Key Policy Issues That Need to be Addressed for a Learning Health System

1. Incentives/Business Case for Data Sharing
2. Standards for Interoperability
3. Assuring Patient Access to Their Information
4. Governance, Privacy Policy
5. Others?
Policy Vehicles in Play

- **Medical Innovation Package**
  - Senate HELP Committee in the middle of three-step mark-up of Senate version of medical innovation package, health IT legislation approved February 9, 2016; final mark-up April 6
  - Hopes for bringing package to Senate floor before June
- **White House Precision Medicine Initiative and Vice President’s Moon Shot for Cancer**
- **Prescription Drug and Medical Device User Fee Authorizations**
- **Implementation of MACRA**
- **Presidential Elections**
- **Ongoing Work of ONC, Interoperability Roadmap, Standards Advisory, EHR Certification, etc.**
- **Reauthorization of PCORI**
- **Market Action**
Senate HELP Committee-Approved Health IT Legislation

- **Information Blocking**
  - Gives HHS Office of Inspector authority to investigate and establish deterrents to information blocking practices that interfere with appropriate sharing of electronic health information

- **Interoperability**
  - Convenes existing data sharing networks to develop a voluntary model framework and common agreement for the secure exchange of health information across existing networks to help foster bridging between networks.
  - Creates a digital provider directory to both facilitate exchange and allow users to verify the correct recipient.
  - Requires that HHS give deference to standards developed in the private sector
  - Requires that certified HIT exchange data with registries if registries are certified to use standards endorsed by ONC
  - Directs the GAO to conduct a study to review methods for securely matching patient records to the correct patient.
Empowering Patients and Improving Patient Access to Their Electronic Health Information

- Supports the certification and development of patient-centered health record technology so that patients can access their health information through secure and user-friendly software that may update automatically.
- Encourages the use of Health Information Exchanges to promote patient access by educating providers and clarifying misunderstandings.
- Requires HHS to clarify situations where it is permissible for providers to share patient information by providing best practices and common cases where sharing is allowed.

Rating System for Users

- Security
- Usability, and
- Interoperability
Policy Influencers

- Align behaviors or outcomes through reimbursement programs
- Tie conditions (e.g., use of standards, make data publicly available, etc.) to use of federal funds (e.g., MACRA, meaningful use, NIH grants, all federal contracts, etc.)
- Create new authorities (e.g., convening, collaboration, etc.)
- Use regulatory mechanisms (e.g., certified EHRs, clinical laboratories, HIPAA enforcement, conditions of participation, etc.) to drive behavior
What the Bipartisan Policy Center is Doing Related to Learning Health System

▪ Continuing to provide technical assistance to Senate HELP Committee on advancing medical innovation legislation
▪ Continuing to push for legislation on information blocking, interoperability and patient access
▪ Launching a series of interviews, roundtable discussions, and research, to develop policy recommendations on the Generation and Use of Real World Evidence
  – Releasing report this summer
  – Public event this summer
  – Policy recommendations and strategy
Some Observations

- **Concept of Learning Health System is not widely known**
- **There is a real opportunity to advance changes in policy**
  - Dissatisfaction with progress made
  - Political drivers on both sides
  - Several vehicles in play or coming up
  - New Administration also offers an opportunity
- **Other factors are driving change**
  - New models of payment and delivery
  - Biomedical innovation
  - Increasingly wired patient
- **Find ways to align priorities with existing hot topics that policymakers, people and organizations are focused on**
Ways That Kanter Foundation and Learning Health System Collaborators Can Influence Policy

- **Pilot Project**
  - Demonstrate how the LHS vision can work in the real world

- **One or Two-Pager, Policy Priorities for a Learning Health System**
  - Targeted strategy to influence legislation, executive branch policy
  - Move quickly to be relevant
  - Build coalition around policy imperatives

- **Public relations campaign, consumer-led**

- **Others?**