

PRIVACY AND MOBILIZING HEALTH DATA: FINDING THE GOLDEN MEAN

Prologue Series



WHAT IS PAST
IS PROLOGUE

Michael O. Leavitt

Secretary
U.S. Department of Health and Human Services

Prologue Series

I have come to understand that public service is a generational relay. Many of the most profound problems are not ours to solve in finality, but rather to incrementally improve during our temporary stewardship.

Three foundation goals thus form the basis for my public service: to leave things better than I found them; to plant seeds for the next generation; and to conclude my work knowing I have given my all.

For nearly sixteen years, my life has evolved in four year terms. I was elected three times as Governor of Utah. Some of what I consider our accomplishments were initiated in my first term, but fully matured in my third. Likewise, some seeds planted in my third term are only now beginning to flower.

Living in four year cycles has taught me the importance of choosing priorities and impressed the need for urgency. Time passes quickly.

I am currently in my fifth year as a member of President George W. Bush's Cabinet. I served first as the Administrator of the Environmental Protection Agency and now as Secretary of Health and Human Services. The constitutional constraints on the President's service imposed limits on what initiatives I might see to completion. However, I view it as my obligation to lead with a longer horizon in mind.

Over time, I have developed a set of tools useful in keeping a long-term vision in mind while managing the day-to-day problems. One such tool is establishing a 5,000 Day Vision, with a 500 Day Plan.

The 5,000 Day Vision is our aspiration for various long-term outcomes. The 500 day plan is more granular, listing what needs to be done now to bring about the larger vision. Both are recalibrated periodically.

As my stewardship comes to a close, it is time to plant seeds for the next generation. I intend to write and deliver a series of formal speeches to convey some of the 5,000 Day Vision and share what I see on our approaching horizon.

I call these speeches *The Prologue Series*. There is a statue behind the National Archives that I look at nearly every day as I drive between HHS and the White House. The statue, the work of Robert Aitken, is called "The Future." It depicts a woman looking up to the horizon from a book as if to ponder what she has just read. At the base of the statue are the words from Shakespeare's *The Tempest* "What is past is prologue."

I have titled this speech in *The Prologue Series*: "Privacy and Mobilizing Health Data: Finding the Golden Mean."

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
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The wider adoption and continued improvement of electronic health records has opened a new era in health care. The capacity to computerize records is only an enabler; the real change is mobilized patient data. Once patient data is able to travel, it can be combined with information from other sources to produce new tools that can increase quality of care, reduce costs, avoid medical errors, and improve convenience. This is a disruptive and exciting transformative change.

Health information will be mobilized. It will not be the technology that limits us, but the sociology that will hold us back.

We need to cultivate a culture of financial investment in health technology.

Mobilizing health data depends on the development of new technology. However, the greatest barrier is not in inventing new technologies, but the secondary steps that ultimately allow people to use them. We need to adopt a standardized vocabulary. We need to cultivate a culture of financial investment in health technology. But the most demanding requirement is finding the balance between increased access to information and privacy. I will address that subject.

Each of us comes into this world with a unique psyche. Hence, people respond to the same situation differently.

Years ago, when two of my sons were ages six and seven, we enrolled them in a summer school program. The younger son is a native risk taker; he is “Mr. Out-There.” The older son is more risk adverse; he is “Mr. Are-You-Sure.”

One day in class the teacher gave out her phone number. To Mr. Out-There, this was an invitation for fun. To his older brother, Mr. Are-You-Sure, calling the teacher just to socialize had predictable dangers.

I listened as the two of them debated if calling was a good idea. Finally, the younger son made clear that he didn't care if his older brother was in on the call; he was dialing. As Mr. Out-There reached for the phone, Mr. Are-You-Sure ran from the room and rolled himself up in the living-room drapes.

The most demanding requirement is finding the balance between increased access to information and privacy.

Both are now grown and are quite successful. Each one is navigating life according to his own unique doctrine of risk.

Likewise, people feel different levels of sensitivity related to their health care. Many people go to a Web site called Patientslikeme.com to discuss their medical condition hoping to share and learn from people with similar problems. People post highly personal medical information

on the internet. They obviously feel the benefit outweighs any personal danger. They are less risk adverse and closer to Mr. Out-There.

Others such as Mr. Are-You-Sure just don't want any information about them available publicly. In their view, any benefits that could be derived from sharing medical information are simply over-ridden by the potential risks.

We have faced this dilemma in other sectors of life and resolved it. Banking is an example.

Years ago, I teased my father about saving his credit-card slips. He was Mr. Are-You-Sure, faithfully saving each credit card receipts so he could compare them to his monthly credit card bill. He didn't trust the system would protect his interests.

Compared to him, I was Mr. Out-There. My experience and nature caused me to believe that assuming the risk of a mistake was worth the convenience of not having to save all those little pieces of paper. In time, I noticed Dad's confidence in the system grew. He quit saving his receipts.

Many people now prefer debit cards to paper checks. Growing numbers conduct all their banking electronically. This is an indication of growing confidence.

If someone offered the most secure banking portal ever invented, but with security so tight or access so complex that people couldn't obtain information from the Web or transfer money out of the account, the users would not be well-served.

As we design the rules of privacy for health information technology, we cannot establish one golden mean for everyone. Instead, we need to provide information to let consumers choose for themselves. We need to give Mr. Out-There and Mr. Are-You-Sure the tools to find their own

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golden mean on the continuum between mobilizing health information and ensuring privacy.

Getting computers to talk with each other is often easier than balancing people's differing values. Identifying doctrines upon which we can all start would be an important contribution. My goal today is to present a framework of foundational doctrines to find the balance between access to information and privacy.

The Department will be releasing basic tools that will support the application of these doctrines. Surely, overtime the tools will be improved upon. However, even in their basic form they are important templates to help Mr. Out-There and Mr. Are-You-Sure find a way to move forward.

Let's start with the five doctrines of a Pathway for Reconciling Mobilization of Health Data and Privacy:

- Individual access and correction
- Openness and transparency
- Individual choice
- Collection, use, and disclosure limitation, and
- Safeguards, data integrity, and accountability

These five doctrines are made up of eleven principles. The first two principles are individual access and correction.

I believe it is a fundamental right to have access to one's own personal health information. Not only do we have a right to access the information, we deserve to get the records in an easy and timely manner. The Health Insurance Portability and Accountability Act (HIPAA) privacy rule requires that we have access to our records now, but these requirements were designed with the retrieval and copying of paper records in mind. Consumers should have the right to request their health information in electronic format and to receive it within a reasonable time.

For example, a woman in Boston requested the medical records about her child who had a complex kidney ailment.

After almost a year and multiple requests, a portion of the records were finally mailed to her. This is unacceptable—and it violates federal law. This is wrong, and institutions that delay fulfilling such requests should be punished.

Incidentally, I believe the right to access one's own medical records should include lab data. The paternalistic days of physicians completely controlling the ordering and sharing of patient's lab results should end. Granted, there are some sensitive lab tests, or situations in which patients are more vulnerable. In those instances, a waiting period to give the provider the opportunity to communicate results is warranted. Perhaps careful exceptions might be appropriate, but these should not be the rule.

I believe consumers should be able to control, add and amend personal health information in products such as personal health records (PHRs). PHRs that include this consumer-controlled function and identify the source of data will be more trusted by both consumers and providers.

The third and fourth principles are openness and transparency. Anybody handling health information, even those not covered by HIPAA, should provide consumers with an easy-to-read, standard notice about how their personal health information is protected. This notice should indicate who their information can or cannot be shared with and under what circumstances information may or may not be disclosed.

If I buy a can of soup or any other food item, I can easily read the nutritional contents on the label in a standard format. Government doesn't tell the soup company what makes a good soup or tell the consumer which soup to buy, but the consumer can easily read the label and decide whether the soup is what he or she wants.

If I decide to use a PHR, I should have a similar easy-to-understand summary that lets me know how my personal

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Government can set some baselines for notice of privacy policies, but should not dictate the level of privacy since consumers have their own golden mean on the continuum between mobilizing health information and ensuring privacy.

The ability to collect and analyze this information is part of a public good that serves the American people and it should be encouraged.

information will be secured and shared, including my rights to determine when and how this information is shared.

For these health information products, such as PHRs, Mr. Are-You-Sure will want more secure environments than Mr. Out-There. Both types of consumers need a means of finding what they want.

We should allow the market to meet the varying demand. Government can set some baselines for notice of privacy policies, but should not dictate the level of privacy since consumers have their own golden mean on the continuum between mobilizing health information and ensuring privacy.

Principle five is individual choice. Generally, where methods of exchanging data are concerned, significant opportunities exist to enhance consumer choice. Accordingly, consumers should be empowered to make decisions about whom, when, and how their personal health information is shared (or not shared).

Web sites like Patientslikeme.com demonstrate the desire of some patients to share their information with an online community, but other patients don't want to share any information. It's their call. They should be able to consent or withhold their consent to share the data, depending on their preferences.

Principles six, seven, and eight are collection, use, and disclosure limitation. There are purposes such as public health surveillance and research on the effectiveness and safety of health care for which data, typically de-identified, is essential to serving the public interest. The ability to collect and analyze this information is part of a public good that serves the American people and it should be encouraged. However, we also must take every precaution to ensure that this data is secured, de-identified when appropriate, and protected wherever possible. This includes protected use and exchange of population and public health data.

The last three principles are safeguards, data integrity, and accountability. Institutions, providers, and researchers must take their commitment to security seriously. We must not tolerate organizations or people who break rules and put consumers' personal health information at risk. Consumers need to be confident that if they are victims of such action, the violators will be held accountable.

The usefulness of health information is dependent on data quality and integrity. Those who hold records must take reasonable steps to ensure that information is accurate and up-to-date. A process must exist in which, if consumers perceive a part of their record is inaccurate, they can notify their provider. If the provider disagrees and believes that part is accurate, the consumer should be able to note the disagreement in the record. Of course, the HIPAA privacy rule provides consumers that right, but this principal should be applied even where the information is not covered by the rule.

I want to elaborate on the components of the toolkit I mentioned earlier. I believe the personal health record will become the leaven in the loaf of health information technology adoption. Once consumers begin to sense the empowerment available, they will demand it. More and more health care players are offering PHRs. Non-health entities are now sensing significant opportunity. Well-branded organizations like Google, Microsoft, and WebMD are partnering with lesser known innovators, insurers, and providers to drive interest in this space. Like all other technology breakthroughs, the market will ultimately begin to discriminate against those unable or unwilling to provide the service.

Doctors will start hearing from their patients if medical records can't be automatically sent to a PHR. When electronic health records become a market necessity, adoption will rapidly increase.

As part of selecting a PHR, consumers should be able to choose their own golden mean on the mobilization-privacy continuum. For that to occur, consumers need an easily understandable disclosure about the protection

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and security of their personal health information. Let me emphasize, the disclosure needs to be simple and avoid the temptation to add endless, mandated requirements.

Other industries and policymakers have been able to inform consumers while avoiding specific mandates about the types of products that can be offered. For example, the Schumer Box for the credit card industry was implemented in 2000. Credit card companies are required to present the consumer with key facts and figures about the lending agreement in a clear, concise manner in a standard table. Credit card companies can still offer an assortment of products, but the consumer is able to understand easily how the products differ based on this standard box.

In 1994, the FDA implemented the nutritional facts label. The label has a standard format. Consumers can read and understand nutritional information and buy products based on their preferences. The label does not mandate the recipe for the soup but it gives consumers the tools they need to make informed choices.

We need to provide consumers with “PHR Facts-At-A-Glance” in a standard format so they can easily read and understand important issues such as how their information is accessed, used, and secured in a PHR. Therefore, we developed a model PHR Facts-At-A-Glance. This will provide the consumer—in a single, standard format—the ability to understand the type of PHR, who can access their information, how their information is used, and the policies and security features of the PHR. This label allows us to give consumers the information that they need to make an informed decision.

We will be seeking feedback on the label and doing consumer testing to ensure it is usable and understandable for consumers. The final version will be released next year.

I would like to give those organizations providing PHRs some advice. I think it is important that they swiftly implement the PHR Facts-At-A-Glance Box when it is

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finalized. By voluntarily using this important tool, the PHR companies will demonstrate their commitment to transparency for the privacy and security of personal information. Transparency demonstrates a commitment to privacy. Unless you voluntarily get ahead of this impetus, at some point a government mandate is inevitable. You will like the outcome better if it is accomplished through collaboration within the industry now, rather than by mandate later.

As a companion tool, we have developed a Web-based notice to inform consumers about PHRs and suggest some questions and issues to consider when selecting a PHR provider. Many of these issues are encompassed in the different options for answers that a PHR company could report in the label. These tools together will empower consumers without limiting the array of products that can be offered to them.

A new type of multi-stakeholder organization has been emerging in some local, regional, and state communities during the last several years. The organizations are designed to improve the quality, value, and affordability of health care and support community health activities, such as public health. These organizations have been referred to by different terms, including Health Information Exchanges (HIEs), Health Information Organizations (HIOs), and Regional Health Information Organizations (RHIOs). Whatever term is used, they are geographically-based health information networks that deliver secure, trusted, and mobile health information in their communities. They accomplish this by overseeing and governing the exchange of health information among hospitals, provider practices, consumers, laboratories, pharmacies, and other health-related organizations.

In fact, thirteen of the organizations that attended the National Health Information Network (NHIN) Forum are geographically-based networks. They exchange health information with other Health Information Exchange organizations across the country using nationally

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recognized health information standards.

These health information networks are powerful solutions in many communities that help to reduce the duplication of tests and medical errors. They also promise to facilitate the sharing of clinical information across settings, improving care delivered to patients. I'm happy to report that over 40 of these networks already are exchanging health information within their communities to support and improve health care delivery.

However, many health information networks are struggling, partly due to distrust and participants' concerns about how to set up agreements and exchange data in a protected, secure manner. We need to provide them with a set of principles and a toolkit to help put these principles into practice. In the absence of such principles and a toolkit, there is confusion and distrust. I am observing such networks being re-invented all over the United States. I am hopeful the toolkit will help remedy some of that.

The toolkit will provide sample language for health information network participation agreements. Incorporating this language in agreements will allow for consistency among policies so that local communities can share data.

Another tool is an initial version of a Data Use and Reciprocal Support Agreement (DURSA), which is a model multi-party data use and sharing agreement for NHIN participants. This has been developed as part of our ongoing work on the geographically-based network.

In the last four years, I have observed the HIPAA's important role. However, I have also observed the great confusion that results from its ambiguities and the strong tendency for people to improperly default to the word "no," often unnecessarily. When that happens, information stops flowing. Unless better understood, these misinterpretations will become molasses in the gear box of mobilized health

information technology.

The remaining tools will be important aids in efforts to relieve part of that problem. First, HHS shortly will issue guidance that clearly explains to technical experts and the general public the extent of the HIPAA Privacy Rule's application to PHRs, patient access to electronic records, and a number of other topics.

We also recognize that small physician practices often have fewer resources to invest. To help them, we will also release the Physician Security Tool, an easy-to-understand guide for small physician practices considering investing in an Electronic Health Records system. They need to know what actions they can take themselves and what they should expect from their vendors.

We also plan to release Privacy and Security Principles for Electronic Health Information Exchange. This document will elaborate on the principles I have outlined herein.

Health information will be mobilized. It will not be the technology that limits us, but the sociology that will hold us back. Mr. Out-There and Mr. Are-You-Sure can only be brought together with common principles and a common commitment to preserve the privacy of every American.

We've been thinking about this commitment in terms of computer use and privacy principles. However, the reality is that those technologies and security measures can bring about truly powerful ends that will transform health care as we know it today. Real value will be created when health information is securely mobilized and consumers have real choices about how to use it.

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They need information to be able to compare price and quality. They need the ability to choose among competing options across state lines.

Americans lack no ingenuity to produce all these tools—and they will produce them in spades. Before we can obtain consumer buy-in on these tools, consumers need to know that they can each find their own golden mean. By laying out this set of principles and this toolkit, I believe we can start a conversation that will lead to the real change we need in order to create value across our health care sector. When consumers can choose, they will pursue the best value.

But I do not pretend this will all be easy. Meaningful improvements in health care require change. In a global economy, there are only three ways to confront change: You can fight it and fail. You can accept it and survive. Or you can lead it and prosper. This is the United States of America. Let us lead.

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