TESTIMONY OF MARK A. ROTHSTEIN, Herbert F. Boehl Chair of Law and Medicine and Director, Institute for Bioethics, Health Policy and Law, University of Louisville School of Medicine

Co-chairs Francis and Houston, members of the Subcommittee and NCVHS staff:

I want to begin by conveying my appreciation to the NCVHS for its continuing efforts to explore issues related to the segmentation or sequestration of sensitive health information in EHRs and EHR networks. As you know, in 2005 the NCVHS held its first hearings on this issue; in 2006, NCVHS raised the issue of whether individuals should have the ability to control the specific contents of their health records accessible via the NHIN; in 2008, NCVHS provided detailed recommendations on sequestration. In 2009, Congress explicitly endorsed the development of sequestration technologies when, in section 3002 of the ARRA, it charged the HIT Policy Committee to make recommendations to ONC on the "segmentation and protection from disclosure of specific and sensitive individually identifiable health information . . . ."

In its February 2008 letter, NCVHS listed 5 examples of possible categories of sensitive health information that might be appropriate for sequestration: domestic violence, mental health, reproductive health, substance abuse, and genetic information. Although no administrative action has been taken in formalizing the concept of sequestration or selecting and defining categories, in May 2008, Congress enacted the Genetic Information Nondiscrimination Act (GINA). One effect of GINA is to add genetic information to substance abuse treatment records, HIV test results, and psychotherapy notes as among the categories of health information for which there are special legal rules.

GINA not only prohibits genetic discrimination in health insurance and employment, it also attempts to protect the privacy interests of individuals with respect to this information. The ability to achieve this goal depends on the development of sequestration technologies. I would like to illustrate this by focusing on genetic discrimination in employment, covered by Title II of GINA.

Pursuant to section 102(d)(3) of the Americans with Disabilities Act (ADA), after a conditional offer of employment, an employer is permitted to require that the individual ("conditional offeree") undergo a post-offer medical examination of unlimited scope. At this time, the employer also is permitted to make the signing of an authorization for the disclosure of the individual's health records a condition of employment.

Under section 202(b) of GINA, it is unlawful for an employer "to request, require, or purchase genetic information with respect to an employee or a family member." I should note here that the definition of "employee" includes applicants and conditional offerees.

Reading these provisions of the ADA and GINA together, an employer can require access to all of an individual's health information, except genetic information. Section 201(4) of GINA

defines "genetic information" as (1) the individual's genetic tests; (2) the genetic tests of family members of the individual; and (3) the manifestation of a disease or disorder in family members of the individual. This final part of the definition essentially includes family health histories.

Now, the question arises as to how the custodian of the individual's health record (e.g., hospital, physician), can comply with an authorization to release all of the individual's health information, excluding genetic information. With paper records, it is practically impossible to review a mountain of charts, lab reports, and narratives about the individual's care. With EHRs, however, it is theoretically possible to develop the software to identify and isolate genetic information. To date, however, no such software exists, either for genetic information or any other subset of sensitive information. Therefore, I strongly recommend that HHS fund research to develop and pilot test these technologies. Without practical solutions, the discussion of sequestration and segmentation becomes hypothetical and the promise of privacy protection in EHRs and the NHIN becomes illusory.

In the rest of my testimony, I will attempt to answer the five specific questions posed to me.

1. What types of genetic information are there, and why are they particularly sensitive?

The field of genetics is changing so quickly that it is difficult to identify all of the types of genetic information or their importance over the next several years. Clearly, there will be more genetic information of various types in health records. Within 5 years, most experts expect that a full genome sequence for an individual will cost $1,000 or less. Other "omics" information will also become increasingly common, including pharmacogenomics, toxicogenomics, and metabanomics. Epigenetic information also is likely to be a part of health records within a decade.

The definition of genetic information in GINA is both broad (i.e., it includes family health histories) and extremely narrow (i.e., it excludes genetic diagnoses and any expressed conditions). Overall, genetic information can be considered genotypic (covered by GINA) or phenotypic (excluded by GINA); it also includes carrier status (covered by GINA), where the health significance is primarily related to reproduction.

Regarding why genetic information is viewed by many people as "particularly sensitive," the following reasons have been suggested: (1) uniqueness, in that the genotype of each individual (except for an identical twin) is different; (2) predictive capability; (3) immutability, because inherited genetic information generally does not change; (4) requirement of testing, meaning that a genetic test is generally needed to learn this information; (5) historical misuse; (6) variability in public knowledge and perspectives, which raises the notion of being sensitive because it is widely viewed as sensitive; (7) impact on family; (8) temporality, suggesting that the knowledge associated with genetic information is likely to increase over time; and (9) ubiquity and ease of procurement. See Amy L. McGuire et al., Confidentiality, Privacy, and Security of Genetic and Genomic Test Information in Electronic Health Records: Points to Consider, Genetics in Medicine 10(7) (2008): 495-499. On the other hand, many commentators have questioned whether

it is a good idea to translate the sensitivity of genetic information into separate policies and laws, often referred to as "genetic exceptionalism." See Mark A. Rothstein, Genetic Exceptionalism and Legislative Pragmatism, Hastings Center Report 35(4) (2005): 27-33.

2. *Are there particular treatment considerations for the use and disclosure of genetic information? For example, what genetic information should be made available in the event that the patient comes for treatment regarding another issue?*

It is difficult to answer the question in the abstract. The answer depends on the reason the individual is seeking care. For example, an individual's genetic predisposition to a certain type of cancer is likely to be irrelevant when an individual is seeking care for a sprained ankle.

The question essentially asks whether there are certain categories of genetic information likely to be important for numerous medical conditions. Yes, there are. I think the best example would be in the field of pharmacogenomics. An individual's genetically mediated response to a certain medication or category of medications (e.g., analgesics, anesthetics) could be of importance in a variety of circumstances.

From a policy standpoint, the question is whether this genetic information would need to be available to all treating health care providers, available only to a subclass of health care providers, or available only via clinical decision support searching sequestered records for drug interactions of a proposed prescription medication.

3. *What are the sequestration and access requirements related to the use and disclosure of genetic information for non-treatment related purposes?*

This is an extremely complicated and contentious issue. I recommend that NCVHS <u>not</u> address these issues until it completes its recommendations for the use and disclosure of sequestered information for treatment. A brief explanation follows.

There are many different disclosures for non-treatment purposes, such as disability insurance, life insurance, long-term care insurance, and workers' compensation claims. In each instance, there must be a determination of the amount of information the entity (i.e., insurer, government agency) needs and has a legal right to receive. For example, in the life insurance context, whether an insurance company has a right to access genetic information in the health record of an applicant depends on the principles of medical underwriting permitted under state law. Enacting GINA, which establishes federal policy for health insurance and employment, took 13 years, and there is still no method for compliance with the limited disclosure provisions in the law. Separate rules for other applications of sensitive information also will take years to develop.

4. *What would implementing such controls mean for patient controls as a whole?*

Nobody knows, but I believe it will be positive. As NCVHS has previously noted, without such controls, patients will be discouraged from seeking prompt health care for stigmatizing conditions.

Because adopting patient controls represents a new model of the traditional physician-patient relationship, it is essential that physicians (and to a lesser extent all health care providers) be targeted for educational programs. The specifics and effects of this change need to be well understood by physicians. Without buy-in from physicians, it will be difficult for sequestration to succeed.

5. *What limits, if any, would you recommend on the patient's control?*

If the patient has too much control, then EHRs will be coextensive with PHRs and physicians and other health care providers will not have confidence that the information is substantially complete, accurate, and timely. On the other hand, if the patient has too little control, then patients will be reluctant to seek care or be forthcoming with sensitive information. It is a delicate balance that NCVHS already has recognized in its letters of 2006 and 2008.

6. *Would a policy permitting sequestration of genetic information have other practical consequences?*

It is difficult to say whether there will be unintended consequences of sequestration. One possible exercise is to review the various categories of health information and their uses set forth in the Privacy Rule. These include law enforcement, public health, research, quality assurance, etc. Next, think whether there are situations in which special rules are needed to avoid unintended consequences in each of these catgories. I would caution, however, that having too many exceptions to patient control will quickly overwhelm the rule.