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Good afternoon. My name is Bill Bernstein. I am the chair of the Health Division at Manatt, Phelps and Phillips. It is an honor to be asked to testify before the Executive Subcommittee of the National Committee on Vital and Health Statistics on the issue of "meaningful use" of EHRs and health information exchange ("HIE").

My work in this arena is quite varied and covers multiple perspectives, including working with the American Health Information Management Association on its State Level HIE Consensus Project, working with individual states, including California, New York, Tennessee, Nebraska, and Colorado, on their statewide health information technology ("health IT") plans, working with leading HIEs and working with hospitals, managed care companies and innovative technology companies that improve care quality by providing patients and providers with more and better information on which to make treatment decisions at the point of care.

Some Initial Observations on Getting It Right

Before I get into my specific thoughts about the appropriate definition of "meaningful use," I wanted to start with a few over-arching points about what I think HIE and the use of EHRs should be aspiring to achieve.

First, I think we need to be clear about the problems we are trying to solve. Some of the main problems are:

- Fragmentation and Disincentives
- Patient and Provider Communication Gaps
- Knowledge/Care Delivery Gaps

Second, HIE and EHRs should not be thought of separately. In all the projects in which I have participated, HIE is critical to realizing the benefits of moving clinical workflows to the digital world. Our objectives should not

be to simply migrate clinical workflows from paper to digital media, but to ensure the timely transfer of patient information in standardized and actionable formats across the entire continuum of care – hospitals, physician offices, nursing homes, and home care settings – for myriad uses, including clinical decision support, health management, quality improvement and population health reporting.

HIE is the link that makes the aspirations of EHR use real. This means that the critical functionalities providers should be required to demonstrate in order to earn an incentive as a meaningful user of certified EHR technology should rely on Internet-based architecture services that redefine EHR products as we know them today. The simple truth is that we have a lot to learn about how the results we seek can best be supported through technology.

Third, given the link between HIE and EHRs, the incentives need to be structured accordingly. This means two things:

- The incentives paid to providers should be for EHRs, HIE and the programs and services that result from their combined use, not EHR hardware and software alone.

- We need to establish a process by which providers may obtain a waiver to have their EHR incentive payments start at a later date if it is determined that HIE services are not available and that they demonstrate a viable plan to achieve HIE connectivity in the near future.

Fourth, to succeed, HIE must be implemented on a statewide or regional basis in accordance with a well-defined federal framework. In other words, the nation's HIE infrastructure must be designed globally and implemented locally. Letting a hundred HIE flowers bloom will perpetuate the siloed system we are trying to replace. This means that the HIE infrastructure should be built upon common nationwide information policies, standards, and technical approaches as well as state and regional "bottom-up" implementation approaches and care coordination to allow local communities and regions to structure their own efforts based on clinical and patient priorities.

Accordingly, the federal government must make the hard decisions necessary to define a specific set of governance, technical, and policy requirements with which all HIEs must comply. If we fail to make these hard decisions, HITECH will result in our pouring the same wine into new bottles with the false hope that it will taste differently.

Fifth, HIEs must be designed and built in ways that take maximum advantage of Internet-based architecture and common HIE protocols, which are technology agnostic and vendor neutral, to achieve inherent scalability. Over-reliance on proprietary systems results in one-off custom integrations and ends up being expensive and brittle. Further, proprietary systems are limited in use and scalability.

Finally, we must keep our eye on the prize. When we look back at whether this investment was well spent, we will measure our success in simple terms: (i) have we improved the quality of care; (ii) have we reduced the inefficiencies and waste that make our current system so unaffordable; (iii) have we integrated care improvement deep into clinician practice and (iv) is the health of the US population improved.

Driving the Market through Minimum Requirements

For the remainder of my testimony, I will focus on the minimum HIE related requirements with which the federal government should obligate recipients of meaningful use payments to comply. Such minimum requirements should address:

- Minimum HIE Organizational and Functional Requirements
- Minimum HIE Use Requirements

While I believe that the minimum requirements can be increased over time to reflect increased expectations for performance, it is essential that we not set the minimum requirement too low so as to doom HITECH's significant investment in health information infrastructure. My experience suggests that the markets will respond to governmental requirements, especially when they are backed by significant economic incentives and penalties.

Minimum HIE Organizational and Functional Requirements

The HIE market has developed slowly over the last five years in fractured and disparate ways and participants have used HIE services to very different ends. Most HIEs developed from the ground-up, with very little federal or state guidance for consistency in use case development, technical architecture, and policy. In large measure, the early HIE structures were influenced by the goals of their sponsors and the realities of funding imperatives. Consequently, each HIE has its own story, from Indiana and its focus on clinical messaging between area hospitals, to Massachusetts and its wiring of three separate communities, to New York and its focus on a publicly financed statewide health information network.

There are many lessons to be learned through each of these initiatives, as well as from many others in other jurisdictions, but the reality is that each is a product of its own circumstances. HITECH represents a new opportunity. Its level of investment, combined with the urgency for reform of our broken health care system, makes it imperative that a national, consistent framework be developed to guide local and regional HIE efforts.

HITECH only provides the scaffolding for a framework. It provides the HHS Secretary with authority to provide grants to states or State Designated Entities to build and operate HIEs. It further requires that recipients of meaningful EHR incentive payments "[demonstrate] to the satisfaction of the Secretary...that such EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination." The statute is silent as to what form the development of HIE should take, leaving it the HHS Secretary to set this course through procurement policy and the development of regulation.

Market experience over the last several years suggests that certain minimum requirements should guide policy development in this arena. Specifically, I would suggest the following:

- The HHS Secretary define Minimum HIE Organizational and Functional Requirements and require that all recipients of HITECH meaningful use EHR payments contract with HIEs that meet these minimum requirements. The Minimum HIE Organizational and Functional Requirements should include:

- Governance requirements aimed at ensuring a multi-stakeholder decision making process that is conducted in an open, transparent and non-discriminatory manner. Governance in this context has many dimensions, including national, state and local levels. While this may seem overly complex, people support what they create, and there is a real need for policy development and implementation at each level of the three levels of governance.

- Technical specifications aimed at ensuring that HIE design complies with federal standards and relies on an Internet-based approach using common, open protocols rather than proprietary systems. Specifications should take into account state issues given that HIPAA does not preempt state law.

- Policies and procedures aimed at ensuring that the HIE has developed a common set of privacy and security policies that all participants will be required to follow. These should include specific policies relating to the 4A's – authentication, authorization, access, audit and breach – as well as consent and consumer access policies.

- The Secretary should establish a process for recognizing HIEs that meet the Minimum HIE Organizational and Functional Requirements and for ensuring that such HIEs conform to federal requirements on an ongoing basis. This process could be accomplished either through direct federal regulation or through third party accreditation of HIE organizations.

- The Secretary should further require that providers devote a portion of their EHR incentive payments to HIEs meeting the Minimum HIE Organizational and Functional Requirements described above. This will ensure that the required HIE infrastructure is available and that its costs of operation are equitably distributed among its users.

Because most of HITECH's investment in health IT is through the EHR meaningful use payments, it is imperative that a structure like the one I have suggested be put in place up-front to guide the way in which this market develops. The creation of such a structure would require purchasers of

EHRs to take into account the policy and technical requirements of the HIEs with which the EHRs will be required to connect to ensure interoperability.

The Secretary also has a significant opportunity to seed the HIE market through the use of HITECH's grant and loan programs. A significant portion (at least 50 percent) of this $2 billion dollar investment should be used to provide grants to states or State Designated Entities to build HIEs that meet the Minimum HIE Organizational and Functional Requirements. The good news is that the market is ready to meet this challenge. All across the country, healthcare stakeholders are beginning to work collaboratively with states to create state plans that will give meaning to HITECH's ambitious agenda of using health IT as a springboard for broader health reforms.

Minimum HIE Use Requirements

By themselves, Minimum HIE Organizational and Functional Requirements are not enough to accomplish HITECH's goals. Requirements must also be created to ensure that participants in HIEs use information to improve care coordination, reduce medical errors, promote wellness, advance public health, and pursue any other number of laudable health improvement objectives.

Toward this end, I would suggest that the receipt of EHR incentive payments be tied to recipients' participation in clinically-driven programs that are proven to improve the quality of health care, while at the same time reducing unnecessary health care expenditures. This is an area where we want to encourage innovation and allow communities of health care stakeholders to form new programs that advance our objectives.

One such program that has been launched in some jurisdictions is the patient centered medical home program. It is interesting to note that NCQA has developed standards and guidelines for accreditation of such programs using a tiered approach that allows for programs to advance in their sophistication over time. Another such program involves the use of advanced clinical decision support and clinical intelligence to identify gaps in care from evidence-based standards and to communicate with doctors and patients about issues that need to addressed. Many more examples exist. The point is we must ensure that steps are taken to use the information provided by HIEs to encourage provider participation in clinical programs that will actually improve care.

Consequently, I would suggest that in parallel to the development of Minimum HIE Organizational and Functional Requirements, the federal government also develop Minimum HIE Use Requirements and that satisfying these requirements be a condition of receipt of meaningful use EHR payments. As with HIEs themselves, it is essential that the Secretary establish a process for recognizing programs that meet the Minimum HIE Use Requirements and for ensuring that such programs comply with federal requirements on an ongoing basis.

Conclusion

The goals of HITECH are truly inspiring. Much work remains to be done to ensure we implement the Act in a way that empowers patients and their providers with the data and knowledge they need to produce the best health outcomes. Thank you for letting me take part in that conversation.