

**National Committee on Vital Health Statistics
Subcommittee on Privacy, Confidentiality, and Security**

Personal Health Records

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Personal health records and other electronic information and communication tools hold significant potential to help people prevent illness, manage their health-related information and transactions, coordinate care, communicate with clinicians, understand health care costs, and take better care of loved ones.

Based on this potential, the Markle Foundation committed in 2001 to anticipate the opportunities and barriers for these emerging technologies. We have researched consumer perceptions and forged consensus among broad groups of leaders and experts representing a wide array of interests and perspectives.

It's been a very exciting journey. In this short period, the potential of the consumer to benefit from health information technology (IT) has grown from a largely unknown concept to a mainstream goal of national policy leaders, and from being an afterthought of the dot-com bubble to being embraced by some of the largest global technology brands of the Internet Age.

Today I'd like to talk about three aspects of this journey:

1. The importance of common-sense information policies that earn the public's trust.
2. Immediate opportunities created by the American Recovery and Reinvestment Act.
3. And a brief vision for the future that depicts how consumers can benefit as personal health information becomes increasingly networked if we stay open to technology and service innovations.

1. Common-Sense Information Policies

Technology companies, health care delivery systems, health insurers, large employers, and others have been proliferating options for consumers to keep their own copies of health information and connect to health-related services online. However, this emerging new space has been evolving without a common set of information practices and expectations. Some of these services are covered under the health information privacy and security regulations of the Health Insurance Portability and Accountability Act (HIPAA), while others are not.

Our public opinion research strongly indicates that most consumers want their health information to be accessible to them electronically, and they overwhelmingly want to make sure it is protected by a set of sound privacy and security practices.¹

Against this background, Markle Connecting for Health convened a group of prominent technology companies, health care providers, health insurers, and consumer and privacy organizations to develop the Common Framework for Networked Personal Health Information.

The framework,² released in June 2008, defines a set of practices that can help protect personal information and enhance consumer participation in online personal health records. It is the first detailed, consensus-based approach to consumer access and privacy practices for important new Internet-based health information services.

There are several keys to consumer adoption of such services, particularly whether consumers find them useful, beneficial, and convenient. Our collaboration and research strongly reinforce the notion that a stable, common-sense set of principles and practices will be an important piece to accelerating consumer demand, improving consumer choices, and even fostering innovation in these emerging services. It is easier to create roadmaps for new tools and services when you know the rules of road.

The framework includes four overviews and fourteen specific technology and policy approaches for consumers to access health services, to obtain and control copies of health information about them, to authorize the sharing of their information with others, and sound privacy and security practices.

As several of the witnesses for this set of hearings can attest, we often have strong disagreements among collaborators when we begin these efforts. However, we've found that practical solutions can emerge when people listen and think together.

¹ See research brief from 2008 survey at:
<http://www.connectingforhealth.org/resources/ResearchBrief-200806.pdf>

² Available online at:
<http://www.connectingforhealth.org/phti/index.html>

The following organizations endorsed the framework when it was released in June, and several others have joined since then:

AARP • Aetna • American Academy of Family Physicians • Association of Online Cancer Resources (ACOR.org) • America's Health Insurance Plans • BlueCross BlueShield Association • CapMed • Center for Democracy and Technology • Center on Medical Record Rights and Privacy • Cisco Systems Inc. • Consumers Union • Dossia • FollowMe • Google • Geisinger Health System • Health Care For All • InterComponentWare Inc. • Intuit Inc. • MedicAlert • Microsoft Corp. • National Breast Cancer Coalition • National Partnership for Women and Families • NewYork-Presbyterian Hospital • Pacific Business Group on Health • Palo Alto Medical Foundation • Partners Healthcare System • RxHub • SureScripts • U.S. Department of Veterans Affairs • Vanderbilt Center for Better Health • WebMD

The framework lays out specific practices that all personal health records (PHRs) and related services can use, whether they are covered by federal privacy rules or not. This is the key breakthrough of this collaboration. In brief, these diverse organizations agree that consumer-focused health information merits some special protections that go beyond those required by HIPAA. Examples include the Common Framework's recommendations for obtaining consumer consent, and prohibitions against discrimination or compelled disclosures of personal information.

2. New opportunities under the American Recovery and Reinvestment Act (ARRA)

Enactment of ARRA in February 2009 provides the foundation for a big potential leap not only in provider-focused electronic health records (EHRs) but also for consumer-focused PHRs.

I will focus briefly on two components of the new law: the privacy provisions and the definitions of “meaningful use” of health IT and “certified or qualified EHR technology.”

Privacy: The ARRA provisions make clear the critical importance of coupling technology and policy requirements. The new law enacts many of the principles and policies specified in the Markle Connecting for Health Common Framework that had been previously unaddressed in regulation or federal law. The Department of Health and Human Services (HHS) is charged with developing regulations and/or guidance for ARRA's new health information privacy provisions and enhanced enforcement, including the following:

- HIPAA security and privacy rules extended to business associates of HIPAA covered entities.
- New provisions for notification to consumers of information breaches.
- Limitations on sales of protected health information.

- New guidance on “minimum necessary” (i.e., the notion that no more than the necessary information should be disclosed).
- Guidance on implementation specification to de-identify protected health information.
- Individual right to access personal information in electronic format.
- Annual guidance on the most effective technical safeguards for carrying out the HIPAA Security Rule.
- Recommendations on technologies that protect the privacy of health information and promote security.
- Restrictions on use of protected health information for marketing.
- Requirement for consumer access to an accounting of disclosures of information maintained in EHRs.

Clearly, the requirements of qualified or certified EHR technology should, over time, include capabilities to comply with the law’s new privacy and security provisions. These requirements must be sequenced strategically so that they can be implemented in a timely way without creating unrealistic software upgrade burdens on clinicians and hospitals.

Meaningful use and certified, qualified EHR: NCVHS held recent hearings about the new law’s requirement for providers and hospitals to show “meaningful use” of health IT and use “certified or qualified EHRs” to be eligible for financial incentives.

The way that HHS defines these two terms will be paramount to the success or failure of the health IT provisions of ARRA. Even more importantly, these near-term decisions by HHS provide an opportunity to create incentive-driven technologies and processes that support health improvement, slow growth in costs, and lay the groundwork for broader health care reforms.

As it did to create the Common Framework for Networked Personal Health Information, Markle convened a diverse set of leaders on the challenges of defining meaningful use and certified or qualified EHRs.

The result of this collaboration is a consensus statement — *Achieving the Health IT Objectives of ARRA: A Framework for ‘Meaningful Use’ and ‘Certified or Qualified EHR’*.³ It contains an initial set of principles and recommendations for getting health IT right under the historic opportunity of this new law.

³ Available online at: http://www.markle.org/downloadable_assets/20090430_meaningful_use.pdf

PROPOSED SIMPLE DEFINITION OF MEANINGFUL USE

Patient-Centered Meaningful Use of Health IT:

Demonstrates that the provider makes use of, and the patient has access to, clinically relevant electronic information about the patient to improve patient outcomes and health status, improve the delivery of care, and control the growth of costs.

Initial Meaningful Use Requirements (2011-2012):

Demonstrates that the provider makes use of, and the patient has access to, clinically relevant electronic information about the patient to improve medication management and coordination of care.

We recommend an initial focus on the use of standard information types or packages for recent *medication histories*, *recent test results* (particularly laboratory values, and when available, imaging and pathology text reports), and *care summaries*. These three classes of information hold significant potential compared with many other types of health information for improvements in coordination of care, medication management, and reduction in duplicative services.

Individuals supporting the document come from a diverse group of consumer, business, and health organizations, including:

AARP • Allscripts • America's Health Insurance Plans • American Academy of Family Physicians • American College of Cardiology • American Medical Association • Association of Online • Cancer Resources (ACOR) • Blue Cross and Blue Shield Association • Center for Democracy and Technology • Center for Information Therapy • Childbirth Connection • Chilmark Research • Consumers Union • DocSite, LLC • Dossia • DrFirst • Google • Health Care For All • Health Level Seven, Inc. • Intel Corporation • The Joint Commission • Keas, Inc. • McKesson Provider Technologies • Medical Group Management Association • Mental Health America • Microsoft Corporation • National Coalition for Cancer Survivorship • National Committee for Quality Assurance (NCQA) • National Consumers League • National Partnership for Women & Families • NewYork-Presbyterian Hospital and NewYork-Presbyterian Healthcare System • Northwest Health Foundation • Prematics, Inc. • ReachMyDoctor • Surescripts • WebMD Health • Zix Corporation

The group agreed on the following principles:

1. **The overarching nationwide goals of health IT investments are to improve health care quality, reduce growth in costs, stimulate innovation, and protect privacy.** The investments should be directed toward achieving clear, specific metrics toward these goals. If the goals and metrics are not clear before technology is commissioned and the incentives are offered, the government will risk wasting valuable resources and losing support from both health care providers and the public for further health IT investments.

2. **These goals can be achieved only through the *effective use of information* to support better decision-making and more effective care processes that improve health outcomes and reduce cost growth.** The goals cannot be achieved through the installation of software or hardware alone. Effective *use* of information is what enables a consumer to play an active role in maintaining health and getting the best care, prevents a patient from suffering a medical error, helps a clinician prescribe the right treatment at the right time, allows a care team to coordinate care in the most effective and affordable way, and benefits efforts to improve quality, accelerate research, and advance public health. The definition of “meaningful use” should hinge on whether information is being *used* to deliver care and support processes that improve patient health status and outcomes. The definition should focus on the needs of patients and consumers, not on the mere presence or functions of technology.
3. **Meaningful use should be demonstrable in the first years of implementation (2011-12) without creating undue burden on clinicians and practices.** The meaningful use definition must optimize *achievability* for providers and *benefits* to patients and consumers. Improving *medication management* and *coordination of care* provides early opportunities for such an optimization. Meaningful use should initially rely on standard information types (such as recent medications and laboratory results) that are electronic and already widely adopted—and that can support metrics to improve medication management and coordination of care.
4. **The definition of meaningful use should gradually expand to encompass more ambitious health improvement aims over time.** To support meaningful use goals that improve health and reduce the growth of costs, additional data types (e.g., problem lists, allergies, vitals, images, findings, procedures, care plans, hospital discharge summaries, patient registration forms) can become increasingly standardized over time to facilitate a set of defined measurements. The phasing-in of expanded requirements should be well-defined early in the process, so that those building or purchasing systems have a clear and realistic path to achieve meaningful use at each stage.
5. **The definition of “qualified or certified EHR technology” should support the goals of meaningful use, security, and privacy.** Processes for certification or qualification will be important to prevent fraud or faulty products (e.g., products that do not sufficiently protect sensitive health information), as well as prevent rewards for superficial or trivial uses of technology. For a technology to be “qualified or certified,” it should embed the capability for clinical practices and hospitals to attain meaningful use, and demonstrate their levels of attainment of such use, without undue additional reporting burdens. It should also comply with the technical requirements for privacy and security under the Health Insurance Portability and Accountability Act (HIPAA) and ARRA. Processes for certification or qualification should allow for product and service innovation toward meeting the goals of meaningful use.

6. **Metrics for achieving meaningful use should account for the heterogeneity of the US health sector and allow for a broad range of providers to participate.** Medical practices that are capable of installing and supporting a comprehensive EHR should be incentivized under ARRA to do so. However, assuming that only comprehensive EHR systems can achieve the goals of meaningful use might delay progress or lock out other lightweight, network-enabled solutions that may achieve the same goals in the near-term and can provide greater functionality over time. Small practices with less technical support should be able to qualify for incentives by using Internet-enabled technologies that can help them to access and use information to help their patients. By emphasizing rewards for actual use of information, and not the mere purchase of specific hardware or software products, public policy can expand the potential of existing information networks and spur innovation to reach health goals and administrative efficiencies.
7. **Consumers, patients, and their families should benefit from health IT through improved access to personal health information without sacrificing their privacy.** ARRA clarifies the individual's right to request electronic copies of personal health information from EHRs for storage by information services of the individual's choosing. The provision by providers of electronic copies of personal health information to consumers should be considered a form of meaningful use of health IT under ARRA.

In summary, ARRA provides the foundation for three things that had largely been missing in the federal government's push to encourage health IT in recent years. The first is a set of privacy practices, which now are subject to rulemaking or guidance by HHS. The second is financial incentives for providers to adopt health IT. And third, as outlined in Section 13405 (e), the consumer has a right to obtain copies in electronic format of personal health information from the EHR of a HIPAA-covered entity, and—provided the individual chooses in a clear, conspicuous and specific way—to direct the covered entity to transmit such electronic copies to an entity or person of the individual's choosing.

The Markle Foundation frameworks I've mentioned today are intended to provide starting principles and practices for the implementation in these critical areas. There is much work still to be done. We appreciate the opportunity to share these frameworks with this committee, and look forward to continuing to support public-private collaboration to make sure we get health IT right under this new law.

3. A vision for the future: The consumer as decision-maker

The title of this panel urges us to look ahead 5 to 10 years. One of the things we've seen over the past decade is that consumers have the capacity to embrace new network-enabled services at an astonishing pace. E-mail, blogging, online banking, social networking, mobile phones, and handheld devices are examples of tools adopted with remarkable rapidity by consumers. A common thread of these examples is that they rely on the power of networks.

Development of a sufficiently flexible network will enable the use of a great variety of personal health technology applications, including many that we cannot imagine today.

The “personal health record” application is not the end goal, nor is the mere aggregation of the consumer’s data. The true test is whether networks make it easier for ordinary people to coordinate and engage more actively in their own health and health care. We want to enable information services that help people use their personal health information and benefit from composite data analysis and decision support services, with end results of better health and health care, better and more coordinated use of health care services, and protection of privacy.

Clinicians have a critical role in realizing the full potential of networked personal health information services. Network-enabled efficiencies and safety improvements are more likely to occur if consumers and clinicians act as partners who share responsibility for updating and sharing personal health information across secure networks, even as they use different applications and tools.

It’s very difficult to predict what types of networked health information services consumers will adopt, and what business models will support them. Rather than trying to predict what the future *will* be, I can describe the characteristics of the environment that can truly benefit people in improving their health and navigating their care.

The characteristics of this environment should enable:

- Consumers to have a rich variety of tools to help make health decisions for selecting doctors, hospitals, health and pharmacy plans, treatments, etc. If this goal is realized it would be uncommon to make a personal health decision without using information tools.
- Consumers to be engaged and empowered with new communication and decision tools that make them an active partners in improving their health. Some early surveys show that when consumers are engaged through personal health tools, their satisfaction levels rise with the doctors and health systems offering those tools.
- Consumers to be viewed as important participants and contributors to the network. Their active participation can be of high value to each other, to providers, policy makers, quality monitors, researchers, drug manufacturers, public health authorities, and many others.
- Consumers to benefit from an open, trusted network that supports a variety of applications, services, and tools available to them to use in improving their health or health care. They should be able to select a robust, highly tailored longitudinal application, or create snapshots “on they fly” by querying the network when needed.
- Consumers to be included in participatory models for research, post-market surveillance efforts, quality-improvement initiatives, and clinical trials. If consumers have confidence in the network and have control over how their data are used, they could benefit from a rich set of opportunities for opt-in services.
- Consumers and clinicians to have more efficient and satisfying means to communicate with one another.

We are already seeing the enormous potential to change the research paradigm for consumer participation in social networking efforts such as PatientsLikeMe. We believe that over the next decade, the opportunity to bolster research and improve public health and health care quality will be very significant if consumers engage in trusted health information networks with services and offerings that provide them with value.

We cannot know today which personal health information tools, services, or ideas will emerge to capture broad consumer participation. However, without networks that people trust, and without innovation, we may never know.

A hardened or narrow view of software will be detrimental to our goals. If, for example, certification processes under ARRA reward only current tools and technologies, then market demand from government could lock out innovations that might emerge to be more meaningful and effective for consumers.

New tools and applications should be encouraged to evolve and derive value from connections to open networks. If consumers find value and trust the environment, it will be much more transformative and much more rapid than the results of any stamp of approval on a particular tool or technology.

Today, a strategic implementation of ARRA is a critical effort in which we can begin to pave the way toward such a future. If we implement ARRA in a way that is overly dependent on current EHR technologies, or in a way that limits the potential for consumer access and participation, then we will have missed a historic opportunity.

We greatly appreciate this committee's exploration of this issues, and thank you for including the Markle Foundation's perspectives in these proceedings.
