

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

NCVHS

REPORT

Enhancing Protections for Uses of Health Data:

A Stewardship Framework

– Summary for Policy Makers –

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Enhancing Protections for Uses of Health Data, A Stewardship Framework

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To protect health data, the health industry currently relies on the Health Insurance Portability and Accountability Act (HIPAA) construct of covered entities and business associates. The National Committee on Vital and Health Statistics (NCVHS) advises the Secretary of Health and Human Services (HHS) on health information policy.

In December, 2007, at the request of the Office of the National Coordinator for Health Information Technology, NCVHS submitted a report to the Secretary recommending a new framework for appropriate data stewardship that encompasses all uses of health data by all users, independent of whether an organization is covered under HIPAA.

The NCVHS report is based on testimony and comments received from 75 stakeholders between June and October, 2007. The proposed conceptual and policy framework balances the benefits, sensitivities, obligations and protections related to the multiple uses of electronically collected and transmitted health data.

This summary, which slightly expands the Executive Summary of the December 2007 report but makes no substantive changes to it, is intended for policy audiences and others with a stake in the uses of health data. The full NCVHS report, which is summarized below, includes the following content:

- Background: the process NCVHS undertook to hear testimony and obtain input;
- Major Themes from the Testimony: summary of the testimony on the current state of health data uses and gaps in protections;
- Guiding Principles: six principles to guide development and implementation of the recommendations;
- Observations and Recommendations: commentary and nine sets of recommendations creating the framework of data stewardship; and
- Appendices: testifiers, commenters, a glossary of terms, and a conceptual framework for health data uses.

The full report, *Enhanced Protections for Uses of Health Data: A Stewardship Framework for "Secondary Uses" of Electronically Collected and Transmitted Health Data*, is available at <http://www.ncvhs.hhs.gov/>

Introduction

Emerging health information technology is ushering in a transformation in health by making clinically rich information more readily available, in a more structured format, and permitting electronic exchange throughout the health and healthcare continuum.

These capabilities are making health data more useful for publicly beneficial purposes such as quality improvement, public health, and research, with the potential to significantly improve health and health care for individuals and populations.

The same capabilities, however, also heighten the possibility that individuals and groups will be harmed and trust in health care providers undermined as a result of inappropriate, unexpected, or unauthorized uses of personal health information. Concern is growing that existing privacy protections do not adequately cover the many and expanding uses and users of health data. Many stakeholders are turning their attention to the need for appropriate stewardship over individuals' health data.

The National Committee on Vital and Health Statisticsⁱ was asked by the Office of the National Coordinator for Health Information Technology to develop a conceptual and policy framework balancing the benefits, sensitivities, obligations,

ⁱNCVHS is the public advisory body on health information policy to the Secretary of Health and Human Services. Its Website is ncvhs.hhs.gov/

ⁱⁱAt present, "chain of trust and accountability" is a term of art with a specific definition and usage within HIPAA, as discussed in Recommendation 1.

ⁱⁱⁱNCVHS, *Enhanced Protections for Uses of Health Data: A Stewardship Framework for "Secondary Uses" of Electronically Collected and Transmitted Health Data*. December 2007.

and protections surrounding the uses of health data for quality, research, and other purposes. (Such uses are often collectively referred to as "secondary uses." However, NCVHS urges abandoning this ill-defined and overly broad term in favor of naming each use of health data—for example, reporting communicable diseases to public health, or informing the quality improvement process.) The objective of this six-month exercise was to identify the practices and mechanisms needed to extend the "chain of trust and accountability" now confined to HIPAA covered entities so that it encompasses all personal health data uses by all users.ⁱⁱ

NCVHS submitted its final report on this subject to the Secretary in December 2007.ⁱⁱⁱ The report summarizes testimony the Committee received between June and October 2007 on the benefits and concerns related to expanded uses of health data and presents NCVHS recommendations for a durable framework covering all uses of health data by all users. The framework applies both to health information collected and used by covered entities or business associates and currently protected under the Health Insurance Portability and Accountability Act (HIPAA) and to personal health information collected and used by organizations that are not HIPAA covered entities. It is intended to guide data stewardship both during and after the transition to a Nationwide Health Information Network (NHIN). The recommendations also identify four areas in which further study and evaluation are needed, as well as additional necessary privacy protections.

This summary was developed to be useful for policy audiences and others with a stake in the uses of health data.

Guiding Principles for Data Stewardship

The National Committee developed the following principles to guide the development and implementation of the recommended stewardship framework:

- The recommended protections maintain or strengthen individuals' health information privacy.
- The recommended protections enable improvements in the health of Americans and the healthcare delivery system of the nation.
- The recommended protections facilitate uses of electronic health information.
- The recommended protections increase the clarity and uniform understanding of laws and regulations pertaining to privacy and security of health information.
- The recommended protections build upon existing legislation and regulations whenever possible.
- The recommended protections minimize administrative burden.

Major Themes in the Testimony

At a series of hearings and in writing, NCVHS received comments from representatives of provider organizations, professional associations, accrediting organizations, consumer organizations, health plans, quality improvement organizations, health information exchanges, data aggregators, and research and public health communities, as well as from individual citizens. The testimony and comments addressed the potential benefits and harms from the uses of health data and how protections should be enhanced. These themes are summarized below.

Potential benefits of health data uses.

There is optimism about the growing number of benefits that can be achieved through uses of health data enabled by health information technology and exchange.

- At the point of care, health information technology enhances access to information and affords patient safety alerts and health maintenance reminders.
- Across the continuum of care, health information exchange enables readily accessible information needed in an emergency, and more complete information for coordination of care among providers.
- For quality measurement, reporting, and improvement, automated and structured data collection enables efficient access to more comprehensive data and potential identification of new opportunities for improvement in care delivery.
- Clinical and population research and disease prevention and control are aided by access to more complete and timely data.

Potential risks and harms from health data uses. Some harms can result from uses of health data enabled by health information technology and exchange.

- Trust in the healthcare system may erode when there is a divergence between the individual’s reasonable expectations about the uses of his or her health data and actual uses of the data for other purposes, without the knowledge and permission of the individual.^{iv}
- Compromises to health care may result when individuals fail to seek treatment or choose to withhold information that could impact decisions about their care because they either do not understand or do not trust the intended protections of their data and identity.
- Risk for discrimination, personal embarrassment, and group-based harm may be heightened by the increased ability to build large databases, compile longitudinal data, re-identify de-identified data, and share data.

Observations about HIPAA. The Committee heard a range of views about the adequacy of HIPAA Privacy and Security Rules. Some commenters asserted that HIPAA provides adequate protections and may need only targeted administrative changes to address gaps or lack of clarity. Some cautioned against adding potentially burdensome and costly processes to HIPAA that may yield counterproductive results. In contrast, others observed that the relationship of business associates and their agents to covered entities needs strengthening, to assure the chain of trust created through business associate contracts and to enable transparency about covered entities’ uses of protected health information. Because HIPAA in its

^{iv}In this context, “the individual” means the person who is the subject of the personal health data in question.

current form does not protect de-identified data, concerns were expressed about uses of de-identified data, and in particular about the increasing ability to potentially re-identify data in merged databases.

Importance of data stewardship. Many commenters stressed the importance of data stewardship in all uses of health data, to provide the foundation for trust. The American Medical Informatics Association defines data stewardship as encompassing “the responsibilities and accountabilities associated with managing, collecting, viewing, storing, sharing, disclosing, or otherwise making use of personal health information.” Some commenters suggested that current regulations do not fully address the expanding interest of consumers in their health data, especially in view of the potential harms from expanded uses of health information technology and exchange. Some people, calling for individual permission for all uses of health data, asserted that individuals have the only role in data stewardship.

Issues regarding specific uses. The following issues were raised with respect to specific uses of health data:

- Regarding **treatment, payment, and healthcare operations** as defined under the HIPAA Privacy Rule, “healthcare operations” is broad in scope and not well understood. It was noted that as the uses of data move further away from the nexus of care, trust may factor more heavily than laws and regulations with respect to individuals’ privacy concerns.
- Regarding **quality measurement, reporting, and improvement** activities, a focus of discussion was whether the HIPAA definition of healthcare operations applies. After reviewing this definition and considering testimony, NCVHS concluded that current quality activities do remain within the

HIPAA definition of healthcare operations. It further suggests that enhancing transparency and applying internal oversight may be sufficient to allay any concerns about adequate health data protections for quality activities.

- Regarding **research**, it was observed that harmonization would enhance the varied existing federal agency regulations. In addition, concern was expressed that as quality activities become more sophisticated, some may evolve into research without the protections that regulations afford to human subjects. The need, in those cases, to distinguish between quality and research and appropriately shepherd quality into research was described.
- Regarding **public health**, it was noted that transparency is variable in data uses such as cancer registries and contacting individuals about potential improvements in specific disease management. Many individuals are unaware of required reporting; others who are aware may choose to see a caregiver under a false name to avoid consequences of reporting. Large databases that use real-time clinical data to potentially improve disease surveillance and public health may present unanticipated issues or concerns for public health activities, despite new and better techniques to protect data.

The use of health data involving monetary exchange was identified as a growing concern. While monetary exchange for health data is sometimes appropriate, some uses may result in harm. For example, people's trust in their providers may diminish as a result of unanticipated uses of their data; someone other than the provider or the individual may have undue influence over their healthcare decisions; or improperly de-identified, but nominally "protected," health information may be used to market to individuals.

NCVHS Recommendations for Enhancing Protections for the Uses of Health Data

Based on the testimony and comments received, and guided by the principles outlined above, the National Committee developed nine sets of recommendations that articulate key attributes of data stewardship in specific contexts and circumstances. The recommendations also envision the transition to the NHIN, identify where further analysis and other actions are needed, and outline additional privacy issues and necessary protections.

The recommendations represent different stages of implementation as well as different arenas of activity. Initially, the focus is on practical solutions that can be implemented immediately to address gaps. In particular, the initial focus is on health data uses that are most immediately enhanced through health information technology and exchange: quality measurement, reporting and improvement, and research. In addition, NCVHS identifies approaches that should be evaluated as the transition to an NHIN takes place. Finally, it recommends additional privacy protections, anti-discrimination measures, and state law mapping that may take longer to implement.

1. Recommendations on data stewardship for accountability and chain of trust within HIPAA:

- a. Covered entities should be specific in their business associate contracts about the following:
 - i. What identifiable health data may be used and for what purpose, by both the business associate and its agents,

- ii. What HIPAA-de-identified data may be used and to whom they are supplied,
 - iii. Requiring business associates to have contracts with their agents that are equivalent to business associate contracts, and
 - iv. Using the HIPAA definition for and de-identification of protected health information.
- b. Covered entities should confirm compliance by business associates with the terms of the business associate contract.
 - c. HHS should provide guidance stipulating that any organization that provides data transmission of protected health information requiring access to the protected health information on a routine basis (for example, a health information exchange or e-prescribing gateway) is a business associate.

2. Recommendations on data stewardship and transparency:

- a. HHS should issue guidance to ensure that individuals have the opportunity to be informed about all potential uses of their health data:
 - i. through education and clarity in the notice of privacy practices and other HIPAA administrative forms and required documentation, and
 - ii. by making information available about the specific uses and users of protected health information, including disclosures to public health, when requested.

- b. HHS should develop and maintain a multi-faceted national education initiative that would enhance transparency regarding uses of health data in an understandable and culturally sensitive manner.

3. Recommendations on data stewardship for individual participation and control over personal health information held by organizations not covered by HIPAA privacy and security rules:

- a. HHS should urge the Federal Trade Commission to utilize its full authority with respect to organizations that are not covered entities or business associates under HIPAA, but that collect personal health information, to ensure that:
 - i. privacy policies on web sites collecting personal health information fully inform users of the uses that will be made of their personal health information, and
 - ii. the organizations do not engage in misleading advertising or other deceptive trade practices.
- b. HHS should assure that an authorization from the individual is obtained for collection, use, and disclosure of personal health information held by any organization not covered by HIPAA.

4. Recommendations on data stewardship and de-identification:

- a. HHS should issue guidance to covered entities that the HIPAA definition of de-identification (i.e., by statistical method or complete safe harbor definition) is the only permitted means to de-identify protected health information.

- b. NCVHS believes there are significant concerns surrounding uses of de-identified data that warrant more thorough analysis. NCVHS will conduct hearings to make subsequent recommendations.

5. Recommendations on data stewardship and security safeguards and controls:

HHS should issue guidance to covered entities to promote uses of technical security measures to reduce unauthorized access, and to ensure that their business associates and agents are fully compliant with HIPAA Security Rule requirements for authorization, access, authentication, and audit control. This guidance also should be directed to organizations that maintain and/or transmit personal health information but are not covered entities.

6. Recommendations on data stewardship and data quality and integrity:

HHS data stewardship guidance should address the precision, accuracy, reliability, completeness, and meaning of data used for quality measurement, reporting, and improvement as well as other uses of health data.

7. Recommendations on data stewardship and oversight for specific uses of health data:

- a. Quality measurement, reporting, and improvement remain within the scope of healthcare operations when conducted by covered entities, their business associates and their agents; across covered entities within an organized health care arrangement; and when under the accountability and data stewardship principles inherent in HIPAA. These uses may be enhanced by a voluntary, proactive oversight process accountable to senior

management and governance of the institution, to ensure compliance with HIPAA.

- b. HHS should promote harmonization of research regulations within HHS and with other Departments that oversee regulations on human research protections, to ensure consistent privacy and human subject protection for all research efforts.
- c. HHS should encourage the Office for Human Research Protections (OHRP), in compiling its clarifying work on the research definition, to continue to work collaboratively with the Office for Civil Rights (OCR) and to leverage the tools newly in use in the industry. The purpose of this effort is to aid in distinguishing how requirements apply to uses of health data for quality and research, especially as questions arise relating to distinctions between research and quality uses of health data under the HIPAA health care operations definition. HHS should also encourage OHRP to widely disseminate its clarifying work, including beyond the research community.
- d. HHS should foster the collaborative efforts between OHRP and OCR to identify approaches to ensure that when a quality study becomes generalizable and evolves into research, HIPAA Privacy and IRB requirements are respected.
- e. Certain areas require further investigation, such as research based solely on data from electronic health records, decedent research, and potential value for common oversight for quality and research within an organization. NCVHS will take the lead in working with OHRP and other federal agencies to further study these areas and make recommendations as appropriate.

8. Recommendations on Transitioning to a Nationwide Health Information Network:

At this time, a definition of an NHIN and its use has not reached sufficient maturity to indicate how individuals can and should exercise choice over uses of their health data within it. Therefore, NCVHS recommends that trial implementations and other federally sponsored demonstrations include evaluation of the following:

- a. the impact of applying good data stewardship,
- b. ways to manage individuals' authorizations,
- c. new methods or techniques to de-identify health data,
- d. chain of trust mechanisms between covered entities and business associates and their agents,
- e. educational modalities to reach their target audiences, and
- f. appropriate safeguards to ensure that there is no unintended harm to individuals if de-identified data are sold to support possible NHIN business models.

^vAll NCVHS letters, recommendations and reports on privacy and confidentiality are posted on the NCVHS website in the section on the Subcommittee on Privacy and Confidentiality, which can be accessed through the NCVHS home page. www.ncvhs.hhs.gov

9. Recommendations on Additional Privacy Protections:

NCVHS has previously made several sets of recommendations setting the broad context for privacy improvement.^v They include the recommendation that privacy rules should apply to all individuals and organizations that create, compile, store, transmit, or use personal health information. In the same vein, States are beginning to enact laws intended to broaden protections. Building on these past efforts, NCVHS now recommends the following:

- a. HHS should work with other federal agencies and Congress for more inclusive federal privacy legislation. In the absence of comprehensive privacy legislation, HHS should address the need for more limited legislation that expands the definition of covered entity under HIPAA, at a minimum to organizations such as vendors of personal health records systems that are not covered entities or business associates.
- b. HHS should work with other federal agencies and Congress for legislative or regulatory measures designed to eliminate or reduce, to the extent possible, the potential discriminatory effects of the misuse of health data.
- c. HHS should support the work of the Health Information Security and Privacy Collaboration (HISPC) to guide harmonization among state laws, where applicable, and to pinpoint to guide harmonization among state laws, where applicable, and to pinpoint where states have made explicit differences. HHS should support a state law mapping repository that clarifies where states differ and which aspects of state laws are more stringent than HIPAA.

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