07/31/privacy-best-practices-for-consumer-genetic-testing-services/

Legal/Regulatory Protections of Consumers

- Federal cont:
  - 45 CFR 46
    - Protection of human subjects
  - Patient Protections and Affordable Care Act
    - Prevents health insurance to prevent coverage based on ‘pre-existing conditions’ (genetic information)

https://fpf.org/2018/07/31/privacy-best-practices-for-consumer-genetic-testing-services/

Legal/Regulatory Protections of Consumers

- State:
  - 48 + DC- genetic discrimination in health insurance
  - 35+ DC- employment
  - 17- life insurance
  - 17- disability insurance
  - 8- long term care insurance
  - CalGINA- emergency medical services, housing, mortgage lending, education and other state funded programs

https://fpf.org/2018/07/31/privacy-best-practices-for-consumer-genetic-testing-services/

Summary

- Industry in evolution
  - Clinical
    - Appropriateness, safety, validity, regulation
      - Regulatory environment
    - Privacy
      - Call for clarity and transparency
      - Best practices
      - Legal and regulatory protections
    - Incorporation into routine healthcare
      - Unfamiliar, provider education

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