Growing Needs (and Costs)

- 133 million+ Americans suffer from chronic conditions such as diabetes, chronic obstructive pulmonary disease, and mental illness (~171 million by 2030)
- U.S. healthcare spending to reach ~$3.5 trillion in 2017, representing 18% of the entire U.S. economy (to reach 20% by 2025)
Construct to Address New Challenges & Opportunities
Connected Health Tech in 21\textsuperscript{st} Century Healthcare Systems

- Strong (and growing) body of evidence shows that connected health tech:
  - Improves patient care
  - Reduces hospitalizations
  - Helps avoid complications
  - Improves patient engagement
  - Reduces healthcare costs
  - Driving Internet of Things marketplace (valued at over $250b in the U.S. alone)
  - Job creation
Challenges & Opportunities – Federal Legislative

• Bills
  • CONNECT for Health Act
  • CHRONIC Care Act
  • Telehealth Modernization Act
  • Affordable Care Act
  • 21st Century Cures Act

• Issues
  • Use of dynamic technical protection mechanisms (e.g., encryption)
  • Law enforcement access to data stored abroad
  • Etc…
Challenges & Opportunities – Federal Regulatory

- HHS Centers for Medicare and Medicaid Services (CMS)
- HHS Office of Civil Rights (OCR)
- HHS Office of the National Coordinator for Health IT (ONC)
- Food and Drug Administration (FDA)
- Federal Communications Commission (FCC)
- Federal Trade Commission (FTC)
- Executive Orders
- HHS Centers for Medicare and Medicaid Services (CMS)
  - Center for Medicare and Medicaid Innovation (CMMI)
  - Annual Physician Fee Schedule (PFS) & other schedules
  - Medicare and CHIP Reauthorization Act (MACRA) implementation
    - Merit-based Incentive Payment System (MIPS)
    - Alternative Payment Models (APMs)
    - Diabetes Prevention Program (DPP)
Challenges & Opportunities – HHS

- HHS Office of Civil Rights (OCR)
  - HIPAA guidance
  - HIPAA enforcement
- HHS Office of the National Coordinator for Health IT (ONC)

HIPAA Check
Challenges & Opportunities – FDA

- Food and Drug Administration (FDA)
  - FDA Guidance – known knowns & known unknowns
  - Streamlining approvals and device updates
Challenges & Opportunities – FCC & FTC

- Federal Communications Commission (FCC)
  - Connect America Fund
  - Spectrum licensing/sharing
  - Internet regulation
- Federal Trade Commission (FTC)
  - Health Breach Notification Rule (non-HIPAA)
  - General consumer protection
• Executive Order - minimizing the economic burden of the patient protection and Affordable Care Act pending repeal