Statement of
Dan Riskin
Founder, Health Fidelity
Consulting faculty, Stanford University

Before the
U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Communications & Technology
and
Subcommittee on Healthcare

Hearing on "21st Century Technology for 21st Century Cures"

July 17, 2014

Post-hearing Questions

Testimony of Dan Riskin

Committee on Energy and Commerce Subcommittee on Communications & Technology and Subcommittee on Healthcare

Questions from the Honorable Joe Pitts

1. The characteristics of big data - Velocity, Variety and Volume - are often minimized when used for healthcare due to the complexity and restraints of HIPAA. Does Congress need to take a fresh look at our privacy laws to enable patients to become "data donors", giving consent to allow their medical data to be shared for longitudinal research.

This question strikes at the heart of how clinical data can be valuable not just for daily patient care, but also for making the practice of healthcare more effective and efficient. Congress could significantly benefit the nation if it took a fresh look at privacy laws to examine how patients can be empowered to consent to specific uses of their data to advance medicine.

The big data opportunity to advance the practice of healthcare is powerful. Based on direction from Congress, an immense quantity of clinical data is now being collected. There is an opportunity to mine these data to understand more effective and efficient clinical approaches that leverage clinical observations, genetic information, consumer biometrics, and consumer observations. Research has been

hindered by inability to consistently extract full clinical data from the electronic health record (interoperability) and inability of patients to consistently authorize use of their data for such research (consent). Each issue will be discussed in turn.

The interoperability requirement to make big data effective for research is a business problem. Given that most data are currently not required to be interoperable from the EHR itself, each health system must independently pay to build custom interfaces to translate portions of the medical record. At a business level, the cost of custom data interfaces is acceptable in certain circumstances and for some data, specifically where it influences the top or bottom line of the health system. An example is extraction of portions of EHR data relevant to and that can support billing optimization. On the other hand, the clinical data needed for research are far more extensive and the business drivers for research are less robust. For example, a study may require testing two interventions against an outcome such as an adverse event, improved symptom, or worsening of disease. Many of these outcomes do not exist as interoperable data, but rather require big data techniques applied to shared full clinical data, including discrete and narrative content on an encounter-by-encounter basis. Thus, within today's federal interoperability requirements, it would be exceedingly expensive and would not make sense for a health system to pay for extraction of the expansive clinical data that could accelerate research. Even interoperability requirements being considered for Meaningful Use Stage III will not be sufficient, as the patient summary represents a tiny fraction of the full clinical data captured in the EHR.

An interoperability mandate that could meaningfully support big data research in healthcare would need to include interoperability of full clinical data.

The consent requirement to enable big data research in healthcare is primarily a logistics challenge. There is currently no consistent approach or guidance for how to safely and consistently garner patient consent for needed research that leverages electronic clinical data. There is no health system that can afford the logistics required to request consent from each patient for each potential question. Similarly, the logistics of meeting multiple privacy and security regimes imposed by the states in addition to those included in HIPAA create an overwhelming data challenge. While the interoperability needs are clear (though not yet addressed), the pathway to support safe and consistent consent is far less clear. Congressional review of approaches to allow safe and consistent use of clinical big data, including potentially identified or re-identifiable patient data, would be a boon to the research world and could greatly expand the value derived from clinical data being captured today.

2. What are the barriers to deploying genomics data into clinical care? When can we expect to see the ultimate big data incorporated into Electronic Health Records to enable personalized medicine to replace many of the trial and error treatments patients receive today?

One of the most powerful uses of clinical data to tailor and improve care will be

integration of clinical and genomic data. Early successes have already been seen in this field.

While the EHR is well set up to capture clinical data at the point of care and to support hospital workflow, these key features reflect a core competency and the majority of spend of EHR companies. Other firms have greater expertise in robust data analytics, genomic integration, or consumer engagement. Just as consumer internet software must frequently interact with other software to be effective, a phenomenon often referenced as "apps," so must health IT advance beyond monolithic software built by one company and upgraded annually.

In a future world, the clinical phenotype (or clinical characteristics of the patient) will be collected by the EHR and the clinical genotype (or genetic characteristics of the patient) will be collected by a lab system. Perhaps consumer information (such as biometrics) is captured by a watch and uploaded to another cloud repository. These data sets can be powerfully integrated to understand relationships of diseases, impact of treatments, and opportunities for intervention. The data needed for these types of analyses are collected today.

There are multiple barriers to combining genomic data with clinical data sets to better tailor therapy.

- Cost: The primary barrier for many years has been cost. Today, basic genetic evaluation with single nucleotide polymorphism (SNP) is simple

and cheap, and full genetic mapping is rapidly becoming available and affordable. This barrier will rapidly disappear based on market forces.

- Interoperability: The next challenge is combining the genetic data with phenotypic data. This cannot be done within the EHR as those systems are being given incentive for deployment, workflow optimization, and maximized reimbursement. It is unlikely that any federal program will give sufficient incentive to the EHR firms to focus meaningful innovation outside of their core areas. Thus, other firms must be given the opportunity to combine and analyze these data sets. Interoperability will be required for emerging software to access the clinical phenotype of the patient. Billing data and patient summaries will not be sufficient, so national interoperability aspirations will need to change before progress can be made.
- Incentives: There is limited incentive to tailor therapy in a fee-for-service world. In its current manifestation, value-based healthcare supports measurement of quality, but gives limited incentive for the multi-year efforts or for the significant infrastructure spend that personalized medicine will require. The payment model would need to actively support tailored therapy, through hospital, professional, and diagnostic reimbursement.
- Privacy: Current privacy policy does not support the patient in consenting to the research and clinical approaches that personalized medicine will require.

3. You state in your testimony that “data-driven healthcare not only assures the right information is available for the right patient at the right time, but also provides pathways for information to be used in less traditional ways, such as population health and patient engagement. In your opinion, what barriers currently exist that this committee and the general public should keep in mind when thinking about the potential of data-driven health care? For instance, some previous witnesses have stated that while the intent of HIPAA is great, it has become burdensome in some areas and actually prohibit the kind of patient empowerment and interaction that we all believe is necessary. Are there others?

To be implemented in the real world, data-driven healthcare requires a combination of technology and workflow.

There are drivers and there are barriers that significantly impact the pace of adoption. The greatest drivers for data-driven healthcare are reimbursement for care improvement, subsidized collection of data, and increasingly powerful technology. The greatest barriers for data-driven healthcare are limited consumer engagement, limited physician incentive to improve care, strong physician disincentive to expend unpaid time on new technology, limited data interoperability, complex privacy policies, and poor alignment of payment incentives. Too often, those who hold patient information see it as a competitive advantage instead of a resource for improving care for all.

While many factors are outside of the scope of Congress, the committee may consider foundational issues of privacy, interoperability, and payment incentives if the goal is to support a more rapid transition to data-driven healthcare. Privacy and interoperability are discussed in previous questions. Payment models are being considered in depth by CMS. One overarching challenge remains the annualized view of payments that restricts personalized and population health efforts that may provide extended benefits over years. These benefits, because of timeframe of benefit, are often not captured by the health system that is asked to invest.

4. You state in your testimony that "through the meaningful use program, our country has footed much of the cost of electronic capture of clinical data." Then you go on to ask "Why wouldn't we require that all data we capture be available for use by innovative companies and technologies that improve care." Can you expand on this idea? Are there barriers that currently prohibit such sharing?

The federal government has subsidized massive expansion of a segment of the healthcare information technology (HIT) industry. This segment, electronic health records, is only one facet of the HIT solution. In fact, analytics and workflow design, which have the greatest potential to influence costs and quality of care, were rarely mentioned in early years of national spend on HIT and are only now coming into the national spotlight. The EHR is important mostly in its ability to feed downstream systems and has done its job well in capturing electronic data.

In an ideal world, the data captured by the EHR would then be shared between software systems so firms with the greatest expertise in areas like population health and patient engagement can compete on equal ground. But, with government funding, the EHR segment finds itself extremely well-funded and in need of expansion opportunities. EHR companies are considering expanding into population health, clinical analytics, disease management, consumer engagement, revenue cycle, and many other areas of healthcare. While other companies may be more expert, they are frequently locked out of the market based on the expense of drawing data out of the EHR. There is a strong financial incentive for EHR companies to prevent easy and efficient access to data, thereby creating data lock in and a competitive advantage across multiple industry segments.

The government has created this challenge through preferential subsidies to one market segment. The data now exist within one set of software systems. Only the government can change policy to require the data be available for other businesses to create products which play to their strength and to recreate an environment of competition.

There is widespread recognition that interoperability should be required, but limited discussion within congress of what specific interoperability is needed. Current focus of discussion is on sharing of patient summaries. This solves a problem known as transition of care. Specifically, if a patient goes to a health

system for care and a different emergency department for an urgent condition, both systems should have the same background clinical information. This problem is obvious and should be solved. But, the more pressing and far reaching problem is that of clinical analytics and population health. This is where the predominant financial benefit in health IT is to be found. Unfortunately, patient summaries provide minimal support for clinical analytics and population health. As an example, a software system may seek the high risk patients that are likely to be readmitted to the hospital and could benefit from resources at home. A physician narrative on follow up clinic visit may state, "This gentleman appears frail and malnourished. He is poorly compliant with his medications as he has been unable to find transport to the pharmacy to have medications refilled. He is coughing profusely." While this is all critical information for population health and all of it would exist in the EHR, absolutely none of it would be included in a patient summary and none of it would make it to the software system used for population health. A patient summary includes a few data elements such as a problem list and a medication list, but ignores content such as social situation, clinical impressions, and risk factors.

So, in fact, congress paid for capture of massive amounts of clinical information, but only asked that a tiny portion be shared with analytics software and other systems that can influence cost and outcomes. With current Meaningful Use Stage III proposals, only a modest portion of information would be shared and available for analytics. Sharing of full clinical data is feasible and needed, but only sharing

of patient summaries is being requested.

The Honorable Anna Eshoo

1. What are your top two policy recommendations that Congress could undertake to improve the adoption of telemedicine?

Telemedicine offers great promise. Potential benefits of telemedical consultation include: reduced costs, reduced patient wait times, better patient experience, more effective triage and use of primary care, better and more immediate access to practitioners of appropriate training and skill, and more efficient team-based medical approaches. Advanced telemedicine platforms currently incorporate secure and private high definition audio and video capabilities, file sharing between patients and doctors, and access to a robust network of physicians.

Few of the challenges in telemedicine are related to technology. Rather, a host of barriers exist related to: reimbursement models, physician licensure, ambiguity regarding the appropriate scope of and standard of care for telemedicine visits, uncertain legal exposure in telemedicine visits, and lack of experience in telemedicine to define best practices.

Telemedicine is desirable for the consumer and can support an efficient health system. Thus, there is a strong national incentive to lower barriers to provision of

telemedicine and support financial viability of virtual care.

There have been extensive discussions on ways to support telemedicine. Two efforts Congress may consider to promote adoption of telemedicine are: (i) guidance to Centers for Medicare & Medicaid Services (CMS) to pilot reimbursement models that support telemedicine and (ii) further legislative definition of acceptable telemedicine practice including standardized telemedical licensure in each state.

Additional areas to consider include approaches to reimbursement for primary and specialty-based virtual care, the Federation of State Medical Boards Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine, and approaches to minimize licensing barriers for physicians that are no longer as geographically tethered as they once were.

2. What are additional steps we can take to encourage interoperability with electronic health records, while ensuring patient privacy and HIPAA standards?

Interoperability is required to support safe transitions of care and to support future needs in clinical analytics and population health. The challenge is that the more data is shared, the more data is at risk. A robust network of electronic usable patient data must be balanced by equally robust privacy and security protections.

To enhance interoperability, requirement of full clinical data sharing should be considered in Meaningful Use Stage III. Sharing patient summaries is simply not sufficient to support clinical analytics and population health.

As data are shared between systems and potentially stored in multiple local and cloud repositories, risk for data breach increases. HIPAA offers robust approaches for managing a data breach once it has occurred, but offers little guidance on preventing the problem. Breach prevention will become increasingly critical as clinical data is increasingly moved and used.

The fact is that we are in a new world of cloud systems and expansive electronic patient data. Best steps in privacy and security are not necessarily clear, so the best answer to the question may be a rational approach to solving the problem rather than a simple solution.

In considering privacy and security legislation, the following broad issues should be seriously considered: Inconsistent security protocols in cloud storage of identified clinical data, failure of health systems to universally require data encryption at rest for data stored behind firewalls, inconsistent encryption of data in transit, different standards of security at the health system level for clinical data used in operations versus clinical data used in research, inconsistent approaches to patient consent for use of data, and limited sophistication in data access privileges

and controls within covered entities and business associates. These challenges are complex and new.

FTC Commissioner Julie Brill has noted that consumer generated health information is growing, through connected devices and the Internet of Things, with health data flows that are occurring outside of any medical context, outside of HIPAA and outside any healthcare regulatory regime. HIPAA has always been a limited scope security and privacy rule. Potential revision should consider the gap where various entities collect or maintain healthcare data but are not covered by the HIPAA Rule. There are significant changes in technology, data, and hospital workflow from what existed even a few years ago.

Finally, consideration should be given to expanding what is considered identifiable. Consistent application of best practices and common policies will help build trust. Patients continue to be concerned with data privacy, and this includes both healthcare and non-healthcare data. Hospitals in many cases must comply with many different requirements including HIPAA, SOX, PCI, and numerous state privacy, security and breach notification laws. An approach focused on overall privacy, security and breach notification requirements for all personally identifiable information (PII), and not just PHI, may be beneficial, expanding from a sectoral approach toward an overall security posture. This may, over time, reduce compliance uncertainty for organizations that are awash in expanding data flow and increasingly complex data use opportunities.