

Fostering Innovative Digital Health Strategies

Agenda – June 23, 2016

8:30 – 9:30 a.m. **Registration and Networking Breakfast**

9:30 – 9:45 a.m. **Welcome – Jodi Daniel, Partner, Crowell & Moring**

9:45 – 11:00 a.m. **Session 1: Trends in the Health Care Economy's Internet of Things**

There is an explosion of mobile apps, wearable sensors, and even ingestibles that are collecting health information and are networked to other sources of data. In this session, we will discuss key trends in the Internet of Things (IoT) for health care. Business leaders will discuss how digital health technologies are being used to improve quality of care, engage patients as consumers, manage population health, and to support clinical research, and will discuss shifts in investment of these technologies.

Panelists:

- Jodi Daniel, Partner, **Crowell & Moring**, and former director of the Office of Policy in the Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services (*Moderator*)
- Zane Burke, President, **Cerner**
- Cheri Falvey, Partner, **Crowell & Moring**, and former general counsel of the Consumer Product Safety Commission
- Melissa M. Goldstein, JD, Assistant Director for Bioethics and Privacy, **Office of Science and Technology Policy Executive Office of the President, The White House**
- Kaveh Safavi, Senior Managing Director, Global Health Industry Lead, **Accenture**

11:00 – 12:15 p.m. **Session 2: Setting up a Platform for Digital Health**

Entities that create digital health platforms, providers that are using platforms to benefit patients, and health plans that encourage the use of digital health technology for consumer engagement, remote monitoring, and telehealth, should all understand the regulatory and practical issues surrounding digital health platforms. This session will focus on FDA and other agency oversight of this technology, integration of digital health technologies into health care company operations, and consumer-side concerns, including privacy and security. The discussion will also identify major legal issues that have emerged from the growing use of digital health technology and the changes in data use and service arrangements.

Panelists:

- Jodi Daniel, Partner, **Crowell & Moring**
- Bakul Patel, Associate Director for Digital Health, **Center for Devices and Radiological Health, FDA**
- Anna Shimanek, Senior Legal Counsel, **CVS Health**
- Paul L. Uhrig, EVP, Chief Administrative, Legal, & Privacy Officer, **Surescripts**
- Ronan Wisdom, Managing Director, **Accenture Digital**

12:15 – 12:30 p.m. Blockchain and Health Care – Jodi Daniel, Partner, Crowell & Moring

12:30 – 12:45 p.m. Break for Lunch

12:45 – 2:00 p.m. Session 3: Lunch – Congressional Digital Health Efforts: Important Legal Changes on the Horizon (PRIVATE SESSION – CLOSED TO MEDIA)

Congress has been actively engaged in health IT issues in the last year, having held numerous hearings and introduced health IT legislation. There are a number of bills recently passed and currently pending that address interoperability, information blocking, FDA oversight of health IT, patient access to their health information, and telehealth. We will highlight key legislative efforts and what is likely to emerge from Congress in 2016 and beyond.

Panelists:

- James Flood, Partner, **Crowell & Moring** (*Moderator*)
- Aimee Grace, CONNECT for Health Act Lead Staffer, Health Policy Advisor, **Office of U.S. Senator Brian Schatz**
- Brett Meeks, Health Counsel, **Senate Committee on Health, Education, Labor and Pensions (HELP)**
- James (J.P.) Paluskiewicz, Professional Staff Member, **Subcommittee on Health, House Committee on Energy & Commerce**
- Arielle Woronoff, Health Counsel, **Subcommittee on Health, House Committee on Energy & Commerce**

2:00 – 3:15 p.m. Session 4: Using the Products of a Digital Health Platform and Big Data – Privacy and Cybersecurity

New sources of digital health data naturally give rise to issues concerning the use and disclosure of the data collected, such as for research, population health, marketing, or for any other purposes. This session will include a discussion of the desired uses for data, the privacy rules regarding such uses, including de-identification of health data, the security risks in aggregating multiple sources of data, needs to protect data from security breaches, and preparing to respond in the event of a breach. We will discuss the scope of HIPAA privacy and security rules regarding collecting and sharing data from digital technologies and OCR guidance. We also will discuss risk mitigation strategies, and identify privacy best practices with using and combining data in new ways.

Panelists:

- Fauzia Zaman-Malik, Managing Director – Legal Global Health Transactions, **Accenture** (*Moderator*)
- Cora Han, Senior Attorney, Division of Privacy and Identity Protection, **Federal Trade Commission**
- Hilary Weckstein, Chief Privacy Officer, **Inovalon, Inc.**
- Evan Wolff, Partner, **Crowell & Moring**, and former advisor to the senior leadership at the Department of Homeland Security

3:15 – 3:30 p.m. Break

3:30 – 4:45 p.m. *Session 5: New Payment Models and New Sources of Data for Care Coordination and Quality Improvement*

Digital health and the IoT are changing the amount of available data, what can be learned from that data, the way health care is delivered, and how people understand their own health. As payors shift from fee-for-service to outcome-based payment models, various incentives encourage coordinated care and patient engagement. This session will focus on new federal payment policies driving these changes, including shared savings programs (e.g., Accountable Care Organizations) and the Merit-Based Incentive Payment System (MIPS). We will discuss new technologies for providing care and managing patients, including telehealth and remote monitoring. The discussion will include operational and workflow issues arising from new health care arrangements as well as issues incorporating data from providers and patients into electronic health records. We will also address legal issues including medical licensure, reimbursement, and liability.

Panelists:

- John Brennan, Partner, **Crowell & Moring** (*Moderator*)
- Dr. Elizabeth Raitz-Cowboy, Southeast Medical Director, **Aetna Life Insurance Company**
- Barbara Ryland, Senior Counsel, **Crowell & Moring**
- Soph Sophocles, Associate General Counsel, **Biogen Idec Inc.**

4:45 – 5:00 p.m. *Closing Remarks*

5:00 p.m. *Networking Reception*