The National Committee on Vital and Health Statistics

The Public Advisory Body to the Secretary of Health and Human Services

The Eleventh Report to Congress

On the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996

As required by the Health Insurance Portability and Accountability Act, Public Law 104-191, Section 263

Submitted to the
Senate Committee on Finance; Committee on Health, Education, Labor and Pensions;
House Committee on Ways and Means; Committee on Education And Labor; and Committee on Energy and Commerce

June, 2014

NCVHS
National Committee on Vital and Health Statistics

The Honorable John Boehner
Speaker of the House of Representatives
H-232 The Capitol
Washington, DC 20515

Dear Mr. Speaker:

I am pleased to transmit our Eleventh Report to Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA). In compliance with section 263, Subtitle F of Public Law 104-191, this report was developed by the National Committee on Vital and Health Statistics (NCVHS), the public advisory committee to the U.S. Department of Health and Human Services (DHHS) on health data, privacy, and health information policy, and covers the period January 2012 through December 2013.

The Administrative Simplification provisions of HIPAA require the Secretary of the Department of Health and Human Services (DHHS) to adopt a variety of standards to support electronic interchange for administrative and financial healthcare transactions, including standards for security and privacy to protect individually identifiable health information. This report summarizes for the Congress advances made in (1) electronic health information; (2) support of administrative processes in health care including standards to support health care reform; (3) the development of a roadmap for standards adoption and implementation; (4) convergence of clinical and administrative requirements; (5) aligning policies and programs to improve efficiency and effectiveness; and (7) measuring success as well as the vision for the future.

As a Federal advisory committee, NCVHS works in partnership with the private sector, other advisory bodies, and the DHHS. NCVHS also serves a unique role in providing a forum for stakeholders to contribute observations and recommendations to the policy-making process. It is this unique, collaborative and transparent process that has allowed for the advances to date and the acquisition of knowledge to provide a vision of the future.

We continue our strong commitment to pursuing improvements in health information that enhance the quality of health care, lower costs, foster advances in technology, improve population health, and facilitate access to care. We hope that you will find this eleventh report informative and useful. We look forward to continued progress on these important issues for the nation's health system. If your staff would like a briefing presentation on any of our past or anticipated activities, please let me know.

Sincerely,

Larry A. Green, M.D. Chairperson
National Committee on Vital and Health Statistics

The National Committee on Vital and Health Statistics (NCVHS) serves as the statutory [42 U.S.C. 242(k)] public advisory body to the Secretary of the Department of Health and Human Services in the area of health data and statistics. In that capacity, the Committee provides advice and assistance to the DHHS and serves as a forum for interaction with interested private sector groups on a variety of key health data issues. The Committee is composed of 18 individuals from the private sector who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Sixteen of the members are appointed by the Secretary of DHHS for terms of four years each, with about four new members being appointed each year. Two additional members are selected by Congress.

NCVHS Membership (See detailed NCVHS roster in Appendix C.)

Larry A. Green, M.D., Chair
Lynn A. Blewett, Ph.D.
John J. Burke, M.B.A, MSPharm.
Raj Chanderraj, M.D., F.A.C.C.
Bruce B. Cohen, Ph.D.
Llewellyn J. Cornelius, Ph.D.
Leslie Pickering Francis, J.D., Ph.D.
Alexandra (Alix) Goss
Linda L. Kloss, M.A., RHIA, FAHIMA
Vickie M. Mays, Ph.D., M.S.P.H.
Sallie Milam, J.D., CIPP, CIPP/G
Len Nichols, Ph.D.
W. Ob Soonthornsima
William W. Stead, M.D.
Walter G. Suarez, M.D., M.P.H.
James M. Walker, M.D., F.A.C.P.

James Scanlon, Executive Staff Director
Deputy Assistant Secretary, Office of Science and Data Policy
Office of the Assistant Secretary for Planning and Evaluation, DHHS

Debbie Jackson, Acting Executive Secretary
National Committee on Vital and Health Statistics
National Center for Health Statistics, CDC

Table of Contents

Executive Summary

Background

This is the Eleventh Report from the National Committee on Vital and Health Statistics (NCVHS) to the Congress describing the advances made in 2012 and 2013 in the adoption and implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The goal of Administrative Simplification is to improve efficiency and eliminate redundancy, costs and labor in all health care administrative processes by adopting and using national electronic standards for electronic exchange of administrative and financial information (such as claims) between providers and health plans, public programs, and others.

During 2012 and 2013, NCVHS heard recurrent themes from stakeholders related to the successful implementation of the next version of administrative transactions. These are:

- Defining the value and benefits of continuing to pursue standardization and reduce variation and inconsistencies in standards adoption;
- Identifying the challenges with unrealistic timelines to implement future standards and operating rules;
- Identifying the implications of further delays and post-implementation adoption issues;
- Understanding the problems if too many changes are occurring at the same time;
- Understanding the required adjustments to embrace and adopt the pending changes;
- Maintaining momentum in the midst of accelerated health care changes and increased complexity;
- Developing innovative and more effective methods of stakeholder collaboration, convergence, cooperation, communication and education, transparency and testing;
- Developing greater focus on adequate prioritization and timing; and
- Sequencing the adoption of these changes as stakeholders continue to consume significant resources in order to meet mandates and deadlines.

Much has been accomplished by the health care industry, the Centers for Medicare and Medicaid services (CMS) and NCVHS during the past two years. Much also remains to be done.

Administrative Simplification Advancements

Significant advances occurred in the adoption of administrative simplification transaction standards, code sets, identifiers and operating rules in 2012 and 2013.

Administrative Transactions and Operating Rules. Two significant advancements were achieved in this period related to transactions and operating rules:

- The version 5010, D.O. 3.0 of the transaction standards was implemented on January 1, 2012. The industry estimates that 80 percent of health care providers have successfully moved to version 5010.

- Operating rules for eligibility for a health plan and health care claims status were adopted on January 1, 2013. Industry has indicated that compliance with the first set of operating rules was strong among commercial health plans and some clearinghouses but, providers were facing challenges with technical and business resources, lack of coordination with multiple trading partners, lack of experience with implementation of operating rules and inconsistent use.

Industry recommendations included: the need to test the new operating rules; more frequent and systematic communications to industry executives and to the industry at large regarding upcoming requirements, transition periods, testing milestones and compliance dates; and considering a web-based voluntary registration process of entities' status towards compliance with the new rules. Operating rules for additional administrative transactions (healthcare claims or encounter, health plan enrollment/disenrollment, health plan premium payments, referral certification and authorization and, health care claims attachments), are under development by the Committee on Operating Rules for Information Exchange (CORE), designated by the Secretary as the authoring entity of operating rules for the remaining HIPAA transactions, as recommended by NCVHS.

ICD-10 Implementation. Throughout the period covered in this report, NCVHS heard two distinct messages regarding the adoption of ICD-10. The majority of industry stakeholders (hospitals, health information managers, large and medium size health care systems and provider organizations, health plans and clearinghouses) consistently called for continuing the momentum towards transition to ICD-10 by the established deadline of October 1, 2013. They reported that they had made significant investments in systems evaluation and remediation, process adjustments and resource education and training, and were in line to be ready to implement the new code sets by the October, 2013 deadline. At the same time, a key sector of the industry, represented by individual providers and medical group managers, consistently raised strong concerns regarding the challenge of achieving a transition to ICD-10 within the defined timeline, and the financial and operating impact that the new code sets would have in practices across the country. In response to these concerns, the Department of Health and Human Services (DHHS) announced in August of 2012 a one-year delay in the implementation of ICD-10 until October 1, 2014.

[Editor's Note: In April of 2014, Congress passed the Protecting Access to Medicare Act, which included a provision requiring the Secretary of HHS to not implement ICD-10 prior to October 1, 2015. In response to this, the Department announced in May of 2014 a one-year realignment of the implementation date for ICD-10 to October 1, 2015[1].]

[1] In April 2014, the Protecting Access to Medicare Act of 2014 was passed. Specifically, section 212 stipulates that "The Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD-10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d-2(c)) and section 162.1002 of title 45, Code of Federal Regulations."

Identifiers. A final rule (77 FR 54665) was published by the DHHS on September 5, 2012[2] requiring health plans to obtain health plan identifiers (HPIDs) by November 5, 2014. Small health plans are required to obtain HPIDs by November 5, 2015. All HIPAA covered entities (providers, health plans, and electronic clearinghouses) are required to use HPIDs in standard transactions by November 7, 2016. The primary purpose of the HPID and the "other entity" identifier (OEID) is to ensure the reliable identification of entities within the HIPAA standard transactions.

Privacy and Security Advancements

NCVHS recognizes the DHHS' many privacy and security accomplishments, noting in particular the publication of the "Omnibus" final health information privacy and security rule in 2013, the considerable and effective outreach efforts both to covered entities and consumers, and the stepped-up enforcement that inspires improved confidence in compliance.

Use of individually identifiable health information is expanding in ways that were not contemplated at the time HIPAA was created in 1996 and the initial set of HIPAA privacy and security regulations was adopted that became effective in 2003. There is a very large portion of health information that is not covered by HIPAA and may not be covered by any privacy law at all. New technologies such as data downloaded by consumers, or data stored in the "cloud" add to the complex array of privacy and security issues surrounding health information.

The "Omnibus" Final Rule. The "Omnibus" final rule (78 FR 5566) published by the DHHS on January 25, 2013[3] modified the Privacy, Security, Enforcement and Breach notification rules under the HITECH Act and implemented changes to the Privacy Rule arising from the Genetic Information Nondiscrimination Act (GINA). The Omnibus rule also expanded many of the HIPAA Privacy and Security rules to business associates; increased penalties for noncompliance to $1.5 million per violation; expanded individual rights allowing patients to obtain a copy of their electronic medical record; and clarified that genetic information is protected under the HIPAA Privacy Rule, prohibiting the use or disclosure of genetic information for underwriting purposes.

Outreach to Regulated entities and Consumers[4]. The DHHS has expanded guidance about methods and approaches to achieve de-identification. In collaboration with the Office of the National Coordinator, a model "Notices of Privacy Practices" was developed for health care providers and health plans to use to communicate with their patients and plan members, In addition, the DHHS Office of the Assistant Secretary for Preparedness and Response, developed a guide to assist law enforcement in obtaining HIPAA Privacy Rule protected information. In its outreach activities, the DHHS uses videos, pamphlets, partners with existing public health

[2] HIPAA Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier, addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD-10-CM and ICD_10-PCS Medical Data Code Sets final rule (77 FR 54665), September 5, 2012.

[3] Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rule (78 FR 5566), January 25, 2013

[4] Healthcare.gov portal and federal and State insurance marketplaces are not covered by HIPAA.

outreach campaign of the Centers for Disease Control and Prevention, as well as new education initiative and online tools.

Enforcement. In 2012, 9,411 investigations were completed, of which 3,361 resulted in a corrective action plan, 5,071 were resolved after review and 979 had no violation. In 2013, OCR resolved 14,300 cases of which 3,740 resulted in corrective action, 993 resulted in a finding of no violation and the rest were resolved after intake and review due to lack of jurisdiction. The most frequent compliance issues included: impermissible uses and disclosures of protected health information, lack of safeguards of protected health information, and lack of patient access to protected health information.

Standards and Public Health/Population Health

While not an explicit component of HIPAA, public health agencies and health care organizations have leveraged the same standards used in administrative transactions to collect and exchange health information for various purposes. Information exchange standards also have been developed for specific public health data collection needs, including vital records (i.e. births, deaths), immunizations, laboratory reporting, syndromic surveillance, communicable disease reporting, specialized public health registries (such as cancer registries) and others. Over the past two years, NCVHS has been working to advance the capabilities of communities, public health agencies, and health care organizations to adopt and use standards for the collection and exchange of health information.

Community Health Data Initiatives. In 2012, NCVHS released a report on "The Community as a Learning System: Using Local Data to Improve Local Health,"[5] which examined how communities can become learning systems and what resources may assist them in this endeavor. The report presented a vision for strengthening local data capabilities and uses with specific suggestions towards better local health, and specific areas where the federal government can take an active role to support the development and functioning of community-oriented learning systems for health. It concluded with steps that DHHS and others can take to support the development and functioning of community-oriented learning systems.
NCVHS's major focus is to advance the development of a Community Data Framework to help communities capture, organize and leverage data from multiple sources, to understand how to use and repurpose data, and optimize data utility and usability. NCVHS also focused on defining a system to assess community readiness to collect, interpret, protect and use data and other tools to improve local health and well-being. NCVHS also seeks to identify and recommend various sources, forms and approaches for delivering technical data assistance and support to communities, including roles and opportunities for the federal government.

Public Health Data Standards. In 2012 and 2013, NCVHS continued to advance the convergence of electronic standards within and across the health care industry. Just in the last four years, there has been a significant increase in the attention, interest, and work towards development and adoption of public health informatics standards in the U.S., with the implementation of the

[5] Available at http://www.ncvhs.hhs.gov

electronic health record (EHR) Meaningful Use Incentives Program, the beginning of care delivery and payment reform under the Affordable Care Act, and new HIPAA Administrative Simplification regulations.

In 2013, NCVHS held a hearing on the current state of public health information systems and standards. Testifiers noted that public health, as an integral component of health and health care, benefits significantly from the adoption and use of informatics standards. Key themes included the need:

- To advance and improve the public health informatics infrastructure and standards development at the Federal, State and local levels;
- To, increase support, focus and engagement on public health informatics standards development, implementation and adoption at the Federal, state and local levels; and
- For resources to support public health programs' engagement in standards development activities and promote adoption of them.

NCVHS strongly believes that the nation's public health system is at a critical juncture and that there is an unprecedented opportunity to invest in advancing the country's public health information infrastructure to ensure it is capable of interacting effectively and efficiently with the rapidly evolving electronic health record systems and health information exchanges of the future. Thus, NCVHS believes there is a need to:

- Pursue the development and implementation of a new public health informatics standards strategic initiative to advance and bring to par public health information systems with electronic health record systems;
- Establish a Public Health Information Infrastructure Trust Fund that will serve as a dedicated funding source to enhance the information infrastructure needed to support all public health functions,
- Establish a National Public Health Informatics Standards Collaboration initiative, in partnership with the public health community, to accelerate the adoption and implementation of standards in public health programs;
- Leverage policy programs and initiatives, including the Affordable Care Act and the EHR Meaningful Use program, to align incentives for public health reporting, stimulate electronic information systems vendor engagement in adopting and using public health data standards, and ensure public health data requirements are incorporated into clinical systems; and
- Develop a new national strategy for public health informatics capacity building, to increase the number of skilled workers in the public health workforce.

A Vision for the Future

Health care today and in the future holds promises that exceed anything envisioned when the administrative simplification provisions of HIPAA were initially implemented in early 2000, and it is this promise that will define the role of NCVHS as the statutory advisory body to the

Secretary on health information policy. There is truly a new paradigm in health care particularly in health information with the expansion of health care coverage through the Affordable Care Act, the adoption of electronic health record systems across the country under the Health Information Technology for Economic and Clinical Health Act (HITECH), the continued adoption of administrative simplification standards, and the alignment and convergence of all these efforts under a cohesive, standards-based, interoperable information infrastructure.

NCVHS believes that as a Federal Advisory Committee Act (FACA) committee it needs to set a vision for itself in creating recommendations that embraces collaboration, partnership, prioritization, consumer needs, flexibility, adaptability, data usefulness and value to create useful and effective recommendations. NCVHS will continue to convene industry hearings, roundtables and workshops to obtain information from subject matter experts and stakeholders.

NCVHS has identified emerging themes heard from within the health care industry for this vision which include the need for: enhanced patient and consumer focus, sound policy and regulatory harmonization, flexibility and agility to embrace change with urgency, effective evolution and perspectives on short versus long term change,; disparity across the industry of means to execute/adopt, and useful data and its effective stewardship. In response to industry requests, NCVHS is working to identify a vision for eHealth, particularly as it relates to administrative processes and defined key milestones through 2020, and to develop a roadmap that will provide guidance to the industry on what lies ahead.

The transformative changes introduced by the Affordable Care Act related to care delivery reform and payment reform offer an unprecedented opportunity to evaluate what the next generation of health information transactions will look like and, how these will need to support the new forms of service coverage, delivery and payment. The traditional processes of enrollment, eligibility, prior authorization, referrals, coordination of benefits, and claim submission and payment, and the data and transactions used to support them, are being challenged by these rapid changes. Quality measurement, reporting and population-based health improvements will play a critical role in defining the new data sets and transactions needed to achieve the triple aim of health reform: better health, better care and lower cost.

Consequently, NCVHS' direction will be to identify and recommend the next generation of administrative simplification standards and operating rules that support health transformation and are aligned with the health IT standards and electronic health record systems used in clinical care. Those standards must simultaneously be used both administratively and clinically to achieve the goals of better health, better care and lower costs.

Data Stewardship. Information has historically been gathered through various sources including inpatient and outpatient data; Federal and State public health surveillance activities; and individual and population surveys. However, the obtained information was limited to the needs of a particular area of concern, resulting in replication and duplication of data and an inability to validate or replicate results. Protection of personal information was not often a priority. Health care information and data have the potential to improve the quality and affordability of

health care, reduce medical and medication errors, improve health, increase prevention, increase early diagnosis, and, improve outcomes across the health care continuum. NCVHS acknowledges its leadership role in this endeavor.

As information technology continues to evolve, NCVHS must ensure that data are easily captured, generated, and used for multiple purposes, while maximizing privacy and security protections and minimizing burden. NCVHS believes that health information policies and standards should: support improved access to affordable efficient and cost effective health care, enhance health care delivery, support evidence-based health care, improve patient safety, mitigate health disparities, support clinical research, and include the consumer as an active participant in their health care. Cognizant of privacy concerns, NCVHS will focus on preservation of privacy while supporting access to health data across the continuum of care.

Convergence of Clinical and Administrative Standards. NCVHS sees convergence between clinical and administrative standards as a critical step into the future that will support and improve individual and population health, while improving efficiency and cost savings in the transmission of information. One challenge that NCVHS acknowledges is facing the health care industry is facing in the convergence of clinical and administrative data is the development of standards that are meaningful, useful, seamless, transparent and cost effective, while ensuring the privacy and security of individually identifiable health information. It is this convergence that will support and incentivize: development of evidence based medicine; clinical indicators that measure quality and effectiveness of interventions; research in new technology, diagnostic tools and interventions to promote health; payment structures that reward effective quality care rather than quantity of care; seamless transitions through the health care system; and processes that utilize resources effectively and efficiently. Through partnerships with stakeholders and the government, NCVHS can assure consumer safety while facilitating an expeditious process for changing and adding standards.

NCVHS has begun a paradigm shift by integrating its work on population health, security, privacy, standards and quality. Future NCVHS activities will assess the health care industry's readiness to better meet communities' needs for meaningful support, harmonize standardized health indicators, merge social media data with traditional data, model the integration of population health and clinical data, and, evaluate "repurposing" and expanded use of data such as surveys, surveillance, clinical and electronic health records.

Roadmap for eHealth Standards Adoption and Implementation. NCVHS envisions eHealth as (1) the means to improve quality of care and health outcomes by providing the mechanism for sharing accurate data and by utilizing dynamic health care standards that have been statistically validated, tested and maintained as health care interventions continue to evolve and (2) an opportunity to be the framework for payment by addressing and integrating the full spectrum of patient-centric health care delivery coupled with measurable outcomes.

The health care industry has expressed to NCVHS the need to develop a strategic plan and a road map for adopting and implementing standards and operating rules in a coordinated, sequential, timely, efficient, and cost-effective manner. NCVHS has heard from the industry

representatives that it is experiencing "implementation fatigue" with uncoordinated, misaligned competing priorities. Consequently NCVHS will evaluate and prioritize the opportunities presented by each statutorily required initiative for its potential to effect changes that result in cost and process benefits.

NCVHS recognizes that development of standards is a dynamic and evolving process that requires input from an open, transparent, and consensus-based effort. NCVHS plans to review and monitor the implications that new electronic information exchanges needed to support the Health Insurance Exchanges will have on current and future standards, specifically as they pertain to enrollment, premium payment, eligibility, quality reporting, payment and payment reform.

Measuring Success. NCVHS believes that success will be achieved if the recommended standards and initiatives result in convergence; improved health care outcomes and lower costs through collection of data; creation of national databases; data integration; improved public health data collection; privacy and security of individually identifiable health information; improved patient care; improved patient/consumer experience; development of effective quality measurements; and, ability to adapt to changing technology.

Conclusion

Health care in the United States is undergoing major transformative changes that are re-shaping the nature and exchange of data and information used for personal, clinical, community, business, and scientific purposes is being contemplated. These changes will revise the way consumers, patients, providers, health plans, employers, government, researchers, and others interact. Transformation of how health care is organized, delivered, and paid for, is also creating an unprecedented opportunity to redefine the way health information is captured, exchanged, and used to improve access, value, quality, safety, equity, efficiency and the public's health and wellness. In this context, NCVHS highlights in this report the many achievements accomplished during the past two years and the gaps and challenges ahead.

Health care of the future holds promises that exceed anything envisioned when HIPAA was implemented and it is those unknowns that will affect the role of NCVHS as the statutory advisory body on health information policy to the Department. NCVHS will continue to provide the venue for industry stakeholders to come together and discuss issues and recommend solutions. It is this collaborative environment that will shepherd the health care industry through the unchartered territory that is to come.

1. Introduction

This report describes the advancements made during 2012 and 2013 in the adoption and implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Administrative Simplification provisions (title II, subtitle F of Pub.L. No. 104-19, adding a new title XI, part C, to the Social Security Act (42 U.S.C. 1320d et seq.)), require the Secretary of Health and Human Services (DHHS) to adopt standards for the electronic transmission of administrative and financial healthcare transactions, including data elements and code sets for those transactions, and for unique identifiers for health care providers, health plans, employers, and individuals. The law also requires adoption of standards to protect privacy of individually identifiable health information.

Congress gave NCVHS the role of advising the Secretary of HHS on the adoption of standards, monitoring their implementation, and reporting annually on progress (see Appendix A). This report is the eleventh of the annual reports and covers the period of October, 2011 through December, 2013. Previous NCVHS reports to Congress on Administrative Simplification may be found at the Committee's web site at: http://www.ncvhs.hhs.gov.

This Eleventh Report to Congress on the Administrative Simplification provisions of HIPAA summarizes for the Congress and the public:

- The advancements in Administrative Simplification made in 2012 and 2013 with regard to adoption of standards, operating rules, code sets, identifiers and enforcement (see Appendix B for an itemized list of standard Transactions and Code Sets);
- Advancements in HIPAA Privacy and Security policies and standards;
- Development of community health data initiatives and the current and future state of public health informatics standards; and
- The vision for the future to support administrative processes in health care including standards to support health care reform; development of a roadmap for standards adoption and implementation; convergence of clinical and administrative requirements; alignment of policies and programs to improve efficiency and effectiveness; and measures for success.

NCVHS also considered the changes in electronic transmissions needed to shape the vision for the future. NCVHS' unique role of creating a public forum for stakeholders, as well as being a standing Federal Advisory Committee working in partnership with the private sector, other advisory bodies, and the DHHS, provides a wealth of knowledge and experience to create the transparent and collaborative environment necessary to shepherd electronic health information into the future.

2. Administrative Simplification Advancements in 2012 and 2013

The Administrative Simplification provisions of HIPAA signed into law in 1996 require the Secretary of the DHHS to adopt a variety of standards to support electronic interchange for administrative and financial healthcare transactions. Enactment of the American Recovery and Reinvestment Act, (ARRA, Public Law 111-5) and in particular Title XIII, the Health Information Technology for Electronic and Clinical Health (HITECH) Act and the Patient Protection and Affordable Care Act (P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152), together referred to as the Affordable Care Act, expanded NCVHS' responsibilities for advising the Secretary on the adoption and implementation of standards in:

- Health care financial and administrative transactions and code sets;
- Unique health identifiers for employers, providers, health plans and individuals;
- Health information privacy and security standards; and
- Medical record information data standards.

In its advisory role to the DHHS and to the Congress, NCVHS continues to serve as the Department's primary liaison with the private sector to obtain the views, perspectives, and concerns of interested and affected parties, as well as their input on issues of health information, health data and health statistics. NCVHS uses this information to construct recommendations to the Secretary and to frame the direction needed for future standards under Administrative Simplification. The NCVHS Subcommittee on Standards has recommended many administrative, financial, billing transactions, clinical use, e-prescribing and clinical documentation standards. NCVHS held eight hearings during late 2011 through 2013. The table below provides a breakdown of the topics and dates of those hearings.

NCVHS Stakeholder Hearings – 2011-2013

Health Care Claims Attachments	November 17, 2011
Status of the Development, Maintenance and Update for Standards and Operating Rules	November 18, 2011
Administrative Transaction Standards, Code Sets and Operating Rules, Industry Status of Planning, Transitioning and Implementation	June 20, 2012
Future of Provider-Payer Information Exchanges in Support of Health Care Transformation	November 15, 2012
Electronic Health Care Claims Attachments Standards and Operating Rules	February 27, 2013
Status of Planning and Implementation of Standards Identified in HIPAA and in the Affordable Care Act	June 17 & 18, 2013
eHealth Vision and Standards Roadmap Roundtable	September 18, 2013
Public Health Data Standards	November 12, 2013

As a result of the public hearings and subsequent full committee and subcommittee deliberations, during 2012 and 2013, NCVHS authored ten letters to the Secretary concerning HIPAA-related matters. The table below summarizes those letters.

NCVHS Letters to the Secretary – 2012-2013

Administrative Simplification Provisions Addressed in Section 10109 of the Affordable Care Act of 2010 (ACA)	March 2, 2012
Additional Analysis of the Update and Maintenance Process for Standards and Operating Rules	March 2, 2012
Health Care Claim Attachments	March 2, 2012
Recommendations to Designate an Authoring Entity and Ensure Industry Collaboration for the Development of Operating Rules for Health Care Administrative Transactions	May 5, 2012
Development of Standards for the Collection of Socioeconomic Status in Health Surveys Conducted by the Department of Health and Human Services	June 22, 2012
Findings from NCVHS Hearings on Administrative Simplification in June 12 – an Update on Health Care Administrative Transactions	September 21, 2012
A Stewardship Framework for the Use of Community Health Data	December 5, 2012
Enhancements to National Council for Prescription Drug Programs (NCPDP) Standard for Pharmacy Claims	June 21, 2013
Attachment Standards for Health Care Claims	June 21, 2013
Findings from the June 2013 NCVHS Hearing on Current State of Administrative Simplification Standards, Code Sets and Operating Rules	September 20, 2013

2.1 Administrative Transactions

In a letter to the Secretary on September 21, 2012, NCVHS provided a summary of its hearings on lessons learned after the first six months of implementation of upgrades to the HIPAA transactions version 5010, D.O. and 3.0; industry readiness for implementing the first set of operating rules; and, concerns about end-to-end testing and certification processes. The letter also provided an update from the Designated Standards Maintenance Organization (DSMO), issues about a new voting infrastructure in the dental code content, and an overview of work with unique device identifiers. Consistent themes heard across these topics included momentum towards success in the midst of accelerated changes and complexity clearly requiring innovative and effective ways of stakeholder collaboration, convergence, cooperation, communication, transparency and testing. The industry has opined that it seeks greater focus on prioritization and timing of adoption of these changes as it continues to spend significant resources to meet a stream of mandates. [6]

2.1.1 Implementation of 5010, D.O. 3.0

Version 5010 of the transaction standards was implemented on January 1, 2012. While version 5010 has been adopted by most health care entities, some providers continue to rely on their clearinghouses to transition their claims from the ASC X12 version 4010/4010A1 (heretofore referred to as version 4010) to the ASC X12 version 5010 D.O. and 3.0 (heretofore referred to as version 5010), while others continue to submit paper-based claims. At the current time, reliance on clearinghouses and payers to process and pay claims has not resulted in any major disruptions. However, with the pending implementation of ICD-10-CM on October 1, 2014, health care entities that have not yet made the required transition to version 5010 will find themselves at risk of not having their claims processed with negative effects on their cash flow.

[6] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services, from the National Committee on Vital and Health Statistics (NCVHS).

In the *NCVHS Tenth HIPAA Report to Cong*ress, NCVHS noted the importance of the implementation of the version 5010 of the X12 HIPAA transaction standards. Included was a concern that according to health care consultant Gartner, small to medium providers (defined as hospitals with less than 400 beds or physician practices with less than 50 physicians) were not actively prepared for version 5010. The Medical Group Management Association (MGMA) on June 15, 2011 released results of a survey confirming Gartner's findings. The MGMA, which supports healthcare administration management and medical practice managers, found that only 9.2 percent of physician practices had done internal testing of version 5010 and 40 percent had yet to schedule such an evaluation.[7]

In its September 21, 2012 letter to the Secretary, NCVHS reported that the industry was still adjusting and working towards achieving full compliance with version 5010. Testifiers at the NCVHS hearings in June 2012 reported issues related to delayed availability of vendor software prior to the version compliance date, delayed testing or incomplete end-to-end testing prior to the compliance date, inconsistent testing, and, publication of Errata by the Accredited Standards Committee (ASC) X12 which impacted timely implementation. However, it was reported that the approach allowing use of both the concurrent and the new versions of the transaction standards during a one-year transition period prior to the compliance date was very valuable. A key message from testifiers was for CMS and NCVHS to consider looking at the entire process for adopting and implementing standards and operating rules, and to define a new roadmap that takes into account sequencing, timing and the impacts of other competing mandates adoption of standards[8].

In a letter to the Secretary during 2013, NCVHS noted and recommended that DHHS work with the DSMO to inform the industry that the current version 5010 is not expected to change until 2017 or later. Since the transition to version 5010 on January 2012, there have been no reports of issues with technical specifications and use of the standards. Industry estimates show that approximately 80 percent of the providers have successfully moved to version 5010. The 20 percent that continue to use version 4010 are mainly small providers who achieve compliance by using clearinghouse services that provide cross-walking from version 4010 to version 5010. However, version 4010 does not support the implementation of ICD-10 code sets, and clearinghouse services cannot cross-walk between ICD-9 and ICD-10 because clearinghouses do not change code assignments or payment determinations of claims. NCVHS recommended that the DHHS should work with the industry to identify current version 4010 users and develop a targeted outreach campaign to explain the implications of not transitioning to version 5010.[9]

2.1.2 Adoption of Standards for Electronic Fund Transfer

[7] NCVHS Tenth HIPAA Report to Congress on the Administrative Simplifications Provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, December 2011, pp 23 & 24.

[8] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

[9] September 20, 2013 letter to Kathleen Sebelius, Secretary, Department of Health and Human Service from the National Committee on Vital and health Statistics (NCVHS).

Section 1104(b)(2)(A) of the Affordable Care Act amended section 1173(a)(2) of the Social Security Act (Act) by adding the electronic fund transfer (EFT) transaction to the list of electronic health care transactions requiring the Secretary to adopt a standard under HIPAA. An EFT is a financial transmission containing payment information. Traditionally, health care payments have been made in the form of paper checks. With an EFT, payment is transmitted through the Automated Clearing House (ACH) Network. The benefits of the EFT have been seen in other industries and include material cost savings, fraud control, and improved cash flow and cash forecasting. The benefits of electronic remittance advice (ERA) and adopted HIPAA transactions have been demonstrated in cost savings in paper and mailings and improvement in payment recovery and reconciliation.[10]

On February 17, 2011 following the December 2010 NCVHS Subcommittee on Standards hearing, NCVHS sent a letter to the Secretary recommending:

- Adoption of a national health care EFT standard (which included the definition of a health care EFT transaction, definition of the standard itself, and adoption of the NACHA CCD+ format for the health care EFT standard;
- Identifying the National Automated Clearinghouse association (NACHA) as the standards development organization responsible for maintaining the health care EFT standard; and
- Adoption of the EFT implementation specifications to align with the content requirements defined in the X12 835 TR3 Report, in particular the CCD+.[11]

Significant support for the adoption of the EFT standards (and related operating rules) was consistently expressed by industry stakeholders during hearings leading to this recommendation. In the January 10, 2012 Interim Final Rule (77 FR 1556), the DHHS adopted the recommended EFT standards with HIPAA covered entities required to be in compliance with the standards by January 1, 2014.[12]

2.1.3 Other Transaction Standards

Transaction standards adopted under HIPAA enable electronic data interchange using a common structure, to minimize reliance on multiple formats, decrease administrative burden on covered entities by creating uniformity in data exchange, and reduce the number of paper forms. Consequently, NCVHS has recommended the adoption of additional transaction standards discussed below.

2.1.3.1 Health Care Claim Attachment

[10] Administrative Simplification: Adoption of Operating Rules for Health care Electronic Funds Transfers (EFT) and Remittance Advice Transactions: Final rule (77 FR 48008), August 10, 2012.

[11] February 17, 2011 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

[12] Administrative Simplification: Adoption of Operating Rules for Health care Electronic Funds Transfers (EFT) and Remittance Advice Transactions: Interim Final rule (77 FR 1556), January 10, 2012.

Section 1173(a)(2)(B) of HIPAA identified health care claim attachments as one of the transactions for which electronic standards were to be adopted. Section 1104 of the Affordable Care Act directed the Secretary to publish final regulations adopting national standards, implementation specifications and operating rules for health care claim attachments by January 1, 2014, and a compliance date of no later than January 1, 2016. A proposed rule to adopt health care claim attachments was published in the Federal Register in 2005; however, a final rule was not adopted at that time due in part to questions about the maturity of the standards.

The term "health care claim attachment" refers to any supplemental documentation needed to support a specific clinical or health care encounter. It can include documentation to support health care claims, referral authorizations, enrollee eligibility inquiries, coordination of benefits, workers' compensation, post-payment claim audits, and provider dispute resolution. Currently, many health care claim attachments are exchanged between providers and health plans with the majority of exchanges done in a solicited manner (that is, the supplemental information is requested). Historically, most exchanges have been conducted via paper mail, fax, and phone. Consequently, few exchanges are done electronically through a health plan's secure portal or via electronic transactions because not all information required is available electronically today.

On November 17, 2011, NCVHS Subcommittee on Standards held a hearing on health care claim attachments to gather information regarding current industry practices, priorities, issues and challenges, and current status, approaches and timeline for completion of the development of the standard. The industry expressed strong support for the identification and adoption of usable standards for health care claims attachments. Because technical information and technology capabilities vary across the country, simple techniques can be used initially, and in time, move towards the electronic-based health care claim attachments. At that time, there was also provider interest in reducing the requested number and types of health care claim attachments. Subsequent to the meeting, NCVHS submitted a letter to the Secretary on March 2, 2012 indicating that it was too early to make formal recommendations to the Secretary regarding the adoption of any standard, implementation specifications or operating rules for health care claim attachments.[13]

On May 5, 2012, NCVHS recommended to the Secretary that the Committee on Operating Rules for Information Exchange (CORE) be designated as the authoring entity to develop operating rules for the health care claim attachment transaction.[14] This recommendation was accepted by the Secretary.

On February 27, 2013, a second NCVHS hearing on health care claim attachment standards was held to determine the status of the development of standards, implementation specifications and operating rules, and the degree of their readiness for adoption and use. There was consensus among the testifiers that the main goals for establishing a standard for electronic

[13] March 2, 2012 Claim Attachments letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS), pp5.

[14] May 5, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS.)

health care claim attachments should be (1) administrative simplification and (2) the seamless electronic exchange of clinical and other medical and administrative information between providers and payers to support payment and health care operation functions.

One of the common themes at the February 27, 2013 hearing was the emerging convergence of administrative and clinical information which is central to the consideration of standards for health care claim attachments. Health care claim attachments were seen as one of the first major opportunities to bridge clinical and administrative health care data and information exchange through standards. Testifiers believed (1) standards should not be limited to health care claim attachments but should be inclusive of any attachment with clinical or administrative information; (2) current privacy and security regulations should be met including identifying specific purpose and requesting only the minimum amount of information needed to achieve the purpose of the request; (3) strict, inflexible prescriptiveness should be avoided in an evolving area; (4) duplicating data and data requirements should be avoided; and (5) there should be active outreach to all stakeholders[15].

In the June 21, 2013 letter to the Secretary NCVHS provided the following recommendations[16]:

(1) Conduct a review of the adoption of standards for clinical and administrative processes considering other programs currently underway (for example, Meaningful Use, Administrative Simplification, Health Reform, Medicare and Medicaid Program Integrity) and develop a roadmap to phase in standards;

(2) Use an incremental, flexible approach to the adoption of standards, implementation specifications and operating rules, and a transition period for industry adoption;

(3) Align rules between the Office of the National Coordinator (ONC) for Health IT and CMS;

(4) Define attachment as a "supplemental documentation needed about a patient(s) to support a specific health care-related event using a standardized format;

(5) Apply attachment-related transaction standards to claims, eligibility, prior authorization, referrals, care management, post-payment audits, and other administrative processes that require supplemental information;

(6) Define attachment standards for query transactions (electronic solicitation of an attachment), response (electronic submission of an attachment) and acknowledgment (electronic confirmation of the receipt of the query and submission of an attachment transaction);

(7) Adopt specified attachment-related transactions;

[15] June 21, 2013 letter on Attachment Standards for Health Care, to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).
[16] ibid

(8) Adopt standards that are agnostic of the selected transport by trading partners to exchange health care claim attachments;

(9) Adopt standards that support submission of structured and unstructured data, however, every effort should be made to maximize the use of structured data;

(10) Support solicited and unsolicited attachment situations through the attachment process;

(11) Emphasize in regulations that applicability of minimum necessary privacy requirements and that covered entities are not permitted to disclose protected health information without a valid permitted purpose for such disclosure should be;

(12) Provide that data must not be requested more than once in an attachment unless it is identifying information;

(13) Permit chained attachment requests should only be permitted in limited circumstances only;

(14) Support the industry's development of operating rules for attachment transactions that address infrastructure and technical needs across industry sectors minimizing the use of companion guides;

(15) Implement a testing program;

(16) Provide collaborative education and outreach;

(17) Consider publishing an expedited Notice of Proposed Rule Making (NPRM) rather than a Final Rule on health care claim attachments; and,

(18) Consider needs of the pharmacy industry in regulations.

At this point, standard operating rules for the health care claim attachments are under development by the operating rule authoring entity.

2.1.3.2 National Council for Prescription Drug Programs (NCPDP) Standard for Pharmacy Claims

On November 18, 2012, the NCVHS Subcommittee on Standards held a hearing to address Administrative Simplification provisions in section 10109 of the Affordable Care Act, the section considering a standard for pharmacy claims. At that meeting the NCPDP reported that pharmacy edits were being used consistently since the implementation guide, data dictionary and code values were created with industry consensus. The NCPDP indicated that requirements for the use of the Reject Codes were specific to fields within the NCPDP Telecommunication Standard and the NCPDP's process allows new Reject Codes to be added, modified or discontinued on a quarterly basis using industry consensus. Once these requests are approved they are published in the next release of the External Code List and are available

for use according to a formal implementation timeline. The pharmacy industry did not have additional recommendations for change.

In a September 2012 report from the DHHS Office of the Inspector General (report # OEI-02-09-00605), concern was raised that there was no way to validate if an inappropriate amount of medication in excess of the quantity prescribed was being dispensed. NCVHS issued a letter to the Secretary on June 21, 2013 that it approved the NCPDP's recommendation to specify the conditional use of the field "Quantity Prescribed" (field # 460-ET), which is currently not in use in the pharmacy claim transaction, to communicate the actual quantity prescribed by the provider, and to republish the Telecommunication Standard Implementation Guide Version D.O. Both NCPDP and NCVHS believe that this use of field # 460-ET would address the Inspector General's concern by providing data to validate whether an inappropriate amount of medication in excess of the prescribed quantity has occurred[17].

2.2 Operating Rules

Through the Affordable Care Act, Congress sought to promote implementation of electronic transactions and achieve cost reduction and efficiency improvements by creating more uniformity through the implementation of standard transactions. This was accomplished by mandating the adoption of a set of operating rules for each of the HIPAA transactions.[18]

Section 1173(g)(1) of the Act, as added by section 1104(b)(2)(C) of the Affordable Care Act, requires the adoption of a "… single set of operating rules for each transaction… to create as much uniformity in the implementation of the electronic standards as possible."[19] The Phase I Measures of Success Report issued by the Council for Affordable Quality Health's Committee on Operating Rules for Information Exchange (CAQH CORE) noted evidence that the use of operating rules for specific health care transactions results in higher use of electronic data interchange (EDI). [20] One area of administrative burden that can be lessened is the time and effort spent on payment collection activities. By automating some of these tasks through the use of EFT and electronic remittance advice (ERA), time and labor can be decreased.

NCVHS is tasked with reviewing any developed operating rules to determine whether the operating rules represent a consensus view of stakeholders and are consistent with other existing standards and with electronic standards adopted for health information technology. Based on this review, NCVHS makes recommendations to the Secretary as to whether the Secretary should adopt such operating rules. Consequently, NCVHS continued to hold hearings to solicit input from stakeholders.

[17] June 21, 2013 letter on enhancements to NCPDP Standard for Pharmacy Claims to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).
[18] Administrative Simplification: Adoption of Operating Rules for Health Care Electronic Funds Transfer and Remittance Advice Transactions: Interim Final Rule (77 FR 48008 - 48012), August 10, 2012.
[19] Ibid, pp. 48011
[20] CAQH CORE Phase 1 Measures of Success Final Report, July 7, 2009." PowerPoint presentation: and "CORE Certification and Testing: a Step-by-Step Overview," February 17, 2011, CAQH and Edifecs Webinar.

On November 18, 2011, the NCVHS Subcommittee on Standards held a hearing to review the status of the development, maintenance and update process for health care administrative transactions standards and operating rules. One of the most important findings and consistently reported observations was the significant increase in the complexity of the development and maintenance process for standards and operating rules. Because this is a rapidly changing area that would benefit from clear and expedited change to take advantage of new developments, NCVHS submitted a letter to the Secretary on March 2, 2012, with the following recommendations for ways to streamline the promulgation and update of standards and operating rules:

(1) Convene a workgroup to fully evaluate the strengths and weaknesses of the Designated Standards Maintenance Organization (DSMO) process;

(2) Create an expedited modification and adoption process for emergency changes to standards and operating rules being established; and

(3) Require mandatory testing before a new version or edition of a standard or operating rule is brought to NCVHS for review and recommendation[21].

In the May 5, 2012 letter to the Secretary, NCVHS recommended designating CORE as the authoring entity of operating rules for the remaining HIPAA transactions. In support of the NCVHS's call for greater collaboration, coordination and active participation across the industry, the letter also included the recommendation to the Secretary to ask CORE to broaden its outreach to industry to be more inclusive of Standards Development Organizations (SDOs) and Data Content Committees (DCCs) to actively participate in the CORE process and that the Workgroup for Electronic Data Interchange (WED) workgroups identify and develop operating rules for each remaining HIPAA transaction.[22] On September 12, 2012, the Secretary concurred with the NCVHS recommendation to name CAQH CORE as the operating rules authoring entity for the remaining HIPAA electronic health care transactions and the additional recommendation that CORE develop and deliver the operating rules through active collaboration and coordination with subject matter experts through a transparent process.[23]

At the NCVHS Subcommittee on Standards hearing held on June 17 & 18, 2013, stakeholders provided testimony on the operating rules. The industry discussed the difficulties with the statutory exclusion of non-covered entities (that is, vendors of practice management systems) that are not required to include or comply with the operating rules and standards, and encouraged NCVHS to recommend application of the same standards of compliance to all entities that exchange HIPAA based transactions. Clearinghouse industry representatives stated their members found the maintenance process for operating rules to be restrictive and

[21] March 2, 2012 letter on Additional Analysis of the Update and Maintenance Process for Standards and Operating Rules to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

[22] May 5, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

[23] September 12, 2012 letter from Kathleen Sebelius, Secretary, Department of Health and Human Services to the National Committee on Vital and health Statistics (NCVHS).

slow and recommended that a process be put in place for faster implementation of changes and updates of operating rules and claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) code sets.

NCVHS, in its September 20, 2013 letter to the Secretary, recommended that the DHHS work with NCVHS, CAQH CORE, and industry stakeholders to make a comprehensive assessment of the level of adoption and use of operating rules, evaluate the aggregate value and benefits of adopting operating rules to optimize business processes that apply to multiple transactions rather than on a transaction by transaction basis, and the current relationship and future opportunities for operating rules to support health reform[24].

2.2.1 Implementation of Operating Rules for Eligibility For a Health Plan and Health Care Claim Status

The first set of operating rules for the eligibility for a health plan and health care claims status standard transactions were adopted in an interim final rule (77 FR 40458) published in the Federal Register on July 8, 2011 and were effective on January 1, 2013[25].

In its September 21, 2012 letter to the Secretary, NCVHS reported that some HIPAA covered entities were well into their preparation plans for eligibility for a health plan and health care claim status operating rules compliance, but many were only in the assessment phase. The NCVHS testifiers expressed their concerns which included practice management systems experiencing challenges meeting connectivity and performance rules, providers not yet transitioned to version 5010 preventing them from using new operating rules, system and implementation issues, and lack of engagement with senior management. NCVHS recommended that focus in the subsequent six months should be on sending strong messages of the need to test the new operating rules; consideration of a high-level communication from the DHHS to industry CEOs/CIOs regarding upcoming requirements; providing more frequent and systematic communications to the industry regarding upcoming requirements, transition periods, testing milestones and compliance dates; consideration of establishing a web-based voluntary registration process of entities' status towards compliance with the new rules; and health plans communicate a consistent message regarding testing and implementation of the new operating rules.[26]

At the June 2013 NCVHS hearing, testifiers indicated compliance with the first set of operating rules was strong among commercial health plans and some clearinghouses but providers were facing challenges with technical and business resources, coordination with multiple trading partners, and inconsistent use. However testifiers were concerned that smaller providers and

[24] September 20, 2013 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and Health Statistics (NCVHS).
[25] Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions: Interim Final Rule (77 FR 40458), July 8, 2011.
[26] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and Health Statistics (NCVHS).

health plans were not using transactions to improve efficiency but, lacking resources and expertise, instead were relying on practice management system vendors.[27]

2.2.2 Planning for Electronic Fund Transfer (EFT) and Electronic Remittance Advice (ERA) Operating Rules

Section 1104(b)(2)(A) of the Affordable Care Act amended section 1173(a)(2) of the Act by adding the electronic fund transfer (EFT) transaction to the list of electronic health care transactions for which the Secretary must adopt a standard under HIPAA. Section 1104(c)(2) of ACA further required the standard to be adopted by January 1, 2012 and effective by January 1, 2014. Section 1104(b)(2)(C) of the Affordable Care Act also added a requirement at section 1173(g)(4)(B)(ii) of the Act, for the Secretary to adopt operating rules for EFT and ERA transactions to be effective no later than January 1, 2014.

On December 7, 2011, NCVHS sent a letter to the Secretary recommending that a set of five EFT and ERA Operating Rules be adopted, conditional on the two authoring entities (CORE and NACHA – the Electronic Payment Association) making certain revisions.[28] NCVHS also recommended that the DHHS fund studies to determine the costs and benefits of both standards and operating rules.[29] In the Interim Final Rule (77 FR 48008) published in the Federal Register on August 10, 2012, the Phase III CORE EFT and ERA Operating Rule Set were adopted effective August 10, 2012 with a compliance date of January 1, 2014.[30]

2.2.3 Status of The Remaining Operating Rules

Section 1104 of the Affordable Care Act requires the adoption of operating rules for transactions for healthcare claims or encounter information, health plan enrollment or disenrollment, health plan premium payments, referral certification and authorization, and, health care claims attachments no later than July 1, 2014. The third set of operating rules for the remaining transactions will be evaluated by NCVHS in 2014 for possible recommendations for adoption.

NCVHS continues to recommend the adoption of a standard for the acknowledgment transaction. Testifiers have indicated the acknowledgment transaction is a critical component of the complete cycle of electronic data interchange in health care adopting and implementing standards for this transaction is imperative.

2.3 Code Sets

[27] September 20, 2013 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and Health Statistics (NCVHS).
[28] December 7, 2011 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and Health Statistics (NCVHS), p. 5.
[29] December 7, 2011 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and Health Statistics (NCVHS).
[30] Administrative Simplification: Adoption of Operating rules for Health Care Electronic Funds Transfer (EFT) and Remittance Advice (RA) Transactions Interim final rule (77 FR 48008), August 10, 2012

NCVHS informed the Secretary in its March 2, 2012 letter of issues raised by testifiers at the November 18, 2012 hearing held by the NCVHS Subcommittee on Standard's hearing. Specifically, testifiers noted the lack of standardization in the claim-edit process. Providers opined they are often faced with multiple, inconsistent, proprietary, and non-transparent claim edit processes designed by individual health plans and other health payment programs. These result in inaccuracies and inconsistencies in the way claims are reported. NCVHS concluded that edit categories would need to be reviewed to develop best practices for potential use by stakeholders; standardize claim edits related to clinical validity, specialty society recommendations, common administrative definitions, or other considerations; collaborate with claims edit software vendors on ways to increase claim edits transparency; and partner with CMS to explore opportunities to increase transparency of the CMS Correct Coding Initiative.[31]

Industry representatives also indicated health care providers are rarely paid the billed amount. Submitted claims are adjusted by the health plan based on contract agreements, secondary payers, benefit coverage, expected co-pays, co-insurance, and other factors. These adjustments are made through the use of four codes: (1) Claim Adjustment Reason Codes (CARCs); (2) Remittance Advice Remark Codes (RARCs); (3) Claim Adjustment Group Codes (CAGCs); and (4) NCPDP External Code List Reject Codes. Because providers receive multiple adjusted payments from different sources, manual reassociation of payment with remittance advice is burdensome. Included in the EFT and remittance advice operating rule set adopted in the August 10, 2012 Interim Final Rule (77 FR 48008), are the CARCs/RARCs/CAGCs/NCPDP reject Codes combinations that can be applied to convey details of the claim denial or payment adjustment to the provider. Health plans can only use the reject Code combinations specified in the "CORE-required Code Combinations for CORE-Defined Business Scenarios" document. However, new or adjusted combinations can be used if the code committees responsible for maintaining codes create a new code or adjust an existing code.[32]

2.3.1 Planning for ICD-10 Implementation

On January 16, 2009, the DHHS published in the Federal Register, a final rule (74 FR 3328), in which the Secretary adopted the ICD-10-CM and ICD-10-PCS medical code sets as the HIPAA standards to replace the previously adopted ICD-9-CM with a compliance date of October 1, 2013[33]. In its September 21, 2012 letter to the Secretary, NCVHS reported that testifiers at its June 2012 hearing (1) emphasized the importance of ensuring that no more delays on the ICD-10 deadline would be considered; (2) indicated the need to maintain the momentum of the process; (3) opined the need to minimize disruptions in care delivery; (4) emphasized that the one-year extension to the compliance date would provide extra time to plan, prepare, and execute end-to-end testing of systems and processes; and (5) emphasized the need for testing.

[31] March 22, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS)

[32] Administrative Simplification: adoption of Operating Rules for Health Care Electronic Funds Transfers (EFT) and Remittance Advice Transactions: Interim Final Rule (77 FR 48008), August 10, 2012.

[33] HIPAA Administrative Simplification Modifications to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS Final Rule (74 FR 3328), January 16, 2009.

NCVHS recommended that CMS should expeditiously promote the establishment of ICD-10 test scenarios and test methods, including sample test data sets for use by the industry[34].

In response to the provider group expressing concerns about their members' ability to meet the October 1, 2013 compliance date and the serious claims payment issues that might ensue, on September 5, 2012, the DHHS published in the Federal Register (77 FR 54665), a final rule announcing a realignment of the implementation date for ICD-10 to October 1, 2014.[35] The extension was positively received by many in the health care industry.[36]

CMS has and continues to work very closely with all industry stakeholders to assess ICD-10 readiness and provide industry support. A new public-private partnership with the Workgroup for Electronic Data Interchange (WEDI) and other industry partners has been developed to offer pre and post-implementation support. CMS has expanded its free ICD-10 technical assistance and training to small, rural health, home health, and other safety-net providers to help them transition to ICD-10. In July 2013, CMS held a national Medicare Fee-for-Service provider call reaching more than 27,000 providers to educate them about ICD-10, discuss best practices, and answering key implementation questions. CMS ICD-10 website at http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10, features industry-inspired tip sheets, fact sheets, and checklists. The website receives about 100,000 visits per month. An ICD-10 implementation tool, the Road to 10, was launched in February 2014 to help small providers make the transition. Two ICD-10 training videos have been released that provide helpful implementation tips and offer free Continuing Medical Education (CME) and Continuing Education (CE) credits. With input from industry stakeholders, new implementation and educational resources are being developed on a rolling basis to help stakeholders in their transition efforts.

[Editor's Note: In March, 2014, Congress passed the Protecting Access to Medicare Act which required a delay in the implementation of ICD-10 of no less than a year, until October, 2015. The new law was signed by the President April 1, 2014. CMS is expected to issue regulations formalizing the new delay in the implementation of ICD-10 until October 1, 2015.]

2.3.2 Other Code-Set, Vocabulary and Terminology Advancements

The Code on Dental Procedures and Nomenclature of Current Dental Terminology (CDT) has been maintained by the Code Revision Committee (CRC), supported by the American Dental Association (ADA) and engaged stakeholders. In its September 21, 2012 letter to the Secretary, NCVHS reported that subsequent to the agreement the ADA had with stakeholders, the CRC

[34] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and Health Statistics (NCVHS),

[35] HIPAA Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier, Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD-10-CM and ICD-10-PCS Medical Data Code Sets Final Rule (77 FR 54665), September 5, 2012.

[36] In April 2014, the Protecting Access to Medicare Act of 2014 was passed. Specifically, section 212 stipulates that "The Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD-10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d-2(c)) and section 162.1002 of title 45, Code of Federal Regulations."

expired in June 2011. The NCVHS testifiers recommended that NCVHS review and provide oversight for the governance and openness of the process of reviewing, adopting and incorporating new codes into the CDT; closely monitor the implementation of new changes; request a progress report from the ADA and dental health plan representatives by the end of the year; look into the maintenance process of all HIPAA-named standard code sets to ensure openness and transparency in their development; and that documented business needs and sound evidence be considered when identifying, reviewing, adopting and incorporating new codes.[37]

2.4 Identifiers

HIPAA required the development, adoption and implementation of four unique health identifiers for use in HIPAA transactions. The first identifier adopted in 2002 was the Employer Identification Number (EIN) issued by the Internal Revenue Service to identify the employer of an individual subject of the transactions. The National Provider Identifier (NPI), a ten-position all numeric, intelligence-free identifier required for use in all HIPAA administrative transactions became effective on May 23, 2007. HIPAA required (and was further mandated by the ACA), development and use of a health plan identifier (HPID). This was further mandated by the ACA. Finally, HIPAA mandated a unique health identifier for individuals.

2.4.1 State of Adoption of Health Plan Identifiers

To implement section 1104(c)(1) of the Affordable Care Act and section 1173(b) of the Act which require the adoption of a standard unique health plan identifier, a final rule (77 FR 54665) was published in the Federal Register on September 5, 2012 that adopted the standard for a national unique health plan identifier (HPID) and a data element that serves as an "other entity" identifier (OEID). The OEID is an identifier for entities that are not health plans, health care providers, or individuals, but that need to be identified in standard transactions[38]. The primary purpose of the HPID and the OEID is to increase standardization within HIPAA standard transactions. Health plans, excluding small health plans, are required to obtain HPIDs by November 5, 2014. Small health plans are required to obtain HPIDs by November 5, 2015. All HIPAA covered entities are required to use HPIDs by November 7, 2016 when they identify health plans with HPIDs in standard transactions.

In March 2013, the DHHS began accepting HPID and OEID applications through the Health Plan and Other Entity Enumeration System (HPOES). HPOES is a module located in the CMS' Health Insurance Oversight System (HIOS) that currently houses a plethora of health plan information. The CMS HPID website provides detailed information to health plans and other entities on how to access HPOES and apply for an HPID and OEID.

[37] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS), pp 5

[38] HIPAA Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier, addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD-10-CM and ICD-10-PCS Medical Data Code SetsFfinal Rule (77 FR 54665), September 5, 2012.

2.4.2 Status of Other Identifiers Used in Administrative Transactions

Several other identifiers are used in administrative transactions, including personal identifiers, provider identifiers, and employer identifiers. Following are important actions taken regarding the first two identifiers noted above.

2.4.2.1 Personal Identifiers

The NCVHS Tenth HIPAA Report to Congress noted development of a personal identifier for patients may have important advantages for linking medical records. While personal identifiers may protect privacy by avoiding the use of other private information to achieve linkage, their usage does raise privacy issues. As indicated in the Tenth Report, as a result of public concern over privacy, the Congress prohibited the DHHS in 1999, from expending appropriations to finalize a standard for personal identifiers. The prohibition on the development of a unique identifier continues and shall hold until legislation is enacted approving the expenditure of appropriations to develop and implement the use of such a standard.[39]

2.4.2.2 National Provider Identifier

In January 2004, a final rule (69 FR 3434) was published in the Federal Register to adopt the National Provider Identifier (NPI) as the standard unique health care provider identifier and established requirements for obtaining and using the NPI. Since that time, pharmacies have encountered situations where the NPI of a prescribing health care provider needs to be included in the pharmacy claim, but the prescribing health care provider does not have an NPI or has not disclosed it.[40] This situation had become notably problematic in the Medicare Part D prescription drug program. To address this problem, a final rule (77 FR 54680-54684) was published in the Federal Register on September 5, 2012 that specifies the circumstances under which an organization-covered health care provider, such as a hospital, must require certain non-covered individual health care providers who are prescribers to obtain and disclose an NPI. The rule specifies the circumstances under which an organization's covered health care provider, such as a hospital, must require certain HIPAA noncovered health care providers, such as physicians who are prescribers, to obtain and disclose an NPI.[41]

2.5 End-to End Testing

On September 28, 2012, CMS undertook development of a process and methodology for end-to-end testing of the Administrative Simplification standards and operating rules based on industry feedback and participation. This process will be an industry wide "Best Practice" for

[39] The language of the law states, "[n]one of the funds made available in this Act may be used to promulgate or adopt any final standard under section 1173(b) of the Social security Act providing for, or providing for the assignment of, a unique health identifier for an individual (except in an individual's capacity as an employer or a health care provider), until legislation is enacted specifically approving the standards. Consolidated Appropriations Act of 2010, Pub. Law No: 111-117, § 511.

[40] Administrative Simplification: Standard Unique Health identifier for Health Care Providers; final rule (69 FR 3434) published on January 23, 2004.

[41] Administrative Simplification: Adoption of a Standard Unique Health Identifier: Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD-10-CM and ICD-10-PCS) Medical Data code Sets; Final Rule (77 FR 54680-54684) published on September 5, 2012.

end-to-end testing that lays the ground work for a more efficient and less time consuming method for health care provider testing of future standards, leading to more rapid adoption of standards. The goal is a process that can be used across all Administrative Simplification Requirements, and ICD-10 as the HIPAA medical code set standard will be the test case used during the pilot.

2.6 Compliance and Enforcement of HIPAA Administrative Simplification Regulations

2.6.1 Status of Health Plan Compliance Certification Regulation

Section 1173(h) of the Social Security Act (Act) includes certification of compliance requirements for health plans. Section 1173(h)(1)(A) of the Act requires health plans to file a statement with the Secretary by December 31, 2013, certifying that the plan's data and information systems are in compliance with the standards and operating rules for eligibility for a health plan, health care claim status, and health care EFT and ERA. Section 1173(h)(1)(B) of the Act mandates that by December 31, 2015 health plan certification of compliance for health care claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health care claim attachments, and referral certification and authorization. Section 1173(h)(5) of the Act mandates that health plans meet the certification of compliance requirements for later versions of the standards and operating rules. Finally, section 1173(j) of the Act specifies penalties for health plans that fail to meet the certification for each day the plan is not in compliance not to exceed $40 per covered life annually.

NCVHS reported in its September 21, 2012 letter to the Secretary that at the June 2012 hearing, testifiers believed the health plan compliance certification process should be simple, practical and operationally efficient. Attestation supported by sample reports was the industry's preferred suggested method as well as external voluntary validation and certification through independent organizations. Testifiers suggested the DHHS consider mechanisms to require other entities (for example, vendors) to meet compliance requirements. Suggestions to CMS for the documentation requirement included testing with trading partners, providing documentation guidelines that focus on simple interchange reports, and publishing a high level testing schedule example to serve as a guide for health plans emphasizing the need for early planning and testing.[42]

On January 2, 2014 a notice of proposed rulemaking (79 FR 298), as required by section 1104 of the ACA, was published in the Federal Register that would require a controlling health plan (CHP) to submit information and documentation demonstrating that it is compliant with certain standards and operating rules adopted by the Secretary under HIPAA of 1996. The proposed

[42] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS), pp 6&7.

rule would also establish penalty fees for a CHP that fails to comply with the certification of compliance requirements.[43]

2.6.2 Enforcement of HIPAA Administrative Simplification Regulations

The Secretary has delegated to CMS enforcement authority for the transactions and code sets, unique identifiers and operating rules. The Office of Civil Rights (OCR) enforces HIPAA privacy and security requirements.

A uniform set of procedures for determining compliance with or enforcement of the HIPAA standards including transactions and code sets, identifiers, privacy, and security was established in the Enforcement Rule for the Administrative Simplification provisions under the HIPAA final rule (71 FR 8390), published in the Federal Register on February 16, 2006.[44] An Interim Final Rule (74 FR 56123) was published in the Federal Register on October 30, 2009. The rule conformed the civil monetary penalty and related provisions of the Enforcement Rule to the statutory changes enacted under the American Recovery and Reinvestment Act thereby strengthening the ability to enforce against entities for HIPAA violations by revising and increasing the civil money penalty (CMP) amounts that could be imposed.[45]

In its September 21, 2012 letter to the Secretary, NCVHS recommended that CMS be funded sufficiently to conduct an adequate sample of compliance audits in accordance with its delegated authority. NCVHS also recommended that CMS use the findings to develop and implement outreach and education programs to address specific industry implementation challenges with standards and/or operating rules.[46]

2.6.2.1 Current Status

In its enforcement role, CMS utilizes the Administrative Simplification Enforcement Tool II (ASET II) for managing and tracking enforcement complaints. ASET II is a web-based application for individuals and organizations to file complaints regarding the use of standards, operating rules, code sets, and/or identifiers in HIPAA transactions. ASET II is able to test disputed health care transactions for compliance with HIPAA standards. Complainants can check the complaint status and update their complaints. The three major components of ASET II are: (1) complainant registration; (2) complaint filing with specific information concerning the alleged violation; and, (3) complaint management to communicate the status of the complaint, append supporting documentation, and indicate status of the complaint for complainant review.

CMS continues to ensure that filed complaints are resolved by the involved parties before reaching the point of issuing a corrective action plan or assessing civil monetary penalties. The overarching enforcement philosophy at CMS is to assist HIPAA covered entities with achieving

[43] Administrative Simplification: Certification of Compliance for Health Plans: Proposed Rule, (79 FR 298) published on January 2, 2014.
[44] HIPAA Administrative Simplification: Enforcement final rule (71 FR 8390) published on February 16, 2006
[45] HIPAA Administrative Simplification: Enforcement final rule (74 FR 56123) published on October 30, 2009
[46] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS), pp 9&10

compliance. This is primarily achieved through improved communication between the complainant and the involved entity, with CMS acting as a facilitator. Most of the filed HIPAA transaction and code set complaints involved failure to comply with the X12, Version 5010 implementation guide requirements, failure to conduct all of the standard transactions, and failure to obtain and use the National Provider Identifier (NPI). No specific transaction violations have been identified that would necessitate generalized outreach or education, however, outreach is conducted during the investigation of alleged violation. From October, 2011 through December 2013, approximately 53 valid complaints were filed for potential HIPAA transaction; code set; and, identifier violations. Due to the collaborative approach to complaint resolution, to date, CMS has not assessed any civil money penalties for violations of the transaction standards.

2.6.2.2 Planned Changes

In 2009 CMS requested input from the industry on HIPAA transaction and code set enforcement process and suggestions for assisting the industry with compliance. The industry response indicated the enforcement process needed to be strengthened and more transparent. Based on the responses to the RFI, CMS is updating the ASET II tool. The upgrade includes additional user friendly features and integration with CMS security requirements and record storage platforms. Plans for conducting transaction and code set compliance audits and improving transparency by publicly posting enforcement statistics are under consideration.

3. Advancements in the Implementation of HIPAA Privacy and Security Policies and Standards

The last few years have seen significant changes to the HIPAA Privacy and Security regime, many due to the implementation of new requirements brought about by the HITECH Act. Most important among these are the issuance of the so-called Omnibus Rule, the expansion of the Office for Civil Rights' outreach efforts to both regulated entities and consumers, and an uptick in enforcement actions that resulted in civil monetary penalties across a broader range of compliance problems.

3.1 Omnibus Privacy Rule

The most important accomplishment of the Department during the reporting period is the issuance of the "Omnibus" Rulemaking in January 2013.[47] The Omnibus Rule comprised four final rules that modified the Privacy, Security, Enforcement and Breach notification rules under the HITECH Act, and implemented changes to the Privacy Rule arising from the Genetic Information Nondiscrimination Act (GINA). It also made other modifications to the HIPAA rules intended to increase workability and flexibility, decrease burden, and better harmonize the requirements with those embedded within other Departmental regulations. The rules were combined into one to reduce the impact and frequency certain compliance activities need to be undertaken by regulated entities.

[47] Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule (78 FR 5566), Jan. 25, 2013.

Finally, the GINA changes in the Omnibus Rule clarified that genetic information is protected

3.2 Remaining HITECH Act Provisions Not Yet Finalized, Including Accounting for Disclosures

Several major changes brought about by the HITECH Act remain unfinished. The most well-known and controversial of these are the regulations expanding the requirement that covered entities provide to the patient, upon request, an accounting of the disclosures made of the patient's record (protected health information). Under the current Privacy Rule, covered entities are required to produce a list of disclosures made of a patient's information during the prior six years, but are not required to include disclosures for (a) for treatment, payment, or health care operations (TPO); (b) to the individual or the individual's personal representative; (c) for notification of, or to persons involved in, an individual's health care or payment for health care, for disaster relief, or for facility directories; (d) pursuant to an authorization; (e) of a limited data set; (f) for national security or intelligence purposes; (g) to correctional institutions or law enforcement officials for certain purposes regarding inmates or individuals in lawful custody; or (h) incident to otherwise permitted or required uses or disclosures. One additional consideration is that accounting for disclosures to health oversight agencies and law enforcement officials must be temporarily suspended on written representation that such accounting would likely impede the agency's or enforcement officials' activities.

The HITECH Act expanded the requirements to provide an accounting of disclosures such that the exception for disclosures to carry out TPO would no longer apply if made through an electronic health record. The time period to receive an accounting of disclosures would be shortened to three years prior to the request, as opposed to six, and covered entities would be required to provide either an accounting of a business associate's disclosures or a list and contact information of all business associates to the individual requesting the accounting.

The DHHS issued a Notice of Proposed Rulemaking (NPRM) in 2011[48] that would expand the requirement to account for disclosures of protected health information that were in place before the HITECH Act, and extend the requirement to uses or disclosures to carry out treatment, payment, and health care operations if the uses or disclosures were through an electronic health record. Using additional authorities, the DHHS further proposed to expand the accounting provision to electronic protected health information in a designated record set and made other proposed changes to improve workability and effectiveness. The DHHS received 448 individual comments, most of which objected to the proposed "access report," remarking on the burden and lack of technical capacity to comply. To date, DHHS has not promulgated a final rule.

[48] HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act; Proposed Rule (76 FR 31426), May 31, 2011.

However, in 2013 the Health Information Technology Policy Committee (HITPC), an advisory committee to the Director of the Office of the National Coordinator for Health Information Technology (ONC), produced recommendations regarding the expansion of the provisions for accounting of disclosures. These recommendations depart significantly from the 2011 NPRM. A working group of the HITPC, comprised of federal and state government officials, advocates, academicians, and representatives of industry, called the "Tiger Team" held a virtual hearing and collected testimony of significant technical challenges and potentially significant costs of some of the 2011 proposals. Members of the NCVHS Privacy, Confidentiality and Security Sub-Committee participated in this hearing. The testimony collected by the Tiger Team provided little evidence that patients would request the new reports or find them valuable. The presenters at the virtual hearing also raised questions as to whether it was appropriate to require the disclosure of the names of particular individuals in the health care setting who may have accessed data, because it might implicate the privacy of those individuals.

The HITPC adopted the recommendations produced by the Tiger Team as a result of the hearings on December 4, 2013, and transmitted them to the Director of ONC. The recommendations urge the DHHS to pursue a step-wise, focused approach to implementation of the new HITECH requirements for accounting of disclosures. The recommended approach prioritizes quality over quantity, where the scope of disclosures and related details to be reported to patients provide information in a format that is useful to patients, without overwhelming them or imposing undue burden on covered entities.

The HITPC's major recommendation regarding implementation is that an expansion of the accounting should initially focus on disclosures external to the entity being asked for the information and should include the name of the recipient entity to which the disclosure was made, rather than the particular recipient individual's name. They further recommended that technologies and policies used to accomplish this should first be piloted by ONC.

The Office for Civil Rights (OCR) has not yet issued guidance or public notices on two other changes made by the HITECH ACT: 1) what is meant by the application of the "minimum necessary" standard to limited data sets; and 2) regulations that would implement the provision calling for the sharing of civil monetary penalties by complainants.

3.3 HIPAA and the Affordable Care Act

Despite much misunderstanding to the contrary, the Healthcare.gov portal and federal and State insurance marketplaces created by the Affordable Care Act are not covered by HIPAA. The marketplace's core functions, including communicating with individuals, obtaining eligibility information, verifying eligibility for insurance and for subsidies, and making referrals of eligible individuals to qualified health plans, are not functions that are regulated by the HIPAA Privacy and Security Rules, and thus the marketplaces are not HIPAA covered entities. There are other privacy and security rules that apply to the federal marketplace, such as the requirements of the Privacy Act of 1974. The health care plans to which individuals are directed are all covered entities, but the marketplace itself is not subject to HIPAA.

3.4 Outreach to Regulated Entities and Consumers

Outside of implementation of new regulations, this reporting period has been a very productive one for OCR to regulated entities and consumers. OCR expanded its offering of materials designed to be helpful to covered entities in implementing their obligations under the Privacy and Security Rules. OCR has recognized a need for broader outreach, and has been pursuing areas where there is a particular need, targeting where the law and its regulations are perceived as a barrier rather than a help. For example, OCR has concerned itself with reaching more rural providers, smaller providers, and those serving in urban areas without the resources of being affiliated with an organization. OCR is starting to offer its materials in other languages and has expanded its use of social media in successful ways.

3.4.1 De-identification

OCR developed useful guidance about methods and approaches to achieve de-identification in accordance with the HIPAA Privacy Rule, in part based on a workshop of convened experts in 2010. The guidance explains and answers questions regarding the two methods that can be used to satisfy the Privacy Rule's de-identification standard: Expert Determination and Safe Harbor. The guidance is intended to assist covered entities to understanding what is meant by de-identification, the general process by which de-identified information is created, and the options available for performing de-identification.

3.4.2 Notices of Privacy Practices

OCR collaborated with ONC to develop a model "Notices of Privacy Practices" for health care providers and health plans to use to communicate with their patients and plan members.[49] Health plans and covered health care providers are required to develop and distribute a notice that provides a clear, user friendly explanation of these rights and practices. In response to requests for additional guidance on how to create a clear, accessible notice that their patients or plan members can understand, in September 2013 OCR and ONC provided separate models for health plans and health care providers. The models are available on OCR's website along with instructions for how to use them. The options are:

- Notice in the form of a booklet;
- A layered notice that presents a summary of the information on the first page, followed by the full content on the following pages;
- A notice with the design elements found in the booklet, but formatted for full page presentation; or
- A text only version of the notice.

The models reflect the regulatory changes of the Omnibus Rule and can serve as the baseline for covered entities working toward compliance with the new requirements. Covered entities

[49] Office for Civil Rights, U.S. Dept. of Health and Human Svcs., Model Notices of Privacy Practices, Revised Feb. 2014, *available at* http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html.

may use these models by entering their specific information into the model and then printing for distribution and posting on their websites. OCR plans to make these materials available in Spanish in 2014.

3.4.3 Blue Card for Law Enforcement

OCR developed a guide for law enforcement in cooperation with the DHHS Office of the Assistant Secretary for Preparedness and Response and the Federal Bureau of Investigation.[50] The new guide is intended to assist law enforcement when trying to obtain health information protected by the HIPAA Privacy Rule. The guide provides a basic description of the Rule and identifies entities that are and are not required to comply. The guide also outlines several disclosure permissions that allow revealing of health information to law enforcement in common law enforcement situations, such as during an emergency response. The guidance is summarized on a pocket-sized blue card that officers can carry with them.

3.4.4 Videos

OCR produced a series of short online videos that have been a particularly popular outreach effort. There are ten videos on a variety of topics, including one, "Your Health Information, Your Rights," which has also been produced in Spanish under the title "Su Información De Salud, Sus Derechos." At the time of publication of this report, the Spanish language video had been viewed over a half million times, and a few of the English language videos had received over 100,000 hits. The full set can be viewed on OCR's You Tube channel.[51]

3.4.5 Continuing Medical Education for providers

Another series of videos produced by OCR specifically targets health care providers. Working with WebMD, OCR has produced three video guides for physicians to help them understand their obligations under the HIPAA Privacy and Security Rules and build a culture of compliance in their practices. Each of these programs is available with free Continuing Medical Education (CME) credits for physicians and Continuing Education (CE) credits for other health care professionals who watch the videos and take the tests that follow. They are available at www.medscape.org and require membership to access:

- Patient Privacy: A Guide for Providers
- HIPAA and You: Building a Culture of Compliance
- Examining Compliance with the HIPAA Privacy Rule

[50] Office for Civil Rights, U.S. Dept. of Health and Human Svcs., Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement, 2013, *available at* <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf>.

[51] OCR's You Tube Channel is US Gov HHSOCR, *available at* <http://www.youtube.com/user/USGovHHSOCR>.

Most of the videos has received close to 10,000 views, and some have significantly surpassed that level of attention. In 2014, another video will be jointly released with CMS addressing electronic health records

HHS conducted a Mobile Device Roundtable in March 2012 and held a 30-day public comment period to identify and gather the tips and information that would be most useful to health care providers and professionals using mobile devices in their work. One result was a video to help explain to physicians, health care providers and other health care professionals who are using smartphones, laptops and tablets in their work, how to protect and secure health information.[52]

3.4.6 Pamphlets

At about the same time as the videos, OCR issued pamphlets intended for consumers on five basic topics including "Your Health Information Privacy Rights", "Privacy, Security, and Electronic Health Records", "Understanding the HIPAA Notice", "Sharing Health Information with Family Members and Friends", and "How to File a Complaint", and produced them in eight non-English versions—Traditional Chinese, Simplified Chinese, Korean, Polish, Russian, Spanish, Tagalog, and Vietnamese—to make them more accessible. The brochures are easily printed from OCR's consumer-facing website.

3.4.7 Information is Powerful Medicine

3.4.8 Other guidance

Following the mass shootings in Newtown, CT, and Aurora, CO, OCR took the opportunity to communicate to the nation's health care providers and ensure they were aware the HIPAA Privacy Rule does not prevent disclosure of necessary information about a patient to law

[52] U.S. Dept. of Health and Human Svcs., Office of the National Coordinator for Health Information Technology, Your Mobile Device and Health Information Privacy and Security, 2013, *available at* <http://www.healthit.gov/providers-professionals/your-mobile-device-and-health-information-privacy-and-security>.

enforcement, family members of the patient, or other persons, when the provider believes the patient presents a serious danger to himself or other people.

In December 2012, OCR launched a new education initiative and set of online tools offering health care providers and organizations practical tips on ways to protect their patients' protected health information when using mobile devices such as laptops, tablets, and smart phones. The initiative is called "Mobile Devices: Know the RISKS. Take the STEPS. PROTECT and SECURE Health Information," and is available at www.HealthIT.gov/mobiledevices.

OCR also issued guidance regarding immunizations information for children in school, information of decedents, and prescription refill reminders.

3.4.9 Audit Program Pilot

OCR instituted a pilot audit program in 2011 that continued through 2012. The purpose of the audit program was to assess HIPAA compliance efforts by a range of covered entities to identify best practices and discover risks and vulnerabilities that may not have come to light through the ongoing complaint investigations and compliance reviews. OCR selected initial subjects designed to provide a broad assessment of the complex and diverse health care industry, looking for as wide a range of types and sizes of covered entities as possible. However, business associates were not included in the first round of audits as there was not yet authority to do so.

During the audit process, the covered entity had the opportunity to discuss identified concerns and describe corrective actions. The final reports submitted to OCR incorporated the steps the entity took to resolve any compliance issues identified by the audit and described any best practices of the entity.

Audits are primarily a compliance improvement activity. The aggregated results of the audits will enable OCR to better understand compliance efforts with particular aspects of the HIPAA Rules. Of course, if a particular audit indicated a serious compliance issue, OCR has the authority to initiate a compliance review to address the problem. However, OCR does not make public the identity of audited entities or the findings of an individual audit.

We expect OCR to use the audit reports to determine what types of technical assistance should be developed and what types of corrective action are most effective, and then make public best practices and guidance targeted to observed compliance challenges.

3.5 Enforcement of Privacy and Security Polices and Standards

In the Tenth NCVHS report on HIPAA, the Committee identified the lack of enforcement by OCR. Subsequent to the report, OCR started to make major contributions by stepping up its enforcement regime. In 2012, OCR resolved 9,411 cases of which 3,361 resulted in a corrective action and 979 resulted in a finding of no violation. The rest were resolved after intake and review due to lack of jurisdiction. In 2013, OCR resolved 14,300 cases of which 3,470 resulted in corrective action and 993 resulted in a finding of no violation.

OCR reports on its major enforcement actions when the investigation leads to a settlement or other conclusion of the case. From the compliance date to the present, OCR reports that the compliance issues investigated most frequently are: impermissible uses and disclosures of protected health information, lack of safeguards of protected health information, lack of patient access to their protected health information, uses or disclosures of more than the minimum necessary protected health information, and lack of administrative safeguards of electronic protected health information. The most common types of covered entities required to take corrective action to achieve voluntary compliance are, in order of frequency: private practices, general hospitals, outpatient facilities, health plans (group health plans and health insurance issuers), and pharmacies.

In particular, the most common types of problems are lost or stolen portable devices, such as laptops, or failure to properly dispose of electronic protected health information (ePHI) once no longer being used. Descriptions of the major cases settled by OCR during 2012 and 2013 may be found here: http://www.hhs.gov/ocr/privacy/hipaa/enforcement/data/index.html. Taken as a group, the cases described below illustrate a broadening enforcement program, not just in the severity of civil penalties imposed but in the variety of entities targeted and types of compliance problems investigated. OCR has used its enforcement authority to take actions against small providers of care, ambulatory and in-patient institutions, a large pharmacy chain, and insurers. It has fined covered entities for many different types of violations, not just breaches of data, but inadequate notices, security risk assessments, or failures to adopt policies and procedures. OCR has yet to take action against a business associate directly because it does not yet have authority to do so, but business associates can expect enforcement actions will be taken against them for similar violations of the HIPAA Privacy and Security Rules as that authority becomes available.

3.5.1 Alaska Department of Health and Human Services

The State of Alaska Department of Health and Human Services (DHHS) agreed to pay the DHHS $1.7 million to settle potential violations of the HIPAA Security Rule in June 2012. Alaska also agreed to take corrective action to improve policies and procedures to safeguard the privacy and security of its patients' protected health information. OCR's investigation followed a breach report submitted by Alaska DHHS as required by the HITECH Act. The report indicated that a portable electronic storage device (USB hard drive) possibly containing electronic protected health information (ePHI) was stolen from the vehicle of a DHHS employee.

Over the course of the investigation, OCR found that DHHS did not have adequate policies and procedures in place to safeguard ePHI. Further, DHHS had not completed a risk analysis, implemented sufficient risk management measures, completed security training for its workforce members, implemented device and media controls, or addressed device and media encryption as required by the HIPAA Security Rule.

In addition to the $1,700,000 settlement, the agreement included a corrective action plan that requires Alaska DHSS to review, revise, and maintain policies and procedures to ensure

compliance with the HIPAA Security Rule. A monitor will report back to OCR regularly on progress of the state's ongoing compliance efforts.

3.5.2 Massachusetts Eye & Ear Infirmary / Massachusetts Eye & Ear Associates, Inc.

Massachusetts Eye and Ear Infirmary and Massachusetts Eye and Ear Associates Inc. (collectively referred to as "MEEI") agreed to pay the U.S. Department of Health and Human Services (DHHS) $1.5 million to settle potential violations of the HIPAA Security Rule and to take corrective action to improve policies and procedures to safeguard the privacy and security of its patients' protected health information. The settlement agreement was announced in September 2012.

The investigation by OCR followed a breach report submitted by MEEI pursuant to the HITECH Act Breach Notification Rule, reporting the theft of an unencrypted personal laptop containing the ePHI of MEEI patients and research subjects. The information contained on the laptop included patients' medications and other clinical information.

OCR's investigation indicated MEEI failed to take necessary steps to comply with certain requirements of the Security Rule, such as conducting a thorough analysis of the risk to the confidentiality of ePHI maintained on portable devices, implementing security measures sufficient to ensure the confidentiality of ePHI that MEEI created, maintained, and transmitted using portable devices, adopting and implementing policies and procedures to restrict access to ePHI to authorized users of portable devices, and adopting and implementing policies and procedures to address security incident identification, reporting, and response. OCR's investigation indicated these failures continued over an extended period of time, demonstrating a long-term, organizational disregard for the requirements of the Security Rule.

3.5.3 The Hospice of North Idaho

3.5.4 Wellpoint, Inc.

application database left the ePHI of 612,402 individuals accessible to unauthorized individuals over the Internet.

OCR's investigation indicated that WellPoint did not implement appropriate administrative and technical safeguards as required under the HIPAA Security Rule, including safeguards for authorizing access to the on-line application database, performing a technical evaluation in response to a software upgrade to its information systems, or verifying the person or entity seeking access to ePHI maintained in its application database. As a result, beginning on Oct. 23, 2009, until Mar. 7, 2010, the investigation indicated that WellPoint impermissibly disclosed the ePHI of 612,402 individuals by allowing access to information maintained in the application database that included names, dates of birth, addresses, Social Security numbers, telephone numbers, and protected health information.

3.5.5 Affinity Health Plan, Inc.

Affinity Health Plan, Inc. settled potential violations of the HIPAA Privacy and Security Rules for $1,215,780 in August 2013, in a case demonstrating the importance of properly disposing of equipment that may have stored personal information before it is recycled, discarded, or returned to a leasing agent. Affinity Health Plan, a not-for-profit managed care plan serving the New York metropolitan area, filed a breach report with OCR on April 15, 2010, as required by the HITECH Act. Affinity indicated it was informed by a representative of CBS Evening News that, as part of an investigatory report, CBS had purchased a photocopier previously leased by Affinity. CBS informed Affinity that the copier Affinity had used contained confidential medical information on the hard drive.

Affinity estimated that up to 344,579 individuals may have been affected by this breach. OCR's investigation indicated that Affinity impermissibly disclosed the protected health information of these affected individuals when it returned multiple photocopiers to leasing agents without erasing the data contained on the copier hard drives. In addition, the investigation revealed Affinity failed to incorporate the ePHI stored on photocopier hard drives in its analysis of risks and vulnerabilities as required by the Security Rule, and failed to implement policies and procedures when returning the photocopiers to its leasing agents. In addition to the $1,215,780 payment, the settlement includes a corrective action plan requiring Affinity to use its best efforts to retrieve all hard drives that were contained on photocopiers previously leased by the plan that remain in the possession of the leasing agent, and to take certain measures to safeguard all ePHI.

3.5.6 Adult & Pediatric Dermatology, P.C

At the end of December, 2013, OCR entered into the first settlement with a covered entity for not having policies and procedures in place to address the breach notification provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, passed as part of American Recovery and Reinvestment Act of 2009 (ARRA). OCR opened an investigation of Adult & Pediatric Dermatology, P.C (APDerm) of Concord, Mass., , a private practice that delivers dermatology services in four locations in Massachusetts and two in New Hampshire,

upon receiving a report that an unencrypted thumb drive containing the ePHI of approximately 2,200 individuals was stolen from a vehicle of one its staff members. The thumb drive was never recovered.

The investigation revealed that APDerm had not conducted an accurate and thorough analysis of the potential risks and vulnerabilities to the confidentiality of ePHI as part of its security management process. Further, APDerm did not fully comply with requirements of the Breach Notification Rule to have in place written policies and procedures and train workforce members.

APDerm agreed to settle potential violations of the HIPAA Privacy, Security, and its Breach Notification Rules, agreeing to a $150,000 payment. APDerm was required to implement a corrective action plan to correct deficiencies in its HIPAA compliance program and a risk analysis and risk management plan to address and mitigate any security risks and vulnerabilities, and to provide an implementation report to OCR.

4. Advancements in the Adoption of Standards for Public Health and Population Health

Achieving standardization in the electronic exchange of health information between public health entities (i.e., Federal, State and local public health agencies) and external health care organizations is also an important goal on the road towards simplification of processes involved in the collection, maintenance and use of health information.

While not an explicit component of HIPAA, public health agencies and health care organizations have been leveraging the same standards used in administrative transactions to collect and exchange health information for various purposes. Information exchange standards have also been developed for specific public health data collection needs, including vital records (births, deaths), immunizations, laboratory reporting, syndromic surveillance, communicable disease reporting, specialized public health registries (such as cancer registries) and others.

During the past two years, NCVHS has been working on several efforts aimed at advancing the capabilities of communities, public health agencies and health care organization to adopt and use standards for the collection and exchange of health information. This section summarizes these efforts.

4.1 Community Health Data Initiatives

NCVHS has been examining the unprecedented opportunities being offered by the current conditions for America's communities to become learning systems for health, able to use data and information to improve the health of their local population.

In 2012, NCVHS released a report on "The Community as a Learning System: Using Local Data to Improve Local Health".[53] The report was the product of a year-long NCVHS Community Health Information Project during which NCVHS examined how communities can become learning systems and what resources exist or are needed to assist them in this endeavor. This initiative has deep roots in NCVHS's population health mission and in the vision and policy recommendations NCVHS has promulgated over its long history.

The 2012 report presented a vision for strengthening local data capabilities and uses with specific suggestions to increase the momentum towards better local health. The report also highlighted the need to identity priorities; build trust through stewardship, governance, privacy protections and engagement; establish partnerships and collaboration; obtain and develop data around a broad definition of health; and, create a community-oriented infrastructure of standardized data, measures and tools, along with guidance on privacy and security. The report also identified specific areas where the Federal government can take an active role in galvanizing the energy of community health movements and support the development and functioning of community-oriented learning systems for health. The report concluded with a

[53] Available from http://www.ncvhs.hhs.gov

series of pathways that the DHHS and others can take to support the development and functioning of community-oriented health learning systems.

Having determined that many communities in the U.S. need assistance to become effective learning systems, NCVHS has set as a major focus for 2014 and beyond to 1) advance the development of a Community Data Framework to help communities capture, organize and leverage data from multiple sources, understand how to use and repurpose data, and optimize data utility and usability; 2) define a system to assess community readiness to use data for action – their ability to collect, interpret, protect and use data and other tools to improve local health and well-being; and 3) identity and recommend various sources, forms and approaches for delivering technical data assistance and support to communities, including roles and opportunities for the Federal government.

In order to achieve these goals, the Committee will be looking at the following determining factors:

- The broad **continuum of data (from individual to population health)** needed for local action, including new data sources and dissemination modalities as well as traditional ones (what's needed?, what's available?, and the gaps);
- The **standards, data stewardship practices and other methods** required to appropriately collect, use and repurpose data;
- The factors that contribute to or militate against **community readiness** for data use and action (an attribute in which communities vary greatly), and the best ways to assess and enhance readiness; and
- The **technical assistance and support** needed by communities across the readiness spectrum (including what's available and the gaps).

4.2 Public Health Data Standards

Between 2012 and 2013, NCVHS continued its efforts to advance the convergence of electronic standards within and across the health care industry. NCVHS did so in order to meet multiple purposes and needs, including not just those related to clinical information exchanges between providers, but also public health data exchanges between providers and public health agencies.

Important progress has been achieved during the past 15 years in the development, testing, adoption and implementation of public health informatics standards. These are the electronic standards that define the message content and format, the vocabulary and terminology used to codify data, the security standards used to protect the data being exchanged, and the transport standards to support the exchange of the data. Significant gains have been achieved in selected public health areas, including vital records reporting (electronic reporting standards for births and deaths), immunization systems, public health laboratory reporting, and syndromic surveillance. Just during the last four years there has been a significant increase in the attention, interest and work towards development and adoption of public health informatics standards in the U.S., with the implementation of the EHR Meaningful Use Incentives Program,

the beginning of care delivery and payment reform under the Affordable Care Act, and new HIPAA Administrative Simplification Regulations.

The pressure and demand for improved information infrastructure capabilities and better technical, analytical, strategic and operational resources within public health agencies has been increased by the rapid adoption of electronic health records and other health information technologies. These include clinical decision support systems; the increased expectations for engagement and active participation in local, regional and national health information exchanges; and the readiness expectations for public health information systems to accept electronic messages from providers (and others), and to respond with information that is useful and actionable. These developments are occurring at a time when financial constraints at the federal, state and local level are limiting even further the availability of such resources.

With this as a backdrop, NCVHS held an initial hearing in late 2013 to review the status of public health informatics standards. During the hearing, testifiers noted that public health, as an integral component of health and health care, benefits significantly from the adoption and use of informatics standards. From a regulatory perspective, testifiers explained there are already basic policies and regulations on standardization in place that cover parts of public health.

Public health informatics standards are developed, adopted, and implemented in response to jurisdictional funding streams driven by specific programmatic business needs and drivers, perpetuating the use of data silos and the lack of coordination in public health systems development. This limits the ability to achieve general support for nationwide collaboration and coordination across public health programs in concert with standards development organizations. Standards adoption by autonomous jurisdictions depends on their ability and willingness to fund a transition to new or enhanced systems, their technical capacity to adopt the new systems, and their understanding of the business purpose driving the use of standards. Also, minimal public health practitioner involvement and engagement in standards development activities represents one of the biggest implementation challenges. This limits their ability to specify and advocate a strong value proposition for widespread adoption and effective use of standards that are essential for data exchange to bring tangible benefits to them and their community partners.

National informatics standards already exist and are well recognized, adopted and used in selected areas in public health such as immunizations, laboratory reporting, and vital registration at the state level. Acceleration in the development and use of public health informatics standards has occurred during the past four years with the rapid adoption of electronic health records (EHR) under the Meaningful Use program, and new requirements and increased expectations from health care providers to exchange health information electronically with public health agencies using nationally adopted standards.

However, much work around public health information systems capabilities and standards adoption and implementation still remains. A number of opportunity areas were identified during the hearing where national informatics standards do not exist yet, or are under

development, such as public health case reports (i.e., reportable conditions, adverse events), registry reporting, and environmental health.

The following are key overarching themes heard during the late 2013 Public Health hearing:

- Need to continue advancing and improving the public health informatics infrastructure at the Federal, State and local level, to be more responsive to the current electronic health information exchange and informatics standardization ecosystem;
- Continued fragmented approaches to public health data standards development and adoption driven by program or state-specific initiatives;
- Need for increased support, focus and engagement on public health informatics standards development, implementation, and adoption at the Federal, state and local levels;
- Maturity and adoptability of standards along with the ability to implement those standards must be considered before adopting and requiring their use;
- Additional resources are needed to support public health programs' engagement in standards development activities and to promote adoption; and
- Need to establish the appropriate incentives for the adoption and implementation of public health informatics standards.

NCVHS strongly believes the nation's public health system is at a critical juncture and that there is an unprecedented opportunity to invest in advancing the country's public health information infrastructure to ensure it is capable of interacting effectively and efficiently with the rapidly evolving electronic health record systems and health information exchanges of the future. Thus, NCVHS believes there is a need to:

- Pursue the development and implementation of a new public health informatics standards strategic initiative to advance and bring to par public health information systems with electronic health record systems;
- Establish a Public Health Information Infrastructure Trust Fund that will serve as a dedicated funding source to enhance the information infrastructure needed to support all public health functions;
- Establish a National Public Health Informatics Standards Collaboration initiative, in partnership with the public health community, to accelerate the adoption and implementation of standards in public health programs;
- Leverage policy programs and initiatives, including the Affordable Care Act and the EHR Meaningful Use program, to align incentives for public health reporting, stimulate electronic information systems vendor engagement in adopting and using public health data standards, and ensure public health data requirements are incorporated into clinical systems; and
- Develop a new national strategy for public health informatics capacity building, to increase the number of skilled workers in the public health workforce.

A letter summarizing observations, findings and recommendations to the Secretary on this topic will be submitted by June, 2014.

5. A Vision for the Future of Health Care Administrative Simplification and eHealth

NCVHS has accomplished much since its inception more than 60 years ago. NCVHS has created an environment where stakeholders have shared their concerns, their successes, and their difficulties, and will continue to provide the venue for these exchanges. NCVHS has listened to and incorporated stakeholder testimonies in their recommendations to the Secretary. It is this collaborative environment with the health care industry and with DHHS that will shepherd the health care industry through the unchartered territory ahead.

Health care of the future holds promises that exceed anything envisioned when HIPAA was first implemented in 2000 and it is the unknown future that will affect the role of NCVHS as the statutory advisory body to the Department on health information policy. The 60th Anniversary Symposium and History noted that at the June 17, 2010 symposium hosted by NCVHS, there were many references to the "accelerating rate of change being spurred by new policy initiatives and the technology revolution."[54] We are truly entering a new paradigm in health care, particularly in health information exchange with the expansion of health care coverage through the Affordable Care Act, adoption of electronic health record standards, and continued adoption of administrative simplification standards.

The NCVHS Tenth HIPAA Report to Congress indicated that there had been important achievements in the prior 15 years towards administrative simplification, privacy, and security protections for health information. But much work remains. The Tenth Report defined the path NCVHS believed needed to be taken in order to fully adopt any intended action.[55] NCVHS still believes that the healthcare industry and the nation need to be fully engaged in the process and set its course. However, NCVHS believes that as a Federal Advisory Committee Act (FACA) committee it needs to set a vision that embraces collaboration, partnership, prioritization, consumer needs, flexibility, adaptability, data usefulness and value, and employ the same in creating useful and effective recommendations.

On March 2, 2012, NCVHS sent a letter to the Secretary addressing Section 10109 of the Affordable Care Act which contains provisions calling for evaluation to improve standardization and uniformity in new financial and administrative activities beyond those addressed in HIPAA. Specifically, section 10109 of the Act requires the Secretary to seek input from NCVHS and the Health Information Technology Policy Committee (HITPC) on administrative simplification including (1) provider enrollment; (2) property and casualty industry inclusion under HIPAA; (3) audit consistency and standardization; and (4) claim edits consistency. In that letter NCVHS

[54] 60th Anniversary Symposium and History 1949-2009, U.S. Department of Health and Human Services, February 2011, pp3
[55] NCVHS Tenth HIPAA Report to Congress on the Administrative Simplifications Provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, December 2011.

recommended that a strategy be established to further explore these four areas in order to develop recommendations for comprehensive improvement.[56]

On March 2, 2012, NCVHS submitted another letter to the Secretary subsequent to the November 18, 2011 NCVHS Subcommittee on Standards hearing which addressed the development, maintenance, and update process for standards and operating rules relating to administrative transactions. NCVHS cited issues raised by stakeholders which included barriers to participation, lack of stakeholder representation, increased complexity of the standards and operating rule maintenance process, timing of vetting of new versions of standards, limited and inconsistent communication, the need for clear definitions of both standard and operating rules, and direction on areas where requests for changes and clarifications should be made. NCVHS acknowledged that the range of standards used in health care to support administrative health data exchange has grown beyond the original HIPAA-adopted standards.[57]

On September 18, 2013, more than twenty industry representatives comprised of subject-matter experts and various stakeholders participated in a day-long NCVHS listening session to discuss the patient's role in a health care system, health care delivery, and health care payment. The purpose of the listening session was to propose ideas on a roadmap to what lies ahead (for example, in upcoming IT standards); milestones required to successfully achieve compliance requirements including development and testing of standards; standard development requirements; and opportunities for better alignment, synergistic coordination, sequencing of requirements, milestones and standards development. NCVHS will continue to convene hearings, roundtables and workshops to obtain such information from experts and stakeholders.

NCVHS has identified emerging themes heard from the health care industry in the past two years. These themes are the need for (1) patient and consumer focus, (2) sound policy and regulatory harmonization, (3) flexibility and agility to embrace change with urgency, (4) effective evolution and perspectives on short versus long term issues, (5) disparity of means to execute/adopt changes, and (6) useful data and effective data stewardship. In response to industry requests, the NCVHS Subcommittee on Standards is working to identify a vision for eHealth, particularly as it relates to administrative processes in identifying key milestones through 2020, and developing a roadmap that will provide guidance to the industry on what lies ahead.

To guide in future deliberations; assessments of options; development of recommendations related to naming, adopting and implementing future standards; and development of a roadmap to aid in determining the timing and sequencing adoption of new standards, NCVHS has identified ten principles to guide future NCVHS projects. Future NCVHS projects will:

[56] March 2, 2012 letter "Administrative Simplification Provisions Addressed in Section 10109 of the Affordable Care Act of 2010(ACA), to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

[57] March, 2012 letter "Additional Analysis of the Update and Maintenance Process for Standards and Operating Rules," to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

(1) Foster alignment with the triple aim of quality health care, improved health and cost effectiveness;
(2) Be actionable by the Secretary and the health care industry;
(3) Improve the data infrastructure;
(4) Ensure the privacy, confidentiality and security of individually identifiable health information;
(5) Not being undertaken elsewhere and require NCVHS to do it;
(6) Have an identifiable audience;
(7) Be directional and strategic;
(8) Be consistent with NCVHS' scope and are appropriately scaled;
(9) Be likely to have a measurable impact; and
(10) Include a commitment and a plan for dissemination.

The sections below summarize the testimony from experts and stakeholders and the direction NCVHS plans to take during the next seven years.

5.1 Transformative Changes

Data traditionally have been considered in relation to finance, payment, and claims. Industry representatives have stated that data should also relate to the patient's needs. NCVHS concurs with the industry and believes the key to transformation of health care in terms of delivery and payment is the patient. NCVHS believes eHealth standards should be patient-centered and consumer-centered, resulting in better health care and, better patient and population health at lower costs without compromising the quality or safety of care. This includes identifying key determinates of "good health," disease prevention, early disease diagnosis, management of chronic disease, and management of end of life issues. Consequently, NCVHS's direction in the ensuing years will be to identify and recommend administrative simplification standards and operating rules that can be used both administratively and clinically to achieve the goals of better health, better care, and lower costs.

5.2 Data Stewardship

The concept of health information is not new. Information has historically been gathered through various sources including inpatient and outpatient data; public health and Federal surveillance activities; and individual and population surveys. However, information obtained was limited to the needs of a particular area of concern and not shared, often resulting in replication of data by different sources, failure to communicate data to ensure that health care is provided safely and is not duplicative, and inability to validated or replicate results. Information gathering by multiple sources was expensive. Protection of patient information was not often a priority. Statutory mandates were developed to address these inequities. HIPAA recognized the importance of patient protections and the Affordable Care Act recognized the importance of administrative simplification and providing financial incentives for health IT adoption by hospitals and health care providers.

Currently, the major sources of health care data remain comparable to the historic sources of information such as: surveys and censuses, surveillance data (for example required disease reporting), health care data (laboratory results, EHRs, registries, and prescription history), administrative data (claims, hospital discharge data and vital records), and research data (for example, clinical trials). Yet other sources of data including transportation, housing, air quality, education and economic factors, to name a few, are needed to truly understand population health.[58] Health care information and data have the potential to improve the quality and affordability of health care, reduce medical and medication errors, improve health, increase prevention, increase early diagnosis, and improve care across the health care continuum. NCVHS sees its role as a leader in this endeavor.

As a result of hearings held in 2007, NCVHS developed recommendations for data stewardship and published the Health Data Stewardship Primer.[59] Data stewardship was described as including accountability and chain of trust, transparency, individual participation, de-identification, security safeguards and controls, data quality and integrity, and oversight of data uses. The Primer identified key principles and practices of Health Data Stewardship that include (1) individual rights; (2) data stewardship in every organization that handles health data; (3) implementation of administrative, technical and physical safeguards to protect information and minimize the risks of unauthorized or inappropriate access, use, or disclosure; and (4) accountability, enforcement, and remedies.[60]

The potential risks of incorrect or inappropriate use of health data have increased recently with the increasing availability of electronic health data and the acceleration in the use and development of technology.

In a letter to the Secretary on December 5, 2012, NCVHS stated that the most important and overarching goals of effective stewardship are to "enhance trust in the process of data collection, management, use, disclosure, or safeguarding." The letter further discussed elements of trust that included openness, transparency and choice; purpose specification; community engagement and participation; data integrity and security; accountability; protecting de-identified data; attending to the risks of enhanced data sets; and stigma and discrimination.[61] Before any recommendations can be made to promote and expand access and use of data, NCVHS believes there is a need to:

(1) Review administrative, clinical, operational, survey results, public health and research data sources currently available and how these data promote access, use and application to improve health and health care;
(2) Identify and monitor current trends and capabilities for information dissemination, access, developments and technologies;

[58] 60th Anniversary Symposium and History 1949-2009, U.S. Department of Health and Human Services, February 2011, pp14.
[59] Available from http://www.ncvhs.hhs.gov
[60] Health Data Stewardship, U.S. Department of Health and Human Services, December 2009.
[61] December 5, 2012 letter "A Stewardship Framework for the Use of Community Health Data," to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

(3) Identify and monitor data and information needed by consumers, patients, providers, health plans, payers, communities and government agencies;
(4) Identify and analyze areas for improving data access, application and policies;
(5) Serve as a forum for promoting and facilitating creative communication to the public, key stakeholders and the technology community about available data and opportunities for use; and
(6) Obtain expert opinion and public input regarding policies and infrastructure to improve data access and innovative use.

As information technology continues to evolve, NCVHS is cognizant of the need for the health care industry to ensure data are easy to generate, use, link, enable multiple uses of data while minimizing burden, ensure data are replicable while ensuring that access is limited to those who need the information, and preserve the privacy and security of individually identifiable health information. However, data should not be generated for their own sake but should be interactive to enable and support better clinical care and population health. Thus, information needs to be comprehensive in scope and capability, close in time to the observation or intervention, efficiently retrievable by the users, collected once, usable, and protective of patient privacy. Underlying the usability of information and data is standardization. As a consequence, NCVHS believes health information policies and standards should support improved access to affordable, efficient and cost effective health care; enhance health care delivery; support evidence-based health care; improve patient safety; mitigate health disparities; support clinical research; and include the consumer as an active participant in their health care. These advances in information technology have created a need for standardized EHRs. Standardization needs to be robust and dynamic to accommodate future needs. Standardization would enable and support interoperability for the collection and sharing of information.

Cognizant of privacy concerns of individually identifiable information, and expanding upon past initiatives, NCVHS will focus on preservation of privacy while supporting the need to ensure patient access to appropriate quality health data across the continuum of care. NCVHS envisions this as a seamless and secure flow of information so that the right information goes to the right place at the right time with the appropriate protections. To address data concerns, in June and September 2012, NCVHS convened several meetings of a newly implemented working group on Data Access and Use to monitor and identify issues and opportunities; review and consider DHHS data resources; examine traditional and new information dissemination strategies, developments, technologies and social media; and identify how to meet evolving health data needs.

NCVHS will continue to foster the key principles and practices of health data stewardship described in the NCVHS Primer on Health Data Stewardship and will continue its process of bringing together multiple points of view by creating a supportive environment for stakeholders and experts to share their visions, experiences and expertise.

5.3 Convergence of Clinical and Administrative Standards

Convergence can be defined as the use of the same data and data sources for multiple appropriate uses with privacy protections. NCVHS sees this convergence as occurring between clinical and administrative standards to (1) support and improve individual and population health and (2) improve efficiency and cost savings in the transmission of information. NCVHS asserts that "a major priority of health information policy should be to facilitate interconnections and enable the multiple uses of health information to meet current and emerging needs … with strong privacy protections."[62] The future provides opportunities to align data, public health, privacy and security.

NCVHS has heard from stakeholders at its hearings during these past two years of the need for convergence. From a public health perspective, convergence means engaging communities to tackle problems that are beyond traditional concepts of health care. This means health and illness definitions must include assessing neighborhood and community status and risk factors, social relationships and risk factors, living conditions, individual status and risk factors, genetic and constitutional factors, identifying and treating early pathology, and chronic disease; and acute care management. Improving individual and population health will require shifting episodic medical care to management; recognizing that physical and mental health are inseparable and viewing populations at multiple levels to identify health status and risk factors.

One challenge facing NCVHS is the convergence of clinical and administrative data in the development of standards that are meaningful, useful, seamless, transparent and cost effective, while ensuring the privacy and security of individually identifiable health information. Another area of convergence is the proliferating area of quality measurement and monitoring and consolidating relevant health information for analysis.

Inherent in convergence is the need to convey and convince health plans, health care providers, and consumers of the importance of data. This requires NCVHS to recommend standards that have demonstrated effectiveness and are adaptable to change. This convergence will be the key indicator of success of future standards that will support and incentivize development of evidence based medicine; clinical indicators that measure quality and effectiveness of interventions; research in new technology, diagnostic tools and interventions to promote health; payment structures that reward effective quality care and not quantity of care while recognizing that not everyone will maintain or be restored to good health; seamless transitions through the health care system where information is readily available and exchanged; and processes that utilize resources effectively and efficiently. Through partnerships with stakeholders and government agencies, NCVHS can work to leverage processes that ensure consumer safety while providing an expeditious process for changing and adding standards.

NCVHS has begun its paradigm shift by integrating its work on population health, security, privacy, standards and quality. Future NCVHS activities will assess the health care industry's readiness to better meet community needs "where they are" in order to provide more meaningful support for improving community health, harmonize standardized health indicators,

[62] 60th Anniversary Symposium and History 1949-2009, U.S. Department of Health and Human Services, February 2011, pp6

merge social media data with traditional data, model the integration of population health and clinical data, and evaluate "repurposing" and expanded use of data such as surveys, surveillance, clinical and electronic health records. Included in future NCVHS activities is the need to conduct a comprehensive review of the entire health care administrative and financial lifecycle and end-to-end process, going from health plan enrollment (834) to eligibility inquiry (270/271), to care delivery messaging (EHR standards for messaging, content, terminology), prior authorization and referral (278 + HL7 clinical message), lab ordering and results (HL7 electronic lab order; lab results response); medication prescription (e-Prescribing standards), health care claims (837s), claim status request/response (276/277), claim attachment request/response (275 + HL7 clinical content), coordination of benefits (837), claim payment (835), and EFTs. Finally, NCVHS will provide the Secretary with actionable recommendations on these matters.

5.4 Roadmap for eHealth Standards Adoption and Implementation

NCVHS has clearly heard from stakeholders on the concept of eHealth. Through their comments, certain themes have emerged to become the genesis of a roadmap for future standards. The themes centered on the need for a consumer-centric, information driven ecosystem that supports anytime, anyplace, and anywhere access to the right information about the right person through a seamless interoperable, secure, efficient and sustainable system of technology, infrastructure, applicable tools and devices. The themes are: (1) sound policy and regulatory harmonization; (2) flexibility and agility to embrace urgency; (3) disparity of means to execute and adopt; (4) patient and consumer focus; (5) effective evolution perspective on short versus long term; and (6) useful data and effective stewardship. The themes are not seen in isolation but are interactive and interdependent. Consequently, NCVHS has taken the emerging themes to develop the following guiding principles for eHealth.

The themes of sound policy and regulatory harmonization, flexibility and agility to embrace urgency, and disparity of means to execute and adopt result in the following guiding principles:

(1) eHealth policies facilitate evolutional, practical, and pragmatic changes in the industry based on clearly defined concepts, objectives and measureable results;
(2) eHealth policies facilitate transformative changes that have a clearly stated vision and goals that crisply define current and future states;
(3) major changes are optimized and aligned to minimize administrative burden to the industry and maximize desired outcomes;
(4) eHealth changes clearly define stakeholders, opportunities and risks;
(5) eHealth changes deploy practical and pragmatic approaches and mitigate implementation and adoption risks while focusing on administrative/clinical processes to achieve the Triple Aim of better care, better health, and lower costs; and
(6) eHealth changes are optimally defined to achieve greater good for the whole while recognizing that changes may not be possible for every entity.

The themes of patient and consumer focus; effective evolutionary perspective on short versus long term, and useful data and effective stewardship result in guiding principles that eHealth:

(1) Policies facilitate or enable capabilities that empower consumers with actionable information in engaging health care; improve providers ability to deliver high quality care and outcomes; optimize cost and reduce waste; and, improve patient safety;
(2) Transformation establishes and articulates a roadmap of short-term and long term changes, minimizes or avoids "throw away" work, allows for course-correction, and anticipates industry and technological advances;
(3) Facilitates effective purposeful data exchanges and uses to empower and inform health care and public health objectives; and,
(4) Utilizes effective data management and stewardship practices to gain stakeholder confidence and trust.

Fundamental to the development of an eHealth roadmap is a common understanding and agreement of the definitions of eHealth. NCVHS envisions eHealth as the means to improve quality of care and health outcomes by providing the mechanism for sharing accurate data and by utilization of dynamic health care standards that have been statistically validated, tested, and maintained as health care interventions continue to evolve. NCVHS also sees eHealth as an opportunity to be the framework for payment by addressing and integrating the full spectrum of patient-centric health delivery with measureable outcomes.

NCVHS believes an eHealth roadmap would be a graphical depiction of standards-based and policy initiatives into the future that would improve sequencing and alignment; take a broad view; serve as a shared vision; and communicate priorities. The eHealth roadmap is also seen as a balanced scoreboard that embraces stakeholders, learning, growth, process, and results.

NCVHS believes that inherent to any roadmap is the assurance of transparency, stakeholder engagement, education, timing and developing standards so that they add value. This involves transparency on who will be affected by the initiative to mitigate the impact of multiple initiatives from different streams. In addition, there is the need for various agencies, stakeholders, and organizations to work together towards a common goal and the need to consider the return on investment in terms of quality care and lower costs. Consequently, NCVHS believes the objectives of a roadmap should be to:

1) Identify information required to support a transformed health care system and the changes in current information processing necessary to satisfy those requirements;
2) Understand key mandates, milestones, and timelines to ensure effective execution, adoption and potential modifications to obtain better alignment to support future information needs; and
3) Be transparent regarding challenges, issues and opportunities.

The industry has voiced the need to develop a strategic plan and a road map for adopting and implementing standards and operating rules in a coordinated, sequential, timely, efficient, and cost-effective manner. The industry has further stated that every effort should be made to ensure the development, assessment, adoption, implementation and evaluation of standards meet the principles of collaboration, coordination, openness, and transparency. NCVHS believes, and as it opined in its September 21, 2012 letter to the Secretary, that the "time has

come to step back and look at how all the current and upcoming IT initiatives (including those related to administrative simplification, quality measurement, payment reform, meaningful use, and health reform) need to nest appropriately into a comprehensive, overarching strategy and plan, rather than continuing to address items and components on a fragmented basis."[63] In that letter, NCVHS recommended that the:

1) CMS should convene a listening session with key stakeholders to discuss the development of a roadmap;
2) Roadmap for future standards work should incorporate the four principles of collaboration, coordination, openness and transparency ;
3) NCVHS should consider requiring testing as part of transitioning towards implementation of new standards and operating rules; and
4) DHHS should convene an industry working session to discuss and define a more effective and formal testing plan.

NCVHS has heard from the industry that it is experiencing "implementation fatigue" with competing priorities. To address industry concerns, NCVHS will need to evaluate the opportunities presented by each statutorily required initiative for its potential to effect changes that result in cost and process benefit. NCVHS will consider the large data sets of claims, payments, clinical data, patient behavior and patient sentiment data to determine how these could be standardized, prioritized, normalized, and moved from strategy to tactics. The challenge will be to create a way that data could be used in real-time to support administrative and clinical decision making, and to relate the data to measurable outcomes.

Finally, NCVHS recognizes that the development of standards is a dynamic and evolving process that requires input from an open, transparent, and consensus-based effort from those who will be using them. This involves identifying existing requirements, sequencing development and implementation of new standards, and timing to ensure the industry is not adversely impacted by multiple or overlapping initiatives.

5.5 eHealth Standards and Health Reform

NCVHS recognizes the need to review and monitor the impact that all the new electronic information exchanges needed to support Health Insurance Exchanges (HIXs) or marketplaces for current and future standards specifically for enrollment, premium payment, eligibility, quality reporting, bundled payment, and other forms of payment and healthcare reform. The HIXs under the Affordable Care Act could present an immediate opportunity to apply these future recommendations. NCVHS plans to review and monitor these developments and make recommendations, as needed. .

5.6 Measuring Success

[63] September 21, 2012 letter to Kathleen Sebelius, Secretary, Department of Health and Human Services from the National Committee on Vital and health Statistics (NCVHS).

The overriding concern at the NCVHS 60th Anniversary Symposium was the need to evaluate the impact of the Affordable Care Act to determine if the significant investment it required has produced the desired outcome.[64] In this report, NCVHS has noted the accomplishments made during the past two years as well as the goals it has for the next seven years (that is, through 2020). But success can only be measured if standards and initiatives demonstrate accomplishments of specified goals of better care, better health, and lower costs. NCVHS believes success will be measured if the recommended standards and initiatives result in:

(1) Convergence of administrative and clinical data;
(2) Collection of medical, environmental and survey data that results in improved health, quality of health care and lower costs;
(3) Creation of national databases with a network of local and state public health agencies working in collaboration with Federal agencies to establish the form and content of data submission;
(4) Integration of data to identify common public health requirements;
(5) Improved public health data collection that includes improvement in completeness, timeliness and quality of data reported; efficient use of hospital discharge data and rapid investigation of disease outbreaks;
(6) Development of public health data standards that define the electronic standards of structure, format, content, coding, vocabulary/terminology, transport and security;
(7) Privacy and security of individually identifiable health information;
(8) Demonstrated improvement in patient care;
(9) Improved patient/consumer experience;
(10) Development of effective quality measurements; and
(11) Ability to adapt to changing technology.

[64] 60th Anniversary Symposium and History 1949-2009, U.S. Department of Health and Human Services, February 2011, pp7

6. Conclusions

Health care in the United States is undergoing major transformative changes that are re-shaping the way consumers, patients, providers, health plans, employers, government, researchers and others interact. Transformation in the way health care is organized, delivered, and paid is also creating unprecedented opportunities to redefine the way health information is captured, exchanged, and used to improve access, value, quality, safety, equity, efficiency and the public's health and wellness. In this context, NCVHS has highlighting in this report the many achievements during the past two years as well as the gaps and challenges ahead.

Health care of the future holds promises that exceed anything envisioned when HIPAA was implemented. It is the unknown future that will affect the role of NCVHS as the statutory advisory body on health information policy to the Department. NCVHS will continue to provide a venue for industry stakeholders to come together and discuss issues and recommend solutions. It is this collaborative environment that will shepherd the health care industry through the unchartered territory that is ahead.

Appendix A: NCVHS Statutory Reporting Requirements for HIPAA

The statutory reporting requirements from P.L. 104-191, Sec. 263. Changes in Membership and Duties of National Committee on Vital and Health Statistics include reporting on:

"A. The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.
B. The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for non-compliance with such standards.[65]
C. Whether the Federal and State governments are receiving information of sufficient quality to meet their responsibilities under such part.
D. Any problems that exist with respect to implementation of such part.
E. The extent to which timetables under such part are being met."

P.L. 104-191, Subtitle F – Administrative Simplification, includes requirements for adoption of the following standards:

- Financial and administrative transactions specified in the Act *and other financial and administrative transactions determined by the Secretary to be appropriate to improve the operation of the health care system and reduce administrative costs*.
- Code sets for appropriate data elements in the transactions.
- Unique health identifiers (ID) for employers, health care providers, health plans, and individuals
- Security standards (for health information).
- Electronic signatures, in coordination with the Secretary of Commerce, as may be needed in the transactions.
- Standards for the transfer of information among health plans for coordination of benefits.
- Timetables for adoption of initial standards and additions/modifications to standards.
- Penalties for failure to comply with requirements and standards.
- Penalties for wrongful disclosures.
- Effect of state law – that HIPAA supersedes contrary State law except with respect to any State law the Secretary determines necessary to prevent fraud and abuse, to ensure appropriate State regulation of insurance and health plans, for state reporting on health care delivery or costs, that addresses controlled substances, or relates to the privacy of individually identifiable health information that may be more stringent than a privacy regulation.
- That HIPAA does not apply to entities processing payment transactions by financial institutions.
- NCVHS changes in membership, with two appointed by members of Congress.
- NCVHS expansion of duties to include providing status reports and recommendations and legislative proposals to the Secretary and Congress related to the adoption of uniform data standards for and the electronic exchange of patient medical record information (PMRI).
- Recommendations to Congress to enact legislation on privacy of health information; and that if such legislation is not enacted within 36 months after enactment of HIPAA, the Secretary will promulgate final regulations containing standards for the privacy of individually identifiable health information (with preemption for State requirements that are more stringent.[66]

[65] The privacy standards were not referenced in this list of subjects because initially HIPAA called for privacy legislation and privacy regulation only if Congress failed to enact such legislation within three years.
[66] Congress did not enact privacy legislation by its self-imposed deadline. As a result, the Secretary promulgated a final Privacy Rule on December 28, 2000, with a modification published August 14, 2002 (effective April 14, 2003) after receiving many unsolicited inquiries and NCVHS holding hearings in August 2001 and January 2002.

Appendix B: Transactions and Code Sets

Financial and administrative transactions are conducted between health plans, clearinghouses, and those providers who conduct electronic transactions.[67] Transaction standards for enrollment in a health plan and premium payment are also available to any entity conducting such processes.

The following transaction standards are currently available for use:

Accredited Standards Committee (ASC) X12

270/271	Eligibility for a Health Plan (Inquiry and Response)
837	Claim or Equivalent Encounter Information (and Coordination of Benefits [COB])
276/277	Claim Status Inquiry and Response
835	Health Care Payment and Remittance Advice (Electronic Remittance Advice [ERA] and Explanation of Benefits [EOB])
278	Referral Certification and Authorization (Health Care Services Request for Review and Response)
834	Enrollment and Disenrollment in a Health Plan
820	Health Plan Premium Payment

National Council for Prescription Drug Programs (NCPDP)

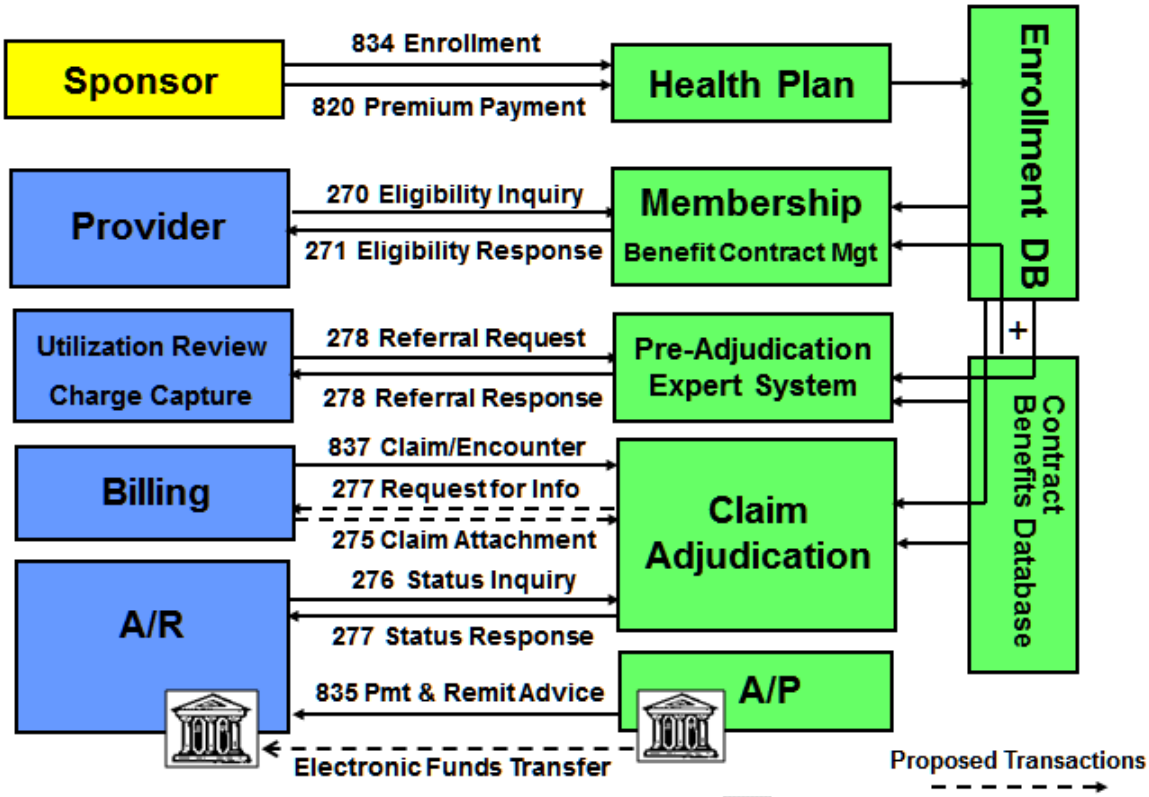
5.1 & D.0	Telecommunication and batch standards for claims. eligibility, and authorization
3.0	Medicaid pharmacy subrogation

HIPAA and ACA have required transactions for health claims attachments and electronic funds transfer that are currently in the process of being considered for adoption.

The following graphic illustrates the typical flow of the financial and administrative transactions in the non-retail pharmacy sector of health care. Those designated by number and name are from the ASC X12 standards development organization.

The retail pharmacy sector utilizes the ASC X12 835 Remittance Advice standard , but uses the National Council for Prescription Drug Program (NCPDP) standards for receiving formulary and benefits information from pharmacy benefits managers (PBMs), submitting claims, coordination of benefits, requesting an eligibility inquiry and receiving a response, and Medicaid subrogation. NCPDP also supports a Telecommunications standard.

[67] The Administrative Simplification Compliance Act of 2001 (ASCA) required all providers who submit claims to Medicare to use electronic transactions by October 16, 2003, except small providers or where a waiver for unusual cases has been obtained from the Secretary of HHS.


Sponsor
834 Enrollment
820 Premium Payment
Health Plan
Enrollment DB
Provider
270 Eligibility Inquiry
271 Eligibility Response
Membership
Benefit Contract Mgt
Utilization Review
Charge Capture
278 Referral Request
278 Referral Response
Pre-Adjudication
Expert System
+
Contract
Benefits Database
Billing
837 Claim/Encounter
277 Request for Info
275 Claim Attachment
Claim
Adjudication
A/R
276 Status Inquiry
277 Status Response
835 Pmt & Remit Advice
A/P
Electronic Funds Transfer
Proposed Transactions

Appendix C: NCVHS Membership

CHAIR
Larry A. Green, M.D.
Professor and Epperson Zorn Chair
Innovation in Family Medicine & Primary Care
Department of Family Medicine
University of Colorado Denver
Health Science Center
Denver, CO

HHS EXECUTIVE STAFF DIRECTOR
James Scanlon
Deputy Assistant Secretary
Office of Science and Data Policy
Office of the Assistant Secretary for Planning and Evaluation, DHHS

EXECUTIVE SECRETARY
Debbie Jackson, M.A.
Classifications and Public Health Data Standards Staff
Office of the Director
National Center for Health Statistics, CDC

MEMBERSHIP

Lynn A. Blewett, Ph.D.
Professor, Division of Health Policy & Management
University of Minnesota
School of Public Health
Minneapolis, MN

John J. Burke, M.B.A, MSPharm.
Vice President, Corporate Compliance Programs
Harvard Pilgrim Health Care, Inc.
Wellesley, MA

Raj Chanderraj, M.D., F.A.C.C.
Nevada Heart & Vascular Center
Las Vegas, NV

Bruce B. Cohen, Ph.D.
Director, Division of Research and Epedimiology
Bureau of Health Information, Statistics,
Research and Evaluation
Massachusetts Department of Public Health
Boston, MA

Llewellyn J. Cornelius, Ph.D.
Professor, University of Maryland
School of Social Work
Baltimore, MD

Leslie Pickering Francis, J.D., Ph.D.
Distinguished Professor of Law and Philosophy
Alfred C. Emery Professor of Law
SJ Quinney College of Law
University of Utah
Salt Lake City, UT

Alexandra (Alix) Goss
Executive Director, Pennsylvania eHealth Partnership Authority
Harrisburg, PA

Linda L. Kloss, M.A.
President, Strategic Advisors Ltd
Chicago, IL

Vickie M. Mays, Ph.D., M.S.P.H.
Professor and Director
UCLA Department of Psychology & Health Services
Los Angeles, CA

Sallie Milam, J.D., C.I.P.P., C.I.P.P./G.
West Virginia's Chief Privacy Officer
West Virginia Executive Branch
Charleston, WV

Len Nichols, Ph.D.
Director, Center for Health Policy Research & Ethics
Professor of Health Policy
College of Health and Human Services
George Mason University
Fairfax, VA

W. Ob Soonthornsima
Senior Vice President
Chief Information Officer and Security Officer
Blue Cross and Blue Shield of Louisiana
Baton Rouge, LA

William W. Stead, M.D.
Associate Vice Chancellor for Health Affairs
Chief Strategy & Information Officer
Vanderbilt University Medical Center
Nashville, TN

Walter G. Suarez, M.D., M.P.H.
Executive Director, Health IT Strategy & Policy
Kaiser Permanente
Silver Spring, MD

James M. Walker, M.D., F.A.C.P
Principal Health Informatician
Siemens Medical Solutions, Inc.
Health Services
Malvern, PA