

TESTIMONY OF MARK A. ROTHSTEIN  
INSTITUTE FOR BIOETHICS, HEALTH POLICY AND LAW  
UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE

Before the

SUBCOMMITTEE ON FEDERAL GOVERNMENT MANAGEMENT, THE  
FEDERAL WORKFORCE AND THE DISTRICT OF COLUMBIA

SENATE COMMITTEE ON HOMELAND SECURITY  
AND GOVERNMENTAL AFFAIRS

*Private Health Records: Privacy Implications of the  
Federal Government's Health Information Technology Initiative*

February 1, 2007

MR. CHAIRMAN and members of the Subcommittee. My name is Mark Rothstein. I am the Herbert F. Boehl Chair of Law and Medicine and Director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine. I am also Chair of the Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics, the statutory public advisory committee to the Secretary of Health and Human Services (HHS) on health information policy. I am testifying today in my individual capacity.

In my testimony today, I want to make only two points. First, HHS has made very little meaningful progress in developing and implementing measures to protect the privacy of health information in electronic health networks. Second, time is of the essence. HHS must begin to act immediately on the key privacy issues, and Congress needs to hold HHS accountable.

1. HHS and Health Privacy

I want to commend the Government Accountability Office (GAO) for its report, Health Information Technology. I believe this report accurately identifies the great challenges in adopting and integrating a comprehensive and effective strategy to protect health privacy, confidentiality, and security as the nation moves to a system of interoperable electronic health record networks.

I specifically agree with the following statement contained in the GAO report (p.14):

“HHS is in the early stages of identifying solutions for protecting personal health information and has not yet defined an overall approach for integrating its various privacy-related initiatives and for addressing key privacy principles.”

To this assessment, I would add my own view that privacy concerns currently lag behind technical development of the Nationwide Health Information Network (NHIN).

Furthermore, I believe the gap is widening as research and development progress while fundamental privacy issues remain largely unexamined and unresolved.

The GAO report referred to the June 2006 letter to the Secretary of HHS from the National Committee on Vital and Health Statistics (NCVHS). The letter followed four public hearings across the country and the oral and written testimony of a wide range of experts and consumers from the U.S. and abroad. It took 18 months and a substantial amount of debate and deliberation among the diverse membership of the NCVHS. If nothing else, it has become very clear to those of us who worked on this letter that these issues are complicated, contentious, and crucial.

Here are just a few of the issues we considered:

- NCVHS noted that a decision is needed on whether individuals should have the option to participate in the NHIN and, if so, whether this choice should be through an opt-in, opt-out, or some other method.

- NCVHS raised the issue of whether individuals should have some control of the contents of their health records disclosed via the NHIN and, if so, how and over what health matters?
- NCVHS recommended that different levels of health information should be disclosed to different health care providers based on their need to know (“role-based access”).
- NCVHS urged HHS to explore whether technology could be developed (“contextual access criteria”) to limit the scope of disclosures when health information is divulged to employers, life insurers, and other entities that condition a financial or other relationship on access to an individual’s health records.
- NCVHS clearly stated that health information privacy protections need to be comprehensive and extend beyond the current HIPAA covered entities “to all individuals and entities that create, compile, store, transmit, or use personal health information in any form and in any setting, including employers, insurers, financial institutions, commercial data providers, applications service providers, and schools.”
- NCVHS stressed the importance of harmonizing all of the various federal statutes and regulations dealing with health privacy, incorporating fair information practices (e.g., rights of access, notice of disclosures) into the NHIN, implementing a vigorous enforcement system, and initiating public education programs to increase understanding of and build trust in the NHIN.

- In all, the letter contained 26 recommendations.

Unfortunately, HHS has not made any discernible progress on developing policies with regard to any of these foundational issues, either before or after the June 2006 letter. The privacy contracts let by HHS in 2005 primarily involve compiling and analyzing state privacy statutes and regulations that may be implicated by the adoption of electronic networks. The American Health Information Community working group dealing with privacy has concentrated on security issues, such as authentication and encryption. The four contractors selected by HHS to develop proposals for the NHIN architecture have not been required or encouraged to include new privacy enhancing technologies, such as contextual access criteria.

It is fair to conclude that health privacy has not received adequate attention at HHS, that prior efforts have lacked coordination and focused on the wrong issues, and that a sense of urgency is lacking.

## 2. Time is of the Essence

I cannot emphasize enough how rapidly the field of health information technology is moving. While HHS organizes more task forces and working groups, the private sector is racing ahead to implement a wide array of health information exchanges, medical record banks, regional health information organizations, and personal health record (PHR) systems. To take but one example, Wal-Mart and other large employers (Intel, BP, Pitney

Bowes, Allied Materials) with a total of 2.5 million employees in the U.S. recently announced that they are developing a PHR system for their employees (called Dossia) in an effort to improve employee health and lower employer health plan costs. Other large employers and health care provider networks are being recruited to form or join similar EHR and PHR alliances. Some of these networks already are operational.

It should be noted that these private sector initiatives with EHR and PHR networks are usually not subject to any federal or state regulation, because they are not covered entities under HIPAA. Furthermore, tens of thousands of other health care providers and health information providers are not covered entities under HIPAA. Most are not covered because they are not involved in the process of electronically submitting claims for health services.

What can be done to get HHS to put health information privacy on the fast track and the right track? I respectfully recommend that Congress condition continued appropriations for development of the NHIN on HHS demonstrating significant progress in addressing privacy issues. I also recommend that Congress play a greater role in oversight on this issue.

What would be “significant progress”? Clearly, HHS needs to address the 26 recommendations made to the Secretary in June 2006 by the NCVHS. (I have attached a copy of the letter and recommendations to my testimony.) The first order of business is for HHS to develop a draft framework for privacy and confidentiality in the NHIN. Then,

the public can participate in the deliberations about the framework. A variety of procedures can increase the level of public participation in this process, such as the following.

- HHS should publish a public request for information about key aspects of its privacy framework.
- HHS should hold a series of public hearings around the country on privacy issues.
- HHS should fund quantitative and qualitative research on public attitudes toward health information privacy.
- HHS should integrate key privacy principles into the NHIN architecture.
- HHS should publish an Advanced Notice of Proposed Rulemaking dealing with privacy in the NHIN.
- HHS should submit a report to Congress identifying gaps in coverage of the HIPAA Privacy Rule and how to address them.
- HHS should initiate public education programs on electronic health records (EHRs) and privacy protections.

MR. CHAIRMAN, I need not remind the members of the Subcommittee of the potential benefits of an effective and efficient NHIN, nor the dangers of an electronic health record system run amok. These issues are discussed in the GAO Report, the NCVHS letter, and elsewhere. One thing is certain. The health benefits of electronic health record networks will never be realized unless the American public has a high degree of trust in network privacy protections. We can't build the network and then build the trust. As the leader of

the NHIN-development effort, HHS must immediately begin to earn the confidence and trust of the American people through an expedited, coordinated, transparent, and public process of policy development leading to comprehensive, effective privacy protections.

Thank you for the opportunity to testify, and I look forward to your questions.