



November 2, 2005

The Honorable Michael O. Leavitt  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Leavitt:

I am pleased to transmit to you the *NCVHS 2003- 2004 Report*. The report reflects accomplishments and priorities of the National Committee on Vital and Health Statistics in an age of advancing health information technology. The Committee's reports and recommendations during this period addressed healthcare information interoperability, implementation of HIPAA standards, electronic prescribing and population health data, along with concerns about privacy and security in this increasing digital age. These activities are in keeping with the Committee's broad charter, as well as in response to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 and the Medicare Modernization Act of 2003.

As reflected in this report, as well as throughout its 55-year history, the Committee is organized to work in partnership with federal agencies, and health community stakeholders in developing guidance and recommendations about data standards, health statistics information systems and services, and coordination of health data requirements. As the statutory public advisory committee on health information policy, the NCVHS is strategically placed to support the Secretary's Health Information Technology initiatives as they develop, with special attention to the American Health Information Community.

We appreciate your consideration of this report of the Committee's accomplishments, mission, and vision during this exciting period of tremendous change.

Sincerely,  
/s/

Simon P. Cohn, M.D., M.P.H., Chairman  
National Committee on Vital and Health Statistic



**The National Committee on  
Vital and Health Statistics  
—NCVHS—**

**2003-2004**

**U. S. Department of Health and Human Services  
Centers for Disease Control and Prevention  
National Center for Health Statistics**

**Hyattsville, Maryland  
September, 2005**

## Foreword

This two-year report gives us a good opportunity to look back on the momentum of recent years and forward to the progress we anticipate in the near future. It is astonishing to realize that the national health information infrastructure (NHII) was little more than a *vision* as recently as November 2001, when the National Committee on Vital and Health Statistics (NCVHS) published its seminal report, *Information for Health: A Strategy for Building the National Health Information Infrastructure*. Using an architectural analogy, we might imagine the NCVHS report as the “rough drawings” for the NHII. The ensuing years have generated more detailed drawings, some of them provided by NCVHS itself. With the appointment of Dr. David Brailer, the first National Coordinator for Health Information Technology, we have a “general contractor” who has been refining the blueprints and assembling the team of builders. Now the construction process is under way and proceeding at a rapid pace.

All in all, this is an exciting time for health information policy, thanks to strong federal leadership, engaged private sector partners, and increasingly well informed consumers. The National Committee is pleased to have contributed so substantially to the Secretary’s health information technology (HIT) initiative and its growing momentum. Getting the right information to the right people at the right time is key to achieving better health for all Americans, and we look forward to new opportunities to support the Department’s objectives to this end.

While a strong national health information infrastructure is a necessary precondition for addressing the health concerns facing our nation today, establishing the technical infrastructure is clearly not sufficient. Unacceptable threats to patient safety, significant health disparities among population groups, and skyrocketing costs are just some of the challenges that necessitate a broad, multi-pronged strategy. Among other things, we need better ways to translate knowledge into quality care, better information to facilitate health improvements for disadvantaged population groups, and privacy protections that strengthen public trust.

These priorities are all part of the broad agenda of the National Committee, and we have been hard at work on them, as the following pages show. The Committee has a 55-year tradition of diligently gathering information and expert opinion, creating a forum for the exchange of views, identifying areas of consensus, pooling the expertise of Committee members and staff, and developing thoughtful recommendations. These approaches have worked well in the past and we look forward to putting them to work in support of the Secretary’s HIT strategy and the American Health Information Community. As we help the Department integrate its information policy activities, we expect new synergies and partnerships to develop across the five domains of NCVHS activity — standards and security, privacy and confidentiality, the NHII, population health and quality. Our efforts will be informed and guided by the Committee’s comprehensive approach to information policy and its mission to help shape policy strategies to improve the population’s health.

Simon Cohn, M.D., Chairman  
John Lumpkin, M.D., Chairman, 1999 - 2005  
August, 2005

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## Executive Summary

This report reviews the recent work and accomplishments of the National Committee on Vital and Health Statistics (NCVHS), the statutory public advisory committee on health information policy to the Secretary of Health and Human Services (HHS). During the two-year period it covers, Mike Leavitt was appointed to replace Tommy Thompson as HHS Secretary. The Committee was gratified that Secretary Leavitt not only moved ahead but quickened the pace on the Department's health information technology (HIT) strategy begun under Secretary Thompson. The pace of the Committee's work increased over this two-year period, as well. It produced 31 letters and reports with recommendations on a broad range of topics, based on extensive consultations with experts in industry and government and with health care consumers. It stepped up its active partnership with the Department around its HIT agenda and continuing priorities in the HIPAA arena as well as on such vital issues as health care quality and race/ethnicity data. Congress added new statutory responsibilities related to e-prescribing to the Committee's charge. And partnerships with health care, informatics and standards organizations intensified.

This report describes the National Committee's activities in the domains of its five subcommittees and workgroups (listed in the Foreword). A marked characteristic of this period, however, was the increasing convergence and overlap among these domains. The information policy issues in the arenas of standards, security, privacy, population health, quality, and the information infrastructure all interact. These interactions necessitate collaborations among NCVHS subgroups, and with other bodies, that are sure to increase in the future.

- **NHII**

As noted, the NCVHS vision for the national health information infrastructure moved vigorously onto the nation's agenda in 2003 and 2004. The President's creation of the Office of the National Coordinator for Health Information Technology (ONCHIT) in May 2004 was consistent with the Committee's call for federal leadership. The Strategic Framework for HIT launched just two months later opened the door for progress on many fronts. The Committee's conceptual framework for the NHII features three co-equal and interactive dimensions of information and its use—personal health, health care provider, and population health. With ONCHIT focusing initially on the provider dimension, the Workgroup chose to focus in this period on the other two dimensions, personal and population health, where progress was less robust. Among other things, it identified significant questions about consumers' ability to control their personal health information and about privacy and confidentiality.

- **Population Health**

In 2003, NCVHS began a relationship with the new Board of Scientific Counselors of the National Center for Health Statistics (NCHS), chartered to advise HHS, CDC and NCHS "regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS." A common interest of the advisory bodies is helping to realize the vision for 21<sup>st</sup> century health statistics, articulated in a joint NCVHS/NCHS/HHS report in 2002. The quality and completeness of data on race and ethnicity is a major NCVHS priority for which the Subcommittee on Populations has stewardship. The

Committee conveyed key findings and recommendations on race and ethnicity data to the Secretary in three letters and a broader commentary during this period.. Its 2003 recommendation that health plans improve and standardize the collection of these data had a rapid and measurable impact. The entire Committee worked in various ways in 2003-2004 to infuse the population health perspective more deeply and concretely into its work. The release in 2003 of the first annual National Reports on Quality and on Health Disparities by the Agency for Health Care Research and Quality heightened the national focus on these major areas of concern and illustrated the need for more complete data.

- **Quality**

In 2004, the Quality Workgroup completed a detailed summary of its findings from the testimony of more than 40 experts over several years. The report includes proposals for improving the measurement of health care quality. These proposals, which focus mainly on the gaps in administrative data, are in four priority areas: assessing health care and health outcomes, reducing disparities, building the information infrastructure to support quality, and balancing patients' interests in quality and confidentiality. The Workgroup then conducted a series of hearings to assess the responses of diverse stakeholders to the proposals, leading to a consensus recommendation to the Department and industry. Seeing the range of information sought by quality initiatives and the burden issues of providers, the Workgroup began to reflect on how the electronic health record (EHR) could facilitate the collection of data elements and the transmission of new knowledge about best practices. It began work on the uses of the NHII for quality improvement in the latter part of 2004.

- **Standards and Security**

In 2003 and 2004, the Subcommittee on Standards and Security sent 12 reports or letters to the Department, transmitting recommendations that became widely accepted. HIPAA regulations began to go into effect in this period, with NCVHS helping industry prepare for compliance and then monitoring implementation. Following a rigorous review, the Committee wrote the Secretary in late 2003 advising that it is in the country's best interest that ICD-10-CM and ICD-10-PCS be adopted as HIPAA standards. Passage of the Medicare Modernization Act around the same time added e-prescribing as an active part of the 2004 agenda, with CMS accelerating the pace of implementation. During this two-year period, the Committee set the stage for the Department's Consolidated Health Informatics (CHI) initiative with recommendations on patient medical record information (PMRI) message format standards and PMRI terminology, developed through close work with industry and the Department. This led to the Department's 2004 CHI decisions and resulted in standards that will significantly affect the practices of the federal government and ultimately the private sector.

- **Privacy and Confidentiality**

The Subcommittee on Privacy and Confidentiality, like the aforementioned Subcommittee, takes the lead on aspects of the National Committee's statutory HIPAA responsibilities. NCVHS advises on content and strategies related to the privacy rule and assesses the adequacy of outreach and education efforts. In late 2003, the Subcommittee began to study the rule's impact and ramifications in several domains, resulting in six letters from NCVHS to the Secretary. The Committee also wrote the Secretary in June 2004, urging the Department to conduct research on the rule's impact in specific

areas and its general impact on the privacy of personal health information. In 2004, the Subcommittee widened its focus to include the privacy issues raised by new NHII/NHIN policies and practices as well as those associated with e-prescribing policies.



## Introduction

The National Committee on Vital and Health Statistics (NCVHS) is the statutory public advisory committee on health information policy to the Secretary of HHS. Its mission is *to advise on shaping a national information strategy for improving the population's health*. Its members are selected for their expertise and distinction as researchers, educators and practitioners in such fields as population-based health, health services, epidemiology, privacy, consumer health advocacy, health research, health statistics, health information systems, and health data standards. Sixteen members are appointed by the HHS Secretary, and two are appointed by Congress. NCVHS has subcommittees and workgroups on standards and security, privacy and confidentiality, populations, quality, and the National Health Information Infrastructure (NHII).

In its 55 years, the Committee has built a strong reputation for thoughtful leadership, and the Department and other constituencies have come to rely on its expertise<sup>1</sup>. It serves as a bridge between the Department and the health care, research and public health communities, as well as the public. It has active relationships with federal and state agencies, other advisory bodies, consumer advocates, representatives of special populations, quality assurance experts, standards development organizations, data users, the health care and insurance industries, and other constituencies. The topical descriptions below show the Committee's efforts to elicit the views and knowledge of experts in these sectors. Six Federal agencies and the National Center for Health Statistics (NCHS) Board of Scientific Counselors send liaisons to the Committee [see Appendix 1], and the full Committee and its subcommittees and workgroups are staffed by individuals representing 21 agencies and offices. All of these collaborations contribute to the Committee's effectiveness across a broad range of health information policy areas.<sup>2</sup>

This report is the latest in a series of periodic reviews of the National Committee's work<sup>3</sup>. To mention a few highlights, the years 2003 and 2004 were a time of unprecedented activity on the health information infrastructure at the highest levels of government and by industry. Many decisions—above all, the President's creation of the Office of the National Coordinator for Health Information Technology (ONCHIT)—moved health information policy in directions envisioned and recommended by

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<sup>1</sup> The Committee was created in 1949 at the request of the World Health Organization as part of an international effort to build national and international health statistics. The statute establishing NCVHS as a Federal advisory committee is 42 U.S.C. 242k(k); the latest NCVHS charter is in Appendix 3. The full Committee meets four times a year, and each of its five subcommittees and workgroups meets several times a year. All meetings are open to the public and broadcast on the Internet.

<sup>2</sup> The Committee used a new metric for assessing its effectiveness in its 2003 report to the General Services Administration (GSA), which tracks all federal advisory committees. Using new GSA performance measures, the staff determined that NCVHS had made 12 sets of recommendations in FY2002, totaling 77 recommendations, and that 71 percent of these were at least partially implemented by the Department.

<sup>3</sup> The history of NCVHS has been well documented through annual or periodic reports from 1949 on, and in special reports on the occasion of the 15<sup>th</sup>, 20<sup>th</sup>, 45<sup>th</sup> and 50<sup>th</sup> anniversaries. Reports, minutes, transcripts and other materials since 1996 are posted on the NCVHS Web-site, [ncvhs.hhs.gov](http://ncvhs.hhs.gov).

NCVHS. In the population health and quality areas, the release in 2003 of the first annual National Reports on Quality and on Health Disparities by the AHRQ offered new opportunities for collaboration and action on issues at the heart of the Committee's work. The 2003 recommendation by NCVHS that health plans improve and standardize the collection of race and ethnicity data had a measurable impact. In addition, the Committee welcomed the news that the President's FY2005 budget included higher-level funding for the NCHS, consistent with a 2003 NCVHS recommendation to the Data Council. During this period as well, the Department's Consolidated Health Informatics (CHI) initiative added to the momentum on the health information infrastructure and demonstrated the administration's commitment to providing leadership on standardization. The Committee set the stage for the CHI initiative through its recommendations on patient medical record information (PMRI) message format standards and PMRI terminology and through close work with industry and the Department, leading to the 2004 CHI decisions. The Committee also embarked in 2004 on new responsibilities for advising on e-prescribing, assigned to NCVHS as part of the Medicare Modernization Act of 2003.

These highlights and many other NCVHS activities are described further below, in the domains of the Committee's subcommittees and workgroups.

## Major Activities and Accomplishments

### 1. National Health Information Infrastructure (NHII)

**NCVHS documents on the NHII, 2003-2004:**

- October 8, 2003 Letter to the Secretary on federal interagency IT research and development initiatives
- September 8, 2004 Letter to the Secretary on the Health IT/NHII Summit

In 2003 and 2004, the NCVHS vision for the national health information infrastructure moved decisively onto the nation's agenda. The Committee had enunciated its NHII vision in the November 2001 report, *Information for Health: A Strategy for Building the National Health Information Infrastructure*. The report, which was developed through extensive hearings and consultations, identified federal leadership as "the most important missing ingredient" in accelerating and coordinating progress on the NHII. It called for "a new senior position and office at HHS (equipped with adequate funding) ... to oversee and coordinate a broad range of health information policy, research, and program activities in different sectors, both public and private" (p.3).

The adequacy of the evolving national information infrastructure for meeting the requirements of the health sector and public health interests was a concern about which the Committee had written the Secretary in October, 2003. Based on findings from a hearing earlier that year, it urged the Department to increase HHS agency participation in federal interagency information technology (IT) research and development initiatives to advance an improved national health information infrastructure and represent health perspectives in the research and development process for the next generation Internet and other aspects of the information infrastructure.

These concerns were largely put to rest by the surge of activity around the NHII that began in early 2004. At the same time that he set a national goal for Americans to have electronic health records within a decade, the President created a new sub-Cabinet level post at HHS to provide national leadership and coordination on health information technology. In May, David J. Brailer, MD, PhD, was appointed the first National Coordinator of Health Information Technology. Then in July, Dr. Brailer unveiled the Health IT Strategic Framework at the HHS Health IT Summit and National Health Information Infrastructure (NHII) conference, which the NCVHS Workgroup on the NHII helped to plan. Dr. Brailer provided an overview, and conference break-out groups reported to the NCVHS NHII Workgroup at an NCHVS meeting at the end of the conference.

In a follow-up letter to the Secretary, the Workgroup called the Strategic Framework "a remarkable achievement in both its speed and balance." It identified several areas needing additional work, and offered to assist the Department in developing strategies for achieving its goals and objective. The areas:

- Issues related to patient control of their personal health information, and general policy issues related to Personal Health Records.

- Approaches, best practices, and issues related to the use of master patient indexes and other methods to assure that healthcare information can be reliably associated with the right individual.
- A research agenda for the NHII, particularly to support strategies in the population health and personal health dimensions of the Framework.
- Issues related to the movement of data between health care, population health, and personal health dimensions and, in general, secondary uses of data from any dimension.
- A comprehensive statement of “Rules of the Road,” including but not limited to interoperability, legal obstacles, and, in general, the key things that potential participants need to know about how to participate in the NHII.

The NCVHS letter also suggested that the Department revisit two issues in 2005: metrics for measuring progress, and conformance testing. These topics join others identified in the September 2004 letter as possible near-term priorities for the NHII Workgroup.

The Committee’s conceptual framework for the NHII features three co-equal, intersecting and interactive dimensions of information and information use—personal health, health care provider, and population health. The 2001 report states that “the greatest value derives from shared information and communication across them” (p.3). In this rapidly-moving arena, the NHII Workgroup weighs possible next steps in terms of how and where its contribution can be most useful. With ONCHIT generating and coordinating the momentum on the provider dimension, the Workgroup has chosen to focus on the two dimensions where progress is less robust. On the population health information infrastructure, the Workgroup held hearings in Atlanta in April 2003 on public health IT systems including registries and the National Electronic Disease Surveillance System (NEDSS), part of the Public Information Network being developed by the Centers for Disease Control and Prevention.

In 2003 and 2004, the Workgroup held several hearings on the personal health dimension, where the goal is to enable consumers to be equal partners in health care decision-making. Personal health records (PHRs) are a component of health IT that is moving ahead rapidly thanks to both the visibility the President gave them and the assiduous efforts of the public-private collaborative, Connecting for Health<sup>4</sup>. However, significant questions remain about consumers’ ability to control their personal health information and privacy and confidentiality issues. The Workgroup has taken time in several meetings and hearings to study this emerging technology and different PHR models and to clarify the policy issues in this area. It plans a letter to the Secretary in 2005, summarizing its findings on PHRs.

## 2. Populations

### **NCVHS documents on populations, 2003-2004:**

- February 28, 2003 Letter to the Secretary - NCVHS Supports NCHS Programs
- March 27, 2003 Letter to the Secretary on Populations-based data for racial and ethnic minorities

<sup>4</sup> <http://www.connectingforhealth.org/resources/generalresources.html>

- September 26, 2003 Letter to the Secretary on Collection of Racial and Ethnic Data by Health Plans
- September 26, 2003 Letter to the Secretary on Recommendations for Targeted Data Collection
- February 20, 2004 Letter to the National Institute of Child Health and Human Development, NIH regarding the establishment of the National Children's Study
- August 23, 2004 Letter to the Secretary - Recommendations on Populations Based Data Collection

Population health principles govern all the work of the National Committee, whose population health mission is stated above. Helping the Committee translate its mission into practical information and policy recommendations is a responsibility of the Subcommittee on Populations. Its charge covers information on the population as a whole and on specific population segments, particularly those whose health status may be adversely affected by determinants such as race, ethnicity, socioeconomic position or disability. The Subcommittee has worked to infuse the population health perspective more deeply and concretely into all the Committee's work. In 2003 and 2004 it organized a series of panel presentations to the full Committee on topics including Canadian approaches to population health; population health and its implications for health statistics; and race, ethnicity and socioeconomic position.

Contributing to the ongoing effort to improve race and ethnicity data was the Subcommittee's major focus during this two-year period. First, it gathered extensive information on data issues for U.S. population groups in far-flung hearings in 2002 and 2003. Then it worked in 2003 and 2004 to turn its findings on the immense and complex data gaps in this area into actionable recommendations to help the government achieve the highest quality of federal data collection and to make this information available and useful to researchers. The Committee conveyed key findings and recommendations on race and ethnicity data to the Secretary in three letters during this period. It also submitted a longer commentary prepared by the Subcommittee, "Recommendations on the Nation's Data for Measuring and Eliminating Health Disparities Associated with Race, Ethnicity, and Socioeconomic Position."

The Committee's September 2003 letter had a measurable impact. The letter recommended that HHS strongly encourage and support public and private sector health plans to collect accurate and complete racial and ethnic data using the revised Office of Management and Budget (OMB) standard categories. It observed that without the collection of standardized racial and ethnic data in health plans, progress toward achieving the national goal of eliminating racial and ethnic disparities could not be monitored. In addition, it pointed out that medical service provider administrative data are a critical source of information on the race and ethnicity of individuals, and that a uniform data collection infrastructure does not exist. Many in industry welcomed these NCVHS recommendations. A year later, a 2004 survey by America's Health Insurance Plans (AHIP) found that half of the plans were collecting race and ethnicity data in at least one of their product lines. This will facilitate identifying, measuring and tracking health and healthcare disparities within and across health plans.

The Subcommittee has led the Committee's effort to prevent or minimize slippage in budgetary support for the important population health surveys of NCHS, as addressed in a February 2003 letter to the Secretary. As noted, the following year's budget in-

cluded a significant increase for NCHS, providing resources to address chronic shortfalls in the Center's programs and to ensure progress in initiatives to improve core data systems. The Subcommittee on Populations also has stewardship of the Committee's relationship with the Center's recently created Board of Scientific Counselors. This relationship opens new ways for the Committee to support the Center and its work. NCHS and its two advisory bodies share a strong interest in carrying out the vision for 21<sup>st</sup> century health statistics that was articulated in the 2002 NCVHS publication with that title<sup>5</sup>. The report was developed collaboratively by NCVHS, NCHS and the HHS Data Council.

With its responsibility for information policy on all population groups, the Subcommittee on Populations may have the broadest portfolio of any NCVHS subcommittee or workgroup. During this period it also reviewed plans for more extensive data collection on children, the National Children's Study, resulting in a February 2004 letter and recommendations. In addition, it began a review of mental health data issues, a focus it plans to continue in 2005. The emphasis on mental health data grew out of concerns about 2001 changes in mental health data collection in a major general health survey that make it more difficult to understand the connections between health status and emotional wellbeing.

By the end of this two-year period, the Subcommittee on Populations was conducting a significant part of its work in collaboration with other NCVHS groups. This is particularly the case with the Quality Workgroup, because improving race and ethnicity data in health care is so critical to the national effort to improve health care quality measurement. Another topic of common interest is functional status, the subject of a 2001 NCVHS report. This topic reemerged in the context of 2004 Quality Workgroup recommendations, discussed below. The Subcommittee is also in dialogue with the Subcommittee on Privacy and Confidentiality, for example about the fact that the cell sizes of survey data on small population groups make it difficult to release these data for research purposes.

### 3. Quality

#### **NCVHS documents on quality, 2003-2004:**

- January 17, 2003 NCVHS Comments on Proposed Measure Set for the National Healthcare Quality Report (NHQR)
- May 2004 Report on Measuring Health Care Quality
- November 5, 2004 Letter to the Secretary - Recommendation on revisions to the Uniform Bill for Hospitals (UB04) and the ANSI ASC X 12N 8371 HIPAA Implementation Guide

The Quality Workgroup takes the lead in the Committee's work on the data and system issues involved in measuring and improving the quality of health and health care. Created in 1998, it is part of the Subcommittee on Populations. Although the Workgroup has focused much of its work on the clinical encounter, part of its mission is to help position clinical quality measurement so it has maximum utility in assessing and improving population health.

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<sup>5</sup> Shaping a health statistics vision for the 21<sup>st</sup> century, November 2002.

The Workgroup works in an environment in which many public, private and joint initiatives are under way to improve quality and quality measures. In its advisory role, the Workgroup orients to and is informed by the priorities of the Agency for Healthcare Research and Quality (AHRQ), which publishes annual reports on health care quality and disparities. The Workgroup began the two-year period by developing comments to AHRQ on its proposed measure set for the first National Healthcare Quality Report (January, 2003). These comments were based primarily on testimony received from public health and health care experts at a July 2002 NCVHS hearing. The National Committee's continuing dialogue with AHRQ keeps the population health uses of quality assessment as a prominent part of its perspectives.

In its early years, the Quality Workgroup organized 17 panel presentations that enabled the Committee to talk with more than 40 experts about the challenges of developing health care quality measures, implementing quality measurement and improvement projects, and using comparative performance data to drive quality improvement. Based on that testimony, the Workgroup developed a 2004 report summarizing its findings and translating them into proposals for improving quality measurement. It identified candidate recommendations in four priority areas: 1) assessing health care and health outcomes, 2) reducing disparities in health and health care, 3) building the data and information infrastructure to support quality, and 4) balancing patients' interests in quality and confidentiality. Some of the recommendations target existing health data systems, some target evolving systems, and a few require policy changes. All come with implementation options to be considered by and in consultation with key stakeholders.

The Workgroup faced two major challenges in developing its report. First, it needed to take into account the extensive activity under way on health care quality and standards. Second, it had to decide how to take advantage of the growing momentum in the development of the NHII, particularly in electronic health records. While much of the Committee's earlier research focused on gaps in administrative data, the Workgroup wanted to make its findings relevant to the transition to EHRs. In general, the Workgroup and Committee chose to frame the 2004 recommendations on quality in the spirit of the Committee's earlier reports on the NHII and 21st century health statistics, —in other words, as a vision document to guide long-term progress through the activities and interests of myriad stakeholders.

Upon completion of its May 2004 report, the Quality Workgroup began an effort to increase the synergy among data standard advances, progress in the health information infrastructure, and quality improvement activities. In June and September 2004 hearings sponsored jointly with the Subcommittee on Standards and Security, members met with representatives of purchasers, providers, health plans, insurers, quality assurance bodies, health information management professionals, and Standards Development Organizations to discuss the feasibility and business case for each of the first eight of the 23 candidate recommendations in the May report. While many participants stressed the importance of consensus and collaboration, the discussions also highlighted differences between purchasers and health care providers about the relative costs and benefits of collecting more data on quality. The late 2004 hearings also highlighted the importance of measuring functional outcomes, a topic that is likely to receive further attention from the Committee in the future.

In addition, the discussion clarified the feasibility of moving ahead with one candidate recommendation that was universally sought by the purchasers of care, endorsed by the providers of care and poised for implementation by the Designated Standards Maintenance Organizations. In a November letter to the Secretary, the Committee recommended “that the next version of the Uniform Bill for Hospitals (UB04) and the ANSI ASC x 12N 8371 HIPAA Implementation Guide be revised to facilitate reporting of a diagnosis indicator to flag diagnoses that were present on admission in secondary diagnosis fields for all inpatient claims transactions.”

A key insight gained from the 2004 hearings was the dramatic increase in the number and types of information sought by various quality initiatives on both inpatient and outpatient encounters. Although claim forms can accommodate selected individual elements (e.g. lab test or vital sign or functional status), the depth and breadth of the quality indicators anticipated by the healthcare community have already exceeded the potential capacity of the claims transaction. This observation triggered discussion and reflection upon the role of the electronic health record (EHR) as a vehicle that facilitates the collection of additional quality data elements and also serves as a means of transferring new knowledge around best practices. The discussion of the transition to multiple EHR uses laid the groundwork for the focus of the Quality Workgroup in 2005.

#### 4. Standards and Security

##### **NCVHS documents on standards and security, 2003-2004**

- June 25, 2003 Report to the Secretary on the Healthcare Industry's readiness to comply with the October 16, 2003 Implementation deadline
- June 25, 2003 Letter to the Secretary on the Status of PMRI Terminology
- September 24, 2003 Letter to the Secretary: CHI Domain Area recommendations
- October 14, 2003 Analysis of ASCA Compliance Plans for Implementing HIPAA Transactions and Codes Standards
- November 5, 2003 Letter to the Secretary- ICD-10 Recommendations
- November 5, 2003 Letter to the Secretary- Comments on CHI domain area recommendations; Patient Medical Record Information (PMRI) Terminology Analysis Reports
- November 5, 2003 Letter to the Secretary - Recommendations for PMRI Terminology Standards
- January 29, 2004 Letter to the Secretary - Final Recommendations on CHI Domain areas
- March 5, 2004 Letter to the Secretary - Recommendations on Claims Attachment
- May 10, 2004 Sixth Annual Report to Congress on the Implementation Of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996
- June 17, 2004 Letter to the Secretary - Recommendations on Standards for Billing of Supplies
- September 2, 2004 Letter to the Secretary - First Set of Recommendations on E-Prescribing Standards

The record of 16 meetings and 12 reports or letters by the Subcommittee on Standards and Security in 2003-2004 reflects the level of engagement and productivity of this subcommittee. More importantly, the wide acceptance of these recommendations by HHS, other federal departments and agencies and the private sector demonstrates the leadership and influence this Subcommittee has provided on the adoption of healthcare information standards as a key element of the foundation for the National Health Information Infrastructure (NHII). The Health Insurance Portability and Accountability Act (HIPAA) of 1996 provided the initial impetus for the work of this Subcommittee,



which manages the Committee's responsibilities for advising the Secretary on the adoption of health data standards, monitoring their implementation, and reporting to Congress annually on the status of implementation. In addition, a new law, the Medicare Modernization Act of 2003, gave the Committee a new set of challenges and responsibilities related to electronic prescribing (e-prescribing). The Subcommittee carries out all its work in close partnership with the Department and the health care industry, with the Department relying heavily on its advice. Through these active working relations, it is able to facilitate consensus within industry, within government, and between the two.

In this two-year period, the HIPAA regulations on transactions and code sets and on privacy went into effect. Final rules also were issued for the national provider identifier and for security standards, leaving only plan identifiers and claims attachment regulations to be sent through the rule-making process. Modifications to the transactions standards and code sets also were published during this period. Besides advising on the content and pace of standardization, another role of the Committee is to help prepare industry for compliance and to assess its readiness. The transition to compliance took effect in October 2003. At its November 2003 meeting, the Committee passed a motion commending the Department "for taking the lead in working with its numerous partners to carry out the complex and contentious transition to HIPAA codes and transaction standards so smoothly."

The Committee's advisory work on HIPAA is described in detail in its regular reports to Congress on HIPAA implementation. The sixth such report, covering September 2002 through December 2003, observes that significant progress occurred on several HIPAA Administrative Simplification standards during that period<sup>6</sup>. While the report applauds the accomplishments, it also observes that the industry's implementation activities and resource planning will be more effective, and the full economic benefits of administrative simplification realized, when the entire suite of standards is finalized. The Committee therefore encouraged the Secretary of HHS to expedite the publication of the remaining rules without delay, and it urged Congress to provide sufficient resources and support to assure successful implementation of this initiative.

Recommending standards for Patient Medical Record Information (PMRI) is another facet of the Committee's responsibilities under HIPAA. The Subcommittee's findings and recommendations were conveyed through a report in 2000 and letters in 2002 and 2003. The potential benefits of the PMRI recommendations became visible during 2003 and 2004. They served as the foundation for standards in the federal Consolidated Health Informatics (CHI) initiative, which is developing and implementing uniform standards for interoperability of clinical information in the federal health care enterprise. During this period, the Committee served in an advisory capacity to the CHI initiative. It held meetings that enabled industry to comment on proposed standards in a number of clinical domains, and it reviewed and commented on all the proposed CHI recommendations. The resulting standards, which were adopted by the Secretaries of HHS and Defense as well as the Veterans Administration, will significantly affect the ways in which the federal government and ultimately the private sector conduct business regarding clinical messaging and terminology.<sup>7</sup>

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<sup>6</sup> <http://www.ncvhs.hhs.gov/sssmemb.htm>

<sup>7</sup> <http://www.hhs.gov/healthit/chiinitiative.html>

The standardization efforts of the Committee began decades ago with its historic work on the International Classification of Diseases (ICD)—an involvement that continues to the present day. With the 10<sup>th</sup> edition of the ICD already implemented in many countries, and in the United States for mortality data, the question of implementation for morbidity purposes in the U.S. has grown more pressing. In 2003, the Committee held hearings on the feasibility and desirability of replacing the existing diagnosis and inpatient procedure coding system, ICD-9-CM, vols. 1, 2 and 3, with ICD-10-CM and ICD-10-PCS, respectively. The findings of a commissioned impact study by the Rand Corporation on the costs and benefits of migrating to a new system were presented to the Committee at its September 2003 meeting, along with overviews and analyses by NCHS, the Centers for Medicare and Medicaid Services (CMS), reactor panels and others. Based on this rigorous process, the Committee wrote the Secretary in November 2003 to convey its recommendation that it is in the country's best interest that ICD-10-CM and ICD-10-PCS be adopted as HIPAA standards. The Department has not yet acted on this recommendation.

Passage of the Medicare Modernization Act (MMA) in late 2003 moved e-prescribing to the fore in 2004. e-Prescribing represents the first broad clinical application that must address all the practical issues involved in standardization, including information linkage, privacy, patient identification, content, and interoperability. The MMA required NCVHS to conduct hearings on e-prescribing, with the input used to recommend to the HHS Secretary standards that could be used to implement e-prescribing in the new Medicare Part D benefit. Soon after his appointment as CMS Administrator, Dr. Mark McClellan told the Committee the Centers wanted to accelerate the implementation of e-prescribing by proposing an initial set of well-established standards by January 2006, when the Medicare Part D benefit was to begin. Taking up the challenge, the Subcommittee worked intensively with industry to create the requirements for e-prescribing standards. The process was extremely successful. The Subcommittee held a series of hearings in which it evaluated industry adoption of e-prescribing, the existing infrastructure, the standards being used, privacy and security policies, and research needs. On this basis, it not only recommended the foundation standards, but also identified the limitations and gaps in these standards and recommended specific HHS and industry action to address these limitations and gaps (see September 2004 letter). These recommendations were later incorporated into a proposed rule, serving as a catalyst for the industry to fill standards gaps and harmonize standards to facilitate and accelerate the adoption and use of e-prescribing. The process also served as a model for obtaining industry input into the regulatory process.

## 5. Privacy and Confidentiality

### **NCVHS documents on privacy and confidentiality, 2003-2004:**

- June 25, 2003 Letter to the Secretary: Program to measure the effects of the Privacy rule
- March 5, 2004 Letter to the Secretary - Recommendation on the effect of the Privacy rule (on public health and research and on health care providers, health plans, and consumers).
- June 17, 2004 Letter to the Secretary - Recommendations on the Effect of the Privacy rule in Banking
- June 17, 2004 Letter to the Secretary - Recommendations on the Effect of the Privacy rule in Law Enforcement

- June 17, 2004 Letter to the Secretary - Recommendations on the Effect of the Privacy rule in Schools
- September 1, 2004 Letter to the Secretary - Implementation of the Privacy rule's marketing provisions
- September 1, 2004 Letter to the Secretary - Privacy Advocate
- September 2, 2004 Letter to the Secretary - Findings and Recommendations on the Impact of the Privacy rule on Fundraising

The NCVHS Subcommittee on Privacy and Confidentiality shares responsibility with the Subcommittee on Standards and Security for helping the Committee advise the Department on HIPAA. As with that Subcommittee, its work on HIPAA is detailed in a regular report to Congress on implementation. With respect to HIPAA, the Subcommittee concerns itself with outreach and education, implementation, and the impact of the privacy rule. It also advises on privacy and confidentiality issues associated with other laws and policies, including the privacy ramifications of the National Health Information Network (NHIN) and e-prescribing.

The Subcommittee began monitoring and advising on the Department's outreach and education efforts in support of the HIPAA privacy rule in mid-2002. After holding hearings in three cities, it ended 2002 with a letter strongly urging the Department to respond to the public's lack of information about privacy rule implementation with significantly increased resources. The letter advocated an immediate and intense effort, including a massive public education program. Since that time, advising on content and strategies and assessing the adequacy of outreach and education with various constituencies has remained a strong facet of the Committee's involvement with the Privacy rule.

After allowing a few months for the implementation process to unfold, the Subcommittee began in late 2003 to study the impact and ramifications of the privacy rule. From the outset, the HHS Office for Civil Rights, which is responsible for enforcement and education, kept the Committee updated about the number, extent, and type of complaints submitted under HIPAA, as well as the Department's plans to address them. The Subcommittee conducted hearings in November 2003 and February and July 2004 that enabled a wide range of constituencies and experts to present their views and experiences regarding the privacy rule. Based on those hearings, the Subcommittee drafted and sent six letters to the Secretary on the effects of the privacy rule in specific domains. The first letter addressed the rule's effects on research and on public health data collection. Among other things, it urged that the rule be harmonized with the Protection of Human Subjects Rule. Subsequent letters addressed the privacy rule's impact on immunization information in schools and on law enforcement, seeking in these cases to ensure that the rule does not impede appropriate governmental functions. (Responding to one NCVHS recommendation, OCR added to its website a new FAQ about disclosures to law enforcement.) The Committee's letters on the privacy rule's impact on marketing, fundraising and banking address a somewhat different set of issues, concerning the balance-point between personal health information privacy and various commercial activities.

The Committee has an abiding interest in the impact of the privacy rule, both on specific activities such as those highlighted above and in general on the privacy of personal health information, the object of the rule. The Committee wrote the Secretary in

June 2004 recommending that the Department conduct research on these questions. It urged the Department, while implementation was at an early stage, to develop methodologies and collect baseline data that could be used to analyze the effects of the Privacy rule. Further, it recommended that the Department initiate such a program to measure the rule's effects. It proposed that the findings could be used to help refine rulemaking, implementation, and enforcement strategies for the privacy rule. To date, the Department has not informed the Committee that it has undertaken the research effort recommended by the Subcommittee. The Committee also wrote the Secretary in September 2004 to commend the outgoing HHS Privacy Advocate John Fanning, with whom the Subcommittee worked closely, and to stress the importance of keeping that position filled.

The privacy issues raised by new NHII/NHIN policies and practices and those associated with new e-prescribing policies began to surface in the middle of 2004. The latter were the focus of the Subcommittee's final 2004 hearing. As for the NHIN, Dr. Brailer sought the Committee's advice on privacy issues in this arena when he met with the NCVHS Executive Subcommittee on the 90th day of his tenure. At the heart of NHIN policy issues is the significant challenge of protecting privacy and confidentiality while also realizing the potential personal and population health benefits of electronic health records. The Subcommittee carried a focus on these issues into its work in 2005.

## Looking Ahead

The Department's Health IT Strategic Framework set in motion a number of ventures that shift from a planning to an action stage in 2005. The National Coordinator for HIT, Dr. David Brailer, calls this period a "flexion point." As demonstrated above, the National Committee helped to bring about the significant changes that are gathering momentum; it now welcomes the challenge of determining how best to marshal its expertise and resources to support the Department's HIT initiative while also pursuing the other critical priorities described above. In all of its activities, it will continue to pursue the mission of shaping a national information strategy for improving the population's health.

## Appendix 1. NCVHS Roster (September 2005) and 2003-2004 Retirees

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